Raph Graybill
Graybill Law Firm, PC
300 4th Street North
PO Box 3586
Great Falls, MT 59403
(406) 452-8566
rgraybill@silverstatelaw.net

Kimberly Parker*
Nicole Rabner*
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue NW,
Washington, DC 20006
(202) 663-6000
nicole.rabner@wilmerhale.com
kimberly.parker@wilmerhale.com

Alan Schoenfeld*
Michelle Nicole Diamond*
Wilmer Cutler Pickering Hale and Dorr LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800
alan.schoenfeld@wilmerhale.com
michelle.diamond@wilmerhale.com

Hana Bajramovic*
Planned Parenthood Federation of America, Inc.
123 William St., 9th Floor
New York, NY 10038
(212) 541-7800
hana.bajramovic@ppfa.org

Alice Clapman*
Planned Parenthood Federation of America, Inc.
1110 Vermont Ave., N.W., Ste. 300
Washington, D.C. 20005
(202) 973-4862
alice.clapman@ppfa.org

Gene R. Jarussi
1631 Zimmerman Tr., Suite 1
Billings, MT 59102
(406) 861-2317
gene@lawmontana.com

Attorneys for Plaintiffs

*Motions for pro hac vice forthcoming

**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. DV-21-00999 Judge: HON. GREGORY R. TODD **REBUTTAL AFFIDAVIT OF COLLEEN P. McNICHOLAS, DO, MSCI, FACOG**

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

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

1. I previously submitted an affidavit in this case, which was filed on August 16, 2021 ("McNicholas Aff."). That affidavit described my qualifications as a board-certified obstetrician-gynecologist ("OB/GYN") and the Chief Medical Officer for Planned Parenthood of the St. Louis Region and Southwest Missouri and Reproductive Health Services of Planned Parenthood of the St. Louis Region. I attach my curriculum vitae to this report as Exhibit A.

2. As in my original declaration, this declaration is based on my years of medical practice and research, my personal knowledge, and my familiarity with relevant medical literature and statistical data recognized as reliable in the medical profession. If called as a witness, I would and could competently testify thereto.

Summary of Opinions

3. I have reviewed the expert declarations submitted by Robin Pierucci, M.D., M.A, Ingrid Skop, M.D., and George Mulcaire-Jones, M.D. Nothing in these declarations alters the conclusions I reached or the opinions I expressed in my prior affidavit.

4. I am submitting this declaration to respond to certain of the statements and opinions expressed in the declarations of Drs. Pierucci, Skop, and Mulcaire-Jones. In particular:

(a) I disagree with Dr. Skop's and Dr. Mulcaire-Jones's opinions on abortion safety;

(b) I disagree with Dr. Pierucci's, Dr. Skop's, and Dr. Mulcaire-Jones's opinions concerning viability;

(c) I disagree with Dr. Pierucci's and Dr. Skop's opinions on fetal pain;

(d) I disagree with Dr. Mulcaire-Jones's opinions about the necessity of the 24-hour mandatory delay;

(e) I disagree with Dr. Skop's and Dr. Mulcaire-Jones's opinions on telemedicine and the necessity of in-person examinations;

(f) I disagree with Dr. Skop's opinions regarding reproductive coercion; and

(g) I disagree with Dr. Skop's opinions on so-called medication abortion "reversal."

5. The fact that I do not address every statement or issue raised in these declarations does not suggest that I agree with them.

Abortion Safety

6. The state's experts paint a dire picture of abortion safety, but the reality is that abortion is extremely safe. As I stated in my original affidavit, *see* McNicholas Aff. ¶¶ 18–21, and as is supported by an abundance of literature,[1] both medication and procedural abortion carry a low risk of complications and a very low risk that hospitalization is necessary to treat a complication. As to medication abortion specifically, 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—have explained that "[t]he risks of medication abortion are similar in magnitude to the risks of

[1] *See, e.g.*, Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 217 (2012); Ushma Upadhyay et al., *Incidence of Emergency Department Visits & Complications After Abortion,* 125 Obstetrics & Gynecology 175, 181 (2015); Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 77–78 (2018) [hereinafter "National Academies Report"].

taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs [nonsteroidal anti-inflammatory drugs]," such as ibuprofen.[2]

7. The studies Dr. Skop cites to support her claim that medication abortion has a high complication rate have serious limitations. For example, she cites to a 2009 study by Niinimäki and colleagues,[3] but that study does not differentiate between different medication abortion protocols.[4] More critically, the Niinimaki study (1) was based on a Finnish health registry that coded all follow-up visits as "complications" regardless of the degree of concern; and (2) inappropriately reported as "hemorrhage" all patient reports of heavy bleeding, even if they were within the expected range and did not require treatment.[5] In response to criticism on these points, the authors themselves acknowledged that in the records they used, "many of the 'complications' are not really such, but rather concerns or adverse events that bring women back to the health care system. ... [The] [r]ate of serious, 'real' complications is rare and rather similar between surgical and medical abortion."[6]

8. While Dr. Skop describes the use of medication abortion past 70 days LMP as "brazen," Skop Decl. ¶ 46, it is evidence-based and standard-of-care practice to use medication

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[2] National Academies Report, *supra* note 1, at 79.

[3] Skop Decl. ¶¶ 47, 50 (citing Maarit Niinimäki et al., *Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795 (2009)).

[4] Niinimäki et al., *supra* note 3, at 796.

[5] Mary Fyerstad et al., *Letters to the Editor: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010); Niinimäki et al., *supra* note 3, at 799–800.

[6] Maarit Niinimäki et al., *Letters to the Editor: Immediate Complications After Medical Compared with Surgical Termination of Pregnancy*, 115 Obstetrics & Gynecology 660 (2010).

abortion through 77 days LMP, *see* McNicholas Aff. ¶ 16.[7] The practice of developing new regimens based on research, including using different dosages or using medications for entirely different uses than for which they were approved by the FDA, is very common in medicine. "Off-label" use is not the same as experimental or research use, and indeed, up to 20% of all drugs are prescribed off-label.[8] While misoprostol today is included in the FDA-approved labeling of mifepristone for use in abortion, it was initially approved by the FDA for oral administration to prevent gastric ulcers.[9] Misoprostol also has a number of important off-label (but evidence-based) uses for gynecological treatments, including labor induction, treatment of spontaneous early pregnancy loss, prevention and treatment of postpartum hemorrhage, and cervical priming before uterine procedures such as hysteroscopy. The state's own expert witness, Dr. Mulcaire-Jones, acknowledges that he prescribes misoprostol off-label to treat spontaneous miscarriage. Mulcaire-Jones Decl. ¶ 12.

9. The risks associated with abortion increase with gestational age, but because they are very low to begin with, abortion remains a very safe procedure even later in the second trimester, with a low mortality risk of 6.7 deaths per 100,000 procedures for abortions at 18 weeks or later.[10] Contrary to the state experts' assertions, *see, e.g.*, Mulcaire-Jones Decl. ¶ 62,

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[7] Notably, the World Health Organization ("WHO") guidelines provide for medication abortion regimens throughout the entirety of pregnancy (for both a combined mifepristone/misoprostol regimen and misoprostol alone). *See Medical Management of Abortion*, WHO, https://www.who.int/reproductivehealth/publications/pocket-guide.pdf (last visited Sept. 16, 2021).

[8] Katrina Furey & Kirsten Wilkins, *Prescribing "Off-Label": What Should a Physician Disclose?*, 18 Am. Med. Ass'n J. Ethics 587, 588 (2016).

[9] ACOG, *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology e31, e31 (2020).

[10] Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998–2010*, 126 Obstetrics & Gynecology 258, 262–63 (2015).

abortion—including abortion later in the second trimester—is far safer than childbirth.[11] For example, the risk of death following childbirth is approximately fourteen times greater than that associated with abortion, and every pregnancy-related complication (such as hemorrhage, infection, and injury to other organs) is more common among people having live births than among those having abortions.[12]

10. Drs. Skop and Mulcaire-Jones find fault with abortion-related morbidity rates on the theory that there is no comprehensive national data on the occurrence of complications from abortion. *See* Mulcaire-Jones Decl. ¶¶ 19–32; Skop Decl. ¶¶ 18–20, 49–50. Importantly, there is also no reporting requirement for non-mortality complications of pregnancy. In any event, the 2015 study by Upadhyay and colleagues, cited above and in my initial report, tracked any complications the study population experienced "without loss to follow-up, addressing a common methodologic limitation of other studies."[13] Dr. Mulcaire-Jones also claims, without evidence, that "complications are generally not reported or considered by abortion providers," suggesting that abortion is more dangerous—by some factor Dr. Mulcaire-Jones does not quantify—than existing data indicate. Mulcaire-Jones Decl. ¶ 30. But it is standard for patients to be instructed to call their abortion provider if they experience complications before presenting elsewhere for care. And as the National Academies recognized, numerous high-quality studies

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[11] Raymond & Grimes, *supra* note 1, at 217.

[12] Raymond & Grimes, *supra* note 1, at 216–17 & fig.1.

[13] Upadhyay et al., *supra* note 1, at 182 ("This study examines postabortion ED visits and complications up to 6 weeks and across multiple facilities without loss to follow-up, addressing a common methodologic limitation of other studies."). In fact, the authors noted that their study might *over*estimate abortion complication rates because it focused on a population with lower incomes and more overall health problems than the general population of abortion patients. *Id.*

exist on the incidence of complications, and those studies converge on a single conclusion: risks of complications from abortion are very low.[14]

11. Dr. Skop's opinions regarding long-term consequences of abortion are also out of step with medical consensus. I am not aware of any data that shows increased risk of preterm birth, abnormal placental attachment, or future infertility caused by abortion (as distinguished from a pregnancy carried to term). *See* Skop Decl. ¶¶ 11, 28–29. Indeed, the American College of Obstetricians and Gynecologists ("ACOG") has stated that a single induced abortion does not lead to future infertility,[15] and the National Academies found "no association between D&E and abnormal placentation," and "no significant association" between abortion and preterm birth.[16] Similarly, Dr. Skop's opinion on the purported link between abortion and breast cancer (Skop Decl. ¶¶ 74–76) has been thoroughly disproven.[17]

12. Dr. Skop opines that there are a number of studies showing that abortion leads to mental health issues. *See* Skop Decl. ¶¶ 23, 27, 78–79. My clinical experiences with patients are consistent with the positions of leading scientific organizations, including the American

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[14] National Academies Report, *supra* note 1, at 10–11, 55–56, 60–65.

[15] ACOG, *Frequently Asked Questions: Abortion Care*, https://www.acog.org/womens-health/faqs/induced-abortion (last visited Sept. 16, 2021) ("Abortion does not increase the risk of breast cancer, depression, or infertility."); *see also* CDC, *Preterm Birth*, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm (last visited Sept. 16, 2021) (listing risk factors for preterm birth, which do not include induced abortion).

[16] National Academies Report, *supra* note 1 at 138, 146.

[17] *See* McNicholas Aff. ¶ 61 & n.46 (citing studies); *see also* National Academies Report, *supra* note 1, at 148–49. Drs. Skop and Mulcaire-Jones inappropriately conflate two medical questions: (1) whether abortion itself carries long-term risks; and (2) whether a pregnancy carried to term, in addition to the health risks it poses, has protective effects (such as reducing certain cancer risks). *See* Skop Decl. ¶¶ 73; Mulcaire-Jones Decl. ¶¶ 51–57. As to the latter question, whatever protective effects pregnancy provides, for obvious reasons it is not the standard of care among gynecologists to advise patients to conceive, or carry to term, as a way of lowering their cancer risk.

Psychological Association ("APA"), the National Academies, and the Royal College of Psychiatrists in the United Kingdom, which have all concluded that abortion does not have a negative impact on patients' mental health.[18] The vast majority of my patients experience relief after abortion.

13. The reports from the APA, National Academies, and Royal College of Psychiatrists have also recognized that much of the published research on mental health outcomes of abortion, like those relied on by Dr. Skop (including multiple studies by Priscilla Coleman), are unreliable because they are based on "selective recall bias, inadequate controls for confounding factors, and inappropriate comparators"—particularly comparisons between patients with undesired pregnancies and patients with desired pregnancies.[19] In contrast, the "Turnaway Study" that Dr. Skop criticizes (Skop Decl. ¶ 79) examined and compared people who received abortions and people who sought abortions but were unable to obtain them.[20] The Turnaway Study "address[es] many of the limitations of other studies" and "contributes unique

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[18] Brenda Major et al., APA, *Report of the APA Task Force on Mental Health and Abortion* 4 (2008) [hereinafter "APA Report"]; National Academies Report, *supra* note 1, at 10, 149–52; Nat'l Collaborating Ctr. for Mental Health, Academy of Medical Royal Colleges, *Induced Abortion and Mental Health: A Systematic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors* 8 (2011) [hereinafter "Royal College Report"].

[19] National Academies Report, *supra* note 1, at 149–50; APA Report, *supra* note 18, at 15–20; Royal College Report, *supra* note 18, at 14–18.

[20] *See, e.g.*, M. Antonia 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 (2017); M. Antonia Biggs et al., *Does Abortion Increase Women's Risk for Post-Traumatic Stress? Findings from a Prospective Longitudinal Cohort Study*, 6 BMJ Open e009698 (2016); M. Antonia Biggs et al., *Mental Health Diagnoses 3 Years After Receiving or Being Denied an Abortion in the United States*, 105 Am. J. Pub. Health 2557 (2015); Diana G. Foster et al., *A Comparison of Depression and Anxiety Symptom Trajectories Between Women Who Had an Abortion and Women Denied One*, 45 Psychol. Med. 2073 (2015).

insight into the consequences of receiving a desired abortion versus being denied the procedure and carrying the pregnancy to term."[21] The results of the Turnaway Study show that "[a]t 2 years, women who had received an abortion had similar or lower levels of depression and anxiety than women denied an abortion" and that at four years follow-up, "[w]omen who had received an abortion were at no higher risk of PTSD than women who had been denied an abortion."[22] In other words, abortion did not increase the risk of mental health issues; to the contrary, "[c]ompared with having had an abortion, having be[en] denied an abortion may be associated with greater risk of initially experiencing more anxiety symptoms."[23]

14. Dr. Skop levels unfounded accusations of bias against the APA—the largest organization of psychologists in the United States—on the basis that it supports access to abortion care. Skop Decl. ¶ 77. But she provides no evidence that the APA reached its position on abortion access for any reason other than that such access is important to mental health, or that the APA was unable to impartially assess the scientific literature relating to mental health and abortion. Dr. Skop also accuses the National Academies of pro-abortion bias because their 208-page report on the safety of abortion disqualified from consideration several studies with which she agrees. *See* Skop Decl. ¶¶ 14–17. But the National Academies applied rigorous methodologic standards to evaluate all available research according to conventional principles of evidence-based medicine that are intended to reduce the risk of bias in a study's conclusions, emphasizing that applying these principles was "particularly important with respect to understanding abortion's long-term health effects, an area in which the relevant literature is

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[21] National Academies Report, *supra* note 1, at 151.

[22] *Id.*

[23] *Id.*

vulnerable to bias."[24] Using this evidence-based approach, the National Academies excluded low-quality research from review, as well as research unlikely to reflect patient outcomes in the context of contemporary U.S. abortion care. The fact that the report excluded the studies with which Dr. Skop agrees speaks to their poor quality, not any alleged bias among the National Academies.

15. As I explained in my original affidavit, patients seek termination of pregnancy for a variety of social and medical reasons, including poverty, youth, having completed their family, and complicating health factors. McNicholas Aff. ¶¶ 11–13. Some patients seek abortion after 20 weeks LMP because of an underlying health condition that places them at serious, heightened risk if they continue the pregnancy. These medical conditions can include hypertension, diabetes, lupus and other auto-immune diseases, kidney disease, and heart disease. Particularly in my time as an academic Family Planning specialist, I have cared for numerous patients for whom terminating a pregnancy was done to protect their health—contrary to Dr. Skop's assertion that abortions are rarely if ever provided for health reasons. *See* Skop Decl. ¶¶ 24, 39.

16. Dr. Skop opines that for patients with a medical indication, D&E abortions "would only worsen [the patient's] condition," advocating instead for premature induction of labor or C-section. Skop Decl. ¶¶ 24, 39–40. But the recommended route of termination in instances with evolving medical conditions is based on the unique circumstances of the patient in front of the provider. In almost all cases, a D&E procedure is much safer than a mid-trimester C-section, particularly for a patient with a serious medical condition. D&E abortions are generally quicker and more predictable than induction abortions and thus often provide additional benefit for patients with worsening medical conditions.

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[24] *Id.* at 38–39.

17. I know both from the literature and my own experience that other common circumstances can lead to a patient seeking an abortion in the second trimester, including delay in suspecting and testing for pregnancy; delay in obtaining funds necessary for the procedure and related expenses (travel, childcare, lost wages); and difficulties locating and traveling to an appropriate provider. Disturbingly, some of my patients have also told me that they were misled about pregnancy-related diagnoses or intentionally delayed in seeking abortion by physicians opposed to their choice to end a pregnancy. As I explained in my initial affidavit, McNicholas Aff. ¶ 19, restrictions 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."[25]

18. I disagree strongly with the state experts' assertion that abortion has no health benefits. Mulcaire-Jones Decl. ¶¶ 50, 58; *see also* Skop Decl. ¶ 42 (stating that abortion is not healthcare). Some patients seek abortion because of underlying health conditions, but even an uncomplicated pregnancy stresses a pregnant person's body, affects every organ system, and poses escalating risks as the pregnancy advances, including during and after labor and delivery. For other patients—including those suffering intimate partner violence or with a history of sexual assault, or those terminating wanted pregnancies due to lethal or severe fetal anomalies—being forced to remain pregnant against their will causes psychological harm in addition to the potential physical harm.

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[25] National Academies Report, *supra* note 1, at 11.

Viability

19. As I explained in my original affidavit, no fetus is viable at 20 weeks LMP or at any earlier gestational age. *See* McNicholas Aff. ¶¶ 34–35. None of the state's experts disagrees with this statement in their declarations. *See* Skop Decl. ¶¶ 31–33; Pierucci Decl. ¶¶ 9–17; Mulcaire-Jones Decl. ¶ 60.

20. I disagree with certain other opinions concerning fetal viability set forth in the declarations of Drs. Pierucci, Skop, and Mulcaire-Jones, and in particular the assertion that "the edge of viability" has moved to 21 weeks. Skop Decl. ¶ 31. This assertion is incorrect in at least two respects. First, because a multitude of factors relevant to a particular fetus's likelihood of survival will differ from pregnancy to pregnancy, there is no bright-line point at which fetuses become viable; viability is pregnancy-specific as well as resource-specific, with some fetuses attaining viability later than others (or never). Thus, even a ban on abortion at a later date than 20 weeks (e.g., at 24 weeks) would necessarily prohibit some abortions prior to viability, because in some cases—depending on pregnancy-specific individual circumstances, including fetal and/or maternal health conditions—a fetus is not viable at that point.

21. Second, the assertion that 21 weeks LMP is when most (or even many) fetuses reach viability is not medically accurate. Even under the best of circumstances, the likelihood of sustained survival outside the womb for a periviable birth before 23 weeks LMP is very low. One recent consensus paper published in the American Journal of Obstetrics and Gynecology, for example, lists survival rates of 5–6% for fetuses under 23 weeks LMP.[26] Such low rates of survival do not reflect a reasonable likelihood of sustained survival outside the womb.

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[26] ACOG & Soc'y Maternal-Fetal Med., *Obstetric Care Consensus No. 6: Periviable Birth*, 130 Obstetrics & Gynecology e187, e188 (2017).

22. The state's experts seek to estimate viability based on the earliest periviable infant to have survived. *See* Skop Decl. ¶ 32; Mulcaire-Jones Decl. ¶ 60. But this misunderstands the very definition of viability, which, again, is a reasonable likelihood of sustained survival outside the womb. An extreme outlier does not show that there is a reasonable likelihood of sustained survival. Importantly, even this extraordinary case did not involve a periviable birth at 20 weeks LMP.

23. Finally, I disagree with Dr. Skop's assertion that "[o]bstetric sonogram in the second trimester estimates gestational age with a margin of error between one and two weeks." Skop Decl. ¶ 34. The study she cites does not support her statement; it provides margins of error of "±7 days from 14–20 weeks, ±10 days from 21–27 weeks."[27]

24. As detailed in ACOG's Practice Bulletin on Ultrasound in Pregnancy, between 9 and 16 weeks, a gestational age estimate based on ultrasound has a precision of ±7 days, and between 16 and 22 weeks, a gestational age estimate based on ultrasound has a precision of ±10 days.[28] If anything, the precision ranges established by ACOG are conservative and overstate the potential inaccuracy of ultrasound-based gestational age dating. A widely respected study concludes that for gestational age dating between 15 and 21 weeks, estimates based on ultrasound have accuracy rates of ± 5 to 7 days.[29] But even by the more conservative figures, Dr. Skop's "one [to] two week[]" range is inaccurate.

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[27] Daniel W. Skupski et al., *Estimating Gestational Age from Ultrasound Fetal Biometrics*, 130 Obstetrics & Gynecology 433, 433 (2017).

[28] ACOG, *Practice Bulletin No. 175: Ultrasound in Pregnancy*, at 8 tbl.1 (2016).

[29] Frank P. Hadlock et al., *How Accurate Is Second Trimester Fetal Dating*, 10 J. Ultrasound Med. 557, 559 (1991).

Fetal Pain

25. I have reviewed and agree with the declaration submitted by Dr. Steven J. Ralston, which details and responds to certain serious inaccuracies in Dr. Pierucci's and Dr. Skop's declarations relating to fetal pain. As Dr. Ralston explains, 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, as key connections to the brain do not develop before that time. Indeed, this consensus was reaffirmed just a few months ago in a joint publication by the Society for Maternal-Fetal Medicine and the Society of Family Planning.[30]

24-Hour Mandatory Delay

26. As I explained in my initial affidavit, the 24-hour mandatory delay serves no purpose and instead causes harm to patients' health. McNicholas Aff. ¶ 41. Dr. Mulcaire-Jones attempts to defend this delay by arguing that other medical procedures, like circumcisions, may be scheduled in advance. Mulcaire-Jones Decl. ¶¶ 69–70. But none of the procedures Dr. Mulcaire-Jones mentions are time-sensitive in the way abortion is; nor are they subject to a *state-mandated* delay. Moreover, in my experience, and as confirmed by numerous studies,[31] most

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[30] Soc'y Maternal-Fetal Med., Soc'y Fam. Planning, Mary E. Norton, Arianna Cassidy, Steven J. Ralston, Debnath Chatterjee, Diana Farmer, Anitra D. Beasley & Monica Dragoman, *Society for Maternal-Fetal Medicine (SMFM) Consult Series #59: The Use of Analgesia and Anesthesia for Maternal-Fetal Procedures*, Am. J. Obstetrics & Gynecology (2021), https://doi.org/10.1016/j.ajog.2021.08.031.

[31] Lauren J. Ralph et al., *The Impact of a Parental Notification Requirement on Illinois Minors' Access to and Decision-Making Around Abortion*, 62 J. Adolescent Health 281, 285 (2018); Lauren J. Ralph et al., *Measuring Decisional Certainty Among Women Seeking Abortion*, 95 Contraception 269, 276 (2017); Sarah C.M. Roberts et al., *Do 72-Hour Waiting Periods and Two-Visit Requirements for Abortion Affect Women's Certainty? A Prospective Cohort Study*, 27 Women's Health Issues 400, 404 (2017); Sarah C.M. Roberts et al., *Utah's 72-Hour Waiting Period for Abortion: Experiences Among a Clinic-Based Sample of Women*, 48 Persp. on Sexual & Reprod. Health 179, 185 (2016); Heather Gould et al., *Predictors of Abortion Counseling Receipt and Helpfulness in the United States*, 23 Women's Health Issues e249, e254 (2013);

people seeking an abortion are sure of their decision by the time they present for the initial counseling visit. Studies have also shown that while mandatory delay laws do not affect decisional certainty, they exacerbate the burdens that patients experience in seeking abortion care, including by increasing costs, prolonging wait times, increasing the risk that a patient will have to reveal their decision to others, and potentially preventing a patient from having the type of abortion that they prefer.[32]

Telemedicine Abortion & In-Person Appointments

27. As I explained at length in my initial affidavit, multiple studies have demonstrated that medication abortion by both site-to-site and direct-to-patient telehealth is just as safe and effective as in person. McNicholas Aff. ¶¶ 46–50. Drs. Skop and Mulcaire-Jones appear to suggest that telemedicine abortion is inappropriate for rural patients, who would be "abandoned" in the event of complications. Skop Decl. ¶ 57; Mulcaire-Jones Decl. ¶ 88. But however a patient receives her medications (whether from the hands of a clinician, or another medical professional, or by mail), any complications she experiences will occur after she takes the second medication at home, making irrelevant the initial location the medication was dispensed.

28. I am aware that PPMT gives its patients a phone number, staffed 24/7 by a medical professional, which they can call with any concerns—regardless of whether those

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Diana Greene Foster et al., *Attitudes and Decision Making Among Women Seeking Abortions at One U.S. Clinic*, 44 Persp. on Sexual & Reprod. Health 117, 122 (2012); *see also* Ushma Kumar et al., *Decision Making and Referral Prior to Abortion: A Qualitative Study of Women's Experiences*, 30 J. Fam. Plan. & Reprod. Health Care 51 (2004).

[32] Caitlin Myers, *Cooling off or Burdened? The Effects of Mandatory Waiting Periods on Abortions and Births*, Institute of Labor Economics (IZA), IZA Discussion Papers 14434 (2021); Roberts et al. (2016), *supra* note 31; Kari White et al., *Experiences Accessing Abortion Care in Alabama Among Women Traveling for Services*, 26 Women's Health Issues 298 (2016); Theodore J. Joyce et al., Guttmacher Inst., *The Impact of State Mandatory Counseling and Waiting Period Laws on Abortion: A Literature Review* (2009).

patients initially accessed care via telemedicine or in person. Most patient concerns are not complications at all and require nothing more than reassurance. In the event that a patient does experience a complication, most can be managed by phone or with a clinic visit—regardless of whether telemedicine was used for the patient's initial visit. In the exceedingly rare circumstance where emergency treatment is needed, patients are referred to the closest emergency department. The rare emergency complications from medication abortion are familiar to emergency physicians because they are very similar to the symptoms and complications of spontaneous miscarriage, which is a condition commonly seen in emergency departments.

29. Indeed, Montana's rural nature should be an argument *for* telemedicine abortion, not against it. Telemedicine improves access for disproportionately affected people living on low incomes and those living in rural and underserved areas who are not readily able to travel.[33] In a study of patients undergoing abortion at Planned Parenthood clinics in Montana, the distance traveled to the clinic decreased from 134 to 115 miles after the introduction of telemedicine; the mean time to appointment also decreased from 14 to 12 days.[34]

30. Telemedicine also allows patients to receive this care earlier in their pregnancy, when the medications are most likely to be effective and the least likely to cause any complications.

31. While the Food and Drug Administration (FDA) has unnecessarily subjected mifepristone to a Risk Evaluation and Mitigation Strategy (REMS) that mandates in-person

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[33] Kate Grindlay et al., *Womens and Providers' Experiences with Medical Abortion Provided Through Telemedicine: A Qualitative Study*, 23 Women's Health Issues e117, e117–22 (2013).

[34] Julia E. Kohn et al., *Introduction of Telemedicine for Medication Abortion: Changes in Service Delivery Patterns in Two U.S. States*, 103 Contraception 151 (2020).

dispensing,[35] the FDA has allowed waiver of this requirement so that researchers can study, among other things, the mailing of the medications. Moreover, I understand that the FDA has suspended the in-person dispensing requirement during the COVID-19 pandemic[36] (thereby allowing direct-to-patient medication abortion) and is currently conducting a full review of mifepristone's REMS requirements.[37] Because of its reconsideration of the REMS, Dr. Skop accuses the FDA of being part of "abortion industry," Skop Decl. ¶ 52, again without any basis.

32. Moreover, as I explain in my initial affidavit, HB 171's requirement that the same physician who provides the medication abortion conduct an in-person exam of the patient (consisting of an ultrasound and Rh testing) is medically unnecessary. It is often medically unnecessary to assess gestational age by ultrasound, *see* McNicholas Aff. ¶ 51; *contra* Skop Decl. ¶¶ 54, 81–83, nor is an ultrasound always necessary to screen for ectopic pregnancy, *see* McNicholas Aff. ¶ 52; *contra* Mulcaire-Jones Decl. ¶¶ 11, 72–74, 96–98; Skop Decl. ¶¶ 55, 84. Lastly, an ultrasound diagnosis of early pregnancy failure, or miscarriage, would not be treated any differently from a medication abortion, *see* McNicholas Aff. ¶ 56; in fact, the mifepristone and misoprostol regimen used for medication abortion is also the most effective regimen to treat miscarriage, as even Dr. Mulcaire-Jones admits. *See* Mulcaire-Jones Decl. ¶ 12 (citing ACOG

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[35] ACOG, *Practice Bulletin No. 225*, *supra* note 9 ("[T]he REMS restrictions for mifepristone do not make the care safer, are not based on medical evidence or need, and create barriers to clinician and patient access to medication abortion. The American College of Obstetricians and Gynecologists advocates the removal of REMS restrictions for mifepristone.").

[36] *See* Letter from Janet Woodcock, M.D., Acting Comm'r of Food & Drugs, FDA, to Maureen G. Phipps, M.D., MPH, FACOG, CEO, Am. College of Obstetricians & Gynecologists & William Grobman, M.D., MBA, President, Soc. for Maternal-Fetal Medicine (Apr. 12, 2021), https://www.aclu.org/letter/fda-response-acog-april-2021.

[37] Joint Motion to Stay Case Pending Agency Review, *Chelius v. Becerra*, No. 1:17-00493 JAO-RT (D. Haw. May 7, 2021), ECF No. 148, https://www.aclu.org/legal-document/joint-motion-stay-case-pending-agency-review.

for the proposition that the misoprostol/mifepristone regimen is most effective, while admitting that he uses a misoprostol-only regimen).

33. Finally, contrary to Dr. Mulcaire-Jones's suggestions, *see* Mulcaire-Jones Decl. ¶ 87, in-person follow up is not always necessary. Patients may instead confirm successful 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.[38] I know from my clinical experience that patients are fully capable of monitoring their own condition at home, distinguishing between expected effects and potentially abnormal effects, and contacting their provider with any concerns. I also know from my clinical experience that patients often appreciate this option, e.g. because they are far from the clinic, have limited transportation, and/or have trouble taking time off from work or finding childcare coverage. It is unnecessarily burdensome for patients to make an additional trip, without any medical benefit.

Reproductive Coercion

34. Dr. Skop's statements regarding the impact of influence, pressure, and coercion surrounding a person's decision to seek abortion are unsupported. Skop Decl. ¶ 44. First, Dr. Skop assumes coercion is unidirectional—that is, she only acknowledges that people experience coercion as an effort to force them to choose abortion. In reality, reproductive coercion takes many forms, including pressuring a person to become pregnant and carry a pregnancy to term or

[38] MIFEPREX (Mifepristone) Tablets Label, FDA, at 4, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (2016) ("Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan.").

to have an abortion, pressuring or coercing a person to have sex, and threatening to leave a relationship if they do not have sex or do not get pregnant.[39]

35. While most people seeking abortion do not experience coercion, those who do may need extra support and a safe environment to discuss their experiences regardless of whether they seek to carry to term or end a pregnancy. I am aware that PPMT screens patients for abortion coercion and assesses decision certainty as part of their informed consent and counseling process. This assessment can also be conducted via telemedicine, *contra* Skop Decl. ¶ 53, and indeed reducing travel can help patients who are experiencing intimate partner violence avoid detection from a controlling partner.

36. Without any evidence whatsoever, Dr. Skop asserts that abortion providers "steer[] [patients] toward medical abortions" for purposes of profit. Skop Decl. ¶ 46. This allegation is insulting and deeply untrue. As a physician, I am bound by my obligation to principles of medical ethics and driven by a commitment to shared decisionmaking, understanding that the patients are the experts in their own lives. The principle of autonomy ensures that patients have the freedom to make healthcare decisions that are best for them, and the principle of justice ensures that patients, regardless of where they live, have access to information about all safe methods. In line with these principles, I inform patients of all their options—medication and procedural abortion, as well as continuing the pregnancy. This is the norm among abortion providers; my colleagues and I are acutely aware of the importance of non-biased counseling that minimizes shame and centers the patient.

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[39] ACOG, *Committee Opinion No. 554: Reproductive & Sexual Coercion* (2013), http://www.ncdsv.org/images/ACOG_ReproductiveAndSexualCoercion_2-2013.pdf.

37. Dr. Skop also presents misleading statistics regarding Planned Parenthood's services, asserting that "ninety-six percent of [Planned Parenthood's] pregnancy services are abortion" and suggesting that this shows evidence of inadequate counseling. Skop Decl. ¶¶ 72, 85. It is not clear where she obtained this figure. There is no category in the Annual Report she cites for "pregnancy services."[40] Instead, the Annual Report states that 3% of Planned Parenthood's medical services are abortion. At any rate, it is not surprising, and does not reflect on the counseling practices of Planned Parenthood's affiliates, that many pregnant people seek abortion services from Planned Parenthood affiliates, given that the Planned Parenthood federation is well-known as a trusted abortion provider, and particularly given how few known abortion providers there are in many states (including Montana).

Medication Abortion "Reversal"

38. As I explained in my initial affidavit, medication abortion "reversal" is an experimental treatment, the safety and efficacy of which has never been demonstrated. McNicholas Aff. ¶¶ 57–58. Dr. Skop works with the Abortion Pill Reversal Network, Skop Decl. ¶ 71, the organization to which, under HB 171, both abortion providers and the state must refer patients (www.abortionpillreversal.com).

39. As Dr. Skop herself admits, ACOG has concluded that "[t]here is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy

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[40] *See* Planned Parenthood, *2019–2020 Annual Report,* at 35, https://www.plannedparenthood.org/uploads/filer_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf (last visited Sept. 16, 2021). If Dr. Skop were to have combined all services that directly related to pregnancy—pregnancy tests, prenatal services, miscarriage care, abortion procedures, and adoption referrals—then she would have calculated that 24% of Planned Parenthood's "pregnancy services" were abortion. Arguably, she should have also included contraceptive services (which prevent pregnancy) as a "pregnancy service," in which case 9% of Planned Parenthood's "pregnancy services" were abortion.

continuing."[41] (Once again, Dr. Skop discounts this study by a major medical organization by accusing it of being an "[a]bortion advocacy medical organization[]," without providing any evidence that ACOG's support for abortion access skews its review of the scientific literature on reversal. Skop Decl. ¶ 65. She, meanwhile, is a member of the American Association of Pro-Life Obstetricians and Gynecologists, a group whose very mission is to oppose abortion. Skop Decl. Ex. A.) Dr. Skop also acknowledges that a recent study raised safety concerns with interrupting the medication abortion regimen. Skop Decl. ¶ 71. She does not address this study, other than to speculate that the concerns raised are more likely to have arisen from the interruption of the medication abortion regimen than from the administration of additional progesterone. Skop Decl. ¶ 71. That speculation, even if eventually confirmed by actual medical evidence, would not alter my basic point that HB 171, by encouraging patients to start and then interrupt a medication abortion, exposes them to risk.

40. Dr. Skop suggests that HB 171's requirement that abortion providers provide patients with information about medication abortion "reversal" will provide them with more "choice." Skop Decl. ¶ 70. She fails to address the obvious concern (raised in my prior affidavit, McNicholas Aff. ¶ 58) that a state-mandated message to patients, delivered *before* they begin the abortion process, that they can reverse this process undermines the critical goal of ensuring that patients do not start the process before they are firmly decided. This is all the more important because, as Dr. Skop herself implicitly concedes, for many patients, simply taking the mifepristone alone will end their pregnancy.

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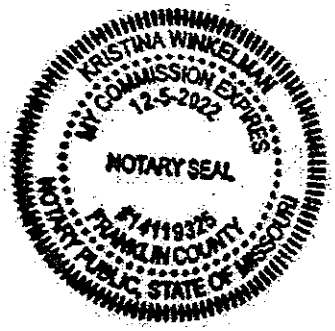
[41] ACOG, *Practice Bulletin No. 225*, *supra* note 9.

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

Colleen P. McNicholas, DO, MSCI, FACOG

Subscribed and sworn to before me this 16 day of September, 2021.

(NOTARIAL SEAL)



Printed Name: KRISTINA WINKELMAN

EXHIBIT A

CURRICULUM VITAE
Colleen Patricia McNicholas, DO, MSCI, FACOG

Date: May 2021

Address:

Planned Parenthood of the St. Louis Region and Southwest Missouri
4251 Forest Park
St. Louis, Missouri 63108

Present Position: Chief Medical Officer
Planned Parenthood of the St. Louis Region and Southwest Missouri

Education:

Undergraduate:	1998-2003	Benedictine University Lisle, Illinois B.S. Forensic Chemistry
Graduate:	2003-2007	Kirksville College of Osteopathic Medicine Kirksville, Missouri Doctor of Osteopathy
	2011-2013	Washington University in St. Louis St. Louis, Missouri Masters of Science in Clinical Investigation
Internship:	2007-2008	Atlanta Medical Center Atlanta, Georgia Internship
Residency:	2008-2011	Washington University School of Medicine Residency in Obstetrics and Gynecology
Fellowship:	2011-2013	Washington University School of Medicine Clinical Instructor – Obstetrics and Gynecology Clinical Fellow – Family Planning

Academic Positions/Employment:

2019 -	Volunteer Clinical Faculty Department of Obstetrics and Gynecology Washington University School of Medicine Barnes Jewish Hospital
2018- 2019	Associate Professor Department of Obstetrics and Gynecology Washington University School of Medicine
2014-2018	Director, Ryan Residency Training Program Washington University School of Medicine

2013- 2018	Assistant Professor Department of Obstetrics and Gynecology Washington University School of Medicine
2012-2014	Missouri Baptist Medical Center, St Louis, MO Laborist

University and Hospital Appointments and Committees:

Appointments

2019-	Attending Physician Memorial Hospital Bellevue, IL
2013-	Attending Physician Barnes Jewish Hospital St. Louis, MO
2014- 2019	Director, Ryan Residency Training Program Department of Obstetrics and Gynecology Washington University School of Medicine
2016- 2019	Co-Director, Fellowship in Family Planning Department of Obstetrics and Gynecology Washington University School of Medicine
2016-2019	Obstetrics and Gynecology Performance Evaluation Committee Washington University/Barnes Jewish OB/GYN Residency
2016-2019	Washington University School of Medicine Institutional Review Board Member
2018-2019	Washington University School of Medicine Committee on Admissions

Committees:

2014- 2017 2017-2019	American College of Obstetrics and Gynecology Committee on the Healthcare for Underserved Women Member
2015- 2017 2017-2020	American College of Obstetrics and Gynecology Underserved Liaison to Committee on Adolescent Health Care
2015- 2019	International Federation of Gynecology and Obstetrics (FIGO) Women's Sexual and Reproductive Rights Committee Master Trainer, Integrating Human Rights in Health
2016-2020	Ibis Reproductive Healthcare Over the counter oral contraceptive working group Policy Subcommittee
2017-	MERCK Global Advisory Board on Contraception

	2017-2020	Washington University School of Medicine OUT Med Advisory Board
	2019-	International Federation of Gynecology and Obstetrics (FIGO) Committee for Human Rights, Refugees, and Violence Against Women
	2021-	American College of Obstetrics and Gynecology (ACOG), Committee on Government Affairs
Volunteer	2015- 2019	Saturday Neighborhood Health Clinic Washington University School of Medicine Volunteer Attending Physician Faculty, Primary Care Volunteer Attending Physician Faculty, Americore Homeless

Medical Licensure and Board Certification:

Licensure

Active: Missouri, Oklahoma, Illinois
Previous: Kansas, Washington

Board Certification:

2014- current	American Board of Obstetrics and Gynecology General Obstetrics and Gynecology Diplomate

Honors and Awards:

2001	Gregory Snoke Memorial Scholarship
2001	American Chemical Society Analytical Achievement Award
2001	American Chemical Society Division of Analytical Chemistry 2001 Undergraduate Award
2002	PGG Industries Foundation J. Earl Burrell Scholarship
2003	Senior Academic Award: College of Arts and Science
2006	Presidents Award: Women in Medicine
2011	Kody Kunda Resident Teaching Award
2012	ACOG Health Policy Rotation, LARC Program January 2013
2012	Physicians for Reproductive Health and Choice (PRCH) Leadership Training Academy
2012	President's Award: St. Louis Gynecologic Society, best research presentation
2016	Fellowship in Family Planning, Warrior Award
2016	Physicians for Reproductive Health, Voices of Courage: A Benefit Celebrating Extraordinary Abortion Providers
2016	2015 Roy M. Pitkin Award, Obstetrics and Gynecology (The Green Journal)
2018	Massingill Family Scholarship, 2018 Robert C. Cefalo Leadership Institute
2018	ACOG District VII Mentor of the year award
2019	Arnold P. Gold, Gold Humanism Honor Society Inductee
2019	Planned Parenthood Media Excellence Award
2019	Human Rights Campaign, St. Louis Leadership Award
2019	Rockwood Reproductive Health, Rights, and Justice Leadership Fellow
2020	American College of Osteopathic Obstetricians and Gynecologists Barbara Hawkes Memorial Presentation
2020	Boston University/ Boston Medical Center, Visiting Professor, Linda J. Heffner Research Day

Editorial Responsibilities:

2011- *Reviewer*, Contraception
2011- *Reviewer*, Journal of Family Planning and Reproductive Health Care
2012- *Reviewer*, American Journal of Obstetrics and Gynecology
2012- *Reviewer*, European Journal of Obstetrics and Gynecology and Reproductive Biology
2013- *Reviewer*, Obstetrics and Gynecology

Professional Societies and Organizations:

2003- Medical Students for Choice
2006-2011 Association of Reproductive Health Professionals
2006- American Congress of Obstetricians and Gynecologists

Leadership Roles

- 2013: The American College of Obstetricians and Gynecologists/Bayer HealthCare Pharmaceuticals Research Fellowship in Contraceptive Counseling (Selection committee)
- 2012-2019: American Congress of Obstetrics and Gynecology Congressional Leadership Conference, participant
  - 2015: Presenter, Reproductive Health Legislation in the States
  - 2016: Presenter, Reproductive Health Legislation in the States
- 2014-2020: Committee on Health Care for Underserved Women
  - Author, CO-Healthcare for Women with Disabilities
  - Author, Policy statement- Marriage and Family Equality
  - ACOG Liaison, AAMC Family Building Webinar series
  - Author, CO- Trauma informed care
- 2015-current: Committee on Adolescent Health Care, Underserved Liaison
- 2015-current: Missouri ACOG Section Advisory Committee, Member
  - 2015- current: Member, Legislative Committee
  - 2019-2021: Secretary/Treasurer
  - 2021- current: Vice Chair, Legistaltive Chair
- 2021- current: Committee on Government Affairs

2006- Gay and Lesbian Medical Association
2006- Women in Medicine
Leadership Roles

- 2010-current Board Member
- 2016: Chair of annual conference, Aug 2016
- 2018-2020: Board Treasurer

2008-2011 St. Louis Obstetrics and Gynecology Society
Leadership Roles: resident board member

2011- Society of Family Planning

Invited Presentations:

2001 Cadmium's effect on Osteoclast Apoptosis
12th Annual Argonne Symposium for Undergraduates in Science, Engineering and Mathematics

2002 Cadmium's effect on Osteoclast Apoptosis
2002 Experimental Biology Conference

2012 Contraception for medically complicated women
Women in Medicine Annual meeting

2013 The troubling trend of legislative interference.
Washington University School of Medicine, OBGYN Grand Rounds.

2013 An update on abortion: Why lesbians and those who treat them should care
The Gay and Lesbian Medical Association

2013 Findings from the Contraceptive CHOICE Project. Are you meeting your patient's contraceptive needs?
Washington University School of Medicine Annual OB/GYN Symposium

2013 Legislative interference and the impact on public health.
Washington University Brown School of Social Work.

2014 Business of Medicine Medical Student Elective Course
Legislating Medicine
Washington University School of Medicine

2014 Practical tips for your first RCT, lessons learned
Lecture in Randomized Control Trial course

2014 Uniting tomorrow's leaders of the RJ movement with providers of today
National Abortion Federation Annual Meeting

2014 Systems based practice and advocating for your patients
Washington University School of Medicine OB/GYN residency core lecture

2014 Abortion in sexual minority populations
National Abortion Federation

2014 Complications of uterine evacuation
St. Louis University OB/GYN Grand Rounds

2014 Medical contraindications in CHOICE Participants using combined hormonal contraception
Over the Counter Oral Contraceptive Working Group

2015 Implementing immediate postpartum LARC
Kansas University OB/GYN grand rounds

2015 The evidence for immediate Post-partum IUD insertion
Kansas City Gynecologic Society

2105 Business of Medicine Medical Student Elective Course
Legislating Medicine
Washington University School of Medicine

2015 Getting Politics Out of the Exam Room: Combating Legislative Interference in

	the Patient-Provider Relationship National Abortion Federation Annual Meeting
2015	Are you meeting your patient's contraceptive needs? Tennessee Department of Health.
2015	Colorado Initiative to reduce unintended pregnancy (webinar): Reducing Unplanned Pregnancies in Colorado through Strategies to Promote Long-Acting Reversible Contraception Huffington Post, Live
2105	Method mix it up: Expanding options to meet the unique contraceptive needs of young people FIGO World Conference
2015	Getting to Yes-Interventions to Increase LARC Acceptance with a Focus on IUC Nurse Practitioners Women's Health Annual Symposium
2015	Put your megaphone where your mouth is: Getting your professional society to speak up Forum on Family Planning
2015	When Politics Trumps Science- Why is Birth control at Center Stage? Carbondale Illinois Grand Rounds
2016	Using research to effectively advocate Physicians for Reproductive Health Leadership Training Academy
2016	Partial Participation and Abortion Training in Residency: A Structure for Optimizing Learning and Clinical Care APGO/CREOG
2016	Are we meeting the needs of our teen and adolescent patients? Our role in preventing unintended pregnancy. Barnes Jewish Hospital/Washington University School of Medicine CME Outreach.
2016	The emerging role of physicians as advocates St Louis OB/GYN Society
2016	Legislation and Advocacy Washington University School of Medicine- Elective course Gun violence as a public health issue
2016	Legislative advocacy and the impact on public health Washington University, Brown School of Social Work
2017	GOV 101 Learning to advocate at the MO legislature
2017	Reevaluating the longevity of LARC GrandRounds, BayState Medical Center
2018	Ryan Residency Program Annual Meeting Patient and Community Advocacy in Residency Training

2018 Physician advocacy, the key to public health
Keynote Speaker
Washington University
Center for Community Health Partnership & Research (CCHPR)
Global Health Center Summer Research Program

2018 XXII World Congress of Gynecology and Obstetrics
Whether, when, and how many: a global movement toward reproductive freedom
Rio de Janeiro, Brazil

2018 Domestic and Global epidemiology of abortion
Washington University, Brown School of Social Work

Research Support:

Role: Principal Investigator
MERCK
Impact of Standardized Counseling on Early Discontinuation for Irregular Bleeding in Users of the Contraceptive Implant
Award: Jan 2020- July 2022
Award Amount: $465,900

3125-946435
Role: Principal Investigator
MERCK
Ovarian function with prolonged use of the implant
Award: January 2017-June2018
Award Amount: $279,126

U01DK106853 (Colditz, Sutcliffe)
Role: Co-investigator
NIH/NIDDK
LUTS prevention in adolescent girls and women across the lifespan
Award: July 1, 2015 - January 1, 2019

(Peipert, McNicholas)
Role: Co-Principal Investigator
Anonymous Donor
EPIC: Evaluating prolonged use of the IUD/implant for Contraception
Award: Sep8, 2014 – Aug 31, 2018
Award Amount: $ 1,000,000

National Institutes of Health- Loan Repayment Program
Role: Principal Investigator
EPIC: Evaluating prolonged use of the IUD/implant for Contraception
Aug 17, 2014- July 31, 2017
Award Amount: $70,000
Aug 1, 2016- July 31, 2018
Award Amount: $70,000
Aug 1, 2018- July 31, 2020

81615 (Peipert, McNicholas)
Role: Co-Principal Investigator

William and Flora Hewlett Foundation
LIFE: Levonorgestrel Intrauterine system For Emergency Contraception; a multicenter randomized trial
June1, 2014- May 31, 2015
Award Amount: $351,500

IRG-58-010-57 (McNicholas)
Role: Principal Investigator
American Cancer Society Institutional Research Grant (ACS-IRG)
Evaluating the impact of the IUD on HPV and cervical cancer risk
January 1, 2014-December 31, 2014
Award Amount: $30,000

SFPRF12-1 (McNicholas)
Role: Principal Investigator
Society of Family Planning Research Fund
Effectiveness of Prolonged use of IUD/Implant for Contraception (EPIC)
January 2012 – July 2014
Award Amount: $70,000

UL1 TR000448 (Evanoff)
Role: Postdoctoral MSCI Scholar
NIH-National Center for Research Resources (NCRR)
Washington University Institute of Clinical and Translational Sciences (ICTS)
July 1, 2011 – June 30, 2013

5T32HD055172-03 (Macones, Peipert)
Role: Clinical fellow, trainee
NIH T32 Research Training Grant
July 1, 2011 – June 30, 2013

Bibliography:

Peer-reviewed Publications:

1. Allsworth JE, Hladky KJ, Hotchkiss T, McNicholas C, Rohn A. Discussion: 'Douching and the risk for sexually transmitted disease' by Tsai et al. *Am J of Obstet and Gynecol* 2009;200(1):e11-4.

2. Stoddard A, McNicholas C, Peipert JF. Efficacy and safety of long-acting reversible contraception. *Drugs*. 2011 May 28;71(8): p. 969-80. PMID: 21668037

3. McNicholas C, Hotchkiss T, Madden T, Zhao Q, Allsworth J, Peipert JF. Immediate postabortion intrauterine device insertion: continuation and satisfaction. *Women Health Iss.* 2012 Jul-Aug; 22(4):e365-369. PMID: 22749197

4. McNicholas C, Peipert JF. Long-acting reversible contraception for adolescents. *Curr Opin Obstet Gyn.* 2012 Oct; 24(5):293-298. PMID: 22781078

5. McNicholas C, Peipert JF. Initiation of long-acting reversible contraceptive methods (IUDs and implant) at pregnancy termination reduces repeat abortion. *Evid Based Med.* 2013 Jun;18(3):e29. PMID: 23161505

6. McNicholas C, Madden T, Zhao Q, Secura G, Allsworth JE, Peipert JF. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. *Am J Obstet Gynecol. 2012* Nov;207(5):384 e381-386. PMID: 23107081

7. McNicholas C, Zhao Q, Secura G, Allsworth J, Madden T, Peipert J. Contraceptive failures in overweight and obese combined hormonal contraceptive users. *Obstet Gynecol.* 2013 March; 121(3):585-92. PMID: 23635622

8. McNicholas C. Transcending politics to promote women's health. *Obstet Gynecol.* 2013 Jul;122(1):151-3. PMID: 23743460

9. Eisenberg D, McNicholas C, Peipert JF. Cost as a barrier to long-acting reversible contraceptive (LARC) use in adolescents. *J Adolescent Health.* 2013 Apr;52(4 Suppl):S59-63. PMID: 23535059

10. Grentzer J, McNicholas C, Peipert J. Use of the etonorgestrel-releasing implant. *Expert Rev. of Obstet and Gynecol.* 8 (4), 337-344. 2013

11. Secura G, McNicholas C. Long-acting reversible contraceptive use among teens prevents unintended pregnancy: a look at the evidence. *Expert Rev. of Obstet Gynecol.* 8(4), 297-299. 2013

12. McNicholas C, Peipert JF, Madipati R, Madden T, Allsworth, J Secura G. Sexually transmitted infection prevalence in a population seeking no-cost contraception. *Sex Transm Dis.* 2013 July;40(7):546-51. PMID: 23965768

13. Sehn JK, Kuroki LM, Hopeman MM, Longman RE, McNicholas CP, Huettner PC. Ovarian complete hydatidiform mole: case study with molecular analysis and review of the literature. *Hum Pathol.* 2013 Dec;44(12):2861-4. PMID: 24134929

14. Madden T, McNicholas C, Zhao Q, Secura G, Eisenberg D, Peipert JF. Association of Age and Parity with IUD Expulsion. *Obstet Gynecol.* 2013 Oct; 124 (4): 718-26. PMID: 4172535

15. Secura G, Madden T, McNicholas C, Mullersman J, Buckel C, Zhao Q, Peipert JF. No-Cost Contraception Reduces Teen Pregnancy, Birth, and Abortion. *New Engl J Med.* 2104 Oct; 371(14); 1316-23. PMCID: 4230891

16. McNicholas C, Madden T, Secura G, Peipert JF. The Contraceptive CHOICE Project Round Up: What we did and what we learned. *Clin Obstet Gynecol.* 2014 Dec; 57(4); 635-43. PMCID: 4216614

17. McNicholas C, Maddipati R, Swor E, Zhao Q, Peipert JF. Use of the Etonogestrel Implant and Levonorgestrel Intrauterine Device Beyond the U.S. Food and Drug Administration-Approved Duration. *Obstet Gynecol,* 2015 Mar; 125(3):599-604.

18. Grentzer J, Peipert J, Zhao Q, McNicholas C, Secura G, Madden T. Risk-based screening for Chlamydia trachomatis and Neisseria gonorrhoeae prior to intrauterine device insertion. *Contraception* 2015 Jun; S0010-7824(15)00250-4. PMID:26093189

19. Mejia M, McNicholas C, Madden T, Peipert J. Association of Baseline Bleeding Pattern on Amenorrhea with Levonorgestrel Intrauterine System Use. *Contraception.* 2016 Nov;94(5):556-560. PMID: 27364099

20. Hou M, McNicholas C, Creinin M. Combined Oral Contraceptive Treatment for Bleeding Complaints with the Etonogestrel Contraceptive Implant: A Randomized Controlled Trial. *Eur J Contracept Reprod Health Care.* 2016 Oct;21(5):361-6. PMID: 27419258

21. Zigler RE, Peipert JF, Zhao Q, Maddipati R, McNicholas C. Long-acting reversible contraception use among residents in obstetrics/gynecology training programs. *Open Access J of Contracept.* 2017 Jan; 2017(8) 1—7. PMID: 29386949

22. Zigler RE, McNicholas C. Unscheduled vaginal bleeding with progestin-only contraceptive use. *Am J of Obstet and Gynecol.* 2017 May;216(5):443-450. PMID: 27988268

23. McNicholas C, Swor E, Wan L, Peipert JF. Prolonged use of the etonogestrel implant and levonorgestrel intrauterine device: 2 years beyond Food and Drug Administration-approved duration. *Am J Obstet Gynecol.* 2017 Jan 29. PMID:28147241

24. McNicholas C, Peripert JF. Is it time to abandon the routine pelvic exam in asymptomatic nonpregnant women? *JAMA* 2017 Mar 7;317(9):910-911. PMID:28267835

25. McNicholas C, Madden T. Meeting the Contraceptive Needs of a Community: Increasing Access to Long-Acting Reversible Contraception. *MO Med.* 2017 May-Jun; 114(3):163-167. PMID:30228573

26. Iseyemi A, Zhao Q, McNicholas C, Peipert JF. Socioeconomic Status As a Risk Factor for Unintended Pregnancy in the Contraceptive CHOICE Project. *Obstet Gynecol.* 2017 Sep;130(3):609-615. PMID: 28796678

27. McNicholas C, Klugman J, Zhao Q, Peipert J. Condom Use and Incident Sexually Transmitted Infection after Initiation of Long-Acting Reversible Contraception. *Am J of Obstet and Gynecol.* 2017 Dec;217(6):672.e1-672.e6. PMID: 28919400

28. Zigler RE, Madden T, Ashby C, Wan L, McNicholas C. Ulipristal Acetate for Unscheduled Bleeding in Etonogestrel Implant Users: A Randomized Controlled Trial. *Obstet Gynecol.* 2018 Oct;132(4):888-894. PMID: 30130151

Non-Peer Reviewed Invited Publications:

1. McNicholas C. Rev. of Recent advances in obstetrics and gynecology, *Royal Society of Medicine Press*, 2008.

2. McNicholas C, Levy B. The original minimally invasive hysterectomy; no hospitalization required. *Expert Rev. of Obstet and Gynecol.* 8(2), 1-3. 2013

Chapters:

1. Gross G, McNicholas C. Rev. of Shoulder dystocia and birth injury: prevention and treatment, by James A. O'Leary 3rd Ed
2. McNicholas C, Peipert JP. Pelvic inflammatory disease. *Practical Pediatric and Adolescent Gynecology*. Oxford. Wiley-Blackwell. ISBN: 978-0-470-67387-4.
3. McNicholas C, Madden T., *2015 Contraceptive counseling for obese women.* In E. Jungheim (Ed) Obesity and Fertility. Springer, New York. ISBN 978-1-4939-2611-4

Abstracts:

1. McNicholas C, Maddipati R, Secura G, Peipert J. Use of the contraceptive implant beyond the FDA-approved duration. Poster Presentation. North American Forum on Family Planning. Miami, FL October 2014.

2. McNicholas C, Swor E, Peipert J, Secura G. Serum etonogestrel levels in women using the contraceptive implant beyond the FDA-approved duration. *Oral Presentation. North American Forum on Family Planning*. Seattle, WA October 2013.

3. McNicholas C, Zhao Q, Peipert J, Secura G. Condom use and incident sexually transmitted infection after initiation of long-acting reversible contraception. *Oral Presentation. 40th Annual Scientific Meeting of the Infectious Diseases Society for Obstetrics and Gynecology*. Sante Fe, NM Aug 2013.

4. McNicholas C, Madden T, Zhao Q, Secura G, Allsworth JE, Peipert JP. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. *Poster Presentation. North American Forum on Family Planning*. Denver, CO. October 2012.

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6. McNicholas C, Maddipati R, Allsworth J, Madden T, Peipert J, Secura G. An epidemiologic comparison of *Chlamydia Trachomatis* and *Trichomonas Vaginalis*: Information from the Contraceptive CHOICE Project. *Poster Presentation, 39th Annual Scientific Meeting of the Infectious Diseases Society for Obstetrics and Gynecology*. Whistler, BC Aug 2012.

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