EAST BATON ROUGE PARISH
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C-755217
33

19TH JUDICIAL DISTRICT COURT
EAST BATON ROUGE PARISH
STATE OF LOUISIANA

NO. C-755217 DIVISION 33

BIRTHMARK DOULA COLLECTIVE, LLC, a Louisiana LLC d/b/a BIRTHMARK, on behalf of itself and its clients, NANCY DAVIS, on behalf of herself, EMILY HOLT, DO, MPH, on behalf of herself and her patients, KAITLYN JOSHUA, on behalf of herself, and KAYLEE SELF, PharmD, on behalf of herself and her patients.

VERSUS

STATE OF LOUISIANA, ELIZABETH MURRILL, in her official capacity as Attorney General of the State of Louisiana, LOUISIANA BOARD OF PHARMACY and LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

FILED: _____ _____
DEPUTY CLERK

PETITION FOR DECLARATORY AND PERMANENT INJUNCTIVE RELIEF ENJOINING THE ENFORCEMENT OF ACT 246 OF THE 2024 REGULAR LEGISLATIVE SESSION

NOW INTO COURT, through undersigned counsel, comes Birthmark Doula Collective LLC, a Louisiana LLC d/b/a Birthmark, on behalf of itself and its clients, Nancy Davis, on her own behalf, Dr. Emily Holt, on her own behalf and on behalf of her patients, Kaitlyn Joshua, on her own behalf, and Pharmacist Kaylee Self, on her own behalf and on behalf of her patients ("Plaintiffs"). Together, Plaintiffs file this Petition for Declaratory and Permanent Injunctive Relief to enjoin the enforcement of Act 246 of the 2024 Legislative Session against the State of Louisiana; Attorney General Elizabeth Murrill, in her official capacity; Louisiana Board of Pharmacy; and Louisiana State Board of Medical Examiners ("Defendants"), and respectfully aver as follows:

SUMMARY OF LAWSUIT

1. This lawsuit challenges Louisiana Act 246 ("Act 246" or "the Act"),[1] a law that delays access to lifesaving treatment for people experiencing obstetrical emergencies and makes

[1] 2024 Leg., Reg. Sess. (La. 2024).

it significantly harder for people with a wide range of physical conditions to obtain proven, effective remedies necessary for their treatment and care.

2. The challenged law classifies misoprostol and mifepristone—two safe and beneficial FDA-approved medications—as controlled dangerous substances.

3. Although Act 246 targets medications sometimes used to provide abortions, it will have little—if any—impact on abortion access because Louisiana already bans abortion in nearly all circumstances.

4. Instead, the harmful impacts of the statute's hasty enactment will be felt primarily by people carrying pregnancies to term, people experiencing miscarriages, and people with a wide range of medical conditions unrelated to pregnancy who rely on these safe and effective medications to treat their conditions. This lawsuit seeks to remedy those harms.

5. For instance, postpartum hemorrhage is a common yet dangerous physical condition that is one of the leading causes of maternal mortality in Louisiana. Misoprostol is a commonly used, effective, and inexpensive treatment for postpartum hemorrhage. For some postpartum hemorrhage patients with certain preexisting conditions, it is the only available treatment. Postpartum hemorrhage is as severe and dangerous as a gunshot wound. Patients experiencing postpartum hemorrhage lose as much blood, and as quickly, as patients suffering from a gunshot wound.

6. Act 246 forces hospitals to put misoprostol in a secure location, delaying access to this life-saving medication during critical emergencies. Hundreds of healthcare providers have expressed serious concerns about the impact that Act 246 will have on their practice and on maternal health outcomes in Louisiana, a state that already has one of the highest rates of maternal mortality in the nation.

7. In all instances, the challenged law arbitrarily, capriciously, or unreasonably discriminates based on physical condition, violating Louisiana's constitutional right to equal protection within the right to individual dignity. In some cases, that discrimination is life-threatening. The challenged law does not substantially further a legitimate state objective, nor is it rationally related to a legitimate state objective.

8. Effective October 1, 2024, Act 246 added misoprostol and mifepristone to Schedule IV of Louisiana's Uniform Controlled Dangerous Substances Law ("Uniform Controlled Dangerous Substances Law").[2] Act 246 amended La. R.S. 14:87.1, 15:1352, 40:964, and 40:969, and created the new statute of La. R.S. 14:87.6.1.

9. By definition, drugs listed in Schedule IV of Louisiana's Uniform Controlled Dangerous Substances Law—like its federal counterpart—have the potential to cause some physical or psychological dependence. Yet in the 36 years since the FDA approved misoprostol and the 24 years since the FDA approved mifepristone, there has been no evidence that either drug carries any risk of physical or psychological dependence. Instead, there is consensus in the medical, public health, and drug regulation communities that neither drug meets the criteria for scheduling—neither the federal Drug Enforcement Authority nor any other state in the country classifies, or has ever classified, misoprostol or mifepristone as a controlled dangerous substance.

10. The Louisiana legislature failed to abide by bedrock legislative and constitutional protections when it passed Act 246 with amendments not germane to the original bill. As enacted, Act 246 contains multiple provisions that do not share a common object or purpose, and the amendments introduced in the House of Representatives failed to comply with the Constitution's important restrictions on legislative instruments.

11. Plaintiffs—birth workers and other medical professionals, advocates, and a pregnant person—represent a diverse array of perspectives. But they each share the goal of making sure that healthcare—and particularly reproductive healthcare—is accessible, safe, and data-driven in Louisiana. They bring this lawsuit because of their grave concerns that Act 246 impedes those goals, threatening their own professional and medical practices and creating untenable risks for their patients' or clients' health, as well as for their own care. As Louisiana taxpayers, Plaintiffs also seek to ensure that the legislative process is fair and transparent, and that constitutional limits on the enactment of new laws are followed and respected by the legislature. Plaintiffs seek declaratory relief, pursuant to La. Code Civ. Proc. art. 1871, *et seq.*, declaring Act 246 invalid, unenforceable, and unconstitutional for the reasons detailed herein, and a permanent injunction,

[2] La. R.S. 40:964.

pursuant to La. Code Civ. Proc. art. 3601, *et seq.*, permanently enjoining enforcement of Act 246 as codified.

JURISDICTION AND VENUE

12. This Court has jurisdiction under Article V, Section 16(A) of the Louisiana Constitution because Plaintiffs bring a civil suit to vindicate their rights under Article I, Section 3 and Article III, Section 15 of the Louisiana Constitution.

13. This Court also has jurisdiction because Plaintiffs seek declaratory and injunctive relief under La. Code Civ. Proc. art. 1871, *et seq.*

14. This suit is filed against the State of Louisiana, state agencies, and their officers. This venue is the judicial district in which the state capitol is located; therefore, venue is proper under Article XII, Section 1 of the Louisiana Constitution and La. R.S. 13:5104(A).

PLAINTIFFS

15. Plaintiff Birthmark Doula Collective, LLC, a Louisiana LLC d/b/a Birthmark ("Birthmark") is a doula-owned cooperative based in New Orleans, Louisiana, dedicated to supporting, educating, and advocating for pregnant and parenting people and their families, with a focus on increasing access to respectful services for communities facing barriers to care. Birthmark believes all birthing people should have dignified, transformative, and powerful birth and parenting experiences that build power, self-determination, and nurturing care within communities. Doulas provide physical, emotional and informational support to people before, during, and after childbirth. They focus on creating a positive birth experience and seek to ensure that their clients' needs and preferences are met during childbirth. Doulas play a vital role in providing culturally sensitive support that respects and incorporates the values and practices of diverse communities, helping to address disparities in maternal health outcomes. Birthmark is committed to birth justice and has a special focus on working with marginalized individuals, particularly Black, Indigenous, and people of color (BIPOC), who face systemic barriers in their health care. Birthmark aims to ensure that all people, regardless of their background, have access to quality doula support and comprehensive reproductive health services. It prioritizes support for BIPOC people, recognizing the disparities they face in maternal health outcomes, while uplifting voices from underserved backgrounds and combatting discrimination. Birthmark's work is rooted

in the belief that everyone deserves respectful, appropriate and supportive care during one of the most significant moments of their lives. Birthmark asserts a claim under La. Const. art. I, § 3 on behalf of itself and its clients and a claim under La. Const. art. III, § 15 on its own behalf as a Louisiana taxpayer.

16. In the summer of 2022, Plaintiff Nancy Davis was denied a medically-indicated pregnancy termination at her local hospital in Baton Rouge, Louisiana. At the time, Davis was told that a Louisiana law prohibited her hospital from providing her care, even though the care she needed was not included in the legal definition of abortion under Louisiana law. She was forced to travel nearly 1,500 miles with her fiancé to access the healthcare she and her family deserved. Davis was approximately 11 weeks pregnant, and she had recently been informed that her fetus had a fatal abnormality—acrania (which is marked by the absence of a skull). There was no chance the fetus would survive. Davis shared her story with media outlets and raised money to cover the travel and logistical costs associated with obtaining appropriate medical care outside of Louisiana. Davis's experience being denied necessary healthcare in Louisiana led her to establish the Nancy Davis Foundation and to advocate for reproductive justice and to aid those who have endured trauma due to prenatal developmental defects during pregnancy. Davis's experience has served as a catalyst for her to share her story and transform her pain into action. She has organized rallies, testified at legislative sessions, and has been a powerful voice raising awareness about the struggles women—particularly those in Louisiana—face accessing essential healthcare. Through her foundation, she seeks to mend broken and traumatized families from diverse backgrounds. She is a Louisiana taxpayer residing in East Baton Rouge Parish. Davis asserts a claim under La. Const. art. III, § 15 on her own behalf as a Louisiana taxpayer.

17. Plaintiff Dr. Emily Holt is a board-certified Family Medicine physician. She graduated magna cum laude from Tulane University with a Bachelor of Arts and Master of Public Health, went to medical school at the Virginia College of Osteopathic Medicine, and completed a residency in Family Medicine at Columbia University—New York Presbyterian in Manhattan. Dr. Holt served New Orleans before, during, and after Hurricane Katrina. Before going to medical school, she was an Emergency Medical Technician for New Orleans Emergency Medical Services. Once she became a physician, she provided comprehensive Family Medicine at St. Thomas

Community Health Center for all ages. Then, as the interim Assistant Medical Director of Tulane Campus Health and the physician on the Eating Concerns Team, Dr. Holt developed a special interest in the unique needs of the young adult population. Dr. Holt opened a new clinic in New Orleans in late September 2024 to serve that special interest. Her new clinic, Poppy Direct Care, is within walking distance of Tulane University and Loyola University New Orleans. Poppy Direct Care specializes in providing medical services for people between the ages of 18 and 45. Dr. Holt resides in Orleans Parish and is a Louisiana taxpayer. Dr. Holt asserts a claim under La. Const. art. I, § 3 on her own behalf as a medical provider and on behalf of her patients, and a claim under La. Const. art. III, § 15 on her own behalf as a Louisiana taxpayer.

18. Plaintiff Kaitlyn Joshua was unable to obtain prenatal care during the first trimester of her pregnancy, which her medical provider's front desk attributed to the state's strict abortion ban. She was also refused treatment for her miscarriage. When Joshua went into labor 11 weeks into her pregnancy, she was turned away from two emergency rooms instead of being provided medication to treat her miscarriage. The medications commonly used to treat miscarriages in such circumstances are misoprostol and/or mifepristone. Since then, she has engaged in advocacy around access to appropriate miscarriage management care. She is a Louisiana taxpayer residing in East Baton Rouge Parish. Joshua asserts a claim under La. Const. art. III, § 15 on her own behalf as a Louisiana taxpayer.

19. Kaylee Self, PharmD, is a pharmacist at Walgreens in Shreveport, Louisiana. Self grew up in the Shreveport and Bossier area and obtained her bachelor's degree in biology from Baylor University, where she graduated cum laude. She earned a Doctor of Pharmacy (PharmD) from the University of Texas at Austin in 2018. During pharmacy school, she completed a one-year rotation in Houston, Texas. Self has been a licensed pharmacist in Louisiana since July 2018. In addition to her Doctor of Pharmacy, she is trained in basic cardiac life support and pharmacy-based immunization. Self also provides medication counseling and medication therapy management and she conducts annual reviews with patients regarding their medications, discusses medication side effects, and provides annual updates to patients' primary care physicians. Self is a community-based pharmacist. She works at her neighborhood pharmacy and can walk to work. Most of her patients also live within a short walk or drive of the pharmacy, and she sees many of

her patients often, up to four or five times per week. She strives to be an accessible healthcare provider who maintains ongoing relationships with her patients, and has frequent interactions with patients that build over time into deep relationships. Self is currently pregnant with her first child. She will likely encounter medical conditions during the course of her pregnancy that could be treated with misoprostol. She resides in Caddo Parish and is a Louisiana taxpayer. Self asserts a claim under La. Const. art. I, § 3 on her own behalf as a pharmacist and a pregnant person and on behalf of her patients, and a claim under La. Const. art. III, § 15 on her own behalf as a Louisiana taxpayer.

20. Plaintiffs have real and actual, legally protectable, and tangible interests at stake in this litigation, which they assert herein as described below.

DEFENDANTS

21. Defendant State of Louisiana is the state government in Louisiana. It originates with the people and is founded on their will alone.[3]

22. Defendant Elizabeth (Liz) Murrill is sued in her official capacity as Attorney General—the "chief legal officer of the state."[4] The Attorney General oversees all district attorneys within the State and can initiate, prosecute, or intervene in any legal proceedings deemed "necessary for the assertion or protection of the rights and interests of the State."[5] Murrill championed the Act from the time of its introduction in the legislature and announced support for the Act days before the Louisiana Governor signed it.

23. Defendant Louisiana Board of Pharmacy ("the Board of Pharmacy") is a state agency tasked with overseeing and regulating the practice of pharmacy. It also engages in the administration and licensure of pharmacists and the licensure, permitting, certification, registration, control, and regulation of all persons and sites, in or out of this state, that sell and disburse drugs or devices to consumers and/or patients or assist in the practice of pharmacy within the state.[6] The Board of Pharmacy also serves as the controlled substance authority for the state,

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[3] La. Const. art. I, § 1.

[4] La. Const. art. IV, § 8.

[5] La. Code Crim. Proc. Ann. § art. 62.

[6] *See e.g.* La. R.S. 37:1171, 37:1201, 37:1221.

and is responsible for issuing controlled dangerous substance licenses ("CDS license(s)") to applicants desiring to conduct research with, manufacture, distribute, procure, possess, prescribe or dispense controlled dangerous substances within the state, including third-party logistics providers.[7] The Board of Pharmacy monitors compliance with the laws and rules regulating controlled dangerous substances.[8] In fact, La. R.S. 40:973(E) authorizes the Board of Pharmacy to inspect pharmacies, CDS licensees, and applicants to ensure compliance with such laws and regulations. La. R.S. 40:984 empowers the Board of Pharmacy's employees to carry firearms, make arrests, execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses, and seize property pursuant to the Uniform Controlled Dangerous Substances Law. Further, the Board of Pharmacy makes referrals to other licensing and regulatory authorities, such as the Louisiana State Board of Medical Examiners and the Louisiana State Board of Nursing, for possible disciplinary action against doctors or nurses related to the Uniform Controlled Dangerous Substances Law and its complex web of regulations.

24. Defendant Louisiana State Board of Medical Examiners is a state agency empowered to grant and revoke the licenses of medical practitioners in Louisiana, impose discipline upon them, and otherwise regulate medical practice in Louisiana. That includes the authority to initiate investigations or disciplinary action against physicians suspected of prescribing, dispensing, or administering controlled substances in a manner that may not comply with all applicable laws and regulations.

FACTUAL ALLEGATIONS

25. On October 1, 2024, Louisiana became the only state in the country to categorize misoprostol and mifepristone as controlled dangerous substances.

26. At the last minute during the legislative process, lawmakers introduced an amendment to include misoprostol and mifepristone on the drug schedule in the Uniform Controlled Dangerous Substances Law to Senate Bill 276 ("S.B. 276"), which, as introduced, had

[7] La. R.S. 40:973.

[8] *Id.*

a different object from the amendment and was in no way related to the subject matter of the amendment. That bill became Act 246.

27. Adding these medications to the Uniform Controlled Dangerous Substances Law subjects medical professionals who prescribe, dispense, or administer misoprostol or mifepristone and their patients who need such medications to a highly regulated legal scheme—despite no medical justification or valid legal basis for doing so—that threatens access to lifesaving medications for certain patients, and improperly interferes with timely and appropriate access for others with a range of physical conditions.

28. Act 246 harms patients who require misoprostol or mifepristone to treat their physical conditions, as well as the medical professionals seeking to provide timely, appropriate, and compassionate care, by (1) impeding and delaying access to potentially lifesaving medications for patients experiencing critical emergent situations, (2) creating unnecessary, burdensome, and possibly prohibitive barriers to access for patients who rely upon misoprostol or mifepristone to manage and treat their chronic physical conditions, and (3) subjecting all patients who need a prescription for misoprostol or mifepristone to an intrusive monitoring system that interferes with their privacy.

29. By contrast, patients with similarly situated physical conditions who are treated with other medications that have a similar risk profile as misoprostol and mifepristone—meaning, drugs with a very low risk profile, both in terms of adverse events and the potential to cause abuse or dependence—do not face these same burdens and barriers to accessing necessary medical treatment, nor do they face the associated infringement on patient dignity and medical autonomy that will result from the Act.

30. The Act also treats medical providers who prescribe misoprostol and mifepristone differently than medical providers who prescribe other medications with a similar risk profile as misoprostol and mifepristone.

31. The Act's discriminatory impact does not substantially further a legitimate state objective, nor is it rationally related to a legitimate state objective.

I. Act 246 Unconstitutionally Discriminates Against Patients on the Basis of Physical Condition and Against Healthcare Providers, Violating the Right to Equal Protection and Individual Dignity under the Louisiana Constitution.

A. Misoprostol and Mifepristone Are Widely Prescribed for a Variety of Medical Conditions.

32. Misoprostol and mifepristone are used in Louisiana every day to safely and effectively treat many physical conditions that are unrelated to abortion.

33. Both drugs are prescribed according to their labels and for off-label purposes. The FDA permits the use of drugs for off-label purposes. Off-label prescribing is legal and common—one in five prescriptions written today is for off-label use.

34. For some patients, misoprostol or mifepristone is the only drug that will treat their physical condition.

35. Some of the conditions that are treated with misoprostol or mifepristone develop quickly and without warning. For patients with these conditions, misoprostol or mifepristone must be provided urgently to reduce harm and, in some cases, save the patient's life.

36. For example, misoprostol is an evidence-based treatment for postpartum hemorrhage because it stops blood loss. Postpartum hemorrhage is a common but potentially life-threatening condition that occurs when a patient experiences severe bleeding after childbirth. Postpartum hemorrhage is one of the leading causes of maternal mortality in the country and state.

37. Some patients with postpartum hemorrhage—including those with hypertension, preeclampsia, or asthma—are unable to use treatments other than misoprostol because they are at risk of adverse side effects from other medications.

38. Additionally, alternative treatments for postpartum hemorrhage are significantly more expensive, more difficult to administer, and/or carry serious side effects.

39. The longer it takes to provide medication to a postpartum hemorrhage patient, the more blood she loses.

40. Postpartum hemorrhage patients can lose hundreds of milliliters of blood per minute—out of a total of about five liters of blood. Therefore, it can take just minutes for a postpartum hemorrhage patient to bleed out, leading to serious maternal morbidity and, potentially, death. Even short delays in accessing misoprostol can be life-threatening for postpartum hemorrhage patients.

41. Misoprostol is also prescribed to manage miscarriages in patients who have experienced a missed miscarriage. A missed miscarriage occurs when the embryo no longer has fetal cardiac activity or was never formed, but the placental and embryonic tissues remain in the uterus. Removal of excess tissue is vital for miscarriage patients. Failure to do so may result in a patient developing sepsis or other dangerous infections. Misoprostol is an effective and commonly used treatment for helping the body expel retained tissue after a missed miscarriage.

42. Misoprostol is on the World Health Organization's list of "essential medicines" for its role in treating miscarriage and both preventing and treating postpartum hemorrhage.[9]

43. Additionally, misoprostol is FDA-approved under the brand name Cytotec to reduce the risk of gastric ulcers caused by NSAIDs (nonsteroidal anti-inflammatory drugs, including aspirin). Cytotec is prescribed to patients with a high risk of complications from gastric ulcers, including the elderly. It is also prescribed to treat patients following bariatric surgery, who are at a high risk of developing ulcers, which can require further surgery and pose a significantly higher risk to their health if the ulcers are not properly treated with misoprostol.

44. Patients with osteoarthritis or rheumatoid arthritis also benefit from misoprostol. The drug diclofenac is used to treat both conditions. Because diclofenac is an NSAID it increases the risk of ulcers, and misoprostol decreases that risk. Thus, Pfizer manufactures a drug called Arthrotec that contains both diclofenac and misoprostol.[10] Arthrotec contains a sufficient amount of misoprostol to be characterized as a controlled substance under the Uniform Controlled Dangerous Substances Law, and by virtue of Act 246, this arthritis drug is now a controlled substance only in Louisiana.

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[9] World Health Org., *The Selection and use of Essential Medicines: 2023 World Health Organization Model List of Essential Medicines 23rd List* (2023), https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1.

[10] *See Arthrotec Drug Label*, FDA (May 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020607s031lbl.pdf.

45. Additionally, Misoprostol is prescribed for cervical preparation before "uterine instrumentation," which is a set of techniques used to evaluate the uterus and cervix during pregnancy.[11]

46. Misoprostol is also used to treat patients before the placement of an intrauterine device (IUD). Misoprostol is often prescribed to patients with a stenotic cervix—which essentially means the opening of the cervix is narrower than normal or, in some cases, completely closed—because it helps to soften and dilate the cervix. It is also prescribed to patients with a history of at least one failed IUD placement attempt and to patients seeking an IUD who have not previously given birth vaginally.[12]

47. Additionally, misoprostol is used for induction of labor or cervical ripening.

48. Misoprostol is also prescribed to post-menopausal patients with cervical stenosis prior to a biopsy used to diagnose precancerous cells or uterine cancer.

49. Mifepristone has multiple purposes and is used to treat physical conditions that are related to pregnancy as well as physical conditions that are unrelated to pregnancy.

50. Like misoprostol, mifepristone is often prescribed for miscarriage management. Evidence supports the use of mifepristone to expedite the expulsion of retained pregnancy tissues after a missed miscarriage.[13]

51. Additionally, mifepristone was originally developed to treat endogenous Cushing's Syndrome, and it is prescribed under the label Korlym for that purpose.

52. Cushing's Syndrome is a condition that occurs when the body releases too much of the hormone cortisol. Too much cortisol increases blood sugar and results in hyperglycemia. Mifepristone treats Cushing's Syndrome by blocking the cortisol from attaching to glucocorticoid receptors.

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[11] *Off-label use*, Misoprostol (2024), https://www.misoprostol.org/off-label-use/; *see, e.g.*, JV Turner et al., *Off-label Use of Misoprostol in Gynaecology*, Nat'l Libr. of Med. (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5058416/.

[12] JV Turner at al., *supra* n.11.

[13] *See* Justin J. Chu et al., *Mifepristone and Misoprostol Versus Misoprostol Alone for the Management of Missed Miscarriage (MifeMiso): A Randomised, Double-Blind, Placebo-Controlled Trial*, Lancet (Sept. 12, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7493715/.

53. Korlym is approved as a "cortisol receptor blocker" for adult patients with Cushing's Syndrome who also have type 2 diabetes or glucose intolerance and who "have failed surgery or are not candidates for surgery."[14] Approximately 1 in 20 patients with Type 2 diabetes have endogenous Cushing's Syndrome.[15]

54. Additionally, mifepristone is an evidence-based off-label treatment for a variety of other purposes, including (1) labor induction; (2) treatment of uterine fibroids;[16] and (3) treatment of ovarian cancer.[17]

55. Plaintiff Dr. Holt provides care at Poppy Direct Care—a new holistic clinic that provides reproductive health care as part of its services. Among other things, she provides IUDs to patients who plan to use IUDs as a method of birth control.

56. While misoprostol is not always recommended for the routine placement of an IUD, placement attempts sometimes fail. For patients who have had a history of at least one failed IUD placement attempt, Dr. Holt plans to provide them with the option to take misoprostol prior to another attempt to place an IUD.

57. As discussed above, *supra* at ¶¶ 45–46, administering misoprostol before placing an IUD can help soften the cervix, making it technically easier for a healthcare provider to insert the device and increasing the chances of successful placement. Patients with a stenotic cervix might benefit from misoprostol because the drug helps to expand the opening of the cervix.

58. Before Act 246 was passed, Dr. Holt also planned to dispense both misoprostol and mifepristone from her clinic to patients as part of miscarriage management.

59. Plaintiff Birthmark's doulas advocate for safe and equitable client care during pregnancy, birth, miscarriage, and postpartum. Each Birthmark doula offers support and advocacy

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[14] *See Korlym Drug Label*, FDA (November 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/202107s008lbl.pdf.

[15] Bruce Jancin, *When to Think Cushing's Syndrome is Type 2 Diabetes*, MDedge (2013), https://www.mdedge.com/endocrinology/article/76645/cardiology/when-think-cushings-syndrome-type-2-diabetes.

[16] Mario Tristan et al., *Mifepristone for Uterine Fibroids*, Nat'l Libr. of Med. (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8212859/.

[17] Alicia A. Goyeneche et al., *Mifepristone Inhibits Ovarian Cancer Cell Growth in Vitro and in Vivo*, Nat'l Libr. of Med. (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2505183/.

for the pregnant people they work with, seeking to assure that each of their clients receives compassionate, non-discriminatory, and appropriate care.

60. Doulas are sometimes the first to even notice signs that a post-partum hemorrhage is occurring because they often stay in the room when doctors or nurses are caring for other patients. In particular, Birthmark's doulas have worked with people experiencing post-partum hemorrhages who have been prescribed misoprostol to treat their condition.

61. Additionally, Birthmark's doulas work with people who experience miscarriages and are prescribed misoprostol for miscarriage management.

62. Finally, many of the people Birthmark's doulas serve are treated with misoprostol to induce labor. Louisiana has the highest rate of pregnancy-related/gestational hypertension[18] and practice guidelines for providers outlined by ACOG recommend induction at 39 weeks using misoprostol.[19] Because Birthmark's clients disproportionately experience preterm labor, high blood pressure, and preeclampsia, Birthmark's clients are administered misoprostol for induction on a more regular basis than the general population of pregnant people. As a result, Birthmark's doulas frequently work with clients who are given misoprostol for the purpose of safely inducing labor and reducing the chances of complications during birth.

63. Plaintiff Kaylee Self fills prescriptions for misoprostol on a regular basis at her pharmacy. Patients visit her pharmacy to obtain misoprostol to treat a variety of physical conditions, including miscarriage management and cervical stenosis before an IUD placement. Additionally, patients may visit her pharmacy to obtain misoprostol prescriptions for other conditions. Although it is less common for Self to fill prescriptions for misoprostol to treat chronic conditions such as gastric ulcers, she has previously filled prescriptions for non-gynecological purposes and anticipates that she could do so in the future when a patient visits the pharmacy with

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[18] Alexander J. Butwick, *Evaluation of US State-Level Variation in Hypertensive Disorders of Pregnancy*, JAMA (October 1, 2020), https://pubmed.ncbi.nlm.nih.gov/33001203/. Hypertension is one of the leading factors contributing to preterm birth in Louisiana. 2023 March of Dimes Report Card for Louisiana, *March of Dimes*, (2023), https://www.marchofdimes.org/peristats/reports/louisiana/report-card.

[19] Katherine Betcher, *Gestational hypertension and induction of labor at 37 weeks: how changing guidelines have affected outcomes*, AJOG (January 2016), https://www.ajog.org/article/S0002-9378(15)01680-4/fulltext.

a prescription for misoprostol to treat a physical condition that is unrelated to pregnancy or reproductive healthcare.

64. Self is currently pregnant, and she also brings this suit on her own behalf as a pregnant person. Misoprostol is frequently used to induce labor in full-term pregnancies, and Self anticipates that she could require misoprostol for that purpose as her pregnancy progresses. Additionally, if there is a complication in Self's delivery, she could require misoprostol to treat postpartum hemorrhage.

B. Louisiana's Uniform Controlled Dangerous Substances Law is a Complex Regulatory Structure.

65. Louisiana has been legislatively responding to drug addiction since 1894.[20] In 1970, after many iterations of laws to address addiction, Louisiana passed the Uniform Controlled Dangerous Substances Act to regulate depressants, opioids, and other drugs that can be highly addictive. The law sought to bring Louisiana in line with the federal system of regulating addictive drugs.[21]

66. Many drugs regulated in the Uniform Controlled Dangerous Substances Law have useful and legitimate medical purposes and are necessary to maintain Louisianans' health and general welfare. However, with the notable exception of mifepristone and misoprostol, by virtue of the passage of Act 246, the drugs regulated in the Uniform Controlled Dangerous Substances Law also have the potential for abuse and can lead to physical and psychological dependence.

67. The Uniform Controlled Dangerous Substances Law, accordingly, seeks to strike a balance—imposing restrictions on drugs with beneficial uses when extensive regulation is justified by the drug's addictive nature and the risk of dependency it causes.

68. There are five "schedules" in the Uniform Controlled Dangerous Substances Law. Schedule I includes those drugs with a high potential for abuse. Drugs in Schedule I have no accepted medical use in the United States and lack accepted safety for the use of the drug under medical supervision. Drugs in Schedule II have a high potential for abuse, a currently accepted

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[20] La. Acts No. 157 (1894).

[21] Vance R. Andrus & Charles R. Moore, *The Uniform Controlled Dangerous Substances Act: An Expositive Review*, 32 La. L. Rev. 56, 62 (1971).

medical use in the United States or a currently accepted medical use with severe restrictions, and abuse of the drug or other substance may lead to severe psychological or physical dependence.

69. Schedules III, IV, and V are defined by reference to the other drugs on the schedule.

70. Schedule III drugs have a potential for abuse that is lower than the drugs in Schedules I and II. Drugs in Schedule III also have an accepted medical use in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

71. Schedule IV drugs have a lower potential for abuse than the drugs listed in Schedule III, but abuse of the drug or other substance may still lead to some physical dependence or psychological dependence.

72. Drugs in Schedule V have a lower potential for abuse than Schedule IV drugs, an accepted medical use in the United States, and abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances listed in Schedule IV.

73. It is unlawful to produce, manufacture, distribute or dispense scheduled drugs, including those drugs included on Schedule IV, except in the highly regulated manner prescribed in the Uniform Controlled Dangerous Substances Law. It is also unlawful to possess a Schedule IV drug with the intent to do any of those things unless a person complies with the Uniform Controlled Dangerous Substances Law.

74. Under the Uniform Controlled Dangerous Substances Law, special licenses are required in order to produce, manufacture, distribute or dispense a Schedule IV drug. A license is also required in order to possess a Schedule IV drug with the intent to do any of those things.

75. When someone engages in one of these acts with a Schedule IV drug without authorization, the punishment is generally between 1–10 years of imprisonment and a fine of $15,000 or less. Several additional statutes can operate to extend that sentence up to 20 years and to increase the fine up to $30,000.

76. Racketeering charges can also be brought if a person manufactures or distributes a Schedule IV drug in a manner prohibited by the Uniform Controlled Dangerous Substances Law.

77. Under the Uniform Controlled Dangerous Substances Law, it is also unlawful for any person knowingly or intentionally to possess a controlled dangerous substance classified in Schedule IV unless such substance was obtained directly or pursuant to a valid prescription or order from a practitioner who is acting in the course of his professional practice, as provided in La. R.S. 40:978.

78. Simple possession of a Schedule IV drug is generally punished with a criminal sentence of 1–5 years' imprisonment and a fine of no more than $5,000. However, several additional statutes can operate to extend that sentence up to 10 years and increase the fine up to $10,000.

79. Some factors that can trigger the additional punishments allowed by these statutes include one's proximity to Drug Free Zones like schools and churches, the criminal history of the person facing potential charges, and the age and school enrollment status of the person who receives a drug.

80. The Louisiana Board of Pharmacy may suspend or revoke a license to manufacture, distribute, or dispense a controlled dangerous substance for several reasons, including failure to timely renew the license.[22]

81. Likewise, the Louisiana Board of Medical Examiners may initiate disciplinary actions for physicians who are convicted of a crime in Louisiana or who prescribe, dispense, or administer controlled substances "without legitimate justification . . . or in other than a legal or legitimate manner."[23]

82. There are dozens of additional statutory and regulatory requirements for physicians, nurses, manufacturers, distributors, pharmacists, and patients that apply when a drug is on the Schedule IV list and do not apply if a drug is not scheduled.

C. Louisiana Act 246 Delays Access to Vital Treatment and Interferes with Privacy for Patients Whose Physical Conditions Are Treated with Misoprostol or Mifepristone.

[22] La. R.S. 40:975.

[23] La. R.S. 37:1285.

83. By adding misoprostol and mifepristone to Louisiana's Uniform Controlled Dangerous Substances Law, Louisiana treats people with physical conditions who rely on misoprostol or mifepristone for their treatment differently than people without those physical conditions and those with other physical conditions.

84. That differential treatment has no valid justification. Instead, it will cause harm, including in the following non-exhaustive ways.

i. Access Delays During Critical Emergencies

85. The United States has a significantly higher rate of maternal mortality than other developed nations.[24] In 2022, 817 women and girls died of maternal causes in the country.[25]

86. Black women and girls die from maternal causes at a substantially higher rate than white women and girls. In 2022, the maternal mortality rate for Black women and girls was approximately 2.5 times the rate for white women and girls.[26]

87. Louisiana has the fifth-highest maternal mortality rate in the country.[27]

88. In Louisiana, postpartum hemorrhage is a significant cause of maternal mortality.

89. Postpartum hemorrhage is a serious risk to pregnant people, accounting for 17 percent of all pregnancy-related maternal deaths in Louisiana from 2011–2016.[28]

90. Fifty percent of deaths in Louisiana caused by postpartum hemorrhage or hypertension—another leading cause of maternal mortality in Louisiana—were deemed preventable by the Pregnancy Associated Maternal Mortality Review Committee.[29]

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[24] Munira Z. Gunja et al., *Insights into the U.S. Maternal Mortality Crisis: An International Comparison*, The Commw. Fund (2024), https://www.commonwealthfund.org/publications/issue-briefs/2024/jun/insights-us-maternal-mortality-crisis-international-comparison#:~:text=Highlights,for%20other%20high%2Dincome%20countries.

[25] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2022*, Cent. Dis. Control Prev.(2024), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2022/maternal-mortality-rates-2022.pdf.

[26] *Id.*

[27] NCHS, *Maternal deaths and mortality rates: Each state, the District of Columbia, United States,* 2018-*2022*, CDC, https://www.cdc.gov/nchs/maternal-mortality/mmr-2018-2022-state-data.pdf.

[28] *Reducing Maternal Morbidity Initiative – Final Report*, La. Dep't. of Health (May 25, 2021), https://ldh.la.gov/assets/oph/Center-PHCH/Center-PH/maternal/LaPQC/RMMI_Final_Report_LongForm_5-25-2021.pdf.

[29] *Id.*

91. Act 246 gravely impacts patient access to critical medical treatment during time-sensitive obstetric emergencies, including postpartum hemorrhage, while not imposing the same dangerous delays for other emergency conditions, including other conditions that lead to severe blood loss.

92. In most cases, Schedule IV drugs must be stored separately from non-controlled substances, with access limited only to select employees with either a license to prescribe controlled substances or an order from a provider who holds such a license.[30]

93. Hospitals and providers often comply with these requirements by implementing systems such as Pyxis to store and monitor supplies of controlled substances. Pyxis is an automated medication dispensing cabinet that exists in a centralized location, requiring authorized providers to step away from treating their patients to log in with a username and password before the controlled substance is dispensed. Medications stored in Pyxis machines, however, are generally not used or needed to treat patients on an emergency basis.

94. Before it was added to Schedule IV, misoprostol was commonly stored at hospitals in easily accessible and often mobile locations, such as obstetric hemorrhage carts or nurses' pockets, so that providers could rapidly administer the medication in time-sensitive emergencies such as postpartum hemorrhage.

95. Because of Act 246, hospitals have been forced to change their patient care protocols to remove misoprostol from obstetric hemorrhage carts or other locations and/or find ways to secure the drug to ensure access is restricted and the drug is secured, as required by law for controlled substances.

96. In most emergent situations, securing misoprostol will increase the time between when providers know that a patient needs misoprostol and when the drug can be administered to a patient experiencing an emergency medical condition.

97. These delays increase the risk of maternal mortality and morbidity, decrease the quality of care, and cause needless suffering.

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[30] La. Admin. Code tit. 46, pt. LIII, § 2717(B).

98. One physician who was recently informed about Act 246 expressed significant concern about the prospect that misoprostol would no longer be on the obstetric hemorrhage cart that is easily accessible in postpartum patients' rooms after childbirth. "What? That's terrifying," he said. "Take it off the carts? That's death. That's a matter of life or death."[31]

99. Hospitals in rural areas and small hospitals without on-site pharmacies may have the most difficult time quickly accessing misoprostol and mifepristone in emergent situations.

100. If a patient requires life-saving treatment with misoprostol or mifepristone in the middle of the night or on the weekend, the delay to access misoprostol or mifepristone may be even longer, creating even more significant risks to patients' health and lives.

101. Hospitals in Louisiana have worked hard to address the state's high rates of maternal mortality and maternal morbidity.

102. Developing effective systems for treating and addressing postpartum hemorrhage, including by ensuring easy access to misoprostol in postpartum patients' hospital rooms, has been a high priority in the state's efforts to address preventable and tragic postpartum deaths.

103. In addition to the serious delays caused by Act 246, the law requires hospitals to change well-established protocols and processes that have proven successful at treating one of the most serious postpartum physical conditions.

104. Patients in Louisiana who experience other blood loss emergencies that are treated with medications other than misoprostol or mifepristone do not face access risks or delays under Act 246.

105. For example, medications like epinephrine and lidocaine are used to address low blood pressure and treat wounds following a gunshot. Both epinephrine and lidocaine are readily available to doctors and nurses in the emergency room when treating a gunshot victim. Because neither epinephrine nor lidocaine is scheduled as a controlled dangerous substance, the drugs can be provided without complying with the Louisiana Uniform Controlled Dangerous Substances Law requirements that impose delays on access.

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[31] Lorena O'Neil, *Doctors Grapple with How to Save Women's Lives Amid "Confusion and Angst" Over New Louisiana Law*, The La. Illuminator (Sept. 3, 2024), https://lailluminator.com/2024/09/03/louisiana-women/.

106. Therefore, patients suffering from postpartum hemorrhage, for example, are treated differently under Act 246 than patients suffering from a gunshot wound, even though both conditions are serious physical conditions that require urgent medical treatment. There is no justification for this differential treatment of patients based on physical condition.

ii. Burdens and Barriers to Accessing Medication at the Pharmacies

107. For patients with physical conditions that are treated with misoprostol or mifepristone, Act 246 imposes burdensome requirements that interfere with continuity of care.

108. First, because prescriptions for controlled dangerous substances do not last as long as other prescriptions, Act 246 will require patients with physical conditions that are treated with misoprostol or mifepristone to see a doctor more frequently to access necessary medical treatment.

109. Prescriptions for Schedule IV drugs expire after six months, whereas prescriptions for drugs other than a controlled dangerous substance listed in Schedules II through IV expire after one year.[32] Expired prescriptions are not refillable or renewable without additional contact with the prescriber.[33] Requiring additional appointments with healthcare providers increases the financial and logistical burden on the patient, which can lead to delays or gaps in their access to vital treatment.

110. Act 246 may also create delays at the pharmacy for patients with valid misoprostol or mifepristone prescriptions.

111. For example, with a controlled substance, there are more processes that may require pharmacist confirmation with a physician, along with additional steps that pharmacists must take to confirm the validity of the prescription.

112. Patients picking up a controlled dangerous substance from a pharmacy may be asked to produce a photo identification card before they can receive their prescription.[34] Thus,

[32] La. Admin. Code tit. 46, pt. LIII, § 2525(B)2; tit. 46, pt. LIII, § 2525(A).

[33] *Id.*; *id.* tit. 46, pt. LIII, § 2525(C).

[34] La. R.S. 40:971(E).

patients who do not have a valid identification card—estimated to be around 11% of people in the U.S.[35]— may not be able to access these drugs even if they have a valid prescription.

113. The ID requirement will disproportionately impact patients who are less likely to have a valid photo identification card. Black and Hispanic patients, patients with disabilities, patients with low incomes, and patients with lower educational attainment may be disproportionately impacted.[36]

114. Even if a patient is not experiencing a critical or life-threatening condition, the delays caused by Act 246 create significant harms. Patients with valid prescriptions for misoprostol or mifepristone may be required to wait for lengthy periods at the pharmacy while pharmacists complete verification calls.

115. When a healthcare provider prescribes a controlled dangerous substance, pharmacists often call the provider for more information about the purpose of the prescription.

116. Requiring a provider to speak to a pharmacist before a prescription can be filled adds to the time it takes for patients to access necessary medication.

117. Additionally, delays may cause or exacerbate stigma and anxiety, particularly for patients experiencing traumatic medical conditions that are treated with misoprostol or mifepristone, like miscarriage.

118. By contrast, patients with other pregnancy-related physical conditions that do not require treatment with misoprostol or mifepristone do not experience these same impacts.

119. For example, pregnant patients who experience nausea and vomiting during pregnancy may be prescribed a combination of doxylamine and pyridoxine ("vitamin B6"). Because neither doxylamine nor vitamin B6 is a controlled dangerous substance, patients experiencing nausea and vomiting during pregnancy can be provided with the drugs without

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[35] *Citizens Without Proof: A Survey of Americans' Possession of Documentary Proof of Citizenship and Photo Identification*, Brennan Ctr. Just. at NYU Sch. of Law (November 2006), https://www.brennancenter.org/sites/default/files/2020-09/download_file_39242.pdf.

[36] *Id.* Additionally, trans and gender-expansive patients may be disproportionately impacted by the ID requirement if the gender marker on their identification card does not match their presentation, potentially leading to increased scrutiny at pharmacies when picking up prescriptions.

complying with the Uniform Controlled Dangerous Substances Law's prescription requirements that impose delays on access.

120. Therefore, patients with nausea and vomiting in pregnancy are treated differently under Act 246 than patients who experience miscarriage, despite the fact that both conditions are complications of pregnancy that can be treated with medications that have no potential for abuse or dependence. There is no justification for this differential treatment of patients based on physical condition.

iii. Interference with Patient Privacy

121. Act 246 also interferes with patient privacy regarding medical conditions and treatment.

122. Act 246 requires misoprostol and mifepristone to be added to the Louisiana Prescription Monitoring Program (PMP). The PMP collects identifying information about patients as well as their medical and prescription details.[37]

123. The PMP is regularly monitored for trends. Law enforcement, parole and probation officers, prosecutors, and Medicaid representatives, among others, can access patients' private medical information on the PMP.[38]

124. Some patients who are treated with misoprostol or mifepristone take their medications daily or several times a day. These patients must pick up large quantities of misoprostol or mifepristone from the pharmacy at regular intervals. For example, patients who take misoprostol to prevent ulcers take 100–200 mcg four times a day, and patients who take mifepristone for Cushing's Syndrome take 300–1200 mcg once a day. This behavior may flag the patient for additional inquiry in the PMP, subjecting them to potential criminal consequences even when they are accurately following their treatment plan and have a lawful prescription.

125. Patients with physical conditions that are not treated with misoprostol or mifepristone but require large quantities of medication at regular intervals are not subjected to the PMP.

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[37] *See* La. Admin. Code tit. 46, pt. LIII, § 2911.

[38] *Id.* tit. 46, pt. LIII, § 2917.

126. For example, patients with asthma may be prescribed inhaled corticosteroids such as beclomethasone as a maintenance medication to reduce the frequency and severity of asthma attacks. These medications are not scheduled, and many patients who take them do so two or more times daily over long periods of time. Patients whose conditions are treated with drugs like beclomethasone do not face the same incursions on privacy regarding their medical status or treatment that patients whose conditions are treated with misoprostol or mifepristone are subjected to under Act 246. Further, asthma patients prescribed inhaled corticosteroids do not face the same delays at the pharmacy and may not be required to display a photo identification to access their prescriptions.

127. Finally, patients whose conditions are not treated with misoprostol or mifepristone may be provided prescriptions that last up to a year, while patients that are prescribed misoprostol or mifepristone may only receive prescriptions for up to six months. *See supra* at ¶ 104.

128. There is no justification for this differential treatment of patients based on their physical condition.

iv. Plaintiffs' Patients and Clients

129. Louisiana courts permit third-party standing if there is a relationship between a plaintiff and third parties and the third parties are hindered in asserting their own rights. Patients experiencing medical conditions will not always be aware that they are at risk of a condition that requires misoprostol or mifepristone, and, given the emergent nature of many conditions, they will not be able to vindicate their rights in court while they are experiencing medical emergencies that require misoprostol or mifepristone.

130. For example, while Birthmark's doulas do not themselves carry, prescribe, or administer misoprostol or mifepristone to their clients, it is a regular part of their practice to advocate for pregnant clients who are prescribed misoprostol by their medical providers before, during, and/or after labor.

131. In the judgment of Birthmark, Act 246 will injure its clients' quality of care. Act 246 requires medical providers to engage in several additional and unnecessary steps to ensure the administration of a safe and effective medication to people with certain physical conditions—medications that people need, and steps that did not need to occur before Act 246. Birthmark's

doulas advocate on behalf of pregnant people to ensure that they have safe, healthy, and empowering deliveries, which frequently includes advocating for clients who require misoprostol before, during, or after delivery. Thus, Act 246 will also add to the time and intensity of each doula's advocacy on behalf of her clients and divert their limited resources from the host of other concerns that occur during birth to the processes and procedures needed to ensure speedy access to post-partum hemorrhage medication. Further, these additional steps may lead to misoprostol not being used early in labor, potentially extending the duration of childbirth for their clients and the duration of their needed assistance.

132. Specifically, because Act 246 will require misoprostol to be kept in a secure area—a requirement that did not exist prior to Act 246's passage—there is a substantial risk that Act 246 will result in delays between the time that misoprostol is needed and the time when the medication can be provided to patients. Regardless of how individual hospitals store and access controlled dangerous substances, retrieving them from a secure area and ensuring that access is limited only to those with appropriate credentials will add time to a highly time-sensitive and urgent situation.

133. Birthmark's doulas will have to learn a variety of new systems that each hospital uses to comply with Act 246 in order to ensure that they can advocate as quickly and effectively as possible for patients who require misoprostol before, during, or after labor. Doulas with Birthmark are passionate about their role as essential members of a person's care team. They abide by ethical and moral values that require them to ease their clients' birth experiences, advocate for their clients' wishes and needs, and empower their clients throughout the birthing process. Research demonstrates that people who include doulas in their process experience a more positive birthing experience. Birthmark's doulas strive to provide a positive birthing experience to their clients by advocating for them and addressing their needs as quickly as possible.

134. Birthmark is concerned that Act 246 will impact its doulas' ability to abide by these beliefs and values to create positive birthing experiences for their clients by imposing unnecessary delays for needed medical care. Patients experiencing postpartum hemorrhage require urgent administration of necessary medication. Even relatively short delays of mere minutes can be catastrophic for patients who are bleeding out at an alarmingly fast rate. Because Birthmark's doulas are often the first people to identify when their clients are experiencing a dangerous post-

partum hemorrhage, they will be the first to notify members of the clients' team that they require urgent administration of medication, which Act 246 will delay. Act 246 will also force Birthmark's doulas to experience trauma as they watch their clients suffering from a life-threatening yet treatable condition while their care team is forced to go to great lengths to access a necessary medication from a secure location that may not even be on the same floor of the facility.

135. In doing so, Act 246 will also increase the trauma and danger of a post-partum hemorrhage for Birthmark's clients. As Birthmark strives to help its clients experience positive, joyful, and empowering birthing experiences, Act 246 is directly at-odds with these goals.

136. Birthmark is also concerned that the requirements imposed by Act 246 will make its advocacy with medical professionals inefficient and significantly more time-consuming due to the frequency with which misoprostol is needed in routine obstetrics and gynecology care.

137. Further, Birthmark is concerned that its clients' medical care team will have to learn a new system to deliver a life-saving medication—which necessarily introduces confusion and the potential for error to a process that had previously been implemented effectively in the hospital.

138. Birthmark's clients are hindered in advocating for their own rights because patients, for instance, cannot go to court to challenge a law while hemorrhaging. Some physical conditions, including gestational diabetes, twin or other multiple pregnancies, and longer laboring periods, may increase the risk of postpartum hemorrhage, but hemorrhaging cannot necessarily be predicted unless or until it occurs.

139. Further, Birthmark's doulas play an important role in seeking to prevent discrimination and disparate care for pregnant people. The law discriminates against Birthmark's clients who need misoprostol without an appropriate state interest, as discussed below. For these reasons, Birthmark brings its claim on behalf of the patients it serves.

140. Finally, as advocates for people experiencing miscarriages and giving birth, Plaintiff Birthmark is well-suited to bring claims on behalf of the clients it serves, whose aligned interests are not abstract or hypothetical. Plaintiff Birthmark is also injured by a law that discriminates against its clients who have physical conditions requiring misoprostol because the law makes its advocacy on behalf of these clients more difficult and frustrates the purpose of its work. This discrimination is likely to lead to worse outcomes for its clients who have physical

conditions that require misoprostol. Louisiana's maternal mortality and morbidity rates directly impact Birthmark's services and the outcomes of its services.

141. Like Birthmark, Plaintiff Dr. Holt also sues on her own behalf as a medical provider who is harmed by Act 246, as well as on behalf of her patients. Part of Dr. Holt's clinic model is that she plans to disburse prescription medicine on-site. She obtained a license to dispense non-controlled substances and intended to disburse both misoprostol and mifepristone in her clinic before the passage of Act 246. However, she will not be able to disburse controlled substances on-site because she does not have a license to do so, and it will likely be costly and administratively burdensome for her small clinic to comply with the necessary protocols.

142. Because Act 246 became effective mere days after Dr. Holt's clinic's grand opening, Dr. Holt now has to send patients who have had a failed IUD placement or who are experiencing a miscarriage out-of-office in search of a pharmacy that will fill their prescriptions. Her patients are now required to locate a pharmacy that carries misoprostol and mifepristone. For those seeking an IUD, they must schedule a second appointment at the clinic to complete the placement of the IUD after they have accessed the medication.

143. Based on information and belief, it can be difficult to find a pharmacy that stocks misoprostol or mifepristone. Even if a pharmacy stocks these drugs, it is not clear that patients will be able to easily access the medications. Even before Act 246, pharmacies in Louisiana routinely denied prescriptions for misoprostol or required providers to explain their reason for prescribing the medication due to a law passed in 2022 that regulated "abortion-inducing drugs." Act 246 creates even more restrictions on access to necessary medications, burdening patients and imposing delays for patients to complete their medical procedures. Because Dr. Holt's patients will not know in advance whether they will experience a failed IUD placement or a miscarriage, her patients will be hindered in asserting their own rights.

144. Dr. Holt is also concerned that her patients will forego necessary medical treatment because of their concerns about the privacy implications of Act 246. In Dr. Holt's experience, her patients are sometimes concerned about being monitored for receiving regular healthcare. She is concerned that they may opt to decline effective and safe medications due to their fears about the PMP and the drugs' scheduling status.

145. Plaintiff Kaylee Self is concerned that Act 246 will delay access to medications for her patients who seek to fill their misoprostol prescriptions at her pharmacy. For this reason, she brings this suit on behalf of her patients as well as herself as a pharmacist and, as explained herein, a pregnant person.

146. First, unlike non-controlled substances, controlled substances cannot be transferred to another pharmacy unless the prescription is being transferred for the purpose of a drug refill. Therefore, if a patient goes to Self's pharmacy to fill a single-use misoprostol prescription and her pharmacy does not have the drug in stock, she will not be able to fill the prescription or transfer it to another pharmacy that has the medication in stock. Although the patient's doctor could cancel the prescription and call it in to another pharmacy that may have the drug in stock, they will not be able to do this if it is late in the day or just before a weekend. This could delay a patient's access to necessary medication to treat a time-sensitive condition, such as a miscarriage.

147. In Self's experience, there are times when her pharmacy does not have misoprostol in stock. Even if Self is able to transfer a prescription for a refill—for example, in a situation where mifepristone or misoprostol are prescribed to a patient as a maintenance drug to treat gastric ulcers or Cushing's Syndrome—Self is concerned that other pharmacies may be unwilling to fill the prescription because of their fears of criminalization.

148. The significant penalties for improperly filling a prescription under Act 246 also make Self extra cautious when dispensing medications. If she has any questions about a prescription or diagnosis code, she calls a patient's doctor for information. Because doctors are not always able to call back quickly, this can result in delays for patients to access their medication, and she sometimes has to ask patients to return to the pharmacy or wait until she hears from their doctors.

149. If a patient's doctor prescribes misoprostol electronically, the prescription will be rejected as a "failed attempt" by Self's pharmacy unless the physician's prescribing software is set up to recognize that misoprostol and mifepristone are controlled. This is because there are more onerous electronic prescribing requirements for controlled substances, including biometric verification requirements for prescribing users. If a prescription is rejected, Self must contact the prescriber to let them know. However, this can delay access to medications for patients because

Self is not always immediately aware that a "failed attempt" has occurred or able to contact prescribers, quickly or at all, depending on the other demands of her day.

150. Additionally, in Self's experience, pharmacists must follow special protocols when handling drugs that are scheduled under state law but not under federal law, and these protocols will add time and burdens to her pharmacy practice that could result in delays to a patient's access to the drugs. Unlike medications that are controlled substances under federal law, drugs like misoprostol are shipped to her pharmacy by suppliers in a bag that also contains non-controlled substances. Since Act 246 went into effect, pharmacists now must separate misoprostol from non-controlled substances to store and account for the drug as a controlled substance. Additionally, Self will have to ensure that patient information is entered into the PMP when she fills prescriptions for misoprostol. She will also need to check the PMP before filling the prescription.

151. In Self's experience, patients who are prescribed misoprostol for physical conditions related to reproductive healthcare—like miscarriage management or to treat a failed IUD placement—often receive the most scrutiny at the pharmacy. This is because patients that require misoprostol to treat reproductive health physical conditions are often prescribed just one or two dosages of the drugs, rather than patients with other physical conditions that receive several tablets a week. Pharmacists, including herself, may be reluctant to fill these prescriptions out of fear that they could be prosecuted, even if the drugs are prescribed for a legal purpose. Self fears that this reluctance could lead to access difficulties for her patients, including delays and outright denials.

152. For example, when prescribing controlled substances like mifepristone and misoprostol, physicians must include certain mandatory information on the prescription, including the patient's birthday, address, the dosage amount, and the number of refills. If any of these required elements are inadvertently left off of a prescription—a common occurrence—Self will be unable to fill the prescription and will instead have to contact the provider and obtain a new prescription. This can take time and lead to extended delays for patients, including those who urgently need the medication to treat a miscarriage.

153. Self has personally witnessed the trauma and damage that delays may cause a patient who urgently requires necessary medication like misoprostol. In 2022, Louisiana passed a

law requiring that certain diagnosis information be added to misoprostol prescriptions. Following that change in the law, Self had to notify patients suffering from miscarriages that she could not fill their prescriptions before calling their doctors to ensure that the appropriate diagnosis codes were used and to verify information related to the prescription. The experience was both traumatic for the patients, who were forced to wait for the much-needed medication, and frustrated the important role that she serves in patient care. As a pharmacist, Self is concerned about being forced to unnecessarily step away from her patients and her urgent work to focus on legal compliance. As a result of Act 246, there will be a significant amount of additional information that the law requires doctors to include on prescriptions for misoprostol. Now, for example, Self will have to make even more calls to patients' physicians to verify required prescription information. She is concerned that Act 246 will thus make her practice less efficient and lead to access delays for her patients, potentially causing additional trauma to patients during a difficult time in their lives.

154. As a result of the close relationships Self has developed with her patients at her community-based pharmacy, she understands her patients' ongoing medical issues and develops a holistic view of their medical history based on her understanding of the medications they take and the multiple providers they see. Self strives to be an empathetic and approachable pharmacist and tirelessly tracks down any missing prescription information to help her patients access their medications. As a pharmacist, Self will have a unique view of the recurring delay issues that Act 246 causes. However, her patients will not be able to enforce their own rights because they will not know whether they will require misoprostol in advance, especially in situations where they require the medication urgently.

155. Finally, as a pregnant person herself, it is likely that Self could require misoprostol at some point during her pregnancy for induction of labor or to treat a post-partum hemorrhage. She is presently enduring an unconstitutionally high risk that she will be discriminated against due to physical condition. Given her pharmacy background and her understanding of the burdens caused by Act 246, Self has a unique understanding of the range of uses of misoprostol and is concerned that, if she requires the medication during her pregnancy, she may face delays and other difficulties with access. Self and Plaintiffs' patients and clients will be subjected to a regulatory regime that, at a minimum, will cause unnecessary burdens, distress, delay, and stigmatization in

seeking the medical care they need, without a valid justification or medical purpose—and could even be life-threatening.

D. Louisiana Act 246 Creates Administrative Burdens and Costs for Providers, Manufacturers, and Distributors.

156. Under Louisiana law, controlled dangerous substances may only be prescribed, manufactured, distributed, or dispensed by people with a CDS license.[39]

157. Act 246 requires providers, manufacturers, and distributors who prescribe or dispense misoprostol or mifepristone to obtain a CDS license.[40]

158. Obtaining a CDS license costs up to $100 and is an administratively burdensome process.

159. In order to prescribe misoprostol and/or mifepristone, providers must have a CDS license that specifically permits them to prescribe Schedule IV drugs.

160. Healthcare providers that do not prescribe misoprostol and/or mifepristone but prescribe other medications that carry similar risk and dependency profiles are not required to obtain a CDS license to prescribe necessary medications to patients.

161. There is no justification for this differential treatment of healthcare providers.

162. Providers can prescribe Schedule IV drugs, including misoprostol and mifepristone, orally, in writing, or electronically. However, electronic prescriptions for scheduled drugs must conform with federal rules established by the U.S. Drug Enforcement Administration ("DEA").

163. Under Louisiana law, only certain people—medical doctors, registered nurses, and advanced practice registered nurses—can administer CDS to patients. The law specifically prevents delegation of medication administration to other members of a patient's care team.[41]

164. Once an individual or entity obtains a CDS license, they must follow reporting and recordkeeping protocols.

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[39] La. Admin. Code tit. 46, pt. LIII, § 2705(A).

[40] *Id.*

[41] *See* La. Admin Code, tit. 46, pt. XLVII, § 3709.

165. Licensees must allocate resources and employee labor to managing records, submitting quarterly reports of acquisitions and transactions, filing annual inventory reports, and providing records of their activities.[42]

166. Licensees seeking to distribute a scheduled drug must also spend time making a good faith inquiry with either the DEA or the Board of Pharmacy to determine whether any new recipient of the controlled substance is adequately licensed and registered to receive it.[43]

167. Act 246 requires providers, manufacturers, and distributors who prescribe or dispense misoprostol or mifepristone to meet minimum requirements for facilities and physical security.[44]

168. Complying with facility and security requirements may involve financially and administratively burdensome measures such as making physical changes to buildings and installing alarm systems.[45]

169. Licensees are also financially responsible for meeting security standards and expanding physical security controls when they become inadequate.[46]

170. Additionally, Act 246 requires manufacturers and distributors to meet burdensome personnel requirements. To maintain their CDS license, manufacturers and distributors must expend resources to employ additional screening in their hiring process for employees who may work with controlled substances, and they must implement clearance areas and personnel management systems to control which employees have access to those areas.[47]

171. Labeling and packaging requirements for Schedule IV drugs will increase costs for manufacturers and distributors working with misoprostol and mifepristone in Louisiana by imposing requirements that are unique to the state.

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[42] La. Admin Code, tit. 46, pt. LIII, § 2735.

[43] *Id.* tit. 46, pt. LIII, § 2715(B)1.

[44] *Id.* tit. 46, pt. LIII, § 2713, tit. 46, pt. LIII, § 2715.

[45] *Id.* tit. 46, pt. LIII, § 2713(A)5-8.

[46] *Id.* tit. 46, pt. LIII, § 2713(B).

[47] *Id.* tit. 46, pt. LIII, § 2721, tit. 46, pt. LIII, § 2715(A)(5).

172. Louisiana law requires commercial packaging for Schedule IV drugs to be tamper-proof and meet labeling requirements indicating that the package contains a Schedule IV controlled substance.[48]

173. Act 246 will therefore require manufacturers and distributors to allocate resources to creating new packaging for misoprostol and mifepristone that only applies in Louisiana.

174. Creating new packaging that exclusively applies to Louisiana drugs may be costly and administratively burdensome for manufacturers and distributors that distribute misoprostol and mifepristone around the country.

175. The Act will also require manufacturers and distributors to expend time and resources segregating and labeling products that are being sent to Louisiana.

176. Plaintiff Dr. Holt is impacted as a provider and as a person who relies on manufacturers and distributors to access these medications. Additionally, Dr. Holt is impacted as a provider who will not be able to delegate the administration of CDS to staff members who are not registered nurses or advanced practice nurses. Dr. Holt also brings her La. Const. art. 1, § 3 claim on her own behalf because the law treats her differently than medical providers that prescribe or dispense medications other than misoprostol or mifepristone that are similarly effective and safe, have no potential of abuse or dependence, and are required for both emergency and routine treatment for other physical conditions.

177. Plaintiff Kaylee Self is impacted as a pharmacist who dispenses misoprostol and mifepristone, and as a person who relies on manufacturers, distributors, and physicians who prescribe the medications to the patients she serves.

178. Specifically, Act 246 forces Self to spend more of her time ensuring compliance with administrative and legal requirements, reducing the time she can devote to filling prescriptions for patients. Self believes that Act 246 turns pharmacists into the "policemen" of the healthcare community, without justification, instead of giving them authority to fill prescriptions according to their training.

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[48] *Id.* tit. 46, pt. LIII, § 2727, tit. 46, pt. LIII, § 2723.

179. Act 246 causes Plaintiffs harm because it requires that they act differently with regard to patients who require misoprostol and mifepristone prescriptions than with patients who require other prescriptions, and they risk criminal liability and professional discipline if they fail to do so.

180. Act 246 singles out the healthcare providers who prescribe or dispense misoprostol and mifepristone for disparate treatment that violates their right to individual dignity by subjecting them to a regulatory regime that, at a minimum, will cause unnecessary burdens, distress, delay, and stigmatization in providing the care their patients need. Additionally, Act 246 unnecessarily burdens and interferes with healthcare providers' medical judgment, ethical obligations, and the physician-patient relationship—all without a valid justification or medical purpose.

E. Act 246 Does Not Substantially Further a Legitimate Government Interest.

181. The legislation's discrimination does not substantially further a legitimate government interest, nor is it rationally related to a legitimate government interest. Both misoprostol and mifepristone are safe medications with no risk of abuse or dependence, and abortion is already illegal in almost all circumstances in Louisiana.

i. Misoprostol and Mifepristone Are Safe Medications that Have No Risk of Abuse or Dependence

182. Misoprostol and mifepristone have been FDA-approved for 36 years and 24 years, respectively.

183. Both drugs are safe and have a low incidence of adverse side effects.

184. By definition, drugs that are scheduled under Schedule IV of the Louisiana Controlled Dangerous Substances Law have (1) a potential for abuse, (2) a currently accepted medical use for treatment, and (3) the potential to lead to physical dependence or psychological dependence if abused.

185. Neither misoprostol nor mifepristone carries any risk of abuse.

186. Neither misoprostol nor mifepristone causes patients to develop physical or psychological dependence.

187. Generally, drug abuse and drug dependence are two forms of substance use disorder.[49]

188. The Louisiana Uniform Controlled Dangerous Substances Law matches the federal Controlled Dangerous Substances Act in nearly all respects.

189. The Schedule IV definition in the Louisiana Uniform Controlled Dangerous Substances Law is identical to the Schedule IV definition in the federal Controlled Substances Act.

190. Although the terms "abuse" and "dependence" are undefined in the Louisiana Uniform Controlled Dangerous Substances Law, the statute defines both "substance abuse" and "drug dependent person." "Substance abuse" is defined as "a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life."[50] In the definition of "drug dependent person," the statute notes that "[d]rug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence."[51]

191. Additionally, both "abuse" and "dependence" have a commonly understood meaning in the medical, public health, and drug regulation communities.

192. The commonly understood meaning of "abuse" and "dependence" is reflected in the FDA's definitions of both terms.

193. The FDA defines "drug abuse" as the "intentional, non-therapeutic use of a drug product or substance, even once, to achieve a desired psychological or physiological effect."[52] A drug's potential for abuse "refers to the likelihood that abuse will occur with a particular drug product or substance."[53]

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[49] *Substance Use Disorder (SUD)*, Cleveland Clinic (Sept. 9, 2024), https://my.clevelandclinic.org/health/diseases/16652-drug-addiction-substance-use-disorder-sud.

[50] La. R.S. 40:961(42).

[51] La. R.S. 40:961(18).

[52] *Assessment of Abuse Potential of Drugs: Guidance for Industry*, FDA CDER (Jan. 2017), https://www.fda.gov/media/116739/download.

[53] *Id.* at 4.

194. Dependence encompasses both physical and psychological dependence.[54]

195. Physical dependence occurs when a person experiences a physiological adaptation in response to repeated drug use, manifested by withdrawal signs or symptoms when they abruptly discontinue the use of a drug.[55]

196. Psychological dependence refers to "a state in which individuals have impaired control over drug use based on the rewarding properties of the drug . . . or the psychological distress produced in the absence of that drug."[56]

197. When the FDA approves new drugs, it considers any evidence about the drug's potential for abuse or dependence as part of the approval process.

198. If the FDA determines that a drug has abuse potential, it works with the drug sponsor to develop animal and, in some cases, human abuse potential studies.

199. During the approval processes for misoprostol and mifepristone, no evidence of abuse or dependence was introduced to the FDA for either drug.

200. During the approval processes for misoprostol and mifepristone, the FDA did not determine that it was necessary to conduct any studies related to misoprostol or mifepristone's potential for abuse or dependence.

201. Drug applicants have an ongoing duty to report new evidence of abuse or dependence that emerges after the FDA approves a drug.

202. No evidence of a potential for abuse or dependence was introduced to the FDA at any point after misoprostol and mifepristone were approved, including when the FDA developed and later amended the risk evaluation and mitigation strategy ("REMS") for mifepristone in 2011, 2016, and again in 2021.

203. Drugs with the potential for abuse typically produce euphoria, hallucinations, or other effects consistent with depressants or stimulants.

204. Neither misoprostol nor mifepristone produces euphoria, hallucinations, or other effects consistent with depressants or stimulants.

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[54] *Id.*

[55] *Id.*

[56] *Id.*

205. Drugs with the potential for abuse or dependence are typically centrally acting.

206. Neither misoprostol nor mifepristone is centrally acting.

207. Drugs with the potential for abuse or dependence typically induce behavioral changes in animals and humans.

208. Neither mifepristone nor misoprostol induce behavioral changes in animals and humans.

209. Drugs with the potential for abuse or dependence typically lead to withdrawal symptoms when use of the drug ceases.

210. Neither misoprostol nor mifepristone cause any withdrawal symptoms.

211. Drugs with the potential for abuse or dependence typically affect specific receptors in the brain that are likely to cause dependence.

212. Neither misoprostol nor mifepristone affects any receptors in the brain that are associated with dependence.

213. If applicable, FDA-approved drugs must include evidence of abuse or dependence on their labels.

214. Neither misoprostol's nor mifepristone's label includes any information about evidence of abuse or dependence.

215. The mifepristone label states that "[n]o serious adverse reactions were reported" in cases where patients take significantly more than the recommended dosage of mifepristone,[57] suggesting that there is also no serious risk of overdose from taking mifepristone.[58]

216. Other drugs that incorporate detectable amounts of misoprostol and mifepristone also do not contain any evidence of a risk of abuse or dependence on their labels.

217. For instance, the Korlym label contains no reference to a risk of abuse or dependence.[59]

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[57] Mifeprex (Mifepristone) Drug Label, FDA (March 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

[58] Risk of overdose is a complication that can accompany substance use disorder. *See* Substance Use Disorder (SUD), *supra* n.46.

[59] *See Korlym Drug Label*, supra n.14.

218. The Cytotec label also contains no warning about a risk of abuse, physical dependence, or psychological dependence.[60]

219. The medical and public health communities agree that neither misoprostol nor mifepristone carries any risk of abuse, physical dependence, or psychological dependence.

220. To the contrary, the drugs are so safe and so low risk that some medical researchers have argued that they should be available over the counter.[61]

221. By law, a drug cannot be scheduled under the federal Controlled Substances Act unless the FDA first conducts a scientific and medical evaluation of the drug's potential for abuse and determines that scheduling is warranted.[62]

222. "[I]f the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance."[63]

223. Both the federal and the state controlled substances laws identify eight factors to be considered when scheduling a drug: (1) its actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled.[64]

224. None of these factors warrant scheduling misoprostol or mifepristone.

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[60] *Cytotec Label*, FDA (2002) https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/19268slr037.pdf.

[61] *See Ongoing Study: Over-the-Counter Medication Abortion*, ANSIRH (Jan. 13, 2022), https://www.ansirh.org/research/ongoing/over-counter-medication-abortion ("[M]ifepristone and misoprostol meet many of the FDA's criteria for being available over the counter. They are safe, have no risk of overdose, are not addictive, and people are already using them safely on their own in many parts of the world.").

[62] *See, e.g.*, 21 U.S.C. § 811(b) (explaining that the Secretary of Health and Human Services, which houses the FDA, must first conduct an evaluation and provide recommendations to the Attorney General regarding a drug's scheduling).

[63] *Id.*

[64] *See* 21 U.S.C. § 811(c); La. R.S. 40:962(C).

225. Neither the FDA, the Drug Enforcement Agency, nor the Department of Health and Human Services have ever determined that these factors warrant the scheduling of misoprostol and mifepristone under federal law.

226. Neither misoprostol nor mifepristone have any potential for abuse or dependence.

227. Further, some drugs in Schedule V of the Uniform Controlled Dangerous Substances Law have a higher risk of abuse and dependence than misoprostol or mifepristone, which is contrary to the requirement that drugs in Schedule IV have a higher risk of abuse and dependence than those in Schedule IV.

228. For example, ezogabine is a depressant that is classified as a Schedule V drug.[65] Ezogabine is approved under the brand name Potiga for the adjunctive treatment of partial-onset seizures in adults.[66] The label for Potiga explains that the drug has a risk of abuse and that a human abuse potential study found that it can cause hallucinations, euphoric mood, and somnolence.[67]

229. Similarly, pregabalin is a depressant that is classified as a Schedule V drug in Louisiana.[68] Pregabalin is approved under the brand name Lyrica to treat a variety of conditions, including partial onset seizures, fibromyalgia, and neuropathic pain.[69] The drug label for Lyrica notes that it is a Schedule V substance that has some evidence of causing euphoria in users.[70] Additionally, abrupt discontinuation of Lyrica is associated with insomnia, nausea, headache, or diarrhea, which are consistent with physical dependence.[71]

230. Both ezogabine and pregabalin have a higher potential for abuse and dependence than misoprostol and mifepristone, even though they are listed in Schedule V of the Louisiana Uniform Controlled Dangerous Substances Law.

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[65] *See* La. R.S. 964, Schedule V(D)(3).

[66] *See Potiga (ezogabine) Drug Label*, FDA (June 2011), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022345Orig1s000Lbl.pdf.

[67] *Id.*

[68] *See* La. R.S. 964, Schedule V(D)(7).

[69] *Lyrica Drug Label*, FDA (May 2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021446s035,022488s013lbl.pdf.

[70] *Id.*

[71] *Id.*

ii. Abortion Is Already Unlawful in Most Circumstances

231. Louisiana bans abortions in most circumstances.[72]

232. Miscarriage management is specifically exempted from the definition of "abortion" in the Abortion Ban.

233. The Abortion Ban provides significant punishments for those who aid and abet, attempt, or conspire to accomplish an unlawful abortion in Louisiana.

234. There is no evidence that adding additional criminal punishments to cover the same conduct that is already criminalized decreases the incidence of that conduct in a jurisdiction.

235. In *Dobbs v. Jackson Women's Health Organization*, the Supreme Court overturned nearly fifty years of settled precedent and held that the Due Process Clause of the Fourteenth Amendment does not confer "a broad right to obtain [an abortion]."[73]

236. *Dobbs* held that a state may regulate abortion without offending the U.S. Constitution.

237. Before Act 246 was passed, Louisiana already restricted the sale, prescription, dispensing, distribution, and delivery of "abortion-inducing drugs," with few exceptions.[74]

238. This case is about the unconstitutional regulation of medications that people need for non-abortion reasons simply because those medications may also be used for an abortion.

239. *Dobbs* does not allow Louisiana lawmakers to pass legislation that arbitrarily limits and/or deprives people whose physical conditions can be treated with misoprostol or mifepristone of access to safe and effective medications.

240. The Louisiana Constitution prohibits Louisiana from discriminating against people on the basis of their physical conditions—even when their physical condition happens to benefit from the same drugs that are used for a medication abortion.

241. *Dobbs* does not absolve the legislature of its responsibility to pass legislation that accords with Louisiana's constitution.

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[72] La. R.S. 14:87.7, 40:1061 ("Abortion Ban").

[73] 597 U.S. 215, 225 (2022).

[74] La. R.S. 14:87.9, 40:962.2(A), 40:1061.11, 40:962.2(F).

II. Act 246 was Passed into Law in Violation of the Louisiana Constitution and With Disregard for the Rights of the Public.

A. Louisiana Added Misoprostol and Mifepristone to Schedule IV of the Uniform Controlled Dangerous Substances Law as an Amendment to an Unrelated Bill.

242. Senator Thomas Pressly pre-filed S.B. 276 in the Louisiana Legislature on March 1, 2024.

243. The initial bill language created the crime of coerced abortion "by means of fraud." As initially conceived and introduced, the bill criminalized knowingly engaging in the use of an abortion-inducing drug to cause an abortion on a pregnant woman without her knowledge or consent. The legislation also amended the abortion code and added the crime of "attempted abortion" to the criminal abortion statutes at La. R.S. 14:87.7 and 14:87.8, and added the crime of criminal abortion by means of abortion-inducing drug (La. R.S. 14:87.9) to the racketeering activity statute.

244. The original version of the legislation did not contain any language about the Uniform Controlled Dangerous Substances Law.

245. After the bill passed the Senate, the House Administration of Criminal Justice Committee ("ACJ Committee") heavily amended the bill with an amendment that was not germane to the original bill.

246. Article III, § 15 of the Louisiana Constitution provides: "Every bill, except the general appropriation bill and bills for the enactment, rearrangement, codification, or revision of a system of laws, shall be confined to one object. Every bill shall contain a brief title indicative of its object. . . . No bill shall be amended in either house to make a change not germane to the bill as introduced."

247. An amendment is germane to a bill if it has a close relationship to the original bill, and is appropriate, relative, and pertinent to it.

248. The ACJ Committee amendments added "any material, compound, mixture, or preparation containing any detectable quantity of mifepristone or misoprostol" to Schedule IV of the Louisiana Uniform Controlled Dangerous Substances Law.

249. The ACJ Committee amendments were the first time that the bill referred to Louisiana's drug schedules or the Uniform Controlled Dangerous Substances Law.

250. The initial bill title had been:

> Creates the crime of coerced criminal abortion by means of fraud to prohibit a third-party from knowingly using an abortion-inducing drug to cause, or attempt to cause, an abortion on an unsuspecting pregnant mother without her knowledge or consent and amends various abortion criminal laws to add the crime of attempted abortion.

251. The bill title was amended in the ACJ Committee to read:

> To amend and reenact R.S. 14:87.1(1)(a) and R.S. 40:969(C) and to enact R.S. 14:87.6.1, R.S. 15:1352(A)(71), and R.S. 40:964 (Schedule IV)(F), relative to abortion; to create the crime of coerced criminal abortion by means of fraud; to provide relative to the crime of criminal abortion by means of abortion-inducing drugs; to provide penalties; to provide relative to the definition of crime racketeering activity; to add certain substances to Schedule IV of the Uniform Controlled Dangerous Substances Law; and to provide for related matters.

252. Notably, when introduced, S.B. 276 did not identify misoprostol or mifepristone at all, and identified, instead, "an abortion-inducing drug," which was not defined in the bill, nor did the bill reference a definition in existing statutes. Where "abortion-inducing drug" is defined in other statutes, the term is not limited to misoprostol and mifepristone. Rather, "Abortion-inducing drug" is defined as "any drug or chemical, or any combination of drugs or chemicals, or any other substance when used with the intent to cause an abortion, including but not limited to RU-486, the Mifeprex regimen, misoprostol (Cytotec), or methotrexate."[75]

253. On the floor of the House of Representatives, lawmakers passed amendments requiring that the Board of Pharmacy notify all pharmacists about this law and that the Louisiana Department of Health notify all healthcare practitioners in Louisiana about the legislation. They also added a severability provision and removed the "attempt crimes" that had been added in the original text of the bill.

254. A bill is considered to have one object if the parts of the bill are reasonably related and have a natural connection to the general subject matter of the legislation. A legislator should

[75] La. R.S. 14:87.1(2)(a).

not have to consider the validity of two unrelated objects when deciding how to vote on a bill. One act, therefore, cannot include incongruous and unrelated matters. Nevertheless, S.B. 276—a bill that violates the single object rule because it includes provisions related to different objects—was brought for a vote before the House.

255. The House passed the amended bill and sent it back to the Senate for concurrence on May 21, 2024. Two days later, the Senate concurred with the amendments and passed the bill, and on May 24, 2024, Governor Jeff Landry signed the bill, which was enrolled as Act 246.

256. While the original legislation created the crime of forcing a pregnant person to ingest an abortion-inducing drug to terminate a pregnancy unknowingly, the legislation, as passed, introduced misoprostol and mifepristone into a complex and heavily regulated system of government with dozens of new restrictions unrelated to the initial bill.

B. Act 246 Passed Despite Serious Concerns Raised by Members of the Louisiana Medical Community.

257. On May 7, 2024, over 200 Louisiana doctors signed an open letter to Senator Thomas Pressly about the dangers of adding misoprostol and mifepristone to the scheduled drugs list. Notably, as detailed herein, the letter was sent to Senator Pressly after the bill was amended in committee because no notice of the proposed amendment was provided to the public or the medical community before the amendment was introduced. The letter detailed medical providers' concerns about delaying access to life-saving treatments.

258. A maternal fetal medicine doctor stated in the media that "the majority of people with a uterus have had a reason to need misoprostol at some point." Others publicly voiced concerns that the legislation would lead to the scheduling of other drugs without justification.

259. The amendment introduced in the ACJ Committee on April 30, 2024, was improper and not germane to the original bill.

260. The amendment text was not available to the public until the committee hearing was already underway, so physicians and other stakeholders did not have time to review the amendment or prepare comments about their concerns.

261. Plaintiffs Nancy Davis and Kaitlyn Joshua, both of whom have actively engaged in legislative advocacy after Louisiana laws impacted their medical care, did not have an opportunity

to testify before lawmakers about the impact that making the drugs controlled substances would have in Louisiana, even though they would have done so if given the opportunity.

262. Once introduced, the amendment was adopted by the committee within minutes and without any opportunity for the public or medical experts to weigh in on the propriety of such a drastic change to the bill or to the Uniform Controlled Dangerous Substances Law.

263. Louisiana Act 246 violated both the single object rule and the germane amendment requirement in Louisiana's Constitution.

C. Louisiana's Efforts to Inform Some Providers of Act 246 have Left Providers Confused and Concerned that the State Still Does Not Understand the Impact of the Legislation.

264. In July, the Louisiana Board of Pharmacy newsletter detailed some implications of the bill's passage and implications.[76] The newsletter contains little guidance, beyond stating:

> The legislature directed the Louisiana Board of Pharmacy to notify all pharmacists in Louisiana about the provisions of the law and to ensure that pharmacists are aware that lawful prescriptions for mifepristone and misoprostol may be filled in accordance with Louisiana Revised Statutes (RS) 14:87.9(C)(6).

265. In that regard, beginning on August 1, 2022—over two years before Act 246 went into effect—Louisiana began requiring doctors who prescribe misoprostol and mifepristone to include a diagnosis or diagnosis code on their prescriptions indicating that the drug is intended for a purpose other than to cause an unlawful abortion.[77] The law also states that filling a prescription for a drug prescribed for a bona fide medical reason shall not subject the pharmacist or the pharmacy to the criminal consequences of this Section of law.

266. On August 22, 2024, a group of 50 doctors sent a letter to the Louisiana Department of Health and Surgeon General Ralph Abraham asking for guidance on how they can prescribe and administer misoprostol and mifepristone once Act 246 goes into effect. The letter specifically mentioned their need to be able to have ready access to misoprostol in an inpatient setting for hemorrhage situations.

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[76] *ACT 246 (Senate Bill 276) of the 2024 Louisiana Legislature – Effective October 1, 2024 (24-07-774)*, Louisiana Board of Pharmacy (July 2024), https://nabp.pharmacy/wp-content/uploads/2024/07/July-2024-Louisiana-State-Newsletter.pdf.

[77] La. R.S. 14:87.9(C)(6).

267. On September 3, 2024, the *Louisiana Illuminator* published an article interviewing doctors about their confusion and concerns related to the impending law.[78] At that time, the doctors had still not heard back from the Department of Health about their concerns or their request for guidance.

268. Three days later, on September 6, 2024, the Department of Health issued a guidance document.[79] The guidance iterated that misoprostol and mifepristone may be prescribed in accordance with La. RS 14:87.9(C)(6).

269. In addition, the guidance stated that both drugs could be "utilized in Louisiana hospitals to treat postpartum hemorrhage and incomplete miscarriages." However, mifepristone is not used for hemorrhaging.

270. The guidance also notes that "certain scheduled drugs" may be "included in a locked or secured area of an obstetric hemorrhage cart or 'crash cart,'" but does not direct hospitals to do so or provide any specific guidance on how to comply with the Act's requirements. The guidance was promptly dismissed by doctors as "not helpful," unrealistic, and clearly written by someone who "has not spent time on a labor unit."[80]

271. Doctors have sought additional guidance from the state health department about how to securely store misoprostol on hemorrhage carts in compliance with the law, but they have yet to receive any response.[81]

272. On September 30, 2024, the American College of Medical Toxicology (ACMT) issued a position statement, "Mifepristone and Misoprostol are Not Controlled Dangerous Substances," which was endorsed by the American Academy of Clinical Toxicology.[82] The ACMT

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[78] Lorena O'Neil, *supra* n.29.

[79] *Louisiana Department of Health Memorandum and Guidance*, Dep't. of Health (Sept. 6, 2024), https://ldh.la.gov/assets/hss/Hospital/Regs/LDH_Memo_and_Guidancee-Act_246_09_06_24.pdf.

[80] Lorena O'Neil, *Doctors Criticize Misoprostol Guidance from Louisiana Department of Health: 'It's not helpful'*, Louisiana Illuminator (Sept. 7, 2024), https://lailluminator.com/2024/09/07/misoprostol-louisiana/.

[81] *See* Lorena O'Neil, *Ochsner, LCMC Health Hospitals to Lock Up Life-Saving Medication Outside Labor and Delivery Rooms*, Louisiana Illuminator (Sept. 27, 2014), https://lailluminator.com/2024/09/27/ochsner-lcmc-miso/.

[82] Maryann Mazer-Amirshahi et al., *ACMT Position Statement: Mifepristone and Misoprostol are Not "Controlled Dangerous Substances"*, American College of Medical Toxicology (September 30, 2024), https://www.acmt.net/wp-content/uploads/2024/09/PS_240930_Mifepristone-and-Misoprostol-are-Not-

enumerated the likely unintended consequences of Act 246, such as delays in administering critical medication, and stated, "In summary, scheduling mifepristone and misoprostol as controlled dangerous substances is not consistent with decades of scientific evidence regarding the safety and misuse and addiction potential of these medications, and may lead to harm. Additionally, it sets a dangerous precedence of politicizing pharmaceutical regulation."[83]

273. The same day, Stella Dantas, MD, FACOG, president of the American College of Obstetricians and Gynecologists, issued a statement regarding Act 246.[84] By classifying mifepristone and misoprostol as controlled substances, "legislators are creating barriers for clinicians in emergency situations in which a patient's life or health could be at risk. In obstetrics and gynecology, minutes or even seconds can be the difference between life and death."[85] Doing so "undermines the work of the Louisiana Perinatal Quality Collaborative" and increases the likelihood of maternal mortality.[86] ACOG stated plainly that added barriers are "quite simply, dangerous."[87]

274. On information and belief, in the absence of clear guidance, pharmacists may deny medication improperly or choose not to stock these medications.

D. Plaintiffs Are Also Harmed as Taxpayers.

275. The Act also harms Plaintiffs Davis, Holt, Joshua, and Self because they are residents of Louisiana who are taxpayers. Birthmark is a Louisiana-based LLC that pays taxes in Louisiana.

276. Act 246 increases the tax burden of Louisiana citizens because it will require various officials—from district attorneys to police officers to court staff—to spend time and money

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Controlled-Dangerous-Substances.pdf; *Mifepristone and Misoprostol are Not "Controlled Dangerous Substances": The American College of Medical Toxicology Issues Position Statement*, American College of Medical Toxicology (September 30, 2024), https://apnews.com/press-release/globenewswire-mobile/medication-ac40c27d240188b7b9a00348316da0f8.

[83] *Id.*

[84] *Statement Regarding the Critical Need for Access to Mifepristone and Misoprostol*, American College of Obstetricians and Gynecologists (September 30, 2024), https://www.acog.org/news/news-releases/2024/09/statement-regarding-the-critical-need-for-access-to-mifepristone-and-misoprostol.

[85] *Id.*

[86] *Id.*

[87] *Id.*

investigating, prosecuting, and judging criminal cases that are brought under the Act. The Act will also require the Louisiana Board of Pharmacy and the Louisiana State Board of Medical Examiners to divert resources to enforce the law and perform additional disciplinary procedures in the event of noncompliance.[88] And the Act will require state hospitals to expend time and resources changing their policies and procedures to comply with its requirements.

277. As taxpayers, Plaintiffs have a right to restrain public servants from transcending their lawful powers or violating their legal duties in any unauthorized manner that would increase the burden of taxation, impact the public fisc, or otherwise unjustly affect the taxpayer or her property.

CAUSES OF ACTION

I. Violation of Article I, Section 3 of the Louisiana Constitution of 1974 (Count I) (Plaintiffs Birthmark, on behalf of itself and its clients, Dr. Emily Holt, on behalf of herself and her patients, and Pharmacist Kaylee Self, on behalf of herself and her patients)

278. Article I, Section 3 of the Louisiana Constitution of 1974, titled "Right to Individual Dignity," provides in relevant part: "No person shall be denied the equal protection of the laws. . . . No law shall arbitrarily, capriciously, or unreasonably discriminate against a person because of birth, age, sex, culture, physical condition, or political ideas or affiliations."

279. Under Article I, Section 3, laws that discriminate on the basis of physical condition are unconstitutional unless they substantially further a legitimate state purpose.

280. Laws that are arbitrary, capricious, or unreasonable do not substantially further a legitimate state purpose.

281. A law discriminates on the basis of physical condition if it makes distinctions based on health or handicap, the nature of an injury or condition, the needs of an injury or condition, or the severity of an injury or condition.

282. By treating people with physical conditions that can be treated with misoprostol and/or mifepristone differently than people with physical conditions that require other treatment with similar risk and dependence profiles as misoprostol and mifepristone, La. R.S. 40:964(F) and

[88] *See Cully v. City of New Orleans*, 173 So.2d 46, 49 (La. App. 4 Cir. 1965) ("[T]he fact that the taxpayer's interest might be small and not susceptible of accurate determination is not sufficient to deprive [a taxpayer] of his right of action.").

40:969(C), as enacted and amended by and through Act 246, discriminate on the basis of physical condition.

283. By treating healthcare providers who prescribe or dispense misoprostol and mifepristone differently than healthcare providers that do not prescribe or dispense misoprostol and mifepristone but prescribe or dispense other medications with similar risk and dependence profiles as misoprostol and/or mifepristone, La. R.S. 40:964(F) and 40:969(C), as enacted and amended by and through Act 246, also discriminates against healthcare providers in violation of Article I, Section 3.

284. These distinctions are arbitrary, capricious, and unreasonable.

285. La. R.S. 40:964(F) and 40:969(C), as enacted and amended by and through Act 246, do not substantially further a legitimate state purpose.

286. La. R.S. 40:964(F) and 40:969(C), as enacted and amended by and through Act 246 are also not rationally related to a legitimate state purpose.

287. Because La. R.S. 40:964(F) and 40:969(C), as enacted and amended by and through Act 246, violate the right to equal protection and individual dignity, the law is invalid and unenforceable, and Plaintiffs are entitled to declaratory and injunctive relief prohibiting Defendants from enforcing or implementing La. R.S. 40:964(F) and 40:969(C), as enacted and amended by and through Act 246.

II. Violation of the Single Object Requirement of Article III, Section 15 of the Louisiana Constitution of 1974 (Count II) (Plaintiffs Birthmark, on behalf of itself, Nancy Davis, on behalf of herself, Dr. Emily Holt, on behalf of herself, Kaitlyn Joshua on behalf of herself, and Pharmacist Kaylee Self, on behalf of herself)

288. Article III, Section 15(A) of the Louisiana Constitution of 1974 provides, in relevant part: "Every bill, except the general appropriation bill and bills for the enactment, rearrangement, codification, or revision of a system of laws, shall be confined to one object" (the "single object rule").

289. The purpose of the single object rule is to ensure that a legislator is not forced to consider the propriety of two unrelated objects when deciding how to vote on a bill. The single object rule prohibits one act from including incongruous and unrelated matters.

290. A law that violates the single object rule must be invalidated if the law's title identifies more than one object.

291. Act 246 violates the single object rule because it involves at least two objects that do not have a natural connection between them: (1) preventing pregnant people from being unknowingly provided with an abortion-inducing drug by means of coercion or fraud for the purpose of causing an abortion, and (2) regulating healthcare providers, pharmacists, manufacturers, distributors, transporters and patients seeking to voluntarily provide or obtain misoprostol or mifepristone for a valid legal purpose, which does not include the purpose of causing an abortion, by classifying misoprostol and mifepristone as Schedule IV drugs under the Louisiana Uniform Controlled Dangerous Substances Law.

292. The title of Act 246 describes at least two objects, including (1) preventing the criminal conduct of abortion fraud and coercion involving the use of an abortion-inducing drug to cause an abortion without the pregnant woman's knowledge or consent, and (2) scheduling misoprostol and mifepristone under Schedule IV of the Uniform Controlled Dangerous Substances Law.

293. There is not a natural connection between these two objects because classifying misoprostol and mifepristone as Schedule IV drugs for those who are seeking to provide or obtain misoprostol or mifepristone for a legal purpose will not accomplish the objective of preventing abortion fraud or coercion.

294. Therefore, Act 246 is invalid in its entirety and Plaintiffs are entitled to declaratory relief that the law is null and void and injunctive relief prohibiting Defendants from enforcing or implementing Act 246.

III. Violation of the Germane Amendment Rule of Article III, Section 15 of the Louisiana Constitution of 1974 (Count III) (Plaintiffs Nancy Davis, on behalf of herself, Birthmark, on behalf of itself, Dr. Emily Holt, on behalf of herself, Kaitlyn Joshua on behalf of herself, and Pharmacist Kaylee Self, on behalf of herself)

295. Article III, Section 15(C) of the Louisiana Constitution of 1974 provides, in relevant part: "No bill shall be amended in either house to make a change not germane to the bill as introduced" (the "germane amendment rule").

296. The germane amendment rule prohibits the legislature from amending a bill to make changes that are not germane to the original bill as introduced. An amendment is not germane if it is not in close relationship, appropriate, relative, or pertinent to the bill as introduced.

297. When introduced in the Legislature, S.B. 276 created the crime of coerced abortion, added a different crime involving criminal abortion by means of abortion-inducing drug to the list of racketeering-eligible crimes, and amended existing abortion ban statutes to include the crime of attempted abortion.

298. The amendments that were then added to S.B. 276 introduced the unrelated purpose of scheduling misoprostol and mifepristone under Schedule IV of the Louisiana Uniform Controlled Dangerous Substances Law, which regulates the legal use of certain prescription medication ("the Drug Scheduling Amendments") to a bill that had another distinct purpose.

299. The Drug Scheduling Amendments were added to S.B. 276 to regulate the legal use of misoprostol and mifepristone. In contrast, the subject matter of S.B. 276 involved the criminal use of a wider range of drugs and substances.

300. The Drug Scheduling Amendments were, therefore, added to a bill with another distinct purpose. The Drug Scheduling Amendments were not germane to the bill as originally introduced because they were not in close relationship, appropriate, relative, or pertinent to the original purpose of the bill as introduced.

301. Therefore, the Drug Scheduling Amendments added to Act 246 are invalid and Plaintiffs are entitled to declaratory relief that such provision of the Act is null and void and injunctive relief prohibiting Defendants from enforcing or implementing La. R.S. 40:964(F), and 40:969(C), as enacted and amended by and through Act 246.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and in some cases their patients and clients, as described above, pray that this Petition be deemed good and sufficient, and after due proceedings, relief is granted as follows:

A. A declaration that Louisiana Act 246:

1) Unconstitutionally discriminates on the basis of physical condition in violation of Article I, Section 3 of the Louisiana Constitution of 1974;

2) Unconstitutionally discriminates against prescribing physicians and pharmacists who fill prescriptions in violation of Article I, Section 3 of the Louisiana Constitution of 1974;

3) Unconstitutionally violates the single object requirement of Article III, Section 15 of the Louisiana Constitution of 1974; and

4) Unconstitutionally violates the germane amendment rule of Article III, Section 15 of the Louisiana Constitution of 1974.

B. A permanent injunction enjoining the enforcement or implementation of Louisiana Act 246, which amends La. R.S. 14:87.1, 15:1352, 40:964, and 40:969, and creates the new statute of La. R.S. 14:87.6.1;

C. Plaintiffs' attorney fees and costs, together with legal interest thereon calculated from the date of judicial demand; and

D. For any and all other general and equitable relief to which Plaintiffs may be entitled.

November 13, 2024

Respectfully submitted:

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*Attorneys for Plaintiffs**

*Plaintiffs' Counsel Anita Yandle and Ronelle Tshiela have simultaneously submitted an application for pro hac vice approval to LSBA and will be submitting a motion for pro hac approval upon LSBA approval.

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