

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION**

WHOLE WOMAN’S HEALTH; WHOLE)	
WOMAN’S HEALTH ALLIANCE; DR. BHAVIK)	
KUMAR; BROOKSIDE WOMEN’S MEDICAL)	
CENTER PA d/b/a BROOKSIDE WOMEN’S)	
HEALTH CENTER and AUSTIN WOMEN’S)	
HEALTH CENTER; DR. LENDOL L. DAVIS;)	
ALAMO CITY SURGERY CENTER PLLC d/b/a)	
ALAMO WOMEN’S REPRODUCTIVE SERVICES;)	CIVIL ACTION
and NOVA HEALTH SYSTEMS, INC. d/b/a)	
REPRODUCTIVE SERVICES,)	CASE NO. 1:16-CV-01300-DAE
)	
Plaintiffs,)	
)	
v.)	
)	
JOHN HELLERSTEDT, M.D., Commissioner of the)	
Texas Department of State Health Services, in his)	
official capacity,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

Plaintiffs, by and through their undersigned attorneys, bring this First Amended Complaint against the above-named Defendant, and his employees, agents, and successors in office, to include, in their ongoing constitutional challenge to regulations applicable to healthcare facilities’ disposition of their patients’ embryonic and fetal tissue, a challenge to new legislation on the same subject, and in support thereof allege the following:

I. PRELIMINARY STATEMENT

1. Pursuant to 42 U.S.C. § 1983, Plaintiffs, Texas health care providers, bring this action on behalf of themselves and their patients. They seek declaratory and injunctive relief from the unconstitutional requirements of:

- the amendments to Title 25, §§ 1.132-1.137 of the Texas Administrative Code, published on December 9, 2016 in the Texas Register, 41 Tex. Reg. 9732-41, (“the 2016 Amendments” or “the Amendments”), and which are the subject of Plaintiffs’ original Complaint, *see Whole Woman’s Health v. Hellerstedt*, 231 F. Supp. 3d 218 (W.D. Tex. 2017) (“*Whole Woman’s Health II*”);¹ and
- Texas Health & Safety Code Title 8, Subtitle B, Chapter 697 (“the Act”), enacted June 6, 2017 as part of Senate Bill 8 of 2017 (“SB 8”), and codified at Tex. Health & Safety Code §§ 697.001-697.009, with an effective date of February 1, 2018, along with any implementing regulations issued thereunder.

2. The Amendments and the Act (collectively, “the Challenged Laws”) prohibit healthcare facilities from treating embryonic and fetal tissue like other kinds of human tissue for purposes of treatment and disposition. Instead, they require, for the first time ever under Texas law, interment or cremation of such tissue.

3. Although the Amendments, when originally proposed, asserted a public health rationale, the Act abandons that pretext and instead states that its purpose is to “express the state’s profound respect for the life of the unborn.”

4. Controlling Supreme Court precedent makes clear that the State may not impose its beliefs about embryonic and fetal tissue onto its citizens. Instead, the sphere of personal liberty protected by the Due Process Clause guarantees individuals the right to form their own beliefs about such matters—based on their own religious and cultural traditions—and to act in accordance with them.

¹ Plaintiffs’ original Complaint in *Whole Woman’s Health II* refers to the Amendments as “the Regulation,” but in subsequent filings, the parties and this Court have called them the “Amendments,” and this Amended Complaint maintains the latter nomenclature.

5. The Challenged Laws impose on women who have a miscarriage management procedure, an ectopic pregnancy surgery, or an abortion the requirement that their tissue be disposed of in a manner associated with human remains, without their consent.

6. The Challenged Laws are medically unnecessary and provide no public health benefit. Further, they threaten women's health and safety by providing no safe harbor for healthcare facilities that send tissue to pathology or crime labs. They also force healthcare providers to work with an extremely limited number of third-party vendors for interment or cremation, threatening healthcare facilities' provision of care and their long-term ability to remain open, as well as increasing costs for women seeking pregnancy-related medical care.

7. The Challenged Laws threaten irreparable injury to Plaintiffs and their patients, including to Plaintiffs' patients' rights to seek pregnancy-related medical care without undue interference by government.

8. Plaintiffs seek declaratory and injunctive relief from these constitutional deprivations.

IV. JURISDICTION AND VENUE

9. Jurisdiction is conferred on this Court by 28 U.S.C. §§ 1331 and 1343(a)(3).

10. Plaintiffs' claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general legal and equitable powers of this Court.

11. Venue is appropriate under 28 U.S.C. § 1391(b)(1) because Defendant resides in this district.

V. PLAINTIFFS

12. Plaintiff Whole Woman's Health has provided high quality reproductive healthcare services, including abortion services and miscarriage management procedures, to Texas women

for two decades. It operates licensed abortion facilities in Fort Worth, McAllen, and San Antonio. Whole Woman's Health sues on behalf of itself and its patients.

13. Plaintiff Whole Woman's Health Alliance is a non-profit organization committed to providing holistic reproductive care for patients, including abortion care and advocacy to eradicate abortion stigma. Since April 2017, it has operated a licensed abortion facility in Austin.

14. Bhavik Kumar, M.D., M.P.H., is a board-certified family medicine physician licensed to practice in the State of Texas. Dr. Kumar is the medical director for Whole Woman's Health's and Whole Woman's Health Alliance's clinics in Texas. He currently provides abortion care at Whole Woman's Health's Alliance's clinic in Austin and has also provided abortion care at Whole Woman's Health's clinics in San Antonio and Fort Worth. Dr. Kumar sues on behalf of himself and his patients.

15. Plaintiff Brookside Women's Medical Center PA (the "Health Centers"), operates a comprehensive women's primary care and gynecological care practice ("Brookside Women's Health Center"), and a licensed abortion facility ("Austin Women's Health Center"), in Austin. The Health Centers offers thousands of patients annually a full range of gynecologic services, including surgical and medical abortion care and miscarriage management. The Health Centers' medical director, Plaintiff Dr. Lendol L. Davis, also undertakes gynecological surgery, including miscarriage management and ectopic pregnancy treatment, at several Austin-area hospitals. The Health Centers and Dr. Davis sue on behalf of themselves and their patients.

16. Plaintiff Alamo City Surgery Center PLLC d/b/a Alamo Women's Reproductive Services ("Alamo"), is a licensed ambulatory surgical facility in San Antonio. Alamo provides a range of reproductive health services, including medication and surgical abortions, to Texas women. Alamo sues on behalf of itself and its patients.

17. Plaintiff Nova Health Systems, Inc. d/b/a Reproductive Services (“Reproductive Services”), operates a licensed abortion facility in El Paso. The El Paso clinic has provided high-quality reproductive healthcare services, including abortion services, to Texas women for nearly four decades, except for a few months in 2015 when the admitting-privileges requirement struck down in *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292 (2016) (“*Whole Woman’s Health I*”) was temporarily in effect. Reproductive Services sues on behalf of itself and its patients.

VI. DEFENDANT

18. Defendant John Hellerstedt, M.D., is the Commissioner of the Texas Department of State Health Services (“DSHS”). DSHS is charged with the Challenged Laws’ enforcement. Commissioner Hellerstedt is sued in his official capacity.

V. FACTUAL ALLEGATIONS

Overview and Generally-Applicable Law

Overview

19. Until last year, Texas had no special regulation of the disposition of tissue from pregnancy-related medical care. All tissue removed from human bodies as part of healthcare was classified by DSHS as “pathological waste,” itself a category of “special waste from health care facilities,”² and healthcare facilities were obliged to ensure its safe and appropriate disposition through medical means. *See generally* 25 TAC §1.136(a)(4).

20. Last year, on DSHS’ behalf, the Texas Health and Human Services Commission (“HHSC”) issued the Amendments, amending DSHS’ regulations governing the disposal of special waste from healthcare facilities. As described in greater detail below, the Amendments

² The other categories of “special waste from health care facilities” are animal waste, body fluids, microbiological waste, and sharp objects such as needles (known as “sharps”).

created a new sub-category of “pathological waste,” called “fetal tissue,” and mandated that this tissue be disposed of exclusively by methods associated with the disposition of human bodies—burial or scattering of ashes—and eliminating all other, medical methods of disposition which had previously been available. The Amendments are subject to a preliminary injunction in this case, and have never taken effect.

21. Subsequently, the State enacted the Act, which created a new, *sui generis* waste classification under Texas law: “embryonic and fetal tissue remains” (“EFTR”). The Act provides explicitly that EFTR is “not pathological waste.” The Act, similarly to the Amendments, prohibits healthcare facilities from disposing of EFTR through any methods other than interment or cremation.

22. The Act is slated to take effect February 1, 2018. Implementing regulations were due to be issued by December 1, 2017, but have not been issued to date.

Relevant Generally-Applicable Law

23. Prior to adopting the Challenged Laws, Texas regulations provided that all body parts, tissue and organs, whether “human materials removed during surgery” or other procedures, or “the products of spontaneous or induced human abortion,” could be disposed of by healthcare facilities using any of the following seven methods³:

- i. grinding and discharging to a sanitary sewer system;
- ii. incineration followed by deposition of the residue in a sanitary landfill;
- iii. steam disinfection followed by interment;
- iv. interment;
- v. moist heat disinfection followed by deposition in a sanitary landfill;

³ There is one exception to the general rule: for “body parts” “removed during surgery” or other procedures, the first method listed above is not available.

- vi. chlorine disinfection/maceration followed by deposition in a sanitary landfill; or
- vii. an approved alternate treatment process, provided that the process renders the item as unrecognizable, followed by deposition in a sanitary landfill.

24. These regulations were enacted in 1989 and remained unchanged in relevant part until adoption of the Amendments. Except as noted *supra* ¶ 23 n.3, there were no distinctions between how healthcare facilities may dispose of “human materials removed during surgery” or other procedures, and “the products of spontaneous or induced human abortion.”

25. Several chapters of other Texas law are cited by the Challenged Laws. Those referred to elsewhere in this Amended Complaint include Chapter 651 of the Texas Occupations Code, which are the regulations of the Texas Funeral Services Commission (TFSC); Chapters 711 and 716 of the Texas Health & Safety Code, which govern “cemeteries” and “cremation,” respectively; and Chapter 326 of Title 30, Texas Administrative Code, which are Texas Commission on Environmental Quality (TCEQ) regulations governing “medical waste management.”

The Challenged Laws

The Amendments—Regulatory History

26. The Amendments were first published in the Texas Register, as a proposed regulation, on July 1, 2016, “[b]efore the ink . . . was dry” on the Supreme Court’s *Whole Woman’s Health I* opinion invalidating two parts of a 2013 Texas statute (“House Bill 2” or “HB 2”) that would have closed most of the State’s abortion clinics. *Whole Woman’s Health II*, 231 F. Supp. 3d at 222.

27. In the then-proposed Amendments’ explanatory preamble, under the heading “Public Benefit,” DSHS stated, “the public benefit anticipated as a result of adopting and enforcing these rules will be enhanced protection of the health and safety of the public.”

28. On or about the same day, Governor Greg Abbott sent a fundraising letter to his supporters. Using inflammatory language, he referred to abortion providers as “soulless,” asked for money, and stated that the then-proposed Amendments’ purpose was to promote “respect for the sanctity of life” and “protect[] human dignity.” The letter does not mention improving public health and safety, nor the prevention of the spread of disease.

29. On July 20, 2016, HHSC Executive Commissioner Charles Smith wrote a letter to a member of the Legislature, stating that, “[i]n line with Governor Abbott’s commitment to protect unborn lives, I directed DSHS to evaluate potential changes to portions of the rules that pertain to disposition of fetal remains. . . . I charged DSHS to determine how this language could be amended, within current statutory authority, to better preserve the dignity of these unborn lives.” The letter does not mention improving the public health and safety, nor the prevention of the spread of disease.

30. DSHS received written public comments about the then-proposed Amendments through July 30, 2016, and also held a public hearing.

31. On September 30, 2016, DSHS withdrew the then-proposed Amendments, and issued new proposed Amendments, whose text was identical to the first version, and which contained a longer explanatory preamble. Under the “Public Benefit” heading of that preamble, DSHS stated, “the public benefit anticipated as a result of adopting and enforcing these rules will be enhanced protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease.”

32. DSHS again received public comments about the then-proposed Amendments, and again held a public hearing.

33. In total, 35,663 written and oral public comments were received, over the course of the two comment periods. Comments opposing the proposed Amendments were received, among many others, from major national and Texas-based medical groups, including the American Congress of Obstetricians and Gynecologists, the Texas Medical Association, the Texas Hospital Association, the Teaching Hospitals of Texas, and the National Abortion Federation. DSHS also received comments in opposition from the Funeral Consumers Alliance of Texas, the Healthcare Waste Institute of the National Waste and Recycling Association, the National Association of Social Workers, and various national and Texas-based women's rights and civil rights organizations.

34. On December 9, 2016, the final Amendments were published in the Texas Register. In its explanatory preamble, under the heading "Public Benefit," DSHS stated, "the public benefit anticipated as a result of adopting and enforcing these rules will be the continued protection of the health and safety of the public by ensuring that the disposition methods specified in the rules continue to be limited to methods that prevent the spread of disease. Additional public benefit will be realized in bringing up-to-date the department's rules to reflect the Legislature's articulated policy objectives of respect for life and protecting the dignity of the unborn."

The Amendments—Operation

35. The 2016 Amendments impose narrow limits on how healthcare facilities may dispose of embryonic or fetal tissue.

36. The Amendments create a new defined term, called "fetal tissue," which is "[a] fetus, body parts, organs or other tissue from a pregnancy," not including "the umbilical cord,

placenta, gestational sac, blood or body fluids.” It therefore includes embryonic tissue from the earliest stages of a pregnancy.

37. The Amendments limit the number of disposal options for “fetal tissue”—whether “removed during surgery” or other procedures, or as the “products of spontaneous or induced human abortion”—to three. Those three are:

- i. interment;
- ii. incineration followed by interment; or
- iii. steam disinfection followed by interment.

38. “[I]nterment” is defined to include “cremation” and “the process of cremation followed by placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter.”

39. The Amendments state that they do “not extend or modify requirements of Texas Health and Safety Code, Chapters 711 and 716, or Texas Occupations Code, Chapter 651, to disposition of fetal tissue.”

40. DSHS stated in its responses to public comments about the Amendments that healthcare facilities are “responsible for ensuring that the fetal tissue disposition is in compliance with these rules” “regardless of where the disposition of waste occurs,” including across state lines.

41. DSHS further stated that a Texas healthcare facility “will need to demonstrate to the department that it has provided for disposition in compliance with the [Amendments]” when disposing of “fetal tissue” outside of Texas.

42. DSHS does not require any facilities to demonstrate that human remains or pathological waste other than “fetal tissue” are disposed of in compliance with Texas law when taken outside of Texas.

43. No Texas law or regulation requires healthcare facilities to ensure the disposition of human remains by any particular method, except in the limited context of medical research and training.

The Amendments—Litigation History

44. On December 12, 2016, Plaintiffs filed this lawsuit, seeking a preliminary and permanent injunction of the Amendments, among other forms of equitable relief.⁴

45. On December 15, 2016, the Court held argument and granted a temporary restraining order. On January 3-4, 2017, the Court held a preliminary injunction hearing and, on January 27, 2017, granted a preliminary injunction, holding that Plaintiffs had established a likelihood of success on the merits of their claims that the Amendments were unconstitutionally vague and imposed an undue burden on women seeking pregnancy-related healthcare.

46. Defendants appealed from this ruling. On March 16, 2017, proceedings in this case were stayed pending the resolution of that appeal. On December 6, 2017, Defendant moved to voluntarily dismiss his appeal, citing the Act's impending effective date. The Court of Appeals granted that motion the next day. On December 15, 2017, this Court ordered the stay lifted.

The Act—Legislative History

47. During the 2017 regular legislative session, the Texas legislature considered and debated several bills containing abortion restrictions, including bills regulating the disposition of embryonic or fetal tissue, but none of these bills was ultimately enacted.

⁴ Plaintiffs' Complaint also sought relief regarding Title 25, § 181.7, of the Texas Administrative Code. Shortly after the case was filed, the parties reached a common understanding regarding that provision's application. *See* Order at 1 n.1, ECF No. 24. Accordingly, it has not been the subject of further litigation.

48. SB 8 as originally drafted and debated was an unrelated abortion restriction, not containing embryonic or fetal tissue regulations. Those, along with other abortion restrictions which had similarly failed to pass as standalone legislation, were attached to SB 8 as last-minute amendments, without committee hearings or debate, and with limited floor debate. The bill was signed into law on June 6, 2017.

49. As enacted, SB 8 contains numerous restrictions on abortion and other forms of pregnancy-related medical care, including Chapter 697, challenged here as the Act.

50. The Act states that its purpose is to “express the state’s profound respect for the life of the unborn by providing for a dignified disposition of embryonic and fetal tissue remains.”

51. The sole statement of purpose in Texas statutes applicable to the disposition of human remains provides that “[DSHS] shall regulate the disposal, transportation, interment, and disinterment of dead bodies to the extent reasonable and necessary to protect public health and safety.”

The Act—Operation

52. The Act establishes a regulatory scheme for EFTR that appears to supersede the Amendments.

53. Contrary to the Amendments, which classify “fetal remains” as a form of “pathological waste,” the Act states, “[e]mbryonic and fetal tissue remains are not pathological waste under state law.” The Act does not categorize EFTR as any other form of waste, nor does it classify EFTR as human remains.

54. The Act creates the term “embryonic and fetal tissue remains” and defines it in relevant part as “an embryo, a fetus, body parts, or organs from a pregnancy that terminates in the death of the embryo or fetus and . . . does not include the umbilical cord, placenta, gestational

sac, blood, or body fluids.” Unlike the Amendments’ definition of “fetal tissue,” the Act’s definition of EFTR does not include “other tissue from a pregnancy.”

55. The Act mandates that “a health care facility in this state that provides health or medical care to a pregnant woman shall dispose of [EFTR] passed or delivered at the facility by:

- i. interment;
- ii. cremation;
- iii. incineration followed by interment; or
- iv. steam disinfection followed by interment.

56. The Act defines “interment” to mean “the disposition of remains by entombment, burial, or placement in a niche.” Unlike the Amendments, the Act’s definition of “interment” does not include “cremation.”

57. Also unlike the Amendments, the Act states that “the umbilical cord, placenta, gestational sac, blood, or body fluids from a pregnancy terminating in the death of the embryo or fetus . . . may be disposed of in the same manner as and with the [EFTR].”

58. The Act also provides that “the ashes resulting from the cremation or incineration of [EFTR] may be interred or scattered in any manner as authorized by law for human remains” and “may not be placed in a landfill,” in contrast to the Amendments, which do not mention landfills.

59. The Act does not state what the “manner[s] as authorized by law” are for scattering of ashes.

60. Since the Act states that “incineration” “shall” be followed by “interment,” which is defined to include only “entombment, burial, or placement in a niche,” there is no logical way for scattering of ashes after incineration to be authorized by law.

61. Commercial incinerators and steam disinfection facilities that treat waste generally dispose of the treated waste in landfills. These facilities manage waste materials together as they come in, and do not have the ability to segregate materials received from customers. Safety risks and regulations prohibit employees from sorting through their customers' waste. Additionally, these facilities' treatment operations are such that waste materials, once processed, are not able to be separated out after an incineration or steam disinfection process.

62. Therefore, there is no way, in practice, for commercial incinerators and steam disinfection facilities to separate out healthcare facilities' EFTR from customers' other waste to ensure the former is interred and not sent to a landfill.

63. The Act also states that "[u]nless otherwise provided by this chapter, Chapters 711 and 716 of this code and Chapter 651, Occupations Code, do not apply to the disposition of [EFTR]." No other provision of the Act states whether or how these Chapters do apply.

64. The Act provides a December 1, 2017 deadline for rulemaking to implement its restrictions regarding EFTR.

65. As of today, the State has not issued implementing regulations. Proposed regulations were published in the Texas Register on November 17, 2017, beginning a thirty-day public notice-and-comment period. A public hearing was held on December 11, 2017. The proposed regulations stated that the earliest date final regulations could have been issued was December 17, 2017.

66. The Act also mandates DSHS to "develop a grant program that uses private donations to provide financial assistance for the costs associated with disposing of embryonic and fetal tissue remains" by October 1, 2017. It also provides for the "establish[ment] and maintain[ance of] a registry of participating funeral homes and cemeteries willing to provide free

common burial or low-cost private burial [and] private nonprofit organizations that register with the department to provide financial assistance,” and further requires DSHS “to make the registry information available on request to a physician, health care facility, or agent of a physician or health care facility,” by December 1, 2017.

67. As of today, the State has not established the grant program, and the registry information is not available upon request.

Ambiguities in the Challenged Laws

68. The Amendments contained serious ambiguities that did not give healthcare providers a reasonable opportunity to know how to comply with them, and allowed DSHS to enforce them arbitrarily. This led the Court to conclude that Plaintiffs had a substantial likelihood of success on the merits of their claim that the Amendments are unconstitutionally vague. *See Whole Woman’s Health II*, 231 F.Supp.3d at 227.

69. The Act has failed to adequately cure these ambiguities. The Act does not give adequate guidance regarding what kinds of licensed facilities may dispose of EFTR, and where cremated ash may be disposed.

The Challenged Laws’ Burdens on Texas Women and Their Families

70. The Challenged Laws place burdens on women seeking pregnancy-related care. They also place burdens on their families.

71. They burden women’s liberty in several ways. First, they force the State’s views about personhood onto all women in Texas, mandating adherence to a particular set of cultural and religious norms that are far from universal. Second, they discourage women from seeking medical care for abortion and miscarriage. Third, they would impose barriers to accessing healthcare by increasing costs and decreasing the availability of services.

72. Women and their families hold a diversity of views on whether and when an embryo or fetus attains the status of a human being. These views are informed by science, culture, spirituality, and religion.

73. Religious traditions teach different values regarding the proper disposition of human bodies.

74. The Challenged Laws enshrine into law an exceedingly narrow set of beliefs regarding embryonic and fetal personhood, and what is appropriate for the disposition of embryonic and fetal tissue. These views do not reflect the diversity of views people hold about when human life begins and the proper disposition of embryonic or fetal tissue.

75. The Challenged Laws violate women's moral agency as independent decision makers and intrude into their most intimate decisions about their bodies and their faith.

76. Texas law predating the Challenged Laws already allowed women to choose burial or scattering of ashes following a pregnancy loss.

77. The Challenged Laws eliminate women's choice. They force interment or scattering of ashes onto all women who obtain surgical miscarriage management, ectopic pregnancy surgery, or an abortion procedure.

78. They do not permit women to grant or withhold their informed consent to disposition by methods associated with human remains versus common medical methods.

79. By depriving women of the moral agency to act in accordance with their own views about personhood, and of the ability to grant their informed consent, the Challenged Laws deprive women of dignity and autonomy.

80. The Challenged Laws' imposition on women's autonomy and invasion of their privacy will also harm women spiritually and emotionally, causing trauma, guilt, shame, anger,

and feelings of exploitation and violation. The Challenged Laws increase the stigma surrounding abortion and miscarriage in Texas.

81. Defendant maintained in preliminary injunction proceedings that Plaintiffs can achieve compliance with the Amendments by working with religious ministries that would facilitate prayer services at embryonic and fetal tissue disposition sites. This will cause particular distress for patients who do not share those ministries' religious beliefs.

82. Defendant maintained in preliminary injunction proceedings that healthcare facilities may store EFTR in freezers for up to a year, and then annually bury it in a mass grave to thaw, or incinerate it and scatter the ashes on any private property (other than a landfill). These practices are not consistent with many peoples' understanding of dignity.

83. Pathological testing of abnormal pregnancy tissue is important for women's health. Plaintiffs routinely send abnormal embryonic and fetal tissue to pathology labs, sometimes out of state, to test for certain diseases, screen for cancer, and determine the cause of abnormalities and the likelihood of recurrence in future pregnancies.

84. Forensic examination of pregnancy tissue is important for evidentiary purposes when law enforcement is investigating sex crimes. Texas law requires that Plaintiffs comply with law enforcement requests for embryonic and fetal tissue.

85. The Challenged Laws require healthcare providers to ensure that embryonic or fetal tissue is disposed of using only a permitted method of disposition, even for tissue sent to a pathology lab or a crime lab.

86. The Challenged Laws provide for healthcare providers to be liable for violations of law by third parties to whom they send this tissue.

87. Because Plaintiffs cannot control how pathology labs and crime labs dispose of tissue after testing, Plaintiffs must either risk liability under the Challenged Laws when sending tissue to pathology labs or crime labs, or risk liability for malpractice or contempt for failing to send tissue to pathology labs or crime labs.

88. The State has provided no guidance to pathology and crime labs, nor to healthcare providers who send tissue to such labs, regarding how to comply with the Challenged Laws.

89. The Challenged Laws require healthcare providers all along the chain of handling any embryonic or fetal tissue—from ob/gyns or primary care providers to hospitals to pathology labs to waste vendors—to deviate from the standard of care and to establish and follow a second, separate protocol for disposition of EFTR, in order to ensure burial or cremation of this tissue, separate from all other tissue. The burdens of doing so will increase the risk of medical error and the complexity of providing pregnancy-related medical care—and therefore, ultimately, its cost as well.

90. The Challenged Laws' burdens could dissuade women from seeking treatment that would result in the compulsory burial or scattering of ashes of the tissue taken from their bodies. It could push some women to stay home and not seek miscarriage care from healthcare facilities. It could push some women to seek medication abortion rather than surgical abortion, even if the latter would otherwise be the better option for them. It could push some women to seek medical care out of state, with consequent delays and increased health risks, interruption of their lives, and expense.

91. The Challenged Laws make the availability of abortion services contingent on the ability and willingness of third-party vendors to inter or scatter the ashes of embryonic and fetal tissue at a non-prohibitive cost.

92. Plaintiffs are not aware of any vendor willing and able to provide burial services for embryonic and fetal tissue whose cost is not an order of magnitude larger than their current special waste disposal costs.

93. The Act's legislative history contains a Fiscal Note that includes reports from two public hospitals surveyed by the Texas Hospital Association. The first estimates burial costs in compliance with the Act would "range between \$218,400-\$655,200" annually; the second reports higher costs on a per-patient basis.

94. A licensed funeral director whom Defendant called to testify at the preliminary injunction hearing in this matter confirmed that, were he legally able to provide disposition services, he would charge many times more than Plaintiffs' current vendors.

95. Plaintiffs are aware of only one facility in the entire state willing and able to provide cremation services for embryonic and fetal tissue from abortion clinics at a cost that is not many times greater than their current disposition costs. It is not clear that this facility is willing and able to handle all EFTR from throughout the state, or whether it may do so legally under the regulations of the Texas Commission on Environmental Quality and the Texas Funeral Services Commission.

96. Even if it were, the Challenged Laws would tie every abortion facility in the state to that one vendor. This would immediately impact abortion clinic operations throughout the state, by making it plain to all that they are at risk of closure should that vendor become unavailable. Clinics would face immediate difficulties obtaining credit, and hiring and retaining staff, due to their uncertain future. This is precisely what happened when HB 2 was enacted.

97. This situation would also allow the vendor, as a monopoly, to raise prices.

98. Additionally, abortion facility vendors can be pressured by anti-abortion activists and by government agencies to cease working with abortion providers. Singling out one business as the sole provider of a legally-required service provides an opportunity to take out a “weak link” in abortion clinic operations, resulting in clinics’ closure.

99. The State has undertaken two wide-ranging investigations of abortion care providers’ medical waste disposal practices within the past few years. Although neither substantiated the allegations for which they were ostensibly initiated, they have served to discourage medical waste disposal companies from working with abortion providers. Several medical waste services providers have recently dropped multiple Plaintiff clinics as customers.

100. With the implementing regulations still not issued weeks after the legal deadline, healthcare providers are being given a much shorter window to plan how they will come into compliance with the implementing regulations before the Act takes effect than that intended by the Texas Legislature. This further adds to the uncertainties and challenges imposed by the State under the Act.

101. Because the Challenged Laws immediately complicate abortion clinics’ operations and threaten their long-term survival, they are a threat to the availability of abortion access in Texas.

102. Once a clinic is closed, it is likely to remain so. A year and a half after *Whole Woman’s Health I*, only three of the more than twenty clinics shuttered by HB 2 have reopened.

103. The Challenged Laws could also significantly increase the cost of miscarriage management and ectopic pregnancy treatment. These costs could be especially high for healthcare facilities, such as doctors’ offices, that dispose of embryonic and fetal tissue on an

occasional basis would have to arrange for special disposition of embryonic and fetal tissue, instead of disposal through their regular medical waste vendor.

104. Additional costs would likely be borne by the patients. Health insurance does not typically cover funeral expenses.

CLAIMS FOR RELIEF

COUNT I

(Liberty)

105. The allegations of paragraphs 1 through 104 are incorporated as though fully set forth herein.

106. The Challenged Laws impose onerous, unjustified, and medically-unnecessary burdens on women seeking miscarriage management, ectopic pregnancy treatment, and abortion care in Texas, in violation of the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

COUNT II

(Vagueness)

107. The allegations of paragraphs 1 through 106 are incorporated as though fully set forth herein.

108. The Challenged Laws do not provide healthcare facilities a reasonable opportunity to know what is required of them, and invite arbitrary and discriminatory enforcement, in violation of the Due Process Clause of the Fourteenth Amendment to the United States Constitution.

COUNT III

(Equal Protection)

109. The allegations of paragraphs 1 through 108 are incorporated as though fully set forth herein.

110. By requiring that healthcare facilities dispose of embryonic and fetal tissue differently from human remains and from other types of human tissue, the Challenged Laws violate Plaintiffs' right to equal protection under the law guaranteed by the Fourteenth Amendment to the United States Constitution.

COUNT IV

(Commerce Clause)

111. The allegations of paragraphs 1 through 110 are incorporated as though fully set forth herein.

112. By requiring healthcare facilities to dispose of embryonic and fetal tissue in compliance with Texas law when disposal occurs in another state, the Challenged Laws are an unconstitutional burden on interstate commerce, in violation of Article I, Section 8 of the United States Constitution.

REQUEST FOR RELIEF

Plaintiffs respectfully request that this Court:

A. Issue a declaratory judgment that

- the amendments to Title 25, §§ 1.132-1.137 of the Texas Administrative Code, which were published on December 9, 2016 in the Texas Register, 41 Tex. Reg. 9732-41; and
- Texas Health & Safety Code Subtitle B, Title 8, Chapter 697, along with any implementing regulations issued thereunder;

are unconstitutional and unenforceable in all of their applications;

B. Permanently enjoin Defendant and his employees, agents, and successors in office from enforcing the Challenged Laws in all of their applications;

C. Award attorney's fees and costs to Plaintiffs pursuant to 42 U.S.C. § 1988; and/or

D. Grant such other and further relief as the Court may deem just, proper, and equitable.

Dated: December 22, 2017

Respectfully submitted,

/s/ David Brown

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**Application for admission *pro hac vice* pending

CERTIFICATE OF SERVICE

I certify that, on this 22nd day of December, 2017, a copy of the foregoing document was electronically filed with the Clerk of Court using the CM/ECF system, which will send notification to all counsel of record.

/s/ David Brown

David Brown