

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

WHOLE WOMAN’S HEALTH, et al., <i>Plaintiffs,</i>	§ § § § § § §	Civil Action No. 1:16-cv-01300-DAE
v.		
JOHN HELLERSTEDT, M.D., <i>Defendant.</i>		

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**DEFENDANT’S FIRST AMENDED ANSWER TO  
PLAINTIFFS’ FIRST AMENDED COMPLAINT**

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Defendant John Hellerstedt, M.D., in his official capacity as Commissioner of the Texas Department of State Health Services (Defendant), files this First Amended Answer to Plaintiffs’ First Amended Complaint. *See* Doc. No. 93.

**I. ANSWER TO PRELIMINARY STATEMENT**

1. Defendant denies that the statutory and regulatory provisions referenced in Paragraph 1 of the First Amended Complaint are unconstitutional, and Defendant denies that Plaintiffs are entitled to any relief. Defendant admits that Plaintiffs purport to bring this action on behalf of themselves and their patients pursuant to 42 U.S.C. § 1983. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 1 of the First Amended Complaint and therefore denies those allegations.

2. Paragraph 2 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that the statutory and regulatory provisions at issue impose requirements for the disposition of embryonic and fetal tissue remains that differ in certain respects

from the requirements for the disposition of other types of human tissue. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 2 of the First Amended Complaint and therefore denies those allegations.

3. Defendant admits that the stated purpose of the statutory provisions at issue 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.” Defendant further admits that the purpose of the new implementing regulations is to implement the Health and Safety Code, Chapter 697, which requires the dignified disposition of embryonic and fetal tissue remains. Defendant admits that the previous version of amendments published on December 9, 2016, included a statement that they would protect public health and safety. Defendant denies the remaining allegations in Paragraph 3 of the First Amended Complaint.

4. Paragraph 4 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations as stated in Paragraph 4 of the First Amended Complaint.

5. Defendant denies the allegations as stated in Paragraph 5 of the First Amended Complaint.

6. Defendant admits that the statutory and regulatory provisions at issue were not enacted based on medical necessity. Defendant denies the remaining allegations as stated in Paragraph 6 of the First Amended Complaint.

7. Defendant denies the allegations in Paragraph 7 of the First Amended Complaint.

8. Defendant denies that the statutory and regulatory provisions at issue are unconstitutional, and Defendant denies that Plaintiffs are entitled to any relief.

#### **IV.<sup>1</sup> ANSWER TO JURISDICTION AND VENUE**

9. Defendant denies that this Court has jurisdiction to the extent any or all Plaintiffs lack standing.

10. Defendant denies that this Court has jurisdiction to grant any relief to the extent any or all Plaintiffs lack standing.

11. Defendant admits that venue is proper only to the extent each Plaintiff can show standing. Defendant denies that this Court is a proper venue to the extent any or all Plaintiffs lack standing.

#### **V. ANSWER TO PLAINTIFFS**

12. Defendant admits that Plaintiff Whole Woman's Health operates licensed abortion facilities in Fort Worth, McAllen, and San Antonio. Defendant further admits that Plaintiff Whole Woman's Health performs abortions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 12 of the First Amended Complaint and therefore denies those allegations.

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<sup>1</sup> This First Amended Answer tracks the section numbers of Plaintiffs' First Amended Complaint. Plaintiffs' First Amended Complaint does not contain a section II or section III.

13. Defendant admits that Plaintiff Whole Woman's Health Alliance operates a licensed abortion facility in Austin and performs abortions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 13 of the First Amended Complaint and therefore denies those allegations.

14. Defendant admits that Plaintiff Bhavik Kumar, M.D., M.P.H., is a family medicine physician licensed to practice in the State of Texas. Defendant further admits that Dr. Kumar has performed abortions in Austin, San Antonio, and Fort Worth. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 14 of the First Amended Complaint and therefore denies those allegations.

15. Defendant admits that Plaintiff Brookside Women's Medical Center PA operates Brookside Women's Health Center in Austin, as well as Austin Women's Health Center, a licensed abortion facility in Austin. Defendant further admits that Austin Women's Health Center and Plaintiff Dr. Lendol L. Davis perform abortions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 15 of the First Amended Complaint and therefore denies those allegations.

16. Defendant admits that Plaintiff Alamo City Surgery Center PLLC d/b/a Alamo Women's Reproductive Services is a licensed ambulatory surgical center in San Antonio and performs abortions. Defendant lacks knowledge or information

sufficient to form a belief about the truth of the remaining allegations in Paragraph 16 of the First Amended Complaint and therefore denies those allegations.

17. Defendant admits that Plaintiff Nova Health Systems, Inc. d/b/a Reproductive Services operates a licensed abortion facility in El Paso and performs abortions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 17 of the First Amended Complaint and therefore denies those allegations.

## **VI. ANSWER TO DEFENDANT**

18. Defendant admits the allegations in Paragraph 18 of the First Amended Complaint.

## **V.<sup>2</sup> ANSWER TO FACTUAL ALLEGATIONS**

19. Defendant admits that the disposition of fetal tissue was previously governed, in part, by the provisions of 25 Texas Administrative Code § 1.136(a)(4). Defendant denies that Plaintiffs' legal characterizations in Paragraph 19 of the First Amended Complaint are accurate.

20. Defendant admits that the Texas Health and Human Services Commission adopted amendments to 25 Texas Administrative Code §§ 1.132-.137, that such amendments were first published in the Texas Register on July 1, 2016, and that such amendments were the subject of a preliminary injunction issued by

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<sup>2</sup> This First Amended Answer tracks the section numbers of Plaintiffs' First Amended Complaint. Plaintiffs' First Amended Complaint contains two sections numbered section V.

this Court. Defendant denies that Plaintiffs' legal characterizations in Paragraph 20 of the First Amended Complaint are accurate.

21. Defendant admits that a portion of Senate Bill 8, codified as Chapter 697 of the Texas Health and Safety Code, governs the disposition of embryonic and fetal tissue remains, as defined by that statute. Defendant denies that Plaintiffs' legal characterizations in Paragraph 21 of the First Amended Complaint are accurate.

22. Defendant admits that Chapter 697 of the Texas Health and Safety Code applies only to the disposition of embryonic and fetal tissue remains that occurs on or after February 1, 2018. Defendant states that implementing regulations are anticipated to be adopted by February 1, 2018. Defendant denies that Plaintiffs' legal characterizations in Paragraph 22 of the First Amended Complaint are accurate.

23. Defendant admits the allegations in Paragraph 23 of the First Amended Complaint.

24. Defendant admits the allegations in Paragraph 24 of the First Amended Complaint.

25. Defendant admits the allegations in Paragraph 25 of the First Amended Complaint.

26. Defendant admits that the Texas Health and Human Services Commission first published proposed amendments to 25 Texas Administrative Code §§ 1.132-.137 in the Texas Register on July 1, 2016. Defendant denies that Plaintiffs'

legal characterizations in Paragraph 26 of the First Amended Complaint are accurate.

27. Defendant admits the allegations in Paragraph 27 of the First Amended Complaint.

28. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28 of the First Amended Complaint and therefore denies those allegations.

29. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 29 of the First Amended Complaint and therefore denies those allegations.

30. Defendant admits the allegations in Paragraph 30 of the First Amended Complaint.

31. Defendant admits the allegations in Paragraph 31 of the First Amended Complaint.

32. Defendant admits the allegations in Paragraph 32 of the First Amended Complaint.

33. Defendant admits that the Texas Department of State Health Services (DSHS) received thousands of written and oral comments on the proposed amendments to 25 Texas Administrative Code §§ 1.132-.137, and that some of those comments were received from the entities named in Paragraph 33 of the First Amended Complaint. Defendant lacks knowledge or information sufficient to form a

belief about the truth of the remaining allegations in Paragraph 33 of the First Amended Complaint and therefore denies those allegations.

34. Defendant admits the allegations in Paragraph 34 of the First Amended Complaint.

35. Defendant denies that Plaintiffs' legal characterizations in Paragraph 35 of the First Amended Complaint are accurate.

36. Defendant admits the allegations in Paragraph 36 of the First Amended Complaint.

37. Defendant admits the allegations in Paragraph 37 of the First Amended Complaint.

38. Defendant admits the allegations in Paragraph 38 of the First Amended Complaint.

39. Defendant admits the allegations in Paragraph 39 of the First Amended Complaint.

40. Defendant admits that DSHS stated in response to public comments that "regardless of where the disposition of waste occurs, the health care-related facility remains responsible for ensuring that the fetal tissue disposition is in compliance with these rules. The department does not have jurisdiction over disposition methods in other states or across state lines." Defendant denies the remaining allegations in Paragraph 40 of the First Amended Complaint.

41. Defendant admits the allegations in Paragraph 41 of the First Amended Complaint.



42. Defendant denies the allegations in Paragraph 42 of the First Amended Complaint.

43. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 43 of the First Amended Complaint because such allegations are vague. Defendant therefore denies those allegations.

44. Defendant admits the allegations in Paragraph 44 of the First Amended Complaint. Defendant denies Plaintiffs are entitled to any relief.

45. Defendant admits the allegations in Paragraph 45 of the First Amended Complaint.

46. Defendant admits the allegations in Paragraph 46 of the First Amended Complaint.

47. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 47 of the First Amended Complaint because such allegations are vague. Defendant therefore denies those allegations.

48. Defendant admits that Senate Bill 8 was amended to include the provisions now codified as Chapter 697 of the Texas Health and Safety Code, and that Senate Bill 8 was signed into law on June 6, 2017. Defendant denies that the provisions of Senate Bill 8 categorically constitute “abortion restrictions.” Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 48 of the First Amended Complaint and therefore denies those allegations.

49. Defendant denies that Plaintiffs' legal characterizations in Paragraph 49 of the First Amended Complaint are accurate.

50. Defendant admits the allegations in Paragraph 50 of the First Amended Complaint.

51. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 51 of the First Amended Complaint because such allegations are vague. Therefore, Defendant denies those allegations.

52. Defendant admits the allegations in Paragraph 52 of the First Amended Complaint.

53. Defendant denies that Plaintiffs' legal characterizations in Paragraph 53 of the First Amended Complaint are accurate. Defendant admits that Senate Bill 8 provides embryonic and fetal tissue remains are not pathological waste under state law.

54. Defendant denies that Plaintiffs' legal characterizations in Paragraph 54 of the First Amended Complaint are accurate. Defendant admits that Senate Bill 8 defines "embryonic and fetal tissue remains" to mean "an embryo, a fetus, body parts, or organs from a pregnancy that terminates in the death of the embryo or fetus and for which the issuance of a fetal death certificate is not required by state law. The term does not include the umbilical cord, placenta, gestational sac, blood, or body fluids."

55. Defendant denies that Plaintiffs' legal characterizations in Paragraph 55 of the First Amended Complaint are accurate. Defendant admits that

Senate Bill 8 generally requires a health care facility in Texas that provides health or medical care to a pregnant woman to “dispose of embryonic and fetal tissue remains that are passed or delivered at the facility by: (1) interment; (2) cremation; (3) incineration followed by interment; or (4) steam disinfection followed by interment.”

56. Defendant denies that Plaintiffs’ legal characterizations in Paragraph 56 of the First Amended Complaint are accurate. Defendant admits that Senate Bill 8 defines “interment” to mean “the disposition of remains by entombment, burial, or placement in a niche.”

57. Defendant denies that Plaintiffs’ legal characterizations in Paragraph 57 of the First Amended Complaint are accurate. Defendant admits that Senate Bill 8 provides that “the umbilical cord, placenta, gestational sac, blood, or body fluids from a pregnancy terminating in the death of the embryo or fetus for which the issuance of a fetal death certificate is not required by state law may be disposed of in the same manner as and with the embryonic and fetal tissue remains from that same pregnancy as authorized by [Chapter 697 of the Texas Health and Safety Code].”

58. Defendant denies that Plaintiffs’ legal characterizations in Paragraph 58 of the First Amended Complaint are accurate. Defendant admits that Senate Bill 8 provides that “[t]he ashes resulting from the cremation or incineration of embryonic and fetal tissue remains: (1) may be interred or scattered in any manner as authorized by law for human remains; and (2) may not be placed in a landfill.”

59. Defendant admits the allegations in Paragraph 59 of the First Amended Complaint.

60. Defendant denies that Plaintiffs' legal characterizations in Paragraph 60 of the First Amended Complaint are accurate.

61. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 61 of the First Amended Complaint and therefore denies those allegations.

62. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 62 of the First Amended Complaint and therefore denies those allegations.

63. Defendant admits that Senate Bill 8 provides 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 embryonic and fetal tissue remains.” Defendant further admits that Senate Bill 8 contains no additional specific references to Chapter 711 or Chapter 716 of the Texas Health and Safety Code or to Chapter 651 of the Texas Occupations Code.

64. Defendant admits that Senate Bill 8 provides that “[n]ot later than December 1, 2017, the executive commissioner of the Health and Human Services Commission shall adopt any rules necessary to implement [Chapter 697 of the Health and Safety Code].”

65. Defendant admits that proposed implementing regulations were published in the Texas Register on November 17, 2017, for notice and comment, and

a public hearing was held on December 11, 2017. Defendant anticipates that the implementing regulations will be adopted by February 1, 2018. Defendant denies the remaining allegations in Paragraph 65 of the First Amended Complaint.

66. Defendant admits that Senate Bill 8 provides that “[t]he department shall develop a grant program that uses private donations to provide financial assistance for the costs associated with disposing of embryonic and fetal tissue remains,” and that Senate Bill 8 requires DSHS to establish such grant program by October 1, 2017. Defendant further admits that Senate Bill 8 provides that “[t]he department shall: (1) establish and maintain a registry of: (A) participating funeral homes and cemeteries willing to provide free common burial or low-cost private burial; and (B) private nonprofit organizations that register with the department to provide financial assistance for the costs associated with burial or cremation of the embryonic and fetal tissue remains of an unborn child; and (2) make the registry information available on request to a physician, health care facility, or agent of a physician or health care facility.” Defendant denies the remaining allegations in Paragraph 66 of the First Amended Complaint.

67. Defendant denies the allegations in Paragraph 67 of the First Amended Complaint. Defendant states that information regarding the grant program and the registry is available at <https://hhs.texas.gov/doing-business-hhs/grants> and at <https://hhs.texas.gov/doing-business-hhs/provider-portals/health-care-facilities-regulation/burial-or-cremation-assistance-registry>.

68. Defendant denies the allegations in Paragraph 68 of the First Amended Complaint.

69. Defendant denies the allegations in Paragraph 69 of the First Amended Complaint.

70. Defendant denies the allegations in Paragraph 70 of the First Amended Complaint.

71. Defendant denies the allegations in Paragraph 71 of the First Amended Complaint.

72. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 72 of the First Amended Complaint and therefore denies those allegations.

73. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 73 of the First Amended Complaint and therefore denies those allegations.

74. Defendant denies the allegations in Paragraph 74 of the First Amended Complaint.

75. Defendant denies the allegations in Paragraph 75 of the First Amended Complaint.

76. Defendant admits that prior to 2017, Texas law permitted hospitals to release the remains of an unintended, intrauterine fetal death on the request of a parent of the unborn child. Defendant denies the remaining allegations in Paragraph 76 of the First Amended Complaint.

77. Defendant denies the allegations in Paragraph 77 of the First Amended Complaint.

78. Defendant denies that Plaintiffs' legal characterizations in Paragraph 78 of the First Amended Complaint are accurate.

79. Defendant denies the allegations in Paragraph 79 of the First Amended Complaint.

80. Defendant denies the allegations in Paragraph 80 of the First Amended Complaint.

81. Defendant admits that he previously argued that Plaintiffs could achieve compliance with the Amendments by accepting services offered by nonprofit organizations. Defendant denies the remaining allegations in Paragraph 81 of the First Amended Complaint.

82. Defendant admits that he previously acknowledged that Plaintiffs could achieve compliance with the Amendments by storing fetal tissue in a freezer, as Plaintiffs already did, and then disposing of the tissue through common burial or incineration followed by the scattering of ashes on private property. Defendant admits that he also based one cost estimate of compliance with the Amendments on an annual common burial or incineration. Defendant denies the remaining allegations in Paragraph 82 of the First Amended Complaint.

83. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 83 of the First Amended Complaint and therefore denies those allegations.

84. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 84 of the First Amended Complaint and therefore denies those allegations.

85. Defendant denies that Plaintiffs' legal characterizations in Paragraph 85 of the First Amended Complaint are accurate.

86. Defendant denies that Plaintiffs' legal characterizations in Paragraph 86 of the First Amended Complaint are accurate.

87. Defendant denies that Plaintiffs' legal characterizations in Paragraph 87 of the First Amended Complaint are accurate. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 87 of the First Amended Complaint and therefore denies those allegations.

88. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 88 of the First Amended Complaint and therefore denies those allegations.

89. Defendant denies the allegations in Paragraph 89 of the First Amended Complaint.

90. Defendant denies the allegations in Paragraph 90 of the First Amended Complaint.

91. Defendant denies the allegations in Paragraph 91 of the First Amended Complaint.



92. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 92 of the First Amended Complaint and therefore denies those allegations.

93. Defendant admits the allegations in Paragraph 93 of the First Amended Complaint.

94. Defendant admits that he called a licensed funeral director to testify at the first preliminary injunction hearing in this cause. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 94 of the First Amended Complaint and therefore denies those allegations.

95. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 95 of the First Amended Complaint and therefore denies those allegations.

96. Defendant denies the allegations in Paragraph 96 of the First Amended Complaint.

97. Defendant denies the allegations in Paragraph 97 of the First Amended Complaint.

98. Defendant denies the allegations in Paragraph 98 of the First Amended Complaint.

99. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 99 of the First Amended Complaint and therefore denies those allegations.

100. Defendant denies Plaintiffs' allegation that implementing regulations have not been issued. Proposed implementing regulations were published in the Texas Register for notice and comment on November 17, 2017, and Defendant anticipates that the implementing regulations will be adopted by February 1, 2018. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 100 of the First Amended Complaint and therefore denies those allegations.

101. Defendant denies the allegations in Paragraph 101 of the First Amended Complaint.

102. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 102 of the First Amended Complaint and therefore denies those allegations.

103. Defendant denies the allegations in Paragraph 103 of the First Amended Complaint.

104. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 104 of the First Amended Complaint and therefore denies those allegations.

**ANSWER TO CLAIMS FOR RELIEF**

**COUNT I**

**(Liberty)**

105. Defendant incorporates by reference his responses to Paragraphs 1-104 of the First Amended Complaint, as set forth above.

106. Defendant denies the allegations in Paragraph 106 of the First Amended Complaint.

**COUNT II**

**(Vagueness)**

107. Defendant incorporates by reference his responses to Paragraphs 1-106 of the First Amended Complaint, as set forth above.

108. Defendant denies the allegations in Paragraph 108 of the First Amended Complaint.

**COUNT III**

**(Equal Protection)**

109. Defendant incorporates by reference his responses to Paragraphs 1-108 of the First Amended Complaint, as set forth above.

110. Defendant denies the allegations in Paragraph 110 of the First Amended Complaint.

**COUNT IV**

**(Commerce Clause)**

111. Defendant incorporates by reference his responses to Paragraphs 1-110 of the First Amended Complaint, as set forth above.

112. Defendant denies the allegations in Paragraph 112 of the First Amended Complaint.

### **ANSWER TO REQUEST FOR RELIEF**

113. Defendant denies the allegations in Plaintiffs' Request for Relief and denies that Plaintiffs are entitled to any relief.

### **DEFENSES**

114. Plaintiffs' claims are barred, in whole or in part, to the extent each Plaintiff lacks standing.

115. Plaintiffs' claims are barred, in whole or in part, to the extent they are not ripe.

116. Plaintiffs' claims are barred, in whole or in part, to the extent they are moot.

117. Plaintiffs' claims, in whole or in part, fail because Plaintiffs have failed to state a claim upon which relief may be granted.

118. All allegations in the First Amended Complaint that have not been specifically admitted are hereby denied.

### **CONCLUSION & PRAYER**

Defendant requests this Court to enter judgment for Defendant and against Plaintiffs, to dismiss Plaintiffs' claims with prejudice, to award Defendant his costs, and to grant Defendant such other relief to which he may be entitled.

Respectfully submitted,

KEN PAXTON  
Attorney General of Texas

JEFFREY C. MATEER  
First Assistant Attorney General

BRANTLEY STARR  
Deputy First Assistant Attorney General

JAMES E. DAVIS  
Deputy Attorney General for Civil Litigation

/s/ Darren McCarty

DARREN MCCARTY  
Special Counsel for Civil Litigation  
Texas Bar No. 24007631

AUSTIN R. NIMOCKS  
Special Counsel for Civil Litigation  
Texas Bar No. 24002695

BETH KLUSMANN  
Assistant Solicitor General  
Texas Bar No. 24036918

KARA HOLSINGER  
Assistant Attorney General  
Texas Bar No. 24065444

BENJAMIN S. WALTON  
Assistant Attorney General  
Texas Bar No. 24075241

OFFICE OF THE ATTORNEY GENERAL  
Administrative Law Division  
P.O. Box 12548, Capitol Station  
Austin, Texas 78711-2548  
Telephone: (512) 475-4300  
Facsimile: (512) 320-0167  
Darren.McCarty@oag.texas.gov  
Austin.Nimocks@oag.texas.gov  
Beth.Klusmann@oag.texas.gov  
Kara.Holsinger@oag.texas.gov  
Benjamin.Walton@oag.texas.gov

***Counsel for Defendant***

**CERTIFICATE OF SERVICE**

I hereby certify that on January 5, 2018, a true and correct copy of this document was electronically filed using the Court's CM/ECF system, which will send notification of such filing to the following counsel of record:

David Brown  
Dipti Singh  
Stephani Toti  
THE LAWYERING PROJECT  
25 Broadway, 9th Fl.  
New York, NY 10004  
dbrown@lawyeringproject.org  
dsingh@lawyeringproject.org  
stoti@lawyeringproject.org

J. Alexander Lawrence  
MORRISON & FOERSTER LLP  
250 W. 55th Street  
New York, NY 10019  
alawrence@mofoc.com

Molly Duane  
CENTER FOR REPRODUCTIVE RIGHTS  
199 Water St. 22nd Floor  
New York, NY 10038  
mduane@reprorights.org

Patrick J. O'Connell  
LAW OFFICES OF PATRICK J. O'CONNELL  
PLLC  
2525 Wallingwood, Bldg. 14  
Austin, Texas 78746  
pat@pjofca.com

/s/ Darren McCarty  
DARREN MCCARTY  
Special Counsel for Civil Litigation