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

WHOLE WOMAN'S HEALTH, ET AL.,	§	
Plaintiffs,	§	
v.	§	CIVIL ACTION No. 1:16-cv-01300-SS
	§	
	§	
JOHN HELLERSTEDT, M.D.,	§	
Defendant.	§	

#### DEFENDANT'S ORIGINAL ANSWER TO PLAINTIFFS' ORIGINAL COMPLAINT

Defendant, John Hellerstedt, M.D., in his official capacity as Commissioner of the Texas Department of State Health Services, files this Original Answer to Plaintiffs' Original Complaint.

Pursuant to Federal Rule of Civil Procedure 8(b), Defendant denies each and every allegation contained in Plaintiffs' Original Complaint except for those expressly admitted herein. In several instances, Defendant has identified statements in the Original Complaint that are legal conclusions or non-factual statements rather than factual assertions. No response to such legal conclusions or non-factual statements is required. However, if such response is required, Defendant denies such legal conclusions and non-factual statements. The headings and numbered paragraphs below directly correlate to the sections and numbered paragraphs of Plaintiffs' Original Complaint. Those titles and headings are reproduced in this Original Answer for organizational purposes only, and Defendant does not admit any matter contained in them.

Defendant states that the first sentence of Plaintiffs' unnumbered introductory paragraph is a directive that requires no response.

Defendants respond to the specifically numbered allegations of the Complaint as follows:

#### I. PRELIMINARY STATEMENT

- 1. Paragraph 1 is a summary of the nature of the lawsuit and requires no response. To the extent a response is required, deny.
- 2. Admit to the extent that the amendments to Title 25, §§ 1.132-.137, of the Texas Administrative Code (rule amendments) relate to the proper disposal of special waste from health-care facilities. Defendant also admits that the rule amendments require the interment of fetal tissue. To the extent a further response is required, deny.
- 3. Admit to the extent that the rule amendments were first published in the Texas Register on July 1, 2016. Defendant denies the inference of the rule amendments as "antiabortion." Defendant denies that the rule amendments "employ[] . . . the same tactics as did the admitting-privileges requirement struck down in [Whole Woman's Health v. Hellerstedt, 136 S. Ct. 2292 (2016)]." And, Defendant denies that the rule amendments function as a "replacement for HB 2, and its response to Plaintiffs' Supreme Court victory." To the extent a further response is required, deny.
- 4. Defendant denies that the rule amendments place a burden on "women seeking pregnancy-related medical care"; "impose a funeral ritual on women who have a miscarriage management procedure, ectopic pregnancy surgery, or an abortion"; or "threaten[] women's health and safety." Defendant denies that there is "an extremely limited number" of third-party vendors for proper disposal of fetal tissue and denies that the rule amendments "threaten[] abortion clinics' provision of care and their long-term ability to remain open." To the extent a further response is required, deny.
- 5. Defendants deny that the rule amendments have no public health benefits; the rule amendments maintain existing health benefits and provide for additional societal benefits focusing

on a respect for unborn life. Defendant denies that the rule amendments are "a pretext for restricting abortion access." To the extent a further response is required, deny.

- 6. Defendant denies that the rule amendments have any effect on Title 25, § 181.7, Texas Administrative Code. Defendant denies that § 181.7 applies to induced abortions. To the extent a further response is required, deny.
- 7. Defendant denies that the rule amendments threaten irreparable injury to Plaintiffs and their patients. Defendant denies that the rule amendments infringe on "patients' rights to seek pregnancy-related medical care" in any way. Defendant denies that the rule amendments threaten the privacy of patients' confidential information. To the extent a further response is required, deny.
- 8. Paragraph 8 is a conclusory statement and summary of what Plaintiffs are seeking and requires no response.

#### II. JURISDICTION AND VENUE

- 9. Admit.
- 10. Admit.
- 11. Admit.

#### III. PLAINTIFFS

- 12. Admit to the extent that Whole Woman's Health is one of the Plaintiffs. Defendant can neither admit nor deny the quality of services provided, the scope of its services, or other details about its operations.
- 13. Admit to the extent that Brookside Women's Medical Center PA is one of the Plaintiffs. Defendant can neither admit nor deny the number of patients that are seen annually or

other details about its operations. Admit that Dr. Lendol L. Davis is one of the Plaintiffs. Defendant can neither admit nor deny the specifics about Dr. Davis's medical practice.

- 14. Admit to the extent that Alamo City Surgery Center PLLC d/b/a Alamo Women's Reproductive Services is one of the Plaintiffs. Defendant can neither admit nor deny that all of the women this Plaintiff provides services to are Texans, the scope of its services, or other details about its operations.
- 15. Admit to the extent that Nova Health Systems, Inc. d/b/a Reproductive Services is one of the Plaintiffs. Defendant can neither admit nor deny that all of the women this Plaintiff provides services to are Texans. Defendant can neither admit nor deny the quality of services provided or the scope of it services. Defendant can neither admit nor deny how long this Plaintiff has been operating in Texas.
- 16. Defendant can neither admit nor deny. Defendant has no knowledge of Plaintiffs' memberships. Defendant can neither admit nor deny the criteria used to publish "Clinical Policy Guidelines" or the quality of the literature.

#### IV. DEFENDANT

17. Admit.

# V. FACTUAL ALLEGATIONS

# The Regulation

- 18. Admit.
- 19. Admit.
- 20. Admit as to the rules prior to amendment.
- 21. Admit to the extent that "may" means "are authorized."

- 22. Admit that the rule amendments reduced the methods of disposition of fetal tissue.

  To the extent a further response is required, deny.
  - 23. Admit.
- 24. Admit that the rule amendments limit options for healthcare providers and facilities to dispose of "fetal tissue" to interment, incineration followed by interment, or steam disinfection followed by interment. Defendant denies that the rule amendments have any effect on Title 25, § 181.7, Texas Administrative Code.
  - 25. Admit.
- 26. Deny. Plaintiffs do not include the entire rule amendment in their analysis in this paragraph. The rule amendment includes "followed by placement of the ashes in a niche, grave, or scattering of ashes as authorized by law, unless prohibited by this subchapter." Cremation and incineration alone do not satisfy the rule amendments.
  - 27. Admit.
- 28. Deny. The rule amendments specifically deleted "sanitary landfill" as an option for deposition of fetal tissue and expressly allow other types of medical waste to be disposed of in a sanitary landfill.
- 29. Admit to the extent that there is currently no law (other than the challenged rules) that "specifically" authorizes the scattering of "ashes of fetal tissue." Defendant denies that an act is prohibited unless it is specifically authorized by a law.
  - 30. Admit.
- 31. Admit to the extent that Chapter 716 pertains to human remains. Defendant denies that ashes from fetal tissue cannot be scattered in accordance with Chapter 716 so long as the ashes are not disposed of in a landfill.

- 32. Admit to the extent the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. Deny to the extent that the Texas Department of State Health Services has jurisdiction over disposition methods in other states or across state lines.
- 33. Admit to the extent the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. Deny to the extent that the Texas Department of State Health Services has jurisdiction over disposition methods in other states or across state lines.
- 34. Admit to the extent the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. Deny to the extent that the Texas Department of State Health Services has jurisdiction over disposition methods in other states or across state lines.
  - 35. Deny.
  - 36. Admit.
- 37. Defendant can neither admit nor deny the generalization regarding the abilities of commercial incinerators and steam disinfection facilities. In addition, Defendant can neither admit nor deny the safety protocols of each facility and their abilities to manage and handle processed waste.
  - 38. Deny.
- 39. Admit to the extent that fetal tissue before six weeks lmp is small and segregating the tissue may be difficult. To the extent that a further response is required, deny.
- 40. Deny. There is no prohibition on including the "placenta, umbilical cord and gestational sac" with the deposition of fetal tissue.

#### The Regulation's Legislative History

- 41. Upon information and belief, Admit.
- 42. Admit to the extent that the Supreme Court case referred to is *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292 (2016), that the proposed regulation was published in the Texas Register on July 1, 2016, following its filing with the Texas Register on June 20, 2016.
  - 43. Admit.
- 44. Defendant can neither admit nor deny nor confirm the authenticity of the referenced letter and its contents as alleged.
- 45. Defendant can neither admit nor deny nor confirm the authenticity of the referenced letter and its contents as alleged.
- 46. Deny in part and admit in part. Public comments were accepted through August 1, 2016.
- 47. Deny that the text of the newly-proposed rule was identical to the prior version. Otherwise, admit.
  - 48. Admit.
  - 49. Admit.
  - 50. Deny.
  - 51. Admit.
  - 52. Admit.

#### The Regulation's Burdens on Texas Women and Their Families

- 53. Deny.
- 54. Admit in part and deny in part. Defendant cannot admit or deny the second sentence regarding how the views of women and their families are formed.

- 55. Admit.
- 56. Deny.
- 57. Deny.
- 58. Plaintiffs' statement is vague and requires more information for Defendant to give an answer, but to the extent an answer is required deny.
  - 59. Deny.
  - 60. Deny.
  - 61. Deny.
  - 62. Deny.
- 63. Defendant can neither admit nor deny this overly broad statement in total. Defendant admits that pathological testing can be important, but the value of any testing varies depending on individual circumstances.
- 64. Defendant can neither admit nor deny. Defendant has no knowledge of Plaintiffs routine business practices or the purpose of any such practices.
- 65. Defendant can neither admit nor deny this overly broad statement in total. Defendant admits that forensic examination can be important, but the value of any such examination depending on individual circumstances.
- 66. Admit to the extent that the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. Deny that the rule amendments changed the ability of health-care facilities to work with pathology or crime labs. To the extent a further response is required, deny.

- 67. Admit to the extent that the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. To the extent a further response is required, deny.
- 68. Admit to the extent that the rule amendments did nothing to change the responsibility of health-care facilities to ensure compliance with the disposition rules. Deny that the rule amendments changed the ability of health-care facilities to work with pathology or crime labs. To the extent a further response is required, deny.
  - 69. Deny.
- 70. Defendant can neither admit nor deny. Defendant cannot know what Plaintiffs are aware of.
- 71. Defendant can neither admit nor deny. Defendant cannot know what Plaintiffs are aware of.
  - 72. Deny.
  - 73. Deny.
  - 74. Deny.
  - 75. Deny.
  - 76. Deny.

# DSHS' New Interpretation of the Law Governing Certificates of Fetal Death (Stillbirth) Threatens Women's Privacy

- 77. Admit to the extent that 25 TAC § 181.7 applies to miscarriages.
- 78. Deny.
- 79. Deny. DSHS has never required, nor do the rule amendments require that a "certificate of fetal death (stillbirth)" be issued for any induced abortion.

- 80. Admit that "DSHS's received comments from . . . the Texas Medical Association, the Texas Hospital Association, and the American Congress of Obstetricians and Gynecologists" but deny that the quote in the sentence is from these commenters.
- 81. Deny to the extent that Title 25, § 181.7, Texas Administrative Code applies to induced abortions.
  - 82. Admit.
- 83. Admit in part and deny in part. Defendant admits that the rule amendments cover an abortion under 350 grams and before twenty weeks lmp. Defendant denies that any induced abortion is exempt from the rule amendments; therefore, "transfer to a licensed funeral director and issuance of a 'certificate of fetal death (stillbirth)'" is not required in the case of an induced abortion.
  - 84. Admit.
- 85. Admit in part and deny in part. A certificate of fetal death (stillbirth) does contain personally-identifying information, but the rule amendments do not require a certificate of fetal death in the case of any induced abortion, regardless of at what age it occurs.
  - 86. Deny.
- 87. Deny generally, and deny the allegation that Defendant has a "new interpretation of 25 Tex. Admin. Code § 181.7."
  - 88. Deny.
  - 89. Deny.
- 90. Defendant can neither admit nor deny. Plaintiffs' statement is predicated on a non-fact. To the extent an answer is required, deny.

## **CLAIMS FOR RELIEF**

## **COUNT I**

## (Liberty)

- 91. This sentence is a directive and requires no answer.
- 92. Deny.

## **COUNT II**

# (Vagueness)

- 93. This sentence is a directive and requires no answer.
- 94. Deny.

# **COUNT III**

# (Privacy)

- 95. This sentence is a directive and requires no answer.
- 96. Deny.

# **COUNT IV**

# (Equal Protection)

- 97. This sentence is a directive and requires no answer.
- 98. Deny.

# **COUNT V**

# (Commerce Clause)

- 99. This sentence is a directive and requires no answer.
- 100. Deny.

## **REQUEST FOR RELIEF**

Defendant admits that Plaintiffs seek the relief stated in Paragraphs A through F of the section entitled "Request for Relief," but Defendant denies that Plaintiffs are entitled to any relief from this Court.

## **DEFENSES TO PLAINTIFFS' ORIGINAL COMPLAINT**

- 1. Defendant asserts the defense of Eleventh Amendment immunity to all claims to which that defense applies.
- 2. Defendant asserts the right to amend these affirmative defenses to assert additional affirmative defenses as they may become known to Defendant.

#### **PRAYER**

For the foregoing reasons, Defendant asks the Court to enter judgment that Plaintiffs take nothing, dismiss Plaintiffs' suit with prejudice, assess costs against Plaintiffs, and award Defendant all other relief that the Court deems appropriate.

Respectfully submitted,

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#### CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 13<sup>th</sup> day of March 2017, a true and complete copy of the above and foregoing document was served on the following via the Court's CM/ECF system and/or by electronic mail:

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