

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
WESTERN DIVISION**

AMERICAN MEDICAL ASSOCIATION,)
on behalf of itself and its members; ACCESS)
INDEPENDENT HEALTH SERVICES, INC.,)
d/b/a RED RIVER WOMEN’S CLINIC, on)
behalf of itself, its physicians, and its staff;)
and KATHRYN L. EGGLESTON, M.D.,)

Plaintiffs,)

v.)

Case No. 1:19-cv-125-DLH-CRH

WAYNE STENEHJEM, in his official capacity)
as Attorney General for the State of North)
Dakota; and BIRCH BURDICK, in his official)
capacity as State Attorney for Cass County, as)
well as their employees, agents, and successors,)
and HEARTBEAT INTERNATIONAL, INC., et al)

Defendants.)

_____)

**ANSWER OF DEFENDANT-INTERVENOR
HEARTBEAT INTERNATIONAL, INC.**

1. Heartbeat admits that Plaintiffs are bringing an action under the First and Fourteenth Amendments to the United States Constitution and 42 U.S.C § 1983 to challenge North Dakota House Bill 1336 of the 2019 Legislative Session and N.D. Cent. Code § 14-02.1-02(11)(a)(2). H.B. 1336 and N.D. Cent. Code § 14-02.1-02(11)(a)(2) speak for themselves. Otherwise, denied.

2. H.B. 1336 speaks for itself. Otherwise, denied.

3. Denied.

4. Heartbeat admits that Plaintiffs seek declaratory and injunctive relief. Otherwise, denied.

5. Admitted.

6. Heartbeat admits that 28 U.S.C. §§ 2201 and 2202, and Federal Rules of Civil Procedure 57 and 65, as well as this Court's powers, generally provide for declaratory and injunctive relief. Heartbeat denies that Plaintiffs are entitled to such relief in this action.

7. Admitted.

8. Heartbeat denies that the American Medical Association is the "voice of organized medicine in the United States." Otherwise, Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

9. Heartbeat denies that "AMA represents virtually all United States physicians, residents, and medical students." Otherwise, Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

10. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

11. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

12. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

13. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

14. Heartbeat admits that Wayne Stenehjem is the Attorney General of the State of North Dakota and is sued in his official capacity. N.D. Cent. Code §§ 54-12-01.3 and 54-12-01.4 speak for themselves. Otherwise, denied.

15. Heartbeat admits that Birch Burdick is the State's Attorney for Cass County and is sued in his official capacity. N.D. Cent. Code §§ 11-16-01(1) and 14-02.1-11 speak for themselves. Otherwise, denied.

16. Denied.

17. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

18. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

19. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

20. Heartbeat admits that chemical abortions are performed through administration of mifepristone and misoprostol, and that mifepristone is also known as RU-486 or by its commercial name, Mifeprex. Heartbeat admits that the FDA first approved Mifeprex in 2000.

Heartbeat further admits that the Food and Drug Administration regulates prescription drugs, including mifepristone and misoprostol. Otherwise, denied.

21. Heartbeat admits that progesterone is necessary to sustain a pregnancy and that mifepristone is a progesterone antagonist.¹ Heartbeat further admits that, according to the 2016 FDA protocol, misoprostol is taken 24 to 48 hours after mifepristone and causes the uterus to contract and expel its contents. Otherwise, denied.

22. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

23. Heartbeat denies that the described regimen is an “evidence-based protocol.” Otherwise, admitted.

24. Heartbeat denies that chemical abortion is “extremely safe.” Otherwise, Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

25. Heartbeat admits that some legitimate uses of an FDA-approved drug may be referred to as “off-label” use. Otherwise, denied.

26. Heartbeat admits that both chemical and surgical abortions may fail to terminate pregnancy, leaving the child alive in its mother’s womb. Heartbeat lacks information sufficient to admit or deny the accuracy of the alleged success rate of chemical abortion, and therefore denies the allegations.

27. Heartbeat admits that physicians are required to obtain informed consent from a woman, in accordance with the state’s informed-consent laws, before performing an abortion on that woman.

¹ Danco Laboratories, LLC (2016), MIFEPREX [package insert] at 10–11, New York, NY, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf.

28. Denied.

29. Heartbeat admits that North Dakota laws provide for informed consent to abortion, to inform women of the nature, risks, consequences, and alternatives of the abortion procedure, as provided in N.D. Cent. Code § 14-02.1 et seq. Otherwise, denied.

30. N.D. Cent. Code § 14-02.1 et seq. speaks for itself.

31. Heartbeat denies that the alleged information is “the information necessary to obtain the patient’s voluntary and informed consent,” to the extent that the allegations exclude the remaining provisions of N.D. Cent. Code § 14-02.1 et seq. Separately, N.D. Cent. Code § 14-02.1-02(11)(a)(3)–(5) speak for themselves.

32. Heartbeat denies that the scientifically and medically accurate fact that “abortion will terminate the life of a whole, separate, unique, living human being” is unrelated to the medical consequences of the abortion procedure to which a woman is consenting. N.D. Cent. Code § 14-02.1-02(11)(a)(2) speaks for itself. Otherwise, denied.

33. N.D. Cent. Code § 14-02.1-02(9) speaks for itself. Heartbeat denies the scientifically incorrect allegation that an unborn human being at all stages of development is not a living human being. Otherwise, denied.

34. N.D. Cent. Code § 14-02.1-02.1(1) speaks for itself. Otherwise, Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

35. N.D. Cent. Code § 14-02.1-03(1) speaks for itself.

36. Heartbeat admits that physicians are subject to professional and ethical obligations, as well as all relevant laws governing their conduct. N.D. Cent. Code § 14-02.1 et seq. speaks for itself. Otherwise, denied.

37. Heartbeat admits that physicians are required to obtain informed consent from a woman before performing an abortion, which includes describing the nature, details, risks, consequences, and alternatives of abortion. N.D. Cent. Code § 14-02.1 et seq. speaks for itself.

38. Heartbeat admits that informed consent occurs in the context of a particular patient and that patient's physician for the particular procedure or treatment at issue. Heartbeat further admits that informed consent is governed by professional and ethical canons, as well as by law, including, in North Dakota as to abortion, by N.D. Cent. Code § 14-02.1 et seq.

Heartbeat admits that the purpose of informed consent is to protect a patient from undergoing a medical procedure or treatment without having a full understanding of the procedure, and thus without voluntarily consenting to it based on full information. Otherwise, denied.

39. Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. N.D. Cent. Code § 14-02.1-03.5(2) and H.B. 1336 speak for themselves.

Otherwise, denied.

45. H.B. 1336 speaks for itself. Otherwise, denied.

46. H.B. 1336 speaks for itself. Otherwise, denied.

47. H.B. 1336 speaks for itself. The North Dakota Supreme Court's decision in *MKB Management Corp. v. Burdick*, 855 N.W. 2d 31, 49 (2014), speaks for itself. Otherwise, denied.

48. H.B. 1336 speaks for itself. Otherwise, Heartbeat lacks information sufficient to admit or deny these allegations, and therefore denies them.

49. N.D. Cent. Code §§ 14-02.1-03.2 and 14-02.1-11 speak for themselves.

50. N.D. Cent. Code §§ 14-02.1-03.2 and 14-02.1-11 speak for themselves.

51. Denied.

52. Denied.

53. Heartbeat admits that after a child's life has been ended in the womb through a complete abortion, the child's mother is no longer pregnant. Otherwise, denied.

54. Heartbeat admits that the legislative history of H.B. 1336 reflects evidence that some women who begin the chemical abortion process by taking mifepristone may, through proper administration of progesterone using the abortion-pill-reversal protocol, successfully reverse the effects of mifepristone and thus halt the abortion and continue their pregnancies. The legislative testimony speaks for itself. Otherwise, denied.

55. Heartbeat admits that the abortion-pill-reversal protocol involves the administration of progesterone orally, vaginally, or through intramuscular injections. Otherwise, denied.

56. Heartbeat admits that oral and vaginal progesterone can be administered by the patient, and that progesterone is widely considered a low-risk medication. Otherwise, denied.

57. Heartbeat admits that progesterone is an FDA-approved drug that has been specifically FDA-approved for use in preventing miscarriages and preterm births.² Heartbeat further admits that “[f]rom the FDA perspective, once the FDA approves a drug, healthcare

² U.S. DEP'T OF HEALTH & HUMAN SERVS., NAT'L INSTS. OF HEALTH, *FDA Approves Drug to Reduce Preterm Birth Risk* (Feb. 16, 2011), <https://www.nichd.nih.gov/newsroom/releases/021611-FDA-approves-drug>.

providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient,”³ and that the abortion-pill-reversal protocol using progesterone is such a use.

58. Denied.

59. Heartbeat admits that, in 2003, the American College of Obstetricians and Gynecologists published an official opinion noting that “studies support the hypothesis that progesterone supplementation reduces preterm birth in a select group of women” by helping to preserve pregnancy, and recommending “further studies . . . to evaluate the use of progesterone in patients with other high-risk obstetrics factors.”⁴ Heartbeat lacks information sufficient to admit or deny the allegations regarding ACOG’s current position on administering progesterone to therapeutically preserve pregnancies after administration of mifepristone, and therefore denies them. Otherwise, denied.

60. The legislative testimony on H.B. 1336 speaks for itself.

61. Heartbeat admits that the administration of mifepristone with misoprostol is more likely to result in a baby being killed and expelled from its mother’s womb than administration of mifepristone alone. Otherwise, denied.

62. Heartbeat admits that progesterone is an FDA-approved drug that has been specifically approved for use in preventing miscarriages and preterm births. Heartbeat further admits that “[f]rom the FDA perspective, once the FDA approves a drug, healthcare providers

³ U.S. FOOD & DRUG ADMIN., *Understanding Unapproved Use of Approved Drugs “Off Label,”* <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last visited Aug. 28, 2019).

⁴ AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *ACOG Committee Opinion on Obstetric Practice No. 291, Use of Progesterone to Reduce Preterm Birth* (Nov. 2003), <https://www.ncbi.nlm.nih.gov/pubmed/14672496>.

generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient,”⁵ and that the abortion-pill-reversal protocol using progesterone is such a use.

63. The legislative record speaks for itself. Otherwise, denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Heartbeat admits that progesterone is an FDA-approved drug that has been specifically FDA-approved for use in preventing miscarriages and preterm births. Heartbeat further admits that “[f]rom the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient,”⁶ and that the abortion-pill-reversal protocol using

⁵ U.S. FOOD & DRUG ADMIN., *Understanding Unapproved Use of Approved Drugs “Off Label,”* *supra* note 3.

⁶ *Id.*

progesterone is such a use. The legislative testimony on H.B. 1336 speaks for itself. Otherwise, denied.

- 76. Denied.
- 77. Denied.
- 78. Denied.
- 79. Denied.
- 80. Denied.
- 81. Denied.
- 82. Denied.
- 83. Heartbeat admits that Plaintiffs reallege these allegations.
- 84. Denied.
- 85. Heartbeat admits that Plaintiffs reallege these allegations.
- 86. Denied.
- 87. Heartbeat admits that Plaintiffs reallege these allegations.
- 88. Denied.

s/ Denise M. Harle

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**Admitted pro hac vice admission*

CERTIFICATE OF SERVICE

I hereby certify that on December 10, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send notification of such filing to counsel for the parties.

s/ Denise M. Harle

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