

2013 SENATE JUDICIARY

SB 2302

2013 SENATE STANDING COMMITTEE MINUTES

Senate Judiciary Committee
Fort Lincoln Room, State Capitol

SB 2302
1/29/2013
Job #17894

Conference Committee

Committee Clerk Signature	
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Minutes:

<i>Attached testimony</i>

Provide for the right to life act

Senator David Hogue - Chairman

Senator Sitte - Introduces the bill - See written testimony. (1)

Senator Armstrong - Asks if this would be in the criminal code.

Senator Sitte - Replies it would probably go into the miscellaneous.

Senator Nelson - Questions the definition of abortions being a crime and said to her it is a medical procedure and has not been declared a crime.

Senator Sitte - Replies that will be struck in an amendment.

David A. Prentice - Senior Fellow for Life Sciences, Family Research Council - See written testimony (2)

Anna Higgins - Director of the Center for Human Dignity, Family Research Council - See written testimony (3)

Gualberto Garcia Jones - Legal Counsel for Personhood USA - See written testimony (4)

Dan Becker - Director of National Right to Life - Field Director of Personhood USA - He asks why we are discussing a bill of this nature.

Senator Sitte - Asks if the board of Right to Life has taken a position as a challenge to Roe at this time.

Becker - He explains there position has changed in the last 3 years.

Dionne Bohl - Ultra sound tech for Trinity Hospital - She gives her opinion on abortion. Proof of life is evident in the ultra sound image.

Maria Wanchek - See written testimony (5)

Opposition

Dr. Kristen Cain - See written testimony (6)

Senator Hogue - Asks her to speak to the costs of IVF in ND.

Dr. Cain - Replies that in ND it is between \$10,000 and \$15,000 per cycle, most of that cost is monitoring of the development of the egg and the retrieval and embryo transfer.

Rebecca Matthews - Bismarck resident - See written testimony (7)

Janet Daley Jury - Hands in written testimony for Linda Linz. (8)

Karla Rose Hanson - Fargo, ND - See written testimony. Hands in testimony for Jennifer Cossette, and Stephanie Dahl. (9)

Janelle Moos - Executive Director of ND Council on Abused Women's Services - See written testimony (10)

Neutral - none

Closed the hearing on 2302

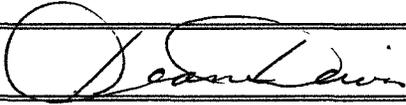
Additional testimony handed in (11)

2013 SENATE STANDING COMMITTEE MINUTES

Senate Judiciary Committee
Fort Lincoln Room, State Capitol

SB2302
2/5/2013
Job #18242

Conference Committee

Committee Clerk Signature 

Minutes:

Senator David Hogue - Chairman

Committee Work

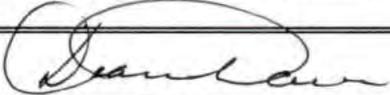
Senator Sitte proposes a hog house amendment. She explains the amendment to the committee. (1) and (2)

2013 SENATE STANDING COMMITTEE MINUTES

Senate Judiciary Committee
Fort Lincoln Room, State Capitol

SB2302
2/5/2013
Job #18328

Conference Committee

Committee Clerk Signature 

Minutes:

Vote

Senator David Hogue - Chairman

Committee work

Senator Sitte moves to adopt amendment 13.8231.02003 (1)
Senator Berry seconded

Discussion

Senator Sitte explains the new amendment and what it does. Senator Nelson said she has a problem with Section 5 and the committee discusses Section 5. Senator Grabinger relates his experience with IVF procedure. Committee continues on discussion on where to put the new changes in the amendment.

Vote 5 yes, 2 no
Motion passes

Senator Sitte moves a do pass as amended
Senator Berry seconded

Discussion

Senator Grabinger expresses that nothing has changed for him with the amendment. Senator Berry asks him why he thinks this won't allow for further IVF treatment. He doesn't see this as the intent of the bill. Senator Grabinger says he has elaborated on that. He points out different sections that he has a problem with.

Vote - 3 yes, 4 no
Fail

Senator Grabinger motions for a do not pass
Senator Nelson seconded

Vote - 4 yes, 3 no
Motion passes
Senator Grabinger will carry

FISCAL NOTE
Requested by Legislative Council
02/06/2013

Amendment to: SB 2302

- 1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	\$0	\$0	\$0	\$0	\$0	\$0
Expenditures	\$0	\$0	\$0	\$0	\$0	\$0
Appropriations	\$0	\$0	\$0	\$0	\$0	\$0

- 1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	\$0	\$0	\$0
Cities	\$0	\$0	\$0
School Districts	\$0	\$0	\$0
Townships	\$0	\$0	\$0

- 2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This bill makes causing an abortion by a physician a class B misdemeanor except in medical emergencies and prohibits human cloning and human research on gametes, embryos, and somatic cells.

- B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

Sections 2 and 3 of the bill could have a fiscal impact on the state and the Office of Attorney General. In the event this bill, if it becomes law, is challenged, the State of North Dakota would likely be ordered to reimburse the challenging party for attorney's fees and costs if they prevail in the lawsuit. At this time, the Office of Attorney General estimates the general fund cost for this purpose could be approximately \$60,000.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

- A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

Not applicable

- B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

Not applicable

- C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

Not applicable

Name: Kathy Roll

Agency: Office of Attorney General

Telephone: 701-328-3622

Date Prepared: 02/07/2013

FISCAL NOTE
Requested by Legislative Council
02/04/2013

Bill/Resolution No.: SB 2302

- 1 A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2011-2013 Biennium		2013-2015 Biennium		2015-2017 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	\$0	\$0	\$0	\$0	\$0	\$0
Expenditures	\$0	\$0	\$60,000	\$0	\$0	\$0
Appropriations	\$0	\$0	\$60,000	\$0	\$0	\$0

- 1 B. **County, city, school district and township fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

	2011-2013 Biennium	2013-2015 Biennium	2015-2017 Biennium
Counties	\$0	\$0	\$0
Cities	\$0	\$0	\$0
School Districts	\$0	\$0	\$0
Townships	\$0	\$0	\$0

- 2 A. **Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

This bill makes causing an abortion by a physician a class B misdemeanor except in medical emergencies and prohibits human cloning and human research on gametes, embryos, and somatic cells.

- B. **Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

Sections 2 and 3 of the bill could have a fiscal impact on the state and the Office of Attorney General. In the event this bill, if it becomes law, is challenged, the state may need to reimburse the challenging party if they prevail in the lawsuit.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

- A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

Not applicable

- B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

If this bill is passed and legally challenged and the challenging party prevails in a lawsuit, the Office of Attorney General would need to reimburse the party for attorney's fees and costs. At this time, the Office of Attorney General estimates the general fund cost for this purpose will be \$60,000.

- C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

If this bill is passed and legally challenged and the challenging party prevails in a lawsuit, the Office of Attorney General would need to reimburse the party for attorney's fees and costs. At this time, the Office of Attorney General estimates the general fund cost for this purpose will be \$60,000.

Name: Kathy Roll

Agency: Office of Attorney General

Telephone: 701-328-3622

Date Prepared: 02/05/2013

February 5, 2013

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2/5/13
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PROPOSED AMENDMENTS TO SENATE BILL NO. 2302

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for the ethical treatment of human embryos; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1.

Definitions.

As used in this Act only:

1. "Donor" means an individual from whose body gametes were obtained, or an individual from whose body cells or tissues were obtained for the purpose of creating gametes or human embryos, whether for valuable consideration or not.
2. "Embryo" means an organism in its earliest stages of development, including the single-cell stage.
3. "Facility" or "medical facility" means any public or private hospital, clinic, center, medical school, medical training institution, health care facility, physician's office, infirmary, dispensary, ambulatory surgical treatment center, or other institution or location wherein medical care is provided to any person.
4. "Gamete" means an egg (oocyte) or sperm.
5. "Human-animal hybrid" means any of the following:
 - a. A human embryo into which a nonhuman cell or a component of a nonhuman cell is introduced so that it is uncertain whether the human embryo is a member of the species homo sapiens;
 - b. An embryo produced by fertilizing a human egg with a nonhuman sperm;
 - c. An embryo produced by fertilizing a nonhuman egg with a human sperm;
 - d. An embryo produced by introducing a nonhuman nucleus into a human egg;
 - e. An embryo produced by introducing a human nucleus into a nonhuman egg;
 - f. An embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form;

- g. A nonhuman life form engineered with the intention of generating functional human gametes within the body of a nonhuman life form; or
- h. A nonhuman life form engineered such that it contains a human brain or a brain derived wholly from human neural tissues.
- 6. "Human embryo" means an organism with a human or predominantly human genetic constitution from the single-cell stage to eight weeks development that is derived by fertilization (in vitro or in utero), parthenogenesis, cloning (somatic cell nuclear transfer), or any other means from one or more human gametes or human diploid cells.
- 7. "In vitro" means outside the human body.
- 8. "In vitro human embryo" means a human embryo created outside the human body.
- 9. "Pay" or "payment" means pay, contract for, or otherwise arrange for the payment of in whole or in part.
- 10. "Valuable consideration" means financial gain or advantage, including cash, in-kind payments, reimbursement for any costs incurred in connection with the removal, processing, disposal, preservation, quality control, storage, transfer, or donation of human gametes, including lost wages of the donor, as well as any other consideration.

SECTION 2.

Ethical treatment of human embryos.

- 1. A person may not intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization of a human egg by a human sperm.
- 2. The creation of an in vitro human embryo may be solely for the purpose of initiating a human pregnancy by means of transfer to the body of a human female for the treatment of human infertility. A pregnancy may not be initiated with the intention of deliberately destroying the embryo for scientific research. A human embryo may not be gestated to the fetal stage for purposes of destroying the fetus in order to harvest tissue, organs, or stem cells. A person may not intentionally or knowingly transfer or attempt to transfer an embryo that is not the product of fertilization of a human egg by a human sperm into a human body.
- 3. A person may not intentionally or knowingly:
 - a. Create or attempt to create a human-animal hybrid;
 - b. Transfer or attempt to transfer a human embryo into a nonhuman womb;
 - c. Transfer or attempt to transfer a nonhuman embryo into a human womb; or
 - d. Transfer or receive for any purpose a human-animal hybrid or any product derived from such hybrid.

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4. This section does not prohibit:
 - a. Research involving the use of transgenic animal models containing human genes;
 - b. Xenotransplantation of human organs, tissues, or cells into recipient animals, including animals at any stage of development before birth, if the xenotransplantation does not violate a prohibition in subsection 3;
 - c. A person from receiving organs, tissues, or cells delivered from outside this state; or
 - d. Cryopreservation of a human embryo.

SECTION 3.

Valuable consideration prohibited.

A person may not give or receive valuable consideration, offer to give or receive valuable consideration, or advertise for the giving or receiving of valuable consideration for the provision of gametes or in vitro human embryos. This section does not regulate or prohibit the procurement of gametes for the treatment of infertility being experienced by the patient from whom the gametes are being derived. This Act may not be construed as prohibiting the cryopreservation of gametes.

SECTION 4.

Identification.

An in vitro human embryo must be given an identification by the facility for use within the medical facility. Records must be maintained identifying the donors associated with the in vitro human embryo. The confidentiality of records kept under this section must be maintained.

SECTION 5.

Care and treatment of in vitro human embryos.

1. A living in vitro human embryo is a biological human being who is not the property of any person. The fertility physician and the medical facility that employs the physician owe a high duty of care to the living in vitro human embryo. Any contractual provision identifying the living in vitro embryo as the property of any party is null and void. The in vitro human embryo may not be intentionally destroyed for any purpose by any person or through the actions of such person.
2. An in vitro human embryo that fails to show any sign of life over a thirty-six-hour period outside a state of cryopreservation may be considered no longer living.

SECTION 6.

Judicial standard.

In disputes arising between any parties regarding an in vitro human embryo, the judicial standard for resolving such disputes is the best interest of the in vitro human embryo.

SECTION 7.

Penalty.

1. It is a class B misdemeanor for a person to violate this Act.
2. A violation of this Act by a physician constitutes grounds for disciplinary action under section 43-17-31.
3. A violation of this Act may be the basis for denying an application for, denying an application for the renewal of, or revoking any license, permit, certificate, or any other form of permission required to practice or engage in a medical-trade, occupation, or profession.
4. A violation this Act by an employee of a licensed health care facility to which the management of said facility consents, knows, or should know may be the basis for denying an application for, denying an application for the renewal of, temporarily suspending, or permanently revoking any operational license, permit, certificate, or any other form of permission required to operate a medical or health care facility.

SECTION 8.

Construction.

1. Nothing in this Act may be construed as creating or recognizing a right to abortion.
2. It is not the intention of this Act to make lawful an abortion that is currently unlawful."

Renumber accordingly

Date: 2/5/13
Roll Call Vote #: 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2302

Senate JUDICIARY Committee

Check here for Conference Committee

Legislative Council Amendment Number 13.8231.02003

Action Taken: Do Pass Do Not Pass Amended Adopt Amendment *as amended*
 Rerefer to Appropriations Reconsider

Motion Made By S. Sitte Seconded By S. Berry

Senators	Yes	No	Senator	Yes	No
Chairman David Hogue	X		Senator Carolyn Nelson		X
Vice Chairman Margaret Sitte	X		Senator John Grabinger		X
Senator Stanley Lyson	X				
Senator Spencer Berry	X				
Senator Kelly Armstrong	X				

Total (Yes) 5 No 2

Absent passes

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 4/5/13
 Roll Call Vote #: 2

**2013 SENATE STANDING COMMITTEE
 ROLL CALL VOTES
 BILL/RESOLUTION NO. 2302**

Senate JUDICIARY Committee

Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: Do Pass Do Not Pass Amended Adopt Amendment
 Rerefer to Appropriations Reconsider

Motion Made By S. Sitte Seconded By S. Berry

Senators	Yes	No	Senator	Yes	No
Chairman David Hogue	X		Senator Carolyn Nelson		X
Vice Chairman Margaret Sitte	X		Senator John Grabinger		X
Senator Stanley Lyson		X			
Senator Spencer Berry	X				
Senator Kelly Armstrong		X			

Total (Yes) 3 No 4

Absent Fail

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 2/5/13
 Roll Call Vote #: 3

**2013 SENATE STANDING COMMITTEE
 ROLL CALL VOTES
 BILL/RESOLUTION NO. 2302**

Senate JUDICIARY Committee

Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: Do Pass Do Not Pass Amended Adopt Amendment
 Rerefer to Appropriations Reconsider

Motion Made By S. Grabinger Seconded By S. Nelson

Senators	Yes	No	Senator	Yes	No
Chairman David Hogue		X	Senator Carolyn Nelson	X	
Vice Chairman Margaret Sitte		X	Senator John Grabinger	X	
Senator Stanley Lyson	X				
Senator Spencer Berry		X			
Senator Kelly Armstrong	X				

Total (Yes) 4 No 3

Absent _____

Floor Assignment S. Grabinger

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2302: Judiciary Committee (Sen. Hogue, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO NOT PASS** (4 YEAS, 3 NAYS, 0 ABSENT AND NOT VOTING). SB 2302 was placed on the Sixth order on the calendar.

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 - b. An embryo produced by fertilizing a human egg with a nonhuman sperm;
 - c. An embryo produced by fertilizing a nonhuman egg with a human sperm;
 - d. An embryo produced by introducing a nonhuman nucleus into a human egg;
 - e. An embryo produced by introducing a human nucleus into a nonhuman egg;
 - f. An embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form;
 - g. A nonhuman life form engineered with the intention of generating functional human gametes within the body of a nonhuman life form;
or
 - h. A nonhuman life form engineered such that it contains a human brain or a brain derived wholly from human neural tissues.

6. "Human embryo" means an organism with a human or predominantly human genetic constitution from the single-cell stage to eight weeks development that is derived by fertilization (in vitro or in utero), parthenogenesis, cloning (somatic cell nuclear transfer), or any other means from one or more human gametes or human diploid cells.
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8. "In vitro human embryo" means a human embryo created outside the human body.
9. "Pay" or "payment" means pay, contract for, or otherwise arrange for the payment of in whole or in part.
10. "Valuable consideration" means financial gain or advantage, including cash, in-kind payments, reimbursement for any costs incurred in connection with the removal, processing, disposal, preservation, quality control, storage, transfer, or donation of human gametes, including lost wages of the donor, as well as any other consideration.

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3. A person may not intentionally or knowingly:
 - a. Create or attempt to create a human-animal hybrid;
 - b. Transfer or attempt to transfer a human embryo into a nonhuman womb;
 - c. Transfer or attempt to transfer a nonhuman embryo into a human womb; or
 - d. Transfer or receive for any purpose a human-animal hybrid or any product derived from such hybrid.
4. This section does not prohibit:
 - a. Research involving the use of transgenic animal models containing human genes;
 - b. Xenotransplantation of human organs, tissues, or cells into recipient animals, including animals at any stage of development before birth, if the xenotransplantation does not violate a prohibition in subsection 3;

- c. A person from receiving organs, tissues, or cells delivered from outside this state; or
- d. Cryopreservation of a human embryo.

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SECTION 5.

Care and treatment of in vitro human embryos.

1. A living in vitro human embryo is a biological human being who is not the property of any person. The fertility physician and the medical facility that employs the physician owe a high duty of care to the living in vitro human embryo. Any contractual provision identifying the living in vitro embryo as the property of any party is null and void. The in vitro human embryo may not be intentionally destroyed for any purpose by any person or through the actions of such person.
2. An in vitro human embryo that fails to show any sign of life over a thirty-six-hour period outside a state of cryopreservation may be considered no longer living.

SECTION 6.

Judicial standard.

In disputes arising between any parties regarding an in vitro human embryo, the judicial standard for resolving such disputes is the best interest of the in vitro human embryo.

SECTION 7.

Penalty.

1. It is a class B misdemeanor for a person to violate this Act.
2. A violation of this Act by a physician constitutes grounds for disciplinary action under section 43-17-31.
3. A violation of this Act may be the basis for denying an application for, denying an application for the renewal of, or revoking any license, permit,

certificate, or any other form of permission required to practice or engage in a medical trade, occupation, or profession.

4. A violation this Act by an employee of a licensed health care facility to which the management of said facility consents, knows, or should know may be the basis for denying an application for, denying an application for the renewal of, temporarily suspending, or permanently revoking any operational license, permit, certificate, or any other form of permission required to operate a medical or health care facility.

SECTION 8.

Construction.

1. Nothing in this Act may be construed as creating or recognizing a right to abortion.
2. It is not the intention of this Act to make lawful an abortion that is currently unlawful."

Renumber accordingly

2013 TESTIMONY

SB 2302

Testimony on SB 2302

January 29, 2013

Mr. Chairman and members of the committee, I am Senator Margaret Sitte from District 35 in Bismarck.

SB 2302, the Right to Life Act, is enabling legislation that would only become law if SCR 4009, the Human Life Constitutional Amendment, is enacted by a vote of the people.

This bill has been the work of many individuals who have spent much time looking at all the issues associated with protecting the right to life of every human being. The bill was once much longer than what you see today. Many national organizations were represented at the table: Family Research Council, National Right to Life, American Life League and Personhood USA. Some of these people who helped write the bill are here today to testify.

In an effort to bring the various groups together in unity, I am presenting a number of amendments and technical corrections. See the attached sheet "Sponsor's proposed amendments to SB 2302."

In Section 1, add new definitions of "abortifacient birth control," "clinically proven," and "contraception." Delete the definitions of "destructive research," "embryonic stem cell," "embryo transfer," "medical emergency," "pluripotent cells," and "prohibited human research."

Section 2 is an abortion ban with protections for life of the mother. Note the amendment that makes it clear that "No physician is authorized to commit an abortion." Subsection 2 a makes it explicitly clear that only abortifacient birth control that terminates or hinders the development of a human being is affected by this bill.

Subsections d, e and f are new language to deal with medical protections for the life of the mother. In d the language assures that treatment for ectopic and molar pregnancies will not be affected. In e,

Nothing in this section may be construed to prohibit a physician acting in a medical emergency to treat any condition which, in reasonable medical judgment, so complicates the medical condition of a pregnant female or preborn child as to necessitate immediate treatment to avert death or for which a delay will create serious risk of substantial or irreversible impairment of a major bodily function. No such condition shall be deemed to exist if it is based on a diagnosis or claim of a mental or emotional condition of the pregnant woman or that the pregnant woman will engage in conduct which she intends to result in death or injury.

Subsection *f* says "All treatment referenced in this section must be performed in a manner conducive to the preservation of life."

Section 3 covers the ethical treatment of human embryos. Dr. David Prentice, Senior Fellow for Life Sciences at Family Research Council, will answer your specific questions on this portion of the bill, including transgenic animal models and xenotransplantation of human cells.

Section 4 prohibits the buying and selling of sperm, eggs or embryos.

Section 5 ensures that each human embryo is identified and that records are maintained.

Section 6 establishes that in vitro human embryos are not property and may not be destroyed.

Section 7 limits the number of human embryos created in a single cycle to the number transferred.

Section 8 protects the best interests of the in vitro human embryo in resolving any disputes.

Section 9 outlines the informed consent requirements for the patients.

Section 10 is being amended to say Sections 3 through 9 may not be construed to affect conduct relating to abortion nor recognizing any independent right to abortion.

Section 11 lists the penalty is a class B misdemeanor. The proposed amendment strikes the language dealing with monetary gain. Other penalties include disciplinary actions against a physician including revocation of license, and sanctions against the health care facility.

Section 12 reiterates that nothing in this act shall be construed as creating or recognizing a right to abortion and it is not the intention of this act to make lawful an abortion that is currently unlawful.

Section 13 sets the effective date as being when the secretary of state certifies to the legislative council that the constitutional amendment has passed. Note the amendment to say every human being at any stage of development in conformity with the Constitutional Amendment language.

This issue is uncharted waters for most legislators, and for that reason, I have invited several people from around the country to provide expert testimony on this bill

This bill is on the cutting edge of determining the ethical treatment of unborn human beings. I urge your favorable consideration of SB 2302.

①

Sponsor's proposed amendments to SB 2302

SECTION 1. Add new definitions

1. "Abortifacient birth control" means an instrument, device, procedure, drug, chemical or other substance that is clinically proven to terminate or hinder the development of a preborn human being.
5. "Clinically proven" means passing a phase III Food and Drug Administration trial for efficacy with multiple published references.
6. "Contraception", "contraceptive measure" and "birth control" means any medicine, device, or ...

Delete definitions of Destructive Research, Embryonic Stem Cell, Embryo Transfer, Medical Emergency, Pluripotent Cells, and Prohibited Human Research.

SECTION 2

~~No physician is authorized to commit an abortion. No abortion is authorized or shall be performed unless to avert the death of the pregnant woman in a medical emergency.~~

2) Construction ~~Contraception~~

- a. Nothing in this section may be construed to prohibit the sale, use, prescription, or administration of a contraceptive measure, drug or chemical. Only abortifacient birth control that can be proven to kill a person shall be affected by this section. In the interest of protecting the health and safety of the people of North Dakota, the state department of health shall provide a list of birth control and abortifacient birth control products along with their clinically proven effects upon women and preborn children.

Keep b and c

- d. Treatment for ectopic and molar pregnancy shall not be affected by this section.
- e. Nothing in this section may be construed to prohibit a physician acting in a medical emergency to treat any condition which, in reasonable medical judgment, so complicates the medical condition of a pregnant female or preborn child as to necessitate immediate treatment to avert death or for which a delay will create serious risk of substantial or irreversible impairment of a major bodily function. No such condition shall be deemed to exist if it is based on a diagnosis or claim of a mental or emotional condition of the pregnant woman or that the pregnant woman will engage in conduct which she intends to result in death or injury.
- f. All treatment referenced in this section must be performed in a manner conducive to the preservation of life.

SECTION 3.

1. The creation of an in vitro human embryo shall be solely for the purpose of initiating a human pregnancy by means of transfer to the uterus body of a human female... **change twice**

SECTION 10.

2. Sections ~~43~~ through 9 of this Act may not be construed to affect conduct relating to abortion...

SECTION 11.

1. It is a class B misdemeanor without imprisonment for a person to violate sections ~~43~~ through 9 of this Act, ~~if that person derives a pecuniary gain from the violation.~~

SECTION 13.

This Act is effective on the date the secretary of state certifies to the legislative council that a constitutional amendment recognizing the inalienable right to life of all every humans being at every any stage of development has been approved by a majority of the voters in a statewide election.

2

Written Testimony of David A. Prentice, Ph.D.
Senior Fellow for Life Sciences, Family Research Council

Judiciary Committee, North Dakota Senate
January 2013

To the Distinguished Chair, Ranking Member and Honored Members of the Committee.

I am a cell biologist, currently working for a think tank in Washington, D.C. and as an adjunct professor at a local university. Previously I spent 20 years as Professor of Life Sciences at Indiana State University and Adjunct Professor of Medical & Molecular Genetics at Indiana University School of Medicine, and I have done federally-funded laboratory research, lectured, and advised on these subjects extensively, in the U.S. and internationally.

We should first deal with the biology and the terminology regarding the subjects of this legislation.

“Zygote. This cell results from the union of an oocyte and a sperm during fertilization. A zygote is the beginning of a new human being (i.e., an embryo).”¹

“The development of a human begins with fertilization, a process by which the *spermatozoon* from the male and the oocyte from the female unite to give rise to a new organism, the *zygote*.”²

“Almost all higher animals start their lives from a single cell, the fertilized ovum (zygote)... The time of fertilization represents the starting point in the life history, or ontogeny, of the individual.”³

So, the entity in question is biologically a human being. The question before you is what respect and rights will be given this earliest stage of human life and all subsequent stages of human life; whether human life can be created in various ways and used for experiments, whether his or her health and the health of his or her mother will be considered and protected.

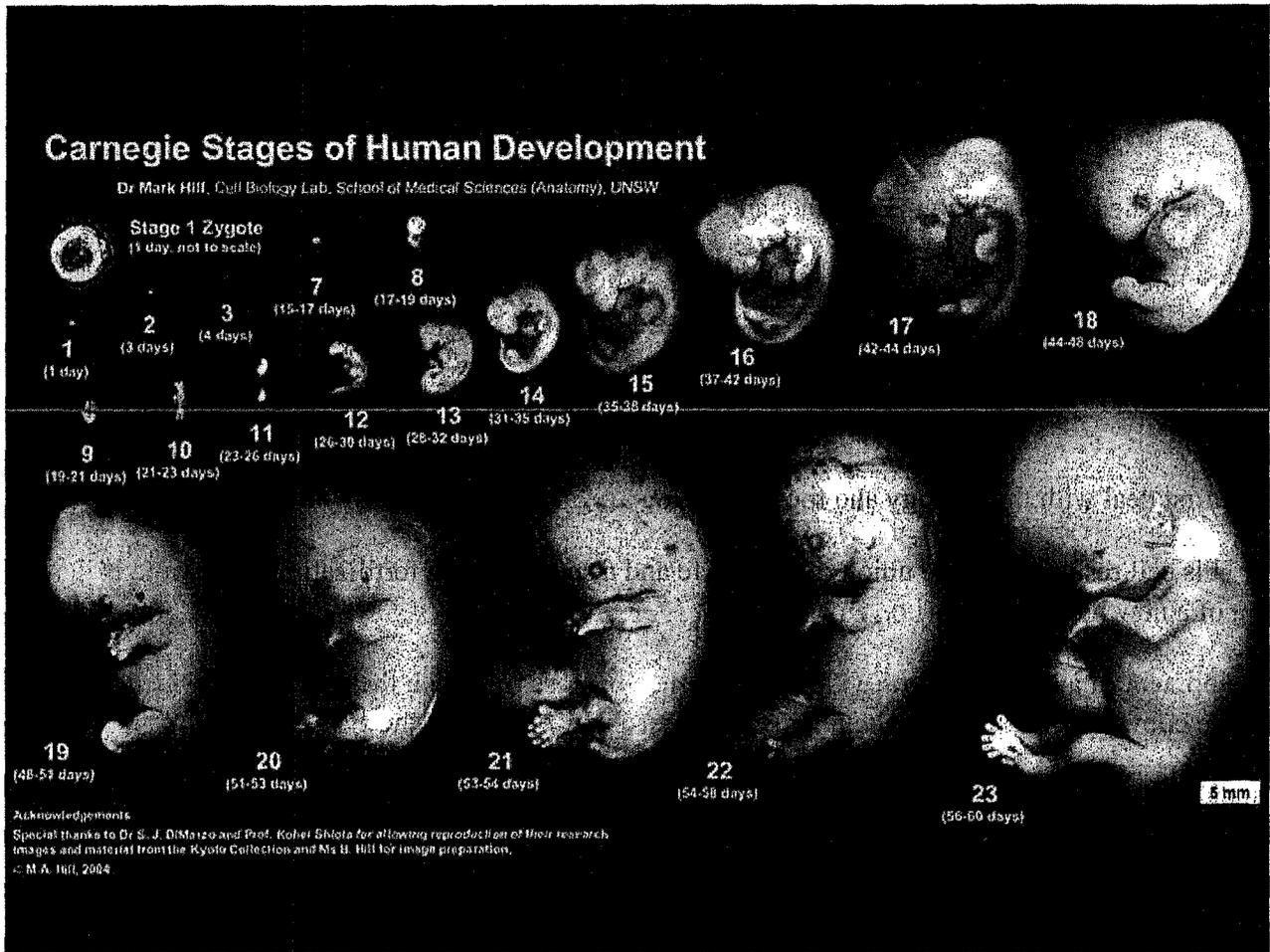
The bill under consideration does not directly address the question of stem cell research. No stem cell research is prohibited by this bill, whether embryonic, iPS, adult, or cord blood stem cells. Any ongoing stem cell research in the state can continue unabated under this bill, including embryonic, induced pluripotent, and adult stem cell research.

What the bill addresses is the human embryo, its creation, and its disposition. Under this bill, human embryos cannot be created other than by fertilization of human egg with human sperm, and the embryos created must be used for reproduction, not for experiments.

¹ Moore, Keith L. and Persaud, T.V.N. *The Developing Human: Clinically Oriented Embryology*. 7th edition. Philadelphia: Saunders 2003, p. 2.

² Sadler, T.W. *Langman's Medical Embryology*. 7th edition. Baltimore: Williams & Wilkins 1995, p. 3.

³ Carlson, Bruce M. *Patten's Foundations of Embryology*. 6th edition. New York: McGraw-Hill, 1996, p. 3.



The bill recognizes that human development is a continuum with the life of the organism beginning at the zygote stage, as noted before.

In terms of stem cell research, any ongoing or future stem cell research, including embryonic stem cell research, is allowed. The bill focuses on the human embryo.

The bill updates the existing statute that prohibits human cloning for any purpose.

To review, human cloning is human asexual reproduction, termed “asexual” because it does not involve the combining of egg and sperm to form an embryo. The focal technique to accomplish this is somatic cell nuclear transfer (SCNT) introducing the nuclear genetic material from one or more human somatic (body) cells into a fertilized or unfertilized egg cell whose nuclear genetic material has been removed or inactivated, producing a human embryo who is virtually genetically identical to an existing or previously existing human being.

Proponents of human cloning hold out two hopes for its use: (1) creating live born children for infertile couples or those grieving over the loss of a loved one, so-called “reproductive cloning” (live birth cloning), and (2) promises of medical miracles to cure diseases by harvesting embryonic stem cells from cloned embryos created from patients, euphemistically termed “therapeutic cloning” (more properly termed research cloning.)

Biologically the process of cloning (somatic cell nuclear transfer; SCNT) produces a zygote, a one-celled embryo, at the starting point for development. Thus, this cloning technique uses a different method of conception, yet still produces a living human organism, an embryo, at the earliest stage of human development. As the Bush President's Council on Bioethics noted, "The first product of SCNT is, on good biological grounds, quite properly regarded as the equivalent of a zygote, and its subsequent stages as embryonic stages in development."⁴

Likewise, the National Institutes of Health has affirmed that SCNT cloning produces an embryo.⁵

The National Academy of Sciences noted the following:

"The method used to initiate the reproductive cloning procedure is called nuclear transplantation, or somatic cell nuclear transfer (SCNT). It involves replacing the chromosomes of a human egg with the nucleus of a body (somatic) cell from a developed human. In reproductive cloning, the egg is then stimulated to undergo the first few divisions to become an aggregate of 64 to 200 cells called a blastocyst. The blastocyst is a preimplantation embryo that contains some cells with the potential to give rise to a fetus and other cells that help to make the placenta. If the blastocyst is placed in a uterus, it can implant and form a fetus. If the blastocyst is instead maintained in the laboratory, cells can be extracted from it and grown on their own."⁶

The equivalence of the embryo, as zygote and blastocyst, has also been noted by the National Academy of Sciences,⁷ which has noted that the embryos produced by fertilization and the embryos produced by SCNT cloning are **indistinguishable**.⁸

Both sexual reproduction (fertilization, egg+sperm) and asexual reproduction (cloning, *i.e.*, somatic cell nuclear transfer) produce a human embryo, a living human organism, species *Homo sapiens*.

Cloning (SCNT) creates an embryo, not stem cells, tissues, or organs.

⁴ "Human Cloning and Human Dignity: An Ethical Inquiry", Report of the President's Council on Bioethics, July 2002; p.50

⁵ See NIH Glossary, under "Therapeutic Cloning" and "Reproductive Cloning"; <http://stemcells.nih.gov/info/glossary.asp>

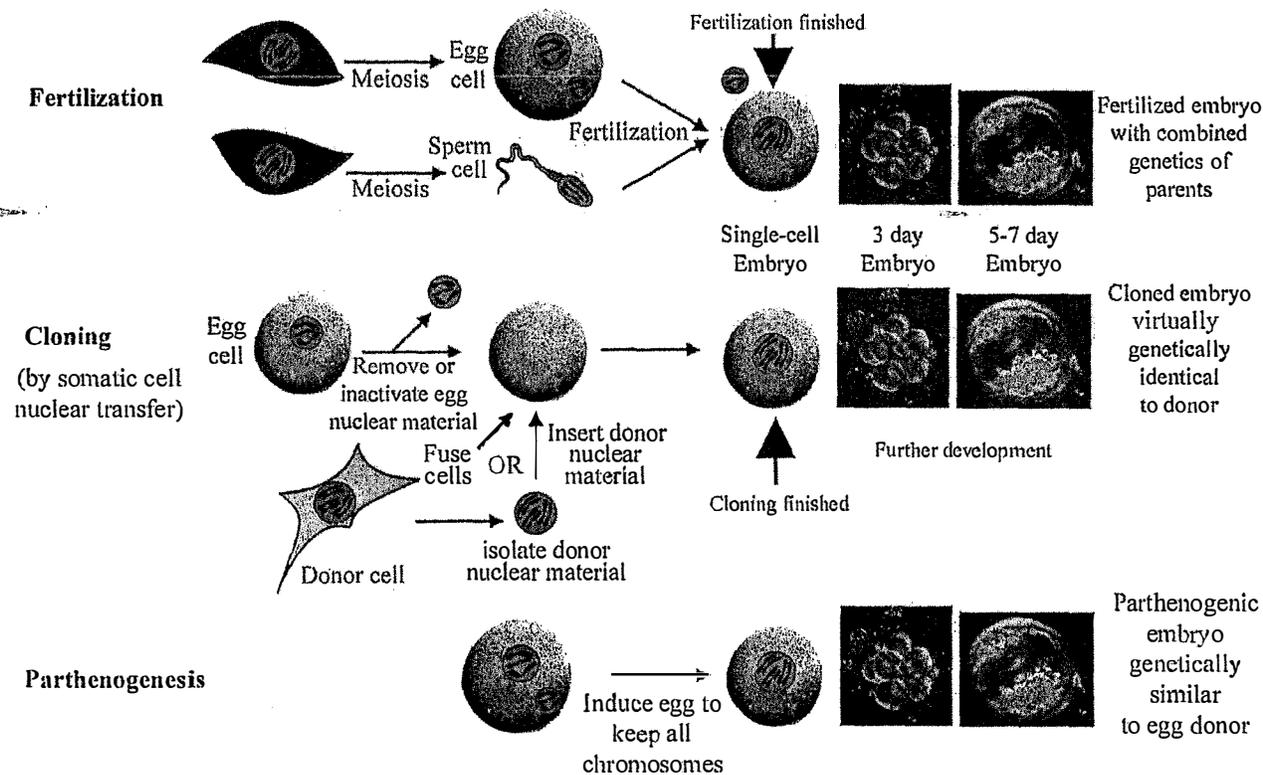
⁶ Scientific and Medical Aspects of Human Reproductive Cloning, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Jan 2002; Preface page xii

⁷ Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Sept 2001; pp 10, 11, 26.

⁸ National Academy of Sciences, Guidelines for Human Embryonic Stem Cell Research (2005), p. 29

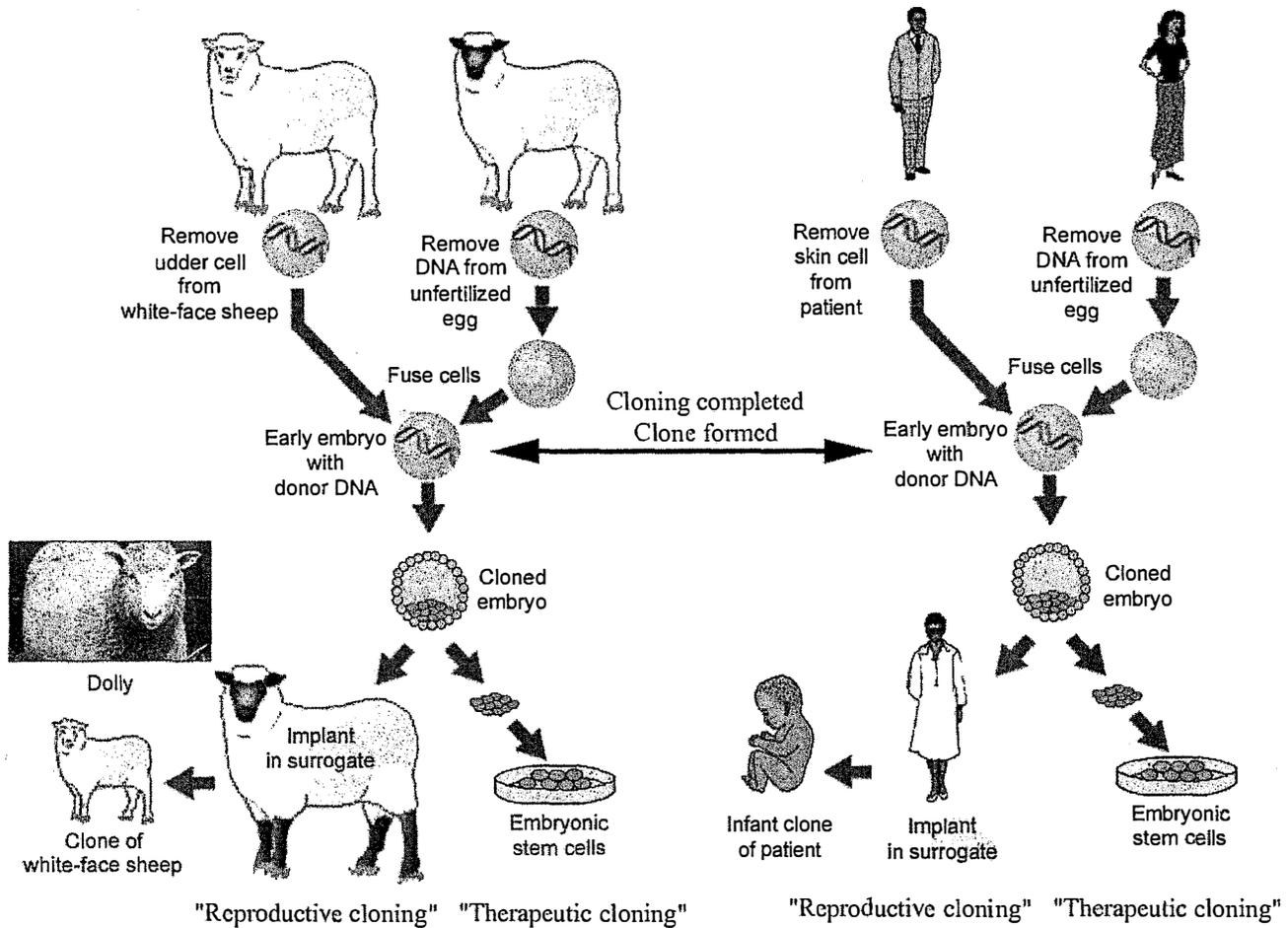
Another technique, “parthenogenesis”, has also been used to create embryos. In this technique, a human egg is chemically treated in such a way to make it retain a complete set of chromosomes, all derived from the egg alone (again, without use of sperm.) Activation allows this parthenogenetic embryo to begin cell division and development, though because all the chromosomes are derived only from an egg, the resulting embryo only proceeds part way through development unless there is some genetic manipulation to activate placental genes. Born parthenogenetic mice have been produced using this technique.⁹

Fertilization compared to Cloning (Somatic Cell Nuclear Transfer, SCNT)



⁹ Kono T et al., Birth of parthenogenetic mice that can develop to adulthood, Nature 428, 860-864, 2004

The cloning technique, somatic cell nuclear transfer (SCNT), was the process used to create the cloned sheep Dolly.



We need to be clear on the terms. **Both "reproductive" and "therapeutic" cloning use exactly the same techniques to create the clone, and the cloned embryos are indistinguishable.** The process, as well as the product, is identical. The only distinction is the purpose for use of the embryo either transfer to a uterus in the hopes of a live birth, or destruction in the hopes of a medical miracle.

The technique of cloning is finished once that first cell, the one-celled embryo (zygote) is formed. Anything beyond that step is simply growth and development. And despite attempts to employ various euphemisms, scientifically, genetically, what is created is a human being; its species is *Homo sapiens*, it is neither fish nor fowl, monkey nor cow it is human. The use of disingenuous euphemisms to describe the embryo as something other than an embryo likewise are not scientific, and diverge from the accepted definitions as put forth by the National Academy of Sciences, the National Institutes of Health, and others, including well-known proponents of human cloning.

This fact is also made clear by leading proponents of embryo research:

Q: The people who use nuclear transfer generally say that the technique is optimized for producing the stem cells rather than making babies. They would not want to equate this with the process that produces embryos that were fit for implantation, and they'd argue that they're using the reproductive process differently ...

A: (**James Thomson**) "See, you're trying to define it away, and it doesn't work. If you create an embryo by nuclear transfer, and you give it to somebody who didn't know where it came from, there would be no test you could do on that embryo to say where it came from. It is what it is. It's true that they have a much lower probability of giving rise to a child. ... But by any reasonable definition, at least at some frequency, you're creating an embryo. If you try to define it away, you're being disingenuous."¹⁰

The assumption that cloning (SCNT) will produce matching tissues for transplant that will not be rejected is still theoretical. When tested in mice in 2002,¹¹ the ES cells from the cloned mouse embryo were rejected by the genetically-identical host:

"Jaenisch addressed the possibility that ES clones derived by nuclear transfer technique could be used to correct genetic defects... However, the donor cells, although derived from the animals with the same genetic background, are rejected by the hosts."¹²

In fact, the best results to date (even though equivocal) in animal studies actually come from gestating cloned animals to the fetal stage and then harvesting tissue stem cells.^{13,14,15}

The idea of therapeutic cloning—cloning an individual to create embryos, from whom stem cells are harvested—was already outdated in 2008 and the science superseded by better, easier scientific methods for matching stem cell production.

Moreover, the assertion that cloning is the only method for preventing immune rejection of transplanted embryonic stem cells is completely false. In an article published March 18, 2002 (Abate, San Francisco Chronicle), researchers with Geron Corp. and with Advanced Cell Technologies admitted that there are ways to prevent rejection of transplanted cells without therapeutic cloning, but that "that message has not gotten out," and that "the need for cloning to overcome immune system rejection has been overstated." The report goes on to note **"the scientific community has put out the message that a ban on therapeutic cloning will prevent researchers from solving the immune-system problem—an argument that seems at best a stretch, and at worst, a deception."**

¹⁰ Stem-cell pioneer does a reality check. James Thomson reflects on science and morality, By Alan Boyle Science editor MSNBC Updated: 4:13 p.m. ET June 22, 2005

¹¹ Rideout WM *et al.*, "Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy," *Cell* 109, 17-27; 5 April 2002 (published online 8 March 2002)

¹² Tsai RYL, Kittappa R, and McKay RDG; "Plasticity, niches, and the use of stem cells"; *Developmental Cell* 2, 707-712; June 2002.

¹³ Lanza R *et al.* Long-term bovine hematopoietic engraftment with clone-derived stem cells. *Cloning Stem Cells* 7, 95-106, 2005

¹⁴ ¹⁴ Lanza R *et al.* Regeneration of the infarcted heart with stem cells derived by nuclear transplantation. *Circ Res* 94, 820-827, 2004

¹⁵ Lanza R *et al.* Generation of histocompatible tissue using nuclear transplantation. *Nat Biotechnol* 20, 689-696, 2002

Other scientists have admitted in testimony that therapeutic cloning will not prevent transplant rejection of cloned tissues:

“There is no question in my mind that the possibility exists that if you are doing an egg donor, and nuclear transfer into an egg, that there possibly exists that that cell -- that the embryonic stem cells derived from that could be rejected. Absolutely.” Dr. John Gearhart, Johns Hopkins¹⁶

“I should say that when you put the nucleus in from a somatic cell, the mitochondria still come from the host.” He concluded, “And in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection and so immunosuppression, mild though it is, will be required for that.” Dr. Irving Weissman, Stanford¹⁷

Dr. James Thomson, who originally isolated human embryonic stem cells, has stated in one of his published papers that cloning is unlikely to be clinically significant.

“[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning by SCNT] becoming a routine clinical procedure...”¹⁸

Other leaders in the embryonic stem cell field have also published similar views, including Australia’s Alan Trounson:¹⁹

“However, it is unlikely that large numbers of mature human oocytes would be available for the production of ES cells, particularly if hundreds are required to produce each ES line... In addition, epigenetic remnants of the somatic cell used as the nuclear donor can cause major functional problems in development, which must remain a concern for ES cells derived by nuclear transfer. ...it would appear unlikely that these strategies will be used extensively for producing ES cells compatible for transplantation.”

The evidence from animal studies indicates that it will indeed require a tremendous number of human oocytes (eggs) to produce even one ES cell line from cloned embryos. Dr. Peter Mombaerts, who was one of the first mouse cloners, estimates that it will require a minimum of 100 eggs.²⁰ The reports from South Korea²¹ of human embryo cloning have been **shown to be a fraud**, but even so the news stories indicate that the researchers obtained over 2,200 human eggs for use in their unsuccessful experiments, through paying women to go through the risky procedures of egg harvesting, as well as through coercion of

¹⁶ Dr. John Gearhart; transcript of the April 25, 2002 meeting of the President’s Council on Bioethics; p.47; <http://www.bioethics.gov/meetings/200204/0425.doc>

¹⁷ Dr. Irving Weissman, Stanford, before the President’s Council on Bioethics on February 13, 2002

¹⁸ Odorico JS, Kaufman DS, Thomson JA, “Multilineage differentiation from human embryonic stem cell lines,” *Stem Cells* 19, 193-204; 2001

¹⁹ Trounson AO, “The derivation and potential use of human embryonic stem cells”, *Reproduction, Fertility, and Development* 13, 523-532; 2001

²⁰ Mombaerts P, “Therapeutic cloning in the mouse”, *Proceedings of the National Academy of Sciences USA* 100, 11924-11925; 30 Sept 2003 (published online 29 August 2003)

²¹ Hwang WS *et al.*, Patient-specific embryonic stem cells derived from human SCNT blastocysts, *Science* published online 19 May 2005

students. At a rate of 100 eggs per patient, to treat, theoretically, the 18 million diabetics in the U.S. by this technique would require at least 1.8 billion human eggs.

The 2008 report of the first and only documented success at cloning human embryos was by the California company Stemagen (in which one of the scientists, Wood, admitted that he cloned himself), and **did not result in any cells** obtained from the clones;²² they attributed this sole cloning success to use of fresh, high-quality human eggs from a nearby fertility clinic with which they were associated. The only reported case of obtaining any embryonic stem cells from cloned primate embryos was in 2007 with monkeys.²³ In this case it took **over 100 eggs each** to produce only 2 ESC lines (one of which had chromosomal problems.) The group had worked for almost 10 years, using around 15,000 monkey eggs.²⁴ Dr. Rudolph Jaenisch, a cloning scientist at Massachusetts Institute of Technology, noted:

“The procedure is very complicated, he said, and has ethical implications because the embryos have to be destroyed to obtain the stem cells. **“Nobody in their right mind would think this is useful for therapies,” Dr. Jaenisch said.** He also noted that the process requires more than 100 oocytes to create a single stem-cell line and that the supply of human oocytes available for research is limited.”²⁵

In a recent profile of Dr. Jaenisch,²⁶ he discussed the uselessness of so-called “therapeutic cloning” and how the technique is of no practical relevance:

“Ten years ago, we talked about the potential of nuclear transfer for therapy. But it turns out the technique was of no practical relevance. You would never do it in humans for a number of reasons. First, it’s very inefficient. With mice, that doesn’t matter because we can do hundreds of transfers to get a few mice. But human cloning is another order of magnitude more difficult than in mice. And people can’t even get the eggs to practice [on]. My former student Kevin Eggan, along with his colleagues at Harvard, spent years putting in place a protocol to get volunteer egg donors. They spent a couple hundred thousand dollars just in advertising. And I think they got one or two donors. Kevin’s postdoc, Dieter Egli, who went to Columbia, told me that he got a couple [of] human nuclear transfers going, but they all arrested at the 6- or 8-cell stage.”

The problem with finding enough human eggs for cloning experiments has led to an interesting alliance of pro-choice and pro-life feminists, forming a group called Hands Off Our Ovaries (see <http://handsoffourovaryes.com>). The group spans the political and ideological spectrum, but are united against this risk of using women and their bodies as raw materials for experiments, including harvesting eggs for cloning experiments.

²² French AJ *et al.*, “Development of human cloned blastocysts following somatic cell nuclear transfer (SCNT) from adult fibroblasts”, *Stem Cells* published online Jan 17, 2008; DOI: 10.1634/stemcells.2007-0252

²³ Byrne JA *et al.*, Producing primate embryonic stem cells by somatic cell nuclear transfer, *Nature* 450, 497, 22 Nov 2007; published online 14 November 2007, doi: 10.1038/nature06357

²⁴ Cyranoski D, Cloned monkey stem cell produced, *Nature* published online 14 November 2007, doi: 10.1038/news.2007.245

²⁵ The Chronicle of Higher Education, Thursday, November 15, 2007

²⁶ Hopkin K, "Ready, Reset, Go" *The Scientist* 25, 52, 2011

Moreover, **allowing “therapeutic” cloning while trying to ban reproductive cloning is unfeasible, and will simply hasten development of the process supposedly to be banned, reproductive cloning.** Again, honest proponents of cloning have noted this themselves:

“It is true that the techniques developed in CRNT [cell replacement through nuclear transfer, aka therapeutic cloning] research can prepare the way scientifically and technically for efforts at reproductive cloning.”²⁷

The American Society for Reproductive Medicine (ASRM), the largest professional organization with expertise in reproductive technologies, says that SCNT is simply the procedure that clones embryos for whatever purpose (whether for starting a pregnancy or destroying for research). And ASRM concedes that if cloning for research is allowed, that research will be used to refine the process and will make it easier to perform “reproductive” cloning:

“If undertaken, the development of SCNT for such therapeutic purposes, in which embryos are not transferred for pregnancy, is likely to produce knowledge that could be used to achieve reproductive SCNT.”²⁸

In terms of the egg issue and numbers involved, one proposal has been to use animal eggs instead, to produce a **human-animal hybrid or “chimera”**. Some have claimed that this is improbable science, yet in 2003 a Chinese lab reported success using rabbit eggs to produce cloned animal-human hybrids,²⁹ and the U.K. in fact issued three licenses to begin such research and in 2008 one lab reported success at creating human-animal hybrid embryos using this technique with cow eggs, though they did not obtain any cells from the cloned embryos.³⁰ Some laboratories, such as Advanced Cell Technology, have failed to produce cells from human-animal hybrid embryos and concluded that the technique is implausible.³¹ It should be noted that the same lab also failed to produce cells from fully-human clones. Such experiments, while ethically questionable and unlikely to produce useable results, are still not impossible, as noted above.

This bill includes prohibitions against production of such human-animal hybrids by various means, including SCNT cloning techniques. There is no valid scientific or medical reason to allow production of these hybrid embryos. The bill does, however, allow use of cells, tissues, and organs for transplant experiments and even for clinical use.

²⁷ Robert P. Lanza, Arthur L. Caplan, Lee M. Silver, Jose B. Cibelli, Michael D. West, Ronald M. Green; "The ethical validity of using nuclear transfer in human transplantation"; *The Journal of the American Medical Association* 284, 3175-3179; Dec 27, 2000.

²⁸ The Ethics Committee of the American Society for Reproductive Medicine; “Human somatic cell nuclear transfer (cloning)”; *Fertility and Sterility* 74, 873-876; November 2000.

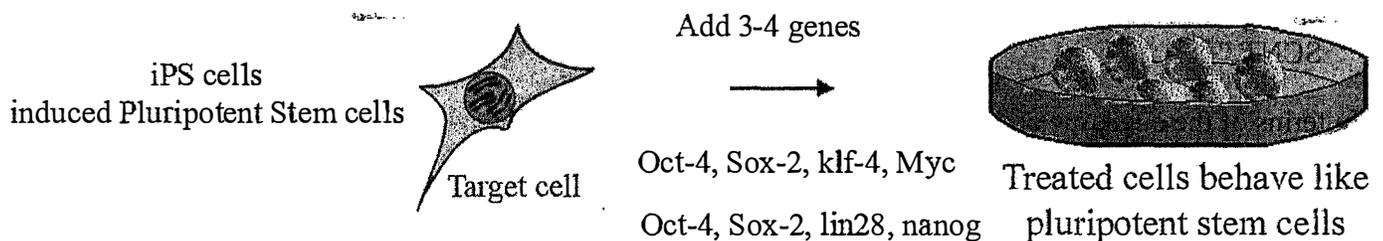
²⁹ Chen Y *et al.*, *Cell Research* 13, 251, 2003

³⁰ Highfield R, “Hybrid embryos made by UK scientists”,
<http://www.telegraph.co.uk/earth/main.jhtml?view=DETAILS&grid=&xml=/earth/2008/04/01/sciembryo101.xml>

³¹ Chung Y *et al.*, *Cloning and Stem Cells* 11, 1, 2009;

Recent advances in stem cell research have overtaken the efforts at cloning. Scientists have now shown that there is an easier, less expensive and more direct method to produce embryonic-type stem cells from a patient's own tissue, with a real potential for a tissue match.. These cells, termed **iPS cells (induced Pluripotent Stem cells)** were first developed in 2006 in mice by the Japanese scientist **Shinya Yamanaka**.³² Yamanaka's lab and the lab of Thomson in the U.S. showed in November 2007 that this same technique could work for humans as well, easily producing human iPS cells directly from human tissue.³³ **Dr. Yamanaka received the 2012 Nobel Prize in Physiology or Medicine** for his groundbreaking development of the technique to create iPS cells.

The straightforward technique involves adding several (usually 3-4) genes directly to a human cell such as a skin cell, reprogramming the cell such that it behaves like an embryonic stem cell, yet without use or production of an embryo, eggs, or cloning.



Thomson's group in their paper showing this first production of human iPS cells noted:

“The human iPS cells described here meet the defining criteria we originally proposed for human ES cells (14), with the significant exception that the iPS cells are not derived from embryos.”

In a subsequent report, Thomson (who was the first successfully to grow human embryonic stem cells in the lab) noted:

“Recently, adult human cell lines were reprogrammed to an ES cell state (induced pluripotent stem cells, iPS cells) (40, 41). These cells possess the therapeutically desired characteristics of ES cells, namely indefinite self-renewal and pluripotency, without the requirement of human embryo destruction.”³⁴

³² Takahashi K and Yamanaka S, Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors, *Cell* 126, 663-676, 25 August 2006

³³ Takahashi K *et al.*, Induction of pluripotent stem cells from adult **human** fibroblasts by defined factors, *Cell* 131, 861-872, 30 November 2007; published online 20 November 2007; Yu J *et al.*, Induced pluripotent stem cell lines derived from **human** somatic cells, *Science* 318, 1917-1920, 21 December 2007, published online 20 November 2007

³⁴ Swaney DL *et al.*, *Proceedings of the National Academy of Science USA* 106, 995-1000, 27 January 2009

Hearing of the impending announcement about iPS cells in 2007, Prof. Ian Wilmut, cloner of Dolly the sheep, publicly forsook cloning technology and his UK license allowing him to clone human embryos, to work on the new iPS cell technology.³⁵

Subsequently, other groups have verified the ability to obtain iPS cells, including from human tissue, and improved on the technique, making it even safer.³⁶

Jaenisch's group has also shown that iPS cells are effective at improving the health of mice with sickle cell anemia. The iPS cells succeeded where cloning had previously failed.³⁷

Discussing this real advance with iPS cells in mice, the researchers noted:

“This demonstrates that IPS cells have the same potential for therapy as embryonic stem cells, without the ethical and practical issues raised in creating embryonic stem cells,” says Jaenisch.³⁸

And

Townes says he and Jaenisch initially collaborated on a project that used nuclear transfer to make corrected stem cells, a process called therapeutic cloning. But the experiments failed, he says, because nuclear transfer was too inefficient to produce the needed cells. The iPS cell technique “is amazingly efficient,” he says.³⁹

Thus, iPS cells fulfill the desire to create embryonic-type stem cells, with the potential for transplant match, but do so without the use of embryos, eggs, or cloning.

While some have claimed the necessity of *human* embryonic stem cells for development of iPS cells, Yamanaka has said this is not true. “Neither eggs nor embryos are necessary. I've never worked with either,” says Shinya Yamanaka. The first instalment of his research appeared a year ago -- and was greeted

³⁵ Roger Highfield, Dolly creator Prof Ian Wilmut shuns cloning, *The Telegraph*, November 16, 2007

³⁶ Kim D *et al.*, *Cell Stem Cell* 4,472, 5 June 2009; Nakagawa M *et al.*, Generation of induced pluripotent stem cells without Myc from mouse and **human** fibroblasts, *Nature Biotechnology* 26, 101-106, January 2008, published online 30 November 2007; Park I-H *et al.*, Reprogramming of **human** somatic cells to pluripotency with defined factors, *Nature* 451, 141-147, 10 January 2008, published online 23 December 2007; Wernig W *et al.*, C-Myc is dispensable for direct reprogramming of mouse fibroblasts, *Cell Stem Cell* published online 28 December 2007; Yamanaka S, Induction of pluripotent stem cells from mouse fibroblasts by four transcription factors, *Cell Proliferation* 41 (suppl 1), 51-56, January 2008; Brambrink T *et al.* Sequential expression of pluripotency markers during direct reprogramming of mouse somatic cells, *Cell Stem Cell* 2, 151-159, February 2008, online 6 February 2008; Aoi T *et al.*, Generation of pluripotent stem cells from adult **mouse liver and stomach** cells, *Science* published online 14 February 2008, doi:10.1126/science.1154884; Stadtfeld M *et al.*, Defining molecular cornerstones during fibroblast to iPS cell reprogramming in mouse, *Cell Stem Cell* 2, __, March 2008, published online 14 February 2008, doi:10.1016/j.stem.2008.02.001; Lowry WE *et al.*, Generation of **human** induced pluripotent stem cells from dermal fibroblasts, *Proc. Natl. Acad. Sci. USA* 105, 2883-2888, 26 February 2008; published online 16 February 2008

³⁷ Hanna J *et al.*, **Treatment of sickle cell anemia mouse model** with iPS cells generated from autologous **skin**, *Science* 318, 1920-1923, 21 December 2007, online 6 Dec 2007

³⁸ Reprogrammed adult cells treat sickle-cell anemia in mice, published 14:10 EST, December 06, 2007, <http://physorg.com/news116172622.html>

³⁹ Gretchen Vogel, Reprogrammed Skin Cells Strut Their Stuff, *ScienceNOW Daily News*, 6 December 2007

with polite scepticism by his colleagues. At the time they were mesmerised by dreams of cloning embryos and dissecting them for their stem cells.⁴⁰

Yamanaka also pointed out the development of iPS cells as an ethical answer to embryonic stem cells.

At the friend’s invitation, he looked down the microscope at one of the human embryos stored at the clinic. The glimpse changed his scientific career.

“When I saw the embryo, I suddenly realized there was such a small difference between it and my daughters,” said Dr. Yamanaka, 45, a father of two and now a professor at the Institute for Integrated Cell-Material Sciences at Kyoto University. “I thought, we can’t keep destroying embryos for our research. There must be another way.”⁴¹

Since November 2007 and the first human iPS cells, groups have created over 1,000 different human iPS cell lines, including over 100 different lines directly from patients with different diseases. In 2008, a Japanese news agency announced that Dr. Yamanaka was preparing to produce iPS cells from a group of 60 patients with various diseases, in order to study disease development and potential treatments in the laboratory.⁴² Ian Wilmut (cloner of Dolly the cloned sheep) has created iPS cell lines from patients with motor neuron disease, to study the disease in the laboratory and possibly to match the patient. Prof. Wilmut had been trying to obtain such cells from cloned human embryos for years, yet succeeded in a short period of time with the iPS cell technique. According to Wilmut:

"This is so much simpler a procedure, quite apart from the ethical issues.⁴³

Some have claimed that SCNT cloning is needed to replace stocks of human embryonic stem cells from IVF embryos. In March 2009, President Obama issued an executive order, and NIH issued guidelines, that allow many more human embryonic stem cell lines to be produced, and allowing federal taxpayer dollars to fund embryonic stem cell research with these newly-established ESC lines, creating an incentive for human embryo destruction. It is worth noting, however, that scientists were most concerned that the oldest, best characterized and reliable stem cell lines, previously funded, be approved;⁴⁴ the stocks of those cells obviously did not need to be replaced. The NIH has at this date approved 200 human embryonic stem cell lines for federal funding, including the oldest and best characterized lines.⁴⁵

Stem cell science has moved beyond the outdated cloning technique. The only reason at this point to practice SCNT cloning would be if the researcher wished to produce cloned embryos for gestation and birth.

Stem cell science has also moved well beyond cloning and hybrids in terms of real treatments for patients.

⁴⁰ Michael Cook, Is therapeutic cloning obsolete?, Mercatornet, Saturday, 16 June 2007

⁴¹ Martin Fackler, "Risk Taking is in his Genes", New York Times Dec 11, 2007

⁴² “Scientists to create iPS cells from Japanese patients”, The Yomiuri Shimbun, Mar. 10, 2008, <http://www.yomiuri.co.jp/dy/features/science/20080310TDY02301.htm>

⁴³ John von Radowitz, Scots team's innovation may help to beat 'shocker of a disease', <http://news.scotsman.com/health/Scots-team39s-innovation-may-help.6314149.jp>

⁴⁴ See, e.g., http://blogs.nature.com/news/thegreatbeyond/2010/04/key_bushera_stem_cell_lines_wi_1.html

⁴⁵ See http://grants.nih.gov/stem_cells/registry/current.htm

A wealth of scientific papers published over the last few years document that **adult stem cells are a much more promising source of stem cells for regenerative medicine**. Some adult stem cells actually do show **pluripotent** flexibility in generation of tissues, meaning that they can generate most or all of the different tissues of the body. These include adult stem cells from various sources, including bone marrow,⁴⁶⁻⁴⁷⁻⁴⁸ peripheral blood,⁴⁹ inner ear,⁵⁰ umbilical cord blood,⁵¹⁻⁵² nasal mucosa,⁵³ amniotic fluid,⁵⁴⁻⁵⁵ and placental amniotic membrane.⁵⁶ As just one example, Wake Forest researchers found that amniotic fluid and placenta contains stem cells that can be easily harvested, show extended growth in culture, show similar flexibility to form other tissues of the body, and can be transplanted without tumors, emphasizes the range of abilities that adult and tissue stem cells possess.

Many references also show that adult stem cells can multiply in culture, retaining their ability to differentiate, and providing sufficient numbers of cells for clinical treatments. Two 2010 papers document factors that stimulate adult stem cells from bone marrow and cord blood to significant growth in numbers. The factor **pleiotrophin** significantly stimulated growth and expansion of bone marrow and cord blood adult stem cells, describing it as a “regenerative growth factor.”⁵⁷ And Boitano *et al.* discovered a factor they called StemRegenin1 (SR1)⁵⁸ that produces robust expansion of bone marrow and cord blood stem cells, what some experts labeled the “holy grail” of hematopoietic transplant medicine.⁵⁹

46 Jiang Y *et al.*; “Pluripotency of mesenchymal stem cells derived from adult marrow”; *Nature* 418, 41-49; 4 July 2002

47 D’Ippolito G *et al.*, “Marrow-isolated adult multilineage inducible (MIAMI) cells, a unique population of postnatal young and old human cells with extensive expansion and differentiation potential”, *J. Cell Science* 117, 2971-2981, 15 July 2004

48 Yoon Y-s *et al.*, “Clonally expanded novel multipotent stem cells from human bone marrow regenerate myocardium after myocardial infarction”, *Journal of Clinical Investigation* 115, 326-338, February 2005

49 Zhao Y *et al.*; “A human peripheral blood monocyte-derived subset acts as pluripotent stem cells”; *Proceedings of the National Academy of Sciences USA* 100, 2426-2431; 4 March 2003

50 Li H *et al.*, “Pluripotent stem cells from the adult mouse inner ear”, *Nature Medicine* 9, 1293-1299, October 2003

51 Kögler G *et al.*, “A new human somatic stem cell from placental cord blood with intrinsic pluripotent differentiation potential”, *J. Experimental Medicine* 200, 123-135, 19 July 2004

52 McGuckin CP *et al.*, Production of stem cells with embryonic characteristics from human umbilical cord blood, *Cell Proliferation* 38, 245-255, August 2005

53 Murrell W *et al.*, “Multipotent stem cells from adult olfactory mucosa”, *Developmental Dynamics* published online 21 March 2005

54 Prusa A-R, Marton E, Rosner M, et al. Oct-4-expressing cells in human amniotic fluid: a new source for stem cell research? *Hum Reprod* 18, 1489-1493, 2003

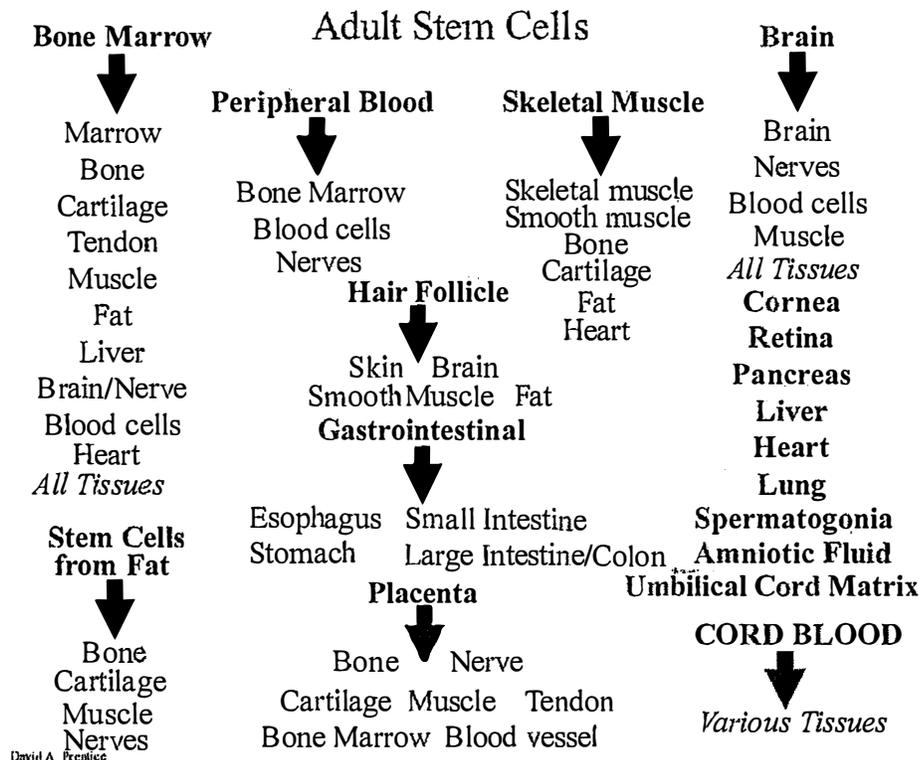
55 De Coppi *et al.*, Isolation of amniotic stem cell lines with potential for therapy, *Nature Biotechnology* published online 7 January 2007; doi:10.1038/nbt1274

56 Miki T *et al.*, Stem cell characteristics of amniotic epithelial cells, *Stem Cells* published online 4 Aug 2005; doi:10.1634/stemcells.004-0357

57 Himburg HA *et al.*, Pleiotrophin regulates the expansion and regeneration of hematopoietic stem cells, *Nature Medicine* 16, 475-482, April 2010

58 Boitano AE *et al.*, Aryl Hydrocarbon Receptor Antagonists Promote the Expansion of Human Hematopoietic Stem Cells, *Science* 329, 1345-1348, 10 Sept 2010

59 Sauvageau G and Humphries RK, The Blood Stem Cell Holy Grail?, *Science* 329, 1291-1292, 10 Sept 2010



The chart shows examples (not all-inclusive) of tissues from which adult stem cells have been isolated, as well as some of the derivatives from those stem cells. Many references also show that adult stem cells can multiply in culture, retaining their ability to differentiate, and providing sufficient numbers of cells for clinical treatments. Adult stem cells have been shown to be effective in treating animal models of disease, including such diseases as diabetes,⁶⁰ stroke,⁶¹ spinal cord injury,⁶² Parkinson's disease,⁶³ and retinal degeneration.⁶⁴

- ⁶⁰ Oh S-H *et al.*, "Adult bone marrow-derived cells transdifferentiating into insulin-producing cells for the treatment of type I diabetes," *Laboratory Investigation* published online 22 March 2004; Kodama S *et al.*, "Islet regeneration during the reversal of autoimmune diabetes in NOD mice", *Science* 302, 1223-1227; 14 Nov 2003; Hess D *et al.*, "Bone marrow-derived stem cells initiate pancreatic regeneration", *Nature Biotechnology* 21, 763-770; July 2003
- ⁶¹ Willing AE *et al.*, "Mobilized peripheral blood stem cells administered intravenously produce functional recovery in stroke", *Cell Transplantation* 12, 449-454; 2003; Arvidsson A *et al.*, "Neuronal replacement from endogenous precursors in the adult brain after stroke"; *Nature Medicine* 8, 963-970; Sept 2002; Riess P *et al.*, "Transplanted neural stem cells survive, differentiate, and improve neurological motor function after experimental traumatic brain injury"; *Neurosurgery* 51, 1043-1052; Oct 2002
- ⁶² Hofstetter CP *et al.*, "Marrow stromal cells form guiding strands in the injured spinal cord and promote recovery", *Proc Natl Acad Sci USA* 99, 2199-2204; 19 February 2002; Sasaki M *et al.*, "Transplantation of an acutely isolated bone marrow fraction repairs demyelinated adult rat spinal cord axons," *Glia* 35, 26-34; July 2001; Ramón-Cueto A *et al.*, "Functional recovery of paraplegic rats and motor axon regeneration in their spinal cords by olfactory ensheathing glia," *Neuron* 25, 425-435; February 2000
- ⁶³ Liker MA *et al.*, "Human neural stem cell transplantation in the MPTP-lesioned mouse"; *Brain Research* 971, 168-177; May 2003; Åkerud P *et al.*, "Persephin-overexpressing neural stem cells regulate the function of nigral dopaminergic neurons and prevent their degeneration in a model of Parkinson's disease"; *Molecular and Cellular Neuroscience* 21, 205-222; Nov 2002; Ourednik J *et al.*, "Neural stem cells display an inherent mechanism for rescuing dysfunctional neurons"; *Nature Biotechnology* 20, 1103-1110; Nov 2002
- ⁶⁴ Otani A *et al.*, "Rescue of retinal degeneration by intravitreally injected adult bone marrow-derived lineage-negative hematopoietic stem cells", *J. Clinical Investigation* 114, 765-774, September 2004; Otani A *et al.*, "Bone marrow derived stem

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But of even greater significance, **adult stem cells are already being used clinically to treat many diseases in human patients.** These include published results with patients, using adult stem cells as reparative treatments with various cancers, autoimmune diseases including multiple sclerosis, lupus, juvenile diabetes and arthritis, anemias including sickle cell anemia, and immunodeficiencies. Adult stem cells are also being used to treat patients by formation of cartilage, growing new corneas to restore sight to blind patients, treatments for stroke, and several groups are using adult stem cells with patients to repair damage after heart attacks. Early clinical trials have shown initial success in patient treatments for Parkinson’s disease⁶⁵ and spinal cord injury (for a list of some conditions already treated in human patients by adult stem cells and cord blood stem cells, please see <http://www.stemcellresearch.org/facts/treatments.htm>). An advantage of using adult stem cells is that in many cases the patient’s own stem cells can be used for the treatment, circumventing the problems of immune rejection, and without tumor formation. The citations given above for adult stem cells are only a sampling, including some more recent references. Other listings can be found in the 2004 President’s Council Report⁶⁶ and in a January 2006 review in the *Journal of Investigative Medicine*.⁶⁷

In terms of *setting the record straight*, the complete and accurate record from peer-reviewed publications shows that adult stem cells have already successfully improved patient health. A completely-referenced defense of the use of adult stem cells for treatments that improve patient health has been published by the journal *Science*. This information has been validated by several other peer-reviewed papers documenting improvement in patient health after adult stem cell treatment, including a paper published February 26, 2008 in the *Journal of the American Medical Association* reviewing 10 years of 69 published patient trials that document the benefit to patient health of adult stem cells for autoimmune conditions such as multiple sclerosis, juvenile diabetes, systemic lupus, and Crohn’s disease, as well as acute and chronic heart damage and peripheral vascular disease.⁶⁸

Peripheral artery disease has now been treated successfully in a number of patients, restoring circulation to limbs and preventing amputation.⁶⁹

Other recent peer-reviewed publications document patient improvement with adult stem cells in treatment of spinal cord injury,⁷⁰ multiple sclerosis,⁷¹ as well as type I (juvenile) diabetes⁷² and type II diabetes,⁷³ as

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cells target retinal astrocytes and can promote or inhibit retinal angiogenesis”; *Nature Medicine* 8, 1004-1010; Sept 2002; Tomita M *et al.*, “Bone marrow derived stem cells can differentiate into retinal cells in injured rat retina”; *Stem Cells* 20, 279-283; 2002

⁶⁵ Levesque MF *et al.*, Therapeutic Microinjection of Autologous Adult Human Neural Stem Cells and Differentiated Neurons for Parkinson’s Disease: Five-Year Post-Operative Outcome, *Bentham Open Stem Cell Journal* 1, 20-29, 2009; doi: 10.2174/1876893800901010020

⁶⁶ Prentice, D, “Adult Stem Cells.” Appendix K in *Monitoring Stem Cell Research: A Report of the President's Council on Bioethics*, 309-346. Washington, D.C.: Government Printing Office, 2004

⁶⁷ Prentice DA, “Current Science of Regenerative Medicine with Stem Cells”, *J. Investigative Medicine* 54, 33-37, January 2006

⁶⁸ Burt RK *et al.*, Clinical applications of blood-derived and marrow-derived stem cells for nonmalignant diseases, *Journal of the American Medical Association* 299, 925-936, 27 February 2008

⁶⁹ See, e.g., Burt RK *et al.*, Autologous peripheral blood CD133⁺ cell implantation for limb salvage in patients with critical limb ischemia, *Bone Marrow Transplantation* 45, 111-116, 2010, published online 18 May 2009; Amann B *et al.*, Autologous Bone Marrow Cell Transplantation Increases Leg Perfusion and Reduces Amputations in Patients With Advanced Critical Limb Ischemia Due to Peripheral Artery Disease, *Cell Transplantation* 18, 371-380, 2009

⁷⁰ Lima C *et al.*, Olfactory Mucosal Autografts and Rehabilitation for Chronic Traumatic Spinal Cord Injury, *Neurorehabilitation and Neural Repair* 24, 10-22, 2010, published on 30 September; Mackay-Sim A *et al.*, Autologous

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well as end-stage liver disease.⁷⁴ Adult stem cells have also shown documented success at treating chronic heart failure in 191 patients,⁷⁵ and restoring sight to blind patients with corneal blindness, even after 50 years of blindness.⁷⁶

Tissue engineering using the patient’s own adult stem cells has been used successfully in the production of a new trachea or windpipe;⁷⁷ the group reports unpublished results that they have improved the technique using *in vivo* regeneration of tissue, successfully treating three more patients, including two patients with tracheal cancer.⁷⁸ A different group has constructed functional urethras for patients.⁷⁹

In another first, Adult stem cells have been used successfully to treat children with a deadly skin disease known as recessive dystrophic epidermolysis bullosa (RDEB; one of the most severe forms of epidermolysis bullosa, a set of genetic skin diseases.) EB affects the skin and lining of the mouth and esophagus, causing skin to blister and scrape off with the slightest friction. The blistering, peeling skin also leads to recurrent infections, and an aggressive form of skin cancer. Most children with EB do not live past their 20's. Previously, there was no treatment and it was considered incurable. Wagner and colleagues published results in the *New England Journal of Medicine* showing effective treatment of EB using donor

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olfactory ensheathing cell transplantation in human paraplegia: a 3-year clinical trial, *Brain* 131, 2376, September 2008; Lima C *et al.*, Olfactory Mucosa Autografts in Human Spinal Cord Injury: A Pilot Clinical Study, *Spinal Cord Medicine* 29, 191, July 2006

⁷¹ Fassas A *et al.*, Long-term results of stem cell transplantation for MS, *Neurology* 76, 1066-1070, 2011; Rice CM *et al.*, Safety and Feasibility of Autologous Bone Marrow Cellular Therapy in Relapsing-Progressive Multiple Sclerosis, *Clinical Pharmacology & Therapeutics* 87, 679-685, June 2010, published online 5 May 2010, doi:10.1038/clpt.2010.44; Burt RK *et al.*, Autologous non-myeloablative haemopoietic stem cell transplantation in relapsing-remitting multiple sclerosis: a phase I/II study, *Lancet Neurology* 8, 244, March 2009

⁷² Voltarelli JC and Couri CEB, Stem cell transplantation for type 1 diabetes mellitus, *Diabetology & Metabolic Syndrome* 1, 4, 2009; doi:10.1186/1758-5996-1-4; Couri CEB *et al.*, C-Peptide Levels and Insulin Independence Following Autologous Nonmyeloablative Hematopoietic Stem Cell Transplantation in Newly Diagnosed Type 1 Diabetes Mellitus, *JAMA* 301, 1573-1579, 2009; Voltarelli JC *et al.*, Autologous Nonmyeloablative Hematopoietic Stem Cell Transplantation in Newly Diagnosed Type 1 Diabetes Mellitus, *JAMA* 297, 1568-1576, 2007

⁷³ Bhansali A *et al.*, Efficacy of Autologous Bone Marrow-Derived Stem Cell Transplantation in Patients With Type 2 Diabetes Mellitus, *Stem Cells and Development* 18, 1407-1415, 2009

⁷⁴ Salama H *et al.*, Autologous Hematopoietic Stem Cell Transplantation in 48 Patients With End-Stage Chronic Liver Diseases, *Cell Transplantation* 19, 1475-1486, 2010

⁷⁵ Strauer B-E, *et al.*, The acute and long-term effects of intracoronary Stem cell Transplantation in 191 patients with chronic heart failure: the STAR-heart study; *Eur. J. Heart Failure* 12, 721-729, 2010

⁷⁶ Rama P *et al.*, Limbal Stem-Cell Therapy and Long-Term Corneal Regeneration, *New England Journal of Medicine* 363, 147-155, 2010

⁷⁷ Macchiarini P *et al.*, Clinical transplantation of a tissue-engineered airway, *Lancet* 372, 2023, December 2008

⁷⁸ UCL surgeons perform revolutionary transplant operation, 19 March 2010, <http://www.ucl.ac.uk/news/news-articles/1003/10031903>; Transplant advance in windpipe cancer, <http://www.physorg.com/news199887055.html>; Bader A and Macchiarini P, Moving towards in situ tracheal regeneration: the bionic tissue engineered transplantation approach, *Journal of Cellular and Molecular Medicine* 14, 1877-1889, July 2010

⁷⁹ Raya-Rivera A *et al.*, Tissue-engineered autologous urethras for patients who need reconstruction: an observational study, *The Lancet* 377, 1175-1182, 2011

adult stem cells.⁸⁰ One of the interesting aspects of this treatment is that it documents that bone marrow adult stem cells can travel to sites of injured skin, increasing production of collagen for these patients.

A 2010 article in the *Journal of the American Medical Association* provides a global perspective on adult stem cell transplants.⁸¹ Researchers looked at how many adult stem cell transplants were taking place in various parts of the world. This particular study looked only at hematopoietic stem cell transplants, *i.e.*, transplants of blood-forming cells, obtained from bone marrow, peripheral blood, and umbilical cord blood; and did not survey uses of other adult stem cell types, such as mesenchymal, adipose-derived, or nasal adult stem cells. The published report found that in 2006, a total of 50,417 transplants were performed worldwide using these adult stem cells. Of that total, 57% used the patient's own adult stem cells, and 43% used donor adult stem cells. Almost half (48%) took place in Europe, followed by the Americas (36%), Asia (14%), and the Eastern Mediterranean and Africa (2%). They note that adult stem cell transplants have become **"the standard of care for many patients"** with blood disorders and malignancies, though they are starting to be used for other conditions including autoimmune disorders and heart disease. They also note that their study **"demonstrates that it is an accepted therapy worldwide"**.

There are currently over 2,600 ongoing or completed FDA-approved clinical trials using adult stem cells.⁸²

Some have criticized legislation such as this, claiming that it would preclude stem cell research, or specifically embryonic stem cell research, or even that it would prohibit commonly used animal tests for pluripotent stem cells. Nothing could be further from the truth. The technique used involves injection of stem cells into immunocompromised mice; pluripotent stem cells form a tumor (called a teratoma) within the mouse, potential data for their ability to form different tissue types. This test is done by injecting the cells into born mice, not mouse embryos.

It has also been hypothesized that patients who might receive injections of stem cells from their clones created and destroyed outside of the state would be at risk of arrest upon entering the state if this bill passes. This interpretation is based on a naïve or willful misreading of the bill. Cells incorporated into a patient's body would not be covered by the bill, just as a patient who eats a hamburger in the U.K. would not be arrested at the state line for transporting hazardous meat that might contain mad cow disease, or who eats sprouts in Germany would not be arrested for potential transport of hazardous microbes.

Internationally, most countries have moved to ban all human cloning, including countries such as France (7 years in jail), Germany (5 years in jail), Canada (5 years in jail), and in March 2005 even the United Nations passed a declaration against all human cloning.

This bill only bans production of cloned human embryos and production of human-animal hybrids. It does not address embryonic stem cell research, nor any stem cell research. No stem cell research is prohibited by this bill, whether embryonic, iPS, adult, cord blood stem cells. This bill does not restrict any vital or

⁸⁰ Researchers Use Stem Cells to Treat Children with Life-Threatening, Blistering Skin Disease, August 12, 2010, <http://www.ahc.umn.edu/media/releases/ebtreatment/index.htm>; Wagner JE *et al.*, Bone Marrow Transplantation for Recessive Dystrophic Epidermolysis Bullosa, *New England Journal of Medicine* 363, 629-639, August 12, 2010

⁸¹ Gratwohl A *et al.*, Hematopoietic stem cell transplantation, *JAMA* 303, 1617-1624, 2010

⁸² Search term: <http://www.clinicaltrials.gov/ct2/results?term=adult+stem+cell+transplants&type=Intr> accessed Jan 27, 2013.

viable medical research. Cloning and nuclear transfer techniques for production of DNA, other molecules, cells other than human embryos, tissues, organs, plants, and animals are all allowed.

There are no valid or compelling grounds ethical, scientific, or medical to allow creation of human embryos for any purpose other than pregnancy, nor produced by any method other than fertilizing a human egg with a human sperm.

Another area addressed in this bill is a limit on the number of human embryos created by fertilization each cycle for purposes of attempting to achieve a pregnancy. There are no limits currently in the United States or in any individual state. We saw the abuse of this practice with the “Octamom” case in California, where six embryos were implanted in the womb, resulting in a multiple birth of 8 babies.

While fertility groups in the U.S. have guidelines for clinics to follow, the CDC notes that 80% of clinics do not follow these guidelines. Other countries including the U.K., Germany, and Italy have addressed this issue legislatively, but not the U.S.

Germany in fact, since 1990, has in place its Embryo Protection Law that makes it against the law to destroy any human embryos (Embryo Protection Law), and prohibits embryo freezing for storage. The language of this bill under consideration mirrors the German Embryo Protection Act. While some have claimed that the protections in this bill and the German law are overly restrictive, a recent 10-year study found that the German success rate for live births showed “internationally comparable levels.”⁸³ Thus, the German experience has shown as good a level of success at live birth of babies as countries such as the U.S. where multiple embryos are created and destroyed in a quality-control manufacturing process.

The German experience as well as that of other countries also shows that transferring low numbers of embryos, including single-embryo transfer, rather than mass production of embryos and transfer of multiple embryos to the woman, is healthier for both mothers and babies.^{84,85,86}

The U.K., in fact, has begun to consider moving to even lower numbers of embryos. Studies have indeed shown that using better techniques, implanting just one embryo can give just as good results for pregnancies as implanting more embryos. The lower numbers make it safer for the mother as well as for the children, and decrease the incidences of multiple births and attendant health risks.⁸⁷

Ovarian Hyperstimulation Syndrome (OHSS) can be a significant complication associated with the usual hormonal treatments to harvest large numbers of eggs for IVF.

⁸³ Gnoth C et al., Final ART success rates: a 10 years survey, Hum. Reprod. 26, 2239-2246, 2011
⁸⁴ Ludwig M et al., Experience with the elective transfer of two embryos under the conditions of the German embryo protection law: results of a retrospective data analysis of 2573 transfer cycles, Hum. Rep. 15, 319-324, 2000
⁸⁵ Sunderam S et al, Assisted Reproductive Technology Surveillance — United States, 2009, Morbidity and Mortality Weekly Surveillance Summaries Vol. 61, No. 7, Nov 2, 2012
⁸⁶ Engmann L et al., Outcome of in vitro fertilization treatment in patients who electively inseminate a limited number of oocytes to avoid creating surplus human embryos for cryopreservation, Fertil Steril 84, 1406-1410, 2005
⁸⁷ Klemetti R et al., Health of Children Born as a Result of In Vitro Fertilization, Pediatrics 118, 1819-1827, 2006

“Between 0.3 and 5% or up to 10% of women who undergo ovarian stimulation to procure oocytes experience severe ovarian hyperstimulation syndrome, which can cause pain, and occasionally leads to hospitalization, renal failure, potential future infertility, and even death.”⁸⁸

Thus, use of no-stimulation (natural cycle) or low-stimulation cycles, as well as single-embryo transfer, would significantly improve health of mothers as well as babies.⁸⁹ The IVF industry in this case would be going back to its roots, as the very first IVF baby, Louis Brown in 1978, was a result of one egg fertilized, one embryo transfer.

At some points the IVF industry has attempted to re-define basic biological terms to further incorrect perceptions about basic human development, and thereby alter attitudes of patients and the public. For example, in previous years the term “pre-embryo” was coined for very early embryos, prior to the stage of implantation in the uterus. Lee Silver, a Princeton biologist, wrote about this in his book, noting:

“I’ll let you in on a secret. The term pre-embryo has been embraced wholeheartedly by IVF [in-vitro fertilization] practitioners for reasons that are political, not scientific. The new term is used to provide the illusion that there is something profoundly different between what we nonmedical biologists still call a six-day-old embryo and what we and everyone else call a sixteen-day-old embryo.

“The term pre-embryo is useful in the political arena where decisions are made about whether to allow early embryo (now called pre-embryo) experimentation...”⁹⁰

One of the leading embryology texts notes this inappropriate use of the term as well:

“The term 'pre-embryo' is not used here for the following reasons: (1) it is ill-defined because it is said to end with the appearance of the primitive streak or to include neurulation; (2) it is inaccurate because purely embryonic cells can already be distinguished after a few days, as can also the embryonic (not pre-embryonic!) disc; (3) it is unjustified because the accepted meaning of the word embryo includes all of the first 8 weeks; (4) it is equivocal because it may convey the erroneous idea that a new human organism is formed at only some considerable time after fertilization; and (5) it was introduced in 1986 'largely for public policy reasons' (Biggers). ... Just as postnatal age begins at birth, prenatal age begins at fertilization.”⁹¹

This bill would provide necessary, distinct protections for human embryos.

Thank you for the opportunity to contribute to the debate on this important issue.

⁸⁸ Magnus D and Cho M, “Issues in Oocyte Donation for Stem Cell Research,” *Science* 308, 1747-1748, 17 June 2005

⁸⁹ Pelinck MJ et al., Cumulative pregnancy rates after three cycles of minimal stimulation IVF and results according to subfertility diagnosis: a multicentre cohort study, *Hum. Rep.* 21, 2375–2383, 2006

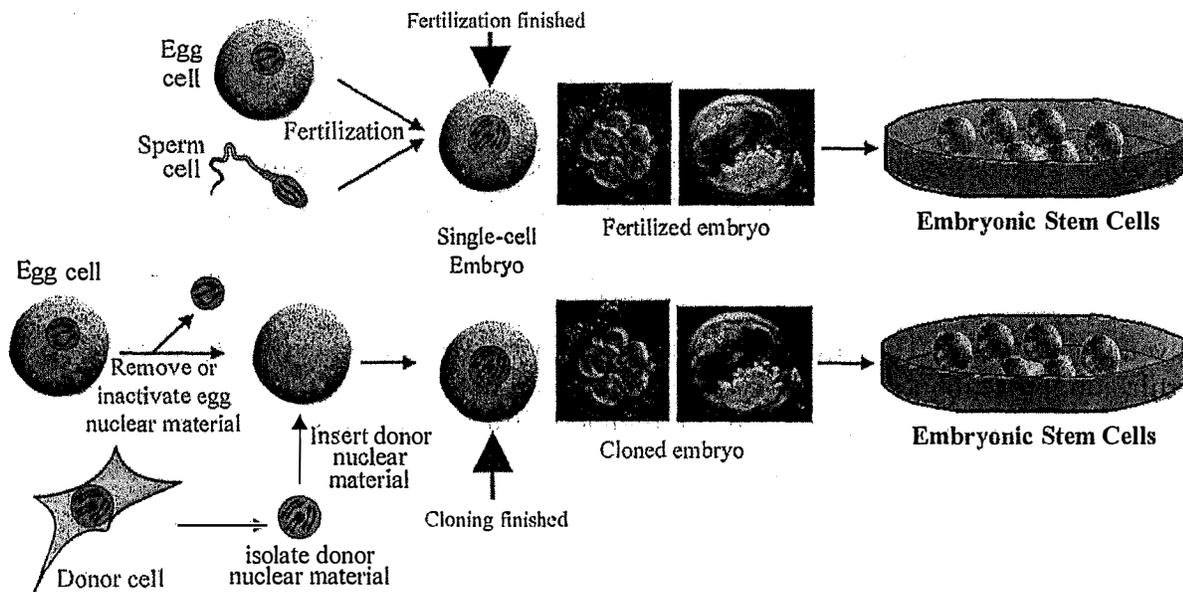
⁹⁰ Lee Silver, *Remaking Eden: Cloning and Beyond in a Brave New World* (New York: Avon Books, 1997), p. 39

⁹¹ Ronan O’Rahilly and Faiola Muller, *Human Embryology & Teratology* (3rd ed.)(New York: Wiley-Liss, 2001), p.88

DIFFERENT TYPES OF STEM CELLS

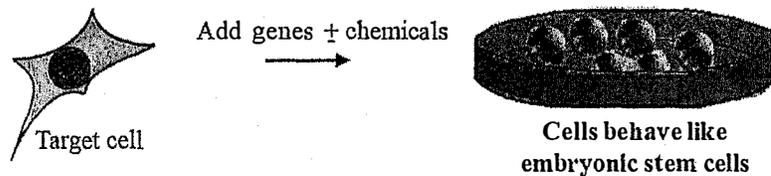
Embryonic Stem Cells

from Embryos created by Fertilization or by Cloning (Somatic Cell Nuclear Transfer)



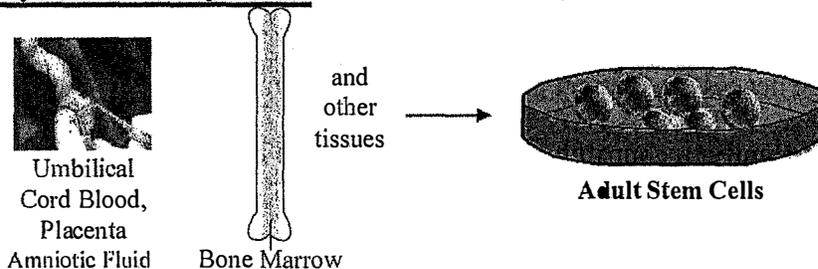
Induced Pluripotent Stem Cells (iPS cells)

from Normal Cells that are Reprogrammed to behave like Embryonic Stem Cells

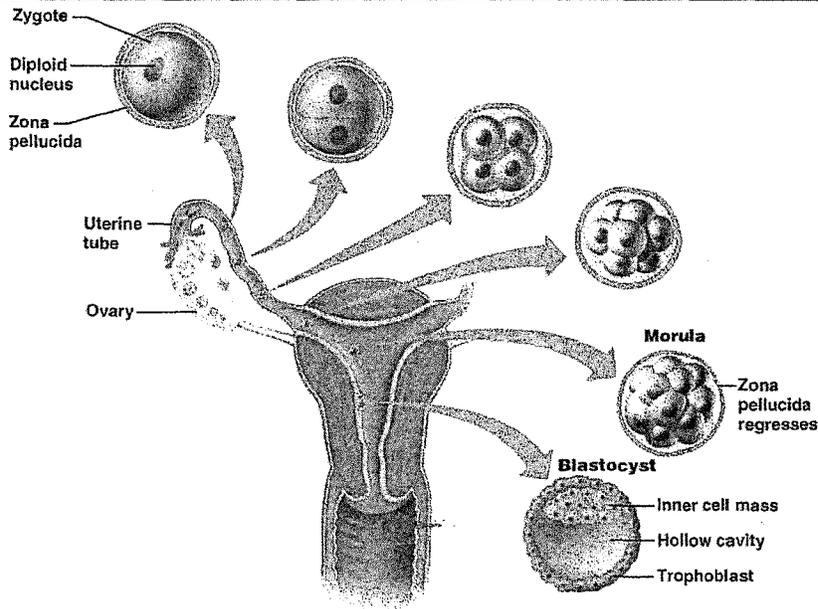


Adult Stem Cells

Stem Cells normally found in body tissues from birth onward, as well as umbilical cord, etc.



NORMAL FERTILIZATION and EMBRYO DEVELOPMENT

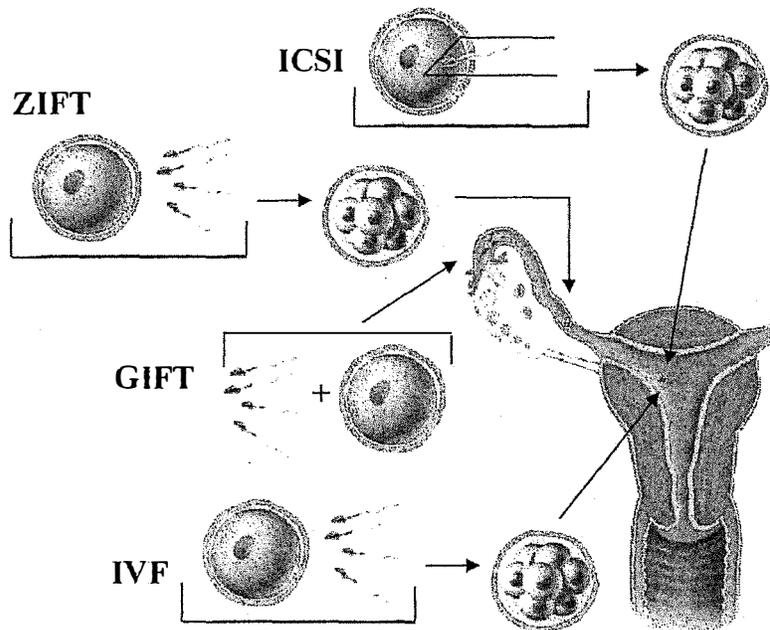


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VARIATIONS OF ASSISTED REPRODUCTIVE TECHNOLOGY

Differences in where fertilization or embryo transfer occurs

- IVF In Vitro Fertilization. Fertilization and maturation in lab, transfer to uterus
- ZIFT Zygote Intra-Fallopian Transfer. Fertilization & maturation in lab, transfer to fallopian tube
- GIFT Gamete Intra-Fallopian Transfer. Fertilization & maturation in fallopian tube, after transfer there
- ICSI IntraCyttoplasmic Sperm Injection. Artificial fertilization, maturation in lab, transfer to uterus



Sixty-Third Legislative Assembly of North Dakota
Senate Judiciary Committee
Testimony of Anna Higgins, J.D.
Director of the Center for Human Dignity, Family Research Council
January 29, 2013

Mr. Chairman and honorable members of the committee, thank you for giving me the opportunity to testify before you today about the critical human rights issue of abortion.

My name is Anna Higgins. I am the Director of the Center for Human Dignity at the Family Research Council, a Christian public policy organization that since 1983 has promoted and defended human life, religious liberty and family values in the United States. We represent more than 1.5 million people from Evangelical, Catholic, and other Christian denominations around the country. I speak today as a representative of Americans who oppose the destruction of human life in the womb. Fundamentally, we believe that life begins at conception and that this life is worthy of respect and equality under the law. We also believe that abortion is incredibly harmful to women, physically and psychologically.

The purpose of this testimony is not to take a political position, rather it is meant to highlight the humanity of the unborn and the detrimental effects of abortion. This testimony will highlight four important points:

- 1) The humanity of the unborn,
- 2) fetal development,
- 3) fetal pain capability, and
- 4) health concerns facing women who have abortions.

Humanity of the Unborn:

The denial of basic human rights of the unborn has become an indefensible position. It is undisputable that an unborn child is a unique person from conception to birth. It is a foundational principle of western thought that life is a fundamental right given to all men by their Creator. It was this principle that guided our founding fathers to declare in our country's first foundational document, that all men are created equal and endowed by their Creator with unalienable rights, among which, predominant is the right to life. Liberty and the pursuit of happiness are of no consequence unless a person is first afforded the most fundamental of all rights, life. As Thomas Jefferson noted, "The God that gave us life, gave us liberty at the same time."¹

Previous to *Roe v. Wade*, the most egregious violation of civil rights handed down by the Supreme Court was *Dred Scott v. Sandford* in which the Court determined that a slave was not a

¹ Thomas Jefferson, *A Summary View of the Rights of British America*, 1774: 135.

person but rather property. This decision was rectified by the 14th amendment which guaranteed due process to all persons. The 14th amendment is violated by the act of abortion.

Abortion denies a unique human being the right to due process and equal protection under the law. Either an unborn child is a person or he is property. If he is a person, as has been determined conclusively by scientific evidence, it is incumbent upon the government, which is instituted to secure our inalienable rights, to protect every person's fundamental right to life in all circumstances.

Protecting all human life from the moment of conception until natural death is not and should not be limited to the narrow practice of abortion. Equality under the law demands that every human being is protected under laws meant for such protective purposes. If the unborn child is truly a unique human being, which we now know to be medically accurate, then protection should be afforded the unborn, regardless of viability, in areas such as homicide statutes, wrongful death, and chemical endangerment of a child. In Alabama, for example, the Alabama Declaration of Rights, the state constitutional provision that establishes inalienable rights for all persons (Ala. Const. 1901, § 1), mirroring the language of the U.S. Declaration of Independence, was cited as a reason to support the applicability of the homicide statute as well as the wrongful death statute to the unborn regardless of viability. The Alabama Supreme Court noted that those words, "affirm that each person has a God-given right to life." (Hamilton v. Scott, October term, 2011-2012, footnote 3, p14).

As Abraham Lincoln said in reflection upon the Declaration of Independence, "nothing stamped with the divine image and likeness was sent into the world to be trodden on and degraded..."² All persons are so stamped from the moment conception.

Whereas after birth, a person is protected from discrimination based on gender, race, and disability, legal abortion and the denial of basic protections to human beings at very early stages of development asks us to discriminate against a person based on his age and development. This position is incompatible with a Constitution and a society that places such high value on the rights of an individual. It is particularly troubling to deny these rights to those persons who do not have a way to speak for themselves but rather rely on those in power for protection.

As President Obama recently reminded us, "This is our first task, caring for our children. It's our first job. If we don't get that right, we don't get anything right. That's how, as a society, we will be judged." Knowing what we now know about the development of the unborn and dangers of abortion, are we honestly prepared to say that legal abortion the denial of the right to life for the unborn is an acceptable price to pay for our liberty?

² Abraham Lincoln, Lewistown, IL, Aug 17, 1858, Speech during Senate contest with Stephen Douglas.

Fetal Development:

When a human sperm penetrates the human egg, a zygote is formed. A zygote is the first cell formed at conception and has “a genetic composition that is absolutely unique to itself, different from any other human that has ever existed, including that of its mother (thus disproving the claim that what is involved in abortion is merely ‘a woman and her body’.”³ The DNA present at this point contains the entire design of the person and guides development of physical characteristics and personality.⁴

If the zygote were not a human being, but a mere collection of human cells, it would exhibit cellular life but it would not exhibit the “coordinated interactions directed toward a higher level of organization.”⁵

In fact, the zygote, upon formation, “acts immediately and decisively to initiate a program of development that will, if uninterrupted by accident, disease, or external intervention, proceed seamlessly through formation of the definitive body, birth, childhood, adolescence, maturity, and aging, ending with death. This coordinated behavior is the very hallmark of an organism.”⁶ The actual pregnancy begins at fertilization, not implantation as noted in the majority of medical dictionaries.⁷

About six days after fertilization, the embryo is implanted into the uterus and at about 22 days, blood is circulating and heartbeat can be detected on ultrasound. At six weeks after conception, a baby has electrical brain activity and eyes, eyelids, nose, mouth, and tongue are formed and at six to seven weeks electrical brain activity can be detected. By eight weeks, the baby, now called a fetus, has all the organs found in any newborn infant. By ten weeks the child can grasp, stretch and kick.⁸

³ Keith Moore and T.V.N Persaud, *The Developing Human: Clinically Oriented Embryology*, 6th ed (Philadelphia: W.B. Saunders Co., 1998): 77, 350.

⁴ Ibid.

⁵ Cathy Cleaver Ruse, Esq. and Rob Schwarzwald, *The Best Pro-Life Arguments for Secular Audiences*, Family Research Council (2011) <http://www.frc.org/brochure/the-best-pro-life-arguments-for-secular-audiences> : 4.

⁶ Maureen L. Condit, “When Does Human Life Begin? A Scientific Perspective,” *The Westchester Institute for Ethics and the Human Person, Westchester Institute White Paper Series* 1, no. 1 (October 2008): 7.

⁷ See Christopher M. Gacek, “Conceiving ‘Pregnancy’: U.S. Medical Dictionaries and Their Definitions of ‘Conception’ and ‘Pregnancy,’” *Insight*, Family Research Council (April 2009) accessed February 26, 2013, <http://downloads.frc.org/EF/EF09D12.pdf>.

⁸ Cathy Cleaver Ruse, Esq. and Rob Schwarzwald, *The Best Pro-Life Arguments for Secular Audiences*, Family Research Council <http://www.frc.org/brochure/the-best-pro-life-arguments-for-secular-audiences>: 7-8, and Ashley Morrow Fragoso, *Fetal Pain, Can Unborn Children Feel Pain in the Womb?* Family Research Council (2010) <http://downloads.frc.org/EF/EF10H06.pdf> : 1-3.

Fetal Pain:

The introduction of various forms of Unborn Fetal Pain Bills on both federal and state levels demonstrates the fact that the issue of fetal pain has become a major concern. Just as modern science has given us a glimpse into the womb; it has also revealed the fact that an unborn child can feel pain. The most common forms of abortion are now thought to cause excruciating pain for the unborn child and this pain can be felt as early as thirteen and a half weeks, although the consensus is that the unborn child can feel pain at least by 20 weeks.

Pain is “a perceptive response to potential or actual tissue damage.”⁹ Dr. Kanwaljeet S. Anand of the University of Arkansas for Medical Sciences and the Pain Neurobiology Laboratory at Arkansas Children’s Hospital Research Institute, testified that children of 20 weeks gestation (or even earlier) possess the ability to feel pain “and the pain perceived by a fetus is possibly more intense than that perceived by term newborns or older children.”¹⁰

Between seven and twelve weeks gestation the unborn child becomes sensitive to stimulation.¹¹ The thalamus and cortex have begun to develop, but nerve pathways have not yet connected the cortex with the lower part of the brain.¹² The brain stem is active at this point in development. At the beginning of the second trimester sensory receptors cover the body of the baby and the hippocampus becomes functional.¹³ At this point, babies respond to invasive procedures. “At 23 weeks, the nerves transport pain signals to the cortex are connected to the rest of the brain, and signals received through the thalamus can be processed in the cortex, allowing for a form of conscious perception...”¹⁴

In the article, “Fetal Pain and Abortion: The Medical Evidence,” Vincent J. Collins, M.D., Steven R. Zielinski, M.D., and Thomas J. Marzen, Esq. note, “The medical evidence plainly points to the existence of pain sensation in the human fetus, at least from the onset of the second trimester of pregnancy, and perhaps during the last weeks the first trimester. It indicates that at least three methods of abortion cause fetal pain.”¹⁵

“Induced abortion will cause pain to a fetus with a functioning nervous system if the method-used stimulates the pain receptors, excites the neural pathways, and the impulse reaches the thalamus. Dilatation and evacuation (D&E), abortion, abortion by saline amnio-infusion, and prostaglandin abortions are capable of stimulating pain receptors and exciting neural pathways.

⁹ Ashley Morrow Fragoso, *Ibid.*

¹⁰ *Ibid* at 4.

¹¹ Ashley Morrow Fragoso, *Fetal Pain, Can Unborn Children Feel Pain in the Womb?* Family Research Council (2010) <http://downloads.frc.org/EF/EF10H06.pdf> : 6.

¹² *Ibid.*

¹³ *Ibid* at 6-7.

¹⁴ *Ibid* at 7.

¹⁵ Vincent J. Collins, M.D., Steven R. Zielinski, M.D., Thomas J. Marzen, Esq., “Fetal Pain and Abortion: The Medical Evidence,” AMERICANS UNITED FOR LIFE, Legal Defense Fund Law and Medicine Series: 12)

These methods of abortion are employed during times in gestation when the fetus can sense pain. It must be concluded, therefore, that they cause pain to the fetus.”¹⁶

“We cannot measure the sum agony of these human beings. We can only know that it was real, hope that it was mercifully brief, and grieve because the ideology that so arrogantly asserts abortion as a “right” has subverted simple human compassion to such a degree that these young human beings continue to die with less concern for their pain that expressed for experimental rats.”¹⁷

There have been about 55 million legal abortions performed in the U.S. since 1973, many on pain-capable children. It is unimaginable that we would dismiss the possibility that these unborn children feel pain during abortion.

Additionally, approximately 92% of abortions are done for purely elective reasons – on healthy women and healthy children. Only 4% are performed for reasons of physical health of the mother and 3% for the health of the baby. About 0.5% of abortions are performed for reasons of rape or incest, another 0.5% in order to hide a pregnancy, and 1% due to pressure from family members.¹⁸

Women’s Health:

The myth that abortion is good for women has slowly been exposed and dispelled by personal experience and medical science. Negative effects of abortion on women range from physical complications like infection, perforations and hemorrhage to serious psychological harm, such as depression, anxiety and even suicide.

Physical Complications: Surgical abortion is a serious medical procedure and its complications should not be diminished.

The most recent CDC Abortion Sureveillance, United States, 2009, reported that there have been 403 deaths resulting from legal abortions since 1972.¹⁹ This number is undoubtedly a low estimate due to the fact that several states, including California, do not report abortion statistics to the CDC.

Premature birthrates following abortions range from 36% increase to as much as 60% increase in cases where women have more than one abortion.²⁰ Other international studies show pervious

¹⁶ Ibid at 10.

¹⁷ Ibid at 12.

¹⁸ Lawrence B. Finer, “Reasons U.S. Women Have Abortions: Quantitative and Qualitative Perspectives, Perspectives on Sexual Health 37, no. 5 (2005): 113-14.

¹⁹ Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, November 23, 2012, Surveillance Summaries, Vol. 61, No. 8, Table 25.

²⁰ Dr. Byron Calhoun, “Induced abortion linked to Preterm Delivery, ”Dec 10 ObGyn News p. 10.

abortions greatly increase the risk of premature birth.²¹ By 2008, at least 59 studies have demonstrated a statistically significant increase in premature birth or low birth weight risk in women with prior induced abortions.²²

Placenta Previa is one condition that has been found to be a significant risk factor for women who have had abortions.

“Placenta Previa is a condition in which the placenta has implanted abnormally low in the uterine cavity. In “partial placenta previa,” a segment of the placenta partially covers the opening to the cervical canal. In “complete placenta previa,” the placenta completely covers the opening to the cervical canal. Placenta previa can be potentially catastrophic to both mother and baby, as it carries the risk of unpredictable, sudden, severe hemorrhage, necessitating emergency C Section as life saving treatment. Very often this emergency occurs at a premature gestational age, increasing the risk for the baby’s favorable outcome. It can be appreciated that placenta previa is no small issue, whether for the patient, for her baby, or for her attending doctor. And it is increased significantly in pregnancies that follow an induced abortion.”²³

“Thorp (OB GYN Survey, Vol 58, No. 1, 2002) analyzed 3 studies, and found in women who had a previous induced abortion a 30% increase in placenta previa rates compared to women with no abortion history. Thorp also noted a meta-analysis by Anath et. al., which found a 70% increase in placenta previa rates in women with a previous abortion compared to women with no abortion history.”²⁴

Other complications include damage to the reproductive system including perforations, future infertility, later ectopic pregnancies or miscarriages, incomplete abortion/retained tissue.²⁵

Late term abortions are especially dangerous to women. A “‘Late-term abortion’ is an inexact medical term that has been used in reference to induced abortions in the 3rd trimester of pregnancy (28-39 weeks) and sometimes to 2nd trimester abortions (13-27 weeks).”²⁶

“According to Gaufberg, Professor of Medicine at Harvard University, post-abortion physical complications at various gestational points are primarily the result of incomplete evacuation of the uterus, uterine atony, infection, and instrumental injury. Specific complications of abortions include the following: (1) complications of anesthesia, (2) postabortion triad (pain, bleeding, low-grade fever), (3) hematometra, (4) retained products of conception, (5) uterine perforation,

²¹ nrlc.org; See also Caroline Moreau, et al, “Previous induced abortions and the risk of very preterm delivery: results of the EPIPAGE study,” British Journal of Obstetrics and Gynecology, Vol. 112 (April 2005): 430-437.

²² American Association of Pro-Life Obstetricians and Gynecologists, (<http://www.aaplog.org/complications-of-induced-abortion/induced-abortion-and-pre-term-birth/general-comments-on-the-increased-risk/>)

²³ American Association of Pro-Life Obstetricians and Gynecologists, (<http://www.aaplog.org/complications-of-induced-abortion/induced-abortion-and-placenta-previa/induced-abortion-and-subsequent-placenta-previa/>)

²⁴ Ibid.

²⁵ nrlc.org.

²⁶ wecareexperts.org, “Late-term Abortion: Antecedent Conditions and Consequences to Women’s Health,” <http://www.wecareexperts.org/sites/default/files/articles/Late-term%20abortion%20health%20consequences.pdf> : 1.

(6) bowel and bladder injury, (7) failed abortion, (8) septic abortion, (9) cervical shock, (10) cervical laceration, and (11) disseminated intravascular coagulation (DIC). At 12-13 weeks, the complication rate is 3-6%, and by well into the second trimester, the complication rate increases to 50%, and possibly higher according to Gaufberg.²⁷

Medical abortion can be even more dangerous than surgical abortion, often due to the fact that women are not necessarily under the care of a doctor when the abortion is performed. Complications from medical abortions range from undiagnosed ectopic pregnancy to significant blood loss and infection, often as a result of incomplete abortion.²⁸

In his comprehensive analysis of RU-486, Chris Gacek notes, “Medical abortions fail frequently, and they often produce serious hemorrhage and infection. For example, according to the April 2011 RU-486 Adverse Events Summary there were reports to FDA that 339 American women had blood loss significant enough to require transfusions. There were 256 reported cases of infection reported in the United States. Approximately 15-20 known deaths have been associated with the regimen worldwide, but this number is almost certainly quite low since our data does not include countries like China and India where the regimen’s use is heavy.”²⁹

Psychological Complications: At the time abortion was legalized not much was known about the psychological scars and risk of mental illness that affect women who have had abortion. Now, 40 years later, we know from the testimony of women themselves and from scientific and medical research that abortion does in fact carry significant psychological risk factors. Approximately 40% of women in the U.S. have had an abortion, which underscores the fact that the issue of mental health and psychological care for post-abortive women is an overwhelming issue that touches many lives and must be addressed with the serious consideration it deserves.³⁰

Previous abortions put a woman at an increased risk for a variety of mental health problems such as panic attacks, panic disorder, agoraphobia, PTSD, bipolar disorder, major depression with and without hierarchy, and substance abuse disorders.³¹

²⁷ Ibid at 2, also noting, “The U.S. mortality rates per 100,000 abortions as reported by Gaufberg are 14.0 for 16-20 weeks and 18.0 for after 21 weeks. Even more dramatic results for second and third trimester abortions were reported by Bartlett et al. using national U.S. data spanning the years from 1988 and 1997. Specifically, per 100,000 abortions, the relative risk of abortion-related mortality was 14.7 at 13–15 weeks of gestation, 29.5 at 16-20 weeks, and 76.6 at or after 21 weeks. Causes of death during the 2nd trimester as reported by Bartlett included hemorrhage, infection, embolism, anesthesia complications, and cardiac and cerebrovascular events.”

²⁸ See Chris Gacek, RU-486 (Mifepristone) Side-Effects 2000-2012, Family Research Council, May 2012 Issue Analysis.

²⁹ Ibid at 15.

³⁰ <http://www.thedailybeast.com/newsweek/blogs/the-human-condition/2010/03/04/about-40-percent-of-american-women-have-had-abortions-the-math-behind-the-stat.html>, See also, Martha Shuping, M.D. and Christopher Gacek, J.D., Ph.D., Post Abortion Suffering, A Psychiatrist Looks at the Effects of Abortion, Family Research Council (2010) <http://downloads.frc.org/EF/EF10B09.pdf>.

³¹ Coleman, P.K., Coyle, C.T., Shuping, M., & Rue, V. (2009), *Induced Abortion and Anxiety, Mood, and Substance Abuse Disorders: Isolating the Effects of Abortion in the National Comorbidity Survey*, Journal of Psychiatric Research, 43, 770–776.

Dr. Priscilla Coleman, author of one of the most comprehensive studies of the mental health risks after abortion notes that,

Overall, women with an abortion history experience an 81% increased risk for mental health problems. The results showed that the level of increased risk associated with abortion varies from 34% to 230% depending on the nature of the outcome. Separate effects were calculated based on the type of mental health outcome with the results revealing the following: the increased risk for anxiety disorders was 34%; for depression it was 37%; for alcohol use/abuse it was 110%, for marijuana use/abuse it was 220%, and for suicide behaviors it was 155%. When compared to unintended pregnancy delivered women had a 55% increased risk of experiencing any mental health problem. Finally, nearly 10% of the incidence of all mental health problems was shown to be directly attributable to abortion.³²

Suicidal behaviors and actions are also an increased risk for women who have had abortions. Suicidal thoughts and behavior are very serious issues and can have devastating impacts on entire families.³³

A few years ago, one young woman, Stacy Zaille, committed suicide after an abortion. Her family has since created a foundation “to facilitate the post-abortion well-being and happiness of women.”³⁴

Stacy’s parents have posted the following on the foundation website: “At age 20 our beautiful daughter, for reasons known only to her, underwent an abortion. She never revealed her situation or her solution to her family. Shortly after the abortion she asked for psychiatric help, she ended therapy after only 3 months. Not long after her 21st birthday, she took her own life. She is missed by all who knew and loved her. We are convinced that if Stacy had been better informed about what she might expect following the abortion (physically and/or emotionally) and if she had been able to share her grief in a safe, supportive environment, she would be with us today.”³⁵

This is not an isolated incident. For more stories from real women who have experienced pain associated with abortion, visit <http://www.abortionchangesyou.com/explore?exploreArtFilter=all> and Operation Outcry, <http://www.operationoutcry.com/?Page=personal>, an organization that “seeks to end the pain of abortion in America and around the world by mobilizing women and men hurt by abortion who share their true stories of the devastating effects of abortion.”

³² Coleman, P.K. (Sept. 2011) “Abortion and Mental Health: A Quantitative Synthesis and Analysis of Research Published from 1995-2009, *British Journal of Psychiatry*.”

³³ See *Induced Abortion and Maternal Suicide*, *THE AMERICAN ASSOCIATION OF PROLIFE OBSTETRICIANS AND GYNECOLOGISTS ABORTION AND SUICIDE SUICIDE ATTEMPTS ASSOCIATED WITH INDUCED ABORTION*, References: Garfinkle, B., et. al., “Stress, Depression, and Suicide: A study of Adolescents in Minnesota” (Minneapolis: Univ Minnesota Extension Service, 1986): <http://www.aaplog.org/complications-of-induced-abortion/induced-abortion-and-maternal-mortality/induced-abortion-and-maternal-suicide/>.

³⁴ <http://www.stacyzaille.org/>.

³⁵ Ibid.

Many women face devastating guilt, regret, stress and depression following an abortion. As a former crisis pregnancy counselor who has met with hundreds of women in crisis pregnancies, I can testify first hand that abortion is not the “cure” for an unwanted pregnancy; rather it is an additional trauma that a women must carry with her for the remainder of her life. This problem must be mitigated.

The 8th Circuit recently acknowledged the devastating impact that abortion has on women in *Planned Parenthood v. Rounds*, July 24, 2012 which involved a dispute over a South Dakota statute that required disclosure to patients seeking abortion of an increased risk of suicide.³⁶ The 8th Circuit court upheld the statute, noting,

Based on the record, the studies submitted by the State are sufficiently reliable to support the truth of the proposition that the relative risk of suicide and suicide ideation is higher for women who abort their pregnancies compared to women who give birth or have not become pregnant. It also is worth noting that Planned Parenthood does not challenge the disclosure that “[d]epression and related psychological distress” is a “known medical risk[] of the [abortion] procedure.” S.D.C.L. § 34-23A-10.1(1)(e)(i); *see also Gonzales v. Carhart*, 550 U.S. 124, 159 (2007) (noting that “[s]evere depression and loss of esteem can follow” an abortion). As a matter of common sense, the onset of depression and psychological distress also would increase one’s risk of suicide and suicide ideation. *See, e.g.,* Ottar Bjerkeset et al., *Gender Differences in the Association of Mixed Anxiety and Depression with Suicide*, 192 *Brit. J. Psychiatry* 474, 474 (2008) (“Depression is thought to be the most important antecedent of suicide . . .”). Thus, there appears to be little dispute about the truthfulness of the required disclosure.”³⁷

Conclusion:

A decision by a Court cannot confer moral legitimacy on any choice. In the case of the abortion, time, science, and personal testimony have revealed devastating consequences on both the unborn child, who loses his life, and the woman who faces possible physical complications and severe psychological issues. All of these problems can be completely mitigated by recognizing the right to life of the unborn and outlawing abortion as an option except in medical emergencies where it is required to save the life of the mother. Additionally, the humanity of the unborn child as evidenced by medical science demands a response that upholds the protection for all life, born and pre-born, under the law.

Any law that denies the humanity of the unborn violates the very foundational ideals upon which this country was formed. Life is not a right that is given by man, thus, neither can it be taken away by man. As long as we protect the act of abortion under the law, we teach the citizens of our country and the world that only certain persons are worthy of being a part of society. It is imperative that we end this arbitrary discrimination against unborn children.

³⁶ <http://www.ca8.uscourts.gov/opndir/12/07/093231P.pdf>.

³⁷ *Ibid* at 14.

The North Dakota Right to Life Act SB 2302
Testimony of Gualberto Garcia Jones, J.D.

SB 2302 begins to describe what a North Dakota Century Code that protects the inalienable right to life would look like.

SB 2302 is a trigger bill, which means that it will not come into force until and if a Personhood Amendment is passed.

The effective date clause states that:

“This Act is effective on the date the secretary of state certifies to the legislative council that a constitutional amendment recognizing the inalienable right to life of every human being at any stage of development has been approved by a majority of the voters in a statewide election.”

Since the early stages of the pro-life movement, the protection of the personhood of the preborn has been the key. Justice Blackmun wrote that “if this suggestion of personhood is established, the appellant’s case, of course, collapses, for the fetus’ right to life would then be guaranteed specifically by the Amendment.”

We understand that a state can’t define what personhood means under the 14th amendment, but a state can challenge Roe V. Wade’s act of supreme judicial tyranny.

This view is in keeping with Supreme Court Justice Antonin Scalia’s observations in his Dissent in Stenberg v. Carhart when he wrote “if only for the sake of its own preservation, the Court should return this matter to the people—where the Constitution, by its silence on the subject, left it—and let them decide, State by State, whether this practice should be allowed. Casey must be

overruled.”

The majority of North Dakotans that have voted you into office want you to put an end to abortion; SB 2302 is a responsible and necessary first step.

SB 2302 is a good first step for several reasons. First it ensures that there will be no immediate costs to the state to litigate this issue, since courts will not be available to the opposition. This is because it is only a trigger statute with no immediate effect other than clarification. Secondly, passing SB 2302 will allow the people of North Dakota to know how different areas of the law will be affected by the passage of a Personhood Amendment.

When passed by the legislature, the Personhood Amendment will surely generate a great deal of public debate as it goes to a vote of the people. The Right to Life Act will help to focus that debate in a concrete and constructive manner. This is simply responsible and forward thinking legislative work.

Tuesday, January 29th 2013

Pending Joint Judicial Committee

Re: Support for Senate Bill 2302 - A BILL for an Act to provide for the right to life act; to provide a penalty; and to provide an effective date.

Most Honorable Members of the Committee:

Thank you for this opportunity to testify in support for Senate Bill 2302. My testimony will last about 10 minutes. I'd like to state that I have two reasons for giving my testimony today. Firstly, I urge you based on four short arguments to vote a do pass on Senate Bill 2302 and bring us another step closer to ending abortion in our state. The second reason for giving this testimony is for those who may be here today that do believe in the right to choose an abortion; that through this testimony they too may come to question the validity of the Roe v Wade outcome. The four arguments are based on: the Declaration of Independence, the 5th, the 9th and the 14th amendments.

To begin, I'd like to play a few audio clips. It's not my intention to construe the words of anyone in these clips but only to call attention to the number of times the question of the unborn as persons comes up. (you can listen to the entire audio clip at www.ovez.org)

(audio clip, tracks 1-7) [1]

As you have just heard from the Roe vs Wade proceedings, the question of abortion is one of personhood. Forty years later we are still debating over the value of unborn life. We are still debating because that "critical" question was never answered by the Supreme Court. It is a blank page in the book of history.

In the final analysis, the Supreme Court dismissed the question of personhood and chose to make freedom of choice the law of the land completely wiping off the board decades of various anti-abortion laws. What was the justification for that? The Supreme Court ruled that the Ninth Amendment's reservation of rights to the people, was **broad** enough to encompass a woman's private decision whether or not to terminate her pregnancy.

Justices White and Rehnquist could not find a basis for stretching the ninth amendment to allow for abortion. Justice White wrote:

"I find nothing in the language or history of the Constitution to support the Court's judgment. The Court simply fashions and announces a new constitutional right for pregnant women and, with scarcely any reason or authority for its action, invests that right with sufficient substance to override most existing state abortion statutes." [2]

Justice White goes on to explain that the worst thing about the decision was that the states became constitutionally disintitiled to weigh in on the subject.

The Ninth Amendment

Under the meaning of the ninth amendment the state laws had already set the precedence that abortion was NOT a right retained by the American people. The people had spoken out against abortion through the state powers for several decades. By the year 1900 every state had anti-abortion laws in place.

During the mid 1800's as medical research discovered that life begins at conception rather than at quickening (which is when the mother feels the fetus move), it became a firm resolution in the minds of the majority of society at that time that unborn life must be preserved and defended. The American Medical Association in a declaratory statement presented to Congress in 1857 had this to say.

If to want of knowledge on a medical point, the slaughter of countless children now steadily perpetrated in our midst, is to be attributed, it is our duty, as physicians, and as good and true men, both publicly and privately, and by every means in our power, to enlighten this ignorance." [3]

to continue:

"If we have ever been thought negligent of the sanctity of foetal life, the means of correcting the error are before us. If we have ever been so indeed, there are materials, and there is good occasion for the establishment of an obstetric code; which, rigorously kept to the standard of our attainments in knowledge, and generally accepted by the profession, would tend to prevent such unnecessary and unjustifiable destruction of human life." [3]

To prove that abortion was not a right retained by the people you can see in my references a diagram of the various state laws regarding abortion up until Roe v. Wade. [4]

The Declaration of Independence

The declaration of Independence, the foundation of the Constitution, says all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness. The Declaration asserts that we are created equal, not born equal and nothing has to be done or accomplished to attain rights. Simply to be in existence is enough.

The Fifth Amendment

The Declaration says that our right to life is unalienable. This means it was given to us and there is nothing we can do to remove it. Echoing and elaborating the words of the declaration the fifth amendment says that persons cannot be deprived of life without due process of law.

The unborn's right to life could be protected under the fifth amendment because fetus' have not yet developed the faculties to make decisions about it's own rights. It hasn't had the opportunity yet to enact on it's own rights. In other words the unborn have a right to act on their rights.

The 14th Amendment

Mrs. Weddington, the attorney who argued the case in front of the supreme court conceded that if a fetus was determined to be a person with constitutional rights then she would have a very difficult case. She claimed that a fetus had no constitution protection under the 14th amendment.

In this next clip please listen very carefully to what Justice Stewart is saying. He's seems absolutely certain that the 14th amendment defines a person as someone who is born. There's a pause while he finds his copy of the Bill of Rights and then goes on to read and then stops as he realizes that the 14th amendment does not in fact define what a person is but rather what a citizen is.

(audio clip, track 8) [5]

Mrs. Weddington asserts that because a person does not become a citizen until after birth that they had no constitutional rights. The constitution however protects any person within the borders of America whether they are a citizens or not. So the 14th amendment can not be construed to say that because you are an unborn person and not a citizen you have no rights. Let me restate that in the positive. If you are a person and if you are within the borders of the US then you ARE protected by the 14th amendment.

Concluding Statements

In my opinion and that of Justices White and Rehnquist, the Supreme Court misused it's power in the Roe v Wade case and it's up to the states to rectify that mistake. We have a momentous opportunity to raise the dignity of the unborn to persons in North Dakota. Based on the vote you make today concerning bill 2032, North Dakota could become the second state, following Virginia, to declare that the right's of a person begin once a sperm and egg become one. It is my hope that we as a people can come to terms with this tragedy, admit that we were wrong and go forth to create a culture that does not have any need of abortion. Where scientific advancements can be made to save the life of the mother *and* the baby, where crimes like rape and incest are sad memories of a by-gone era. Where a generation of people are not pitted against their own posterity and finally a realization that it is Life which makes any of this possible in the first place.

Thank you for your time and attention. If anyone else here wants a copy of my testimony come see me afterwards.

References

[1] http://www.oyez.org/cases/1970-1979/1971/1971_70_18#reargument

Track 1:

Justice Byron R. White: Well, what if– would you lose your case if the fetus was a person?

Track 2:

Ms Weddington: If the state could show that the fetus was a person under the Fourteenth Amendment or under some other amendment or part of the constitution, then you would have the situation of trying-- you would have a state compelling interest which, in some instances, can outweigh a fundamental right.

Track 3:

Justice Harry A. Blackmun: Well, do I get from this then that your case depends primarily on the proposition that the fetus has no constitutional rights?

Track 4:

Justice Potter Stewart: ... if you're correct in your basic submission that an unborn fetus is a person, then abortion law such as that which New York has is grossly unconstitutional, isn't it?

Mr. Flowers: That's right.

Yes, sir.

Justice Potter Stewart: Allowing the killing of people.

Mr. Flowers: Yes, sir.

Justice Potter Stewart: Of persons.

Track 5:

Justice Potter Stewart: Well, if it were established that an unborn fetus is a person within the protection of the Fourteenth Amendment, you would have almost an impossible case here, would you not?

Ms Weddington: I would have a very difficult case. [Laughter]

Justice Potter Stewart: You certainly would because you'd have the same kind of thing you'd have to say that this would be the equivalent to after the child was born.

Ms Weddington: That's right.

Justice Potter Stewart: If the mother thought that it bothered her health having the child around, she could have it killed.

Isn't that correct?

Ms Weddington: That's correct.

Track 6:

Justice Potter Stewart: How should we-- how should that question be decided?

Is it a legal question, a constitutional question, a medical question, a philosophical question, a religious question, what is it?

Track 7:

Justice Potter Stewart: And the basic constitutional question initially is whether or not an unborn fetus is a person, isn't it?

Mr. Flowers: Yes, and entirely to the constitutional perspective.

Justice Potter Stewart: It's critical to this case, is it not?

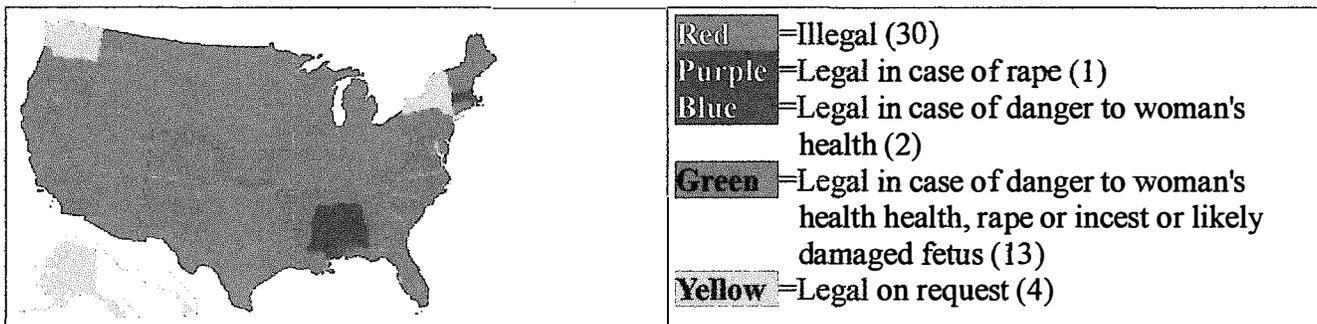
Mr. Flowers: Yes, sir, it is...

[2] Wikipedia "Roe v. Wade", [http://en.wikipedia.org/wiki/Roe vs. Wade](http://en.wikipedia.org/wiki/Roe_vs._Wade)

[3] [http://ama.nmtvault.com/jsp/viewer2.jsp?doc_id=Transactions%2Fama arch %2FAD200001%2F00000012&page_name=00760076&view_width=640.0&rotation=0&query1=&col lection_filter=All&collection name=Transactions&zoom factor=current&showThumbNails=false](http://ama.nmtvault.com/jsp/viewer2.jsp?doc_id=Transactions%2Fama%2FAD200001%2F00000012&page_name=00760076&view_width=640.0&rotation=0&query1=&collection_filter=All&collection_name=Transactions&zoom_factor=current&showThumbNails=false)

www.ama-assn.org, click on About AMA, click on Our History, click on AMA Digital Collection, The Transactions of the American Medical Association, Author: American Medical Association, Publication Date: 1859, Page 76

[4] Wikipedia "Abortion in the United States.", [http://en.wikipedia.org/wiki/Abortion in the United States](http://en.wikipedia.org/wiki/Abortion_in_the_United_States)



[5] http://www.oyez.org/cases/1970-1979/1971/1971_70_18#reargument

Track 8:

Justice Potter Stewart: Any person born or naturalized in the United States doesn't-- oh, that's not a definition of a person, but that's a definition of a citizen.

To hear the complete audio clip of Roe vs. Wade oral arguments visit www.oyez.org, click on cases, click on the year 1971 and find in alphabetical order.

Contact Information:

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January 28, 2013

Sen. David Hogue

Chair, Senate Judiciary Committee

North Dakota Senate

600 East Blvd

Bismarck, ND 58505

Dear Chairman Hogue:

I am Dr. Kristen Cain, and I am a reproductive endocrinologist practicing in Fargo. I am writing to urge you to oppose measures outlined in SB2302 which would endanger lives of women and fetuses in North Dakota and curtail reproductive freedom of North Dakota residents.

I graduated from Jamestown College in Jamestown, ND with a BA in chemistry, biology, and math and then attended Johns Hopkins School of Medicine. I did an internship in internal Medicine at the University of Virginia and returned to Hopkins for my residency in Obstetrics and Gynecology. I then did a fellowship in Reproductive Endocrinology and Infertility at UCLA. Following my training, I served as an Assistant Professor at SUNY Stony Brook and Winthrop University Hospital for 16 years while running the largest and most successful IVF practice on Long Island, NY. I have over 20 years of experience and expertise in infertility, third party reproduction, embryology, women's health, contraception, and ectopic pregnancy. I am currently working in Fargo where I have happily returned to my family and my roots.

SB2302 is a dangerous piece of legislation. It unclearly states that contraception that can kill a person should be prohibited. The fact is that every type of contraception has medical risks and a person using any type of birth control can die of complications, including blood clots of the lung, stroke, and even anaphylaxis due to latex allergy from a condom. Contraception prevents conception. Thanks to the increased use of effective contraception, abortions are at the lowest rate since accurate numbers have become available. Eliminating contraception in the state of North Dakota will increase abortions and also increase maternal deaths. Deaths will occur from complications of unintended pregnancies and from women seeking illegal abortions by unregulated, unlicensed, and untrained providers. Only 3 maternal deaths were recorded in North Dakota in the past year, and 2 of them were motor vehicle accidents. None were from abortions. But globally, a woman dies every 8 minutes somewhere in the world due to an illegal abortion. Do we really want that here?

SB2302 does not specifically exempt abortion for pregnancies resulting from incest or rape. It does not exempt treatment of incomplete or inevitable spontaneous abortions and it does not allow for

treatment of ectopic pregnancy. The so-called protective language in this bill is unclear and subject to broad interpretation. Medical providers who are not skilled in the reading and interpretation of legal documents will not be able to interpret subtleties in this bill. We are at risk for having a situation like the one recently in Ireland, in which the hospital would not evacuate the uterus of a Hindu woman with sepsis and rupture of membranes at 17 weeks, because the fetus still had a heartbeat and the providers feared legal repercussions. She tragically died, to "save" a doomed fetus, that could not possibly live outside her body. Of course, the fetus also died, as it would have anyway. This will happen here, with a law like this in place. In fact, similar scenarios already occur in North Dakota hospitals, even though there is no prohibition at present.

SB2302 limits the number of eggs to be fertilized in IVF to only the number to be transferred. Because we currently only transfer 1 or 2 embryos in good prognosis IVF patients under 40, this would result in us only being able to inseminate 1 or 2 eggs. It prohibits freezing of embryos, which protects embryos, and doesn't harm them. The fact is that only 1 of every 10 fertilized eggs has the capability of becoming a living, breathing human being. 50% of all implanted embryos miscarry. Human reproduction is inefficient by nature. The ability to generate multiple eggs in a single cycle for IVF and to preserve the extra embryos for another IVF attempt or even another baby in a few years is an important part of fertility treatment. Limiting IVF in this way would result in more multiple pregnancies, more spontaneous losses, more fetal reduction, and more babies born with complications of multiple birth and prematurity, not less. It would also increase the risk to the mother, as she is forced to undergo 5 or more cycles to conceive instead of one, with 5 or more exposures to medication, anesthesia, and surgical egg retrieval. Such limitations will make IVF very unappealing to patients who will then opt for treatments using fertility drugs and intercourse, which do not allow any control over the number of fertilized eggs in the uterus. This will actually increase the rate of high order multiples and their attendant risks and costs to the North Dakota taxpayers.

SB2302 prohibits "valuable consideration" for sperm and egg donors. The anticipated benefit to North Dakotans by this measure is unclear, and not stated in the bill. Sperm and egg donors are paid for their time, travel, and inconvenience in donating their tissue. Eliminating payment restricts donation to known donors only. Donation is tightly regulated by the FDA and tissues banks are regularly inspected. To date, these measures have proved to be safe, and not a single case of HIV transmission has occurred due to donation of anonymous sperm or eggs. Eliminating the ability of anonymous persons to donate tissue would cause many problems for the people of North Dakota. First, those who have lost their fertility due to cancer treatment would not be allowed to benefit from this treatment. Second, every case of custody and child support suits arising from third party reproduction has come from a known donor cycle, in which no payment was made. Volunteer sperm donors, in particular, will make donations out of the physician's office without the benefit of legal counsel or screening for genetic, infectious, and psychological disease that could complicate the donation. This section does nothing to protect or benefit the citizens of North Dakota, and inhibits viable family-building options for them.

SB2302 would prohibit all research in all humans because all medical procedures carry risk of death or injury. This would also eliminate the ability to investigate causes of spontaneous abortions by doing genetic and chromosomal testing on embryonic tissue. It would eliminate all stem cell research, which

has been making huge strides in the areas of Type 1 diabetes, cancer, spinal cord injuries, and Parkinson's disease. The nature of all research is that the benefit to the treatment is unknown and may not exist. That is why research is necessary. North Dakota would suffer from this lack of medical advancement.

Finally, Section 8 of SB2302 regarding Judicial Standard gives greater rights to an unborn or even unconceived, unimplanted embryo than to the born human woman who is carrying it. This is not backed by any science and reduces all women of reproductive age to a legal status that is lower than a single-celled fertilized egg. At present, the woman carrying the child has the primary rights, and in medicine is the primary person who is treated. In most cases, what's good for the mother is good for the child, and this is not an issue. But again, this law will lead to maternal deaths in futile attempts to avoid aborting doomed fetuses, and both will be lost.

Therefore, we urge you to oppose SB2302.

Respectfully,



Kristen Cain, MD FACOG

Testimony from

Rebecca Matthews

Senate Bills 4009, 2302, and 2303

January 29, 2013

Chairman Hogue and members of the Senate Judiciary committee, I am Rebecca Matthews from Bismarck. I am here to oppose this legislation and the 2 previous bills because these very difficult decisions should only be for a family to make in consultation with their doctor, not for politicians.

At 16 weeks pregnant I found out our hopes of having our third child turned into having our third and fourth child. They were identical twin girls. That was the last good news of our pregnancy. Immediately we were watched for twin to twin transfusion syndrome (TTTS). This is a syndrome where the twins share a placenta and share blood flow. At a little over 18 weeks it was critical we needed to address the TTTS. We chose to fly to Cincinnati OH for evaluation and possible laser surgery to address the shared blood supply between our twins. Before leaving Bismarck my husband and I named our twins Anna and Emily. At the Fetal Care Center in Ohio we received extensive assessments of both girls. TTTS was not our greatest worry. Emily was much smaller and only had a small percentage of the placenta and a vementus cord insertion. Anna was much bigger and had a larger percentage of the placenta. Anna had mild to moderate pulmonary valve stenosis of her heart. Emily had changes in blood flow to her brain. They then gave us our treatment options:

1. To go on bed rest with weekly visits to a MFM (a doctor that specializes in high risk pregnancies) in Minneapolis to monitor Anna's heart, Emily's blood flow, and to watch for progression of TTTS. TTTS has a "Mortality rates approach 80-100 percent if left untreated, especially when it presents prior than 20 weeks gestation" From Fetal Care Center information.
2. We could go ahead with the laser procedure to cut the shared blood vessels to hopefully protect Anna if Emily died. Due to our issue being more of a placental share issue then a clear cut TTTS they were unsure the morbidity/mortality of this procedure for our twins.
3. We could have a fetoscopic cord coagulations. This would end Emily's life that was already affected by her inability to get adequate blood supply. On the other hand it would protect Anna. Because of the shared blood vessels in the placenta if Emily died it could end Anna's life or cause major neurological deficits. We could revisit this option at our future appointments in Minneapolis if Emily's blood flow changed. The doctors told us we would have warning of her demise to make this decision.

The team provided us with all the medical information, answered our questions, and gave us a number to reach them if we had more questions. Then they told my husband and I what I hold most dear. To go back to our hotel and talk about what treatment option WE wanted. We could not believe our choices were to have premature babies with health issues, one baby with neurological issues, or saving only one twin.

My husband and I decided with the medical information and our backgrounds as an Occupational Therapist and a Nurse Anesthetist we would take a wait and see approach. When and if Emily had blood flow changes we would terminate to save Anna. Prior to leaving the Fetal Care center we had another ultrasound and an amniocentesis and nothing had changed. We flew home with a planned trip to Minneapolis in a week.

I remember returning home so afraid of what bed rest, micro-preemies, and the babies needing to be in Minneapolis would do to our then 4 and 6 year old. How were we going to afford all the trips and medical care even before they were born? With me being a stay at home mom who would do my job of caring for me kids? I was scared of all the health complications that may be ahead. Would they need to come home on oxygen? Would they have cerebral palsy? Would they need a feeding tube?

My husband and I prepared for our first trip to Minneapolis.

I never made my first appointment to Minneapolis. 4 days after returning home and not feeling the babies move I called my OB. On June 19' 2007 I found out my girls no longer had heart beats. I was induced and delivered my still born babies Anna and Emily on June 21' 2007, days shy from 21 weeks gestation.

My husband and I made the best decision we could with the medical information we had at the time. It was OUR decision to make. I do not know if our decision would be the same now, five years later. All I know is that no decision is right or wrong, but is different given the medical information and the family's decisions.

I wish we lived in a perfect world where pregnancies were always happy and healthy. We do not live in that world. These medical decisions are for families to decide with consultation with their medical team, not for government to make. If we lived in a perfect world Anna and Emily would have been healthy and thriving at 21 weeks gestation but in this imperfect world we lived the nightmare of losing our precious twins.

January 27, 2013

To whom it may concern:

On April 8, 2010, my 19 year old daughter Hannah, a student at NDSU and member of the women's basketball team was diagnosed with Hodgkins Lymphoma. Hannah's oncologist discussed with us that because Hannah was so young and going into chemo the most ideal thing to do would be to address her chances of being able to have children in the future. Because her cancer was progressed and her heart rate extremely high, chemotherapy was started immediately and we could not address any egg retrieval process as it would take too long and she couldn't afford to wait.

Hannah went through six months of chemotherapy treatment followed by a full three weeks of radiation. Something we've discussed often since her cancer diagnosis and treatment is that Hannah hopes her treatments will not interfere with her ability to have a family someday.

Unfortunately, once again on December 18, 2012, Hannah was told her Hodgkins Lymphoma had returned. Our family has cried and accepted that once again Hannah is faced with cancer. Hannah had many things that she expressed as concerns and worries as she thought through what another round of cancer would do to disrupt her life once. Her key concerns included what treatment would be like, will she finally be able to beat the cancer this time, would she be able to keep her nursing classes going, would she be able to fulfill her summer nursing internship and would chemotherapy and a stem cell transplant completely take away her chances of someday having children of her own. What we set out to do was address those concerns for Hannah.

Hannah's oncologist said that this time, the first thing they would do is set up an appointment at the Sanford Reproductive Clinic in Fargo so that we could explore the option of egg retrieval. As we met with Doctor Cain for the first time, we learned that her past chemotherapy may have already damaged her ovaries and that we could try the fertility process but couldn't be guaranteed that it would work. Within a week, Hannah started the process and several days later the ultrasound showed that one of Hannah's ovaries was working better than the other and that it was beginning to produce the follicles they were hoping to see.

I can't begin to tell you how excited Hannah was that there would be hope for successful egg retrieval. A decision that had to be made was whether eggs or embryos would be frozen. Hannah's been dating Adam for 4 1/2 years and they plan to marry, so the two of them decided to fertilize the eggs and freeze the embryos. Based on the information shared with our family, we felt that going the embryo route would give Hannah and Adam the best chance for a family someday in the future, should her cancer treatments take away that possibility by damaging her reproductive system. Thankfully, the process worked for Hannah and she now has embryos frozen for use in the future. When she received word from the clinic that they were able to fertilize a number of eggs to be frozen, Hannah was ecstatic and in a better place mentally and emotionally as she started chemo this past week.

As Hannah's mother, I've watched Hannah go through cancer treatments once before and an important aspect to her overall health is her personal well-being and hope. Having the option of in vitro available to her and knowing that as she goes into this round of treatment she has an option to become a mother someday in spite of cancer, brings her that element of hope she needs. Cancer has robbed her of many things these past few years and the one wish I have for her is that she beat cancer, graduate from her nursing program, marry and have her own family.

This past Friday I learned of the North Dakota legislators looking to make it illegal to freeze embryos. I can't begin to tell you how saddened I felt after hearing the news and wanted to share Hannah's story, as making a change to the law as is being proposed would take away options and hope for people like Hannah. As Hannah has started her treatments this past week, I couldn't stand before you and have put together this letter instead.

Good people should have a choice and if it weren't for the in vitro process, my daughter in the future may not have a chance to be a mother because of cancer. I also currently have a 34 year old niece going through the process at this time and more than anything, she and her husband want to be parents. In vitro is an option that gives good people who would make great parents a chance to make that happen. Please do not take away the option to freeze embryos and take away choice and options from good people like Hannah. Hope is what keeps her going each day and I'm thankful that the option was there for her this past month before she started her cancer treatments.

Linda Linz

**Testimony to the Senate Judiciary Committee
from Karla Rose Hanson of Fargo, N.D.
1/29/2013**

For SB 2302 specifically:

I'd like to echo the same concerns that I voiced about Senate Concurrent Resolution 4009, although I won't take the time to repeat everything, and I'd like to make additional comments related to Senate Bill 2302. I strongly oppose any limit to in vitro fertilization. Senate Bill 2302 limits the number of in vitro embryos created in a single cycle to the number to be transferred in that cycle. By banning the freezing of embryos, you are creating a significantly bigger burden on couples financially, physically and emotionally, making the in vitro fertilization process nearly prohibitive for most couples.

As I mentioned in my earlier testimony, I used IVF three times – one fresh cycle and two frozen cycles. The cost of creating and retrieving the eggs for a fresh cycle is about \$15,000 versus \$2,000 for a frozen cycle. The fresh cycle required a great number of costly medications, including very painful shots. And the process of retrieving the eggs was far more physically intrusive compared to the process of preparing my body for a frozen embryo transfer. If my husband and I would have had to endure the physical, financial and emotional burden of only fresh cycles, we likely would have only done one attempt, if any at all, further reducing our chances of ever conceiving a child.

Another consideration is embryo donation. Once we were done building our family, my husband and I made the decision to donate our remaining frozen embryos. For many couples, their only hope of achieving a full-term pregnancy begins with donated embryos, and there is a waiting list of several years. In fact, there are 72 couples across the country working with Reprotech, the company in Minneapolis that my husband and I worked with, who are waiting to receive donated embryos. So banning freezing embryos would have a significant impact on a couple's ability to build families in this way.

Please recommend a "do not pass" on SB 2302. Also, I am including a letter from a friend who has gone through IVF for your records.

**Testimony to the Senate Judiciary Committee
SCR 4099, SB 2302, SB 2303
1/29/2013**

My name is Jennifer Cossette and I live in West Fargo. I recommend Do Not Pass. Here are two wonderful reasons why:

Zoey Ryan and Khloe Dawn, born January 11, 2012.

My husband and I tried for 4 years to get pregnant. It finally happened thru IVF. This is not a process you enter into lightly. There are a lot of things to consider and emotions to go thru-and that is just to make the initial appointment. The process of going thru fertility is not an easy one either. It is a big commitment; a lot of doctor appointments, lifestyle changes, different kinds of medications to take, and also some pain. But it is all worth it when you get to hold your child in your arms. Couples going thru infertility issues deserve the chance to make their dreams of having a family come true. There should not be ANY limitations on that. More and more couples are going thru this....more than likely someone you all know. Please do not shatter their dreams of having a family of their own. I am very glad and thankful there is the technology to assist in this. Please Do Not Pass SCR 4009, SB2302 and SB 2303- leave the healthcare decisions to patients and doctors. Thank you for your time.

Jennifer Cossette



Testimony regarding North Dakota SB- 2302- January 29, 2013

My name is Stephanie Dahl, and I am a physician and an infertility specialist in Fargo. My job is to help families that are struggling with infertility have a baby. I would like to give you a little information on my background so you understand my training and my credentials to testify on this bill.

I have sixteen years of training and seven years of experience as a Reproductive Endocrinologist and Infertility specialist. I am double Board Certified in Obstetrics and Gynecology and in Reproductive Endocrinology and Infertility. Therefore, I have the knowledge, background and expertise in the fields of anatomy and physiology, women's health care, obstetrics and gynecology, early pregnancy, and embryology to testify at this hearing.

I am a member of the American Society for Reproductive Medicine which is composed of 8,000 physicians in Obstetrics and Gynecology, Reproductive Endocrinology, Infertility and Urology. I am also a member of the American College of Obstetrics and Gynecology. Both organizations oppose so-called "personhood bills".

SB 2302

Senate Bill 2302 would prohibit cryopreservation of all embryos. This means **cancer patients** would not be allowed to cryopreserve embryos before starting cancer treatment. Cancer treatments including chemotherapy and radiation often destroy their ovaries and may render women sterile. Embryo cryopreservation is currently the gold standard for fertility preservation for cancer patients.

Senate Bill 2302 would only allow us to fertilize one or two eggs during an IVF cycle (the number of eggs we fertilize is limited to the number of embryos we transfer). Because many eggs don't fertilize and embryos don't always survive in culture, **80% of patients would have no embryos to transfer and would have to go through another IVF cycle.** Each cycle of IVF costs **\$12,000- \$17,000** which is cost prohibitive for many families.

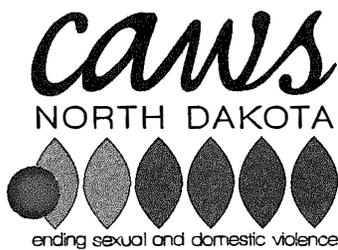
Senate Bill 2302 would prohibit the use of donor sperm and donor egg in North Dakota. Donor egg is the only option to become pregnant for women who have lost their ovaries due to cysts, cancer, premature ovarian failure, and other medical conditions.

The supporters of this bill have stated that Louisiana has a similar law which allows IVF in their state to continue. However, I have attached a copy of the LA law and there are major differences. The LA law states that embryos are considered "juridicial persons". The LA law does not impair the ability to freeze embryos because it implicitly states that embryos may be cryopreserved. The LA law was written to allow fertility patients to utilize IVF to have a family and to prohibit creating embryos to be sold or used only for research purposes.

Regardless of what the supporters of the bill say, it comes down to this: if this bill becomes law in ND--- **we will NOT offer IVF at our center in Fargo** and this is the only IVF program in the entire state.

Thank you for your time.

Stephanie Dahl, M.D.



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Testimony on SB 2302
Senate Judiciary Committee
January 28, 2013

Chair Hogue and Members of the Committee:

My name is Janelle Moos. I am speaking this morning on behalf of the North Dakota Council on Abused Women's Services in opposition to SB 2302.

Our Coalition is a membership based organization that consists of 21 local domestic violence and rape crisis centers located throughout the state that provide services to domestic violence, sexual assault, and stalking victims in all 53 counties and the reservations in North Dakota. Last year alone, these centers provided services to nearly 900 victims of sexual assault.

We have specific concerns regarding Section 2, subsection 2, subdivision c on pg. 6 of the bill that states "The state of North Dakota does not punish the crime of sexual assault with the death penalty, and neither shall persons conceived through a sexual assault be punished with the loss of life."

Crimes like sexual assault are very complex and require a significant amount of time, resources, and expertise in order to consider the victim's safety, experience and perspective.

Several studies indicate that few sexual assault victims report the crime and even fewer do so immediately. The National Violence Against Women Survey conducted in 1992 and again in 2006 indicated that a very small minority (16-19%) of victims reported their sexual assault to law enforcement. Of these, only ¼ reported the crime within 24 hours. In other words, most victims don't report their sexual assault to the police, and when they do, it is usually after some

delay. Pregnancy that results because of a rape can make reporting or participating in the criminal justice system even more traumatic for the victim.

Data from ND Supreme Court, that state in 2011, 47 cases of sexual assault (NDCC 12.1-20-07) were prosecuted. Of those cases 15% (7) were dismissed, 28% (13) were reduced to a different offense, and 43% (20) were found guilty. Comparatively, 143 cases of gross sexual imposition (NDCC 12.1-20-03) were prosecuted. Of those cases, 18% (26) were dismissed, 10% (14) were reduced to a different offense, and 36% (52) were found guilty, while nearly 30% of cases are still open.

As you can see, we have a relatively low prosecution rate and no death penalty in the state of ND. Rape victims need access to justice after an assault and if they are pregnant because of the assault they need to be able to make choices and SB 2302 all but eliminates that right for victims to choose.

I urge you to oppose SB2302.

Thank You.

Mr. Chairman, Members of the Committee, thank you for the opportunity to address you this morning. My name is ShaunAnne Tangney, and I am from Minot. This is the third time in as many legislative sessions that I have addressed legislative committees regarding specious personhood legislation such as the one before us today. Once again, I find the proposed legislation so fraught with logical, scientific, and legal error that I am compelled to testify against it.

The reference throughout the bill to a fetus as a "child," an "unborn child," or a "preborn child" requires disambiguation. First, this kind of "personhood argument" is a reinterpretation of United States law and history by people with extreme religious views. Any careful and rigorous and honest study leads to the conclusion that America was founded as a free country, not a theocracy, and there can be no imposition of religious beliefs in the United States. Second, such "personhood" arguments commit the fallacy of equivocation in that they attempt to equate the biological concept of "human being" or "human life" with the political concept of "person." Persons have rights, rights being the principles that identify our proper freedom of action—which is another way of saying that rights are ascribed to persons who exist in a society (a hermit living alone in a cave all his or her life would have no need for rights). Rights cannot be applied to an embryo, zygote, or fetus because none of those live in a society. Each of those are dependent upon a living woman, and cannot exist separate from her. An embryo, zygote, or fetus may be seen as a potential person, but to ascribe rights to a potential person is a profound error, and commits the fallacy of the continuum. The fact that a zygote may develop into a born infant does not prove the zygote to be the same thing as a born infant—any more than an acorn is an oak tree or a caterpillar is a butterfly. As philosopher Leonard Peikoff observes, to treat a zygote as a potential adult human is the same thing as treating an adult human as a potential corpse. In sum, the "personhood" debate and language is fraught with logical, historical, and political errors, and should be avoided by legislators.

The bill is also problematic as it does not reflect actual human gestational biology correctly. It tries to inflame the sentiment by implying that any movement or physical development on the part of the fetus "makes it human." In the embryonic stage, the zygote is invisible to the naked eye, has no human organs, and no human form, no capacity for emotion or awareness; indeed, a human zygote at this stage looks very similar to those of many other species. At the fetal stage of development, while the heart, hands, feet, brain, and other organs are present from week six, they are only at the beginning of development and exhibit only minimal and largely uncontrolled or unconscious movements. Any breathing-like movement of the lungs in the fetus is not breathing per se, but rather mere stimulation of lung development. It is also important to note that the circulatory system of a fetus works differently from that of born humans because the lungs are not in use. Finally, it is worth noting here that a fetus is not capable of feeling pain until the third trimester.

Quite frankly, this bill is stupefying in its ignorance of basic human biology. Every time a man ejaculates—for the purposes of conception or otherwise—some 300,000,000 sperm are released—and yet men are never challenged for the destruction of those 300,000,000 so-called “preborn children.” Indeed, when sperm and egg do meet and attach in the human body, forming a zygote, the human body works diligently to kill or destroy the rest of the ejaculated sperm so as not to endanger the development of the zygote. Similarly, 50% of all zygotes fail to implant in the uterus and die, and yet we would never consider holding every pregnant woman liable for murder even though we know her body willingly and knowingly destroyed millions of so-called “preborn children.” My point is this: the language of the “preborn child” creates a very slippery slope, and is in fact disingenuous.

The language regarding a “human-hybrid animal” also seems ignorant of basic biology. Science is clear on the fact that a human sperm cannot penetrate the egg of any other animal, and that a human egg cannot be penetrated by the sperm of any other animal. Sperm and egg of all species have a kind of “lock and key” protection system, only allowing for fertilization by a member of the same species, thus ensuring the survival of that species as distinct and separate. And while there has been some media hype about the creation of “chimera”—a creature that is part human and part animal—a bill that is clearly an anti-abortion bill is no place to address that hype. The use of nonhuman animals to produce human organs, cells, or blood, is certainly one of great ethical concern, and it deserves an ethical debate, not a flat-out veto. Finally, the definition in the bill of pluripotent cells is also problematic. Pluripotent cells—or stem cells—can never develop into a fetal or adult organism because they lack the potential to contribute to embryonic tissue such as the placenta. The bill tries to include stem cells as so-called “preborn children,” but this is not scientifically correct.

While this bill has carefully crafted language regarding the prohibition or restriction of many different kinds of medical research or procedures that might injure or destroy a zygote or fetus, it would create unstable ground for patients and physicians alike. As I have testified before, between 2000 and 2009 I underwent ten surgeries. Several of these required X-rays, MRIs, CT scans, and HIDA scans. Before each procedure, I was asked whether or not I was pregnant because those kinds of tests can harm a fetus. I always answered “no,” because as far as I knew, I was not pregnant—but as we all know, a woman can be quite far along in a pregnancy and not know that she is pregnant. Were this bill to be passed into law, both women and doctors could be held liable for such an error. Furthermore, women might cease to seek out critical healthcare for fear of prosecution, and doctors might cease to offer or prescribe such critical healthcare for a similar fear of prosecution.

The bill also includes carefully crafted language regarding contraception in its none-too-thinly-veiled attack on birth control. Even though overwhelmingly safe and effective, drugs as the birth control pill, the “morning after pill,” and such devices as the IUD, which, although designed to prevent fertilization, can sometimes prevent

the implementation of a fetus. However, birth control and abortion are two vastly different things and should not be confused. Indeed, while the population is evenly split on abortion (in 2010, 46% identified as "pro-life;" 45% identified as "pro-choice"), 99% of all women who have ever had intercourse have used some form of contraception, and 82% have used the oral contraceptive pill, clearly indicating that the majority of the population is in favor of birth control. The North Dakota state legislature is not in place to ratify or make legal the extremist concerns of a fringe group, but to represent the majority of the population. Enacting a bill into law that so clearly goes against the beliefs and practices of the majority of the population is wrongheaded and anti-democratic.

Finally, this bill lays the groundwork to ban abortion without exception, even in cases of rape, incest, or danger to the woman, and yet it does so in a sneaky, abstruse, and callous manner that I find unbefitting of the North Dakota state legislature. It threatens the physical and mental health of women on so many levels that it can only be described as draconian. For all of the reasons outlined above, I urge you in the strongest possible way to recommend a DO NOT PASS on SB2302. It represents fringe values, it exhibits an ignorance of human biology, and promotes poorly and ignorantly conceived law. It is a bad bill and should not become North Dakota State Law.

Thank you for your time and attention to this matter.
Respectfully,
ShaunAnne Tangney
Minot, North Dakota



Additional
testimony
e-mailed

2302

11

February 6, 2013

To the Distinguished Senators of North Dakota:

Thank you once again for the opportunity to present testimony on legislation before the Judiciary Committee this session. Regarding the particular bills before the Senate, I would strongly recommend a **DO PASS ON SB 2302**.

The group RESOLVE has circulated numerous misperceptions and inaccurate statements about SB 2302, the “Right to Life Act”. The false information regarding the biological and medical facts of the bill and of infertility treatment amount to scare tactics. In an effort to provide accuracy and facts for your debate, I am sending some clarifying information. This letter does not attempt to address every one of the incorrect arguments, but does attempt to correct the most egregious falsehoods.

One misleading statement has been that legislators with no medical training should not make laws pertaining to the regulation of medicine. Yet legislators are elected to promote the health and safety of the public. It is definitely in the public interest to have sound public policy and regulation of matters related to public health. It is especially in the public interest to

One false statement has been that passage of SB 2302 would mean young female cancer patients would no longer be able to preserve their fertility. The statement suggests that the only way to address future fertility is by superovulating the woman with massive doses of hormones to obtain large numbers of eggs, then fertilizing all of these eggs to create large numbers of embryos, which can be frozen for future transfer to the uterus.

The statement is blatantly false. Fertility can be preserved by freezing eggs rather than embryos. This has been done for many years now, and over 2,000 babies around the world have been born using this technology, especially in cases of young women preserving their fertility before cancer treatment.¹ The success of freezing eggs rather than embryos has been documented, including in a recent review by Dr. Jeffrey Boldt, with whom I worked in the past. Dr. Boldt is Scientific Director of Assisted Fertility Services in Indianapolis, clinical associate professor of Medical and Molecular Genetics at Indiana University School of Medicine, and Scientific Director for The World Egg Bank. He notes in his review paper that use of freezing eggs has produced:

“pregnancy rates that rival those obtained with either frozen-embryo transfer or fresh IVF.”²

Related to this, another false statement made is that SB 2302 would eliminate egg donation in North Dakota. However, what the bill eliminates is cash payments and inducements for egg

¹ E.g., Porcu E. *et al.*, Healthy twins delivered after oocyte cryopreservation and bilateral ovariectomy for ovarian cancer, *Reproductive Biomedicine Online* 17, 265, 2008.

² Boldt J, Current results with slow freezing and vitrification of the human oocyte, *Reproductive BioMedicine Online* 23, 314, 2011

donation or trafficking in eggs or embryos. Egg donation is a practice that provides incentives for young women to risk their health, and even their lives, to donate eggs for payment. The practice, often undertaken by “egg brokers”, solicits young fertile women to undergo injection with high doses of hormones in order to produce large numbers of eggs. This practice has significant health risks. As many as 10-20% of women in some studies have reported health complications, which in some cases has led to hospitalization, kidney failure, infertility, and even death.^{3,4} The bill SB 2302 is a reasonable measure meant to protect women from exploitation and to protect embryos from trafficking for profit. This provision mirrors provisions found in almost every adoption statute in the nation. The purpose of such laws is to remove the financial incentive to buy and sell children like commodities and to protect women from exploitation. Likewise, the elimination of the use of valuable consideration in SB 2302 is a reasonable measure already in common practice throughout the realm of adoption law and will protect women and children from financial exploitation. Altruistic egg donations would still be allowed.

Finally, SB 2302 would make it clear that human embryos are not property, just as born human children are not property.

The provisions of SB 2302 will improve public health and protect the lives of mothers and babies, making for a healthier North Dakota.

If I can answer any other questions, please do not hesitate to contact me.

Sincerely,



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³ Magnus D and Cho M, “Issues in Oocyte Donation for Stem Cell Research,” Science 308, 1747-1748, 17 June 2005
⁴ Shmorgun D et al., The Diagnosis and Management of Ovarian Hyperstimulation Syndrome, J OB Gyn Canada 268, 1156, 2011

Final ART success rates: a 10 years survey

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BACKGROUND: Cumulative pregnancy rates (CPRs) and live birth rates (CLBRs) are much better indicators of success in IVF programmes than cross-sectional figures per cycle or embryo transfer. They allow a better estimation of patient's chances of having a child and enable comparisons between centres and treatment strategies.

METHODS: A 10 year cohort study of patients undergoing their first assisted reproductive technique cycle was conducted. Patients were followed until live birth or discontinuation of treatment. All IVF and ICSI cycles and cryo-cycles with embryos derived from frozen pronuclear stage oocytes were included. The CPR and CLBR were estimated using the Kaplan–Meier method for both the number of treatment cycles and transferred embryos. The analysis assumed that couples who did not return for subsequent treatment cycles would have had the same chance of success as those who had continued treatment.

RESULTS: A total of 3011 women treated between 1998 and 2007 were included, and 2068 children were born; women already with a live birth re-entered the analysis as a 'new patient'. For 3394 'patients under observation' with 8048 cycles, the CLBR was 52% after 3 cycles (the median number of cycles per patient), 72% after 6 cycles and 85% after 12 cycles. A CLBR of ~50% was achieved for patients aged under 40 years, after the cumulative transfer of six embryos. The mean live birth rate from one fresh cycle and its subsequent cryo-cycle(s) was 33%. Our analysis also shows that ART can reach natural fertility rates but not exceed them.

CONCLUSIONS: Most couples with infertility problems can be treated successfully if they continue treatment. Thereby ART can reach natural fertility rates. Even with the restrictions in place as a result of the German Embryo Protection Law, CLBR reach internationally comparable levels.

Key words: cumulative pregnancy rate / cumulative live birth rate / natural fertility rate / German Embryo Protection Act

Introduction

All IVF patients want to know their chances of success. Generally, the success rates of assisted reproductive techniques (ARTs) are given as clinical pregnancy rates (PRs) per started cycle, oocyte retrieval or embryo transfer and often determined relative to maternal age. At first glance, these rates seem to be disappointingly low, but it is the final ART success rate that is most pertinent to a patient's decision on whether to undertake treatment (Hull, 1994). Furthermore, final ART success rates [cumulative pregnancy rate (CPR) and live birth rate (CLBR)] appear to be a much better indicator of quality and success in IVF programmes and probably allow better comparisons between different centres (Lintsen *et al.*, 2010). This is of particular importance for cross-comparison of IVF results between different countries, especially as an increasing number of patients are looking for cross-

border treatment. CPR and CLBR should reflect possible advantages or disadvantages of national IVF policies (restrictions and liberations) and individual treatment strategies of different IVF clinics. Moreover, CPR and CLBR are the most important figures for basing economic and political considerations of ART efficacy and reimbursement costs.

The German national index and most of the international indexes have not published CLBR so far (www.deutsches-ivf-register.de). Several previous studies have calculated cumulative success rates but have some limitations because of inconsistent inclusion criteria, inconsistent treatment procedures or no reporting CLBR (Tan *et al.*, 1992; Hull, 1994; Bergh *et al.*, 1995; Dor *et al.*, 1996; Osmanagaoglu *et al.*, 1999; Kovacs *et al.*, 2001; Olivius *et al.*, 2002; Ubaldi *et al.*, 2004; Lundin and Bergh, 2007; Pelinck *et al.*, 2008; Sundstrom and Saldeen, 2009). More recent studies have published CPR comparing single versus double embryo transfer and discussed the impact on



treatment policy (Sundstrom and Saldeen, 2009; Gelbaya et al., 2010), and one German study has reported on CPR with respect to national restrictions and dropout reasons (Schroder et al., 2004). However, only one centre has published their CLBR, including cryo-cycles with transfers of previously frozen embryos, as well as their treatment policy in detail (Klipstein et al., 2005; Malizia et al., 2009; Moragianni and Penzias, 2010). Furthermore, in most previous studies on CLBR and CPR, the methodological management of women with live birth coming for another child remains completely unclear.

In Germany, the performance of an ART is bound by very strict regulations by law (German Embryo Protection Law of 13th December 1990 <http://www.bmj.bund.de/files/1148/ESchG.pdf>) and also influenced by general health insurances (Gemeinsamer Bundesausschuss der Ärzte und Krankenkassen, <http://www.g-ba.de>). Until 2004, up to four fresh IVF- and IVF/ICSI cycles were fully covered by insurance. Since then, half the cost of IVF- and IVF/ICSI cycles is covered by the couple with the remainder paid by insurance and only for a maximum of three cycles. Cryo-cycles are entirely privately funded. The change in the reimbursement regulation in 2004 caused a significant drop in the number of treatment cycles in Germany. All numbers and other statistical data are published yearly by the national IVF register and can be seen at www.deutsches-ivf-register.de.

According to the German Embryo Protection Law of 1990, the cell-culture of more than three pronuclears (PNs) is prohibited because only as many oocytes at the PN stage as are planned to be transferred in one cycle are allowed to be cultured. PNs that are not intended for implantation within one cycle have to be discarded or cryopreserved. As a consequence, prolonged embryo culture with the selection of the best embryos or blastocysts and embryo cryopreservation is prohibited. Embryo cryopreservation is allowed only in cases of emergency. There is an ongoing and viable discussion on the interpretation of the German Embryo Protection Law. Therefore, the question arises of whether the strategy of one IVF or ICSI-cycle and its subsequent cryo-cycle(s) yields a lower cumulative CPR and CLBR than one IVF or ICSI-cycle with prolonged embryo culture and embryo selection before transfer.

In this cohort study, we calculated CPR and CLBR by the Kaplan–Meier-method (Kaplan and Meier, 1958), which allows for the estimation of CPR and CLBR without under- or overestimation, which is of particular importance if patients are censored for reasons other than pregnancy or live birth. The Kaplan–Meier method assumes inherently that those who exit treatment for reasons other than pregnancy or live birth have the same probability of future success as those who continued.

We performed this 10-year survey from 1998 to 2007 in a single IVF centre in Germany in order to provide estimates of the final success that a couple would have if continuing treatment and to allow comparisons with international success figures. We included all IVF, IVF/ICSI and cryo-cycles involving the transfer of embryos derived from frozen PN stage oocytes.

Materials and Methods

Data collection and analysis

All ART cycles included IVF, IVF/ICSI and cryo-cycles with embryos from cryopreserved PN stage oocytes but no oocyte donations as it is

prohibited in Germany. Cycles between January 1998 and December 2007 were observed in a cohort study, including all women undergoing their first fresh cycle in our centre. These women were followed as 'patients under observation' until either discontinuation of their treatment or live birth as the primary outcome. All patients without a live birth who returned for further treatment underwent a further attempt. Cycles without oocyte retrieval were not included. Only cryo-cycles with embryo transfer were considered. For the Kaplan–Meier estimations, women already with a live birth re-entered the analysis as a 'new patient under observation' if they underwent further ART. Patients who did not return (perhaps because they changed the IVF centre or stopped treatment for any other reason) were censored after the last treatment.

This study was conducted in accordance with the principles of the Declaration of Helsinki. Medical and laboratory data were recorded using the clinic management program MEDISTAR, the IVF laboratory managing program RECDATE and Microsoft EXCEL. Data collected included the length of time trying to conceive, information of previous treatments for infertility and, if available, the reason of discontinuation, relevant information about ovarian stimulation and procedures in the IVF laboratory and outcomes of the treatment cycles. All couples had to sign an informed consent about data storage and anonymous results reporting and transfer to the national register.

Data were analysed using the SAS package, version 9 (SAS Institute Inc., Cary/USA). Kaplan–Meier survival rates were estimated over all treatment cycles or number of transferred embryos. The usual survival rates with means and 2 standard errors approximating the 95% confidence interval (CI) were computed and the cumulative probability curves (non-parametric distribution functions) were derived for the CLBR or CPR. Since age is the major factor of importance for the success rates (Lass et al., 1998; Bar-Hava et al., 1999), Kaplan–Meier curves were additionally calculated separately for different age groups. Additionally, we also calculated non-estimated live birth rates (LBRs) and PRs for one treatment sequence, which is one fresh cycle followed by its subsequent cryo-cycle(s), to allow comparisons with cross-sectional statistics. Statistical significance was derived by the Log-rank-test for Kaplan–Meier survival rates and the t-test for other continuous data.

Fresh cycles

The fresh IVF- or IVF/ICSI-cycle treatment strategies have previously been described in detail (Gnoth et al., 2008). The main indications for ART were male subfertility (65%), tubal pathology (12%), endometriosis (12%), idiopathic infertility (9%) and repeated polyfollicular development in gonadotrophin stimulation cycles for IUI (2%). The majority of patients began treatment with a monophasic oral contraceptive pill on Days 3–5 of the cycle. The long agonist protocol was used preferentially. In about 20% of all fresh cycles, stimulation was according to the antagonist protocol especially in cases of expected low ovarian response. Controlled ovarian hyperstimulation (COH) was performed with either recombinant follitropin α or β (rec FSH) or urinary HMG. The starting dosage was adjusted according to the patient's age, Anti-Müllerian hormone and antral follicle count. Most of our patients under 35 years of age were started with 150 mIU/ml. In patients with expected or proved low ovarian response (≤ 4 oocytes in a previous cycle), we started with 300 mIU/ml. After 5 days of stimulation, the follicular development was assessed by ultrasound and hormonal measurements. If necessary, the dose of gonadotrophins was adjusted. Transvaginal oocyte retrieval was performed 35 h after ovulation induction. The luteal phase was supported with vaginal application of progesterone and in the case of low ovarian response, vaginal estradiol (E_2) was used additionally. In accordance with the regulations, two PN stage oocytes were cultured if a transfer of two embryos was planned

or three PN stage oocytes if three embryos should be transferred in one cycle. In all cases, a PN scoring was performed. All supernumerous PN stage oocytes were frozen. Approximately 30% of all fresh cycles were conducted as IVF and 70% were conducted as IVF/ICSI. The number of embryos transferred depended on maternal age, parity, number of previous attempts and the couple's wish, and was 2.06 per transfer on average. The ongoing clinical PR was considered to be the secondary outcome measure defined as a gestational sac and heart beat assessed by vaginal ultrasound 2–3 weeks after a positive pregnancy test.

Cryo-cycles

Cycles with the transfer of embryos derived from cryopreserved PN stage oocytes were performed after priming the endometrium with a vaginal application of 2–4 mg micronized E₂ per day. Luteal phase was initiated with additional vaginal application of progesterone after ultrasound assessment of the endometrium ideally showing a trilaminar pattern and a thickness of at least 7 mm. The PN stage oocytes were thawed on Day 3 of vaginal progesterone and transferred after 2 days of embryo culture (Day 5 of vaginal progesterone). Clinical pregnancy was confirmed as before.

Results

Overall 3011 individual women were eligible for inclusion. Women already with a live birth re-entered the analysis as a 'new patient'. Therefore, 3394 'patients under observation' contributed 8048 cycles, which are summarized in Table I. The mean duration of involuntary infertility was 3.4 years before ART indicating serious subfertility (Gnath *et al.*, 2005). The overall mean number of treatment cycles was 2.7 (median: 3) per patient (range 1–22). This resulted in 2193 clinical pregnancies and 1718 deliveries, producing a total of 2068 children (1373 singletons, 680 twins and 15 triplets). The transfer of embryos in cryo-cycles accounted for 20% of live births. The miscarriage rate was 19.5%, and the ectopic PR was 2.2%. The clinical PR was 27.2% per oocyte retrieval. The transfer of three embryos in a cryo-cycle was as effective for PR per embryo transfer as the transfer of two embryos in a fresh cycle.

Cumulative live birth rates

Figure 1 shows the overall CLBR for all treatment cycles with oocyte retrieval and all age groups. The CLBR were 52% after 3 cycles (approximate 95% CI: 50–54%), 72% after 6 cycles (approximate 95% CI: 69–74%), 85% after 12 cycles (approximate 95% CI: 80–89%) and 94% after 18 treatment cycles (approximate 95% CI: 85–100%). The maximum number of treatment cycles that resulted in a successful pregnancy was 18 with the birth of healthy twins. Because of the re-entry of women after a live birth as 'new patients', we included 3394 'patients under observation' in the estimations of CLBRs and CPRs (Fig. 1). The proportion of re-entry in 'patients under observation' is 11.3%. The maximum of re-entry is three times with four children born to one woman after treatment for infertility in our centre. CLBR and CPR did not differ according to whether re-entry was allowed or not.

Figure 2 shows the CLBR, for all treatment cycles with oocyte retrieval, stratified for the different age groups. The Log-rank test revealed a significantly lower LBR for women over 40 years of age. Although the CLBR also seemed to be lower in age group over 35 up to 40 years of age, it failed to reach statistical significance when compared with the younger age groups.

Table I Basic characteristics of patients and treatment cycles.

Time	1998–2007
Total number of individual women	3011
Patients under observation	3394 (with 383 re entries after live birth)
Total cycle number observed	8048
Patient's age (entire study, before and after the change of reimbursement policy in Germany in 2004)	33.74 ± 4.4 years; minimum 20 years, maximum 46 years of age (all patients, entire study) 34.33 ± 4.74 years (before 2004, not pregnant in study time) ^a 35.75 ± 4.4 years (2004 and beyond, not pregnant in study time) ^a 32.73 ± 8.8 years (before 2004, finally pregnant) ^a 33.71 ± 3.9 years (2004 and beyond, finally pregnant) ^a
Duration of infertility	3.4 years
Cycles/patient (entire study, before and after the change of reimbursement policy in Germany in 2004)	2.7 ± 1.3 (mean, entire study) 2.4 ± 1.7 (before 2004, not pregnant in study time) ^a 2.7 ± 1.9 (2004 and beyond, not pregnant in study time) ^a 1.9 ± 1.4 (2004 and beyond, finally pregnant) 1.9 ± 1.4 (2004 and beyond, finally pregnant)
Maximum cycles/patient	22
Oocytes/retrieval	10.35 (mean)
Embryos transferred/cycle	2.06 (mean)
IVF cycles	30% of all fresh cycles
IVF/ICSI-cycles	70% of all fresh cycles
Cryo cycles	34% of all cycles
Mean pregnancy rate	27.3%/cycle
Miscarriage rate	19.5%/cycle
Stillbirth rate	0.4%/birth
Ectopic pregnancy rate	2.2%/cycle

^aSignificant difference between the subgroups.

Figure 3 shows the CLBR according to the number of transferred embryos. Except for women over 40 years of age, an overall CLBR of ~50% was reached after the cumulative transfer of six embryos, in two or up to six cycles.

There was no statistical significant difference in the overall CLBR between the IVF and ICSI groups, when all ages were considered. However, when women over 35 and up to 40 were examined separately, ICSI was the more favourable option (*P* = 0.002 for CPR and *P* = 0.0040 for CLBR).

Cumulative pregnancy rates

The overall ongoing CPRs were 79% after 6 cycles (approximate 95% CI: 77–82%), 91% after 12 cycles (approximate 95% CI: 88–95%) and 100% after 18 treatment cycles.

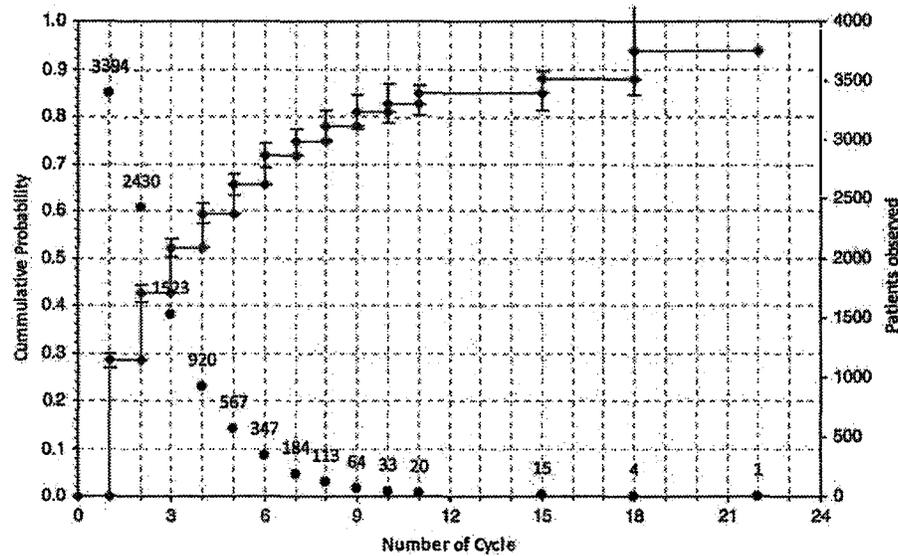


Figure 1 Overall CLBR (means \pm 2 standard errors to give the 95% region) for all patients and age classes over the number of treatment cycles. For each cycle, the number of 'patients observed' up to this time is given.

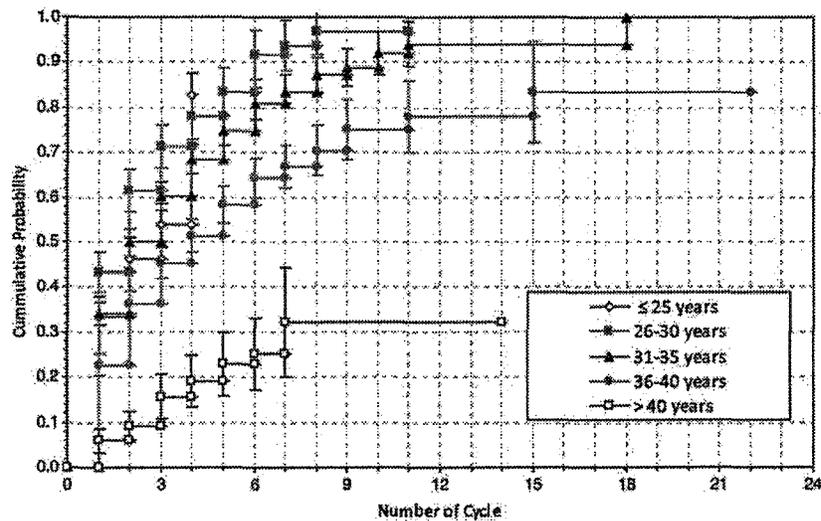


Figure 2 CLBRs (means \pm 2 standard errors to give the 95% region) for all patients stratified for the different age groups.

Pregnancy and LBRs out of one fresh cycle and its cryo-cycles

The mean ongoing PR (not estimated) from one fresh cycle and its subsequent cryo-cycle(s) (therapy sequence) was 41%, 39% in the IVF group and 42% in the IVF/ICSI group. Women in their 30s were the biggest group seeking ART (74% of all women), and for this group the PR from one fresh cycles and its cryo-cycles was 43%. There was no difference in outcome between IVF and ICSI per therapy sequence.

The mean LBR (not estimated) out of one fresh cycle and its subsequent cryo-cycle(s) was 33%, 31% in the IVF group and 34% in the ICSI group. For women in their 30s, the mean LBR from one fresh cycle and its cryo-cycles was 34%. Again there was no statistically significant difference between IVF and ICSI per therapy sequence.

A maximum of four pregnancies and maximum of three live births occurred from one therapy sequence of one fresh cycle and its subsequent cryo-cycles.

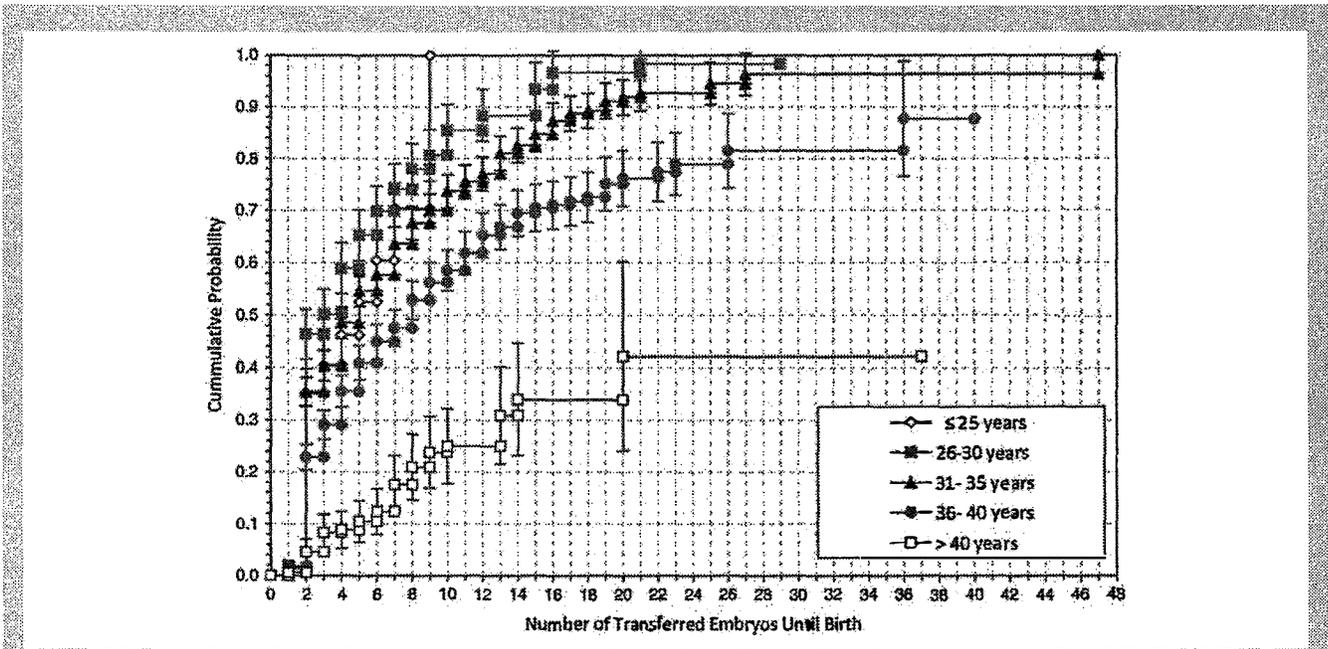


Figure 3 CLBRs (means \pm 2 standard errors to give the 95% region) for all patients stratified for the different age groups over the number of transferred embryos.

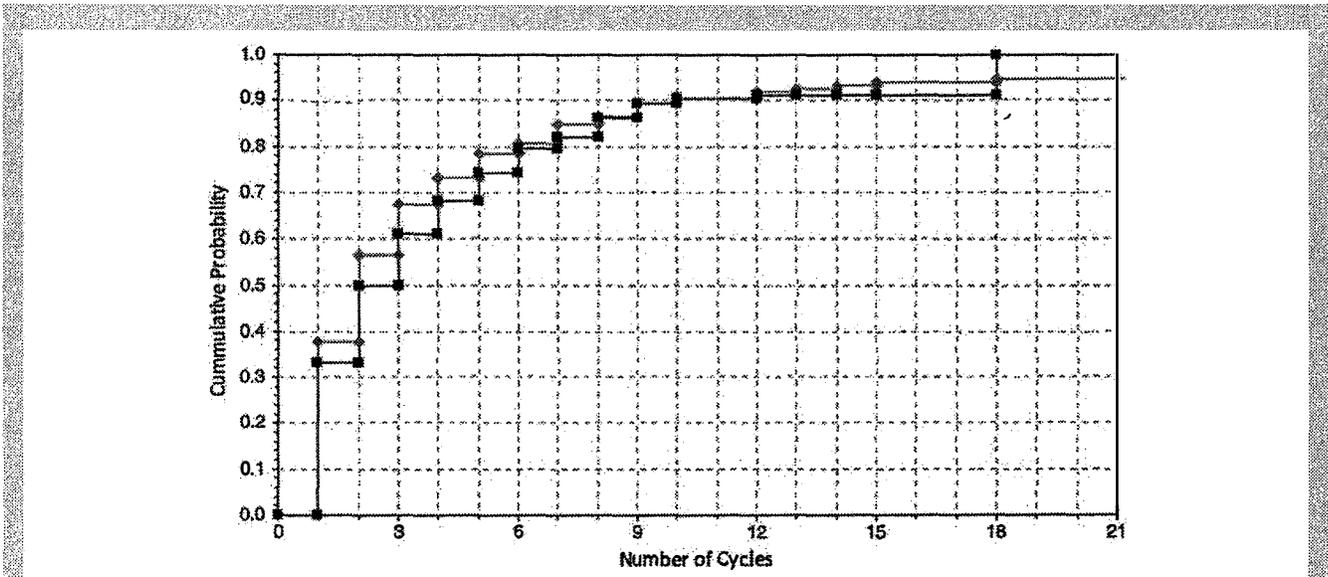


Figure 4 CPRs after ART (squares, 3394 patients) and CPRs in natural cycles [(Gnoth et al., 2003), diamonds, 340 patients].

CPRs after ART and in natural cycles after spontaneous conception

When plotting our data of CPR after ART into the graph of CPR in natural cycles from our 'Time to pregnancy-study' (Gnoth et al., 2003), the curve shapes were found to be nearly congruent (Fig. 4).

Discussion

A total of 3011 individual women who had treatment between 1998 and 2007 were included in our survey and 2068 children were born. Women already with a live birth re-entered the analysis as new 'patients under observation'. Our overall CLBR in 3394 'patients under observation' with 8048 cycles were 52% after 3 cycles

(median number of cycles per patient), 72% after 6 cycles, 85% after 12 and 94% after 18 treatment cycles. The mean, not estimated, LBR from one fresh cycle and its subsequent cryo-cycle(s) was 33%. Therefore, as previously noted (Damario *et al.*, 2000), cryopreservation of PN stage oocytes is an effective treatment strategy that optimizes the final results from one oocyte retrieval. Provided patients continue with treatment, the likelihood of success is high as shown by Kaplan–Meier figures. Obviously, during infertility treatment, many women re-evaluate their situation, and our figures are useful to aid their decisions on whether to continue with treatment, on the number of future cycles and on the number of embryos to be transferred the next time. This is important in cases in which only one embryo is intended or probably only available for the next transfer.

In this study, we did not classify patients or cycles according to the different causes of infertility because even recent studies have shown that CLBR do not vary substantially with the indication for ART (Dor *et al.*, 1996; Lintsen *et al.*, 2007, 2010).

With the use of the Kaplan–Meier method, which censors data for patients who did not return for further treatment for any reasons, we assume that those women would have had the same chance of a live birth by treatment as those who continued. This approach is a matter of contention as some authors have suggested it as possibly too optimistic (Stolwijk *et al.*, 1996, 2000; Sharma *et al.*, 2002) because of the possible early dropout of women with a poor prognosis and no realistic chance of a pregnancy or a live birth in subsequent treatment cycles (Hendriks *et al.*, 2008). So a rigorous pessimistic approach assumes that women, who did not return for further treatment, have a zero chance for achieving a pregnancy. On the other hand, patients with a poor prognosis might be more inclined to continue treatment if this seems to be the only chance of success (Roest *et al.*, 1998) resulting in an underestimation of real CPR and CLBR.

There are many factors that can result in such over- or underestimation of cumulative success rates if the reasons for dropout are not taken into account (Verberg *et al.*, 2008) although patients' true dropout reasons mostly remain unknown. The 'methodological' bias is mainly influenced by treatment strategy and counselling (Verberg *et al.*, 2008). So, the realistic CLBR lies in between the two extremes but may be closer to the optimistic assumption as natural conceptions do occur in women who have ceased ART. A study by Verhagen *et al.* (2008) found the PR in patients who were advised to stop treatment because of a medical indication (repeated fertilization failure after ICSI or very poor ovarian response), yet continued treatment, to be 14%. So, selective dropout of patients with poor treatment prognosis does not necessarily disadvantage our assumptions as it depends on the centre's treatment strategy and the population studied (Roest *et al.*, 1998; Schroder *et al.*, 2004). In case of a negative pregnancy test, patients with a good prognosis are generally encouraged to continue treatment. However, also in cases of doubtful prognosis, patients may be advised to go for further treatment cycles as the only reasonable way to achieve success (Croucher *et al.*, 1998; Klinkert *et al.*, 2004). Of course, this decision purely depends on the wishes of the couple. Another important aspect is the existence of alternatives for couples with a poor prognosis, e.g. oocyte donation, which is prohibited in Germany. As long as one, at least moderately developed embryo was present on the day of transfer, we encouraged patients to continue treatment in case of a negative test. So in this study, towards the higher number of treatment cycles, we may have an

accumulation of patients with limited prognosis reducing the overestimation bias.

Our CPR and CLBR could also be biased because some couples, even with good prognosis, probably did not return for further treatment after unsuccessful cycles because of financial reasons. Before 2004, four cycles were fully reimbursed, but then legislation required couples to privately fund half the cost of ART, resulting in a massive drop in procedures conducted from 2003 to 2004 and beyond (yearbooks of the German IVF Index on www.deutsches-ivf-register.de). The mean maternal age and the mean number of cycles per 'patient under observation' who did not conceive increased significantly after 2003 in our study, reducing overestimation failures. However, the median number of treatment cycles remained unchanged with three cycles per 'patient under observation' before 2004 and beyond. The overall ART success rates were not affected by this policy change, which was proved by usual, continuous cross-sectional statistics and separate calculations of CLBR before and after 2004.

Women with a live birth re-entering the study for a next child were included as 'new patients under observation' in all estimations of CLBRs and CPRs. We are aware of this minimal lack of independence in censoring by re-entering individual women as new patients after a live birth. Re-entry of patients is not a problem in usual survival analysis (e.g. survival of cancer patients) but there is an inherited bias in cumulative ART success rates, which is not discussed in most success studies. In this study, the proportion of re-entries in 'patients under observation' is relatively low. However, this still might result in overestimation of cumulative ART success rates (Molloy *et al.*, 1995), though only with a significant effect on the first two cycles (Stolwijk *et al.*, 2000). Based on our experiences with the calculation of CPR in natural cycles, this bias of re-entry is very small because of the long child spacing in our population (Gnoth *et al.*, 2003). Therefore, CLBR and CPR did not differ whether re-entry was allowed or not. Allowing re-entry in the analysis best reflects the real situation in treatment and counselling of couples.

Some of our couples changed to another IVF centre, a practice also recorded in the national index where our patient's migration is around 7%. Therefore, for ~3–4% of our patients, their 'first cycle' in our centre may already be their cycle two or three, further reducing the overestimation bias just mentioned.

In exactly 4% of all fresh cycles with supernumerous PN stage oocytes, they were not cryopreserved, but discarded, mainly because of financial reasons of the couple. Therefore, the mean PR and LBR out of one fresh cycle are slightly underestimated as well.

An important strength of this survey is consistency in that the centre's treatment policy remained nearly unchanged throughout the entire survey with the same team of reproductive specialists and the same responsible embryologists. Treatment methods did not change substantially either in the entire survey except for a continuous increase in the proportion of ICSI cycles. Over time, antagonists were introduced, laser-assisted hatching was offered and recently polar body biopsy, spindle view and zona imaging has been added to the repertoire of methods. Quarterly, cross-sectional statistics showed a slight increase in clinical PRs per transfer over the years, which was not tested for significance and was not attributed to new methods or drugs yet.

For all the reasons above, we assume that the inherited methodological overestimation bias in our study is relatively small but it cannot

be assessed exactly. Possibly, the slightly optimistic success rates best reflect counselling situations: the couple's future chances of live birth is based on the rates of those who continued in the past.

Recently, single centre CLBRs were published by Malizia *et al.* from the Waltham-IVF centre, Boston/USA (Malizia *et al.*, 2009). Compared with their optimistic assumptions, our CLBR after six cycles is the same: 72%. This is very interesting, because of completely different treatment strategies in both IVF centres. According to the German Embryo Protection Law, it is not allowed to culture more PN stage oocytes than the embryos which are to be transferred later in that cycle. Therefore, embryo selection as performed by this and many other foreign centres probably with prolonged cell-culture is not possible here. We strictly cryopreserved all supernumerous PN stage oocytes for later cryo-cycles. Embryos were cryopreserved only in very rare cases for emergency reasons. Obviously, completely different treatment strategies may lead to the same results: a CLBR of 72% after six treatment cycles. Just for patients over 40 years of age, we achieved a lower CLBR presumably because of study cohort differences, as there was a high proportion of women over 40 entering the IVF programme but then turning to oocyte donation early in Waltham.

The congruent CPR after ART and CPR in natural cycles (Gnoth *et al.*, 2003) (Fig. 4) are in line with recently published simulation models (Stanford *et al.*, 2010) and provide reliable experimental evidence as support, because of the same methodological approaches in both of our studies. This strongly suggests that ART can reach natural fertility rates but cannot exceed them.

Most of the patients in this study did not undergo many treatment cycles (mean 2.7; median 3 with a CLBR of ~50%)—even those with reasonable good prognosis for final success—because they probably could not afford the emotional or financial cost independent of the reimbursement. However, from the medical point of view, there is no reason for generally restricting the number of cycles e.g. to three, as done in Germany.

It was our intention to calculate final success rates for live birth to facilitate counselling of couples with infertility problems and to highlight the potential of ART even under rigorous restrictions by law. In this respect, it is important to emphasize again that reproductive medicine can be successful for most couples if they continue treatment.

Authors' roles

C.G. played a role in study design, running of the cycles, statistical analysis and writing the manuscript. B.M. took part in raw data collection and quality checking. T.S. was involved in raw data preparation, statistical analysis and proofreading. K.F. and J.T. were involved in study design, running the cycles and proofreading. E.G. took part in statistical mentoring, performing the final statistical analysis and writing the manuscript.

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Outcome of in vitro fertilization treatment in patients who electively inseminate a limited number of oocytes to avoid creating surplus human embryos for cryopreservation

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Objective: To determine whether the outcome of IVF treatment in patients who electively inseminate a limited number of oocytes is comparable to that in a group of good-prognostic or poor-prognostic patients.

Design: Retrospective clinical study.

Setting: University-based tertiary fertility center.

Patient(s): Two hundred three women under the age of 40 years.

Intervention(s): Patients undergoing their first cycle of IVF who elected to have no more than four oocytes inseminated (study group) or who produced only four or fewer oocytes (poor-prognostic group) or who had excess embryos cryopreserved (good-prognostic group).

Main Outcome Measure(s): Implantation rate, clinical pregnancy rate, and ongoing pregnancy rate.

Result(s): There were no significant differences in the implantation rate for the study group when compared with the good-prognostic group or the poor-prognostic group. The clinical pregnancy rate (62.5% vs. 64%) and ongoing-pregnancy or birth rate (56.3% vs. 60.7%) were similar between the study group and the good-prognostic group. However, the clinical pregnancy rate (62.5% vs. 29.7%) and ongoing-pregnancy rate (56.3% vs. 24.3%) were higher in the study group compared with the poor-prognostic group.

Conclusion(s): Inseminating fewer oocytes in patients who elect not to cryopreserve excess embryos does not adversely affect their probability of conception. (*Fertil Steril*® 2005;84:1406–10. ©2005 by American Society for Reproductive Medicine.)

Key Words: Limited insemination of oocytes, cryopreservation, in-vitro fertilization, poor responders, avoiding surplus embryos

The option of cryopreserving excess embryos allows the opportunity to inseminate all oocytes retrieved, thereby increasing the probability of obtaining a large number of embryos. This offers the advantage of selecting the best-quality embryos for transfer from a large embryo cohort pool, potentially enhancing the probability of conception. Several studies have confirmed that a large embryo cohort size after IVF treatment is an important predictor of the quality of embryos transferred (1), as well as both birth and multiple-birth rates (2, 3).

A certain group of patients may elect not to destroy or cryopreserve surplus embryos. It is debatable how to best avoid creating surplus embryos for such patients without jeopardizing their chances of success after an IVF treatment. The options include limiting the number of embryos created

either by utilizing a protocol of natural-cycle IVF or of minimal ovarian stimulation or by limiting the number of oocytes inseminated during IVF (4).

In our program, patients who elect not to cryopreserve have the number of oocytes inseminated limited to no more than four. This may result in a limited number of embryos and in fewer good-quality embryos for transfer than if there was a large embryo cohort pool. Further, it is well established that the probability of conception is low when fewer oocytes are retrieved in poor responders during IVF treatment (5–8). However, there is a lack of data in the literature about the outcome of IVF treatment if a limited number of oocytes are electively inseminated in patients who otherwise are normal responders.

The purpose of this study, therefore, was to determine whether the outcome of IVF treatment in patients who had no more than four oocytes inseminated is comparable to that in a group of patients who had surplus embryos cryopreserved (good-prognostic group) and in a group of patients who produced only four or fewer oocytes (poor-prognostic group). The information derived from this study will be

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important in counseling this group of patients and guiding them in making an informed decision.

MATERIALS AND METHODS

Patients

This is a retrospective clinical study that was performed at the Center for Advanced Reproductive Services at the University of Connecticut Health Center. Only patients who were younger than 40 years of age and who underwent their first cycle of IVF treatment between January 2000 and December 2003 were included in the analyses. The data comprised a total of 203 patients, including women who elected to have no more than four oocytes inseminated (study group; 16 women), those who had excess embryos cryopreserved (good-prognostic group; 150 women), and those who produced four or fewer oocytes (poor-prognostic group; 37 women). Approval for this study was obtained from the institutional review board at the University of Connecticut Health Center.

Treatment Protocol

All the women underwent a standard IVF treatment protocol that involved the use of the luteal-phase GnRH agonist protocol. All patients started 0.5 mg of leuprolide acetate (Lupron; TAP Pharmaceuticals, North Chicago, IL) in the midluteal phase of the preceding cycle. A transvaginal ultrasound and serum E₂ then were performed after the onset of menses to confirm pituitary suppression, as shown by the absence of follicular activity and a serum E₂ level of <75 pg/mL. Once pituitary suppression was achieved, the administration of recombinant FSH (Gonal F; Serono, Inc., Rockland, MA) was commenced, either alone or in combination with purified urinary (Repronex; Ferring Pharmaceuticals, Inc., Suffern, NY). The dose of leuprolide acetate then was reduced to 0.25 mg daily and was continued until the day of hCG (Profasi; Serono Laboratories, Randolph, MA) administration. The standard daily starting dose of gonadotropins was 150–450 IU, depending on patient's age, body mass index, basal serum FSH levels, previous ovarian response, and ovarian morphology.

Monitoring of follicular growth was achieved with serial ultrasound and serum E₂ measurements, and the dose of gonadotropins was adjusted, if necessary, according to follicular response. When two or three leading follicles were ≥18 mm in diameter, hCG in a dose ranging from 3,300 to 10,000 IU was administered intramuscularly depending on follicular response and serum E₂ levels (9). Transvaginal ultrasound-directed oocyte retrieval was performed approximately 35 hours after hCG administration. Embryo transfer was performed 72 to 76 hours after oocyte retrieval. All patients received 50 mg of P in oil daily IM for luteal support, starting the evening after oocyte retrieval and continuing until a negative pregnancy test or a viable fetus was documented by transvaginal sonography.

Supernumerary embryos of good quality then were cryopreserved on the day of the embryo transfer with the patients' consent. The embryos were graded according to the criteria described by Cummins and coworkers (10). Grade 1 embryos have equal-sized blastomeres and no fragmentation, grade 2 embryos have equal-sized blastomeres and <20% fragmentation, grade 3 embryos have unequal-sized blastomeres and no fragmentation, grade 4 embryos have unequal-sized blastomeres and >20% fragmentation, and grade 5 embryos have unequal-sized blastomeres and severe fragmentation. Good-quality embryos were defined as six or more blastomeres with an embryo grading of 1, 2, or 3.

Statistical Analysis

The main outcome variables were implantation rate, clinical pregnancy rate, and ongoing-pregnancy rate. Clinical pregnancy was defined as a positive serum β-hCG test result with ultrasound evidence of a gestational sac. The implantation rate was defined as the number of gestational sacs, as assessed by ultrasound at 7 weeks' gestation, divided by the number of embryos transferred for each patient.

All analyses were performed by using the Statistical Package for the Social Sciences (release 6.0; SPSS Inc., Chicago, IL). Because the data were not normally distributed, the Kruskal-Wallis test was used for continuous variables. Fisher's exact or χ² tests were used for categorical variables where appropriate. Data are presented as mean ± SD unless otherwise stated. All P values quoted are two-tailed, and values <.05 were taken to indicate statistical significance.

RESULTS

A total of 203 women undergoing their first cycle of IVF fulfilled the study criteria. They were comprised of 16 women who elected to have no more than four oocytes inseminated, 150 women who had excess embryos cryopreserved, and 37 women who produced four or fewer oocytes.

The mean age of the patients in the study group (33.4 ± 3.9 years) was not significantly different from that of the good-prognostic group (33.3 ± 2.6 years) or the poor-prognostic group (34.8 ± 3.2 years). A comparable proportion of patients underwent intracytoplasmic sperm injection in the study group (69.3%), good-prognostic group (68.8%), and poor-prognostic group (73%). Two cycles (9.5%) in the poor-prognostic group did not have any embryo transfer because of failed fertilization (1 cycle) and failure of embryo development (1 cycle). All the cycles in the good-prognostic or study groups resulted in embryo transfer.

The outcome of ovarian response is shown in Table 1. The mean numbers of oocytes retrieved and embryos transferred were similar between the study and the good-prognostic groups, although there were intentionally more oocytes inseminated and therefore more embryos available in the good-prognostic group than the study group. When compared with the poor-prognostic group, the study group had

**TABLE 1****Outcome of ovarian response.**

Parameter	Study group (n = 16)	Poor-prognostic group (n = 37)	Good-prognostic group (n = 150)
No. of oocytes	12.8 ± 6.0 ^a	3.46 ± 0.7	14.0 ± 5.8 ^a
No. of oocytes inseminated	3.4 ± 0.6 ^b	3.0 ± 0.9 ^b	14.0 ± 5.7
No. of oocytes fertilized	2.9 ± 0.7 ^b	2.0 ± 1.0 ^b	10.2 ± 4.2
Fertilization rate (%)	86.4 ± 19.2	68.0 ± 30.4	74.4 ± 15.7
No. of embryos transferred	2.6 ± 0.7 ^c	1.9 ± 0.8	2.1 ± 0.3
No. of good-quality embryos transferred	1.3 ± 1.1	0.7 ± 0.8	2.0 ± 0.4
No. of embryos frozen	0	0	5.3 ± 2.9

^a P<.01 compared with the poor-prognostic group.^b P<.01 compared with the good-prognostic group.^c P<.01 compared with the poor- and good-prognostic groups.

Engmann. Insemination of fewer oocytes. Fertil Steril 2005.

significantly more oocytes retrieved and embryos transferred, although the number of oocytes inseminated and embryos available were similar. There were no significant differences in the fertilization rate among the three groups.

There were no significant differences in the implantation rate for the study group (35.7%) when compared with that of the good-prognostic group (47.5%) or the poor-prognostic group (21.7%; Table 2). The clinical pregnancy rate (62.5% vs. 64%) and ongoing-pregnancy rate (56.3% vs. 60.7%) were similar between the study group and the good-prognostic group. However, the clinical pregnancy rate (62.5% vs. 29.7%, P<.05) and ongoing-pregnancy rate (56.3% vs. 24.3%, P<.05) were significantly higher in the study group compared with the poor-prognostic group (Table 2). The ongoing multiple-pregnancy rate was not significantly different among the three groups (Table 2). There were no triplets in the study and poor-prognostic groups; however, the incidence of ongoing triplet-pregnancy rate in the good-prognostic group was 2.1%. The ongoing twin-pregnancy rate was 44.4% in the study group, compared with 40.6% and 33.3% in the good- and poor-prognostic groups, respectively.

DISCUSSION

This study clearly has demonstrated that inseminating fewer oocytes in women who elect not to cryopreserve surplus embryos does not adversely affect their probability of conception and should be considered a viable option for such patients. The clinical-pregnancy and ongoing-pregnancy rates are comparable to those of a good-prognostic group of patients but significantly higher than those of poor responders.

For ethical or moral reasons, some patients object to destroying or cryopreserving surplus embryos that have been created from IVF treatment and that may have the potential to implant. Regardless of the reasons for such a decision, it is our duty as clinicians to discuss the best evidence available that will help patients make an informed decision. Counseling these patients appropriately is a dilemma because of the relative lack of evidence about the outcomes of the various options.

The options available for patients who elect not to destroy or cryopreserve surplus embryos include declining IVF and considering adoption (4). Alternatively, they can limit the number of embryos they create by undergoing natural-cycle

TABLE 2**Outcome of IVF treatment.**

Parameter	Study group	Poor-prognostic group	Good-prognostic group
Implantation rate, % (n)	35.7 (15/42)	21.7 (15/69)	47.5 (151/318)
Clinical pregnancy rate, % (n)	62.5 (10/16)	29.7 (11/37) ^a	64 (96/150)
Ongoing pregnancy rate, % (n)	56.3 (9/16)	24.3 (9/37) ^a	60.7 (91/150)
Ongoing multiple pregnancy rate, % (n)	44.4 (4/9)	33.3 (3/9)	42.8 (39/91)

^a P<.05 when compared with the study and good-prognostic groups.

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IVF or minimal-stimulation IVF or by limiting the number of oocytes inseminated for IVF (4). Under these circumstances, all embryos of good quality will be transferred, and there will be no extra embryos to cryopreserve or destroy.

Our program has adopted the approach of inseminating no more than four oocytes and replacing all the available good-quality embryos in women who elect not to cryopreserve surplus embryos. Because this approach limits the number of embryos created, the ability to select the best-quality embryos from a larger embryo cohort may be compromised. Devreker and coworkers (1) have shown that the quality of embryos transferred declines when fewer than five embryos are created. Further, when fewer embryos are created during an IVF cycle, the probability of birth declines (3). Therefore, patients who respond poorly to ovarian stimulation and produce five or fewer oocytes have a low probability of conception (6, 8). However, there are no data in the literature about the outcome of IVF treatment in women who may otherwise be normal responders but who had only limited oocytes inseminated.

It is important to distinguish this group of patients who otherwise are normal responders and who produce a good number of oocytes from poor responders who produce only a few oocytes after superovulation, resulting in embryos with poor implantation potential. Our data demonstrate that patients who respond well to treatment but have fewer oocytes inseminated by choice behave like the good-prognostic patients and produce a cohort of good-quality oocytes that become good-quality embryos capable of implanting.

However, there are potential limitations of this approach that should be discussed with patients before treatment. First, because no embryos are frozen, patients forego the advantages of a frozen replacement cycle. Second, there is a likelihood for transfer of more embryos than recommended for the patient's age, which may result in an increase in the multiple-pregnancy rate. Third, because fewer oocytes are inseminated, there is a risk that no embryos will be transferred because of failure of fertilization or embryo development. A thorough discussion regarding the number of oocytes to inseminate also should be undertaken with the couple before treatment.

Although natural-cycle IVF is relatively low risk, less expensive, and offers a unique opportunity for fewer oocytes to be produced and inseminated without the creation of surplus embryos, the relatively low success rate (11, 12) makes it less appealing to both patients and clinicians. In a review of 20 published studies consisting of about 1,800 natural IVF cycles, Pelinck and colleagues (12) showed that the cancellation rate was about 55%, attributed to the lack of embryos created, and that the pregnancy rate per transfer was about 7.6%.

Minimal ovarian stimulation to reduce the number of oocytes produced and hence the number of embryos created

is another potential option for patients who wish to avoid creating surplus embryos. Additionally, this approach will reduce the amount of gonadotropins required for controlled ovarian stimulation and will avoid unnecessary added cost from the extra medications used. It has been argued that minimal ovarian stimulation may result in fewer embryos, a reduction in the number of good-quality embryos available for transfer, and a decline in pregnancy rate (1). However, published results using minimal ovarian stimulation protocols have been promising. Several retrospective studies have suggested that minimal ovarian stimulation using a clomiphene citrate and low-dose gonadotropin protocol resulted in a pregnancy rate comparable to that of a group of patients who underwent normal ovarian stimulation protocol (13, 14).

In future, it may be advisable to reduce the dose of gonadotropin required for controlled ovarian stimulation to obtain fewer oocytes for insemination in this group of patients. There is a need for further studies to evaluate whether reducing the dose of gonadotropin to reduce the number of oocytes retrieved adversely affects cycle outcome in this group of patients.

In conclusion, inseminating a limited number of oocytes in a group of patients who choose to avoid creating surplus embryos for cryopreservation or destruction does not adversely affect the outcome of their cycle. It is also clear that such patients perform better than a group of poor-prognosis patients who inseminated a fewer number of oocytes because of poor ovarian response. However, it is important for couples to understand the potential risks of such an approach as well as the advantages of a frozen-embryo replacement cycle. This information is useful in counseling such patients on the options available to them before undergoing IVF treatment.

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February 5, 2013

PROPOSED AMENDMENTS TO SENATE BILL NO. 2302

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for the ethical treatment of human embryos; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1.

Definitions.

As used in this Act only:

1. "Donor" means an individual from whose body gametes were obtained, or an individual from whose body cells or tissues were obtained for the purpose of creating gametes or human embryos, whether for valuable consideration or not.
2. "Embryo" means an organism in its earliest stages of development, including the single-cell stage.
3. "Facility" or "medical facility" means any public or private hospital, clinic, center, medical school, medical training institution, health care facility, physician's office, infirmary, dispensary, ambulatory surgical treatment center, or other institution or location wherein medical care is provided to any person.
4. "Gamete" means an egg (oocyte) or sperm.
5. "Human-animal hybrid" means any of the following:
 - a. A human embryo into which a nonhuman cell or a component of a nonhuman cell is introduced so that it is uncertain whether the human embryo is a member of the species homo sapiens;
 - b. An embryo produced by fertilizing a human egg with a nonhuman sperm;
 - c. An embryo produced by fertilizing a nonhuman egg with a human sperm;
 - d. An embryo produced by introducing a nonhuman nucleus into a human egg;
 - e. An embryo produced by introducing a human nucleus into a nonhuman egg;
 - f. An embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form;

- g. A nonhuman life form engineered with the intention of generating functional human gametes within the body of a nonhuman life form; or
- h. A nonhuman life form engineered such that it contains a human brain or a brain derived wholly from human neural tissues.
6. "Human embryo" means an organism with a human or predominantly human genetic constitution from the single-cell stage to eight weeks development that is derived by fertilization (in vitro or in utero), parthenogenesis, cloning (somatic cell nuclear transfer), or any other means from one or more human gametes or human diploid cells.
7. "In vitro" means outside the human body.
8. "In vitro human embryo" means a human embryo created outside the human body.
9. "Pay" or "payment" means pay, contract for, or otherwise arrange for the payment of in whole or in part.
10. "Valuable consideration" means financial gain or advantage, including cash, in-kind payments, reimbursement for any costs incurred in connection with the removal, processing, disposal, preservation, quality control, storage, transfer, or donation of human gametes, including lost wages of the donor, as well as any other consideration.

SECTION 2.

Ethical treatment of human embryos.

1. A person may not intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization of a human egg by a human sperm.
2. The creation of an in vitro human embryo may be solely for the purpose of initiating a human pregnancy by means of transfer to the body of a human female for the treatment of human infertility. A pregnancy may not be initiated with the intention of deliberately destroying the embryo for scientific research. A human embryo may not be gestated to the fetal stage for purposes of destroying the fetus in order to harvest tissue, organs, or stem cells. A person may not intentionally or knowingly transfer or attempt to transfer an embryo that is not the product of fertilization of a human egg by a human sperm into a human body.
3. A person may not intentionally or knowingly:
- a. Create or attempt to create a human-animal hybrid;
 - b. Transfer or attempt to transfer a human embryo into a nonhuman womb;
 - c. Transfer or attempt to transfer a nonhuman embryo into a human womb; or
 - d. Transfer or receive for any purpose a human-animal hybrid or any product derived from such hybrid.

4. This section does not prohibit:

- a. Research involving the use of transgenic animal models containing human genes;
- b. Xenotransplantation of human organs, tissues, or cells into recipient animals, including animals at any stage of development before birth, if the xenotransplantation does not violate a prohibition in subsection 3; or
- c. A person from receiving organs, tissues, or cells delivered from outside this state.

SECTION 3.

Valuable consideration prohibited.

A person may not give or receive valuable consideration, offer to give or receive valuable consideration, or advertise for the giving or receiving of valuable consideration for the provision of gametes or in vitro human embryos. This section does not regulate or prohibit the procurement of gametes for the treatment of infertility being experienced by the patient from whom the gametes are being derived. This section may not be construed as prohibiting the cryopreservation of gametes.

SECTION 4.

Identification.

An in vitro human embryo must be given an identification by the facility for use within the medical facility. Records must be maintained identifying the donors associated with the in vitro human embryo. The confidentiality of records kept under this section must be maintained.

SECTION 5.

Care and treatment of in vitro human embryos.

1. A living in vitro human embryo is a biological human being who is not the property of any person. The fertility physician and the medical facility that employs the physician owe a high duty of care to the living in vitro human embryo. Any contractual provision identifying the living in vitro embryo as the property of any party is null and void. The in vitro human embryo may not be intentionally destroyed for any purpose by any person or through the actions of such person.
2. An in vitro human embryo that fails to show any sign of life over a thirty-six-hour period outside a state of cryopreservation may be considered no longer living.

SECTION 6.

Judicial standard.

In disputes arising between any parties regarding an in vitro human embryo, the judicial standard for resolving such disputes is the best interest of the in vitro human embryo.

SECTION 7.

Penalty.

1. It is a class B misdemeanor for a person to violate this Act.
2. A violation of this Act by a physician constitutes grounds for disciplinary action under section 43-17-31.
3. A violation of this Act may be the basis for denying an application for, denying an application for the renewal of, or revoking any license, permit, certificate, or any other form of permission required to practice or engage in a medical trade, occupation, or profession.
4. A violation this Act by an employee of a licensed health care facility to which the management of said facility consents, knows, or should know may be the basis for denying an application for, denying an application for the renewal of, temporarily suspending, or permanently revoking any operational license, permit, certificate, or any other form of permission required to operate a medical or health care facility.

SECTION 8.

Construction.

1. Nothing in this Act may be construed as creating or recognizing a right to abortion.
2. It is not the intention of this Act to make lawful an abortion that is currently unlawful."

Renumber accordingly

2011

**FIRST ENGROSSMENT
with Senate Amendments
ENGROSSED HOUSE BILL NO. 1450**

2303 (2)
2013
≈ SB 2303

Introduced by

Representatives Ruby, Karls, Kasper

Senators Larsen, Nodland, Sitte

1 A BILL for an Act to create and enact a new section to chapter 12.1-17 of the North Dakota
2 Century Code, relating to the application of sections in chapter 12.1-17 to certain medical
3 procedures; and to amend and reenact sections 12.1-01-04 and 12.1-16-06 of the North Dakota
4 Century Code, relating to the definition of human being and the application of sections in
5 chapter 12.1-16 to certain medical procedures.

6 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

7 **SECTION 1. AMENDMENT.** Section 12.1-01-04 of the North Dakota Century Code is
8 amended and reenacted as follows:

9 **12.1-01-04. General definitions.**

10 As used in this title, unless a different meaning plainly is required:

- 11 1. "Act" or "action" means a bodily movement, whether voluntary or involuntary.
- 12 2. "Acted", "acts", and "actions" include, where relevant, "omitted to act" and "omissions
13 to act".
- 14 3. "Actor" includes, where relevant, a person guilty of an omission.
- 15 4. "Bodily injury" means any impairment of physical condition, including physical pain.
- 16 5. "Court" means any of the following courts: the supreme court, a district court, and
17 where relevant, a municipal court.
- 18 6. "Dangerous weapon" means, but is not limited to, any switchblade or gravity knife,
19 machete, scimitar, stiletto, sword, or dagger; any billy, blackjack, sap, bludgeon,
20 cudgel, metal knuckles, or sand club; any slungshot; any bow and arrow, crossbow, or
21 spear; any weapon which will expel, or is readily capable of expelling, a projectile by
22 the action of a spring, compressed air, or compressed gas including any such weapon,
23 loaded or unloaded, commonly referred to as a BB gun, air rifle, or CO₂ gun; and any

- 1 projector of a bomb or any object containing or capable of producing and emitting any
2 noxious liquid, gas, or substance.
- 3 7. "Destructive device" means any explosive, incendiary or poison gas bomb, grenade,
4 mine, rocket, missile, or similar device.
- 5 8. "Explosive" means gunpowders, powders used for blasting, all forms of high
6 explosives, blasting materials, fuses (other than electric circuit breakers), detonators
7 and other detonating agents, smokeless powders, and any chemical compounds,
8 mechanical mixture, or other ingredients in such proportions, quantities, or packing
9 that ignition by fire, by friction, by concussion, by percussion, or by detonation of the
10 compound, or material, or any part thereof may cause an explosion.
- 11 9. Repealed by S.L. 1975, ch. 116, § 33.
- 12 10. "Firearm" means any weapon which will expel, or is readily capable of expelling, a
13 projectile by the action of an explosive and includes any such weapon, loaded or
14 unloaded, commonly referred to as a pistol, revolver, rifle, gun, machine gun, shotgun,
15 bazooka, or cannon.
- 16 11. "Force" means physical action.
- 17 12. "Government" means:
- 18 a. The government of this state or any political subdivision of this state;
19 b. Any agency, subdivision, or department of the foregoing, including the executive,
20 legislative, and judicial branches;
21 c. Any corporation or other entity established by law to carry on any governmental
22 function; and
23 d. Any commission, corporation, or agency established by statute, compact, or
24 contract between or among governments for the execution of intergovernmental
25 programs.
- 26 13. "Governmental function" includes any activity which one or more public servants are
27 legally authorized to undertake on behalf of government.
- 28 14. "Harm" means loss, disadvantage, or injury to the person affected, and includes loss,
29 disadvantage, or injury to any other person in whose welfare the person affected is
30 interested.

Sixty-second
Legislative Assembly

- 1 15. "Human being" means an individual member of the species homo sapiens at every
2 stage of development.
- 3 16. "Included offense" means an offense:
4 a. Which is established by proof of the same or less than all the facts required to
5 establish commission of the offense charged;
6 b. Which consists of criminal facilitation of or an attempt or solicitation to commit the
7 offense charged; or
8 c. Which differed from the offense charged only in that it constitutes a less serious
9 harm or risk of harm to the same person, property, or public interest, or because
10 a lesser degree of culpability suffices to establish its commission.
- 11 ~~16-17.~~ "Includes" should be read as if the phrase "but is not limited to" were also set forth.
- 12 ~~17-18.~~ "Law enforcement officer" or "peace officer" means a public servant authorized by law
13 or by a government agency or branch to enforce the law and to conduct or engage in
14 investigations or prosecutions for violations of law.
- 15 ~~18-19.~~ "Local" means of or pertaining to any political subdivision of the state.
- 16 ~~19-20.~~ Repealed by S.L. 1975, ch. 116, § 33.
- 17 ~~20-21.~~ "Offense" means conduct for which a term of imprisonment or a fine is authorized by
18 statute after conviction.
- 19 ~~21-22.~~ "Official action" includes a decision, opinion, recommendation, vote, or other exercise
20 of discretion by any government agency.
- 21 ~~22-23.~~ "Official proceeding" means a proceeding heard or which may be heard before any
22 government agency or branch or public servant authorized to take evidence under
23 oath, including any referee, hearing examiner, commissioner, notary, or other person
24 taking testimony or a deposition in connection with any such proceeding.
- 25 ~~23-24.~~ "Omission" means a failure to act.
- 26 ~~24-25.~~ As used in this title and in sections outside this title which define offenses, "person"
27 includes, where relevant, a corporation, limited liability company, partnership,
28 unincorporated association, or other legal entity. When used to designate a party
29 whose property may be the subject of action constituting an offense, the word "person"
30 includes a government which may lawfully own property in this state. Person includes
31 all human beings.

Sixty-second
Legislative Assembly

- 1 ~~25-26.~~ "Political subdivision" as used in this title and in any statute outside this title which
2 defines an offense means a county, city, school district, township, and any other local
3 governmental entity created by law.
- 4 ~~26-27.~~ "Property" includes both real and personal property.
- 5 ~~27-28.~~ "Public servant" as used in this title and in any statute outside this title which defines
6 an offense means any officer or employee of government, including law enforcement
7 officers, whether elected or appointed, and any person participating in the
8 performance of a governmental function, but the term does not include witnesses.
- 9 ~~28-29.~~ "Risk assessment" means an initial phase with a secondary process approved by the
10 department of human services for the evaluation of the likelihood that a person who
11 committed an offense will commit another similar offense. The initial phase is an
12 assessment tool that is administered by a trained probation and parole officer. A
13 predetermined score on the initial phase initiates the secondary process that includes
14 a clinical interview, psychological testing, and verification through collateral information
15 or psychophysiological testing, or both. The department of human services shall
16 perform the secondary process of the risk assessment.
- 17 ~~29-30.~~ "Serious bodily injury" means bodily injury that creates a substantial risk of death or
18 which causes serious permanent disfigurement, unconsciousness, extreme pain,
19 permanent loss or impairment of the function of any bodily member or organ, a bone
20 fracture, or impediment of air flow or blood flow to the brain or lungs.
- 21 ~~30-31.~~ "Signature" includes any name, mark, or sign written or affixed with intent to
22 authenticate any instrument or writing.
- 23 ~~31-32.~~ "Substantial bodily injury" means a substantial temporary disfigurement, loss, or
24 impairment of the function of any bodily member or organ.
- 25 ~~32-33.~~ "Thing of value" or "thing of pecuniary value" means a thing of value in the form of
26 money, tangible or intangible property, commercial interests, or anything else the
27 primary significance of which is economic gain to the recipient.
- 28 ~~33-34.~~ "Writing" includes printing, typewriting, and copying.
- 29 Words used in the singular include the plural, and the plural the singular. Words in the
30 masculine gender include the feminine and neuter genders. Words used in the present tense
31 include the future tense, but exclude the past tense.

1 **SECTION 2. AMENDMENT.** Section 12.1-16-06 of the North Dakota Century Code is
2 amended and reenacted as follows:

3 **12.1-16-06. Construction.**

4 1. Sections 12.1-16-04 through 12.1-16-06 do not preclude the use of medications or
5 procedures necessary to relieve a person's pain or discomfort if the use of the
6 medications or procedures is not intentionally or knowingly prescribed or administered
7 to cause the death of ~~that~~ a person. In addition, sections 12.1-16-04 through
8 12.1-16-06 do not preclude the withholding or withdrawal of life-prolonging treatment
9 pursuant to state or federal law.

10 2. Sections 12.1-16-01 through 12.1-16-03 do not apply to:

- 11 a. Medical treatment for life-threatening conditions provided to a person by a
12 physician licensed to practice medicine under chapter 43-17 which results in the
13 accidental or unintentional injury or death of another person.
- 14 b. Medical treatment for life-threatening conditions in pregnancy.
- 15 c. The screening, collecting, preparing, transferring, or cryopreserving of a human
16 being created through in vitro fertilization for the purpose of being transferred to a
17 human uterus.
- 18 d. The disposal or destruction of a fertilized human ovum, zygote, or embryo,
19 created through in vitro fertilization, which has been subject to medical testing
20 and analysis, and in the reasonable judgment of a medical professional, if
21 transferred to a human uterus, would not produce a live birth.
- 22 e. The disposal or destruction of a fertilized human ovum, zygote, or embryo,
23 created through in vitro fertilization which has not progressed in development for
24 thirty-six hours in culture.
- 25 f. Contraception administered before a clinically diagnosable pregnancy of a
26 woman.
- 27 g. The termination of a pregnancy that resulted from gross sexual imposition, sexual
28 imposition, sexual abuse of a ward, or incest, as those offenses are defined in
29 chapter 12.1-20.

1 3. Sections 12.1-16-01 through 12.1-16-03 apply only to the principal actor, other than
2 the pregnant woman, with respect to criminal conduct upon a person who has not yet
3 been born.

4 **SECTION 3.** A new section to chapter 12.1-17 of the North Dakota Century Code is created
5 and enacted as follows:

6 **Construction.**

7 1. Sections 12.1-17-01 through 12.1-17-03 do not apply to:

- 8 a. Medical treatment for life-threatening conditions provided to a person by a
9 physician licensed to practice medicine under chapter 43-17 which results in the
10 accidental or unintentional injury or death of another person.
11 b. Medical treatment for life-threatening conditions in pregnancy.
12 c. The screening, collecting, preparing, transferring, or cryopreserving of a human
13 being created through in vitro fertilization for the purpose of being transferred to a
14 human uterus.
15 d. The disposal or destruction of a fertilized human ovum, zygote, or embryo,
16 created through in vitro fertilization, which has been subject to medical testing
17 and analysis, and in the reasonable judgment of a medical professional, if
18 transferred to a human uterus, would not produce a live birth.
19 e. The disposal or destruction of a fertilized human ovum, zygote, or embryo,
20 created through in vitro fertilization which has not progressed in development for
21 thirty-six hours in culture.
22 f. Contraception administered before a clinically diagnosable pregnancy of a
23 woman.
24 g. The termination of a pregnancy that resulted from gross sexual imposition, sexual
25 imposition, sexual abuse of a ward, or incest, as those offenses are defined in
26 chapter 12.1-20.

27 2. Sections 12.1-17-01 through 12.1-17-03 apply only to the principal actor, other than
28 the pregnant woman, with respect to criminal conduct upon a person who has not yet
29 been born.

February 5, 2013

PROPOSED AMENDMENTS TO SENATE BILL NO. 2302

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for the ethical treatment of human embryos; and to provide a penalty.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1.

Definitions.

As used in this Act only:

1. "Donor" means an individual from whose body gametes were obtained, or an individual from whose body cells or tissues were obtained for the purpose of creating gametes or human embryos, whether for valuable consideration or not.
2. "Embryo" means an organism in its earliest stages of development, including the single-cell stage.
3. "Facility" or "medical facility" means any public or private hospital, clinic, center, medical school, medical training institution, health care facility, physician's office, infirmary, dispensary, ambulatory surgical treatment center, or other institution or location wherein medical care is provided to any person.
4. "Gamete" means an egg (oocyte) or sperm.
5. "Human-animal hybrid" means any of the following:
 - a. A human embryo into which a nonhuman cell or a component of a nonhuman cell is introduced so that it is uncertain whether the human embryo is a member of the species homo sapiens;
 - b. An embryo produced by fertilizing a human egg with a nonhuman sperm;
 - c. An embryo produced by fertilizing a nonhuman egg with a human sperm;
 - d. An embryo produced by introducing a nonhuman nucleus into a human egg;
 - e. An embryo produced by introducing a human nucleus into a nonhuman egg;
 - f. An embryo containing at least haploid sets of chromosomes from both a human and a nonhuman life form;

- g. A nonhuman life form engineered with the intention of generating functional human gametes within the body of a nonhuman life form; or
- h. A nonhuman life form engineered such that it contains a human brain or a brain derived wholly from human neural tissues.
6. "Human embryo" means an organism with a human or predominantly human genetic constitution from the single-cell stage to eight weeks development that is derived by fertilization (in vitro or in utero), parthenogenesis, cloning (somatic cell nuclear transfer), or any other means from one or more human gametes or human diploid cells.
7. "In vitro" means outside the human body.
8. "In vitro human embryo" means a human embryo created outside the human body.
9. "Pay" or "payment" means pay, contract for, or otherwise arrange for the payment of in whole or in part.
10. "Valuable consideration" means financial gain or advantage, including cash, in-kind payments, reimbursement for any costs incurred in connection with the removal, processing, disposal, preservation, quality control, storage, transfer, or donation of human gametes, including lost wages of the donor, as well as any other consideration.

SECTION 2.

Ethical treatment of human embryos.

1. A person may not intentionally or knowingly create or attempt to create an in vitro human embryo by any means other than fertilization of a human egg by a human sperm.
2. The creation of an in vitro human embryo may be solely for the purpose of initiating a human pregnancy by means of transfer to the body of a human female for the treatment of human infertility. A pregnancy may not be initiated with the intention of deliberately destroying the embryo for scientific research. A human embryo may not be gestated to the fetal stage for purposes of destroying the fetus in order to harvest tissue, organs, or stem cells. A person may not intentionally or knowingly transfer or attempt to transfer an embryo that is not the product of fertilization of a human egg by a human sperm into a human body.
3. A person may not intentionally or knowingly:
- a. Create or attempt to create a human-animal hybrid;
 - b. Transfer or attempt to transfer a human embryo into a nonhuman womb;
 - c. Transfer or attempt to transfer a nonhuman embryo into a human womb; or
 - d. Transfer or receive for any purpose a human-animal hybrid or any product derived from such hybrid.

4. This section does not prohibit:

- a. Research involving the use of transgenic animal models containing human genes;
- b. Xenotransplantation of human organs, tissues, or cells into recipient animals, including animals at any stage of development before birth, if the xenotransplantation does not violate a prohibition in subsection 3; or
- c. A person from receiving organs, tissues, or cells delivered from outside this state.

SECTION 3.

Valuable consideration prohibited.

A person may not give or receive valuable consideration, offer to give or receive valuable consideration, or advertise for the giving or receiving of valuable consideration for the provision of gametes or in vitro human embryos. This section does not regulate or prohibit the procurement of gametes for the treatment of infertility being experienced by the patient from whom the gametes are being derived. This section may not be construed as prohibiting the cryopreservation of gametes.

SECTION 4.

Identification.

An in vitro human embryo must be given an identification by the facility for use within the medical facility. Records must be maintained identifying the donors associated with the in vitro human embryo. The confidentiality of records kept under this section must be maintained.

SECTION 5.

Care and treatment of in vitro human embryos.

1. A living in vitro human embryo is a biological human being who is not the property of any person. The fertility physician and the medical facility that employs the physician owe a high duty of care to the living in vitro human embryo. Any contractual provision identifying the living in vitro embryo as the property of any party is null and void. The in vitro human embryo may not be intentionally destroyed for any purpose by any person or through the actions of such person.
2. An in vitro human embryo that fails to show any sign of life over a thirty-six-hour period outside a state of cryopreservation may be considered no longer living.

SECTION 6.

Judicial standard.

In disputes arising between any parties regarding an in vitro human embryo, the judicial standard for resolving such disputes is the best interest of the in vitro human embryo.

SECTION 7.

Penalty.

1. It is a class B misdemeanor for a person to violate this Act.
2. A violation of this Act by a physician constitutes grounds for disciplinary action under section 43-17-31.
3. A violation of this Act may be the basis for denying an application for, denying an application for the renewal of, or revoking any license, permit, certificate, or any other form of permission required to practice or engage in a medical trade, occupation, or profession.
4. A violation this Act by an employee of a licensed health care facility to which the management of said facility consents, knows, or should know may be the basis for denying an application for, denying an application for the renewal of, temporarily suspending, or permanently revoking any operational license, permit, certificate, or any other form of permission required to operate a medical or health care facility.

SECTION 8.

Construction.

1. Nothing in this Act may be construed as creating or recognizing a right to abortion.
2. It is not the intention of this Act to make lawful an abortion that is currently unlawful."

Renumber accordingly