Questions for the Record from Senator Charles Grassley
U.S. Senate Committee on the Judiciary
"The Continued Assault on Reproductive Freedoms in a Post-*Dobbs* America"
March 20, 2024

Questions for Doctor Monique C. Wubbenhorst:

(1) Medical facilities of all sorts have security measures limiting who can access certain areas. For example, a hospital's nursery has tight security measures to ensure the safety and security of the newborn infants in the hospital's care. Similarly, operating rooms in medical facilities have safeguards to ensure patient safety and security during procedures.

Is there a minimum level of security in vitro fertilization (IVF) facilities should have to ensure the safety of embryos? If so, what security factors ought to be considered?

Thank you for this question. It is my opinion that IVF facilities should have several types and layers of security, because there are two types of security to be considered. One is concerned with access to embryos by unauthorized people, including those with potentially malicious intent. The other is concerned with preserving the safety and physical integrity of embryos. The latter can be compromised by equipment failures or staff errors.

Physical security can be promoted by introducing the following regulations, many of which are in place at many health facilities:

a. At a minimum, the embryology laboratory should have a separate, locked entrance within the hospital or clinic. There should not be access to the laboratory from outside the building.
b. Consideration should be given to hiring a receptionist for physical presence in the clinic near the access door to the laboratory.
c. Only staff with proper identification should have access to the embryology laboratory and freezers.
d. Badge access should be used to enter the laboratory and to enter the freezer area.
e. Freezers should be locked (physically or electronically). Access to the freezer should be recorded.
f. Cameras should be installed to monitor activity within the laboratory.
g. Monitoring of the IVF laboratory and freezer area by building security staff (i.e., walk-through on watchman's rounds) should be included as part of general facility security measures.

The protection of embryos can be promoted by introducing the following regulations:

a. IVF clinics and laboratories should adopt federal biobanking standards. These standards provide guidance as to the handling, transportation and storage of biospecimens. Although an embryo is a human being, not a biospecimen,

federal biobanking standards should be updated and expanded to apply to IVF laboratories so as to protect embryos.

b. An alarm system should be installed to notify staff of unauthorized access to the laboratory or freezer area.
c. Freezers should be set up in such a way that, if they begin to warm, alarms will go off.
d. All freezers should be connected to a generator as a backup power supply (e.g. a generator), in the event of a prolonged power failure, which could result in the thawing and death of embryos.
e. Routine infection control and sterility protocols should be in place in IVF clinics.
f. As noted above, building security staff (i.e., walk-through on watchman's rounds) should monitor the IVF laboratory and freezer area to check for high temperature or other environmental problems as part of general facility security measures.

(2) Based on your experience, does the IVF industry need better regulation to protect women, would-be mothers, and the embryos created? If so, what types of measures ought be considered by the Federal Government or by the states?

Again, thank you for this question. Media reports show, and the IVF industry itself admits (https://news.virginia.edu/content/uva-law-professor-examines-wild-west-fertility-industry; https://www.nytimes.com/roomfordebate/2011/09/13/making-laws-about-making-babies/fertility-industry-is-a-wild-west indicate that better regulation is needed to protect women and men seeking to become mothers and fathers, and their embryos. The Alabama case is one example of how a basic lack of adequate security related to laboratory and freezer access led to the death of multiple embryos. As noted, the IVF industry has been called the "Wild West". A study of lawsuits against IVF clinics for lost, damaged and destroyed embryos, from the medical journal *Fertility and Sterility*, noted that for the cases seen "Allegations range from business practices to product liability and are seldom for medical malpractice. Our results suggest that best practices in storage of frozen embryos should include not only improvements in hardware and monitoring of storage conditions of specimens but also setting standards for communications among patients, providers, and embryology laboratories regarding disposition of embryos" (Letterie G, Fox D. Lawsuit frequency and claims basis over lost, damaged, and destroyed frozen embryos over a 10-year period. *Fertil Steril Rep* 2020;1:78–82. 2020).

These and other problems identified in, and by, the IVF industry could effectively be addressed through federal or state legislation. Such problems include:

1. **A lack of standards and accreditation of IVF clinics and laboratories by an independent regulatory body.** Voluntary self-regulation of ART programs has not been shown to be effective. Not all ART programs or facilities are members of professional organizations, such as the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM). Moreover, these professional organizations do not independently confirm that their members follow their voluntary guidelines. At present, unlike other laboratories involved with human health, IVF clinics and laboratories are not accountable to standards and accreditation by an independent regulatory body. The implications are obvious. In addition, prospective parents have no data regarding clinic safety and adherence to good clinical practice standards.
2. **A lack of standards and accreditation for laboratory equipment**. Similarly, there are no standards for equipment used in IVF, specifically the cryogenic storage tanks used to hold frozen eggs and embryos. As noted above, according to Professor Dov Fox of the UCSD Law School, these devices are currently less regulated than kitchen equipment or farm tools. Equipment failures for cryogenic tanks have led to catastrophic outcomes, including the loss of embryos, and egg and sperm cells.

3. **A lack of standards for laboratory security**, such as were seen in the Alabama case.

4. **A lack of oversight and mandated data collection for IVF clinic outcomes, complications and demographic characteristics of women and men who utilize IVF.** There are currently no mechanisms for data collection from IVF clinics, despite the pressing need to understand outcomes for IVF. While clinics publish data on success rates from IVF, what constitutes success is measured in terms of live births. There is no mention of adverse effects and complications for mothers undergoing IVF, or of long-term outcomes in children.

5. **A lack of restrictions on the number of embryos that can be conceived through IVF, and no laws regulating the fate of embryos who are abandoned.** This is one of the most serious problems related to IVF. The lack of IVF regulation has led to the large-scale conception of embryonic human beings without oversight or accountability. IVF clinics continue to allow families to create multiple embryos, despite the fact that many will not be implanted and will end up either frozen indefinitely or destroyed. The variety of "options" for parents with embryos that they do not wish to be transferred shows the need for legislation to address this pressing issue, which has implications for both mothers and children. "With the average number of stored embryos averaging 6 per individual, approximately 1.5 million embryos are currently cryopreserved in the United States, many stored for 5 years or longer" (Michele Martens, et al. Disposition Options for Cryopreserved Embryos: Results of an Educational Program, 19 j. *Nurse Practitioners* 104646 (June 2023). It is estimated that 1/3 of these embryos are abandoned, either being left frozen or destroyed. Families may inform the clinic that they do not wish to use any "extra" embryos, or they may stop responding to communications, or paying storage fees. "Research suggests that education and counseling about the donation process and benefits could increase donation rates. However, very few frozen embryos are actually donated to infertile individuals (Martens et al, 2023). "[I]ndividuals often reported that a lack of education and poorly timed conversations related to embryo disposition were barriers that resulted in low donation rates." "Upon the initial informed consent at the beginning of the IVF process, most individuals intend to donate or store embryos. However, when a decision was required, approximately 72% of individuals decided to forgo donation, increasing the number of cryopreserved embryos" (Martens et al, 2023). Notably, although many countries limit the number of embryos that can be created or transferred during the IVF process, the U.S. does not. Thus, millions of human embryonic children are stored in "cryogenic nurseries"; for many of these children, the facilities could more accurately be called "cryogenic orphanages". Many are ultimately either destroyed outright, or sold or donated for experimental purposes.
6. **A lack of restrictions on the number of embryos that can be implanted.** The number of embryos implanted in an IVF cycle is directly related to maternal and fetal outcome. While there has been a steady decline in the number of embryos transferred per cycle, society guidelines fail to recommend a maximum number of embryos to transfer. Multiple gestations are associated with increased maternal, fetal and

newborn morbidity and mortality. In some situations, "selective termination", or abortion of one twin or triplet, is recommended or performed, even though, according to the American Society for Reproductive Medicine, "the procedure may result in the loss of all fetuses, it does not completely eliminate the risks associated with multiple pregnancies, and it may have adverse psychological consequences…Moreover, multifetal pregnancy reduction is not an acceptable option for many women" (Practice Committee of the American Society for Reproductive Medicine and the Practice Committee for the Society for Assisted Reproductive Technologies, Guidance on the limits to the number of embryos to transfer: a committee opinion. *Fertility and Sterility*, vol. 116, No. 3, September 2021).

7. **A lack of regulation of sperm and egg cell donors.** Recent reports of sperm donors fathering dozens of children (in one case, 150 of them; in another case 200), or transmitting genetic abnormalities to their children, show the problems associated with this unregulated industry. Similarly, the process of "egg harvesting" represents a commodification of reproduction and women's bodies. The IVF industry seeks women between the ages of 18 and 25 for "egg harvesting" because they produce the healthiest and most efficient eggs for use in ART and research. A typical egg donor for eggs used in IVF procedures can expect to be paid between $5,000 and $10,000 per cycle (How Much Money Do Egg Donors Get Paid?, Bright Expectations (June 29, 2018), https://www.brightexpectationsagency.com/blog/how-much-money-egg-donors-paid/). Women on college campuses are promised large sums of money for their eggs, and it is not clear whether adequate informed consent is given for the procedure. During the process, ovarian hyperstimulation is used to obtain 10 or more eggs per treatment. Over several cycles, this represents a significant portion of a woman's total complement of eggs, which cannot be recovered. The risks of hyperstimulation and egg retrieval include infertility, infection, ovarian torsion, blood clots, kidney failure, premature menopause, ovarian cysts, chronic pelvic pain, stroke, reproductive cancers, and death (Kathleen Sloan, The Dark Side of Third-Party Reproduction, *Pub. Discourse* (Aug. 3, 2015), https://www.thepublicdiscourse.com/2015/08/15413/. Few states mandate disclosure of risk and procurement of informed consent prior to performing "egg harvesting" procedures, and even fewer limit advertisements and solicitations related to egg harvesting. There is "little to no peer-reviewed medical research on the effects of egg procurement on women's health" (Kallie Fell & Paul Ramsey, A Comprehensive Report on the Risks of ART, Ctr. For Bioethics & Culture Network, May 2023, available at https://cbc-network.org/wp-content/uploads/2023/05/Comprehensive-Paper-on-ART-Final.pdf).
8. **No laws restricting the destruction and disposal of embryos.** As noted earlier, embryos are disposed of literally by being discarded as laboratory medical waste; heated; killed by chemicals or disinfectants; or otherwise disposed of.
9. **No laws regulating human experimentation on embryos.** Because embryos cannot by definition give consent, they are subject to being used in a variety of experiments, including the creation of chimeras (human-animal hybrids) and engineered embryos. There are clear ethical and moral problems related to this topic.
10. **No laws regarding sex selection or preimplantation genetic testing of embryos.** Such testing, as noted earlier, is eugenics in its purest form, and leads to the selective

targeting and destruction of human beings. This occurs even where the reasons for screening are not medical, for example, when a specific eye color may be desired.

11. **No laws requiring informed consent.** IVF is associated with significant risks to mothers, even in a singleton pregnancy. Obstetricians caring for mothers who conceived using IVF, manage them as high-risk patients. Risks include significantly delivery complications, risk of uterine rupture, need for transfusion, and higher rates of preeclampsia and gestational diabetes. Another study examining in-hospital complications of women who conceived using ART found that "pregnancies conceived by ART have higher risks of adverse obstetric outcomes and vascular complications compared with spontaneous conception" (Pensee Wu, et al., In-Hospital Complications in Pregnancies Conceived by Assisted Reproductive Technology. *J. Am. Heart Assoc.* e022658. (Mar. 2022). In this study, women using ART to conceive had higher rates of comorbidities such as diabetes, hypertension, obesity, hyperlipidemia, and other medical problems. These women also were at higher risk of cesarean delivery, preterm birth, and placental abruption than those who conceived spontaneously, with increased risk of preeclampsia, acute kidney injury, ischemic stroke, arrhythmia, and venous thromboembolism. Another study found similar results, finding that ART pregnancies had "significantly increased risk of pregnancy-induced hypertension, gestational diabetes mellitus, placenta previa, placental abruption, antepartum hemorrhage, postpartum hemorrhage, polyhydramnios, oligohydramnios, cesarean sections, preterm and very preterm birth, low and very low birth weight, small for gestational age, perinatal mortality, and congenital malformation when compared to singleton pregnancies conceived naturally" (Fell et al). The risk for severe maternal and fetal morbidities is increased for women utilizing IVF with donor eggs, including increased risks for unplanned hysterectomy, pregestational and gestational hypertension, and intensive care (ICU) admissions for the mother.

    IVF is also associated with adverse effects in children. In a 2020 international study, it was found that "[t]he risk of congenital malformations is approximately one-third higher in children conceived with the aid of IVF technology than in other children". This includes cardiac malformations, musculoskeletal malformations, and genitourinary malformations. The study also found that "the risks of preterm birth and low birth weight are, respectively 1.7 and 1.5 times higher in IVF singleton pregnancies than in non-IVF pregnancies" (M. Wolff & T. Haaf, In Vitro Fertilization Technology and Child Health, 117 *Deutsches Ärzteblatt International* 23-30, 23 (2020). A 2017 study found that "IVF has been associated with an increased risk of adverse obstetric and perinatal outcomes including hypertensive disorders of pregnancy, preterm labor and preterm delivery, and low birth weight. IVF pregnancies have also been associated with congenital anomalies, imprinting disorders, and neurodevelopmental disorders" (C. Sullivan-Pyke et al., In Vitro Fertilization and Adverse Obstetric and Perinatal Outcomes, *Seminars in Perinatology* 345-53, 345 (October 2017). Low birth weight children are also at increased risk for adverse metabolic outcomes throughout life including obesity, hypertension, and diabetes. Other studies have found that children conceived through IVF may have higher blood pressure, adiposity, glucose levels, more generalized vascular dysfunction, higher risks for certain muscle and liver cancers, and

premature cardiovascular disease (E. Kamphuis, et al., Are we overusing IVF?, 348 *British Med. J.* g252 (2014); C. Williams, et al., Cancer Risk among Children Born after Assisted Conception. *NEJM* Vol 369: 1819-27 (2013); U. Scherrer, et al., Systemic and Pulmonary Vascular Dysfunction in Children Conceived by Assisted Reproductive Technologies, 125 *Circulation* 1890-96, 1890 (2012). These risks must be spelled out clearly and in detail in informed consent.

Legislative measures that could be considered include:

1. Establish standards for obtaining informed consent from couples and individuals seeking ART.
2. Establish facility standards for IVF laboratories.
3. Establish standards for IVF equipment.
4. Require collection and dissemination of data on outcomes from IVF.
5. Limit the number of embryos that can be created in any reproductive cycle.
6. Reduce multiple gestations and the risk of fetal reduction by limiting the number of embryos transferred in any reproductive cycle.
7. Institute annual reporting requirements for IVF.
8. Prohibit eugenic testing of embryos.
9. Prohibit the experimental use of embryos.
10. Prohibit the sale of gametes.
11. Prohibit the sale of embryos.
12. Develop regulations to protect embryos that have been abandoned.

Federal laws (from other countries) have attempted to address some of the above concerns. For example, several countries limit the number of embryos that can be conceived through IVF. Belgium, Brazil, Denmark, Germany, Hungary, Italy, Saudi Arabia, Singapore, Spain, Sweden, Switzerland, and the United Kingdom limit the number of embryos that can be transferred in a cycle, usually to two or three.

In Germany, the "Act for the Protection of Embryos" (attached) provides a wide range of protections for prospective mothers and fathers, and embryos, including by forbidding the fertilization of more than three embryos, the transfer of more than one embryo to a woman. It bans surrogacy, sex selection, preimplantation testing (with some exceptions), and the creation of human embryos for experimental purposes. It also prohibits the creation of human-animal chimeras, the use of more than one couple's gametes to create an embryo, artificial modification of human germ cell lines, and the sale of embryos. Penalties are described for violations of the Law. The Law does not address the disposition of embryos. However, under the law, more embryos cannot be created than are to be transferred to the mother.

At the state level, Louisiana's IVF law recognizes the humanity of the embryo, but still allows IVF. Model legislation using the principles embodied in Louisiana's law could help States to develop their own laws, which would protect prospective parents and embryos.

To summarize, it is clear from recent history that, as noted, voluntary self-regulation of IVF programs is not effective, despite the efforts of professional societies. Because prospective

parents often feel a sense of desperation and even hopelessness when infertility is an obstacle to building their families; they are vulnerable to potential exploitation, inadequate informed consent, and severe financial burdens. Parents have the right to full disclosure of the risks as well as the benefits of IVF. Embryos, as human beings, should not be destroyed, manipulated or subject to eugenic procedures. Addressing the problems outlined above represents an opportunity for elected officials to intervene to protect families and their children, and to uphold human dignity.

Monique Chireau Wubbenhorst, M.D., M.P.H., FACOG, FAHA

Federal Law Gazette, Part I, No. 69, issued in Bonn, 19th December 1990, page 2746

Act
for the Protection of Embryos
(The Embryo Protection Act)*

Gesetz
zum Schutz von Embryonen
(*Embryonenschutzgesetz – ESchG*)

Of 13th December 1990 (BGBl. I p. 2746), last amended by Article 1 of the Law of 21st November 2011 (BGBl. I p. 2228)

Section 1

Improper use of reproduction technology

(1) Whosoever

1. transfers to a woman an unfertilised egg cell collected from another woman,
2. undertakes to fertilise artificially an egg cell for any purpose other than bringing about a pregnancy in the woman from whom the egg cell was collected,
3. undertakes, within one treatment cycle, to transfer more than three embryos to a woman,
4. undertakes, by gamete intrafallopian transfer, to fertilise more than three egg cells within one treatment cycle,
5. undertakes to fertilise more egg cells from a woman than may be transferred to her within one treatment cycle,
6. removes an embryo from a woman before its implantation in the uterus is completed, in order to transfer it to another woman or to use it for a purpose other than its preservation, or
7. undertakes to carry out an artificial fertilisation of a woman who is prepared to give up her child permanently after birth to third parties (surrogate mother) or to transfer a human embryo to her.

shall be punished with up to three years' imprisonment or a fine.

(2) Likewise anyone shall be punished who

1. brings about artificially the penetration of a human egg cell by a human sperm cell, or
2. inserts a human sperm cell into a human egg cell artificially,

* Disclaimer: Translations of any materials into languages other than German are intended solely as a convenience to the non-German-reading public. If any questions arise related to the accuracy of the information contained in the translation, please refer to the German version of the document which is the official version of the document. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes.

without intending to bring about a pregnancy in the woman from whom the egg cell was collected.

(3)

1. In the cases of subsection 1, numbers 1, 2 and 6, the woman from whom the egg cell or embryo was collected, and likewise the woman to whom the egg cell or embryo will be transferred, and

2. in the cases of subsection 1, number 7, the surrogate mother and likewise the person who wishes to permanently take care of the child,

shall not be liable to punishment.

(4) In the cases of subsection 1, number 6, and subsection 2, any attempt shall be punishable.

Section 2

Improper use of human embryos

(1) Whosoever sells a human embryo created outside the woman's body, or removed from the woman before the completion of implantation in the uterus, or makes it available, or acquires or uses it for a purpose other than its preservation, shall be punished with up to three years' imprisonment or a fine.

(2) Likewise anyone shall be punished who causes a human embryo to develop further outside the woman's body for any purpose other than the bringing about of a pregnancy.

(3) Any attempt shall be punishable.

Section 3

Forbidden sex selection

Whosoever undertakes to fertilise artificially a human egg cell with a sperm cell that is selected for the sex chromosome contained in it, shall be punished with up to one year’s imprisonment or a fine. This shall not apply when the selection of a sperm cell is made by a physician in order to preserve the child from developing Duchenne-type muscular dystrophy or a similarly severe sex-linked genetic illness, and the illness threatening the child is recognised as being of appropriate severity by the body responsible according to Land legislation.

Section 3a

Pre-implantation genetic diagnosis; Authority to issue ordinances

(1) Whosoever subjects the cells of an embryo to *in vitro* genetic screening prior to its intrauterine transfer (pre-implantation genetic diagnosis) shall be punished with up to one year's imprisonment or a fine.

(2) Where the genetic pre-disposition of the woman from whom the egg cell was collected, or that of the man producing the sperm cell, or both, suggest that their offspring will be highly

likely to have a serious genetic illness, it shall not be an offence for anyone who intends to bring about a pregnancy to subject the cells of the embryo to state-of-the-art *in-vitro* genetic screening for this illness prior to intrauterine transfer, if the woman from whom the egg cell was collected gives her written consent.
Nor shall it be an offence for anyone to carry out, with the written consent of the woman from whom the egg cell was collected, pre-implantation genetic diagnosis in an embryo to identify an abnormality that would be highly likely to lead to still-birth or miscarriage.

(3) Pre-implantation genetic diagnosis as set out in subsection 2 may only be performed

1. when the woman has given her informed consent after having been informed and counselled on the medical, psychological and social implications of the genetic screening of the embryonic cells requested by her,

2. after an interdisciplinary ethics committee at the approved centres for pre-implantation genetic diagnosis has verified compliance with the requirements of subsection 2 and delivered a favourable opinion and

3. by a specifically qualified physician in centres approved for pre-implantation genetic diagnosis that have the diagnostic, medical and technological resources necessary to carry out the procedures involved in pre-implantation genetic diagnosis.

The approved centres shall report, in an anonymised form, the measures carried out within the framework of pre-implantation genetic diagnosis, including the cases dismissed by the ethics committees, to a central body for documentation purposes. The Federal Government shall issue an ordinance with the approval of the *Bundesrat*, to stipulate the details regarding

1. the number of and the approval requirements for the centres where pre-implantation genetic diagnosis may be performed, including the qualification of the physicians working there and the period of validity of the approval,

2. the establishment, composition, functioning and financing of the ethics committees for pre-implantation genetic diagnosis,

3. the establishment, structure and organisation of the central body that will be responsible for documenting the measures performed within the framework of pre-implantation genetic diagnosis,

4. the requirements for the reporting of measures performed within the framework of pre-implantation genetic diagnosis to the central body and the requirements for documentation.

(4) Whosoever, in breach of subsection 3 sentence 1, performs pre-implantation genetic diagnosis commits an administrative offence. The administrative offence shall be punishable with a fine of up to fifty-thousand euros.

(5) No physician shall be under an obligation to perform or take part in a measure as set out in subsection 2.
Non-participation may not lead to any disadvantage for the physician concerned.

(6) The Federal Government shall draw up, every four years, a report on the experience with pre-implantation genetic diagnosis. Based on central documentation and anonymised data, the report shall contain the number of measures performed each year as well as a scientific evaluation.

Section 4

Unauthorised fertilisation, unauthorised embryo transfer and artificial fertilisation after death

(1) Whosoever

1. undertakes artificially to fertilise an egg cell without the woman whose egg cell is to be fertilised, and the man whose sperm cell will be used for fertilisation, having given consent,

2. undertakes to transfer an embryo to a woman without her consent, or

3. knowingly fertilises artificially an egg cell with the sperm of a man after his death

shall be punished with up to three years' imprisonment or a fine.

(2) In the case of subsection 1 number 3, the woman in whom the artificial fertilisation was performed shall not be liable to punishment.

Section 5

Artificial alteration of human germ line cells

(1) Whosoever artificially alters the genetic information of a human germ line cell shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who uses a human germ cell with artificially altered genetic information for fertilisation.

(3) Any attempt shall be punishable.

(4) Subsection 1 shall not apply to

1. the artificial alteration of the genetic information of a germ cell situated outside the body, if any use of it for fertilisation is ruled out,

2. the artificial alteration of the genetic information of any other autologous germ line cell that has been removed from a dead embryo or fetus, a human being or a deceased person, if it is ruled out that

   a) it will be transferred to an embryo, fetus or human being or

   b) a germ cell will originate from it,

   and likewise

3. vaccinations, radiation, chemotherapeutic or other treatments which are not intended to alter the genetic information of germ line cells.

Section 6

Cloning

(1) Whosoever causes artificially a human embryo to develop with the same genetic information as another embryo, fetus, human being or deceased person shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who transfers to a woman an embryo as specified in subsection 1.

(3) Any attempt shall be punishable.

Section 7

Creation of chimeras and hybrids

(1) Whosoever undertakes

1. to combine embryos with different genetic information to form a cluster of cells, using at least one human embryo,

2. to combine a human embryo with a cell that contains genetic information different from the embryo cells and, so combined, is able to differentiate further, or

3. by fertilisation of a human egg cell with the sperm of an animal or by fertilisation of an animal’s egg cell with human sperm, to engineer an embryo that is able to differentiate,

shall be punished with up to five years' imprisonment or a fine.

(2) Likewise anyone shall be punished who undertakes

1. to transfer an embryo arising out of a procedure defined in subsection 1 to

   a) a woman or

   b) an animal

   or

2. to transfer a human embryo to an animal.

Section 8

Definition

(1) For the purposes of this Act, an embryo shall already mean the human egg cell, fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual under the appropriate conditions.

(2) In the first twenty-four hours after nuclear fusion, the fertilised human egg cell shall be held to be capable of development unless it is established before the expiry of this time period that it will not develop beyond the one-cell stage.

(3) Germ line cells, for the purpose of this Act, shall be all cells that, in one cell-line, lead from the fertilised egg and sperm cells to the resultant human being and, further, the egg cell from the insertion of or penetration by the sperm cell until the completion of fertilisation by fusion of the nuclei.

Section 9

Medical prerogative

Only a physician shall be entitled to carry out

1. artificial fertilisation,

2. pre-implantation genetic diagnosis,

3. transfer of a human embryo to a woman,

4. preservation of a human embryo or human egg cell which has already been penetrated by a human sperm cell or into which a human sperm cell has been artificially inserted.

Section 10

Voluntary participation

No one shall be under an obligation to carry out the measures described in section 9 above or to take part in them.

Section 11

Offences against the medical prerogative

(1) Whosoever, without being a physician,

1. carries out an artificial fertilisation contrary to section 9 number 1,

2. carries out pre-implantation genetic diagnosis contrary to section 9 number 2, or

3. transfers a human embryo to a woman contrary to section 9 number 3,

shall be punished with up to one year’s imprisonment or a fine.

(2) In the case of section 9 number 1, a woman who carries out an artificial insemination on herself, and the man whose sperm is used for artificial insemination shall not be liable to punishment.

Section 12

Administrative fines

(1) An administrative offence shall be deemed to have been committed by a person who, without being a physician, in violation of section 9 number 4, preserves a human embryo or a human egg cell as described therein.

(2) The commission of an administrative offence may be punished with a fine not exceeding two thousand five hundred euros.

Section 13

Entry into force

This Act shall enter into force on 1st January 1991.

The constitutional rights of the *Bundesrat* have been observed.

The above Act is herewith signed and will be published in the Federal Law Gazette (*Bundesgesetzblatt*).

Bonn, 13th December 1990

The Federal President
Weizsäcker

The Federal Chancellor
Dr. Helmut Kohl

The Federal Minister of Justice
Engelhard

The Federal Minister for Youth, Family and Health
Ursula Lehr

The Federal Minister for Research and Technology
Riesenhuber