

Date: February 25, 2009

To: The Center for Reproductive Rights

From: White & Case LLP

Re: European laws governing in vitro fertilization

This memorandum provides an overview of legislation relating to in vitro fertilization (“IVF”) in Belgium, France, Germany, Italy, Sweden, and the United Kingdom. This memorandum is divided by country, and Parts I and II of each country section discuss the regulation and destruction of embryos and gametes in the context of IVF. Parts III and IV cover marital status and age restrictions imposed on individuals seeking to receive assisted reproductive treatments. Part V sets forth the framework governing subsidization of in vitro fertilization treatment, Part VI pertains to penalties for violating the applicable regulations, and Part VII provides miscellaneous information on the regulation of in vitro fertilization in the aforementioned countries. Attached hereto as Annex A is a glossary of relevant terms used in this memo.

Belgium

The two main laws in Belgium relating to in vitro fertilization are the Law Concerning Medically-Assisted Insemination (*Loi relative à la procréation médicalement assistée et à la destination des embryons surnuméraires et de gamètes*)¹ of July 2007, and the Law Concerning Research on In Vitro Embryos (*Loi relative à la recherche sur les embryons en vitro*)² of May 2003. Belgium has moderate and permissive regulations in the area of medically-assisted reproduction, which may be related to the fact that research institutes in Belgium are active in the field of reproductive technology.

I. Regulation of Embryos and Gametes

a. The Law Concerning Medically-Assisted Insemination

1. Creation of Embryos

Article 9 states that subject to medical opinion, it is not permissible to remove gametes for creating new embryos so long as there are existing cryoconserved embryos that meet required health standards. Such health standards are determined by the fertility clinic.

2. Storage of Embryos

¹ 2007-07-06/32 Sécurité Sociale 2007023090, July 17, 2007, p. 38575, available at <http://www.belgiumlex.be/V2/belgiumlex/website/en/index.html>.

² 2003-05-11/31 Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement 2003022592, May 28, 2003, p. 29287, available at <http://www.belgiumlex.be/V2/belgiumlex/website/en/index.html>.

Article 10 states that unimplanted embryos may be cryconserved with respect to plans for present or subsequent medically-assisted insemination. If such embryos are not used prior to the limitation period (Article 17 provides for a period of five years; Article 18 allows an extension request for this limitation period, which must be provided in writing for approval by the fertility clinic), they may either be destroyed, used in a program of scientific research (governed by the Law Concerning Research on In Vitro Embryos), or used in a program of embryo donation.

3. Use of Embryos

Articles 13(1) and (2) state that the parent(s) seeking medically-assisted insemination must sign an agreement with the fertility clinic which provides for the use of the unimplanted embryos in the case of separation, divorce, permanent incapacity, death of one of the parents or a difference of opinion between the two parents. It must also provide for the use of the unimplanted embryos in the case that the cryoconservation exceeds the specified limitation period as outlined in Articles 17 and 18.

Article 15 states that if specified in the agreement with the fertility clinic, post-mortem implantation of a cryoconserved embryo is permissible, within the time periods specified in Article 16. Article 16 stipulates that the post-mortem implantation must occur between six months and two years after the death of the parent.

4. Research on Embryos

Article 19 states that research on unimplanted cryoconserved embryos is permitted; Article 20 states that the decision to donate unimplanted embryos to research must be outlined in the agreement between the parent(s) and the fertility clinic, governed by the Law Concerning Research on In Vitro Embryos, and that the donation of unimplanted embryos may be rescinded at any time before the commencement of the research program.

5. Donation / Sale of Embryos

Article 22 states that unimplanted embryo donation is legal, but the selling of unimplanted embryos is prohibited. Moreover, the motive for the donation cannot be based either on eugenics (race) or sex (with the exception of sex-related illnesses). Matching donors and donees is not considered a donation based on eugenics. The simultaneous implantation of embryos of different donors is prohibited (Article 25), and embryos from the same donor cannot be used for the birth of children in more than six different women (Article 26). Once the donation process has commenced, it is irrevocable (Article 30). The time period for which the embryos are to be cryogenetically preserved is to be determined by the fertility clinic (Article 34).

6. Regulation of Gametes / Gonads / Gonad Fragments

Articles 37 to 42 provide for the same treatment of gametes/gonads/gonad fragments as for the treatment of embryos discussed above (with the exception of a 10-year limitation period for the cryconservation of gametes/gonads/gonad fragments).

7. Genetic Testing of Embryos

Articles 66 to 69 permit pre-implantation genetic testing, but such testing is not to be undertaken on the grounds of eugenics (race) or sex.

b. The Law Concerning Research on In Vitro Embryos

The Law Concerning Research on In Vitro Embryos outlines the parameters of embryonic research in Belgium. Article 3 states that such research must have a therapeutic purpose or advance knowledge in the areas of fertility, sterility, organ or tissue transplant/grafting, and the prevention or treatment of illness. Article 3 also states that research may only be undertaken on an embryo within the first 14 days of development (exclusive of the freezing period).

Article 5 states that the creation of hybrids, commercial research and research based on eugenics (race) or sex is prohibited. Article 6 states that human cloning is prohibited.

II. Destruction of Embryos and Gametes

Article 10 of the Law Concerning Medically-Assisted Insemination permits the destruction of cryoconserved embryos which are not used prior to the specified time period (discussed above in Articles 17 and 18). Article 10 also permits the destruction of these embryos prior to the limitation period, if the cryoconservation is not undertaken in accordance with the objectives of the agreement signed between the parent(s) and the fertility clinic.

Article 75 states that unimplanted cryoconserved embryos, gonads, and gonad fragments that were created prior to the enactment of this law will be treated in accordance with the wishes of the parent(s) (defined as the individual or individuals who have signed an agreement with a fertility clinic to proceed with medically-assisted insemination). If such wishes cannot be determined, these embryos/gonads/gonad fragments will be destroyed in accordance with the limitation periods specified in the law.

III. Marital Status Restrictions

There are no marital status requirements in either law.

IV. Age Restrictions

Article 4 of the Law Concerning Medically-Assisted Insemination states that the removal of gametes, embryo implantation, and the insemination of gametes is available to adult women aged 45 and under. Embryo implantation and gamete insemination is not available to women above

the age of 47. The removal of gametes for cryoconservation, the taking of additional embryos, gonads, or fragments of gonads may be available to a female below the age of majority (in accordance with certain specified medical standards).

V. IVF Subsidization Scheme

The subsidization of IVF in Belgium is governed by the Royal Decree amending the Royal Decree of April 25, 2002 Concerning Hospital Financing (*Arrêté royal modifiant l'arrêté royal du 25 avril 2002 relatif à la fixation et à la liquidation du budget des moyens financiers des hôpitaux*) of June 2003.³ Presently, the Belgian government subsidizes 100% of the first six cycles of IVF treatment for women under the age of 43. The IVF treatment subsidization scheme for women between the ages of 43 and 47 is unclear.

Annex 15 outlines the conditions of IVF subsidization. For women below the age of 35, only one fresh embryo may be implanted in the first cycle, and two fresh embryos may be implanted in the second cycle (if the quality of the embryo is poor). Two fresh embryos (maximum) may be implanted in the third and subsequent cycles. There is an exception in the first two cycles when thawed (instead of fresh) embryos are used. In this case, two embryos (maximum) may be implanted. For women between the ages of 35 and 39, two fresh embryos may be implanted (maximum) in the first and second cycles, and three fresh embryos (maximum) may be implanted in the third and subsequent cycles. It is only in the case of women between the ages of 39 and 42 that there is no limitation on the number of embryos that may be implanted.

VI. Penalties

a. The Law Concerning Medically-Assisted Insemination

Article 73 states that any infraction with respect to the provisions of this Law will be punished by a period of imprisonment between one and five years and/or a fine of between EUR 1000 and 10000.

Article 74 states that in light of Article 73, a judge may also prohibit any medical or research activity for a period of five years.

b. The Law Concerning Research on In Vitro Embryos

Article 13 provides for the same penalties discussed above, for violations of Articles 3(5), 4, 5 and 6, as well as the judicial prohibition of any medical or research activity for a period of five years with respect to Article 6.

VII. Miscellaneous

³ 2003-22-6/27 Service Public Federal Santé Publique, Sécurité de la Chaîne Alimentaire et Environnement 20032403, June 4, 2003, p. 32127.

Article 6(2) of the Law Concerning Medically-Assisted Insemination states that if a fertility clinic provides medically-assisted insemination to a parent or to parents; it must provide psychological support before and throughout the course of the treatment.

Article 48 states that the government will impose an indemnity for travelling expenses or lost salary for a gamete donor. This indemnity could also provide for any hospitalization relating to the donation procedure.

France

In France, in vitro fertilization is regulated by several laws and decrees including:

- Law 2004-800 dated August 6, 2004 Relating to Bioethics,⁴
- Decree No. 2006-126 dated February 6, 2006, and
- Law on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis dated July 29, 1994.⁵

The most important law in the regulation of IVF is Law 2004-800 dated August 6, 2004 Relating to Bioethics (“Bioethics Law of 2004”). The Bioethics Law of 2004 is broad in scope and regulates, among other things organ procurement, procreation, human embryology and genetics. The Bioethics Law of 2004 articulates three foundational values: (i) respect for the dignity of the human embryo⁶; (ii) respect for all stages of life; and (iii) respect for human rights.⁷ Additionally, the Bioethics Law of 2004 gives the French Biomedicine Agency (*Agence de la biomedecine*) regulatory responsibility for technologies, research, and activities regarding reproductive cells, in vitro embryos, in vivo embryos and fetuses, and birth or abortion.

Decree No. 2006 – 126 regulates research on embryos and embryonic cells. The Decree permits the French Biomedicine Agency to authorize research on embryos and embryonic stem cells “if such research is likely to facilitate major progress in treatment and could not be carried out by an alternative approach of comparable efficacy, in the current state of scientific knowledge.”⁸ In practice, the Decree gives the French Biomedicine Agency the power to authorize, control, monitor, and supervise all research on embryos and embryonic cells.

The law on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis regulates gene therapy and gene therapy products.⁹ The French Biomedicine Agency, pursuant to the Bioethics Law, is responsible for monitoring and regulating research on gene therapy in conjunction with the French Health Products Safety Agency.¹⁰

I. Regulation of Embryos and Gametes

⁴Law No. 2004-800 of Aug. 6, 2004, J.O. No. 182, Aug. 7, 2004, p. 14040.

⁵Law No. 94-654 of July 29, 1994, J.O., July 30, 1994, p. 11050.

⁶The Bioethics Law of 2004 incorporates Chapter II, Article 16 of the French Civil Code, which deals with respect for the human body. Article 16 ensures the primacy of the person and sets out the fact that human beings are to be treated with dignity from the beginning of their lives. See Law No. 2004-800 of Aug. 6, 2004, J.O. No. 182, Aug. 7, 2004, see art. L2151.

⁷Law No. 2004-800 of Aug. 6, 2004, J.O. No. 182, Aug. 7, 2004, p. 14040.

⁸Press Release, Agence de la Biomedecine, Publication of the Decree Relating to Research on Human Embryos and Embryonic Stem Cells (Feb. 7, 2006), available at <http://www.agence-biomedecine.fr/uploads/document/Decret-embryon-VA.pdf>.

⁹Genetics & Public Policy Center, Human Genetic Modification: Law no. 94-654 Governing the Donation and Use of Elements and Products of the Human Body, Medically Assisted Reproduction, and Prenatal Diagnosis [France], http://www.dnapolicy.org/policy.international.php?action=detail&laws_id=37.

¹⁰Id.

a. Research and Storage of Embryos

The Bioethics Law of 2004 prohibits the creation of embryos for research purposes. Since the Decree was adopted in 2006, research on supernumerary¹¹ embryos created by in vitro fertilization that are no longer needed by parents is permitted.¹² Specifically, this means research can be conducted in three different situations, in all of which the embryo has been created by in vitro fertilization. First, research can be conducted on “spare” embryos no longer required by parents, if the parents have provided their written consent to donate the embryo for research purposes. “This consent, once given, must be reaffirmed after a three-month reflection period.”¹³ Second, provided the authorization from the parents has been received, research can be done on embryos that are unsuitable for reimplantation.¹⁴ Third, research can be conducted on embryos that are unsuitable for storage or carry an abnormality that was detected by preimplantation diagnosis.¹⁵

The French Biomedicine Agency must approve all research projects in advance and regulates each project on a case-by-case basis. The Agency also monitors and evaluates all research that is conducted and is responsible for importing, storing and disposing of embryo tissues and cells required for research purposes.¹⁶ The French Biomedicine Agency tightly controls and regulates research on stem cells.

The French Biomedicine Agency requires research activities to have the ability to store appropriate human stem cell lines “*in situ* or in a partner organization with an established storage convention.”¹⁷ All storage facilities must be authorized by the French Biomedicine Agency. Such authorizations are only valid for a limited time period, not to exceed five years. Additionally, the French Biomedicine Agency reserves the right to inspect storage facilities through the period of authorization.¹⁸

b. Storage / Donation of Gametes

¹¹ See Annex A for definition of “supernumerary embryo.” Press release, Agence de la Biomedecine, Publication of the Decree Relating to Research on Human Embryos and Embryonic Stem Cells (February 7, 2006), available at <http://www.agence-biomedecine.fr/uploads/document/Decret-embryon-VA.pdf>.

¹² Human Fertility and Embryology Bill, 2007-2008, H.L. Bill [6], at 74-75 (Gr. Brit.).

¹³ Press Release, Agence de la Biomedecine, Publication of the Decree Relating to Research on Human Embryos and Embryonic Stem Cells (Feb. 7, 2006), available at <http://www.agence-biomedecine.fr/uploads/document/Decret-embryon-VA.pdf>.

¹⁴ *Id.* In both situations described above, the consent of one parent is sufficient only where the other parent has passed away.

¹⁵ *Id.*

¹⁶ L'Agence de la Biomedecine, The French Biomedicine Agency: Mission and Objectives, http://www.agence-biomedecine.fr/uploads/document/doc_agenceva.pdf.

¹⁷ Press Release, Agence de la Biomedecine, Publication of the Decree Relating to Research on Human Embryos and Embryonic Stem Cells (Feb. 7, 2006), available at <http://www.agence-biomedecine.fr/uploads/document/Decret-embryon-VA.pdf>.

¹⁸ *Id.*

In addition, in vitro fertilization is only available if a couple is infertile or if there is a risk of transmitting a disease were the couple to procreate naturally.¹⁹ In this situation, the heterosexual couple could use an egg or gonad that had been donated by a third party.²⁰ The French Biomedicine Agency also regulates the donation of gametes.²¹

The Bioethics Law of 2004 also permits self-storage of gametes or reproductive tissues with a view to in vitro fertilization where an individual requires a medical procedure that may affect her fertility. For example, an individual diagnosed with cancer that requires chemotherapy would be permitted to store gametes or reproductive tissues with a view to in vitro fertilization.²²

II. Destruction of Embryos and Gametes

The Bioethics Law of 2004 does not contain specific provisions about the destruction of embryos that were created for purposes of in vitro fertilization. Rather, the Bioethics Laws of 2004 addresses the destruction of embryos in the context of research.

As previously noted, the creation of embryos for research purposes is prohibited under the Bioethics Law of 2004.²³ Therefore, as described in greater detail below, only embryos conceived in vitro in a medically assisted program can be used for research. As noted above, the French Biomedicine Agency regulates all research on embryos and stem cells. In practice, such regulation often occurs on a case by case basis. Thus, the rules and regulations for storing and destroying embryos may vary.

III. Marital Status Restrictions

The French regulations place restrictions on the persons entitled to vitro fertilization and when they can access the procedure. First, medically assisted procreation (i.e. in vitro fertilization) is only available to a married heterosexual couple or a heterosexual couple that can prove they have been living together for at least two years, both partners are still alive, and they are of procreation age.²⁴ Individuals may not access in vitro fertilization procedures.²⁵ However, the Bioethics Act of 2004 does allow individuals to store gametes or reproductive tissues with a

¹⁹ Council of Europe, Steering Committee on Bioethics (CDBI), Survey and Replies by Member States to the Questionnaire on Access to Medically Assisted Procreation (MAP) and Origin Rights-to-Know Post-Map 20 (July 2005), http://www.coe.int/t/e/legal_affairs/legal_co-operation/bioethics/texts_and_documents/INF_2005_7%20e%20MAP.pdf.

²⁰ Law No. 2004-800 of Aug. 6, 2004, J.O. No. 182, Aug. 7, 2004, ch. IV, arts. L1244-1 to L1244-12.

²¹ L'Agence de la Biomedecine, *The French Biomedicine Agency: Mission and Objectives*, http://www.agence-biomedecine.fr/uploads/document/doc_agenceva.pdf (“[The French Biomedicine Agency] ensures that health professionals respect the legal provisions on using parts of the human body and the French rules concerning the free, anonymous and consenting donation of organs, tissues, cells, gametes and embryos.”).

²² *Id.*

²³ Human Fertility and Embryology Bill, 2007-2008, H.L. Bill [6], at 74-75 (Gr. Brit.).

²⁴ Council of Europe, Steering Committee on Bioethics (CDBI), *supra* note 15, at 16.

²⁵ *Id.*

view to further medically assisted procreation for persons that need a medical intervention that may affect fertility.²⁶

IV. Age Restrictions

In vitro fertilization is not publically funded for women older than 43 years of age.²⁷ It is unclear whether women below 43 years of age are eligible for privately funded IVF treatments.

V. IVF Subsidization Scheme

France has a national system of health care and requires all residents to have health insurance.²⁸ France has provided public funding for IVF since 2000.²⁹ However, public funding is limited to heterosexual couples that qualify for the procedure (i.e. are infertile or risk transmitting a disease). Legally, there is no limit on the number of in vitro fertilization attempts that will be publicly funded. However, medically, the maximum recommended number of attempts is four. A couple may pursue IVF treatments an additional four times after the birth of a living child.³⁰

VI. Penalties

Research on embryos without the authorization of the French Biomedicine Agency or research that extends beyond the limitations provided in the laws described above is punishable by a fine of EUR 100,000 and seven years imprisonment.³¹ Additionally, the French Biomedicine Agency can suspend research or the operation of storage facilities if its instructions are not followed or if embryos are not handled appropriately.

VII. Miscellaneous

Surrogacy is not permitted in France.³²

²⁶ *Id.*

²⁷ Council of Europe, Steering Committee on Bioethics (CDBI), *supra* note 15, at 26.

²⁸ The French health care system is a mixed public-private system that has been recognized by the World Health Organization as an outstanding system. See Victor G. Rodwin, The Health Care System Under French National Health Insurance: Lessons for Health Reform in the United States, 93:1 Am. J. of Pub. Health 31 (Jan. 2003). (“The health system in France is dominated by solo-based, fee-for-service private practice for ambulatory care and public hospitals for acute institutional care, among which patients are free to navigate and be reimbursed under [national health insurance]. All residents are automatically enrolled with an insurance fund based on their occupational status. In addition, 90% of the population subscribes to supplementary health insurance to cover other benefits not covered under [national health insurance]. Another distinguishing feature of the French health system is its proprietary hospital sector, the largest in Europe, which is accessible to all insured patients.”).

²⁹ Council of Europe, Steering Committee on Bioethics (CDBI), *supra* note 15, at 20.

³⁰ *Id.* at 29-30.

³¹ Brigitte Gratton, Survey on the National Regulations in the European Union regarding Human Embryos, 23 http://ec.europa.eu/european_group_ethics/publications/docs/nat_reg_en.pdf. See also Law No. 2004-800 of Aug. 6, 2004, J.O. No. 182, Aug. 7, 2004, art. 21.

³² Council of Europe, Steering Committee on Bioethics (CDBI), *supra* note 15, at 51.

The Bioethics Law of 2004 contains a provision requiring the law to be amended within five years.³³ Thus, the law is due to be reviewed by the French Parliament in 2009. The French Biomedicine Agency has been preparing for that review by conducting public surveys, studies and making recommendations for revisions to the Bioethics Law of 2004.³⁴

³³ Council of Europe, Summary of Laws in France, http://www.coe.int/t/e/legal_affairs/legal_co-operation/bioethics/news/France%20E.asp.

³⁴ L'Agence de la Biomedecine, Publication of the Decree Relating to Research on Human Embryos and Embryonic Stem Cells, <http://www.agence-biomedecine.fr/uploads/document/Decret-embryon-VA.pdf>.

Germany

The primary rules affecting in vitro fertilization and its subsidization in Germany consist of the following two statutes and two guidelines:

- German Act on the Protection of Embryos (*Embryonenschutzgesetz*);
- Guidelines of the German Medical Association on the Performance of Assisted Reproduction (*Richtlinie der Bundesaerztekammer zur Durchfuehrung der assistierten Reproduktion als Beschreibung des aktuellen aertzlichen (Berufts-) Standes*);
- German Social Code V (*Sozialgesetzbuch V*);
- Guidelines of the Federal Joint Committee of Medical Doctors and Health Insurances regarding Medical Measures for Artificial Fertilization (*Richtlinien über ärztliche Maßnahmen zur künstlichen Befruchtung des Gemeinsamen Bundesausschusses der Ärzte und Krankenkassen*).

A distinguishing feature in the regulation of medical services in the German health care system is the important role, alongside that of the legislature, played by the self-governing bodies of service providers and health insurance funds. The legislature creates the legal framework; the medical self-governing bodies, formed by the national associations of medical doctors and dentists, the German Hospital Federation and the federal associations of health insurances, develop and implement in detail which services will be provided and under which conditions. The primary decision-making agency for the self-governing bodies is the Federal Joint Committee of Medical Doctors and Health Insurances (the “*Gemeinsamer Bundesausschuss der Ärzte und Krankenkassen*”). In vitro fertilization in Germany is similarly regulated in this manner.

I. Regulation of Embryos and Gametes

Below is a summary of the relevant provisions of the German Act on the Protection of Embryos (the “German Act”) and the Guidelines of the German Medical Association on the Performance of Assisted Reproduction Technologies (the “Guidelines of the German Medical Association”).

1. German Act on the Protection of Embryos

a. Improper Use of Procreational Technologies

Section 1 of the German Act prohibits:

- transferring more than three embryos per fertilization attempt (“cycle”) to a woman;
- fertilizing more than three ova per cycle by gamete intrafallopian transfer;³⁵
- fertilizing more of a woman’s ova than are planned to be transferred to the woman in that cycle;

³⁵ See Annex A for definition of “gamete intrafallopian transfer.”

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- artificially causing a sperm cell to penetrate an ovum, or artificially inserting a sperm cell into an ovum for any reason other than to cause the woman from whom the ovum originates to become pregnant;
- transferring an unfertilized ovum to a woman other than the donor of the ovum;
- artificially fertilizing a woman's ovum for any reason other than to cause that woman to become pregnant;
- removing an embryo from a woman's uterus prior to the completion of its nidation in order to transfer it to another woman, or to use the embryo in any way or for any reason other than its preservation;
- artificially fertilizing or transferring an embryo to a woman who is prepared and willing to permanently surrender the child after birth to a third party (surrogate; "*Ersatzmutter*").

Penalties for the improper use of procreational technologies: Punishment ranges from monetary fines to three years in prison. In the last four scenarios listed above, there is no criminal liability for the woman who donates the ovum or the embryo, the woman to whom the ovum or embryo is transferred, the surrogate mother or the third party who agrees to take custody of the child.

b. Improper Use of Human Embryos

Section 2 of the German Act prohibits:

- selling an extracorporeally created human embryo or an embryo that was removed from a woman's uterus prior to the completion of its nidation, or giving away, buying or using such an embryo in any way or for any reason other than its preservation;
- causing a human embryo to further develop extracorporeally for any reason other than to cause a pregnancy.

Penalties for the improper use of human embryos: Punishment ranges from monetary fines to three years in prison.

c. Prohibited Selection of Gender

Section 3 of the German Act prohibits artificially fertilizing an ovum with a sperm cell that was specifically selected because of its sex chromosome. Such a selection is allowed only if it is used to protect the future child from Duchenne muscular dystrophy or some other sex-linked genetic disease which has been recognized as sufficiently serious by the appropriate regulatory body.

Penalties for illegally selecting gender: Punishment ranges from monetary fines to one year in prison. Artificially fertilizing an ovum with a sperm cell that was specifically selected because of its sex chromosome is a criminal act.³⁶ Every person who participates in any way in such a

³⁶ See German commentary Erbs/Kohlhaas, *Strafrechtliche Nebengesetze*, 169. Aufl., 2008, para. 3, Rn. 1.

procedure is potentially criminally liable. However, the statute does not specify which persons are to be held criminally liable.

d. Unauthorized Fertilization, Unauthorized Transfer of Embryos and Artificial Fertilization Post Mortem

Section 4 of the German Act prohibits:

- artificially fertilizing a woman's ovum without her consent and without the consent of the man whose sperm cells are used;
- transferring an embryo to a woman without her consent;
- intentionally fertilizing an ovum with the sperm cells of a man after his death, irrespective of any agreement between the couple.

Penalties for violations: Punishment ranges from monetary fines to three years in prison. In the last scenario listed above, the woman is not criminally liable.

e. Artificial Modification of Human Germ Line

Section 5 of the German Act prohibits:

- artificially modifying the genetic information of a human germ line (*Keimbahnzelle*), with the following exceptions:
 - artificial modification of the genetic information of a gamete (*Keimzelle*) that is outside the human body, if the gamete will not be used for fertilization;
 - artificial modification of the genetic information of some other in the body naturally produced germ line that was taken from a dead fruit of womb (*Leibesfrucht*), a human being, alive or a deceased, and this germ line: (1) will not be transferred to an embryo, fetus or human being, and (2) will not result in a gamete.
 - immunization, actinotherapeutic,³⁷ chemo therapeutic, or other treatment, which is not aimed at the modification of the genetic information of a germ line.
- using a human gamete, the genetic information of which has been artificially modified, for fertilization

Penalties for violations: Punishment ranges from monetary fines to five years in prison.

f. Cloning

Section 6 of the German Act prohibits:

- artificially effecting the development of a human embryo with the same genetic information as another embryo, fetus, or human being, alive or deceased;

³⁷ See Annex A for definition of "actinotherapeutic treatment."

- transferring such an embryo to a woman.

Penalties for violations: Punishment ranges from monetary fines to five years in prison.

g. Creation of Chimeras and Hybrids

Section 7 of the German Act prohibits:

- merging embryos with different genetic information by using at least one human embryo to create a united cell structure;
- conjoining a human embryo with a cell that contains different genetic information than the cells of the embryo and that, together with the conjoined embryo, is able to further differentiate itself;
- creating a distinguishable embryo by fertilizing a human ovum with sperm cells of an animal or by fertilizing an ovum of an animal with human sperm cells;
- transferring an embryo created in one of the ways described above to a woman or an animal;
- transferring a human embryo to an animal.

Penalties for violations: Punishment ranges from monetary fines to five years in prison.

h. Definition

According to Section 8 of the German Act, the term embryo, as used in this statute, means:

- a fertilized, viable human ovum beginning with the time of karyogamy (*Kernverschmelzung*);
- every totipotent³⁸ cell taken from an embryo, which, when all other prerequisites are fulfilled, is able to divide and develop into an individual human being.

i. Medical Doctor

According to Section 9 of the German Act, only a medical doctor is allowed to carry out:

- artificial fertilization;
- transfer of a human embryo to a woman.
- preservation of a human embryo or a human ovum into which a human sperm cell has penetrated or was artificially inserted.

Penalties for violations: Penalties for violations of the regulations on artificial fertilization and the transfer of a human embryo to a woman range from monetary fines to one year in prison. There is no criminal liability for a woman who performs artificial insemination on herself and the man whose sperm is used for the artificial insemination. The penalty for allowing a person

³⁸ See Annex A for definition of “totipotent.”

other than a medical doctor to preserve a human embryo or human ovum is a monetary fine of up to EUR 2,500.

j. Voluntary Participation

Under Section 10 of the German Act, no one is obligated to carry out or participate in the procedures described in Section 9 of the German Act.

2. Guidelines of the German Medical Association on the Performance of Assisted Reproduction Technologies (the “Guidelines”)

These Guidelines describe the current medical (professional) standards that must be adhered to by medical doctors. Noncompliance with these Guidelines may lead to criminal charges and sanctions under professional regulations. Furthermore, these Guidelines are part of most of the State Medical Associations’ Professional Codes of Conduct.

a. Medical Requirements

(1) Homologous³⁹ In Vitro Fertilization with Intrauterine Embryo Transfer of Up to Three Embryos (Section 2.1.3 of the Guidelines)

This treatment may be utilized if one of the following conditions is present:

- uterine tube blockage or uterine tube insufficiency;
- male fertilization malfunction.

In the event of the following conditions, this treatment may be utilized only upon further scrutiny:

- endometriosis of sufficient relevance;
- idiopathic infertility.⁴⁰

(2) Heterologous⁴¹ In Vitro Fertilization with Intrauterine Embryo Transfer (Section 2.1.7 of the Guidelines)

This treatment may be utilized if one of the following conditions is present:

- severe male fertilization malfunction;
- unsuccessful deployment of intrauterine insemination and/or insemination inside the uterine tube and/or in vitro fertilization and/or intracytoplasmic sperm injection using homologous sperm (with the appropriate indications being present);

³⁹ Homologous sperm means the sperm of the husband or partner in a steady relationship, Guidelines § 1.5.

⁴⁰ This is only a sufficient indication if all diagnostic measures were carried out and hormonal stimulation, intrauterine insemination and/or insemination inside the uterine tube were not successful.

⁴¹ Heterologous sperm means the sperm of a sperm donor, Guidelines § 1.5.

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- unsuccessful deployment of heterologous insemination;
- a high risk for a child with a severe, genetically conditioned disease was diagnosed after human-genetic consultations.

Section 5.3 of the Guidelines lists additional requirements to be met when heterologous sperms are used:

- Medical aspects

The medical doctor must ensure that certain, enumerated safeguards are followed before using heterologous sperm in order to prevent infections with HIV, Hepatitis B and C, and other serious diseases.

- Psychosocial consultation

The future parents must be advised with regard to possible psychosocial and ethical problems that might arise due to the use of heterologous sperm.

- Legal aspects

The doctor must ensure that the future parents and the sperm donor have been advised about possible legal consequences of this treatment (e.g., the child's future right to request information about its parentage, the child's future right to pursue legal options for a court to declare the sperm donor to be its father with all legal consequences).

The doctor must also keep records about the identity of the sperm donor, his consent to the disclosure of his personal data if requested by the child, and the future parents' consent to the use of heterologous sperm, the documentation of the sperm's origin and the doctor's release from his/her confidentiality obligations in the event that the child requests information in the future.

(3) Contraindications (Section 2.2 of the Guidelines)

After determining which indications are present, the following contraindications must be considered:

Absolute contraindications:

- All contraindications against a pregnancy.

The following contraindications are taken into account but are not dispositive:

- Risk for the health of the mother and the development of the child caused by the pregnancy;
- Psychogenic fertilization malfunction (e.g., sexual disorder as main reason for sterility)

b. General Requirements

(1) Legal requirements (Section 3.1 of the Guidelines)

- Marital status requirements (*See* III. Marital Status Restrictions)
- Requirements under the German Act must be fulfilled
- Requirements under the German Social Code

If the in vitro fertilization is (partly) paid for by statutory health insurance, additional requirements under the German Social Code V and the Guidelines regarding Medical Measures for Artificial Fertilization of the Federal Joint Committee of Medical Doctors and Health Insurances must be met. For further discussion, see below under V. In Vitro Fertilization Subsidization Scheme.

- Requirements under Professional Regulations (A medical doctor who is active in the field of assisted reproduction must meet certain professional, human resources, technical and quality management requirements.)

(2) Information, education, consultation and consent (Section 3.2 of the Guidelines)

The doctor must advise the couple about the following issues, which are further elaborated in the Guidelines:

- Medical aspects;
- Psychological aspects;
- Human-genetic consultation to prevent genetically conditioned diseases that run in the family;
- Independent consultation (suggestion of a consultation by a doctor not affiliated with the treating doctor);
- Costs;
- Documentation.

c. Requirements for Specific Methods

(1) Cryopreservation (Section 5.2 of the Guidelines)

- Cryopreservation of ova in the pronucleus phase is allowed for the treatment of infertile women;
- Cryopreservation of embryos is only allowed in exceptional cases if the transfer of the embryo was not possible during the treatment cycle;
- The further cultivation of ova in the pronucleus phase is allowed only for the purpose of a transfer and only with the consent of the couple;
- Cryopreservation of ova is allowed;

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- Cryopreservation of ovarian tissue is allowed;
- Cryopreservation of ejaculated, epididymal and testicular spermatozoon or testicle tissue is allowed.

(2) Use of heterologous sperm cells (Section 5.3 of the Guidelines)

See discussion above under 2.a.(2). Heterologous In Vitro Fertilization with Intrauterine Embryo Transfer.

II. Destruction of Embryos and Gametes

1. Embryos

The rules in the German Act and the Guidelines aim to prevent the creation of surplus embryos. However, there are situations when the creation of surplus embryos is unavoidable; for example, when the woman refuses to give her consent to the transfer of the embryo in accordance with Section 4 of the German Act. These surplus embryos are cryopreserved.

Since no statute or guideline in Germany regulates the handling of surplus embryos, there is legal uncertainty about whether the destruction of surplus embryos is allowed or prohibited under the German Act. In 2008, a criminal division of the district court Berlin (*Landgericht Berlin*) decided that, in the case before it, the active destruction of surplus embryos as well as the omission of life saving measures (leaving the embryo to die) was allowed and not a crime under the German Act. However, the Superior Court of Justice Berlin decided that the district court's decision, that the active destruction of surplus embryos was not a crime, was incorrect and remanded the case back to another criminal division of the district court Berlin. The Superior Court of Justice Berlin agreed, however, that the omission of life saving measures (leaving the embryo to die) was not prohibited under the German Act. These decisions continue the ongoing discussion in Germany about whether the active destruction of surplus embryos and the omission of life saving measures are allowed or prohibited under German law. The German legislature will have to regulate the issue but has not yet done so despite many requests throughout the years.⁴²

2. Gametes

Cryopreserved gametes and ova in the pronucleus phase are discarded once the cryopreservation contract has been terminated.

III. Marital Status Restrictions

According to Section 3.1 of the Guidelines, generally, methods of assisted reproduction should only be utilized for married couples, and in general, only the sperm cells of the husband should be used. If sperm cells of a third person are used, the additional requirements of heterologous insemination must be met.

⁴² Decision dated Oct. 9, 2008; see Annex B.

Methods of assisted reproduction may also be utilized by an unmarried woman, if the treating doctor determines that the woman is in a stable relationship with an unmarried man, and this man will acknowledge paternity of the future child.

In these circumstances, only sperm cells of this partner should generally be used. If sperm cells of another third person are used, the additional requirements of heterologous insemination must be met. Heterologous insemination may not be performed on women who are not in a stable relationship or who are in a homosexual relationship.⁴³

IV. Age Restrictions

Although there are no absolute age restrictions governing the age at which a woman may receive in vitro fertilization treatment, the Guidelines recommend taking the age of the woman into consideration when deciding on the number of embryos to be transferred to the woman. Multiple pregnancies should be avoided because of the risks associated with the health of the woman and children. Because the likelihood of a multiple pregnancy is higher for younger women, for the first two in vitro fertilization attempts of a woman who is 38 years of age or younger, it is recommended that only two or fewer embryos be transferred.

V. IVF Subsidization Scheme

1. German Social Code V

According to Section 27a of the German Social Code V, an insured party may receive a subsidization of 50% of the cost of assisted reproduction. However, in order to receive such subsidization, all of the following requirements must be met:

- a medical doctor must determine that assisted reproductive methods are medically necessary;
- a medical doctor must determine that there is sufficient likelihood of pregnancy as a result of the assisted reproduction measures; a pregnancy is deemed to no longer be sufficiently likely if assisted reproduction procedures have been performed three times without leading to a pregnancy;
- the persons that are to receive assisted reproduction treatments must be married;
- only ova and sperm of the spouses may be used;
- the spouses were counseled with regard to the medical and psychosocial aspects of assisted reproduction by a medical doctor who will not perform the assisted reproductive measures, and were referred to a medical doctor with the required license to perform such treatments;
- the insured party must be 25 years of age or older;
- the woman must be below 40 years of age;
- the man must be below 50 years of age; and

⁴³ This assertion is not explicitly stated in either the statute or the Guidelines. However, such a policy is mentioned in the commentary to the Guidelines.

- the insurance company must approve the treatment plan presented to it prior to the treatments.

2. Guidelines regarding Medical Measures for Artificial Fertilization of the Federal Joint Committee of Medical Doctors and Health Insurances

These guidelines set forth medical details governing the requirements, manner and extent of the medical measures that fulfill the statutory requirements of Section 27a of the German Social Code V.

- The health insurance only subsidizes the treatment of the person insured under the policy. If the spouse is not insured by the same insurance company, his/her treatment is not covered. His/her insurance will have to be involved;
- Measures and services that go beyond the assisted reproduction are not covered, such as cryopreservation of sperm cells, ova in the pronucleus phase, or embryos that have not yet been transferred;
- Both spouses must be HIV-negative and the woman must be immunized against the rubella virus.

VI. Penalties

Penalties for violations of the relevant statutes and guidelines governing in vitro fertilization range from a monetary fine to five years in prison. In Germany, a monetary fine is determined by the criminal court on a daily rate basis (*Tagessatz*) in accordance with the German Criminal Code (*Strafgesetzbuch*). The monetary fine depends on both the amount of a daily rate (*Höhe des Tagessatzes*) and the number of daily rates (*Anzahl der Tagessaetze*). The amount of a daily rate is dependent on the economic situation of the perpetrator and ranges from a minimum of EUR 1 to a maximum of EUR 5,000 per day, unless the violated provision sets forth a different maximum amount. The number of daily rates ranges from five to 360. The specific penalties for different types of violations are discussed above under the relevant sections.

VII. Miscellaneous

1. Preimplantation Genetic Diagnosis

Preimplantation genetic diagnosis is the examination of an embryo prior to its transfer to a woman to determine whether a chromosomal disorder or specific genetic mutation is present. Germany has not enacted a statute to regulate this procedure. In 2001, a preimplantation genetic diagnosis statute was proposed but never enacted. Therefore, legal uncertainty exists about whether preimplantation genetic diagnosis is allowed or prohibited under the German Act.

In 2008, a criminal division of the district court Berlin (*Landgericht Berlin*) decided that, in the case before it, preimplantation genetic diagnosis was allowed and not a crime under the German Act. However, the Superior Court of Justice Berlin decided that the district court's decision was

incorrect and remanded the case to another criminal division of the district court Berlin.⁴⁴ Similar to the debate over the proper handling of surplus embryos, there is an ongoing discussion on the legal status of preimplantation genetic diagnosis under German law.

2. Polar Body Diagnosis

Polar body diagnosis is the examination of the first and, if possible, the second polar body of the ovum to determine whether a genetic or chromosomal disorder is present in the haploid, female chromosome set. In Germany, this diagnosis is permitted prior to the creation of an embryo.

3. Selection of Embryos based on Morphologic Criteria

Morphologic observation is used to distinguish between viable and non-viable embryos and allows a single embryo transfer. This kind of selection is not allowed in Germany according to Section 1, subsection 1, No. 3 and 5 of the German Act. It is, however, the subject of a controversial debate on whether such a selection should be allowed.

⁴⁴ Decision dated Oct. 9, 2008; see Annex B.

Italy

Law No. 4 of February 19, 2004 “Norms in Relation to Medically Assisted Procreation”⁴⁵ regulates IVF in Italy. This law was influenced greatly by Catholic doctrine. The effect of the law has been to force many Italians to pursue “fertility tourism” in other countries.⁴⁶ There are reports that fertility tourism by Italians has increased three-fold since March 2004.⁴⁷

I. Regulation of Embryos and Gametes

a. Protection of Embryos

Article 1(2) of the law on Norms in Relation to Medically Assisted Procreation “...grants rights to all subjects involved, including the conceived.” The law does not state that the embryo itself has legal status; however, scholars have hypothesized that the effect of the law and subsequent cases could result in granting full legal status to the embryo.⁴⁸ One scholar notes that “the law establishes the rights of the unborn from the moment the woman accepts the fertilization of her eggs. At that point she loses all rights to bodily autonomy and is coerced by law into implantation against her will, her body being reduced to the status of incubator.”⁴⁹ It has also been argued that the “Italian law has ensured the rights of the embryo, diseased or healthy, have superseded the rights of the mother.”⁵⁰

b. Research on Embryos

Article 13(1) prohibits any experimentation on a human embryo. Article 13(3)(b) specifically prohibits any form of eugenic selection of embryos and gametes aimed at predetermining their genetic characteristics, with the exception of interventions for diagnostic and therapeutic ends. It has been argued that this provision is illogical when one considers the availability of abortion; the reasoning is that if a couple knows a genetically faulty embryo is implanted, the couple can choose to abort the fetus later, so it is illogical to prohibit the destruction of that faulty embryo and thereby “put[] the mother’s mental and physical health at further risk.”⁵¹

c. Implantation / Storage of Embryos

Article 14 of Italy’s IVF law prohibits the cryogenic conservation of embryos, and states that the number of embryos that can be created is limited to a maximum of three embryos, all of which

⁴⁵Law 40/2004 of Feb. 19, 2004, 2004 Gazz. Uff. No. 45 (Feb. 24, 2004).

⁴⁶Jess Burton, *Restrictive Fertility Law Forces Italian Patients Abroad*, BioNews, Dec. 12, 2006, http://www.ivf.net/ivf/restrictive_fertility_law_forces_italian_patients_abroad-o2409.html.

⁴⁷Rachel Anne Fenton, *Catholic Doctrine Versus Women’s Rights*, 14 Med. L.J. 73, 102 (2006) (citing *La Repubblica* of May 25, 2005)

⁴⁸Fenton, *supra* note 24, at 104.

⁴⁹*Id.*

⁵⁰*Id.* at 104-05.

⁵¹*Id.* at 102.

must be implanted contemporaneously. A study has found that the prohibition on freezing embryos may “markedly reduce the chance of conception per stimulation cycle, in particular in women retrieving a high number of oocytes [egg cells].”⁵² This is especially true for older women, since fertilization rates decline with age.⁵³

Furthermore, Article 14(3) provides that if the transfer of the embryo into the uterus is not possible for unforeseen health reasons of the woman, cryogenic conservation is permitted until the embryo can be transferred, which shall be as soon as possible. The law does not appear to envision the problem of the woman never becoming healthy enough to permit transfer of the embryo, and does not address what to do with the remaining embryos should this occur. With regard to unhealthy embryos, the Ministry of Health guidelines refer to the possibility of the embryo not being implanted and to the transfer not being coercive; in such a case, the affected embryo is to be maintained until its natural demise.⁵⁴ However, this guideline does not appear to extend to the case of healthy embryos that can never be transferred to the woman.

II. Destruction of Embryos and Gametes

Article 14(1) of the Italian law prohibits the destruction of embryos. It has been argued that the prohibition on the destruction of embryos is illogical given that the Italian abortion law permits the same practice in relation to fetuses.⁵⁵ Furthermore, it could be argued that this provision interferes with the right to freedom of treatment, because a woman no longer has a choice regarding the implantation of embryos once her eggs have been fertilized.⁵⁶

III. Marital Status Restrictions

Article 5(1) of the Italian legislation limits access to medically assisted procreation to couples composed of opposite sexes, who are either married or living together. Furthermore, Article 4(1) requires certification of infertility in order to be eligible for assisted reproductive technologies. However, the denial of access to medically assisted procreation for single women appears to be incongruous within the Italian legal system because Law 151 of 1975 gives children born out of wedlock equivalent rights to children born to a married couple. Therefore, one could argue that the requirements of Article 5(1) contradict this equality.⁵⁷

IV. Age Restrictions

⁵² G. Ragni et al., The 2004 Italian Legislation Regulating Assisted Reproduction Technology: a Multicentre Survey on the Results of the IVF Cycles, 20:8 Human Reproduction (Apr. 7, 2005).

⁵³ Giuseppe Benagiano & Luca Gianaroli, The New Italian IVF Legislation, 9:2 Reproductive Biomedicine Online 117, 118 (Aug. 2004), available at www.rbmonline.com/Article//1376.

⁵⁴ Fenton, *supra* note 24, at 105 (citing Law 40/2004, art. 7. Linee Guida Contenenti le Indicazioni delle Procedure e delle Tecniche di Procreazione Medicalmente Assistita, available at www.ministerodellasalute.it).

⁵⁵ *Id.* at 102.

⁵⁶ Giuseppe Benagiano & Luca Gianaroli, *supra* note 4, at 118-19. (citing Lim & Tsakok, Age-related Decline in Fertility: a Link to Degenerative Oocytes?, Fertility and Sterility 68, 265-71 (1997)).

⁵⁷ *Id.* at 88.

Article 5(1) of the Italian legislation limits access to medically assisted procreation to persons of potentially fertile age. This age is not defined in the legislation itself.

V. IVF Subsidization Scheme

Article 18 of the Italian Law No. 4 creates a fund with the Ministry of Health for medically assisted procreation techniques. In 2004, at the time of creation of this law, the endowment of the fund was EUR 6.8 million. The Italian law does not stipulate to what extent procedures will be funded and what, if any, conditions are necessary to receive funding.

VI. Penalties

The penalty for violations of Article 4(3) (the prohibition on the use of donor sperm, eggs and surrogacy) is an administrative sanction of between EUR 300,000 and 600,000. The penalty for a violation of Article 5 (access to treatment) is an administrative sanction of between EUR 200,000 and 400,000. These penalties are the most lenient in Italy's law on IVF because they only consist of monetary sanctions. However, the exorbitant financial sanctions imposed by these penalties would be most likely successful deterrents to violating this law.

Violations of Article 13(1) (prohibition on experimenting on human embryos) are punished with a jail term of two to six years and a fine of between EUR 50,000 and 150,000.

The penalty for violations of the prohibition on the destruction and freezing of embryos, and the requirement that a maximum of three embryos be created and all implanted (Article 14), includes a prison term of up to three years and a fine of between EUR 50,000 and 150,000.

In addition, a one to three year suspension is imposed on any health professional guilty of violating one of the prohibitions in the act.

VII. Miscellaneous

Although Article 4(1) requires certification of infertility in order to be eligible for assisted reproductive technologies, Article 4(3) prohibits the use of donor sperm, eggs and surrogacy. Thus, a fertile woman is denied the opportunity to conceive a child under this Act if her husband or partner is infertile.

Sweden

Swedish Law 1988:711 on fertilization outside the human body regulates in vitro fertilization in Sweden (the “Swedish IVF Law”). The law has been in place since June 14, 1988 and has been updated and modified by other laws during the last twenty years. Additionally, the National Board of Health and Welfare Regulation Regarding Assisted IVF (the “IVF Regulation”) has identified requirements that individuals must fulfill in order to be eligible for subsidized IVF treatments.⁵⁸

I. Regulation of Embryos and Gametes

a. Single Embryo Transfer

The Swedish IVF Law does not contain provisions specifically regulating embryos; however, Section 11 provides that the government or an authority appointed by the government may, “with a view to protecting life and health, issue additional regulations relating to fertilization of a woman’s egg outside her body and introduction of a fertilized egg to a woman’s body.”⁵⁹ In 2003, the Swedish Board of Health and Welfare issued guidelines recommending a single embryo transfer into a woman, rather than the transfer of multiple embryos.⁶⁰ Therefore, single embryo transfers are now standard in Swedish clinics.⁶¹ The implantation of two embryos is only permitted when the risk of multiple births is “considered to be low,” which is normally the case for women above 38 years of age.⁶²

b. Donation of Embryos / Sperm

Section 3 of the IVF law requires that a fertilized egg may only be introduced into a woman’s body, when such egg is not the woman’s own egg, if the egg is fertilized by the spouse, common-law spouse, or registered partner, in accordance with the Swedish law on registered partnership.⁶³ Thus, IVF treatment with donated sperm or donated eggs is allowed under certain circumstances.⁶⁴

c. Location for IVF Treatment

⁵⁸ National Board of Health and Welfare regulation regarding assisted IVF (SOSFS 2002:X (M)).

⁵⁹ Law 1988:711, § 11 (citing Law (2002:252)).

⁶⁰ Anders Svensson, Mark Connolly, Federico Gallo & Leif Hägglund, Long-term Fiscal Implications of Subsidizing In-Vitro Fertilization in Sweden: A Lifetime Tax Perspective, 36:8 Scand. J. Pub. Health 841, 846 (2008).

⁶¹ Id. See also Swedish Nat’l Bd. of Health & Welfare, Childbirth after IVF Treatment in Sweden 1982 -2001, 2001-112-1 (May 2006).

⁶² P.O. Karlström & C. Bergh, Reducing the Number of Embryos Transferred in Sweden -- Impact on Delivery and Multiple Birth Rates, 22.8 Human Reproduction 2202, 2202 (June 11, 2007).

⁶³ Law (1994:1117).

⁶⁴ Riitta Burrell, Assisted Reproduction in Nordic Countries, Nordic Committee on Bioethics, 2005 (citing (Prop. 2001/02:89 (Swed.)).

According to Section 4 of the Swedish IVF Law, IVF treatment must occur in a publicly funded hospital, unless the National Board of Health and Welfare allows the treatment to occur elsewhere. However, Section 4 further provides that if the egg is not the woman's own, or if the sperm is not the spouse's or the common-law spouse's sperm, the introduction of the egg may only be carried out in those hospitals that have been granted the right to educate medical doctors pursuant to an agreement among the universities that carry out medical doctor education and the relevant County Council.⁶⁵

II. Destruction of Embryos and Gametes

The Swedish IVF Law does not contain any provisions discussing the destruction of embryos. There is no penalty in the law for destroying an embryo.

III. Marital Status Restrictions

According to Section 3 of the Swedish IVF Law, a fertilized egg may only be introduced into a woman's body if the woman is married, in a registered partnership, or has a common-law spouse. Furthermore, the spouse, partner or common-law spouse must consent to IVF in writing. Thus, a woman who is not in some type of recognized relationship does not have the right to IVF treatments.

However, Sweden recently entertained a legislative proposal that would permit single women to receive IVF treatment. Since the majority of the members of the Swedish Parliament supports this proposal, it was generally expected that the proposal would be approved by the Parliament early this year. However, on February 24, 2009, the Parliament's Committee on Health and Welfare discussed the proposal and decided that the parliamentary vote on the proposal would be postponed until further notice. The Committee explained that it needs to better analyze the proposal and its ramifications.⁶⁶

Swedish journalists have posited that the Committee postponed the vote on the proposed legislation because the Christian Democratic Party, which is the only strict opponent of the proposal, is a member of Sweden's four-party coalition government, and the other parties in the coalition were reluctant to upset this party by allowing the Parliament approve the proposal.⁶⁷

IV. Age Restrictions

Section 2 of the Swedish IVF Law states that the donor of the egg or sperm shall be "of age." However, the law does not specify any age limits or contain an upper limit restriction on the age of the woman receiving the IVF treatment.⁶⁸

⁶⁵ Law 1988:711, § 4 (citing Law (2002:252)). County Councils are the 21 political subdivisions in Sweden that share the responsibility of providing health care with the national government.

⁶⁶ SVT, [No to a Single Insemination](http://svt.se/svt/jsp/Crosslink.jsp?d=22620&a=1456552&lid=puff_1456579&lpos=rubrik), Feb. 24, 2009, available at http://svt.se/svt/jsp/Crosslink.jsp?d=22620&a=1456552&lid=puff_1456579&lpos=rubrik (Swed.).

⁶⁷ *Id.*

V. In Vitro Fertilization Subsidization Scheme

The National healthcare system of Sweden fully reimburses IVF treatment costs at public clinics for patients who meet the requirements specified in the IVF Regulation.⁶⁹ However, each patient must pay a general administrative fee of 100 to 150 Swedish Kronor, which is charged by publicly funded hospitals to all patients.⁷⁰

a. Single Embryo Transfers

The national health care plan provides financial coverage for an unlimited number of IVF cycles “in which a single embryo is transferred, but only up to four cycles if more than one embryo is transferred.”⁷¹

b. National Board of Health and Welfare Regulation Regarding Assisted IVF

According to the IVF Regulation, a woman must comply with certain marital status restrictions, discussed above in III. Marital Status Restrictions; obtain the written consent of her husband, common-law husband or registered partner; and fulfill various health, psychological and social requirements to receive IVF treatments that are subsidized by the National healthcare system.

1. Health Requirements⁷²

In order to receive subsidized IVF treatments, all couples must be tested for the Human Immunodeficiency Virus (HIV), Human T-lymphotropic virus (HTLV) I, HTLV II, Hepatitis B, Hepatitis C and Syphilis. Furthermore, the couple may only receive assisted IVF if the aforementioned diseases or infections are unlikely to be transferred to the woman or child through fertilization. Lastly, IVF may only be carried out if the pregnancy or any disease (other than those listed above) will not risk the life or health of the woman or the child.

2. Psychological and Social Requirements⁷³

The IVF Regulation further requires that all couples undergo an examination by a physician and psychologist for any somatic or psychological disorders and disabilities, with a view to ensuring

⁶⁸ Swedish Nat'l Bd. of Health & Welfare, Childbirth after IVF Treatment in Sweden 1982 -2001, 2001-112-1 (May 2006).

⁶⁹ Svensson, *supra* note 51, at 842. See also Maria Granberg, Matts Wikland & Lars Hamberger, Financing of IVF/ET in the Nordic Countries, 77 *Acta Obstetrica et Gynecologica* 63, 65 (June 11, 2003); (SOSFS 2002:X(M)).

⁷⁰ Financing Policies of IVF in Sweden, <http://politiskfilosofi.blogg.se/2006/june/financing-policies-of-ivf-in-sweden.html> (June 8, 2006, 16:55:41) (The blog text is extracted from a study titled *In Vitro Fertilization - A Moral Inquiry* by a Swedish researcher Karim Jeberi, who also maintains the blog. Mr. Jeberi specializes in analytical philosophy.).

⁷¹ Tarun Jain, Stacey A. Missimer & Mark D. Hornstein, Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the United States, 350:16 *New Eng. J. Med.* 1639, 1645 (Apr. 15, 2004).

⁷² SOSFS 2002:X(M) at ch. 3-§1.

⁷³ *Id.* at Ch. 4-§1.

that the parents are able to care for the child through her/his infancy. Specifically, the physician must ensure that:

- both partners wish to have a child;
- the couple's relationship is stable and lasting;
- the couple has the ability to take care of and raise a child;
- the couple is emotionally, practically, socially and legally ready to accept the child as their own;
- the couple is aware of and able to deal with the inequality that can be caused by the fact that the child's genes will be originating from only one of the parents; and
- the couple will tell the child about her/his origin.

3. Age Restrictions⁷⁴

The IVF Regulation also places age restrictions on couples who seek subsidized IVF treatments. It requires that the age of the prospective mother should not have reached the point at which fertility is normally rapidly declining. Although the IVF Regulation does not identify a specific age, the various County Councils have identified maximum age requirements that range from 37 to 43 years for the subsidization of IVF treatments.⁷⁵

Furthermore, the IVF Regulation indicates that the age of the prospective father should allow him to take care of the child throughout her/his childhood. Again, the regulation does not indicate a specific age. Most County Councils have set a maximum age limit of 55 years, and two County Councils have not set a maximum age for the prospective father.⁷⁶

Lastly, although the IVF Regulation does not suggest a minimum age for the parents who undergo IVF treatment, the County Councils generally require a minimum age for the parents, which ranges from 19 to 24 years.

c. IVF Treatment in Private Clinics

As a result of the limits on IVF cycles and the aforementioned requirements that must be met by the couple pursuing IVF treatment, waiting lists for IVF treatment have developed.⁷⁷ Therefore, many couples pay for IVF treatment outside of the public health care system, in private clinics.⁷⁸ Private clinics are not required to subject couples to the tests required by the IVF Regulation.⁷⁹ Furthermore, private clinics can offer IVF treatments to single women.⁸⁰

⁷⁴ *Id.* at Ch. 4-§1.

⁷⁵ Jeberi, *supra* note 68.

⁷⁶ *Id.*

⁷⁷ Jain, *supra* note 69, at 1645.

⁷⁸ Svensson, *supra* note 51, at 842.

⁷⁹ Jeberi, *supra* note 68.

⁸⁰ *Id.*

The National healthcare system does not reimburse the costs of IVF treatment.⁸¹ Approximately 68% of assisted reproductive technology treatments in Sweden are publicly financed, and 32% are financed privately.⁸²

d. Long-term Financial Implications of IVF Subsidization

A recent article surveyed the long-term fiscal implications of subsidizing IVF treatment in Sweden and found that state funding for IVF does not negatively impact Sweden's fiscal budget in the long term. Instead, state-subsidized IVF treatments generate a positive net value for the state over the lifetime of the IVF offspring.⁸³ Thus, this article presents an argument for government subsidization of assisted reproductive technologies, using the Sweden as a case study.

VI. VI. Penalties

Section 9 of the Swedish IVF Law provides that anyone who "habitually or for gain" commits a breach of Section 3 (*See I, ¶ 2 and III*) or Section 4 (*See I, ¶ 3*) shall be ordered to pay a fine or sentenced to imprisonment not exceeding six months. The amount of the fine is not specified.

VII. Miscellaneous

In Sweden, public health clinics may refuse to provide IVF treatments to couples who already have a child together.⁸⁴ However, this restriction does not exist in private clinics.⁸⁵

⁸¹ Granberg, *supra* note 67, at 65.

⁸² Svensson, *supra* note 51, at 842.

⁸³ *Id.*

⁸⁴ Swedish Nat'l Bd. of Health & Welfare, Childbirth after IVF Treatment in Sweden 1982 -2001, 2001-112-1 (May 2006).

⁸⁵ *Id.*

United Kingdom

The current United Kingdom legislation governing *in vitro* fertilization and related issues is the Human Fertilisation and Embryology Act 2008 (the “HFE Act 2008”),⁸⁶ which amends the Human Fertilisation and Embryology Act 1990 (the “HFE Act 1990,” these two Acts, generally, the “HFE Act”) and provides additional rules regarding assisted reproduction.⁸⁷ The most relevant sections of the HFE Act 2008, which amend the previous act, will become effective in November of 2009.⁸⁸ Both the HFE Act 1990 and the HFE Act 2008 are addressed herein.

Pursuant to the HFE Act, the Human Fertilisation and Embryology Authority (HFEA), an executive, non-departmental public statutory body, was created for licensing, monitoring, and providing information and advice regarding the HFE Act and human assisted reproduction and embryo research.⁸⁹

The main purposes of the HFE Act are (1) to grant licenses to those desiring to offer infertility treatment, and (2) to grant licenses to researchers wishing to work with human gametes and embryos. This portion of the memorandum will focus on the former of these two purposes, but will touch on the topic of research regulations inasmuch as they pertain to protection and destruction of embryos.

I. Regulation of Embryos and Gametes

a. Protection of Embryos

In response to the birth of the first baby conceived using *in vitro* fertilization, a Committee of Inquiry was appointed to consider developments in human fertilization and embryology. In 1985, the Committee published a report—the “Warnock Report”—that provided its findings. With respect to the morality of the use of human embryos, the Warnock Report stated:

[T]he law provides a measure of protection for the human embryo *in vivo* it is clear that the human embryo under our definition of the term is not, under the present law of the UK, accorded the same status as a living child or adult nor do we necessarily wish it to be accorded that status. Nevertheless we are agreed that the embryo of the human species ought to have a special status and that no one

⁸⁶ Human Fertilisation and Embryology Act, 2008, c. 22 (U.K.).

⁸⁷ The main elements of the HFE Act 2008 relevant to this memorandum are:

- (1) Ensuring that the creation and use of all human embryos outside the body, regardless of the method used to create them, are subject to regulation;
- (2) Banning the selection of sex of offspring for non-medical reasons;
- (3) Retaining the duty to take into account the “welfare of the child” when providing fertility treatment, but removing the “the need for a father” language; and
- (4) Providing for the recognition of same sex couples as legal parents of children conceived using alternative reproductive methods.

⁸⁸ Human Fertilisation and Embryology Act, 2008 (U.K.).

⁸⁹ Human Fertilisation and Embryology Act, 1990, c. 37, §§ 5-8 (U.K.); see also Human Fertilisation and Embryology Act, 2008, c. 22, §§ 5-10 (U.K.) (amending relevant sections in the HFE Act 1990).

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should undertake research on human embryos the purposes of which would be achieved by the use of animals or in some other way. The status of the embryo is a matter of fundamental principle which should be enshrined in legislation. **We recommend that the embryo of the human species should be afforded some protection in law.**⁹⁰

The HFE Act itself, or any other legislation relating to the creation and use of embryos, however, does not contain similar language.

b. Creation of Embryos

Under UK legislation, there is no prohibition on the creation of human embryos for use other than for placement in a woman. Under the HFE Act 1990, in the context of fertility treatment, licenses may be granted for creating embryos in vitro or for procuring, keeping, testing, processing, and distributing such embryos.⁹¹ In addition, licenses for research may be granted for creating embryos in vitro or for keeping and using embryos, as long as the proposed research is necessary or desirable in advancing fertility treatments or has other appropriate purposes.⁹²

With respect to treatment licenses, the HFE Act 2008 expands the class of permitted activities that can be licensed to include using embryos for the purpose of training in embryo biopsy, embryo storage, or other embryological techniques.⁹³ With regard to research licenses, the HFE Act 2008 expands the field of permitted activities to include creation of human admixed embryos (as described below), and also expands the class of acceptable purposes for embryological research.⁹⁴

There are, however, laws regulating which embryos may be used for IVF and how long embryos may be kept and stored, as well as various provisions limiting creation and alteration of embryos with respect to science and technology, as described below.

c. Use of Embryos and Gametes

Effective consent (signed in writing, and not withdrawn) is required from all persons whose cells or gametes are used to create an embryo or a human admixed embryo.⁹⁵ Other than this requirement, there are no restrictions on use of a person's gametes or embryos created from a person's gametes in the treatment of another person, as long as effective consent has been obtained.

⁹⁰ Dept. of Health and Soc. Sec., Report of the Committee of the Inquiry into Human Fertilisation and Embryology, July 1984, Cmnd. 9314 (emphasis added).

⁹¹ Human Fertilisation and Embryology Act, 1990, c. 22, § 1(1), sched. 2 (U.K.).

⁹² *Id.* at § 3.

⁹³ Human Fertilisation and Embryology Act, 2008, c. 37, § 2(2)(a), sched. 2 (U.K.) (adding subsection (ca) to § 1(1) of Schedule 2 of the HFE 1990).

⁹⁴ *Id.* at § 3 (replacing §3 in the HFE Act 1990).

⁹⁵ Human Fertilisation and Embryology Act, 1990, c. 22, § 5, sched. 3 (U.K.).

d. Regulation of Embryos for IVF Use

One of the functions of the HFE Act is to regulate the type of embryos that may be used for IVF treatment purposes. The HFE Act 1990 prohibits anyone from placing a live embryo other than a human embryo, or live gametes other than human gametes, inside a woman.⁹⁶ The HFE Act 2008, in light of scientific and technological developments, amends this provision in order to prevent implantation of embryos that have been genetically altered, other than in limited circumstances. Under the HFE Act 2008, it is prohibited to place in a woman an embryo:

- whose nuclear or mitochondrial DNA has been altered or which has not had cells added (other than by division);
- which has been formed by an egg or sperm that
 - was not harvested from the ovaries of a woman or testes of a man or
 - whose nuclear or mitochondrial DNA has been altered; or
- was created by cloning.⁹⁷

However, the HFE Act 2008 provides, under amended Section 3ZA(5), that regulations may expand the limited class of permitted embryos for IVF use to include embryos or eggs which have been altered so as to prevent the transmission of serious mitochondrial diseases, should technology to do so become available and safe.⁹⁸

e. Genetic Screening and Selection

The HFE Act 2008 introduces regulations on screening of embryos, the primary purpose of which is to ban selecting the sex of offspring for non-medical reasons. Under these regulations, testing of an embryo is only licensable under certain circumstances. Permitted purposes of embryo testing are:

- establishing whether the embryo has an abnormality that may affect its capacity to result in a live birth,⁹⁹
- establishing whether the embryo has abnormalities (but only in the case where there is a particular risk of an abnormality that presents a significant risk of serious physical or mental disability, serious illness, or other serious medical condition),¹⁰⁰
- establishing the sex of the embryo (but only in the case where there is a particular risk that any resulting child will develop a gender-related serious physical or mental disability, serious illness, or serious medical condition),¹⁰¹

⁹⁶ Human Fertilisation and Embryology Act, 1990, c. 37, §§ 3(2)(a)-(b) (U.K.).

⁹⁷ Human Fertilisation and Embryology Act, 2008, c. 22, § 3(2) and § 3(5) (U.K.) (adding §§ 3ZA(1)-(4) in the HFE 1990).

⁹⁸ *Id.* at § 3(5) (adding § 3ZA(5) in the HFE 1990).

⁹⁹ Human Fertilisation and Embryology Act, 2008, c. 22, § 1ZA(1)(a), sched. 2 (U.K.).

¹⁰⁰ Human Fertilisation and Embryology Act, 2008, c. 22, §§ 1ZA(1)(b) and 1ZA(2), sched. 2 (U.K.).

¹⁰¹ Human Fertilisation and Embryology Act, 2008, c. 22, §§ 1ZA(1)(c) and 1ZA(3), sched. 2 (U.K.).

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- establishing that tissues of a resulting child would be compatible with a child of the people from whom the gametes for the embryo were taken,¹⁰² and
- establishing whose gametes were used in the creation of the embryo (if there are doubts as to origin).¹⁰³¹⁰⁴

Thus, the new UK legislation allows for screening in cases where resulting offspring would face abnormalities and screening for “savior” siblings would be permitted. Sex-screening is only permitted in cases of risk of serious medical conditions. Furthermore, the HFE Act 2008 explicitly prohibits the licensing of any procedure designed to secure a particular sex of a child, unless there is a risk that the child will possess a serious medical condition.¹⁰⁵

The HFE Act 2008 also provides that persons, gametes, or embryos known to have a gene, chromosome, or mitochondrial abnormality involving a significant risk of serious physical or mental disability, serious illness, or other serious medical condition must not be preferred over other persons, gametes, or embryos when considering a donor or when determining which embryo to place inside a woman.¹⁰⁶

f. Human Admixed Embryos

The HFE Act 2008, in recognition of scientific advancements and research that would propose to mix human and animal genetic material, established provisions regulating such gametes and embryos (generally called “human admixed” embryos).¹⁰⁷ No human admixed embryos, any other embryos except human embryos, or gametes other than human gametes, may be placed inside a woman.¹⁰⁸ Similar to human embryos, human admixed embryos may not be kept or used longer than the earlier of the appearance of the primitive streak, or 14 days from when the creation process began.¹⁰⁹

II. Destruction of Embryos and Gametes

In the UK, there are no prohibitions on the destruction of embryos in general.

Under the HFE Act 1990, a human embryo cannot be kept or used after the appearance of the primitive streak,¹¹⁰ which is considered to have appeared not later than the end of a period of 14 days beginning with the day on which the gametes were mixed, not counting any time during

¹⁰² Human Fertilisation and Embryology Act, 2008, c. 22, §§ 1ZA(1)(d) and 1ZA(4), sched. 2 (U.K.).

¹⁰³ Human Fertilisation and Embryology Act, 2008, c. 22, § 1ZA(1)(e), sched. 2 (U.K.).

¹⁰⁴ Human Fertilisation and Embryology Act, 2008, c. 22, § 1ZA, sched. 2 (U.K.).

¹⁰⁵ *Id.* at § 1ZB.

¹⁰⁶ *Id.* at § 14(4) (adding §§ 13(6E)(8)-(13) in the HFE 1990).

¹⁰⁷ Human Fertilisation and Embryology Act, 2008, c. 22, § 4 (U.K.) (adding § 4A in the HFE Act 1990).

¹⁰⁸ *Id.* (adding § 4A(1) in the HFE 1990).

¹⁰⁹ *Id.* (adding § 4A(3) in the HFE 1990).

¹¹⁰ The primitive streak represents the first signs of neural development, and after this point, an embryo cannot divide and become twins.

which the embryo is stored.¹¹¹ The maximum storage time for embryos and gametes is five years.¹¹² If gametes or embryos are in storage at the end of the maximum statutory period, they are to be destroyed.¹¹³

These regulations are largely unchanged by the HFE Act 2008,¹¹⁴ except that the statutory maximum period for storage of embryos and human admixed embryos is expanded to 10 years.¹¹⁵

III. Marital Status Restrictions

There are no technical marital status restrictions on IVF treatment under the HFE Act. The HFE Act 1990 does specify that a licensed IVF treatment provider must take into account the welfare of the child who may be born as a result of the treatment, including the need of the child *for a father*, as well as any other child that may be affected by the birth.¹¹⁶ This statement suggests that it could be possible for treatment to be refused to unmarried couples, same-sex couples, and single women. Other portions of the HFE Act 1990, however, allow for treatment to be provided to a woman or an unmarried couple, which implies that marriage is not required. For instance, § 13(6) provides that no woman shall be provided with IVF treatment services “unless the woman being treated and, where she is being treated together with a man, the man have been” given an opportunity to receive counseling related to the procedures.¹¹⁷ This language implies that the woman receiving treatment may do so without a man, and that a man with whom she may be treated need not be her husband.

In contrast, the HFE Act 2008 explicitly removes all references to “the need for a father” from the HFA Act, instead requiring that the need for “supportive parenting” be considered as a prerequisite for IVF treatment.¹¹⁸ In addition, the HFE Act 2008 revises the above-mentioned § 13(6) dealing with pre-treatment counseling to apply to the woman receiving treatment “and any man *or woman* who is to be treated together with her,” specifically allowing for same-sex couples.¹¹⁹

In addition, Part 2 of the HFE Act 2008, which addresses the determination of legal parenthood in cases involving assisted reproduction, contains equivalent provisions applicable to same-sex parents as those previously in place for opposite-sex couples.¹²⁰

¹¹¹ Human Fertilisation and Embryology Act, 1990, c. 37, §§ 3(3)-(4) (U.K.).

¹¹² *Id.* at §§ 14(3)-(4).

¹¹³ *Id.* at § 14(1)(c).

¹¹⁴ In addition, the HFE Act 2008 provides that this 14 day period after which an embryo may not be kept or used shall commence the day on which the process of creating the embryo began, rather than the day when the gametes were mixed. *See* Human Fertilisation and Embryology Act, 2008, c. 22, § 3(4) (U.K.).

¹¹⁵ Human Fertilisation and Embryology Act, 2008, c. 22, § 16(3) (U.K.) (amending § 14(4) of the HFE Act 1990).

¹¹⁶ Human Fertilisation and Embryology Act, 1990, c. 37, § 13(5) (U.K.).

¹¹⁷ Human Fertilisation and Embryology Act, 1990, c. 37, § 13(6) (U.K.).

¹¹⁸ Human Fertility and Embryology Act, 2008, c. 22, § 14(3) (U.K.) (amending § 13(6) of the HFE Act 1990).

¹¹⁹ *Id.*

¹²⁰ Human Fertilisation and Embryology Act, 2008, c. 22, §§ 42-50 (U.K.).

IV. Age Restrictions

In the UK, there are no legislative restrictions on the age of women eligible to receive IVF treatment. The National Health System, which is the socialized publicly-funded health care system in the UK that provides healthcare to anyone normally residing in the UK, issues recommendations, that might pragmatically limit the availability of treatment for women aged 40 years or older because of funding, as described below.

V. IVF Subsidization Scheme

The National Institute for Health and Clinical Excellence (“NICE”), in its guidelines for infertility treatment, suggests that three cycles of stimulated IVF should be provided to couples where the woman is aged between 23-39 years and there is an identified cause of infertility or unexplained fertility of at least three years.¹²¹ It is not, however, mandatory for procedures provided for in the guidelines to be funded; the policies set forth in the guidelines are implemented through local branches of the National Health System and Primary Care Trusts (PCTs), and it appears that the guidelines will be phased in, although the guidelines do not indicate a timeline for this process. The Secretary of State for Health at the time the NICE guidelines were published stated that as of April 2005, all eligible women should receive at least one state-funded cycle of IVF.¹²²

VI. Penalties

The HFE Act provides for penalties for violating its regulations, and these punishments depend upon the nature of the offense.

Under the HFE Act 1990, the most serious offenses, punishable by imprisonment for a term not to exceed 10 years, by a fine, or both, are:

- placing a live non-human embryo or live non-human gametes inside a woman,¹²³
- using female germ cells for the purpose of providing fertility services,¹²⁴
- mixing human gametes with animal gametes,¹²⁵
- keeping or using an embryo after the appearance of the primitive streak (or 14 days),¹²⁶
- placing a human embryo in an animal,¹²⁷ and

¹²¹ Nat'l Inst. for Health and Clinical Excellence, Clinical Guideline 11, (Feb. 2004), <http://www.niceorg.uk/CG011>

¹²² Press Notice, Dept. of Health, 2004/0069 (Feb. 2004) (*available at* <http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=109373&NewsAreaID=2&NavigatedFromDepartment=False>).

¹²³ Prohibited by the Human Fertilisation and Embryology Act, 1990, c. 37, § 3(2) (U.K.).

¹²⁴ Prohibited by the Human Fertilisation and Embryology Act, 1990, c. 22, § 3A (U.K.).

¹²⁵ Prohibited by the Human Fertilisation and Embryology Act, 1990, c. 37, § 4(1)(c) (U.K.).

¹²⁶ Prohibited by the Human Fertilisation and Embryology Act, 1990, c. 37, § 3(3)(a) and § 3(4) (U.K.).

¹²⁷ Prohibited by the Human Fertilisation and Embryology Act, 1990, c. 37, § 3(3)(b) (U.K.).

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- keeping or using an embryo in any other circumstances in contravention of regulations.¹²⁸¹²⁹

The HFE Act 2008 amends these provisions to provide more detail, but does not substantially change the penalties themselves. For instance, the HFE Act 2008 prohibits placing of any non-permitted embryos or gametes inside a woman (rather than only non-human embryos or gametes under the HFE Act 1990), and replaces the prohibition on mixing human and non-human gametes with more specific regulations pertaining to human admixed embryos and related issues.¹³⁰

Other offenses under the HFE Act 1990 are not considered as serious. If a person is convicted of one of the following offenses on indictment (trial by jury), it is punishable by imprisonment for a term not to exceed two years, by a fine, or both.¹³¹ If a person is convicted of one of the following offenses on summary conviction (bench trial, in front of a judge alone), it is punishable by imprisonment for a term not to exceed six months, or a fine not exceeding the statutory maximum, or both.¹³² These offenses are:

- bringing about the creation of a human embryo without a license,¹³³
- keeping or using any gametes without a license,¹³⁴
- placing sperm and eggs in a woman in circumstances specified under regulations without a license,¹³⁵
- failing to comply with directions involving the keeping or holding of things or information relating to a license to be transferred,¹³⁶
- providing information known to be false or misleading (or recklessly provided) for the purposes for the grant of a license, and
- with respect to agents of the HFEA, disclosing information prohibited by the HFE Act.¹³⁷¹³⁸

The HFE Act 2008 amends these provisions slightly and adds a few offenses to the above list. The description of the offense relating to compliance with directions involving keeping and holding things relating to a transferred license is updated in accordance with related new rules.¹³⁹

¹²⁸ Prohibited under the Human Fertilisation and Embryology Act, 1990, c. 37, § 3(3)(c) (U.K.).

¹²⁹ Human Fertilisation and Embryology Act, 1990, c. 37, § 41(1) (U.K.) (as amended by the Criminal Justice and Public Order Act, 1994, c. 33 156(3) (U.K.)).

¹³⁰ Human Fertilisation and Embryology Act, 2008, c. 22, §§ 29(1)-(2) (U.K.).

¹³¹ Human Fertilisation and Embryology Act, 1990, c. 37, §§ 41(4)(a), (41)(5)(a) (U.K.).

¹³² *Id.* at §§ 41(4)(b), (41)(5)(b) (U.K.).

¹³³ Prohibited under the Human Fertilisation and Embryology Act, 1990, c. 37, § 3(1) (U.K.).

¹³⁴ Prohibited under the Human Fertilisation and Embryology Act, 1990, c. 37, §§ 4(1)(a)-(b) (U.K.).

¹³⁵ Prohibited under the Human Fertilisation and Embryology Act, 1990, c. 37, § 4(3) (U.K.).

¹³⁶ Human Fertilisation and Embryology Act, 1990, c.37 § 24(7).

¹³⁷ Human Fertilisation and Embryology Act, 1990, c.37 § 33 (as amended).

¹³⁸ *Id.* at §§ 41(2)-5) (as amended to include § 4(2)(bb)).

¹³⁹ Human Fertilisation and Embryology Act, 2008, c. 37, § 29(3)(c) (U.K.) (amending the HFE Act 1990 c.37 § 41(2)(d) to reference directions under § 24(5D)).

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Also, the prohibition on HFEA agents disclosing information is updated to reflect changes in the disclosure rules.¹⁴⁰ In addition, procuring, testing, processing, or distributing gametes or embryos intended for human application, except pursuant to a license or third-party agreement, are also offenses according to the 2008 amendments.¹⁴¹

In addition, the HFEA may suspend or revoke the license of anyone who commits an offense under the HFE Act.¹⁴²

VII. Miscellaneous

Surrogacy, including through the use of IVF treatment, is permitted in the UK and regulated by various legislation.¹⁴³

¹⁴⁰ *Id.* at § 29(5) (amending the HFE Act 1990 c.37 § 41(5) to reference updated § 33A).

¹⁴¹ *Id.* at §§ 29(3)(a)-(b) (U.K.) (adding prohibitions on contravention of §§ 3(1B) and 4(1A) of the HFE Act of 1990 (as amended)).

¹⁴² Human Fertilisation and Embryology Act, 1990, c. 37, §§ 18(2)(b), 22 (U.K.); see also Human Fertilisation and Embryology Act, 2008, c. 22, §§ 18 (U.K.) (amending the HFE Act 1990 to move the previous provision of § 18(2) (b) to § 18(2)(h)), 20 (amending the HFE Act 1990 to include § 19C, providing for the authority to suspend a license).

¹⁴³ Surrogacy Arrangements Act, 1985, c. 49 (U.K.); see also Human Fertilisation and Embryology Act, 1990, c. 37, § 36 (U.K.) (amending the Surrogacy Arrangements Act 1985); Human Fertilisation and Embryology Act, 2008, c. 22, § 59 (U.K.) (amending the Surrogacy Arrangements Act 1985).

Annex A

Glossary¹⁴⁴

Actinotherapeutic Treatment: a radiation therapeutic treatment

Chimera: an individual, organ, or part consisting of tissues of diverse genetic constitution, such as the tissue of a human and an animal

Contraindication: a symptom or condition that makes a particular treatment or procedure inadvisable

Cryopreservation: preservation of sperm or eggs by subjection to extremely low temperatures; freezing

Endometriosis: the presence and growth of functioning endometrial tissue in places other than the uterus that often results in severe pain and infertility

Epididymal: of the system of ducts that lies on each testicle, connecting them to the vas deferens, and holds sperm as they mature

Gamete: a mature male or female germ cell usually possessing a haploid chromosome set and capable of initiating formation of a new diploid individual by fusion with a gamete of the opposite sex

Gamete intrafallopian transfer: a method of assisted reproduction in cases of infertility in which eggs are obtained from an ovary, mixed with sperm, and inserted into a fallopian tube

Germ line: the cellular lineage especially of a sexually reproducing animal from which eggs and sperm are derived and in which a cell undergoing mutation can be passed to the next generation

Heterologous in vitro fertilization: in vitro fertilization whereby a woman's ovum is fertilized using the sperm of a sperm donor (a third party that is not the husband of the woman or partner in a stable relationship with the woman)

Homologous in vitro fertilization: in vitro fertilization whereby a woman's ovum is fertilized using the sperm of her husband or partner in a stable relationship

Human admixed embryo: embryos that contain both human and animal matter

Intracytoplasmic sperm injection: a method of artificial fertilization whereby a single sperm is injected into an ovum using a fine glass needle

Intrauterine: of, situated in, used in, or occurring within the uterus

¹⁴⁴ Merriam-Webster Medical Dictionary, available at <http://www.merriam-webster.com>.

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Karyogamy: the fusion of cell nuclei during fertilization

Nidation: the process of attachment of the embryo to the uterine wall

Pronucleus phase: the time during which the nucleus of an egg or sperm cell has entered the ovum but has not yet fused with another sperm or egg in fertilization

Primitive Streak: A structure that develops in an embryo during early stages of development, which establishes an axis around which all of the future developmental structures will form, and after this point, the embryo cannot divide to become twins. This generally develops after 14 days in humans. Some bioethicists believe that experimentation on embryos should only be conducted prior to this point because the primitive streak signifies the beginning of development of a single, unique human being.

Supernumerary Embryo: an embryo conceived in vitro within the framework of assisted reproductive treatments

Totipotent: capable of developing into a complete organism or differentiating into any of its cells or tissues