

**NATIONAL REGULATORY FRAMEWORKS REGARDING
HUMAN REPRODUCTIVE GENETIC TESTING
(Preimplantation genetic Diagnosis/Prenatal Diagnosis)**

A Report for the Genetics and Public Policy Center

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NATIONAL REGULATORY FRAMEWORKS REGARDING HUMAN REPRODUCTIVE GENETIC TESTING (Preimplantation genetic Diagnosis/Prenatal Diagnosis) (PGD/PND)

Advances in reproductive genetic testing techniques, such as prenatal diagnosis (PND) and preimplantation diagnosis (PGD), have enabled prospective parents to know whether their child will be born with a certain genetic disorder or the possible outcomes of current or future pregnancies. PND, which is performed *in vivo* during pregnancy, is a diagnostic or pre-symptomatic test that can rule out the presence of specific medical conditions in the fetus. As an alternative to PND, PGD can also be used to screen for genetic conditions at an earlier embryonic stage *in vitro* after IVF. PGD tests a single cell of an embryo to detect any genetic abnormality; only the embryos that lack chromosomal or genetic defects are selected to be implanted into the uterus. Both PND and PGD have the potential to be used for non-medical purposes motivated by cultural or social reasons, i.e., for sex selection, which raises social, legal and ethical questions.

This report provides a comparative survey of international approaches to reproductive genetic testing with summary charts and a compendium. The legal status of PND and PGD is not uniform among the different countries, so regulatory systems cannot be generalized. However, having an understanding of how different government agencies or national ethics committees govern reproductive genetic testing may encourage public debate and facilitate policy making in the United States in this field.

AUSTRALIA

- *Western Australian Human Reproductive Technology Act 1991* (amended by the Human Reproductive Technology Act of 1996).
- *South Australia Reproductive Technology Act 1988 (An Act to Regulate the Use of Reproductive Technology and Research Involving Experimentation with Human Reproductive Material)*.
- Australian Medical Association, *Human Genetic Issues*, (2000).
- National Health and Medical Research Council, *Ethical Aspects of Human Genetic Testing: an Information Paper*, (2000).
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Recommended 'Best Practice' Guidelines on Antenatal Screening for Down Syndrome and other Fetal Aneuploidy*, (2001).

- Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Prenatal Diagnosis Interim Policy (2.3)*, (2001).
- *Victoria Infertility Treatment Act No. 63/1995* (version incorporating amendments as of July 1, 2002).
- *Research Involving Human Embryos Act*, (2002).
- *Prohibition of Human Cloning Act No. 144/2002 (An Act to prohibit human cloning and other unacceptable practices associated with reproductive technology, and for related purposes)*, (2002).
- Australia Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia*, (2003).
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists, *Antenatal Screening Tests*, (2003).
- National Health and Medical Research Council, *Ethical guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*, (September 2004), http://www.nhmrc.gov.au/publications/_files/e56.pdf
- Australian Government, *Legislation Review*, (December 2005), http://www.lockhartreview.com.au/_files/Legislation%20Review%20Reports%20Full%20Doc-19Dec05.pdf

Descriptive Synopsis

In Australia, the regulation of assisted reproductive technologies (ART), as well as PGD, is complex and not uniform among the different states. For example, PGD is allowed under strict conditions in all Australian states except Western Australia. According to the *South Australian Reproductive Technology Act* (1988), ART is restricted to infertile couples at risk of transmitting a genetic defect to their child. In contrast, the *Western Australia Human Reproductive Technology Act* (1991) makes conducting diagnostic tests on human embryos without prior approval from the Reproductive Technology Council a criminal offence. Additionally, Western Australia requires that all research or tests have a therapeutic intent and be in accordance with current scientific and medical knowledge as to procedures that are least likely to harm the embryo.

Both legislation and ethical guidelines in Australia prohibit sex selection for non-medical reasons. The state of Victoria bans the performance of ART procedures for the purpose of producing (or attempting to produce) a child of a particular sex. It sanctions the practice with fines and up to two years of imprisonment. The ban does not prohibit selecting the sex of an embryo when “it is necessary for the child to be of a particular sex so as to avoid the risk of transmission of a genetic abnormality or a disease to the child.”

The National Health and Medical Research Council (NHMRC) also bans sex selection for non-medical purposes in its report “Ethical guidelines on the use of assisted reproductive technology in clinical practice and research” (2004). It is the council’s opinion that sex

selection should only be allowed to “reduce the risk of transmission of a serious genetic condition.” The guidelines go further and provide specific indications for PGD. For example, the council recommends that PGD not be used to prevent conditions that do not seriously harm the person to be born, or for selection in favor of a genetic defect or disability. Furthermore, PGD must not be used to select for compatible tissue for use by another person, except in the case of siblings (in which case the advice of a clinical ethics committee must be sought).

PND in Australia is not regulated by law but is allowed under professional guidelines established by the NHMRC. Under the guidelines, PND may be performed if it is known that a fetus is at risk of a particular disorder (i.e. cases in which the parents have previously birthed an affected child or both parents are known to be carriers of a recessive disorder) (“Ethical Aspects of Human Genetic Testing: An Information Paper”, 2000). PND may also be performed as a population screening tool offered to all pregnant women to determine if a fetus is at increased risk of spina bifida or Down syndrome (Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2001). In its “Statement on Human Experimentation” (1992), the NHMRC recommends that PND may be carried out in cases where the procedure is consistent with the promotion of life or health of the fetus. The Australian Medical Association in its recommendations on genetic testing for PGD and PND (2000) further requires that the disease affecting the embryo or the fetus be “permanent.”

At the federal level, the Reproductive Technology Accreditation Committee is in charge of licensing and accrediting all centers that perform ART procedures and genetic testing. Research projects including gametes, embryos, and/or fetuses must be approved by an Ethics Licensing Committee.

CANADA

- Society of Obstetricians and Gynaecologists of Canada, *Statement on Gender Selection*, (December 1994).
- Canadian College of Medical Geneticists, Canadian Association of Genetic Counsellors, Canadian Nurses Association, College of Family Physicians of Canada, and Genetic Committee of the Society of Obstetricians and Gynaecologists of Canada, *Practice Guidelines for Health Care Providers involved in Prenatal Screening and Diagnosis*, (August 1998).
- Canadian Fertility and Andrology Society and Society of Obstetricians and Gynaecologists of Canada, *Policy Statement: Ethical Issues in Assisted Reproduction*, (January 1999).
- Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists and Genetics Committee of the Society of Obstetricians and Gynaecologists of Canada, *Canadian Guidelines for Prenatal Diagnosis: Genetic Indications for Prenatal Diagnosis*, (June 2001).
- *Assisted Human Reproduction Act*, (2004), <http://laws.justice.gc.ca/en/A-13.4/index.html>

- Health Canada, Assisted Human Reproduction Implementation Office, *Issues Related to the Regulation of Pre-implantation Genetic Diagnosis under the Assisted Human Reproduction Act*, Consultation Document (2005), http://www.hc-sc.gc.ca/ahc-asc/public-consult/col/pgd-dgp/cons1_e.html

Descriptive Synopsis

In Canada, PGD was not regulated until the enactment of the *Assisted Human Reproduction Act* (AHR Act) in 2004. This Act provides, “No person shall knowingly for the purpose of creating a human being, perform any procedure or provide, prescribe or administer any thing that would ensure or increase the probability that an embryo will be on a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease.” (Art. 5(1)(e)). Sex-selection for non-medical purposes, therefore, is strictly prohibited. Concerning access, Canadian law does not discriminate based on sexual orientation or marital status. Preserving human individuality and diversity as well as the integrity of the genome are also fundamental principles protected by Canadian law.

The AHR Act establishes a broad regulatory and licensing framework for PGD, mandating that the individual licensed to undertake PGD be qualified as specified in regulations still to be developed. The AHR Act, provides the regulations and licensing framework for the use of PGD in Canada. The Assisted Human Reproduction Agency of Canada (AHRAC), created under the AHR Act, is in charge of renewing, amending, suspending or revoking licenses regarding PGD. However, the agency is not yet in operation.

PGD is also permitted under professional guidelines in Canada. The Canadian Fertility and Andrology Society/Society of Obstetricians and Gynaecologists of Canada joint report on assisted reproduction (1999) recommends that sex determination by PGD be only available for medical reasons and that PGD not be used for eugenic purposes. The Prenatal Diagnosis Committee of the Canadian College of Medical Geneticists (CCMG) and the Genetics Committee of the Society of Obstetricians and Gynaecologists of Canada (SOGC) have established guidelines recommending indications for PND which include: increased risk for chromosome abnormalities, neural tube defects, biomedical and molecular indicators, and results of carrier screenings (“*Canadian Guidelines for Prenatal Diagnosis: Genetic Indications for Prenatal Diagnosis*,” 2001). The *Practice Guidelines for Health Care Providers involved in Prenatal Screening and Diagnosis* (1998) also require that women or couples with ethnic backgrounds with an increased risk of certain single gene disorders be provided prenatal screening and diagnosis.

CHINA

- *Law on Maternal and Infant Health Care* (adopted at the Tenth Meeting of the Standing Committee of the Eighth National People’s Congress, October 27, 1994 – effective as of June 1, 1995), http://www.unescap.org/esid/psis/population/database/poplaws/law_china/ch_record006.htm

- Ministry of Health, *Ethical Principles of Human Assisted Reproductive Technologies*, 14:1 Eubios Journal of Asian and International Bioethics 8 (January 2004).
- Ministry of Health, *Regulation on Human Assisted Reproductive Technologies (2001)*, 14:1 Eubios Journal of Asian and International Bioethics 8 (January 2004).

Descriptive Synopsis

China's Law on Maternal and Infant Health Care regulates genetic disease diagnosis and pre-natal diagnosis. Under this law, PND is explicitly permitted but sex identification of the fetus by technical means is forbidden unless it is positively necessary on medical grounds. PND is indicated when the physician detects or suspects an abnormality with the fetus. In addition, all medical and health institutions (and their personnel) carrying out genetic diagnosis and PND must meet requirements and technical standards set out by the administrative department of public health authority. Failure to comply with the law will result in administrative sanctions.

The Ministry of Health, under their regulations and guiding principles on human assisted reproductive technologies, has also banned sex selection for non-medical purposes, as well as the commercial use of gametes, zygotes, and embryos.

FRANCE

- *National Advisory Committee on Bioethics and National College of Gynaecology and Obstetricians Guidelines*, (1997).
- Council of Europe, *Convention on Human Rights and Biomedicine*, (1997).
- *Code de la santé publique (Public Health Code Law no. 2001-588)*, (July 2001).
- Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé (National Consultative Ethics Committee for Health and Life Sciences), *Reflections Concerning the Extension of Preimplantation Genetic Diagnosis, Opinion no. 72*, (2002), <http://www.ccne-ethique.fr/english/start.htm>
- *Loi no 94-654 du 29 juillet 1994 Relative au Don et à l'utilisation des Éléments et Produits du Corps Humain, à l'assistance Médicale à la Procréation et au Diagnostic Prénatal*, <http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SPSX9400032L> revised by the *Loi no. 2004-800 du 6 août 2004 relative à la bioéthique*, <http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=SANX0100053L>
- Comité Consultatif National d'Éthique pour les sciences de la vie et de la santé (National Consultative Ethics Committee for Health and Life Sciences), *Generalised Prenatal Screening for Cystic Fibrosis, Opinion no. 83*, (2004), <http://www.ccne-ethique.fr/english/start.htm>

- Agence de la biomedecine (French Biomedicine Agency),
<http://www.agence-biomedecine.fr/fr/experts/pegh-dpi.asp>,
<http://www.agence-biomedecine.fr/fr/experts/pegh-dpn.asp>

Descriptive Synopsis

Reproductive genetic technologies are regulated under the *Law no. 94-654 governing the donation and use of elements and products of the human body, medically assisted reproduction, and prenatal diagnosis* (1994) which was revised in 2004 by the *Bioethics Law no. 2004-800*. The new Bioethics Law created the French Biomedicine Agency, which is responsible for evaluating the quality and safety of medical research and practices and ensuring compliance with the present legal framework. The agency also has the mandate to license to practitioners and centers involved in reproductive technologies. PGD is permitted in France for the selection of healthy embryos when a parent or other close relative has a serious genetic disease. PGD to provide a tissue match for an ill sibling is also allowed. However, PGD for sex selection is only allowed for medical reasons and prohibited for cultural reasons or for family balancing. PND is permitted under French law, but it should be noted that all assisted reproductive technologies are only accessible to heterosexual couples who are of age to procreate and are married or have lived together for at least two years prior to the reproductive procedure. Violators of the law are sanctioned by imprisonment, fines, or revocation of licenses.

“In its *Opinion no. 83* (2004), the National Consultative Ethics Committee for Health and Life Sciences takes a negative stance on prenatal screening for genetic diseases in general and for cystic fibrosis, in particular. It recommends that generalized prenatal screening for cystic fibrosis should not be encouraged at the present time. However, for carriers or at-risk families, it encourages prenatal screening before marriage or conception.”

France has signed but not ratified the *1997 European Convention on Human Rights and Biomedicine*.

GERMANY

- *Act for the Protection of Embryos - Embryos Protection Act* (Embryonenschutzgesetz - EschG), (December 1990).
- German Medical Association, *Diskussionsentwurf zu einer Richtlinie zur Präimplantationsdiagnostik*, (2000),
<http://www.bundesaerztekammer.de/30/Richtlinien/Richtidx/PraeimpEntwurf/10Diskuss.html> (in German)
- Deutscher Bundestag, *Shlussbericht der Enquete-Kommission, Recht und Ethik der modernen Medizin (Law and Ethics in Modern Medicine)*, (2002), (in German).
- German National Ethics Council (Nationaler Ethikrat), *Genetic Diagnosis Before and During Pregnancy*, (2003),
http://www.ethikrat.org/english/publications/Stn_PID_engl.pdf

Descriptive Synopsis

Germany's *Embryo Protection Act of 1990* defines an embryo as a "fertilized human egg capable of developing from the time of fusion of the nuclei, and each totipotent cell removed from an embryo that is capable of dividing or developing into an individual human being if the necessary conditions prevail." The use of embryos "for any other purpose not serving its preservation" will be punished with imprisonment. Therefore, PGD, which removes totipotent cells, is prohibited by German law because the cells would be utilized in a manner inconsistent with the preservation of the embryo. Sex selection is a criminal offense punishable by imprisonment and fines, unless it is done by a physician in order to prevent Duchenne muscular dystrophy or a similar "severe sex-linked genetic illness, and if the illness threatening the child has been recognized as being similarly severe by the body responsible in accordance with... the legislation."

In 2003 the German National Ethics Council issued a report on PGD, which does not take a stance on whether PGD should be permitted but rather presents the opposing arguments concerning the procedure. The council recommends that the German government adopt a new comprehensive reproductive medicine act regulating PGD and antenatal (prenatal) testing in particular.

With respect to PND, it is part of standard antenatal care, allowed under the *Embryo Protection Act*, to identify potential risks in all pregnant women. In performing PND, the doctor must take into consideration the interests of both the expectant mother and the fetus. However, the detection of a relevant fetal disability (embryopathic indication) does not justify performing PND.

There is ongoing debate in Germany concerning the acceptability of PGD using non-totipotent cells. The German Medical Association presented draft directives in 2000 following a symposium on reproductive medicine, which recommend that PGD be allowed under severely controlled conditions. However, in 2002, the parliamentary commission on "Law and Ethics in Modern Medicine" rejected reversing the prohibition of PGD by a vote of 16 to 3 with arguments in favor of assuring the protection of the embryo.

INDIA

- Indian Council of Medical Research, *Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects*, (2000), <http://icmr.nic.in/ethical.pdf>
- Government of India, Department of Biotechnology, Ministry of Science and Technology, *Ethical Policies on the Human Genome, Genetic Research and Services*, (June 2001), <http://dbtindia.nic.in/publication/publicmain.html>
- *The Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Amendment Act*, (2001, amended 2003).

- Indian Council of Medical Research, *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India*, (2004), http://www.icmr.nic.in/art_clinic/art_clinic.htm

Descriptive Synopsis

In India PGD is prohibited except to detect specific genetic and chromosomal abnormalities or sex-linked genetic disorders. The *Law on Pre-natal Diagnostic Techniques* “provides the prohibition of sex selection, before or after conception,” and aims to prevent “sex determination leading to female foeticide.” Therefore, sex selection for cultural reasons and for family balancing is banned in India.

The Indian Council of Medical Research’s *National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India* prohibits sex selection “at any stage of fertilization, except to avoid the risk of transmission of a genetic abnormality assessed through PGD.” Moreover, the guidelines prohibit ART clinics from providing couples with a child of a desired sex.

India strictly regulates PND. The practice is admissible only in order to detect fetal abnormalities or genetic, metabolic or chromosomal disorders. By law, PND may be conducted only if the pregnant woman meets one of the following conditions: a) is more than thirty-five years of age, b) has two or more spontaneous abortions, c) has been exposed to potentially teratogenic agents, such as drugs, radiation, infection, or chemicals, d) she or her spouse has a family history of mental retardation or physical deformities, such as spasticity or other genetic disease, or, f) any other condition specified by the state supervisory board.

ISRAEL

- *National Health Regulations on IVF*, (1987).
- *Rules as to the Administration of a Sperm Bank and Guidelines for Performing Artificial Insemination*, (1992).
- *National Health Law*, (1994).
- *Surrogacy Agreements Law No. 5756-1996 (IVF)*, (1996).
- *Genetic Information Law No. 5761-2000*, (2000).

Descriptive Synopsis

As in many other industrialized countries, PND in Israel is considered an element of standard medical care. There is no specific legislation on PND in Israel, but it falls under the authority of the director general of the Ministry of Health.

The *National Health Law* delineates prenatal genetic tests to be subsidized by the government. It includes three categories: amniocentesis for women aged 35 years or older at the beginning of the pregnancy (as part of the program for the prenatal detection of Down syndrome), carrier genetic screening for Tay-Sachs, and Thalassemia for high-risk groups.

Israel has one of the most liberal legislative frameworks on *in vitro* fertilization and several of its legislative provisions relate, directly or indirectly, to PGD. PGD is a legal procedure and is considered more acceptable than abortion. The *National Health Regulations on IVF* establish that an “ovum may only be removed for the purpose of fertilization and implantation after fertilization.” The director general of the Ministry of Health has the authority to license and oversee hospitals and clinics that have been authorized to carry out IVF and genetic testing. The *Genetic Information Law* determines the conditions for licensing genetic testing laboratories and establishes penalties for its violation (ranging from imprisonment to the imposition of fines).

The Ministry of Health established a Helsinki Committee for Genetics to examine case-by-case and approve or reject applications for genetic research projects involving human beings, including research on pre-implantation embryos.

In 2005, the National Bioethics Council of Israel reviewed recommendations on the use of PGD for sex selection issued by the Ministry of Health (which in turn were based on recommendations issued by the Bioethics Committee of the Israel National Academy of Sciences and Humanities and the National (Helsinki) Committee on Medical Experimentation in Human Beings). Under these regulations, sex selection is permissible in principle only for medical purposes, but in some very exceptional circumstances sex selection may be approved for social reasons or “family balancing” (BMJ 2205;330:1228). The possibility of a serious and real threat to the mental health of one of the parents is considered to be a “medical purpose” in exceptional cases, subject to approval by a national board established by the Ministry of Health.

JAPAN

- Japan Society of Human Genetics, *Guidelines for Genetic Counseling and Prenatal Diagnosis*, 6:5 Eubios Journal of Asian and International Bioethics, 138 (September 1996).
- Japan Society of Human Genetics, *Guidelines for Genetic Testing, Using DNA Analysis*, 6 Eubios Journal of Asian and International Bioethics, 137 (September 1996).
- Japan Society of Obstetrics & Gynecology, *Guidelines on Preimplantation Genetic Diagnosis*, (October 1998), <http://www2.unescobkk.org/eubios/EJ115/ej115d.htm>
- Council for Science and Technology, Bioethics Committee, *Fundamental Principles of Research on the Human Genome*, (June 2000).
- Japan Society of Human Genetics, *Guidelines for Genetic Testing*, 46: 3 J. Hum.Genet., 163 (2001),

<http://www.springerlink.com/media/pfluvlvkkgm6xrrvbfk/contributions/e/x/w/5/exw55kqt6v07jyq9.pdf>

- Japan Society of Human Genetics, Japan Society of Obstetrics and Gynecology, Japan Society for Pediatric Genetics, Japanese Society for Familial Tumor, Japanese Society for Gene Diagnosis and Therapy, Japanese Society for Genetic Counselling, Japanese Society for Inherited Metabolic Diseases, Japanese Society of Laboratory Medicine, Japanese Society for Mass-screening, and Japanese Teratology Society, *Guidelines for Genetic Testing*, (August 2003, English version October 2004), http://jshg.jp/e/index_e.htm

Descriptive Synopsis

PGD and PND in Japan are not regulated by law but are governed by professional guidelines. In 2003, ten genetic-medicine-related societies published a comprehensive guideline to incorporate and expand on previously established guidelines. The “*Guidelines for Genetic Testing*” (2003) cover the particular conditions for PND but do not mention PGD specifically. For example, the guidelines specify that the prediction that the fetus will contract a “severe disorder” is a criterion for “invasive prenatal test and diagnosis.” As well, the gender of the fetus should not be disclosed except for prenatal diagnosis for severe X-linked disorders.

The Japan Society of Human Genetics (JSHG) has adopted their own “Guidelines for Genetic Testing,” (2001) which provide minimum standards for the permissibility of both PGD and PND. For example, under the guidelines, PGD should be considered when: either parent is a carrier of chromosomal abnormality, a carrier of severe autosomal dominant disease, both parents are carriers of severe autosomal recessive disease, the mother is a carrier of a severe sex-linked disease, and in addition, does not want an abortion. PGD in Japan is conducted as “clinical research” and approval is required on a case-by-case basis by the Japanese Society of Obstetrics and Gynecology (“Guidelines on preimplantation genetic diagnosis” (1998)). The guidelines adopted by the JSHG also specify that sex determination of the fetus, as well as sex selection, is prohibited “except when testing for an X-linked hereditary disease.” The JSHG further recommends that if a client requests genetic testing, the doctor has full discretion to refuse if the request is against social or ethical norms or against the doctor’s personal principles.

MEXICO

- *General Health Law of 7 February 1984* (amended June 2006), <http://info4.juridicas.unam.mx/ijure/tcfed/159.htm?s=> (in Spanish)
- *Regulation of the General Health Law on Scientific Research* (January 1987), http://www.respyn.uanl.mx/iv/3/contexto/reglamento_investigacion.htm (in Spanish)

Descriptive Synopsis

Mexican legislation does not explicitly regulate PGD or PND. The *General Health Law* and the *Regulation on Scientific Research* establish that it is only permissible to conduct assisted

reproduction in order to solve infertility problems which cannot be solved otherwise, and that the moral, cultural, and social perspectives of the couple must be respected, even when their perspective differs from the investigator's. The regulation also mandates that research on embryos and fetuses can only be conducted for the benefit of the embryo, the fetus or the pregnant mother, respectively, and only when their "security/integrity is guaranteed" (Art. 56).

PND is a regular procedure in Mexico, while PGD is only conducted in few private institutions (and only since 2004). The regulation of PGD has been subject to ample parliamentary debate, and several bills have been introduced. Most of the draft bills call for restricting use of the procedure to serious conditions and for prohibiting PGD sex selection for non-medical purposes.

THE NETHERLANDS

- Council of Europe, *Convention on Human Rights and Biomedicine*, (1997), <http://www.oup.co.uk/pdf/bt/cassese/cases/part3/ch16/1121.pdf>
- Health Council of the Netherlands, *IVF-Related Research*, (1998), <http://www.gr.nl/pdf.php?ID=617&p=1>
- *Law of 1998, Containing Regulations with Regard to Medical-Scientific Research on Humans*, (1998).
- *Law on Special Medical Procedures 1999*, (last amended by the Law of 5 July 2000).
- *Act Containing Rules Relating to the Use of Gametes and Embryos (Embryos Act)*, (October 2001).
- Health Council of the Netherlands, *Prenatal Screening: Down's Syndrome, Neural Tube Defects, Routine Ultrasonography*, (May 2001), <http://www.gr.nl/adviezen.php?ID=447>
- Health Council of the Netherlands, *Pre-implantation genetic diagnosis*, The Hague, (2006), <http://www.healthcouncil.nl/adviezen.php?ID=1333>

Descriptive Synopsis

PGD in the Netherlands is offered within the framework of medical research, according to the Health Council of the Netherlands ("IVF-related research", 1998), and is strictly regulated by law under the *Embryos Act* (2001). Under the *Embryos Act*, PGD is only permitted for the diagnosis of severe and untreatable genetic conditions if it "can reasonably be assumed that the research will lead to new insights with regard to research or therapeutic methods that are aimed at inducing pregnancy and the birth of a healthy child."

Sex selection is prohibited unless, according to "scientifically sound opinion," the child is at risk of having a serious sex-linked disease. All research must be approved by the Central

Committee for Research, which determines whether the criteria for PGD have been observed. The *Embryos Act* sanctions any violations of the Act with imprisonment and fines.

There is no specific legislation regarding PND in the Netherlands except for the *Law on Special Medical Procedures* (1999), which regulates clinical genetic services, including PND. Prenatal diagnosis can only be provided by centers approved by the Ministry of Health.

In the latest report published by the Health Council of the Netherlands, “Pre-implantation genetic diagnosis” (2006), the council proposes broadening the indications for PGD under strict conditions. The council finds PGD acceptable for serious disorders where no (or only very invasive) treatment is available. However, it advises that the regular use of preimplantation genetic screening should be discouraged.

Under the 1997 *Council of Europe Convention on Human Rights and Biomedicine*, which the Netherlands has signed but not ratified, genetic testing may be done only for medical purposes or for scientific research linked to health purposes, and only with appropriate genetic counseling. Sex selection is prohibited except to prevent hereditary sex-related diseases.

SOUTH AFRICA

- Department of Health, Sub-Directorate of Human Genetics, *Human Genetics Policy Guidelines for the Management and Prevention of Genetic Disorders, Birth Defects and Disabilities*, (2003), <http://www.capegateway.gov.za/Text/2003/humangenetics.pdf>
- Department of Health, Sub-Directorate of Human Genetics, *Diagnostic Genetic Tests - South Africa*, (2004), http://www.doh.gov.za/docs/2004/diagnostic_gene_tests/index.html
- Medical Research Council of South Africa, *Guidelines on Ethics for Medical Research (General Principles/Reproductive Biology and Genetic Research – books 1 & 2)*, (2002 and 2005), <http://www.sahealthinfo.org/ethics/index.htm>

Descriptive Synopsis

South Africa does not regulate PGD explicitly by legislation or professional guidelines. However, the Medical Research Council of South Africa states that the use of recombinant technology in selecting fetal sex is unethical if done for non-medical purposes. It is the council’s opinion that gender testing may be beneficial in connection with sex-linked diseases and therapeutic abortion, but should be subject to the general guidelines and laws in South Africa. The council makes a broad statement on embryo research, requiring that all tests that determine non-sex-linked genetic diseases should be subject to the same general ethical guidelines. Genetic counseling should be provided to all research participants, and obtaining informed consent is crucial in the context of health research.

The Department of Health’s Genetic Policy Guidelines (2003) recommend that PND be available for women of reproductive age and individuals and families at high risk for genetic disorders or birth defects. As stated in the guidelines, PND should “be performed only for

reasons relevant to the health of the fetus and only to detect genetic conditions or fetal malformations.”

The “Diagnostic Genetic Tests – South Africa” document published by the Department of Health provides a detailed list (as of 2004) of laboratories in South Africa and genetic tests conducted there.

SOUTH KOREA

- *Bioethics and Biosafety Act*, (2005), <http://www.koreabioethics.net/5-2/7.doc>

Descriptive Synopsis

The *Bioethics and Biosafety Act* regulates biotechnologies in general with no specific mention of PGD or PND. However, under the Act, tests on embryos or fetuses can only be performed to diagnose muscular dystrophy or other DNA-related diseases as stipulated by the president of South Korea. The Act also bans sex selection and prohibits obtaining personal benefit (monetary or non-monetary) in exchange for sperm or oocytes. Any medical institution wishing to conduct artificial fertilization, perform DNA testing, or generate embryos through fertilization must obtain prior authorization from the minister of health and welfare. Embryos may be stored for up to five years, following which they may be used for research aimed at developing contraception and infertility treatments, or research aimed at curing rare or incurable diseases, as decreed by the president. Violators of the Act are subject to imprisonment or fines.

SINGAPORE

- *Human Cloning and Other Prohibited Practices Act*, (2004), <http://www.moh.gov.sg/corp/systems/acts/GG.pdf>
- Bioethics Advisory Committee of Singapore, *Genetic Testing and Genetic Research*, (2005), <http://www.bioethics-singapore.org/resources/pdf/GTGR%20Report.pdf>
- Ministry of Health, Licensing & Accreditation Branch, *Directives for Private Healthcare Institutions Providing Assisted Reproduction Services: Regulation 4 of the Private Hospitals and Medical Clinics Regulations* (CAP 248, Reg 1), (March 2006), https://www.moh-ela.gov.sg/ela/docroot/html/assisted_reproduction_services_directives.pdf

Descriptive Synopsis

The report on genetic testing issued by the Bioethics Advisory Committee (BAC) states that PGD is a valuable option for couples since it allows the detection of certain genetic diseases.

However, the process remains ethically debatable because of concerns that PGD can, in principle, be used to select favorable traits, rather than to exclude of genetic diseases. The BAC recommends that PGD be permitted, but subject to licensing and monitoring by a relevant authority (i.e., a research ethics committee or institutional review board) and should be limited to the prevention of serious genetic disorders. PGD for non-medical sex selection should be prohibited. In addition, any research involving human embryos for reproductive purposes should require prior approval from the Ministry of Health.

The BAC further recommends that PND be limited to the detection of serious medical disorders and not allowed for non-medical purposes.

The BAC guidelines reflect the views expressed in the Ministry of Health's directive concerning assisted reproductive services. The Ministry of Health prohibits ART for non-medical purposes and adds that these reproductive procedures should only be carried out on married couples. Sperm-sorting techniques for sex selection is explicitly prohibited. Furthermore, before providing PGD or any other new services, all assisted reproductive centers must obtain approval from the Ministry of Health.

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Descriptive Synopsis

The *Federal Constitution of the Swiss Confederation* and the *Federal Law on Medically Assisted Reproduction* prohibit PGD. The federal law states, “the removal of one or several cells in embryo in vitro and their analysis are prohibited.” Additionally, the legislation proscribes that “medically assisted procreation methods [are not] authorized for the development of certain qualities in the child or for research.”

The 1997 *European Convention on Human Rights and Biomedicine*, which Switzerland has signed but not yet ratified, expressly prohibits sex selection “except where serious hereditary sex-related disease is to be avoided” (Article 14). Under the convention, “tests which are predictive of genetic disease or which serve either to identify the subject as a carrier of a gene

responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purpose, and subject to appropriate genetic counselling” (Article 12).

Switzerland’s laws also prohibit sex selection of embryos and fetuses for non-medical traits. The *Federal Law on Medically Assisted Reproduction* proscribes the use of medically assisted procreation procedures to “influence (or select) the sex or any other characteristic of the (future) child, except when the risk of transmission of a serious and incurable disease to the descendants cannot be isolated in any other way.” Moreover, the Swiss Academy for Medical Sciences has drafted guidelines for genetic testing. Sex selection is considered “inappropriate if [the] aim is merely to determine the sex of the embryo or fetus or other factors that do not constitute a threat to health.”

Switzerland allows PND under strict conditions set forward by the *Federal Constitution* and the *Federal Law on Medically Assisted Reproduction*. Medically assisted procreation methods are authorized only in the case of sterility or “the danger of transmission of a serious disease cannot be averted and any other prenatal investigations are to be undertaken only if there is a well founded fear of a genetic risk. The diagnosis has to be based on a specific medical question, and the answer will be limited to this question.”

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Descriptive Synopsis

The regulation of reproductive technologies in the United Kingdom falls under the *Human Fertilization and Embryology Act* (HFE Act) (1990), which covers, among other techniques, *in vitro* fertilization and donor insemination, but does not address PGD or PND specifically. Under the HFE Act, consent from egg donors is required for the creation of embryos and for any purpose for which oocytes might be used. Under U.K. laws, access to reproductive genetic testing is available to couples (heterosexual or homosexual) as well as to single women. Any infringements of the HFE Act constitute a criminal act resulting in imprisonment, the imposition of fines, or the revocation of licenses.

Regarding PGD and PND, the U.K. has adopted a mixed public-private approach that implicitly permits the two procedures. The HFE Act created the HFE Authority (HFEA), a national regulatory agency with the power to issue licenses and monitor clinics that carry out reproductive genetic testing. Under its *Code of Practice* (2003), all research projects must seek approval from a “properly constituted ethics committee” before applying to the HFEA for a license. The HFEA *Code of Practice* also sets out minimum standards for centers performing genetic testing and requires that they limit their determination of carrier status to inherited recessive disorders.

The HFEA explicitly prohibits sex selection of embryos for social or cultural reasons as well as the use of sperm-sorting techniques for sex selection. In 2003 the HFEA published recommendations proposing that current legislation permitting sex selection to avoid sex-linked disorders should continue. It further recommended that gender selection through sperm sorting should be regulated in the U.K.

According to the *Consultation Document of PGD* (2000) of the HFEA and the Advisory Committee on Genetic Testing (ACGT), PGD is not acceptable for testing “social or psychological characteristics, normal physical variations, or any other conditions which are not associated with disability or a serious medical condition.” PGD should, however, be accessible to individuals who have a known family history of serious genetic disorders. Neither the HFEA nor the ACGT have adopted a list enumerating which conditions constitute “serious genetic disorders,” leaving clinical teams and patients to decide. Concerning fetal abnormalities, centers applying the Royal College of Obstetricians and Gynaecologists (RCOG)’s criteria for termination of pregnancy limit the use of PND to cases where there is precise diagnosis and “substantial risk” of “serious handicap.”

The Department of Health enacted the “Guiding Principles for Commissioners of NHS” which state the reasons for requesting PGD, including “patients with chromosomal disorders” and “couples at risk of transmitting serious genetic disorders to their offspring.” The principles recommend that priority be on cases where the risk of the offspring being affected by a disorder is greater than 10 percent.

The use of PGD to diagnose of late-onset disorders is permitted but should only be done after full genetic counseling, according to the ACGT and the Human Genetics Commission (HGC) (“Report on Genetic Testing for Late Onset Disorders,” 1998). The HGC also recently released recommendations encouraging additional research in order to make PGD safer and more effective while promoting long-term follow-up of children born after HLA matching (“Making Babies: Reproductive Decisions and Genetic Technologies,” 2006).

The House of Commons Science and Technology Committee on the HFEA Act recently released a controversial report (“House Report,” 2005) suggesting moving away from the current regulatory model. Recommendations included reducing state intervention in reproductive testing and changing legislation to allow sex selection for non-medical reasons.

In 2004 the HFEA conducted a review of its policy on pre-implantation tissue typing, concluding that PGD tissue typing should continue to be available, subject to appropriate safeguards and approval on a case-by-case basis in circumstances where there is a need for potentially life-saving tissue of therapeutic benefit for an affected child.

Finally, the aforementioned HGC in its 2006 report “Making Babies: Reproductive Decisions and Genetic Technologies” issued a series of recommendations for the improvement of the practice of PND and PGD in the U.K. The HGC recommends that efforts be made to develop screening techniques that do not reveal carrier status (unless it would compromise the reliability of the test or unless the information about the status is clinically important to the child’s health). The HGC also recommends that the HFEA Act be amended to permit more satisfactory and systematic follow-up of all children born following PGD, especially those children born after HLA matching, and that the Medical Research Council should support appropriate research.

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Descriptive Synopsis

In the United States, there is no uniform or comprehensive system for the regulation of assisted reproductive technologies, including reproductive genetic testing. The federal government does not have direct jurisdiction over the practice of medicine. Moreover, it has banned all federal funding for research involving the creation or destruction of embryos. Consequently, the regulatory framework for reproductive genetic testing in the United States is characterized by a patchwork of federal and state regulation. Professional self-regulation also plays a central role in the governance of this field. Federal oversight of these technologies is spread among several agencies, whose jurisdiction in the area of assisted reproductive technologies and genetic testing is derived from existing statutes having broader applicability.

Clinical Laboratory Improvement Amendments of 1988 (CLIA): All laboratory tests performed for the purpose of providing health information to an individual must be conducted in laboratories certified under CLIA. CLIA requires the government to certify all laboratories performing testing to provide “information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” Tests are regulated according to their level of complexity: waived, moderate, or high complexity. The regulatory requirements applied to these laboratories increase in stringency with the complexity of the test performed. Under CLIA, the Health Care Financing Administration’s (HCFA) Division of Laboratory Systems develops standards for laboratory certification. However, CLIA has no specific jurisdiction to regulate such aspects of genetic tests as clinical validity and utility, informed consent, or the provision of genetic counseling. Moreover, the Centers for Medicare and Medicaid Services (CMS), which administers CLIA, has taken the position that laboratories that perform PGD are not considered “clinical laboratories” under CLIA.

Food and Drug Administration (FDA): Under the Federal Food, Drug and Cosmetic Act, in vitro diagnostic products, i.e., products used to diagnose a disease or condition, are regulated as medical devices by FDA. However, not all products used by clinical laboratories to perform genetics testing are regulated as in vitro diagnostic products. In fact, FDA has limited oversight over the majority of tests used in PGD because many genetic laboratories develop their own tests, and these “home brews” are not generally under FDA’s purview. Furthermore, FDA does not have the authority to regulate the practice of medicine, leaving significant discretion to physicians as to how to use FDA-regulated products. FDA also has authority to regulate certain aspects of human tissue, but it is unclear whether and to what extent tissues used in PGD could be under FDA jurisdiction, and thus subject to pre-market review.

Centers for Disease Control and Prevention (CDC): The 1992 *Fertility Clinic Success Rate and Certification Act* (FCSRCA) requires that the Secretary of Health and Human Services (HHS), through the CDC, develop national reporting guidelines for ART. The Act also requires the Secretary to develop a model program for the certification of embryo laboratories to be carried out voluntarily by interested states. Under the Act, all clinics providing IVF services are required to report pregnancy success rates annually to the federal government. The CDC is in charge of analyzing the data and making it available to the public. However, the Act does not require clinics to report the use or outcome of PGD.

Office for Protection from Research Risks (OPRR): An additional level of oversight is provided during the research phase of genetic testing, but only when the research involves

human subjects or identifiable samples of DNA. Regulations governing the protection of human research subjects are administered by the OPRR and FDA. OPRR oversees the protection of human subjects in all research funded by HHS, while FDA oversees the protection of human research subjects in trials of investigational devices, drugs, or biologics being developed for eventual commercial use.

As mentioned above, regulation of the practice of medicine involving PND and PGD falls to state laws or professional guidelines. To date, no state has adopted laws directly addressing PGD and PND, leaving researchers and clinicians to voluntarily abide by guidelines established by professional organizations.

In addition, several advisory bodies have reviewed the oversight of reproductive genetic testing in the United States and have made recommendations for improvement (Genetics and Public Policy Center, 2004 and President's Council on Bioethics, 2004).

The American Society for Reproductive Medicine (ASRM) has provided oversight of PGD through various opinion statements. The ASRM believes that "PGD should be regarded as an established technique with specific and expanding applications for standard clinical practice." ASRM also states that, while the use of PGD for the purpose of preventing sex-linked diseases is ethical, the use of PGD solely for sex selection is "discouraged."

In turn, the American College of Obstetricians and Gynecologists has adopted best practice guidelines and opinions on the regulation and clinical practice of PND.