GENETIC TESTING AND COUNSELLING

EUROPEAN GUIDANCE

EUROPEAN ETHICAL - LEGAL PAPERS N°3
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Within the Centre for Biomedical Ethics and Law of the Catholic University of Leuven - one of the leading bioethical and legal research centres in Europe - we are involved as coordinator, partner or participant in different European research projects. Biomedical ethics and law are rapidly evolving disciplines. Although there exists already a great number of specialized peer reviewed journals and series of books in both disciplines we felt a growing need for a medium through which the results of our research can directly be presented to the research community and the interested community at large. To meet this need we decided to start the *European Ethical-Legal Papers*. Such papers will also contribute to the transparency we owe to society that finances our research efforts. We also hope that it will contribute to the discussion and the exchange of information and ideas among researchers in Europe and elsewhere.

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I. INTRODUCTION

Research into the identification of genes and their mutations correlating with diseases or inherited disorders has resulted in the availability of genetic tests. This has led to intense debates about the potential psychological, social, legal and ethical consequences of genetic testing and the question of an appropriate framework of regulation, information, guidance and education to guarantee a careful and beneficial application of this promising technology.

The Independent Expert Group, who developed 25 recommendations on the ethical, legal and social implications of genetic testing, stressed in its fourth recommendation of the report *Ethical, legal and social aspects of genetic testing: research, development and clinical applications* that (4a) “materials and resources should be developed and made available at the EU, national and local level to provide information about genetic testing, genetic screening, and pharmacogenetics” and that (4d) “concerted efforts to promote dialogue, education, information and debate should be encouraged.”

The ethical workpackage of the Eurogentest project took as one of its objectives to answer this need of information and education about the ethical and legal aspects of genetic testing and genetic counselling. This European Ethical – Legal Paper 3 provides an overview of existing guidance about ethical issues in genetic testing and counselling. It is mainly constituted of policy statements, guidelines, position papers, recommendations or reports that have been issued by professional associations and societies (for example genetic societies; medical and paediatric associations), national bioethics committees, national institutes of health, European associations, and NGOs.

Documents were only selected for this publication if they were (at least partly) dealing with ethical issues regarding genetic testing, genetic screening and genetic counselling. In particular, documents were included if, for example, they were discussing and providing recommendations on issues as confidentiality or informed consent in genetic counselling, genetic testing of minors; prenatal diagnosis;
preimplantation genetic diagnosis; sex selection; paternity testing; genetic testing and insurance; genetic testing and employment. Documents providing recommendations regarding DNA banking, patents, therapeutic and reproductive cloning, stem cell research or pharmacogenetics were not considered for inclusion. In addition, only documents that were published since 1990 have been included.

Only documents coming from European countries (the 27 E.U. members states and members of the European Economic Area (Norway, Iceland, Liechtenstein and Switzerland), European associations and international organisations, have been integrated in this booklet. After a short presentation of the guideline provider, we present shortly the content of each document, and the original name if the document has been elaborated in another language than English, together with information about the availability if it is not or only partly available online. Documents that have been issued by public bodies receive the symbol ☐️, private bodies the symbol ☐️. For every country, we presented first the public bodies, followed by the private bodies.

We hope that this European Ethical – Legal Paper will provide a useful guide to all health care providers and the general public, as it would contain the major documents tackling the ethical dilemmas and conflicts that arise in the context of the patient-physician relation in the framework of a genetic test. Although we have tried to include as many relevant position papers, statements, opinions, guidelines, reports and recommendations as possible, a language bias and a selection bias might have led to the absence of some useful and relevant documents. Therefore we welcome all reactions on www.cbmer.be


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II. AUSTRIA

§ 1. Austrian Bioethics Commission

By an order issued by Federal Chancellor Schüssel on 29 June 2001, a Bioethics Commission was established at the Federal Chancellery. The constituent meeting was held on 2 July 2001. The task of the Bioethics Commission is to advise the Federal Chancellor from an ethical point of view on all social, natural scientific and legal issues arising from the scientific developments in human medicine and human biology. This includes in particular the submission of recommendations for practical use and suggestions for enacting the necessary legal provisions as well as the preparation of expert opinions on specific issues. The Commission exercises its advisory function independently.

http://www.bundeskanzleramt.at


Abstract: This report of the Bioethics Commission on preimplantation genetic diagnosis (PGD) basically consists of three parts. In Part I the arguments brought forward in the current national and international discussion are presented in a descriptive way. Besides the scientific-medical aspects of PGD, the report summarizes thoughts on ethical and legal admissibility of this method as well as on possible options for legal policy. The subsequent parts of this report contain on the one hand the opinion in favour of a restricted approval of PGD (Part II) and on the other hand the opinion in favour of maintaining the present legislation unchanged (Part III). The essential arguments as well as the subsequent recommendations for each one of these different opinions are presented.

Original name: Präimplantationsdiagnostik
§ 1. National Consultative Committee for Bioethics (NCCB)

Established in 1993, the NCCB examines issues raised by new developments in research and developments in biology, medicine and health care. It provides an analysis regarding the ethical, social and legal aspects of these developments, in particular regarding the preservation of human dignity and patient rights.

http://www.health.fgov.be/bioeth

A. Recommendation on predictive genetic tests and HIV-tests in occupational health (2002, no. 20)

**Abstract:** After a presentation of the principles and organization of the occupational health in Belgium and the medical state of the art regarding predictive genetic tests and HIV-testing, this document offers an analysis of the legal context in Belgium. In its ethical analysis two positions are described. At the end of the document some policy recommendations are offered.

**Original name:** Advies nr. 20 van 18 november 2002 betreffende predictieve genetische tests en HIV-tests in het kader van arbeidsverhoudingen. The document is only available in French or Dutch.

B. Recommendation regarding sex selection for non-medical reasons (2003, no. 22)

**Abstract:** This document offers an overview of five different positions regarding sex-selection for non-medical reasons. The first position is a disapproval of sex selection for non-medical reasons based on philosophical arguments and on other fundamental concerns.
such as the instrumentalisation of a child, unacceptable parental autonomy, the illusion of a perfect child, the illusion of a perfect family, pressure on the woman and the problems related to the technology. The second position is a disapproval of sex selection for non-medical reasons based on the features of conception, the familial and social context, precaution and the universality criterion. The third position accepts sex-selection for non-medical reasons if this is based on a concept of family balancing. The fourth position argues for a prudential position. Position five defends a complete parental autonomy.

**Original name:** Advies nr. 22 van 19 mei 2003 betreffende geslachtskeuze om niet-medische redenen. The document is only available in French or Dutch.

C. Recommendation regarding the conservation of blood cards and the confidential character of information for the detection of inherited metabolic disorders (2003, no. 25)

**Abstract:** This document deals with the conservation of blood cards and the confidential character of information for the detection of inherited metabolic disorders. It offers scientific information, an analysis of the ethical questions, and specific conclusions.

**Original name:** Advies nr. 25 van 17 november 2003 betreffende de bewaartijd van de bloedkaartjes en het vertrouwelijke karakter van de gegevens voor het opsporen van aangeboren metabolische afwijkingen. The document is only available in French or Dutch.

D. Recommendation on the free availability of genetic tests (2004, no. 32)

**Abstract:** This document discusses the issue of free availability of genetic tests. It defines this type of direct testing and describes the current practice of genetic testing in Belgium. It describes also the legal framework and current practice regarding direct testing. In its ethical analysis the document discusses the protection of the person and his family (in relation to the interpretation of the results, confidentiality, reliability of the test, conservation and further use of
personal information) and the protection of the public. The document concludes with a series of common recommendations from the whole commission and two divergent positions.

**Original name:** Advies nr. 32 van 5 juli 2004 betreffende de vrije beschikbaarheid van genetische tests. The document is only available in French or Dutch.

§ 2. **Belgian Society of Human Genetics (BeSHG)**

The Belgian Society of Human Genetics (BeSHG) was launched in March 2000. The aim of the Society is to allow all scientists involved in the field of human genetics, working in all Belgian universities, and all independent research institutes or genetic centers in Belgium to have an official representative Society in Belgium. The BeSHG is aimed at promoting Human Genetics in its wider sense, among others by supporting genetic research, improving exchanges between Belgium and foreign countries, organising scientific meetings, and enhancing collaboration between Belgian labs. The BeSHG will represent the community of Belgian geneticists towards the other national and international Societies of Genetics, and is intended to become a discussion forum on scientific, professional, social and ethical issues linked to the practice of human genetics.

[http://www.beshg.be](http://www.beshg.be)

A. **Guidelines for predictive genetic testing for late onset disorders (2003)**

**Abstract:** These guidelines for good practice apply to predictive genetic testing of adults who are at risk of developing a specific and serious hereditary late onset disease and who are capable of making an informed choice. Susceptibility testing for multifactorial late onset disorders is not considered in this document. The guidelines do not apply to community screening for genetic disorders (that is, screening people who do not have a significant family history). Following elements are discussed in these guidelines: differences between genetic tests and other tests in medical practice; scientific and clinical
validity of the predictive genetic test; genetic laboratories; “over the counter” predictive genetic testing; principle of autonomy; information needed by those requesting predictive genetic testing; support in relation to predictive genetic testing; psychological counselling in the context of predictive genetic testing; necessity of protocols; prenatal and preimplantation genetic testing for late onset disorders; predictive testing in children and adolescents; definitions.
§ 1. Danish Council of Ethics

The Danish Council of Ethics is established in 1988 with as main objective to provide the Danish Parliament, official authorities and the public with ongoing advice and information about ethical problems raised by developments within the National Health Service and the field of biomedicine.

A. Fetal diagnosis and ethics (1990)

**Abstract:** This report deals with diagnostic techniques employed prior to birth. After an introduction, it provides in Chapter 2 a technical outline with an overview of the fetal diagnostic methods in use. Chapter 3 provides an overview of the scope and content of counselling. Chapter 4 contains a brief outline of the conclusions in a selection of reports on fetal diagnosis. Chapter 5 provides overriding ethical considerations on fetal diagnosis. In the last Chapter the Council provides in five sections its own position: fetal diagnosis and induced abortion; fetal diagnosis and the attitude towards suffering; access to fetal diagnosis; counselling in connection with fetal diagnosis; fetal diagnosis viewed in a broader perspective.

**Original name:** Fosterdiagnostik og etik

B. Ethics and mapping of the human genome. Protection of sensitive personal information; Genetic screening; Genetic testing in appointments. (1993)

**Abstract:** This book contains three documents. In the first report, the Danish Council of Ethics clarifies the consideration of an ethical and
legal nature which should be made in the disclosure, registration, storage and dissemination of sensitive personal information for medical treatment and research. It forms part of an analysis of the ethical and legal consequences of mapping the human genome. The second document has as purpose to shed light on genetic screening and the problems associated with it. A brief presentation of the general nature of screening is followed by a discussion of the ethical problems linked with screening and possible approaches that can be adopted. In the third document, the Danish Council of Ethics presents its comments on the Minister of Labour’s bill to prohibit the use of genetic tests in appointments and in underwriting pensions and insurance.

C. Debate outline on fetal diagnostics (1998)

Abstract: The purpose of the debate outline is to focus on the ethical problems associated with the use and development of fetal diagnostics. The document offers a status report on developments in fetal diagnostics, an overview of the Council’s deliberations and views, a discussion on the issue whether fetal diagnostics should be offered to everyone or to risk groups, the issue of information and counselling and recommendations from the Danish Council of Ethics.

Original name: Debatoplæg om fosterdiagnostik.


Abstract: The purpose of the report is to focus on the ethical issues linked with the use of presymptomatic genetic testing. The main topics that are discussed are the right to know and the right not to know about one’s genetic status, presymptomatic genetic testing of minors, social and psychological effects of presymptomatic genetic testing, priority-setting and genetic counselling in connection with presymptomatic genetic testing.
Original name: Génundersøgelse af raske - Redegørelse om præsymptomatisk géndiagnostik.


Abstract: In this report, the Danish Council of Ethics focuses on the ethical problems connected with screening. After an introduction, it describes screening and discusses the status and examples of screening programmes. It considers also the social and psychological effects of screening programmes. Before offering recommendations, the Danish Council of Ethics has collected its deliberations and discussion into four main topics. The first topic deals with the risk of pathologization and anxietization versus the hope of being cured of disease. The second topic discusses how to relate to the fact that some of the participants in a screening programme will be given false results. The third topic is about the degree the health service should deploy resources on the ill or the possible ill. The last topic is about the way an unsolicited approach from the health authorities is perceived and how much information should be given at the time of the approach.

Original name: Screening - En redegørelse

F. Microinsemination and pre-implantation genetic diagnosis (2003)

Abstract: In the report the Danish Council of Ethics takes a stance on a number of problem issues relating to the use of microinsemination and pre-implantation genetic diagnosis (PGD). For example, whether or not it is ethically acceptable to use PGD for the purpose of preventing a child with a severe and possibly hereditary disorder from entering the world. Or whether or not it is acceptable to use PGD to examine embryos for histocompatibility purely with a view to making it possible to donate to a sick sister or brother

Original name: Etiske problemer vedrørende kunstig befrugtning. Mikroinsemination og præimplantationsdiagnostik
§ 1. National Consultative Ethics Committee for Health and Life Sciences (CCNE)

The CCNE was established by a decree signed by the President of the French Republic on 23rd February 1983, and was enacted in the law of 29th July 1994. Now, according to the law of 6th August 2004, the Committee's mission is to give opinions on ethical problems and societal issues raised by progress in the fields of biology, medicine, and health. The CCNE is a purely consultative body, and it may be tasked by Presidents of Parliamentary Assemblies, members of the Government, an establishment for higher education, a public institution, or an officially recognized foundation whose main activity is research, technological development, or the promotion and protection of health.


A. Opinion on embryo research aiming to achieve pre-transfer genetic diagnosis for which a moratorium was declared in 1986 (1990, no. 19)

Abstract: After time for reflection provided by the moratorium, and taking into account scientific knowledge acquired in recent years, which has made it possible to gain a better understanding of the problems involved, the CCNE reached the following conclusions: 1. Medical indications for a pre-transfer genetic diagnosis are exceptional for infertile couples who could benefit from in vitro fertilization; 2. Couples at high risk of conceiving a child affected by a severe genetic disease can benefit from existing widely used prenatal diagnosis methods which have already proved reliable; 3. Pre-transfer genetic diagnosis would lead to misuse of indications for medically assisted reproduction and subjecting fertile couples to the constraints and hazards of these methods. Research on embryos to be re-implanted may lead to serious impairment of the human genetic
heritage. As a consequence, the CCNE reiterates the ethical considerations in its previous Opinion and recommends that pre-transfer genetic diagnosis should not be undertaken.

**Original name:** Avis sur les recherches sur l'embryon soumises à moratoire depuis 1986 et qui visent à permettre la réalisation d'un diagnostic génétique avant transplantation.

B. Opinion regarding the application of genetic testing to individual studies, family studies and population studies. (Problems Related to DNA “Banks”, Cell “Banks” and Computerization) (1991, no. 25)

**Abstract:** With progress in human genetics it has become possible to investigate individual genetic information using a single DNA sample. This opinion deals with ethical rules at the individual level; family studies; quality of information and training of medical personnel; registers, DNA Banks, computerization. Furthermore, it discusses various applications (Diseases for which the method of genetic transmission is known; Research on genetic factors possibly related to non-monogenic diseases; multifactorial disease; Genetic identity testing). It discusses also various ethical requirements that should be taken into account when these operations are performed: respect for the right of self-governance, the right to know, confidentiality and respect for privacy, information and the training of medical personnel.

**Original name:** Avis sur l'application des tests génétiques aux études individuelles, études familiales et études de population. (Problèmes des "banques de l'ADN, des "banques" de cellules et de l'informatisation des données).

C. Ethical issues raised by mandatory genetic testing for female participants in the Albertville Games (1992, no. 30)

**Abstract:** This opinion of the CCNE discusses the use of a genetic test for female participants in order to identify the sex of the athletes.

**Original name:** Questions éthiques posées par l'obligation de tests génétiques pour les concurrentes des jeux d'Albertville.
D. Opinion concerning the identification of patients suffering from glaucoma in France and on chromosomal location of the causative gene or genes (1993, no. 33)

Abstract: This opinion from the CCNE has been elaborated after a request from the Committee to combat glaucoma. It discusses whether it would be useful to identify patients suffering from glaucoma in France, screening for undiscovered cases, and locate the causative gene or genes so as to develop new therapy and prevention through systematic blood test screening.

Original name: Avis sur le recensement des glaucomateux en France et la localisation chromosomique du (ou des) gène (s) responsable(s).

E. Opinion and recommendations on"Genetics and medecine : from prediction to prevention". Reports. (No. 46, 1995)

Abstract: This document offers firstly scientific information about the roles of genes in diseases, the methods of analysis of genetic characteristics and the scope of applications of genetic characteristics studies (presymptomatic diagnosis, evaluation of genetic risk for descendants, and testing genetic susceptibility for severe diseases in adults). Secondly, in the ethics part it describes basic rules and references in medical genetics, guidelines and ethical rules for the private life of individuals (regarding conditions when offering tests, announcing results to the person concerned, conditions of familial studies, conservation and utilization of data), reflections concerning the dignity of the individual in society, and reflections on the responsibilities of society towards individuals. The document offers also specific recommendations.

Original name: Avis et recommandations sur "Génétique et Médecine : de la prédiction à la prévention". Rapport.
F. Congenital handicaps and prejudice (2001, no. 68)

Abstract: This opinion of the CCNE deals with society’s responsibilities as regards its handicapped members, and with the issues arising out of the notion of a personal prejudice suffered because of being born handicapped. This opinion has been requested by the Minister for Employment and Solidarity for consultation about the place in society of handicapped adults and children, the intrinsic value of a handicapped life as related to non birth, and good medical practices entailing liability on the part of prenatal diagnosis practitioners.

Original name: Handicaps congénitaux et préjudice.

G. Reflections on an extension of preimplantation genetic diagnosis (2002, no. 72)

Abstract: Preimplantation genetic diagnosis has been authorized in France since 1994, but is strictly limited to cases in which “there is a strong probability that the unborn child will be affected by a particularly severe disorder.” This document from the CCNE discusses whether an extension of preimplantation genetic diagnosis should be accepted, no longer in the sole interest of the child, but in the interest of a third party.

Original name: Réflexions sur l’extension du diagnostic préimplantatoire.

H. Regarding the obligation to disclose genetic information of concern to the family in the event of medical necessity (2003, no. 76)

Abstract: This document discusses whether there should be a legal obligation for persons who have been diagnosed for a serious genetic disorder or for a predisposition thereto, to advise other members of their families who could benefit effectively from treatment and/or
preventive measures. This legal obligation would also apply to physicians who had not supplied the information of concern to the family. The document discusses the specificities of genetic testing, the possible preventive care, the issue of secrecy, the concept of mandatory medical notification and the rights and duties of the proband.

**Original name:** A propos de l’obligation d’information génétique familiale en cas de nécessité médicale.

I. Generalised prenatal screening for cystic fibrosis (2004, no. 83)

**Abstract:** This document discusses the debate about prenatal screening for cystic fibrosis to a sample of a random population instead of to cases where there is a family history of cystic fibrosis or if one of the members of the couple is known to be heterozygous. The documents considers the technical aspects, legal considerations, the psycho-relational consequences of uncertainty, the social perception of the choice between termination of pregnancy and the birth of sick children, ethical issues arising out of the protocol and general points raised by the proposal. It concludes with specific recommendations.

**Original name:** Le dépistage prénatal généralisé de la mucoviscidose.

J. Problems connected to marketing self-test kits for HIV screening and diagnosis of genetic disease (2004, no. 86)

**Abstract:** This document discusses the ethical problems raised by the sale in France of self-testing kits to screen for HIV contamination and to diagnose genetic diseases. It discusses the state of the art related to self-testing kits, the right to know in relation to self-testing, the objectives of self-test kits related to the screening for HIV-positive status and to the identification of genetic status.

**Original name:** Problèmes posés par la commercialisation d'autotests permettant le dépistage de l'infection VIH et le diagnostic de maladies génétiques.
§ 1. German National Ethics Council (Nationale Ethikrat)

Following the Federal Government's decision of 2 May 2001, the National Ethics Council was inaugurated on 8 June 2001 as a national forum for dialogue on ethical issues in the life sciences. It is intended to be the central organ for interdisciplinary discourse between the natural sciences, medicine, theology and philosophy, and the social and legal sciences, and to express views on ethical issues relating to new developments in the field of the life sciences and on their consequences for the individual and society. The National Ethics Council has up to 25 members, who represent the scientific, medical, theological, philosophical, social, legal, ecological and economic worlds and are appointed for a four-year term by the Federal Chancellor.

http://www.ethikrat.org


Abstract: The Opinion is divided into two parts. The first part outlines the scientific and medical foundations, as well as the sociological aspects, of the debate on prenatal diagnosis and preimplantation genetic diagnosis (PGD), as well as the current legal situation in Germany. Explanatory material for this part is given in a separate appendix. The second part begins with a discussion of the arguments for the retention and more detailed specification of the prohibition of assisted reproduction for diagnostic purposes, and hence of PGD, provided for in the German Embryo Protection Law. This is followed by an account of the arguments in favour of the responsible approval of PGD subject to narrowly defined conditions.

Original name: Genetische Diagnostik vor und während der Schwangerschaft
B. Predictive health information in pre-employment medical examinations (2005)

Abstract: The issue addressed by this Opinion is the permissibility of making the conclusion of a private-sector contract of employment or appointment as a permanent civil servant conditional upon the collection and use of predictive health information. The Opinion is thus concerned with the medical potential, the ethical evaluation and the legal limits of the use of information on the risks of illness in the engagement of private-sector employees and permanent civil servants.

Original name: Prädiktive Gesundheitsinformationen bei Einstellungsuntersuchungen.

§ 2. German Medical Association (BÄK)

The Bundesärztekammer (BÄK) is the central organisation in the system of medical self-administration in Germany. It represents the interests of the physicians in matters relating to professional policy. As the joint association of the 17 State Chambers of Physicians in Germany, the German Medical Association plays an active role in the opinion-forming process in relation to health policy in society, and in legislative procedures.

http://www.bundesaerztekammer.de

A. Recommendations on prenatal diagnosis for diseases and the susceptibility for diseases (1998)

Abstract: Following elements are discussed in this document: goal of prenatal diagnosis; information and counselling of pregnant women; elements of prenatal diagnosis; post-test counselling; preimplantation genetic diagnosis; preconceptional diagnosis; intrauterine therapy; quality assurance; ethical aspects of prenatal diagnosis; legal aspects.

Original name: Richtlinien zur pränatalen Diagnostik von Krankheiten und Krankheitsdispositionen. This document is only available in German.
B. Recommendations on predictive genetic testing (2003)

**Abstract:** This document discusses following elements on predictive genetic testing: definition; possibilities and limits of quantification of genetic risk; the index-patient; legal basic conditions.

**Original name:** Richtlinien zur prädiktiven genetischen Diagnostik. This document is only available in German.

§ 3. German Research Foundation (DFG)

The Deutsche Forschungsgemeinschaft (German Research Foundation) is the central, self-governing research funding organisation that promotes research at universities and other publicly financed research institutions in Germany. The DFG serves all branches of science and the humanities by funding research projects and facilitating cooperation among researchers. It established a Senate Commission on Genetic Research to discuss the advances in genetics.

[http://www.dfg.de](http://www.dfg.de)


**Abstract:** In this statement, the Senate Commission on Genetic Research deals with a variety of ethical, legal, and social questions arising from handling this novel genetic knowledge.

**Original name:** Humangenomforschung und prädiktive genetische Diagnostik: Möglichkeiten, Grenzen, Konsequenzen. Only an English summary of the document is available online.

**Abstract:** After a scientific introduction on the variability of the human genome and genetic diseases, this document provides more information on genetic diagnosis in medical practice (methods; applications and interpretation of genetic test procedures; types of predictive diagnosis; quality assurance of genetic testing procedures; genetic counselling). Thereafter it offers an extensive consideration of the ethical and legal aspects of predictive genetic diagnosis: special characteristics of genetic knowledge; ethical and legal principles; preventing damage and ensuring personal autonomy in dealing with genetic data (among others tests performed on persons unable to give their informed consent; restriction of the performance of genetic tests to the medical profession; quality assurance of genetic testing procedures; data protection and professional confidentiality); handling genetic specimen and data banks; labour and insurance law issues arising from predictive genetic diagnosis. It offers also specific recommendations.

**Original name:** Prädiktive genetische Diagnostik.

§ 4. Bioethik-Kommission Bayern

The local government in Bayern (Germany) installed in 2001 an independent bioethics commission to study the ethical questions of life sciences.

http://www.bioethik-kommission.bayern.de/


**Abstract:** This document provides recommendations about the provision of predictive genetic tests.

**Original name:** Stellungnahme zu prädiktiven genetischen Tests. This document is only available in German.

Abstract: This document provides recommendations about preimplantation genetic diagnosis.

Original name: Stellungnahme zur Präimplantationsdiagnostik (PID). This document is only available in German.

§ 5. German Society of Human Genetics (GfH)

The German Society of Human Genetics (GfH), founded in 1987, is the primary professional membership organization for human geneticists in Germany. It counts more than 1000 members, including researchers, academics, clinicians, laboratory practice professionals, genetic counselors and others involved in or with special interest in human genetics. Most relevant policy documents for this publication have been issued by the Committee for Public Relations and Ethical Issues of the GfH.

http://www.gfhev.de

A. Statement on the prenatal diagnosis of sex (1990)

Abstract: The German Society of Human Genetics considers the use of prenatal diagnosis to choose infant sex as indefensible.

Original name: Erklärung zur pränatalen Geschlechtsdiagnostik.

B. Statement on population screening for heterozygotes (1991)

Abstract: In this document population screening is rejected, due to the absence of a necessary framework. This includes in particular an adequately informed public, sufficient information about the acceptance or rejection of such test procedures by the public, and the guarantee that the necessary genetic counselling will be available.
**Original name:** Stellungnahme zum Heterozygoten-Bevölkerungs-screening

C. Statement on prenatal paternity testing (1992)

**Abstract:** The German Society of Human Genetics considers prenatal diagnosis justifiable only within the framework of medical indications.

**Original name:** Stellungnahme zur pränatalen Vaterschaftsdiagnostik

D. Statement on postnatal predictive genetic diagnosis (1993)

**Abstract:** This statement provides recommendations on predictive genetic diagnosis. It considers numerous problems that must be carefully approached and regulated: information, absence of pressure, non-directiveness, data protection…

**Original name:** Stellungnahme zur postnatalen prädiktiven genetischen Diagnostik.

E. Statement on prenatal diagnosis and termination of pregnancy (1993)

**Abstract:** It is recognized that the presence or considerable risk of an unremediable impairment of the child’s health can be so severe that it can not be demanded of the woman that the pregnancy be continued. The members of the German Society of Human Genetics basically take a protective stance toward unborn human life, and when a prenatal diagnosis is not normal, they make an exception only if the expectant woman requests to terminate the pregnancy within the legal framework.

**Original name:** Stellungnahme zur vorgeburtlichen Diagnostik und zum Schwangerschaftsabbruch
F. Information for genetic counselling and the informed consent (1994)

**Abstract:** This document discusses the identity of the genetic counselling procedure and the procedure of informed consent.

**Original name:** Information zur genetischen Beratung und Einverständniserklärung.

G. Statement on preimplantation diagnosis (1995)

**Abstract:** The German Society of Human Genetics (GfH) is of the opinion that preimplantation diagnosis that is legal within the framework of professional regulations should basically be made available to all women who carry a specific genetic risk for a severe infantile disease or developmental disorder and who would like to have the risk clarified by this method. The GfH recognizes the same dangers and possibilities for misuse as in conventional prenatal diagnosis, especially when it is not used for strictly medical questions.

**Original name:** Stellungnahme zur Präimplantationsdiagnostik

H. Statement and recommendation on confidentiality (1995)

**Abstract:** This document provides some recommendations on the problem of confidentiality in the physician-patient relationship in the context of genetics.

**Original name:** Stellungnahme und Empfehlung zur Schweigepflichtproblematik. The document is only available in German.

Abstract: This statement provides recommendations on the genetic testing in children and adolescents.

Original name: Stellungnahme zur genetischen Diagnostik bei Kindern und Jugendlichen.


Abstract: This position paper describes a view on human genetics and describes following elements: principles; goals; relation to social injustice and disadvantage; services, access, utilization; individual autonomy in planning for the future and family planning; confidentiality and physician-patient privilege; the right of the patient to be fully informed; genetic counselling; postnatal predictive diagnosis; recognition of heterozygotes and heterozygote screening; prenatal diagnosis; gene therapy

Original name: Positionspapier der Deutschen Gesellschaft für Humangenetik.


Abstract: These guidelines provide recommendations on genetic counselling

Original name: Leitlinien zur Genetische Beratung. This document is only available in German.
§ 1. National Bioethics Committee

The Commission is an independent advisory body of experts addressed to public authorities either by its own initiative or upon request. Its mission is to highlight the interaction of life sciences and contemporary social values. More particularly the Commission, among other things, investigates the ethical, social and legal aspects that arise from scientific advances in biology, biotechnology, medicine and genetics. It was established by Law no. 2667 in 1998.

http://www.bioethics.gr


Abstract: This document considers the ethical and social issues which arise from the collection and use of genetic data. It considers following elements: consent (general principle, content of information prior to consent, warrants for the protection of confidentiality or anonymity, form of consent, future research on anonymous samples or genetic data, future research on confidential samples or genetic data, research on population groups, prohibition of hierarchical orders to conduct research in specific cases); disclosure (the right to know and the right not to know, disclosure of genetic data to third parties, disclosure of genetic data in the context of labour relations, disclosure of genetic information in the context of insurance), genetic tests on embryos, genetic tests on population groups, storage of biological samples and genetic information.

Original name: Κλωνοποίηση
§ 1. Medical Council

The Medical Council protects the interests of the public when dealing with registered medical practitioners. The Council was established by the Medical Practitioners Act 1978 and commenced operation in April 1979. The principal roles of the Medical Council include: assuring the quality of undergraduate education of doctors, assuring the quality of postgraduate training of specialists, registration of doctors, disciplinary procedures, guidance on professional standards / ethical conduct.

http://www.medicalcouncil.ie

A. A guide to ethical conduct and behaviour (2004, 6th ed.)

Abstract: This guide is a set of ethical principles which doctors must apply to the clinical situations in which they work. It contains following sections: conduct and behaviour; doctors and patients; professional responsibilities; doctors in practice; confidentiality and consent; genetic testing and reproductive medicine.
§ 1. National Bioethics Committee

The Italian National Bioethics Committee was established in 1990, following a decree of 1988. The Committee's Tasks consist mainly of addressing the ethical and legal problems that may emerge as a result of the progress of research and the emergence of possible new applications of clinical interest, taking into account the safeguarding of fundamental human rights and human dignity.

http://www.governo.it/bioetica

A. Prenatal diagnosis (1992)

Abstract: This document provides recommendations on the provision of prenatal diagnosis.

Original name: Diagnosi prenatali. This document is only available in Italian.

B. Bioethical guidelines for genetic testing (1999)

Abstract: In the first section of the document, after the introduction of several general concepts related to DNA and the main technologies for manipulating it (biotechnologies), the actual genetic tests are defined and their applications described, both in the field of health promotion and in fields unrelated to the health of the individual or the community. The second section documents the state of the art in Italy, and contains a survey of the structures providing genetic tests and of the current reference legislation. In the third section, the various bioethical implications of the problem are treated. The document is
concluded by a chapter on European and international legislation and a glossary of the main terms used.

**Original name:** Orientimenti bioetici per i test genetici.

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### § 2. National Commission for Biosecurity and Biotechnology (CNBB)

The National Commission for Biosecurity and Bioetotechnology (Comitato Nazionale per la Biosicurezza e le Biotecnologie (CNBB)) has been established in 1992. Its main activities are the coordination of activities in the field of biotechnology, to develop comments on international and European developments in the field of biotechnology, to provide scientific support to governmental and legal initiatives and to divulge technical and scientific information.

[http://www.governo.it/biotecnologie/](http://www.governo.it/biotecnologie/)

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### A. Guidelines for genetic testing (1998)

**Abstract:** The document contains among others following elements: genetic tests (definition and classification); objectives of the guidelines; scientific validation of the genetic tests; requirements to the laboratories that want to perform a genetic test; management of genetic tests (counselling and informed consent; (non)-directive counselling; genetic testing in minors; communication of the result; confidentiality and privacy; conflict of interest; access to the tests; education of health care professionals); recommendations.

**Original name:** Linee guida per test genetici (Comitato Nazionale per la Biosicurezza e le Biotecnologie). This document is only available in Italian.
§ 1. Health Council of the Netherlands

The Health Council of the Netherlands (Gezondheidsraad) is an independent scientific advisory body whose task is to advise Ministers and Parliament in the field of public health.

http://www.gr.nl/

A. Genetic screening (1994)

Abstract: This report considers genetic screening to mean any kind of test performed for the systematic early detection or exclusion of a hereditary disease or a predisposition to such a disease, or in order to determine whether a person carries a predisposition which may produce a hereditary disease in offspring. Following elements are discussed in the document: hereditary disorders; screening throughout life; effects of genetic screening; psychology; ethics; law; social considerations; assessment of screening programmes.

Original name: Genetische screening.

B. IVF-related research (1998)

Abstract: With this report the IVF Committee of the Health Council concludes its response to the request for an advisory report submitted in 1994. The report indicates the current level of knowledge with regard to pre-implantation genetic diagnosis (PGD) and describes current developments in the field of research concerned with improving IVF. A separate chapter is devoted to the issue of whether it is permissible to use human embryos for research aimed at further developing PGD or improving IVF. It also explores the conditions to
be imposed on such research. Finally, the Committee reviews its previous reports, in terms of the extent to which the introduction of artificial reproduction technology in the Netherlands has been judiciously implemented.

**Original name:** IVF: afrondende advisering.

C. Clinical genetic testing and counselling (1999)

**Abstract:** In the light of recent developments in the field of clinical genetics, the committee makes the following recommendations: genetic counselling and the associated test activities should continue to be concentrated in the nominated centres; the professional groups involved in clinical genetics should have responsibility for drafting and updating quality requirements; in this context, the government's role should be supervisory; forecasts regarding the level of provision required in this field should take account of the rapid increase in demand for counselling regarding hereditary forms of cancer.

**Original name:** Klinisch-genetisch onderzoek en erfelijkheids-advisering. Only an English summary is available.


**Abstract:** The present advisory report is a response to questions which the Minister of Health, Welfare and Sport has put to the Council with regard to methodological, psychological, ethical and legal aspects of various forms of antenatal screening for Down’s syndrome and neural tube defects and of routine ultrasound examination during pregnancy.

**Original name:** Prenatale screening: Downsyndroom, neurale buisdefecten, routineechoscopie. Only an English summary is available.
E. Application of genetics in health care. Consequences of the developments for the current legal and regulatory system (2003)

Abstract: The following question stood at the basis of this report: “To what extent do laws and regulations or their underlying principles require amendment because of the consequences that using genetics has for the legal position of the patient/individual?” This report examines this central question from the vantage point of various distinct fields. Chapter 2 is related to the context of provision of care, Chapter 3 outlines scientific research and Chapter 4 looks at screening. Chapter 5 examines the use of genetics outside healthcare and Chapter 6 focuses on the phenomenon of storing and using genetic data and human material. The final chapter provides an overall summing-up that explains and draws connections between subjects that overarch several chapters.

Original name: Toepassing van de genetica in de gezondheidszorg. Gevolgen van de ontwikkelingen voor de huidige wet- en regelgeving. Only an English summary is available.


Abstract: What are the best tests for detecting neural tube defects and Down’s syndrome in a foetus during pregnancy? And what is the best way to conduct this prenatal screening? These are the central issues in this advisory report. The aim of screening is to provide people who wish for it with information about the presence or absence of the disorder in question. This enables them to terminate the pregnancy where appropriate or to make preparations for the birth of a child with Down’s syndrome or a neural tube defect. Prenatal screening for Down’s syndrome and neural tube defects was also addressed in another report, which was published by a Health Council Committee in 2001. The present report contains the findings of a Committee of the Health Council based on the most recent developments.
G. Neonatal screening (2005)

Abstract: A heel prick is used to take a sample of blood from practically all newborns in the Netherlands to screen them for three disorders: phenylketonuria (PKU), congenital hypothyroidism (CHT) and adrenogenital syndrome (AGS). Early diagnosis is necessary with metabolic diseases of this kind so that timely treatment can be given to prevent irreversible damage to health. Parents can also be informed about the likelihood of a repetition with any subsequent child. In the Netherlands, the State Secretary for Health, Welfare and Sport has asked the Health Council to examine whether the criteria for screening newborns are still adequate and whether it would be advisable to expand the screening package. In this advisory report, the Health Council’s Committee on Neonatal Screening discusses the criteria for screening newborns. The key concern is the health benefit that can be gained. On the basis of the criteria, more than thirty disorders have been assessed for which international reference literature suggests screening is beneficial. The report also discusses the fact that neonatal screening detects carriers (those who have inherited a mutation but are not themselves sick). These may be parents of patients but, in some cases, also newborns. The report also discusses the consequences that expanding screening would have for informing parents and requesting parental consent.
§ 1. National Council of Ethics for the Life Sciences

The National Council of Ethics for the Life Sciences has been established in 1990 as an independent and advisory body providing recommendations on social, legal and ethical issues in the life sciences.

http://www.cnecv.gov.pt

A. Statement on the ethical implications of genomics (2001)

Abstract: This document provides scientific information on genetics, considers the ethical implications of genetics and discusses various issues, such as genetic determinism, solidarity, human dignity, preimplantation genetic diagnosis and commercialization.

Original name: Relatório e parecer sobre implicações éticas da genómica. This document is only available in Portuguese.
§ 1. Medical Association of Catalunya

The physicians of Catalunya are regrouped in the Col·legis de Metges de Catalunya (Medical Association of Catalunya).

http://www.comb.cat

A. Ethical aspects of the use of genetic tests

Abstract: This document provides recommendations about the provision of genetic tests.

Original title: Aspectos éticos de la utilización de pruebas genéticas (Spanish). This document is only available in Spanish and Catalan.
§ 1. Swedish National Council on Medical Ethics (SNCME)

The Swedish National Council on Medical Ethics is a national body with an independent status within the Government Offices. Administratively, the council is affiliated with the Ministry of Health and Social Affairs. The council is an advisory board to the Swedish government on ethical issues raised by scientific and technological advances in biomedicine. The Council shall stimulate exchange of information and ideas and promote discussion on new medical research and applications.

http://www.smer.gov.se


Abstract: In order to obtain comments, the Council of Europe Steering Committee on Bioethics (CDBI) has agreed with the publication of the working document on the applications of genetics for health purposes, together with an explanatory note. The document is the result of the discussions so far of the Working Party on Human Genetics, and it is made public under the responsibility of the Party. The Swedish Council on Medical Ethics greatly appreciates the ongoing efforts of the Working Party and the CDBI, and wishes to extend comments that may be of use for the elaboration of an additional protocol to the Convention on Human Rights and Biomedicine. This document is an overview of suggestions and comments on this working document from the Council of Europe.
B. Statement of opinion of pre-implantation genetic diagnosis (2004)

Abstract: In this document, the SNCME discusses the medical and ethical conditions for pre-implantation genetic diagnosis (PGD). It discusses among others the medical background, existing regulations, general observations about the issues of medical ethics (human dignity, doing good, respect for self-determination and integrity, not doing harm, fairness, sex selection, sliding criteria) and their applications in PGD diagnosing severe inherited disorders and pre-implantation genetic screening.


Original name: Yttrande om införande av en ny fosterdiagnostisk metod. This document is only available in Swedish.

D. Opinion on the preliminary law proposal, “Genetics, integrity and ethics“ (SOU 2004:20)

Original name: Remissyttrande över SOU 2004:20 Genetik, integritet och etik. This document is only available in Swedish.
§ 1. Swiss Academy of Medical Sciences (SAMS)

The Swiss Academy of Medical Sciences (SAMS) was founded in 1943 by the five Swiss medical faculties, the two veterinary medical faculties and the Swiss Medical Association. Today the activity of the SAMS is concentrated on the clarification of ethical questions in connection with medical developments and their effects on society; a comprehensive reflection on the future of medicine; engagement in university, scientific and education politics; promotion of the professional training; support of the high quality of the research; and the connection between scientific medicine and medical practice.

http://www.samw.ch/

A. Medical-ethical guidelines for genetic investigations in humans (1993)

Abstract: These guidelines define the basic conditions for the procedures to be adopted by the physician in regard to medico-genetic investigations. They are restricted to investigations to detect or exclude hereditary factors responsible for disease. They are valid for all investigations carried out before or after birth and which allow conclusions to be drawn regarding such hereditary factors. They show how such investigations are to be carried out in the individual and in families, as well as for screening examinations. The recommendations are dealing with the conditions for performing genetic investigations, the duty to inform, genetic counselling, obligatory consent and decision on disclosure of the results of the investigations, long-term support of the person investigated, quality assurance, professional secrecy and data protection, employment, insurance and research.
§ 2. Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE)

In the debate on the Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, FMedG), there was agreement in both chambers of the Swiss Parliament that it was important – given the ever-increasing relevance of the issues – to establish a permanent body concerned with biomedical ethics. Under Article 28 of the Act, approved by Parliament on 18 December 1998, a "national ethics commission" was to be set up as an independent, extra-parliamentary deliberative body. The National Advisory Commission on Biomedical Ethics was established by the Federal Council on 3 July 2001.

http://www.nek-cne.ch

A. Preimplantation genetic diagnosis (2005, no. 10)

Abstract: In its Opinion no. 10/2005, the Swiss National Advisory Commission on Biomedical Ethics (NEK-CNE) presents detailed ethical arguments and recommendations for the regulation of preimplantation genetic diagnosis (PGD). A majority of the Commission recommends that the existing wholesale ban on PGD should be replaced by restricted legalization, with an indication-based approach.

§ 3. Swiss Society of Medical Genetics

The Swiss Society of Medical Genetics is committed to promoting and maintaining excellence in genetic counselling, diagnosis and care in Switzerland, and in providing support and information to all interested parties.

http://www.ssgm.ch/

Abstract: Genetic testing consists of medical examinations aimed at detecting or ruling out the presence of hereditary illnesses or predisposition to such illnesses in a person, by directly or indirectly analysing their genetic heritage (chromosomes, genes). This guideline provides some recommendations on genetic counselling.


Abstract: This document presents Best Practice Guidelines for Swiss laboratories reporting molecular genetic diagnostic testing of constitutional mutations. The aim of the guidelines is to improve the quality of reporting in Switzerland and to help laboratories to provide the most understandable and complete reports of their analyses. It provides also requirements for genetic counselling.
§ 1. Human Fertilisation & Embryology Authority (HFEA)

The Human Fertilisation and Embryology Authority (HFEA) is a statutory body, created in 1991 under the Human Fertilisation and Embryology Act (1990). Its primary remit is to license and monitor UK clinics that offer IVF (in vitro fertilisation) and DI (donor insemination) treatments, and all UK-based research into human embryos. It also regulates the storage of eggs, sperm and embryos.

http://www.hfea.gov.uk


Abstract: This report presents a summary of the available information about the scientific and technical aspects of sex selection together with the results of a public consultation (opinion survey, qualitative research and comments on consultation paper). It offers also a review of the regulation of techniques for sex selection. In its conclusion and recommendations, the report addresses the social and ethical issues surrounding sex selection, and the safety and efficacy of the techniques used, taking into account the views of the key stakeholders and the interested public.


Abstract: The object of the Human Fertilisation & Embryology Authority Code of Practice is concerned with areas of practice which raise fundamental ethical and social questions. Each part of the Code is prefaced by the relevant legislations, the practical implications of which are further explained in the text. Following topics are addressed in the Code of Practice: staff; facilities and administrative procedures;
welfare of the child and the assessment of those seeking treatment; assessing and screening potential donors; information; consent; counselling; use of gametes and embryos; storage and handling of gametes and embryos; research; records; confidentiality; complaints; preimplantation testing; witnessing clinical and laboratory procedures; intra-cytoplasmic sperm-injection. The Code of Practice is regularly reviewed and amended in light of experience and to keep pace with the latest developments in clinical practice and evolving public concern.

§ 2. Human Genetics Commission (HGC)

The Human Genetics Commission is the UK Government's advisory body on new developments in human genetics and how they impact on individual lives. It provides the Government advice on human genetics with a particular focus on the social, ethical and legal issues. One of its key roles is to promote debate and to listen to what the public and the stakeholders have to say. They are committed to openness and transparency. Following a review of the regulatory framework for biotechnology by the government, the work of the Advisory Committee of Genetic Testing (ACGT) has been subsumed in 2000 into the Human Genetics Commission. Therefore, all publications from the ACGT have been listed under the Human Genetics Commission.

http://www.hgc.gov.uk

A. Code of practice and guidance on human genetic testing services supplied direct to the public (1997)

Abstract: This document has been written by the Advisory Committee on Genetic Testing (ACGT). In this document, the ACGT provides a code of practice and guidance about various issues related to genetic testing services: (1) testing laboratories, equipment and reagents; (2) confidentiality and storage of samples and records; (3) tests that may be supplied; (4) who may be supplied tests; (5) customer information; (6) genetic consultation; (7) involvement of general medical practitioners.

Abstract: This document has been written by the Advisory Committee on Genetic Testing (ACGT). ACGT’s aim in this report is to set out the issues to be considered before genetic testing for late onset disorders is offered and during the provision of such tests. The major issues identified in this report relate principally to requests for genetic testing from healthy relatives of patients with a late onset genetic disorder. Population based screening, diagnostic testing of symptomatic individuals and genetic susceptibility testing for common diseases are briefly considered in Annexes A, B and C. Following issues are discussed in the report: why do people request genetic testing for late onset disorders; scientific and clinical validity of the test; laboratories undertaking genetic testing for late onset disorders; information needed by those being tested; support in relation to genetic testing; consent to genetic testing; testing of young children and adolescents for late onset disorders; prenatal genetic testing for late onset disorders; genetic testing and results of research studies.

C. Prenatal genetic testing (2000)

Abstract: This paper reports on issues to be considered when providing prenatal genetic testing services. After an overview of the background of prenatal genetic testing (what is prenatal genetic testing?; methods of prental genetic testing; the conditions tested), the report tackles various issues in prenatal genetic testing (organization and structure; access to prenatal genetic testing diagnostic services; appropriateness of testing; legal and ethical issues; information; outcomes; quality assessment; research; rare disorders). This document provides a list of 28 recommendations on service organization, undertaking testing, outcome of testing, service standards and research.

Abstract: At the request of Ministers, the Human Genetics Commission (HGC) has been reviewing the wider social and ethical implications of the use of genetic information in insurance. The HGC concluded that it was important to establish a clear and defensible regulatory system which not only balances the interests of insurers, insured persons, and the broader community but also enjoys the confidence of the public. In order to achieve this aim, the HGC has therefore decided to recommend to the Government an immediate moratorium on the use by insurance companies of the results of genetic tests. This document describes the background and the features of this moratorium.


Abstract: The aim of the Human Genetics Commission (HGC) in this report is to suggest how interests in genetic privacy and confidentiality can be protected in a way that does not harm comparably important interests of others. The HGC has set out a number of principles to achieve this, many of which are laid down in international declarations and conventions which seek to establish a common ethical framework. The HGC has set out a concept of genetic solidarity and altruism: sharing our genetic information can give rise to opportunities to help other people and for other people to help us and we have a common interest in the benefits that medically-based genetic research may bring. The HGC has also drawn up some principles based on the overarching idea of the respect for persons, which means that everyone should have their rights and dignity respected in the same way regardless of their genetic characteristics. The HGC examined existing protections of personal genetic information and has made recommendations for their monitoring and possible improvement. Having stressed the importance of consent and confidentiality, the HGC considered that it may be necessary to test a person after death to help a living relative and recommends that
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doctors should presume that the dead person would have wanted to help the relative and therefore would have given their consent to post mortem testing. The HGC also considers that disclosure of sensitive personal genetic information without consent may be justified in rare cases where a patient refuses to consent to such disclosure but the benefit to other family members or the wider public substantially outweighs the need to respect confidentiality. The HGC further provides some recommendations on medical research and personal genetic information, as well as on insurance and employment. Based on its findings, the HGC advances that there is much support for the use of the National DNA Database to help the police to investigate crime. However, the HGC recommends, that in order to increase and maintain public confidence there should be an independent body, which would include lay members, to oversee the way the National DNA Database works.

F. Genes direct. Ensuring the effective oversight of genetic tests supplied directly to the public. (2003)

Abstract: The Human Genetics Commission (HGC) was asked by Health and Science Ministers to ‘give priority to a more thorough review of the provision of genetic tests to the public. The HGC does not set out to create precise recommendations to regulate direct genetic testing, but believes that the best way of protecting the public is through a combination of legal controls on the sale of tests and professional self-regulation of those who might supply tests. The HGC suggests a framework which can guide those bodies that are responsible for regulation to make sure, that companies only market high quality tests, with good customer support and that they do not seek to misuse the power of modern genetics as a marketing tool.


Abstract: The Human Genetics Commission (HGC) and the UK National Screening Committee (NSC) were asked to provide an initial analysis of the case for and against genetic profiling of babies at birth. By profiling they mean the analysis of a person’s entire genome in
order to reveal the majority of their genetic variations. Their basic conclusions and recommendations are: Genetic profiling is feasible and likely to become available commercially is less than 20 years; Before the offer of universal genetic profiling could be considered at a population level, steps would need to be taken to preclude any misuse of information derived from it; Genetic profiling is unlikely to be publicly affordable within 20 years; For newborn genetic profiling, issues of consent and the welfare of the child are problematic; Genetic profiling may in the future have clinical potential but its effectiveness cannot yet be judged; there is a pressing need to develop a programme of research to define the full costs and potential benefits of genetic profiling for the health of children and adults; Genetic profiling cannot be applied as an NHS screening programme in the near future. The topic should be kept under review and be revisited in five years.


Abstract: In June 2003, the Human Genetics Commission (HGC) established a Working Group to examine the effects of developments in human genetics on the kind of choices are facing people having children, and the wider social implications of these choices. In a first chapter, this report sets out some principles that should be held as most relevant into the consideration of policy and practice in reproductive decision making and genetics. The second and third chapter discusses respectively the history of genetic science; and prenatal and neonatal screening and diagnostic testing. The fourth chapter deals with preimplantation genetic diagnosis. The firth chapter analyzes assisted reproductive technologies, genetics and reproductive choice. The sixth chapter deals with the framework and organisation of genetic services. The last chapter has as aim to scan the horizon and focus on future developments.
§ 3. Department of Health

The Department of Health’s aim is to improve the health and wellbeing of the people of England. Its work includes setting national standards and shaping the direction of the NHS and social care services, and promoting healthier living. Health and social care services are delivered through the NHS, local authorities, arm’s length bodies and other public and private sector organizations.

http://www.dh.gov.uk

A. Code of practice and guidance on genetic paternity testing services (2001)

Abstract: An ad hoc Group on Genetic Paternity Testing Services was brought together for the express purpose of considering genetic paternity testing services provided in the United Kingdom. The Group's membership included representatives from commissioners of genetic paternity testing services, providers of such services, patient groups, clinicians, academics and scientists. The Code has been considered by the Genetic Testing Sub-group of the Human Genetics Commission.

B. Our Inheritance, Our Future. Realising the potential of genetics in the NHS (2003)

Abstract: This White Paper sets out a plan of action and investment in genetics for the NHS in England, as well as covering wider UK genetics policy issues. In Chapter 6, it addresses the moratorium of genetic tests in insurance, the ban on human cloning, the regulation of new reproductive techniques and gene therapy, the protection of genetic information, the prevention of unfair discrimination, the consent to genetic testing, the direct to the public genetic testing, genetics and behaviour, and paternity testing
C. Concordat and moratorium on genetics and insurance (2005)

Abstract: The Government and the insurance industry recognise and wish to respond to understandable concerns about the potential use of personal genetic data by insurance companies. They consider that the relationship between medical data and insurance underwriting should be proportionate and based on sound evidence. This document provides a single high-level policy agreement on the use of genetic test results in insurance underwriting practices. It is informed by discussions between the Association of British Insurers, its member companies and the Government, the Genetics and Insurance Committee, the Human Genetics Commission, patient groups and other interested parties.

§ 4. British Medical Association (BMA)

The British Medical Association (BMA) represents doctors from all branches of medicine all over the UK. It is a voluntary professional association of doctors, that speaks for doctors at home and abroad, provides services for its members, and that acts as an independent trade union, scientific and educational body, and publisher. Its Medical Ethics Committee debates issues related to ethics and law in medicine.

http://www.bma.org.uk


Abstract: This book (not freely available on the website), containing various specific recommendations, discusses following topics: (1) why genetic advances create dilemmas as well as benefits; problems of terminology; ethical duties of health professionals; areas where there appears to be public consensus; and principles which should be taken into account in decision-making; (2) basic introduction to human genetics; (3) ethical issues which arise in relation to prenatal testing for those with a family history of a genetic disorder and prenatal screening of whole populations or groups; (4) ethical issues raised by
genetic testing of adults and children with a family history of genetic disorder; (5) ethical issues raised by genetic screening of populations or groups of adults and children where there is no family history of genetic disorder; (6) provision of information and genetic counselling; (7) consideration of boundaries between accepted, controversial, and unacceptable uses of genetic information; (8) use of genetic information by insurance and employers; (9) paternity testing; establishing consanguinity for immigration purposes; genetic testing in criminal investigation; (10) overview of regulatory bodies and organizations; (11) the Human Genome Project; the Human Genome Diversity Project; gene therapy; behavioural genetics; and cloning.

B. Medical information and insurance. Joint guidelines from the British Medical Association and the Association of British Insurers (2002)

Abstract: This joint guidance has been drawn up by the British Medical Association and the Association of British Insurers to set out best practice and practical advice on the use of medical information in insurance. It is primarily designed for general practitioners and other doctors who are asked to provide medical information to insurance companies. It includes information and recommendations about medical factors in insurance, medical reports, general practitioners reports, independent medical reports, content of reports, explanations, release of information to verify claims, deceased people, fees, return and quality of reports. It includes also recommendations on the use of genetic information.


Abstract: Genetic information is increasingly being used to establish family relationships, usually but not exclusively paternity. New developments have led to the provision of paternity testing direct to the public, using testing kits that are sent off for analysis. This document presents general principles regarding paternity testing, the legal position, ethical obligations, the issue of ‘motherless’ testing and the issue of testing without consent.
§ 5. Nuffield Council on Bioethics (HGC)

The terms of reference of the Nuffield Council on Bioethics are to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern; to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body; in the light of the outcome of its work, to public reports; and to make representations, as the Council may judge appropriate. The Nuffield Council on Bioethics is funded jointly by the Medical Research Council, the Nuffield Foundation and the Wellcome Trust.

[Link to website: http://www.nuffieldbioethics.org]

A. Genetic screening. Ethical issues (1993)

**Abstract:** The aims of this report were to survey recent and prospective advances in genetic screening and its applications, to review the benefits and to identify and define the ethical issues that arise, or could potentially arise from genetic screening. It examined consent, counselling and confidentiality in the light of the experience of genetic testing for rare disorders such as Huntington’s disease, and carrier screening for disease which are less rare, such as cystic fibrosis and sickle cell anaemia. The report recommended that participation in all screening programmes should only be on a voluntary basis and that adequately informed consent must be obtained from participants. It also recommended that counselling should be readily available for those being screened, as well as those being tested on account of a family history of a genetic disorder. The Council recognised that the results of screening might have serious implications for members of a family. When genetic screening revealed information that might have implications for the relatives of the person being screened, the report recommended that health professionals should explain why the information should be communicated to other family members. They should then seek to persuade individuals, if persuasion should be necessary, to allow the disclosure of relevant genetic information to
other family members who might benefit from it. Where a screened individual did not wish to inform relatives of a genetic risk or to give permission for test results to be used by them, the Council accepted that under exceptional circumstances it may be appropriate to disclose genetic results ‘without consent’ to benefit family members. The legal interpretation would be that there is an exception to the duty of confidentiality where the disclosure is in the public interest. In the context of public policy, the report recommended that the Department of Health, in consultation with the appropriate professional bodies, should formulate detailed criteria for the introduction of programmes for genetic screening and establish a central coordinating body to review such programmes and monitor their implementation. This was seen to be an essential safeguard against abuse. The report also considered implications for employment and insurance, proposing early discussions between government and the insurance industry about the future use of genetic data. It recommended that screening in the context of employment should be strictly limited and only be undertaken if accompanied by safeguards for employees after appropriate consultation.

B. Mental disorders and genetics. The ethical context (1998)

Abstract: This report examines the ethical issues that may arise in the course of genetic research into mental disorders and in the application of that research in clinical and other settings. Some of these issues arise because the conditions are genetic, and other because they relate to mental disorders. A broad and humanistic perspective may be considered to have two basic ethical requirements; respect for human beings and human dignity, and the limitation of harm to, and suffering of, all human beings. The Working Party considered both rare single gene disorders, focusing on the examples of Huntington’s disease and early onset Alzheimer’s disease, and common mental disorders, such as schizophrenia and the more common late onset form of Alzheimer’s disease, influenced by susceptibility genes and by environmental factors. The ethical issues associated with mental disorders concern the implications for reproductive decisions, the stigma associated with mental disorders and the fact that some disorders may impair the capacity to make decisions. The Working
Party concludes that genetic tests will not be particularly useful in the near future in diagnosing mental disorders with more complex causes, for prenatal diagnosis or for population screening. It is more probable that identifying genes involved in susceptibility to common mental disorders will lead to the development of more effective drug treatments. Even if a number of susceptibility genes were identified for a particular disorder, the report concludes that, without an understanding of their interaction, they would not be adequate for predicting individual risk in a clinical setting. The Working Party recommends that genetic testing for susceptibility genes which offer relatively low predictive or diagnostic certainty will be discouraged, unless there is a clear medical benefit to the patient. The genetic testing of children requires special safeguards and the Working Party recommends that predictive genetic testing and testing for carrier status for mental or indeed other disorders in children is strongly discouraged. Genetic testing for mental and other disorders in adoption raises important and complex issues which require appropriate guidance. While the best safeguards against new eugenic pressure is freely given, properly informed consent, guidelines for the establishment and maintaince of genetic register are needed. The report recommends that the confidential nature of genetic information be maintained but recognises that, exceptionally, disclosure to close family members might be justified. Recommendations are also made about the use of genetic information in insurance and employment. For most people with a mental disorder, arrangements about consent to research participation should not be any different from those required for others. However, for those who are only intermittently competent, consent should be sought only when they are competent. For the incompetent, participation in non-therapeutic research is considered ethical, subject to strict safeguards.

C. Genetics and human behaviour. The ethical context (2002)

Abstract: The first two parts of the report explain the historical and scientific background to research in the field of behavioural genetics. Chapter 2 outlines the history of the eugenetics movement and its profound effect on the development of clinical genetics and developmental psychology since the Second World War. Chapter 3
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attempts to explain what is meant by the suggestion that genes influence or affect human behaviour. There are various ways in which one can study the contribution that genetic factors make to human behaviour. Chapter 4 examines one of these approaches, namely quantitative genetics. This field of research aims to determine the extent to which variation in a trait is genetically influenced in a population. It uses statistical methods to examine and compare groups of people without focusing on particular genes. Chapter 5 explains another approach, that of molecular genetics. This attempts to identify differences in particular genes that contribute to variations between particular individuals. A third approach is the use of animals to try to examine the effects of particular genes on behaviour. Chapter 6 examines this type of research. The third part of the report, Chapters 7-11, contains reviews of the findings that have been obtained to date in each of these methods of research, with respect to the behavioural traits already listed: intelligence, personality, antisocial behaviour and sexual orientation. The fourth part of the report examines the ethical, legal and policy issues and offers a series of conclusions and recommendations. A starting point is the Unesco Universal Declaration on the Human Genome and Human Rights which states that the ‘human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity.’ Chapter 12 begins by discussing whether there is an inherent conflict between understanding the genetic influences on behaviour and human dignity, as it is expressed in the concepts of free will and moral responsibility. Chapter 13 then addresses some of the potential applications of the research including genetics, medical and environmental interventions aimed at changing behavioural traits, as well as prenatal selection. Chapter 14 is concerned with the implications of research in behavioural genetics for the criminal justice system, in relation to attributions of legal responsibility and sentencing, and in predicting antisocial behaviour. Chapter 15 considers genetic testing and selection with regard to education, employment and insurance.

**Abstract:** The report begins by summarising the aims and recommendations of the 1993 Report. Technological advances over the past 13 years, and the current policy, advisory and regulatory situations are then briefly reviewed in Chapters 2 and 3, respectively. Consideration is given in Chapters 4 and 5 to the current delivery of screening services; the provision of information available to patients; procedures for consent, counselling and confidentiality; and education. The report describes developments in employment and insurance policy relating to genetic screening in Chapter 6. The Supplement concludes with a number of recommendations.

§ 6. British Society for Human Genetics (BSHG)

Founded in 1996, the British Society for Human Genetics provides a forum for professionals involved in Genetics as a clinical service and research. Its membership is in excess of 1750 and includes a wide spectrum of clinical, laboratory and research disciplines. It is constituted of the Clinical Genetics Society, the Association of Clinical Cytogeneticists, the Clinical Molecular Genetics Society, the Association of Genetic Nurses and Counsellors and the Cancer Genetics Group.


**Abstract:** The Working Party was asked to examine current attitudes and practices, focus attention on any difficulties rose by the genetic testing of children and make appropriate recommendations about future practice. The objectives led the Working Party to examine two questions. To what extent does such testing take place now? Under what circumstances is such testing justified, and when might it be better deferred until the child is older? This document is the report of these activities.
B. BSHG Statement on genetics and life insurance (1998)

Abstract: This statement deals with the relation between medical genetics and insurance. In particular, it states that applications must not be asked to undergo a genetic test in order to obtain any type of insurance. It discusses also the issue of disclosure of pre-existing genetic test results and the opportunity for a constructive role for the insurance industry.


See Royal College of Physicians

§ 7. Royal College of Physicians

The Royal College of Physicians is a registered charity established in 1518 that aims to ensure high quality care for patients by promoting the highest standards of medical practice. It provides and sets standards in clinical practice and education and training, conducts assessments and examinations, quality assures external audit programmes, supports doctors in their practice of medicine, and advises the Government, public and the profession on health care issues.

http://www.rcplondon.ac.uk

A. Clinical genetics services: Activity, outcome, effectiveness and quality (1998)

Abstract: As the science of genetics advances, clinical genetic services will come under increasing pressure. A report published by the Royal College of Physicians in 1996, Clinical genetics services in the 21st century, set out how the service should develop and the staff and resources that will be needed to meet increasing demands and expectations as discoveries of the genetic component of many common diseases unfold. This report describes the activities of a
clinical genetic service in relation to individual patients - and equally important their families - including diagnosis, risk assessment, genetic counselling, laboratory services and long-term anticipatory care. The report discusses the difficulties of assessing the effectiveness of genetic services and recommends further research. It affirms that preventing the birth of children with disability, or propensity for later illness, is not the primary function of a genetic advisory service, though it may be one of its effects. Its main functions are to help parents make informed choices about reproduction and to ensure that those with genetic diseases and their relatives can participate in screening and early treatment of disease


Abstract: This report has been elaborated together with the Royal College of Pathologists and the British Society for Human Genetics (constituting together the Joint Committee on Medical Genetics). This document is a response to the requests from genetics professionals for clarification of issues of consent and confidentiality in clinical practice, particularly with regard to the requirements of the Data Protection Act 1998 and the Human Tissue Act 2004. As well as clarifying issues surrounding consent and confidentiality in genetic practice, the report identifies key practice points and lists documents which may be helpful when seeking consent. On some issues the report makes recommendations from practice. The report covers general aspects of consent applied to genetics, the sharing of information with other family members and between professionals, genetic investigations performed on stored material, the Human Tissue Act 2004, consent and DNA analysis, the Data Protection Act 1998 and the processing of medical genetic information
§ 8. Genetic Interest Group

The Genetic Interest Group is a national alliance of organisations with a membership over 120 charities which support children, families and individuals affected by genetic disorders. Its primary goal is to promote awareness and understanding of genetic disorders so that high quality services for people affected by genetic conditions are developed and made available to all who need them.

http://www.gig.org.uk


Abstract: The genetic testing of children is an issue that has been much debated by the Genetic Interest Group (GIG) and its member organisations. The GIG therefore welcomes the report from the Clinical Genetics Society, but considered this report to be deficient and flawed in a number of areas. After an overview of general issues of concern, this document deals specifically with the presymptomatic diagnosis of childhood-onset conditions, the testing for carrier status, the testing for adult-onset conditions, the testing for adoption and the prenatal testing.

B. Guidelines for genetic services (1998)

Abstract: The purpose of these guidelines is to help genetic and other providers and commissioners, in partnership with service users, set and monitor standards, identify areas for improvement, devise strategies to develop and improve the services, and plan for the future. The guidelines have been developed in consultation with both professionals and service users. They offer in particular the user’s perspective of the services, and are designed to complement professional guidelines. The guidelines are dealing with following elements: making the service available, improving access and equity,
partnership with users and professional collaboration, providing information, counselling and support, long-term follow up and contact of at-risk relatives, standards for clinical and laboratory services, monitoring and evaluation.

C. Confidentiality guidelines (1998)

Abstract: This document concerns the issue of the sharing of genetic information within families and between professional clinical geneticists. Genetic information is taken to mean any data of clinical relevance to the genetic status of an affected or at risk individual. No distinction is made between, for example, family information arising from a counselling session, phenotypic observations made during clinical evaluation or laboratory test results. The report aims to support, supplement and formalise existing best practice. It tried to provide a framework of written guidelines that define both limits to individual guidelines in the medical genetics context and how issues and conflicts relating to confidential information can best be approaches in daily practice.

§ 9. Association of British Insurers

The ABI (Association of British Insurers) represents the collective interests of the UK’s insurance industry. The Association speaks out on issues of common interest; helps to inform and participate in debates on public policy issues; and also acts as an advocate for high standards of customer service in the insurance industry. The Association has around 400 companies in membership.

http://www.abi.org.uk


Abstract: This document offers a code practice (a standard), which ABI member companies must meet and upon which companies may
wish to build. The Code of Practice is set in the context of current legal requirements, ethics and commercial insurance practice. In the second edition certain revisions have been made: this edition clarifies some of the existing requirements on insurers; introduces a new requirement reflecting the transfer of role from the Genetic Adviser to the independent Genetics and Insurance Committee in evaluating the validity of genetic test results for insurance use; the confidentiality guidelines have been rewritten to take into account the Data Protection Act 1998.

B. Medical information and insurance. Joint guidelines from the British Medical Association and the Association of British Insurers (2002)

See British Medical Association

§ 10. GeneWatch UK

GeneWatch UK is a not-for-profit group that monitors developments in genetic technologies from a public interest, environmental protection and animal welfare perspective. GeneWatch believes people should have a voice in whether or how these technologies are used and campaigns for safeguards for people, animals and the environment. GeneWatch works on all aspects of genetic technologies - from GM crops and foods to genetic testing of humans.

http://www.genewatch.org

A. Genetic testing in the workplace (2003)

Abstract: This report is concerned with the potential misuse of genetic information by employers. It provides a brief introduction to the kinds of genetic tests that might be used for employment purposes and reviews the research evidence linking genes to occupational illness. The limitations of this research are then discussed. A short description of current research activity in this area in both the USA and the UK is also provided. The report goes on to consider why
employers might be interested in using genetic tests and whether they would be likely to benefit from their introduction. Current UK legislation surrounding workplace health and safety is reviewed to consider how genetic testing might fit with current employment practice and the legal roles and responsibilities of employers. The implications for employees are also discussed, highlighting potential benefits and the possibility of genetic discrimination. Finally, the limitations of existing UK laws and safeguards are considered and the changes necessary to prevent genetic discrimination in employment are identified.

B. Genetic discrimination by insurers and employers: still looming on the horizon (2006)

Abstract: This document is an update on the use of genetic test results by employers and insurers. It updates previous reports and briefings of the organization by providing a guide to the types of tests that are available and evidence that employers and insurers are interested in using them; recent cases of genetic discrimination and evidence that the prospects of discrimination may deter people from taking genetic tests; a summary of laws around the world to prevent genetic discrimination.
§ 1. Council of Europe

Set up in 1949, the Council of Europe is an intergovernmental organisation which fosters political, legal, and cultural cooperation between its 46 member European pluralistic democracies. The Council of Europe operates through three main bodies, the Committee of Ministers, the Parliamentary Assembly and the Congress of Local and Regional Authorities of Europe. Set up under the direct authority of the Committee of Ministers, the Ad hoc Committee of experts on Bioethics (CAHBI) which became in 1992 the Steering Committee on Bioethics (CDBI) has, since 1985, been responsible for the intergovernmental activities of the Council of Europe in the field of bioethics. The work of CAHBI, and then of the CDBI, has led to the adoption of Recommendations of the Committee of Ministers and to the preparation of the Convention on Human Rights and Biomedicine, and its additional protocols. The CDBI also set up a Working Party on Human Genetics.

A. Recommendation No. R(90)13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling (Committee of Ministers) (1990)

Abstract: This document recommends the governments of member states to adopt legislation in conformity with the principles contained in this recommendation or to take any other measures to ensure their implementation. The principles are focusing on the importance of pre- and posttest counselling, the purpose of prenatal genetic screening and/or prenatal genetic diagnostics tests, the conditions to carry out such tests, the counselling process, the free and informed consent, confidentiality and privacy.
B. Recommendation No. R(92)3 on genetic testing and screening for health care purposes (Committee of Ministers) (1992)

Abstract: This document recommends that the governments of the member states be guided in their legislation and policy by the principles and recommendations set out in this document and promote in their educational systems the teaching of human genetics. This document provides recommendations on the rules for good practice in genetic testing and screening (informing the public; quality of genetic services; counselling and support), access to genetic tests (equality of access – non-discrimination; self-determination; non-compulsory nature of tests; insurance), data protection and professional secrecy (data protection; professional secrecy; separate storage of genetic information; unexpected findings) and research (supervision; handling of data).

C. Recommendation No. R(94)11 on screening as a tool of preventive medicine (Committee of Ministers) (1992)

Abstract: This document recommends to governments of member states that they take account in their national health planning regulations and legislations of the conclusions and recommendations set out in this document. This document contains following parts: ethical and legal values; criteria for selecting diseases suitable for screening; economic aspects; quality assurance; organisation; research and general remarks.


Abstract: This document is the outcome of the Working Party’s discussions on the applications of genetics for health purposes, with a view to the elaboration of an additional Protocol to the Convention on Human Rights and Biomedicine. It provides recommendations on following elements: information to be given prior to consent or authorisation; general rule on consent; persons not able to consent; quality of genetic services; equitable access to genetic services;
genetic counselling; respect for private life and access to the results of an application of genetics; individual genetic tests on living persons, genetic tests on deceased persons; genetic screening for health purposes; research. There is also an explanatory note to the working document.

§ 2. European Group on Ethics and Science and New Technologies (EGESNT)

The Group is a neutral, independent, pluralist and multidisciplinary body, composed of fifteen experts appointed by the Commission for their expertise and personal qualities. The task of the Group is to examine ethical questions arising from science and new technologies and on this basis to issue Opinions to the European Commission in connection with the preparation and implementation of Community legislation or policies.

http://ec.europa.eu/european_group_ethics

A. Ethical aspects on prenatal diagnosis (1996, no. 6)

Abstract: The EGESNT opinion deals with prenatal diagnosis which allows the examination of pregnancies at high risk of fetal anomaly or genetic disease to rule out or confirm the presence of such an anomaly or disease using invasive techniques (amniocentesis, chorionic villus sampling or fetal blood sampling. It deals among other issues with the free and informed consent of the woman or couple concerned, genetic counselling and confidentiality of test results.

B. Ethical aspects of genetic testing in the workplace (2003, no. 19)

Abstract: The first part this Opinion describes the scientific background regarding genetic testing in the workplace. It explains genetic testing, the application of genetic testing in the context of employment, genes and diseases, the methodology for genetic testing, the validity, reliability and predictability of genetic tests, and the practice regarding employer utilisation of genetic testing. The second
part of this opinion describes the legal background at national, Community and international level. The third part of the Opinion discusses ethical issues that can be related either to the performance of the genetic testing itself, or to the use of the data which have been obtained by genetic testing.

§ 3. European Parliament. Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine

At the sitting of 13 December 2000 the European Parliament pursuant to Article 150(2) of the Rules of Procedure, adopted a decision on setting up a temporary committee on human genetics and other new technologies in modern medicine. To comply with its brief, the temporary committee appointed Francesco Fiori rapporteur at its constituent meeting of 16 January 2001. It considered the draft report at its meetings of 27 August, 10 September, 2, 8 and 10 October, 24 October and 5 and 6 November. The report was tabled on 8 November 2001.


Abstract: This document summarises the work of the Temporary Committee on Human Genetics, set up on 13 December 2000. After an introduction to the scientific aspects of human genetics, the description of the powers and responsibilities of the European Union in the field of human genetics and international and European legal instruments, the document has been seeking, on the one hand, to comprehend the potential medical applications of human genetics for the diagnosis and treatment of certain diseases, and on the other hand, it has been attempting to identify the consequences that might ensure from such applications, the use of genetic information, and the patentability of living matters.
§ 4. Nordic Committee on Bioethics

To further promote Nordic cooperation and exchange of information between scientists, parliamentarians and opinion leaders on ethical aspects of biotechnological research, development and application a Nordic committee on Bioethics was formed in 1989. The Committee is a regional initiative with representatives from Iceland, Denmark, Norway, Finland, Sweden and an observer from Faroe Islands.

http://www.ncbio.org

A. Ethics and genetic testing (1994)

Original name: Etik & Gentester. This document is not available in English.


Abstract: The report examines the appropriation of assisted reproductive technologies in the Nordic countries at the level of policy-making. It traces the policy designing process in each country from governmental committees or working parties to parliamentary proceedings. It describes formative events and debates. In the end, the report identifies some of the factors that account for the divergence of assisted reproductive technologies policies among the Nordic countries.
§ 5. European Commission Expert Group

An expert group was invited by the European Commission to discuss the ethical, legal and social implications of genetic testing over the course of one year. It included various disciplines and stakeholders who were already involved or particularly interested in the topic. Representatives came from the industry, from NGOs and scientists and representatives from academic institutions with different backgrounds specialised in the field. The participants came from various national backgrounds within Europe and numbers were well balanced between men and women. This expert group finished its activities after the publication of their recommendations.


A. 25 recommendations on the ethical, legal and social implications of genetic testing

Abstract: The 25 recommendations are organised intro three chapters addressing the general framework, the implementation of genetic testing in health care systems, and genetic testing as a research tool. The 25 recommendations try, where possible, to address the relevant actors. Sometimes they also take the tone of a ‘code of conduct’. Hence these recommendations should function partly as a ‘code of conduct’ for any actor in the field of genetic testing and partly as an ‘action plan for genetic testing’ to be implemented by policy-makers in the near future. These recommendations were discussed during a stakeholder conference organised by the European Commission on 6-7 May, 2004 in Brussels.
§ 6. European Society of Human Genetics (ESHG)

The European Society of Human Genetics (ESHG) is an international professional society founded in 1967 which promotes research in basic and applied human and medical genetics and facilitates contact between all persons who share these aims. The Public and Professional Policy Committee in the ESHG studies social and ethical issues related to developments in the field of genetics.

http://www.eshg.org

A. Population genetic screening programmes: technical, social and ethical issues

Abstract: Genetic screening is increasingly possible for a larger number of disorders. The question of whether or not this approach should be offered at the population level is a challenge to healthcare providers, the medical community and policy makers. Genetic screening can be of benefit but can also do harm. The availability of genetic tests at low cost may lead to the systematic offer of screening tests without the appropriate medical environment for providing information prior to testing and counselling afterwards. There is therefore a need to introduce effective and acceptable safeguards, standards and procedures relating to the implementation and organisation of genetic screening programmes. This document offers the recommendations from the Public and Professional Policy Committee of the European Society of Human Genetics.

B. Genetic information and testing in insurance and employment: technical, social and ethical issues (2000)

Abstract: One of the more complex policy issues accompanying developments in genetic knowledge relates to how personal genetic information, such as the results of genetic tests are to be used. To discuss these issues as they relate to insurance and employment and produce recommendations from the professional point of view, the Public and Professional Policy Committee (PPPC) of the European
Society of Human Genetics organized a workshop in February, 2000 in Manchester (UK) to which 47 experts from 14 European countries were invited. Based on their working paper and this workshop, the PPPC issued this document in which it formulates recommendations regarding genetic information and insurance and employment.

C. Provision of Genetic Services in Europe: Current Practices and Issues

Abstract: This document offers the recommendations from the Public and Professional Policy Committee of the European Society of Human Genetics about the provision of genetic services in Europe. It discusses following elements: aims and scope of genetic services; regulation and access; consent, information and counselling; rare genetic diseases; genetic influences in common diseases; education and training of non-specialist providers; moving from research to clinics.


Abstract: The purpose of this document prepared by the Public and Professional Policy Committee of the European Society of Human Genetics together with the European Society of Human Reproduction and Embryology was to outline a framework for development of guidelines for the interface between genetics and assisted reproductive technologies (ART). The document discusses the goals of services and current possibilities, genetic studies of IVF couples, preimplantation genetic diagnosis and screening, selection of donors based on genetic information, counselling in the relation of genetics and ART, potential adverse effects of ART, quality and safety of procedures, research framework, public health dimension/public policy, ethical questions, psychological issues, and scenarios for the future.
§ 7. **European Society of Human Reproduction and Embryology (ESHRE)**

The European Society of Human Reproduction and Embryology (ESHRE) was officially founded in 1985. The main aim of ESHRE is to promote interest in, and understanding of, reproductive biology and medicine. It does this through facilitating research and subsequent dissemination of research findings in human reproduction and embryology to the general public, scientists, clinicians and patient associations; it also works to inform politicians and policy makers throughout Europe. On a more applied level, it aims to promote improvements in clinical practice through organizing teaching, training and continuing medical education activities, developing and maintaining data registries and implementing methods to improve safety and quality assurance in clinical and laboratory procedures.

[http://www.eshre.com](http://www.eshre.com)

A. **Taskforce 5: Preimplantation genetic diagnosis (2003)**

**Abstract:** The ESHRE Ethics Task Force sets out a recommended multidisciplinary approach to the application of preimplantation genetic diagnosis (PGD). The statement includes consideration of fundamental ethical principles, specific problems in cases of high genetic risk, and PGD for aneuploidy screening, HLA typing and sex selection for non-medical reasons.

B. **Taskforce 9: The application of preimplantation genetic diagnosis for human leukocyte antigen typing of embryos (2005)**

**Abstract:** This document from the ESHRE Taskforce on Ethics and Law considers ethical questions and specific dilemmas concerning preimplantation genetic diagnosis for human leukocyte antigen typing of embryos. This application is particularly complex because the interests of the sick child needing a transplantation should be balanced against the interests of the future donor child who may result from the
technique. It is concluded that, if parents intend to love the child, the creation and use as a donor is not inherently disrespectful.


Abstract: See European Society of Human Genetics

D. ESHRE PGD Consortium ‘Best practice guidelines for clinical preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS)

Abstract: The guidelines of the ESHRE are not intended as rules or fixed protocols that must be followed, nor are they legally binding. The unique needs of individual patients may justify deviation from these guidelines, and they must be applied according to individual patient needs using professional judgment. These guidelines provide recommendations on following issues: organization of PGD/PGS centres; counselling, informed consent and approval (genetic counselling, treatment-related counselling, psychological evaluation, approvals); patient inclusion/exclusion criteria; referrals; clinical IVF protocol; embryo culture and biopsy; FISH-based diagnosis; PCR-based diagnosis; embryo-transfer; quality control and quality assurance.

§ 8. Conference of European Churches

The Conference of European Churches (CEC) is a fellowship of 126 Orthodox, Protestant, Anglican and Old Catholic Churches from all countries of Europe, plus 43 associated organisations. CEC was founded in 1959. It has offices in Geneva, Brussels and Strasbourg.

http://www.cec-kek.org
A. Genetic testing and predictive medicine (2003)

**Abstract:** The Commission for Church and Society of the Conference of European Churches (CEC) has approved a document on the issue "Genetic testing and predictive medicine". While welcoming developments in medical genetics, the document points out the "real difficulties" brought about by predictive medicine, namely the risk of fostering a vision of the future as an inescapable fate and the risk of discrimination linked to the search for the "perfect child". The document has been prepared by the Working Group on Bioethics of the Commission for Church and Society of CEC. The group is composed of scientists and theologians from different European countries.

§ 9. EuropaBio

EuropaBio is the political voice of the biotechnology industry in Europe. This association of biindustries has some 60 corporate members operating worldwide, 14 associates, 5 regions and 25 national biotechnology associations, representing 1500 small and medium sized biotech companies in Europe. Members of EuropaBio are involved in research, development, testing, manufacturing and commercialisation of biotechnology products and processes. Their corporate members have a wide range of activities: human and animal health care, diagnostics, bio-informatics, chemicals, crop protection, agriculture, food and environmental products and services.

http://www.europabio.org


**Abstract:** This position paper has been prepared by EuropaBio and includes input from independent experts. It is intended for policy makers and the public at large. The document has following structure: introduction: genetic tests and disease – definitions; human medical genetic information; technical, developmental and regulatory aspects
of human medical genetic tests; counselling; societal, ethical, and legal aspects.

§ 10. European Trade Union Confederation

The European Trade Union Confederation (ETUC) was set up in 1973 to promote the interests of working people at European level and to represent them in the EU institutions. The ETUC is one of the European social partners and is recognised by the European Union, by the Council of Europe and by EFTA as the only representative cross-sectoral trade union organisation at European level.

http://www.etuc.org

A. European Trade Union Confederation’s view on genetic testing and the workplace

Abstract: This document represents the opinion of the European Trade Union Confederation on genetic testing and the workplace. The full text can not be downloaded or printed, but can be read at http://hesa.etui-rehs.org/uk/newsevents/files/EGE-EN.pdf
§ 1. UNESCO. General conference

The General Conference of the Unesco (United Nations Educational, Scientific and Cultural Organization) consists of the representatives of the States Members of the Organization. It meets every two years, and is attended by Member States and Associate Members, together with observers for non-Member-States, intergovernmental organizations, non-governmental organizations (NGOs). The General Conference determines the policies and the main lines of work of the Organization.

http://www.unesco.org

A. Universal declaration on the human genome and human rights (1997)

Abstract: Following issues are treated in this document: human dignity and the human genome project; rights of the persons concerned; research on the human genome; conditions for the exercise of scientific activity; solidarity and international cooperation; promotion of the principles set out in the Declaration; implementation of the Declaration.


Abstract: After some general provisions and explanation of terminology, following issues are treated in this document: procedures; non-discrimination and non-stigmatization; data collection (consent, withdrawal of consent, the right to decide whether or not to be informed about research results, genetic counselling, collection of biological samples for forensic medicine or in civil, criminal or other legal proceedings), processing of genetic data (access, privacy and confidentiality, accuracy, reliability, quality and
security); the use of genetic data (change of purpose, stored biological samples, circulation and international cooperation, sharing of benefits), storage (monitoring and management framework, destruction, cross matching), promotion and implementation (implementation; ethics education, training and information; Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC); denial of acts contrary to human rights, fundamental freedoms and human dignity).

§ 2. UNESCO. International Bioethics Committee

The International Bioethics Committee (IBC) is a body of 36 independent experts that follows progress in the life sciences and its applications in order to ensure respect for human dignity and freedom. It was created in 1993. It is part of UNESCO - the United Nations Educational, Scientific and Cultural Organization that was founded on 16 November 1945

http://www.unesco.org

A. Report on genetic screening and testing (1994)

Abstract: This report has been prepared on behalf of a Subcommittee established by the International Bioethics Committee by UNESCO. It has been amended in the light of discussion both by the Subcommittee and by the full IBC at its September 1994 meeting. The structure of the report is as follows: what are the problems and why are these problems pressing?; the ethical issues to be faced; contribution to a possible declaration; contribution to a possible convention.


Abstract: This report on genetic counselling and its bioethical implications is a natural extension of the 1994 Report on genetic screening. This report examines first the scope and practice of genetic counselling today (definition, professional qualification and certification, accessibility to genetic counselling, time of counselling,
information provided, language, government involvement, and public authorities) then bioethical issues related to scientific questions (genetic technologies and gene categories), to welfare of the persons receiving counselling and finally to moral issues for society at large.


Abstract: In order to ensure respect for the dignity of the human person, the Universal Declaration on the Human Genome and Human Rights proclaimed the confidentiality of genetic data. This confidentiality, thus affirmed, seeks to protect the individual against the disclosure of the data that belongs to him. However, while this principle of confidentiality is recognised, its protection must necessarily be regulated. This report identifies different kinds of genetic data and studies in detail the principle of confidentiality in relation to genetic data. It focuses on the features of the principle, the issue of disclosure (to the person concerned, to family members, to third parties). In addition, the report studies limitations on the principle of confidentiality and awareness-raising and education.


Abstract: The purpose of this report is to describe PGD and discuss the major ethical issues related to its application and to review the ethical aspects of germ cell intervention in this context. It discusses following elements: preimplantation diagnosis (methodology, indications, organization and regulation, comparison between PGD and prenatal diagnosis, extension of indications for PGD, ethical considerations) aneuploidy testing to improve IVF results and germ-line intervention. It concludes the report with an analysis of future developments and dilemmas.
§ 3. World Health Organization

The World Health Organization is the United Nations specialized agency for health. It was established on 7 April 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health. WHO is governed by 193 Member States through the World Health Assembly. The Genomic Resource Centre has been developed by WHO's Human Genetics to provide information and to raise awareness on human genetics and human genomics.

http://www.who.org

A. Statement of WHO expert advisory group on ethical issues in medical genetics (1998)

Abstract: A meeting of WHO experts in genetics was convened in Geneva, Switzerland, from 15 to 16 December 1997, to review proposed international guidelines on ethical issues in medical genetics and genetic services. The recommendations offered in this document focus on general ethical considerations, the proper use of genetic data, voluntary use of genetic screening and testing, genetic screening and testing, genetic testing in pregnancy, reproductive cloning in humans, equitable access, genetic samples from individuals and families, confidentiality of genetic data, genetic counselling, patenting, somatic cell gene therapy, education in genetics.

B. Proposed international guidelines on ethical issues in medical genetics and genetic services. Report of a WHO meeting (1998)

Abstract: The content of this document was unanimously agreed upon by the experts present at the WHO meeting on ethical issues in medical genetics in Geneva on 15-16 December 1997. The document studies following components: ethical principles in medicine, goals and practices of medical genetics, application of ethical principles to genetic services, genetic counselling, genetic screening and testing, informed consent and genetic testing, presymptomatic and

Abstract: The document reviews ethical issues in medical genetics and genetic services. The recommendations in this document do not have the level of consensus among professionals that was reached in the Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services, but they are intended as points of departure for genetics professionals and public health officials to develop policies and practices in their own nations. This document discusses ethical problems in medical genetics today in developed and developing nations. These problems include equitable access to services, voluntary versus mandatory counselling, testing and screening, safeguarding of individual and parental choices, full disclosure of information, confidentiality versus duties to relatives at genetic risk, privacy of genetic information from institutional third parties, directive versus non-directive counselling, non-medical uses of prenatal diagnosis (including sex selection), and issues in research and gene therapy.

§ 4. Organization for economic co-operation and development (OECD)

The Organisation for Economic Co-operation and Development is a forum where the governments of 30 market democracies work together to address the economic, social and governance challenges of globalisation as well as to exploit its opportunities. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and co-ordinate domestic and international policies.

http://www.oecd.org
A. Genetic testing. Policy issues for the new millennium (2001)

**Abstract:** Genetic tests are being developed at an impressive rate and a significant number has already reached the market. Substantial involvement of the private market has led to unprecedented growth in commercial genetic testing services and in trade of such services. This trend is expected to increase as knowledge gained from the mapping of the human genome and of single nucleotide polymorphisms is applied to the identification of disease-causing genes and of inherited differences in drug responses. The potential socio-economic and ethical impacts are staggering. This report provides a state-of-the-art review of advances in genetic testing and of main international policy concerns drawing from the OECD workshop on “Genetic testing: Policy issues for the new millennium”, held in Vienna on 23-25 February 2000.

§ 5. **World Medical Association**

The World Medical Association (WMA) is an international organization representing physicians. It was founded on 17 September 1947, when physicians from 27 different countries met at the First General Assembly of the WMA in Paris. The organization was created to ensure the independence of physicians, and to work for the highest possible standards of ethical behaviour and care by physicians, at all times. This was particularly important to physicians after the Second World War, and therefore the WMA has always been an independent confederation of free professional associations. Funding has been by the annual contributions of its members, which has now grown to approximately 80 National Medical Associations.

[http://www.wma.net](http://www.wma.net)


**Abstract:** This document has been adopted by the 39th World Medical Assembly Madrid, Spain, October 1987 and rescinded at the WMA General Assembly, Santiago 2005. The World Medical
Association has adopted the following statement to assist physicians with the ethical and professional issues that arise from scientific advances in the field of genetics. It offers recommendations on genetic counselling and genetic engineering.

B. Statement on genetics and medicine (2005)

Abstract: This document has been adopted on the WMA General Assembly, Santiago 2005. Genetics is an area of medicine with enormous medical, social, ethical and legal implications. The WMA has developed this statement in order to address some of these concerns and provide guidance to physicians. These guidelines should be updated in accordance with developments in the field of genetics.

§ 6. International Federation of Gynecology and Obstetrics (FIGO)

FIGO – the International Federation of Gynecology and Obstetrics – is a worldwide organisation that groups obstetricians and gynecologists. The mission of FIGO is to promote the well-being of women and to raise the standard of practice in obstetrics and gynecology. FIGO has grown from an organisation representing the forty-two national societies which attended the founding meeting on the 26th of July, 1954, in Geneva into an organisation representing obstetricians and gynecologists worldwide. FIGO is a benevolent, non-profit organisation composed of 113 member societies.


Abstract: In 1985 FIGO set up the Committee for the Ethical Aspects of Human Reproduction and Women’s Health. The main objectives of the committee focus on recording and studying the general ethical problems which emanate from research and practice in women’s health as well as bringing these issues to the attention of physicians.
and the public in developed and developing countries. This document regroups recommendations that have been published since 1985. It provides guidelines about general issues in women’s health and advocacy, issues in genetics and pre-embryo research, issues in conception and reproductive endocrinology, issues regarding pregnancy and maternal/fetal issues, issues regarding neonates, issues in contraception and abortion, issues in advertising and marketing health services.

§ 7. International Society of Nurses in Genetics (ISONG)

The International Society of Nurses in Genetics (ISONG) is a global nursing specialty organization dedicated to fostering the scientific and professional growth of nurses in human genetics and genomics worldwide.

http://www.isong.org

A. Informed decision-making and consent: the role of nursing (2000)

Abstract: The indispensable initial step in the preparation for genetic testing is the process of ‘informed consent’. According to the ISONG, nurses have a central role to play in providing information and support to individuals, families and communities in the multiphase processes of genetic testing. With genetics knowledge, nurses can advocate, educate, counsel and support patients and families during the informed decision making and consent process. This position statement offers some recommendations about the role of nursing in informed decision-making and consent.

B. Privacy and Confidentiality of Genetic Information: The Role of the Nurse (2001)

Abstract: This document was drafted by the ISONG Ethics & Social Policy Committee. In summary, privacy and confidentiality of all health information is of great concern to nurses in all practice settings.
Assuring privacy and confidentiality of genetic information, in particular, demands continued vigilance on the part of all nurses as genetic technologies and discoveries are translated into clinical application and practice.

C. Genetic counselling for vulnerable populations: the role of nursing (2002)

**Abstract:** Nurses in all practice settings care for vulnerable clients and populations with genetic-related health concerns, and share with other team members the responsibility to ensure that optimum and appropriate genetic counselling is made available. This can be accomplished through nursing participation in the genetic counselling process, wherein counselling methods and outcomes have been tailored to most directly and efficiently address client-centred goals of persons from vulnerable populations. This guideline addresses the role of nursing in genetic counselling.


**Abstract:** This document recognizes the role of genomics as an integral component in the promotion of public’s health and wellbeing. It advocates and promotes the right of the individual or family to voluntarily choose or not choose to seek genomic healthcare services.

§ 8. Disabled Peoples’ International

Disabled Peoples’ International (DPI) is a human rights organization committed to the protection of disabled people’s rights and the promotion of their full and equal participation in society. Established in 1981, DPI is represented through active membership of national organizations of disabled people in over 130 countries.

[http://www.dpi.org](http://www.dpi.org)
A. Disabled people speak on the ‘new genetics’

**Abstract:** Recognizing that advances in human genetics and medical-based quality of life decisions raise serious ethical issues for both disabled and non-disabled people, the organization Disabled People International discusses issues which must be considered within the framework of enduring diversity of humankind. It discusses in particular prenatal screening and testing, pre-implantation genetic diagnosis, infanticide on the grounds of impairment, euthanasia, genetic determinism, gene therapy and gene patenting.

§ 9. **International Huntington Association**

The International Huntington Association (IHA) is a federation of national voluntary health agencies that share common concern for individuals with Huntington's Disease (HD) and their families. Each agency promotes lay and professional education; individual and family support; psycho-social, clinical and biomedical research; and ethical and legal considerations related to Huntington's Disease in its respective country.

[http://www.huntington-assoc.com](http://www.huntington-assoc.com)

A. Guidelines for the molecular genetics predictive test in HD (1994)

**Abstract:** This document offers recommendations concerning the use of a predictive test for the detection of Huntington Disease. These recommendations were drawn up by a committee consisting of representatives of the International Huntington Association and the World Federation of Neurology Research Group on Huntington’s chorea.
§ 10. International Society for Neonatal Screening

The society has the objective of promoting the carrying out of appropriate screening for foetal, neonatal and infant sicknesses and disorders, worldwide. It intends to achieve this objective by developing, coordinating and maintaining practice and quality standards; carrying out or commissioning scientific research and the enlargement of scientific knowledge concerning neonatal screening by means of meetings, symposia, discussions, reports and publications; contributing to development and teaching; harmonizing screening programs, methods and protocols.

环节 http://www.isns-neoscreening.org

A. ISNS general guidelines for neonatal screening (s.d.)

Abstract: This document contains following sections: neonatal, an accepted medical intervention; general recommendations; organization of programmes; legal and ethical considerations; research; recommendations for screening for specific disorders.
N° 1 – H. NYS, et al., “Patient Rights in the EU – Czech Republic”, 

N° 2 – H. NYS, et al., “Patient Rights in the EU – Denmark”, 