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Final Report

Submitted by the Study Commission on "Law and Ethics in Modern Medicine"*

* Set up by the German Bundestag through a decision adopted on 24 March 2000 – Bundestag Document 14/3011

Final report in connection with:

Interim Report of the Study Commission on "Law and Ethics in Modern Medicine"
Subreport on the Topic of Intellectual Property Rights in Biotechnology (Bundestag Document 14/5157)

Second Interim Report of the Study Commission on "Law and Ethics in Modern Medicine"
Subreport on Stem Cell Research (Bundestag Document 14/7546)

Preface

The knowledge and skills mastered by researchers in biomedicine today are growing at a breathtaking pace. Proactive interventions are nowadays possible in borderline situations of human existence where in the past people knew they were in the hands of fate, chance or God Almighty (procreation, birth and death, disease and disability). This gives rise to hopes, but also to fears.

One must distinguish between areas in which new findings can be expected to be beneficial and other areas in which they will involve risks. Criteria to make this distinction can be derived from ethics for the individual and from law for society as a whole. While ethics and law are not identical, both are closely connected. This is clearly illustrated by the fundamental rights enshrined in the German Constitution. Voluntary compliance with the law can only be expected if the law is in keeping with a society's values, and hence, appears to be plausible and right.

The plurality of outlooks on life in our society leads to not only a diversity of values but also uncertainty as far as values are concerned. In the case of biomedicine, this is aggravated by the fact that scientific progress is nowadays achieved through international co-operation, so that different value systems are bound to clash with each other. The dichotomy between rejection and acceptance, between fears and hopes can lead to conflicts in society. The task of legislation in this context is to create legal certainty. However, legal instruments will only be convincing if they are the result of a debate with the public and if all relevant aspects have been taken into consideration by the German Bundestag in its deliberations.

After having previously submitted two Interim Reports, the Study Commission on "Law and Ethics in Modern Medicine" is now submitting its Final Report. Unfortunately, there are still some "white spots" that have yet to be resolved with regard to many fields of action in modern medicine because time was too short to deal with these topics. Perhaps one of the most important achievements of the Study Commission – in addition to its reports – has been its contribution to a broadly-based public debate and the development of a debate culture that is appropriate to the subject. In its Final Report, the Study Commission presents not only the written findings of its work but also a method for finding a consensus against the background of a passionate ethical controversy.

I would like to thank the experts as well as the staff in the secretariat and in the MP offices for the work they have done in the Study Commission.

Margot v. Renesse

Chairwoman of the Study Commission on

"Law and Ethics in Modern Medicine"

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[1] In addition, the Study Commission has submitted the following interim reports:
- Interim Report of the Study Commission on "Law and Ethics in Modern Medicine" – Subreport on the Topic of Intellectual Property Rights in Biotechnology (Bundestag Document 14/5157)
- Second Interim Report of the Study Commission on "Law and Ethics in Modern Medicine" – Subreport on Stem Cell Research (Bundestag Document 14/7546)

See the Annex of the present report for detailed tables of contents of these interim reports.

A Introduction

The Commission's Brief

Continuous progress achieved in biology and medicine gives rise to fundamental ethical and legal questions and problems that call for considerable discussion in society and pose a challenge for the legislator.

Against this background, the German Bundestag – with the approval of all the parliamentary groups – decided on 24 March 2000 to set up the Study Commission on "Law and Ethics in Modern Medicine". The mandate given to the Study Commission was to study medical progress, practical research as well as associated questions and problems, taking into consideration ethical, constitutional, social, legistlative and political aspects, and to prepare the ground and pave the way for necessary decisions to be taken by the German Bundestag. In particular, the Commission was asked to develop "recommendations for an ethical assessment of, potential ways for society to deal with, and legislative as well as administrative action with regard to, medical issues affecting the future".

More specifically, the Study Commission was given the following mandate (Bundestag Document 14/3011):

> "to describe the status quo with regard to major current and future trends and associated problems in modern medical research, diagnosis and treatment, taking into consideration ethical, constitutional, social, legislative and political aspects;
>
> to examine the pertinent research practice and in particular to draw attention to areas not covered by legislation or only inadequately so;
>
> to develop criteria for defining limits to be imposed on medical research, diagnosis and treatment and their applications, reflecting the unconditional respect for human dignity."

In addition, the German Parliament requested that the Commission should participate in the deliberations on draft legislation and in the preparation of decisions to be taken by the German Bundestag in areas affecting the Commission's programme of work. Furthermore, the Commission's work was intended to stimulate a more profound public discourse on issues associated with the development and application of biotechnology and modern medicine.

Composition of the Study Commission

The Commission was composed of 13 members of Parliament as well as 13 experts who could not be members of the German Bundestag or of the German Federal Government. The parliamentary groups of the German Bundestag appointed 13 parliamentarians as deputy members. The Commission members were nominated by the parliamentary groups represented in the German Bundestag and appointed by the President of the German Bundestag.[2]

Margot v. Renesse, Member of Parliament for the SPD, was appointed Chairperson of the Study Commission on "Law and Ethics in Modern Medicine", and Hubert Hüppe, Member of Parliament for the CDU/CSU, was appointed Deputy Chairman.

The administration of the German Bundestag established a secretariat to provide organisational and academic support to the Study Commission.[3]

The Commission's Method of Work

At the beginning of its deliberations, the Commission selected three key areas of modern medicine for its work, each of which was dealt with by one of the Commission's dedicated issue groups:

– Reproduction Medicine and Embryo Protection (Issue Group 1);

– Applied Medical Research / New Diagnostic and Therapeutic Methods (Issue Group 2);

– Genetic Data (Issue Group 3).

Based on intensive discussions and in-depth talks with external experts, the issue groups prepared drafts for the relevant chapters of the Commission's reports. These drafts, which were developed in the course of 25 meetings (Issue Groups 1 and 3) and 30 meetings (Issue Group 2), included not only a description of the current status with regard to the issues and relevant discussions, but also proposals for an assessment of, as well as recommendations on, the various issues.

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[2] Cf. Art. 56(2) of the German Bundestag's Rules of Procedure for more information on the nomination of members. See G, Annex 6 for more information on the Study Commission members.

[3] Cf. G, Annex 7 for more information on the Commission's secretariat.

The drafts of the report segments drawn up by the issue groups as well as other working papers prepared by members of the Commission were used as a basis for the plenary deliberations of the Commission during a total of 37 meetings. On 29 April 2002, the Commission members voted unanimously in favour of adopting the Commission's Final Report and thus concluded its deliberations.

In addition to benefiting from the knowledge and experience of its members, the Commission drew on a variety of external information sources in its work.

1. Public hearings and exchanges of information

   The Commission held four public hearings. With the public hearing on a "European Discourse on Ethical Issues in Modern Medicine" held on 19 November 2001, the Commission also hoped to accelerate an international networking of discourses on biopolitical issues.[4]

2. Talks with external experts

   Between May 2000 and April 2002, the Commission's issue groups invited external experts for an exchange of information in the framework of a total of ten non-public hearings.[5]

3. Written statements submitted by external experts

   In order to prepare its public and non-public hearings as well as exchanges of information, the Commission asked external experts to submit written statements.

4. Expert opinions

   A total of seven expert opinions on key problem areas were prepared on behalf of the Commission.[6]

5. Fact-finding missions by delegations

   Finally, there were also fact-finding missions by delegations in order to collect information on the current status of discussions on, or attitudes to, biopolitical issues. From 23 April 2001 to 1 May 2001, members of the Commission visited the United States. Another group of Commission members visited the United Kingdom and Iceland from 17 to 22 September 2001.

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[4] Cf. Overview of Public Hearings in G, Annex 8.
[5] Cf. Overview of Non-public Hearings of Experts by Issue Groups in G, Annex 9.
[6] Cf. Overview of Expert Opinions in G, Annex 11.

Interim Reports

In the course of its work, the Study Commission has submitted two interim reports:

1. Interim Report on the "Protection of Intellectual Property in Biotechnology"

   The title of the First Interim Report, which was completed in January 2001, was "Interim Report on the Protection of Intellectual Property in Biotechnology" (Bundestag Document 14/5157). The Commission used the opportunity provided by the preparations for translating the European Union's Biopatent Directive into German law to present the results of its deliberations on future developments for the protection of biotechnological inventions.

2. Interim Report on "Stem Cell Research"

   In November 2001, the Commission presented its Second Interim Report on "Stem Cell Research" (Bundestag Document 14/7546) to the German Bundestag. This report was drawn up on the basis of a relevant mandate assigned by the German Bundestag on 5 July 2001. At the time, the Bundestag decided to deal with the question of research into imported, human and pluripotent embryonic stem cells before the end of the year and to take into consideration an opinion submitted by the Study Commission on this issue (Bundestag Document 14/6551).

Expert Opinion

In accordance with its mandate, the Commission was expected to participate in preparing decisions to be taken by the German Bundestag during the ongoing legislative period. For this reason, in February 2002, it submitted an expert opinion on the draft of a Stem Cell Act[7].

Involvement of the Public

The Commission had been asked by the German Bundestag to ensure that interested groups in society, institutions and associations as well as the Churches would be adequately involved in its deliberations and to make a contribution toward stimulating a more profound public discourse on emerging medical issues that will be relevant in the future.

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[7] Bill submitted by Dr. Maria Böhmer, MP; Wolf-Michael Catenhusen, MP; Andrea Fischer (Berlin), MP, and others; Bill designed to safeguard the protection of embryos in connection with the import and use of human embryonic stem cells (Stem Cell Act) (Bundestag Document 14/8394).

In order to fulfil this obligation, the Commission organised several public dialogue events that were designed to give citizens as well as professionally interested individuals and pressure groups an opportunity to have a dialogue with the members of the Commission.

The first public dialogue event of the Commission, which took place on 11 December 2000 in Bethel, was devoted to the two topics "What should modern medicine be like?" and "Individuals incapable of giving their consent and medical research".

A second dialogue event, which was held on 26 March 2001 at the Humboldt-Universität in Berlin, dealt with the topic of "Using Genetic Data".

A third public dialogue event organised by the Commission was held on 2 July 2001 at the Friedrich-Schiller-Universität in Jena. This event was focused on the "Doctor/Patient Relationship" as well as "Hospices, Terminal Care and Euthanasia".

In order to be able to involve the interested public more effectively in its discussions, the Commission also made use of the Internet by establishing online forums and by carrying out online conferences. At www.bundestag.de/medizin, interested individuals were able to download a variety of documents and sources of information which the Commission had made available.

B Ethical and Legal Landmarks

1 Human dignity / human rights

Human dignity, as well as the basic and human rights ensuing from human dignity, constitute the fundamental yardstick to be applied to any ethical and legal assessment of modern medicine. When establishing the Study Commission on "Law and Ethics in Modern Medicine"[8] and in its policy debate of 31 May 2001 on biotechnology and modern medicine (Plenary Minutes 14/173), the German Bundestag underlined that human dignity was a binding principle for any policy on biomedicine. In the discussion on the ethical and legal criteria to be applied when assessing new possibilities offered by modern medicine, there were frequent references to human dignity and human rights.[9]

Relevant texts adopted by the Council of Europe, UNESCO and the United Nations on questions of bioethics show that the concept of human dignity and human rights also plays a particular role in the international discussion on questions of biomedicine. Starting from the Anglo-Saxon countries, there are basically two approaches: one is the deontological approach (i.e. based on the concept of professional duties or legal ethics), and the other is the consequential approach (i.e. focusing exclusively on the *consequences* of actions).[10]

It is difficult to form an opinion based on the concept of human dignity because the term itself is used in a variety of different contexts. There has been a long-standing philosophical discussion about human dignity, as well as interpretations under constitutional law and the use of the term in colloquial language – and the meanings ascribed to human dignity in these different uses are not identical. Some bioethics experts explicitly reject the notion of human dignity and ethical standards associated with this notion because they suggest that such notions and standards are based on ideological convictions for which there is no longer any foundation in a secularised society.

On the other hand, the Study Commission has worked on the assumption that, even in a secularised society, actions must be guided by generally binding principles that underlie any decision-making process of weighing the pros and cons in a particular case. Furthermore, the

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[8] The task of the Commission is in particular "to develop criteria for establishing limits to medical research, diagnosis and therapy as well as their applications, including the absolute principle of the respect for human dignity" (Bundestag Document 14/3011).

[9] Baumgartner et al. 1997; Benda 2001; Braun 2000b; Braun 2001b; Dörr et al. 2000; Geyer 2001; Graumann 2001a; Höffe 2001; Knoepffler/Haniel 2000; Lauffs 2001; Luther 2001b; Reiter 2001; Rendtorff 2000; Schneider 2000; Schwartländer 1998; Spaemann 2001a;Werner 2000 and others.

[10] This approach is also applied in Germany (Birnbacher 1997; Hoerster 1995;1998; Merkel 2001).

Commission has assumed that the concepts of human dignity and human rights provide an indispensable framework for dealing with issues of modern medicine from the perspective of ethics and legal ethics.

1.1 The evolution of, and rationale for, the concept of human dignity

In ancient philosophy, the term "dignity" is used in two different contexts.[11] On the one hand, "dignity" describes the outstanding rank of an individual in society. "Dignity" is primarily used in this context to describe an individual's achievement or function in society. When "dignity" is used with this meaning, individuals can have more or less dignity. This meaning reflects an achievement-oriented concept of human dignity.

However, in the Ancient World, there was also the notion that "dignity" was what distinguished human beings from other creatures and that, hence, dignity was intrinsic in every human being and that it was inalienable. This concept of human dignity is universal because it encompasses all human beings by virtue of the fact that they are human.

According to Christian belief, human beings were created by God in his image.[12] When perceived in this way, human dignity is based on the belief that human beings are God's image and directly related to God, as confirmed also by the incarnation of God in Jesus Christ.

During the Renaissance period, the Italian humanist Pico della Mirandola emphasised the idea of freedom in connection with the notion that human beings have been created in God's image. Pico della Mirandola suggested that human dignity was based on the ability of human beings to generate themselves through the exercise of freedom.

In the Modern Age and the Age of Enlightenment, attention focused increasingly on the idea of the self-determination of human beings through the exercise of reason as an inherently human characteristic. According to the French philosopher Blaise Pascal, human dignity was derived from the qualification of human beings as rational beings. Samuel Pufendorf, whose tenets influenced the American Declaration of Human Rights of 1776, linked this idea of human beings as rational creatures with that of the equality of all human beings, since all human beings had this characteristic by virtue of their human nature.

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[11] For more information on the evolution of the concept of human dignity, cf. Horstmann 1980, p. 1126; Spaemann 1987; Bayertz 1999.

[12] Genesis 1, 26-27.

The concept of human dignity also played an important role in the philosophy of Immanuel Kant, who uses the concept of human dignity as derived from Jewish-Christian tradition and gives it a secularised meaning that transcends the religious context.

Approximately in the middle of the 19th century, the concept of human dignity became a guiding political notion of the labour movement. Demands for an existence in human dignity and conditions fit for human beings were among the primary concerns of the early Socialists. The German philosopher and social critic Karl Marx wrote in his Contribution to the Critique of Hegel's Philosophy of Right:

> "The criticism of religion ends with the teaching that man is the highest essence for man – hence, with the categorical imperative to overthrow all relations in which man is a debased, enslaved, abandoned, despicable essence …"[13]

In Germany's legal tradition, particular importance is attached to Kant's rationale for human dignity. In the "kingdom of human ends", Kant distinguishes between that which has a price and that which has a dignity:

> "Whatever has a price can be replaced by something else as its equivalent; on the other hand, whatever is above all price, and therefore admits of no equivalent, has a dignity."[14]

Having a price means being replaceable by something else, and hence, being a means to another end, while having dignity means being an end in itself. Only an essence that is capable of setting ends for itself can qualify as the ultimate reference point, i.e. as an end in itself for any setting of ends. The reason why human nature has dignity is, according to Kant, man's moral autonomy, i.e. man's ability to submit to the moral law of his own free will, i.e. to be moral. The reason for human dignity is man's moral ability.

According to Kant, having human dignity means being able to claim to be treated "always as an end and never as a means only"[15], i.e. not to be instrumentalised in one's individual essence. No human being should be treated only as a means to the ends of others. The subject of human dignity must not be made a mere object at the disposal of another person's will. Furthermore, the dignity of each human being must not be offset against other ends – otherwise it would not be dignity, but only one value among others.

[13] Marx 1982, p. 177.
[14] Kant 1980, p. 68.
[15] Kant 1980, p. 61.

Another interpretation of Kant is based on the concept of humanity[16] developed by Kant as a regulative idea of humanity demanding a sense a duty from the individual, as well as Kant's philosophy of history. Kant suggests that it is not possible for reason to develop fully in the individual human being but only in all of humanity as a species. According to Kant, the "idea of humanity" is embodied in each human being and makes each human being a bearer of dignity.

The idea of human dignity has also been subject to critical arguments, relating on the one hand to the substance of, and the rationale for, human dignity or the underlying moral philosophical concept of Immanuel Kant, and on the other hand, the scope of human dignity at the beginning and at the end of life.

It was argued, for instance, by Arthur Schopenhauer[17] and others that the concept of human dignity did not have any normative substance of its own and that, furthermore, it combined various contradictory moral rights (human rights). However, particularly if there are conflicts between basic rights (e.g. in the discussion on euthanasia, which involves a conflict between the right of self-determination and the right to live), it is important to uphold not only the various basic rights but also the inviolability of human dignity as a moral or legal claim in its own right and to identify human dignity as the normative ground from which the various human rights can be derived, differentiated from each other and further developed.

Some also argued that Kant's notion of dignity was based on a concept of autonomy and transcendental freedom that could only be justified at the expense of controversial metaphysical assumptions.

As a consequence of this realisation, two approaches were pursued in moral philosophy. One approach does without any moral justification, while the other tries to find a secular justification for moral principles. Although supported by many contemporary bioethicists, the first approach has proven to be inadequate because it does not provide any guidance on how to resolve contentious issues: The actual behaviour of human beings alone cannot be used to draw conclusions about the normative correctness of such behaviour. On the other hand, it is not possible to do completely without such conclusions. While it may make sense in some cases to leave the question of the validity of specific moral standards open, when it is difficult to settle these questions directly, and instead to limit oneself to the plausibility of medium-

[16] Braun 2000b, p. 67 ff.
[17] Schopenhauer 1988, p. 412.

range standards or justifications based on context or procedure, this does not eliminate the presumed binding effect of moral rules and their need for justification or their redeemability in principle. Moral communication can therefore not do without having recourse to justified values and norms.

For this reason, modern ethics also uphold the principle of the justifiability of moral rules; however, the question as to whether this justifiability can be redeemed by having recourse to something absolute or ultimate (Karl-Otto Apel[18], Alan Gewirth[19] and others) or to the best achievable plausibility (Ernst Tugendhat[20] and others) or to the prerequisites assumed in each communicative discourse (Jürgen Habermas[21], Karl-Otto Apel[22]). Kant is drawn on in the first and last position, since Kant already starts from the assumption that in all instances where moral standards are perceived to be obligatory the validity of the moral obligation is taken for granted and that it can be demonstrated merely by having recourse to the "fact" of the reason of moral judgement.

To this end, Jürgen Habermas draws attention to moral communication: Moral communication replaces the individual human being's reason and moral laws. In moral communication, the participants decide on the validity of moral standards on the basis of arguments that meet with general consent. A consensus on the validity of a standard has been achieved if all those who are potentially concerned could easily agree to it. This shows that moral justification should be based on the presumption of those obligations that, as rationally acting individuals, we could not reasonably doubt because we have always presumed their validity in our communicative transactions.

Some more recent arguments put forward against the concept of human dignity have fundamentally challenged the possibility of a universalist concept of morality.

Some feminists, for instance, have argued that Kant's concept of human dignity was based on the fiction of human beings as free and independent rational subjects. They say that this concept therefore reflects a "typically male" perspective of the phenomenon of morality. The message that this criticism aims to convey is that moral rules are always power-based or power-oriented and that, hence, they establish or maintain hierarchical power relations, e.g. between men and women. However, the criticism of hierarchical power relations also refers to

[18] Apel 1988.
[19] Gewirth 1978.
[20] Tugendhat 1993.
[21] Habermas 1991.

a normative demand that, in the final analysis, is founded on human dignity, i.e. that equality of human rights requires equitable social conditions.[23]

Another argument that is often put forward denies that there can be any absolute values, rules or principles like human dignity and the basic rights anchored in human dignity. The supporters of this argument suggest that in today's world values and norms can no longer claim absolute validity but only relative validity as a function of culture. They say that a single universal morality does not exist; instead, there are many different, culturally influenced moralities. If a Western, Kantian-style moral concept is elevated to an internationally binding yardstick, they argue, this would depreciate the moral traditions of other cultures. However, this objection also has recourse to a universalist standard, i.e. that of equal respect for the differences in the cultural socialisation of human beings. In addition, it should be pointed out that individuals who are adversely affected or threatened by intercultural conflicts usually do not demand respect for specific cultural rights but for universal rights (basic rights of individuals) which, in turn, stem from human dignity.

The Study Commission feels – particularly with a view to the criticism relating to gender-specific or culture-specific discrimination – that it is imperative to recognise the validity of the individual's basic rights that are based on human dignity.

What is controversial is the scope of the inviolability of human dignity, as demonstrated by the question: "*Who* is the bearer of human dignity?" Some suggest, for instance, that linking the validity of human dignity to members of the human species and broadening its scope to cover unborn human beings, even including fertilised egg cells, is inadmissible naturalisation. What they overlook is that this linkage of dignity to human beings and its extension to include unborn human beings result from the normative claim of attributing dignity to human beings because of their human nature, irrespective of any other characteristics.[24] Hence, the burden of proof is on those who want to impose restrictions. Consequently, the question is not: "Who qualifies for human dignity", but: "Who can reasonably be denied human dignity?". All attempts made at drawing lines between human beings who qualify for human dignity and those who do not or who deserve "more or less" human dignity are problematic. All empirical criteria used to draw such lines have recourse to such abilities as sensitivity, the ability to

[22] Apel 1988.

[23] This criticism is justified when it is related to a theoretical contractual moral concept, which is based on the premise that the rationale for moral subjects to submit to prevailing rules is that they want to defend their own rights. In the group of human beings to be considered from a moral perspective, this would leave out all those who, because of limited abilities or social exclusion, are incapable of harming others.

suffer, self-awareness, rationality, the ability to co-operate or to have self-respect. Such criteria are always more or less arbitrary and lead to morally questionable conclusions. A newborn child, for instance, does not yet have any self-awareness and would not suffer if killed free of pain. The same applies to human beings who are comatose or demented or who are severely mentally disabled. For this reason, it must be assumed that human dignity can neither be acquired over time nor lost.

1.2 Human dignity as a concept in international law

After World War II and the experience with the terror regime of the Nazis, the concept of dignity was introduced in international law.

The Universal Declaration of Human Rights of 10 December 1948, for instance, states in its preamble:

> "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world"

The United Nations have thus adopted a universalist concept of human dignity. Dignity is inherent in human beings merely because they are members of the "human species" ("members of the human family"). There is no need for any additional conditions, qualifications or prerequisites. The Universal Declaration of Human Rights also refers to the concept of dignity in its Art. 1, which says:

> "All human beings are born free and equal in dignity and rights."

The Nuremberg Code of 1947, which is part of the judgement of the Nuremberg trial of physicians, is one response to the horrors of Nazi medicine. Its principle is:

> "The voluntary consent of the human subject is absolutely essential".[25]

This principle is a concrete application of the principle of non-instrumentalisation that is contained in the concept of human dignity.[26]

The requirement of informed consent is also laid down in the International Covenant on Civil and Political Rights (Civil Covenant) of 1966. The *Civil Covenant* is a concrete application of the Universal Declaration of Human Rights and translates the latter's principles into effective

[24] Spaemann 1996; 2001b, pp. 417-428.
[25] The original Code of 1947 is reprinted, inter alia, in Kolb/Seithe 1998, p. 455.
[26] Wunder 2001b.

international law. Art. 7 of the Civil Covenant states explicitly that performing human experiments without the free consent of the subjects violates human rights.

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, adopted by the Council of Europe on 4 October 1997, contains in its preamble both the concept of human dignity and the protection of human beings as members of the human species:

> "Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being (...)."

The protection of human dignity is also enshrined in Art. 1 of the Convention on Human Rights and Biomedicine:

> "Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."

The provisions in the Convention on Human Rights and Biomedicine, according to which it is admissible to carry out research, for the benefit of others, on persons not able to consent to such research, have sparked off vehement controversies in the German Bundestag and in society at large.

The EU Charter of Fundamental Rights is the most recent international law document to incorporate the concept of human dignity. In its Art. 1, the Charter says:

> "The dignity of the human person must be respected and protected."

1.3 Human dignity as a constitutional principle

In the Federal Republic of Germany, human dignity is the "hub of the system of values enshrined in the Constitution"[27] and the foundation as well as the rationale for the validity of the fundamental rights. The guarantee of human dignity in the German Constitution has three

[27] Federal Constitutional Court, judgement of 5 June 1973, BVerfGE 35, p. 202 (25).

functions: It is the yardstick for all decisions involving an interpretation of applicable law; it is the objective of all actions by public authorities; and it is the foundation for the fundamental rights attributed to the individual.

The prominent position assigned to human dignity in Art. 1 of the German Constitution ("Human dignity is inviolable. To respect and protect it is the duty of all state authority.") was a response to the crimes of National Socialism, a regime in which the individual was worth nothing and where the individual was only ascribed any value if he or she served the Nazi concept of the "people" (German: "Volk"). These crimes included the policy of annihilating allegedly inferior races or groups, the selection and extermination of "unworthy life", the medical human experiments in the concentration camps as well as the war of extermination. Against the background of this history, the concept of human dignity has been specified in the consistent practice of the courts by defining facts that constitute a violation of human dignity.

Indisputably, the genesis of the concept and of the principle of human dignity in the German Constitution is linked with fundamental Christian beliefs. However, the genesis of Art. 1 also shows that the "mothers and fathers of the Constitution" deliberately abstained from founding the principle of human dignity on certain ideological and philosophical convictions. Proposed wordings – in which the dignity of the human being was derived from "eternal rights inherent in every one by nature" or in which dignity was declared to have been given to human beings "by God" – were not accepted. Abstaining from the use of religiously or ideologically influenced wordings is in keeping with the secularised and pluralistic character of a modern State. Law and politics in a modern State are no longer based on common religious or ideological convictions that could be claimed to be binding for all members of society. However, even in a society that is characterised by a diversity of cultural values and convictions, it must be possible to claim validity for constitutional principles. The principle of human dignity enshrined in the Constitution perpetuates the humanistic and universalistic elements of Christianity and preserves them without making itself dependent on their religious foundation. It is a principle that may have emerged from a specific cultural tradition but that, at the same time, can be valid for all human beings and provide the basis for mutual respect, especially in a modern pluralistic society.

The principle of human dignity takes up a central position in the German Constitution. Under Art. 79(3) of the Constitution, any amendment to the principles laid down in Art. 1 of the Constitution is inadmissible. Furthermore, the dignity of human beings is "inviolable", i.e. it

escapes the weighing of interests that otherwise applies to fundamental rights. Wherever the dignity of human beings is affected, it applies "absolutely, without the possibility of weighing interests".[28]

It is important that the protection of human dignity is, on the one hand, an objective value; on the other hand, however, it is extremely closely linked to legal rights.[29] The principle laid down in Art. 1(1) that public authorities have a duty to protect the dignity of human beings is then "transformed" in Art. 1(2) into concrete rights,[30] which says:

> "The German people therefore acknowledge inviolable and inalienable human rights as the basis of every human community, of peace and of justice in the world."

Hence, human dignity and human rights are closely linked with each other in the German Constitution; human rights ensue from the foundation of human dignity ("*therefore*"), and human dignity has to be particularised by human rights. The German Constitution starts from the assumption that human dignity is a given and that it is not created by the Constitution. And like the concept of human dignity, the concept of human rights is essentially universalistic, i.e. it applies to all human beings, without requiring any prior performance or specific "qualities". The German Constitutional Court has stated in this context that the concept of human dignity is:

> "linked to the human being's entitlement to social value and respect, which forbids making the human being a mere object of the State or subjecting the human being to a treatment that fundamentally questions the human being's quality as a subject. Human dignity within this meaning is not only the personal dignity of a given individual, but the dignity of the human being as a member of the human species. Every human being – irrespective of his or her characteristics, achievements or social status – has human dignity. This also applies to persons who, because of their physical or mental condition, cannot act rationally. Even 'undignified' behaviour does not lead to the loss of human dignity."[31]

In the German Constitution's systematic approach, human rights are transposed into directly effective law in the form of fundamental rights. The first Article of the German Constitution to be mentioned in this context is Art. 2, which lays down personal rights of freedom and integrity such as the right to life and physical integrity. However, other fundamental rights such as the freedom of conscience, faith, expression and assembly are essentially concrete

[28] Federal Constitutional Court, judgement of 3 June 1987, BVerfGE 75, p. 369 (380).
[29] Dürig 1998, XIf.
[30] Dürig 1998, XI.
[31] Federal Constitutional Court, judgement of 20 October 1992, BVerfGE 87, p. 209 (228).

applications of human dignity. In the event of conflicting fundamental rights, interests must therefore be weighed carefully.

In the systematic approach to fundamental rights, particular emphasis is placed on the principle of equality, laid down in Art. 3 of the German Constitution, which expresses the universal character of fundamental and human rights. The concept that the status of fundamental and human rights does not depend on the individual's physical and mental capabilities is also contained in Art. 3(3) sentence 2: "No person shall be disfavoured because of disability."

Hence, persons with disabilities do not first have to render a certain performance or acquire certain characteristics to be able to claim fundamental and human rights; instead, they are included in the equality of persons in law from the onset.

There is one major point in which human dignity as the foundation of fundamental rights differs from the latter: While human dignity – both as a right of the individual and as an objective of the State – is not open to being weighed against other legal interests, fundamental rights may in principle be restricted, i.e. they do not apply absolutely. For most fundamental rights, the text of the Constitution states explicitly that they may be restricted by law, however, while preserving their essence (Art. 19(2) of the German Constitution). However, even if no restriction is mentioned (e.g. freedom of research), no fundamental right applies without inherent bounds.

No principle – no matter how compelling it may be – provides in itself the rules for its application. Like fundamental rights in general, the principle of human dignity must be interpreted if it is to be applied. During the process of the genesis of Art. 1 of the German Constitution, the first President of the Republic of Germany, Theodor Heuss, already referred to human dignity as a "non-interpreted concept".[32] Interpretations are frequently controversial. At the level of the interpretation of the Constitution, for instance, the various concepts of dignity can be found in the form of the acquisition theory and the status theory of dignity. In this context, it should be noted that the theory of acquired dignity has not gained acceptance.[33]

[32] Heuss, quoted according to Benda 1985, p. 213 f.

[33] One attempt at interpreting human dignity in terms of the theory of acquired dignity was made by the jurist and sociologist Niklas Luhmann (Luhmann 1974, p. 68 ff.). According to Luhmann, dignity is neither part of the human being's natural state, nor is it a value. For *Luhmann*, dignity can only be acquired by virtue of an individual's achievement; however, individuals may also fail in their endeavours. The objection that can be

Aside from the theory of acquired dignity, there is the theory of recognition or communication of dignity.[34] According to this theory, dignity is a relational concept that is constituted by a specific community of recognition or communication. The advocates of this theory suggest that the members of a community of recognition mutually acknowledge that they have dignity. However, within the concept of dignity as defined in the theory of recognition, it is also possible for the members of the recognition community to refuse to admit certain human beings to this community. Hence, dignity is attributed by third parties; the question as to who has dignity and who does not is decided by those who are already members of the "recognition community".[35] Both the theory of acquired dignity and the theory of recognition of dignity have proven not to be very viable because they are either inconsistent (recognition theory) or not compatible with the intentions and the substance of Art. 1(1) of the German Constitution (theory of acquired dignity). To get any further, one must therefore turn to the status theory of dignity or the theory of intrinsic dignity. The status theory suggests that all human beings have human dignity, irrespective of their personal characteristics and capabilities. Human dignity is not a certificate that an individual could acquire by submitting proof of certain achievements or capabilities; instead, human dignity is a universal status that is inherent in all human beings as such.

The view that all human beings have dignity has become generally accepted in the Federal Republic of Germany:

> "The dignity of 'the' human being, i.e. 'every human being' is protected. An individual's nationality, age, intellectual maturity and ability to communicate are irrelevant; dignity is not contingent on any conditions, not even perceptiveness, and hence, not on the awareness of one's own dignity, let alone an appropriate behaviour."[36]

raised against this theory is that, if dignity were restricted to dignity produced by individuals themselves, as suggested by Luhmann, this would leave all those without protection who, in the eyes of productive persons, are not fit or no longer fit to acquire dignity (Reiter 2001, p. 449). This means that those who are most likely to need protection would drop out of the scope of protection of human dignity. For the Luhmann critic Christian Starck, the protection of dignity under the Constitution would therefore be completely undermined if it were dependent on the personal efforts made by an individual to acquire dignity.

[34] Cf. Hofmann 1993, pp. 353 ff.

[35] Hasso Hoffmann (1993), who is the major advocate of the "recognition theory", evidently refuses to accept this logical consequence of his approach *after* the establishment of the "recognition community": "Consequently, the mutual promise to recognise each other as community members of equal dignity rules out the possibility of granting anyone the power – for whatever reason – to deny another individual this status in principle" (p. 376). In the final analysis, this position is therefore inconsistent.

[36] Kunig 2000, para. 11.

The German Federal Constitution Court has stated: "Wherever human life exists, it has human dignity."[37] This statement expresses

> "a clear-cut rejection of material concepts of dignity, in the sense that an individual could only claim respect and protection under Art. 1 for himself or herself as of a certain stage in his or her physical, mental or moral development or as of a certain degree of maturity."[38]

Based on our Constitution, there is therefore no such thing as "unworthy life" or "an encumbrance" that society would be allowed to get rid of.[39]

A comprehensive view of human beings – one which does not reduce them to their intellectuality – will take into account that the nature of human beings also includes their imperfection and their individuality. If human dignity is applied as a yardstick, allowance must also be made for human imperfection and human shortcomings.[40]

A concept of human rights and human dignity which demonstrates that lessons have been learnt from the Nazi past and that human beings will never again be allowed to be classified as more or less "valuable" – or worse, as "unworthy life" – cannot reduce the individual human being to his or her intellectual capabilities. It must also take into account that human beings are always also physical, imperfect and vulnerable beings, and it must ensure respect, especially for those who are particularly dependent on protection.

In a world in which knowledge and skills are growing more and more rapidly, it is necessary to determine over and over again whether new social, technological and medical developments impinge on human dignity.

1.4 Substantive elements of human dignity

The concept of human dignity is not comprehensively and finally defined in the German Constitution and, in fact, it would not make sense to apply a rigid definition because such a definition could never accommodate all potential violations. Since human dignity is not an empty phrase but has practical relevance, it is necessary to specify its scope of application. There are above all three questions that need to be specified: *To whom* does the protection of human dignity apply? *What does this protection comprise*? *And what is the relationship between the protection of human dignity and other fundamental rights*?

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[37] Federal Constitutional Court, judgement of 25 February 1975, BVerfGE 39, p. 1 (41).
[38] Höfling 1999, para. 46.
[39] Cf. Dreier 1996, para. 46.

1.4.1 To whom does the protection of human dignity apply?

According to the wording of the German Constitution, "human" dignity is inviolable. Article 1 of the Constitution does not specify any additional prequisites. Hence, a human being does not need any specific characteristics or capabilities in order to qualify for the protection of human dignity guaranteed by the Constitution. Every human being – whether old or young, strong or weak, healthy or sick – is entitled to the respect of his or her dignity. This duty to protect human dignity also applies to unborn life.

A new phenomenon in the history of the human race – one which needs to be incorporated into the system of human rights – is the existence of human embryos outside the human body. Owing to technological developments, it is now possible to conceive embryos without any direct sexual relationship between a man and a woman and to keep them alive outside the woman's body, at least for a certain period of time. Unlike sexual conception, *in-vitro* fertilisation always involves third parties who perform the technical act of fertilisation, who cultivate and conserve the embryo or transfer the embryo into the uterus. The embryo's lack of protection *in vitro* gives rise to new risks of manipulation or usage – risks that human embryos who were naturally conceived are not exposed to in the same way because, in the woman's body, they are largely protected from access by third parties. It can therefore be stated that, unlike the conceived embryo, the produced embryo is the least protected being in the world. The new access opportunities created by *in-vitro* fertilisation have also given rise to new requirements for protection.

In-vitro fertilisation has led to the creation of human beings who exist outside the womb in a way hitherto unknown, before – physically connected with a woman's body – they develop into independently viable individuals, as is the case in pregnancy. In its jurisprudence to date, the German Constitutional Court has not yet given a conclusive answer to the question as to what status is accorded to human embryos *in vitro* in terms of fundamental rights. While the Federal Constitutional Court has found in its abortion judgements that human beings have human dignity from the onset, these judgements were limited to cases of pregnancy, i.e. the development of the embryo as of the moment of nidation in the uterus.

Both *in vitro* and *in vivo*, embryos have the capability to develop into a human being. Regardless of the importance to be attributed to nidation in the uterus for the embryo's further development, an embryo produced *in vitro* is already a human being who, following nidation,

[40] Cf. Benda 1985, p. 230 f.

will develop into an individual. In both cases, the embryo can develop into a child who, looking back, can refer to the embryo it once was as "I".

Many people perceive the human embryo as already being a "human being" in the full sense of the term, while others see the embryo as a future or potential human being. However, it is indisputable that, according to the status theory of dignity, the concept of the human being cannot be limited to members of the human species who are self-aware and capable of speaking, acting or interacting. Instead, being human is seen as a development process that invariably also includes phases in which capabilities that are considered to be "specifically human" – such as self-awareness, language, etc. – have not yet developed at all, or in which such capabilities are not fully present or in varying degrees. If such a broad concept of the human being is applied, human embryos cannot be barred from the protection of human dignity.

Digression: Ethical criteria applying to the use of human embryos *in vitro*

The question of the embryo's moral and legal status is particularly relevant when it comes to the use of human embryos – in particular, embryos produced outside the womb who need special protection because of the associated exposure to third-party access. This also includes the question as to what legal interest can be ascribed to an unborn human being from a moral perspective and what ethical (and legal) claims or obligations for protection can be derived from such interest. Irrespective of the legal perspective, the answers given to this question with regard to the embryo *in vitro* reflect *different fundamental positions* in our society. These positions differ in terms of whether the embryo should already be fully protected during this early phase prior to its existence, or whether the level of protection to be afforded increases with the embryo's development, reaching full protection only after a certain phase of development.

Full protection of the human embryo

The advocates of the *first position* assume that the human being's quality as an end in itself – which is due to the fact that human beings are subjects who are responsible for their actions – also extends to the living being that the subject is identical with and that has the ability to be a moral subject (species/identity criterion). Since there is continuity between the born human and the unborn human being from whom the born human being has developed (continuity argument), the unborn human being is equally entitled to protection as of the point in time

when a new living being has developed who, as such, has the real ability to develop into a born human being (potentiality argument).

The advocates of the first position believe that this is the case when, during the fertilisation process, a new living being with an individual genome has formed that will determine the further development of the human being. Since the development of the human being created through fertilisation is a continuum, they argue, choosing any other time for the onset of protection would be arbitrary. In addition, the advocates of this position suggest that it would be incompatible with one of the principles inherent in the concept of human rights to make the protection contingent on any criterion other than the fact that the subject involved has to be a human being.

If one assumes, as the advocates of the first position do, that physical life is the prerequisite to a being's ability to be a moral subject, then the *inviolability of human dignity* and *the protection of human life* are closely interrelated. This gives rise to the question as to whether, from this perspective, any violation of the protection of human life is tantamount to a violation of human dignity, or whether it is possible to make a distinction between the two claims for protection.

Some proponents of this position believe that it is not possible to make such a distinction and that the protection of human dignity inevitably encompasses full protection of human life – as of the union of the egg cell and the sperm cell. When it comes to attributing moral status or protection, the question arises as to whether the human embryo is already a bearer or subject of rights in the early stages of development, or whether the human embryo is entitled to status and the protection of human dignity solely because of the fact that the embryo is a human being identical to the subject meriting protection. The view held in this context is that the human being has inherent dignity, regardless of the question as to whether, or not, the embryo is already a person in law.

Graduated protection of the human embryo

However, some people also believe that, while the embryo has human dignity from the onset, this dignity does not command absolute protection of human life at the same time. While it is not admissible to weigh human dignity against other fundamental rights, ethical values, interests or principles, this does not apply to the principle of the protection of human life. The advocates of this position argue that the destruction of an embryo's life does not necessarily

violate human dignity. They suggest that it is even an ethical necessity to weigh the protection of human life against other values or fundamental rights. They believe that the weight of the obligation to protect human life increases and calls for growing protection, the more the embryo progresses towards the moment of birth.

The proponents of a *second position* assume that full protection (which the human being merits as a person in law) only applies as of a certain stage of the human being's development, and that the human embryo merits protection that is derived from this full protection – in particular during the early stages of development.

The advocates of a *more radical form of this second position* assume that a human being qualifies as a *person* and merits the necessary protection only if that human being has certain characteristics that are normally acquired by a human being in the course of his or her development. This may be the possession of specific interests that may be injured and therefore create rights, or the possession of capabilities such as self-awareness, a forward-looking approach, etc. that are necessary to develop interest preferences and create a generally applicable prohibition to kill. This more radical form of the second position is open to the fundamental objection that it does not meet one of the requirements contained in the concept of human rights: the moral status inherent in the human being and the protection resulting from this status must not be dependent on it being granted by third parties; it must be contingent on no condition other than the fact that the human being is human, and it must therefore be assumed that all human beings are fundamentally equal from an ethical and a legal perspective.

The proponents of a *more gradualistic form of the second position* assume that the human being merits protection upon completion of fertilisation. However, they suggest that the level of protection follows the stages of the unborn human being's development after completion of fertilisation, and that full protection (which is associated with the title to human dignity or the inalienable right to life) is only called for once a certain stage of the development has been reached. Relevant milestones in the development that have been mentioned in this context include: the beginning of morphogenesis marked by the development of the primitive streak, the exclusion of natural formation of multiples and the associated final individuation, the nidation in the uterus, the development of the neuronal structures for the conscious processing of stimuli (beginning of cerebral activity), the capacity to survive outside the uterus, etc. Particular importance is attached to the first three characteristics mentioned above because

they mark the difference between the embryo *in vitro* and *in utero*, and they refer to the point reached in the development approximately 12 to 14 days upon completion of fertilisation.

While the advocates of the gradualistic position can argue that the development of a human being is a process, it is – like many other gradualistic positions – open to the objection that any definition of a morally relevant dividing line within a continuum is bound to be arbitrary to some extent.

Common elements and differences

What the first two positions regarding the moral status of the human embryo have in common (i.e. the position of equivalent protection and the gradualistic version of the second position) is that they see the completion of fertilisation as the *beginning of human life*, and that they suggest that this human life merits protection from the onset and that, therefore, human life cannot be used, for whatever purpose, by third parties at any time during its development. This is a reflection of the fundamental moral conviction that human life has inherent value that is independent of whether this value is accorded by third parties and that, hence, human life merits protection as such.

The *major differences* between the two latter positions become manifest when competing interests are weighed against each other: According to the gradualistic view, it seems acceptable to weigh the embryo's entitlement to protection in the early stages of its development against high-priority objectives because, during these stages of development, the embryo does not yet have to be accorded the full moral status that applies at later stages. For advocates of the former position, weighing is only legitimate, if at all, if there is a conflict between two interests or evils of equal rank.

The constitutional status of the human embryo *in vitro* has not yet explicitly been the subject of a judgement by the German Federal Constitutional Court. Nevertheless, the views expressed by the German Federal Constitutional Court in connection with its two judgements on abortion suggest that the Court tends to side with the former of the two ethical positions mentioned above.

1.4.2 What does the protection of human dignity comprise?

In addition to the question as to who has human dignity, the question arises as to what the protection of human dignity comprises. Since it has not yet been possible to develop a

positive definition and since it is even questionable whether such a positive definition is desirable in the first place (because it is bound to be inflexible), the approach to human dignity will continue to be based on violations.[41] This view is also absolutely predominant among academic experts specialised in constitutional law.[42] Furthermore, the German Federal Constitutional Court's rulings are also regularly grounded in this perspective:

> "As far as the (…) principle of the inviolability of human dignity is concerned, (…) the crucial question is under what circumstance human dignity may be violated. It is obvious that it is not possible to give a general answer to this question; instead, each case must be assessed on its own merits."[43]

Dürig's much-cited "object formula" also addressess the violation of human dignity:

> "Human dignity is at stake whenever a concrete human being is degraded to an object, a mere means, a fungible quantity."[44]

In this context, it must be borne in mind that a violation of human dignity does not necessarily have to become openly manifest, as is true in many cases that are generally recognised (obligation to wear the Star of David, tattooing of a number, subjecting naked people to public ridicule, branding, torture …). More subtle behaviour – which appears to be less "rough" and "inhumane" at first glance – may also constitute a violation of human dignity. Cases to be considered in this conctext include total surveillance of individuals and data collection, as well as manipulating others by means of deceit or psychiatric drugs, even without inflicting pain or "shedding blood". A violation of human dignity – for example, by killing a human being – does not necessarily have to be associated with *a particularly mean character* on the part of the perpetrator. Hence, it does not make any difference whether a human being is killed because the perpetrator believes that "Jews are members of an inferior race" and that it therefore seems "acceptable" to perform fatal human experiments on them, or whether the perpetrator performs fatal research in order to develop new therapies that are designed to save human lives. The actual motivation of a perpetrator *as such* must certainly be assessed differently. However, an action that is prohibited under the Constitution cannot be deemed

[41] Höfling 1995, p. 859.
[42] Cf. Kunig 2000, para. 22; Dreier 1996, para. 37; Höfling 1999, para. 15.
[43] German Federal Constitutional Court 30, p. 1 (25).
[44] Dürig 1956, p. 127; 1972, para. 28 and 34.

justified merely because of its underlying motivation. "Good intentions" cannot "remedy" an objective violation of human dignity.[45]

However, Dürig's formula is only a first step in this approach. The German Federal Constitutional Court has been cautious in its appraisal of this formula:

> "General formulas – such as: the human being must not be degraded to a mere object of state authority – can only indicate the direction in which cases of a violation of human dignity could be found."[46]

A list of undisputed violations of human dignity shows that the cases involved are particularly severe violations: Torture, slavery, mass expulsion, genocide, humiliation, branding, persecution, ostracising.[47] If one also takes into consideration that human dignity is "inviolable" – i.e. not susceptible to being weighed against other fundamental rights – and that its validity cannot be curtailed (not even by a majority amending the Constitution), then this suggests that "an absolute core area of human existence"[48] is covered by the safeguard of human dignity.[49] The guarantee of human dignity in the German Constitution is not a "small coin" (Günter Dürig); instead, it is an "iron ration" (Count Vitzthum) that should only be used if it is absolutely necessary.

For this reason, it is neither possible nor useful to provide a final definition of the scope of application of the guarantee of human dignity. It will not be possible either to find a positive definition of human dignity in connection with legal and ethical issues relating to modern medicine. However, it is possible to describe concrete principles relating to the protection of human dignity in four areas. These relate to guaranteeing

1. fundamental equality before the law,
2. personal rights of freedom and integrity,
3. rights to social claims and
4. rights of political participation.

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[45] Cf. Höfling 1995, p. 860; Kunig 2000, para. 24; Dreier 1996, para. 39. Conversely, however, an action performed by someone "with the intention to degrade" another person does not constitute a violation of human dignity if the "intensity of the intervention does not reach the level of a violation of human dignity" (Höfling loc. cit.; Kunig loc. cit.).

[46] German Federal Constitutional Court 30, p. 1 (25).

[47] Cf. Klein 1999, para. 12.

[48] Höfling 1995, p. 860.

[49] Cf. Starck 1985, para. 14: "The protection of human dignity does not guarantee all good, pleasant and useful things imaginable; instead, it must be fundamentally understood to be valid."

Comments on (1) above: Granting fundamental equality before the law touches upon the core of the concept of guaranteeing human dignity. If human dignity is an inherent status of each human being, then each human being has rights. While some fundamental rights may be restricted under certain circumstances, this does not apply to the "right to have rights" (Hannah Arendt). Consequently, it is not possible to deprive specific groups of human beings – on account of certain characteristics – of their status of having rights in the first place. In addition, human beings or groups of human beings must not be subjected to unjustified unequal treatment on account of certain characteristics or particularities. In the field of medicine, for instance, this means that it is not admissible to declare that persons who are not able to consent to research are objects without any rights. Furthermore, equality before the law means that human beings must not be discriminated against on account of their genetic make-up or disability.

Comments on (2) above: Fundamental defence rights protect individuals from encroachments on their personal freedom and integrity. The primary consequence of the application of this principle in the field of medicine is that it is necessary to respect an individual's self-determination, as reflected by the requirement to obtain an individual's informed consent. This means that taking an individual's organ or tissue or collecting his or her genetic data constitutes a violation of that individual's personal right if he or she has not given his or her consent voluntarily – without coercion or pressure – based on prior information.

Comments on (3) above: Rights to social claims are necessary to safeguard the presence of conditions without which individuals would not be capable of exercising their rights in the first place. Guaranteeing minimum survival needs as well as access to health services, for instance, are a prerequisite for individuals to live and exercise their personal rights in the first place. Individuals who, because of disease or disability, cannot provide an adequate living for themselves have a right to receiving support from society.

However, the guarantee of human dignity does not provide any information on the exact scope of such social claims. In addition, it must be pointed out that personal protection rights such as the right to physical integrity cannot be annulled by the claims of others; it is not possible for anyone to claim the organs of another person, for instance.

Comments on (4) above: Another prerequisite for individuals to exercise their personal rights of freedom and integrity is to have rights of participation, i.e. the opportunity to participate in decision-making processes of general relevance. In a democracy, the right to vote or the

freedom of the press and freedom of assembly must therefore be seen as measures designed to safeguard the guarantee of human dignity. Citizens must have the possibility to state themselves how they would like to interpret and apply their claims to dignity and legal rights. In the context of modern medicine, participation can mean that citizens must be given the opportunity to form their own opinions on controversial ethical, legal and social issues in modern medicine, and to express these opinions. Participation also means that specific social groups must not be allowed to impose their value system or their perspective on other groups; instead, those who will be affected by decisions must also have an opportunity to develop their own views with regard to the problems at hand and the basis for a moral assessment, and to express these views. Furthermore, social groups with less influence and resources in society than others must also be given an opportunity to participate in the opinion-forming and decision-making processes relating to issues of modern medicine.

For these reasons, the guarantee of human dignity needs to be supported by statutory provisions and this, in turn, calls for the opportunity in a democratic society to participate in the processes that lead to the adoption of generally binding rules and decisions.

1.4.3 The relationship between the guarantee of human dignity and other fundamental rights

Human dignity is "inviolable". It cannot be restricted by the legislator. And it must not be weighed against any other interests or values. Human dignity takes absolute precedence. This is not generally true for other fundamental rights (Art. 2 ff. of the German Constitution). Some are subject to the constitutional requirement of a specific statute, while others are at least subject to limitations inherent in the Constitution. Hence, this gives rise to the question as to the relationship between the guarantee of human dignity and other fundamental rights, in particular the right to life.

The scope of protection of human dignity and that of other fundamental rights are obviously not identical. A violation of a fundamental right is not always tantamount to a violation of human dignity. On the other hand, as the wording of Art. 1(3) suggests, there is a connection between human dignity and the "subsequent" fundamental rights. Jeopardies to, and violations of, human dignity are hardly conceivable in isolation. They will regularly affect one of the areas of life that are covered by the protection afforded by one of the specific fundamental liberties or by the guarantees of equality.[50] Hence, the unlimited scope of protection of human

[50] Cf. Höfling 1995, p. 861; Pieroth/Schlink, Art. 1, para. 414.

dignity – which is similar to a blanket clause – does not necessarily overlap with the scope of protection afforded by other fundamental rights. Torture, for instance, constitutes not only an encroachment on the right to physical integrity but also a violation of human dignity. On the other hand, other bodily injuries may be admissible by law or not severe enough to constitute a violation of human dignity.

Likewise, not every killing of a human being or jeopardy to the life of a human being automatically constitutes a violation of human dignity. Cases to be considered in this context include acts in self-defence or the deployment of armed forces or rescue forces.[51] For this reason, it cannot be assumed automatically that, in the event of conflicting fundamental rights, an embryo's right to life must invariably be granted precedence.

On the other hand, it would be wrong to assume that, in view of the lack of congruence between the guarantee of human dignity and the right to life, there is a wide gap between the two scopes of protection – as if nothing were more natural than the compatilibity between the killing of human beings and human dignity. Instead, it is important to ensure that any restrictions imposed on the right to life – e.g. in the context of the protection of embryos – are contingent on the presence of conflict situations that must be as severe as in the case of the classical exemptions from the prohibition of killing.[52] As a rule, it must be assumed that killing a human being encroaches upon the scope of protection afforded by human dignity and cannot be justified.[53] However, it cannot be precluded – and it would not be incompatible with the embryo's status of dignity – that one would refrain, in the event of a pregnancy conflict, from insisting that an embryo should be carried to term against the woman's will, so that terminating the pregnancy may prove to be the only way to preserve the dignity and the rights of the woman.

2 Ethical landmarks for the individual and for society

2.1 Moral convictions and ethical criteria as a basis of law

Ethical criteria that can serve as landmarks for legislation regulating the use of modern medicine include not only the concept of the inviolable dignity of the human being but also

[51] Sacksofsky 2001.

[52] Examples cited in literature by constitutional experts include not only self-defence but also – and especially – the policeman shooting and killing an individual to save another person's life and the duty of soldiers, policemen and firemen to risk their lives. Cf. Dreier 1995, p. 1037.

[53] Or in other words: The scope of human dignity contained in the right to life is much greater than the scope of human dignity contained in, say, the freedom of expression or the right to secrecy of telecommunications.

fundamental moral convictions that safeguard the conditions without which this dignity cannot be effectively protected. For the human being is a physical being that can only develop through social interaction with individuals who mutually acknowledge each other. The physical and social nature of the human being therefore leads to certain fundamental claims that are reflected by moral value concepts associated with the notion of human dignity and by the catalogue of fundamental rights derived from human dignity. These fundamental claims also underly the law governing medicine as well as the ethics of the medical profession, and they include not only fundamental claims and rights that primarily affect the *individual* but also claims and rights that are relevant for *social interaction*.

This connection between ethics and law is clearly manifest in the German Constitution, which – after the end of National Socialism – was designed to be a value platform for the entire legal system, and hence, law applying to all citizens. Article 1 of the German Constitution, which establishes the inviolability of the dignity of human beings as an overriding rule of law, claims unalterable validity, more so than any other provision of the Constitution. The purpose of this provision is to guarantee that there will never be a repetition of the crimes committed during the period of National Socialism, which the authors of the Constitution had in mind when they drafted the Constitution. The concept of dignity used in the German Constitution goes back to the historical traditions of Ancient Greek, Roman, Jewish and Christian ideas as well as ideas that emerged during European Enlightenment; its legal substance has been extensively developed by the jurisprudence of the German Federal Constitutional Court.

In view of the variety of roots in the history of ideas from which the concept of the inviolable dignity of the human being has grown and in view of the different ways in which it is interpreted from the perspective of different ideologies, one has to be extremely cautious when assessing the impact and the importance to be attributed to the concept of dignity in the practical application of law. Otherwise, there is a risk that one might draw conclusions from this concept that are based on a given prior interpretation. Without any doubt, however, the purpose of Art. 1 of the German Constitution is to ensure that the human being's absolute and inalienable special status in animate and inanimate nature must be respected in law by all state authority and also by the legal system itself.

To this day, the validity of the precept of the dignity of the human being, as established by Art. 1 of the German Constitution, is supported by a broadly based consensus in society. The value of human dignity, which is mentioned before all other legal provisions in the German

Constitution, leaves its mark on the legal system, and conversely, the fundamental ethical importance of this value is cemented by the legal system. Since human dignity is a fundamental statutory norm that is based on a concensus, it is of course also binding for those who do not acknowledge an absolute guarantee of dignity for the human being in their system of ethical values.

2.2 Consensual moral convictions and ethical criteria in medicine

2.2.1 Relative to the individual

2.2.1.1 Fundamental moral convictions and basic rights

When it comes to deciding what is *morally* necessary, forbidden or permitted, the individual will rely on the system of moral norms that he or she considers to be binding and whose scrutiny is a matter of *ethics*. In terms of their nature, the moral notions acknowledged by the individual go further than law and are personally more binding than statutory principles and prohibitions. For this reason, the law must not force individuals to do things that conflict with their conscience.

Moral norms become binding for individuals in the context of the perception that individuals have of themselves, other human beings and also their environment. There are various reasons why moral norms can become binding for individuals: It may be due to the fundamental value judgement that ascribes absolute value to the human being because the latter is himself or herself committed to being good; however, it may also be due to the recognition of other human beings as equal partners in a relationship of mutual recognition; or it may be due to the willingness – fed by other motives – to adopt a moral standpoint. In this context, each individual must grant the freedom to everyone else to be bound by the moral commitment that they have recognised as being relevant for themselves. Hence, the *core of any ethics* is the individual's willingness to grant the same status to all human beings in their capacity as members of the human species and to recognise them as subjects setting ends for themselves and as addressees of moral responsibility.

However, if human beings are beings in whose nature it is to freely and autonomously determine their own actions, then they must be granted the *catalogue of fundamental rights* that safeguard their survival and permit their personal development in the natural and social environment. We find this catalogue of fundamental rights – initially worded in the form of rights designed to protect the individual against interventions by the State – in the

constitutional provisions following Art. 1 of the German Constitution. These rights are based on the guarantee of human dignity as the "ground for fundamental rights", and they represent the "fan-out" of the human being's special status protected under the heading of "dignity". The wording of these provisions at the same time provides an answer to the questions as to extent to which fundamental rights that conflict with other legal interests can be curtailed without violating human dignity. This implies that it is possible to curtail fundamental rights.

The fundamental rights derived from human dignity are related, on the one hand, to the ability of human beings to be the subjects of their own thoughts, wishes and actions. This includes first and foremost the demand to recognise every human being's *freedom* to act in accordance with the ideas that an individual has determined to be good or binding. This fundamental freedom, without which human beings cannot be moral subjects, becomes manifest in the demand for the *self-determination* of each individual and in the demand for the free development of an individual's personality; however, this freedom also includes the *freedom of expression and of conscience,* as well as the *freedom of individuals to practise a religion of their own choice*. Since in a science-based culture the freedom to be able to follow one's own judgement also includes the *freedom of research*, the rights associated with such freedom are also protected as fundamental rights.

On the other hand, since the human being is a physical and social being, the fundamental claims ensuing from human dignity, as well as the fundamental rights derived from such claims, are designed to safeguard the physical and social conditions without which a being of that nature cannot live its way of life. These fundamental claims and the fundamental rights derived from them include in particular the claim to safeguard the *integrity of life and limb*, the claim to safeguard *ownership of property*, the claim to obtain *social services* and to safeguard a *sound environment*.

It can be assumed that all claims derived from an individual's human dignity bear the risk of intrapersonal and interpersonal conflicts. When interpersonal conflicts arise with regard to any of the claims described above, the principle that applies is that any right claimed by an individual is necessarily limited by the fact that another person may claim the same right. The only right that cannot be restricted is the individual's right to human dignity.

2.2.1.2 Ethical principles in medicine

Fundamental moral convictions are also manifest in the system of specific *professional ethical norms* that have evolved in medicine since antiquity. Such professional ethics is

indispensable, especially in professions in which the exercise of the profession can severely affect other human beings. In the case of medicine, the code of professional ethics includes a number of professional duties, such as not to harm patients (*nil nocere*), to gear all actions to the goal of curing the patients (*salus aegroti suprema lex*), to exercise the profession in accordance with the state of the art, i.e. to use one's skills and the available resources to cure patients and to attend further training courses in order to preserve and update one's professional competence. For doctors, this means that they should empathise with patients, be truthful in the information they provide to patients, observe confidentiality and secrecy vis-à-vis third parties, etc.

The primary duty of all doctors under their code of professional ethics – not least because of the inevitable asymmetry in the relationship between doctors and patients – is to respect the autonomy of patients, in particular when patients decide that they do not want any medical treatment. Any medical intervention must be legitimated not only by the rules of medical art (medical indication) but also by the patient's will. For this reason, professional ethics stipulates – not least after the experience of abusive actions by doctors during the period of National Socialism and the Nuremberg Code of 1947 resulting from this experience – that any medical intervention is subject to the patient's informed consent. Owing to the Belmont Report[54], this principle has also become the first of three or four principles that are part of the "four-principle way" in medical ethics (autonomy, non-maleficence, beneficence, justice[55]), which was developed in the United States and acknowledged worldwide. The principles mentioned in the Council of Europe's Convention on Human Rights and Biomedicine include not only the protection of human dignity (Art. 1) and the principles of professional ethics (Art. 4) but also the principle of the patient's informed consent at a prominent place (Art. 6); however, the Convention also contains provisions (which are subject to a controversial debate in Germany) according to which it is admissible to carry out research that "consumes" embryos and research for the benefit of others on persons not able to consent to such research.

Actions of doctors often make it necessary to *reflect on ethics and to weigh conflicting interests* when ethical principles or prohibitions or interests and objectives conflict with each

[54] The Belmont Report was published in 1978 by the National Commission for the Protection of Human Subjects in Research in Biomedical and Behavioural Research: The Report, which was entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research", mainly dealt with institutional precautions to be taken in order to ensure the voluntary and informed consent of subjects in research projects. In this report, the principles of the respect for an individual's autonomy, as well as beneficence and justice were used as normative reference points.

[55] The principle of self-determination or the respect for an individual's autonomy, the principle of non-maleficence, the principle of beneficence and the principle of justice. Cf. Beauchamp/Childress 1994.

other, as in the case of the conflict between confidentiality vis-à-vis the patient on the one hand, and the protection of third-party interests on the other hand. In such cases, merely listing a doctor's duties under the code of professional ethics is as inadequate as citing the pertinent rules: there are even limits to sophisticated case histories.

What is needed therefore is *ethical judgement on the part of the players involved*. This should be the primary choice, rather than giving preference to one of several conflicting values or combining all values with each other by means of a *practical concordance*, while sparing each of them as much as possible. This applies both to finding a practical norm in the event of conflicting moral intentions and to weighing interests in a given specific case. What is required of doctors in the latter case is not only their discriminating judgement but also their ability and willingness to assume responsibility. Beyond all norms and rules, medical professional ethics therefore relies on mindsets and attitudes (virtues).

2.2.1.3 Ethical principles in research

In modern medicine, research plays a key role whose importance will continue to increase in future. Research is needed not only in order to obtain basic knowledge that can lead to the development of new diagnostic, therapeutic and preventive approaches and in order to make these concepts ready for application; research is also necessary in order to guarantee the safety and quality of many medical interventions. Hence, research in modern medicine is not only a scientific but also an ethical necessity.

However, each medical intervention that involves research in human beings needs to be particularly justified from an ethical and legal perspective. Unlike the actions of doctors, whose purpose is the diagnosis and therapy (including prevention) of patients in the context of a doctor/patient relationship and which, hence, are strictly for the benefit of the individuals concerned, research activities are designed to identify regularties, ideally regular interactions between specific factors. The research subjects are of interest in so far as these persons might represent a potential case of an assumed regularity. All other factors must be disregarded; from the perspective of research, patients are seen as test subjects.

Within medical research, it is possible to pursue the objectives of both medical treatment and research at the same time, e.g. when newly developed drugs are tested in stage III and IV clinical trials; however, these two types of objectives may also differ from each other if the research involved is still without any benefit for the test subjects, as in the case of human experiments or stage I drug testing.

Since it is inevitable – because of the objectives mentioned above and the relevant methodological criteria – that patients or research subjects are more or less instrumentalised when they are involved in research studies, and since such research is associated with particular risks and potential harm, it can only be justified from an ethical and legal perspective if it meets specific additional criteria.

It goes without saying that the norms of ethical law and medical ethics mentioned above apply without restriction to the treatment of patients in the context of research projects. However, in view of the associated research activities, it is necessary to observe additional rules; this applies in particular to research in human beings where such research is of no therapeutic value for the persons concerned. The additional criteria to be met in such cases includes first and foremost the informed consent of the persons concerned, which would be required anyway for any therapeutic intervention; however, in the context of research, this consent needs to be obtained in writing and documented. In addition, it is necessary to demonstrate that there is no alternative to the research activity concerned, that the expected scientific benefit is significant, and that the ratio of the potential injuries and risks to the expected therapeutic or cognitive benefit is acceptable. Patients must be able to discontinue their participation in a given study at any time without any adverse effects on their health or the treatment of their disease, and they must be covered by an insurance policy for test subjects during the period of their participation in the study. Furthermore, an independent ethics review committee must be involved in the study. In this context, it is necessary to examine the composition and the powers of the ethics review committee. If studies are conducted in particularly innovative fields, in which it is difficult to predict the risks involved, it is necessary to establish additional review procedures, such as an additional central ethics review committee with special expertise in the field under investigation; furthermore, research may be limited to special centres and subject to compulsory registration.

Studies conducted in persons who are not able to give their informed consent to a planned study programme pose a particular problem. If the study can be expected to provide – at least a potential – benefit for the person concerned, and if this benefit outweighs the potential risks, it is ethically and legally justifiable – also according to the World Medical Association's Helsinki Declaration on Medical Research in Human Subjects and the Council of Europe's Convention on Human Rights and Biomedicine – that the informed consent is given by a legally authorised representative. Under the German Medicines Act (AMG), it is permitted

within narrow limits to conduct research in minors, providing that the purpose of the research is to test procedures or agents designed to diagnose or prevent children's diseases.[56]

One controversial issue is the question as to whether it is admissible to carry out research for the benefit of others on persons who are not able to consent to such research. From an ethical perspective, the answer to this question depends on whether the research procedure (which is not carried out for the potential benefit of the person who is not able to consent to such research and which can only be justified by the benefit that this research provides for other persons in this group) as such already constitutes an inadmissible instrumentalisation of the person concerned and is therefore a matter that is beyond the decision-making power of the legally authorised representative. The decision-making power vested in custodians allows the latter to give their approval only to procedures that are in the best interest of the persons under their care.[57] The Council of Europe's Convention on Human Rights and Biomedicine permits research to be carried out for the benefit of others on persons not able to consent to such research if it entails only "minimal risk" and "minimal burden" for the individual concerned and if there are no alternatives to cure the group concerned.[58] In addition, the responsible ethics review committee and the legally authorised representative must have given their approval and the person concerned must not have shown any signs of refusal. Similar provisions are also contained in the Helsinki Declaration as amended in Edinburgh in the year 2000.

The critics of the Convention on Human Rights and Biomedicine have pointed out that it is often not possible for outsiders to correctly assess what a minimal burden is in the subjective perception of a person without the capacity to consent. Most of the persons involved in this context perceive the world intuitively and can very well be subjectively frightened by procedures which are generally considered to pose a minimal burden. Hence, there is a general risk that research carried out for the benefit of others may wrongfully instrumentalise individuals who belong to this group of persons.

[56] This is based on the assumption that preventive examinations and vaccinations are potentially beneficial for children and adolescents. Pursuant to Section 40(4) No. 2 of the German Medicines Act, the application in healthy minors of a drug in a clinical trial "must be indicated according to evidence in medical science to identify diseases in minors or to protect minors from diseases."

[57] Parental custody must also be exercised only in the best interest of the child. This prevents parents from giving their approval to procedures for the benefit of others if such procedures do not provide any personal benefit for their child.

[58] Cf. Chapter E Desiderata, 1.2 Research in human beings not able to consent to such research

On the other hand, the supporters of the Convention on Human Rights and Biomedicine have pointed out that if no research is carried out on persons without the capacity to consent, this group may at least partly be excluded from medical progress and potential cures.

Under the relevant statutory provisions that are in force in Germany, custodians are not allowed to give their approval to research procedures carried out exclusively for the benefit of others, because custodians can only give their approval to research that is in the best interest of the person under their care. This precludes research to be carried out, for the benefit of others, on persons who are not able themselves to give their consent. However, the linkage to the potential benefit opens a grey area.

2.2.2 Relative to social interaction

From a perspective of social ethics, the current practice and new developments in modern medicine must be seen against the background of the dynamic and complex structure of modern societies. Developments within the realm of modern medicine change social reality in a variety of ways – both for the better and for the worse. They create new options for action and thus also impose new decision-making constraints; they influence role expectations, e.g. vis-à-vis expectant parents; they change the doctor/patient relationship; they change medical practice as well as the entire health care system; and they change our perception of life, disease and death. The associated direct and indirect consequences for society can only be analysed and ethically assessed through transdisciplinary co-operation between social sciences and ethics.

As far as the Study Commission's work is concerned, this means that it is necessary:

– to identify – against the background of ethical norms – problematic social conditions and consequences of modern medicine, in particular with a view to new options for action,

– to determine options for action that could change social structures for the better, and

– to develop solutions, taking into consideration the prevailing social conditions and the analysis of the options for action that have been identified.

2.2.2.1 Social ethics defined as institutional ethics

Unlike individual ethics, social ethics accentuates the rights that the individual can claim vis-à-vis society or the duties that the individual has vis-à-vis society, seen as a community of rights of all human beings living in this society.

This means that social ethics involves the anchoring of subjective rights in society and the institutional backing of such rights, as well as the "responsibility for one's social environment".[59] When defined in this way, social ethics is tantamount to "institutional ethics" (Wilhelm Korff). Because of the international interlinkage between the science and business communities, it has become increasingly necessary to adopt an international perspective.

2.2.2.2 Social ethics defined as structural ethics

In addition, dynamic changes in social values and norms play an important role in social ethics. An individual's personal moral convictions are influenced by systems of societal norms, and conversely, the actions of individuals based on such convictions have an impact on the systems of societal norms. This correlation can be described as the "dialectical relationship between subjective and objective reality".[60] The same applies to actions by public bodies – e.g. in science and medicine – and to relevant political decisions. On the one hand, they shape and change reality in society; on the other hand, however, they rely on the legitimacy provided by social values and norms. These social structures are also the subject of social reflection. When defined in this way, social ethics can also be considered to be tantamount to "structural ethics" (Wilhelm Korff).

Modern societies do not have an integrative social structure that is legitimised by interpretations of meanings that are "monopolistically administered" by religious institutions.[61] However, this does not suggest that modern societies do not convey any meaning in the course of growing "rationalisation" (Max Weber). The only difference is that this meaning is no longer the same for all members of society; instead, it is "privatised", as it were: Increasingly, individuals seem to draw meaning from their personal close-range environment (family, partnership, circle of friends) as well as from natural sciences and the economy. The resulting diversity of lifestyles, moral and political convictions as well as views of the world and images of man that coexist in modern societies poses a particular challenge for social ethics.

Despite such complex social structures, actions by public bodies must still be guided by universally valid principles of social ethics, if they are not to serve exclusively particular interests. The question is what principles can be considered to be universally valid. The principles that qualify for this purpose are primarily principles that are aimed at creating

[59] Korff 1998.
[60] Berger/Luckmann 1969.
[61] Luckmann 1980.

structural and institutional justice in society, based on the protection of human dignity and human rights.

2.2.2.3 Justice

Justice is the normative yardstick for the assessment of societal institutions and structures. "(E)ven the most effective and well-coordinated laws and institutions (must) be amended or repealed if they are unjust."[62] In this context, the primary concern is social justice (and not justice as a personal virtue), and hence, the just distribution of rights and duties, as well as social and economic goods. The idea of moral equality forms the basis of all modern concepts of justice. However, there are considerable differences between the various concepts of justice.

A utilitarian concept of justice – based, for instance, on the objective of benefit maximisation – takes insufficient account of fundamental moral rights and distribution aspects and in the final analysis therefore infringes on the idea of moral equality. However, assuming that there inalienable rights and adopting an "impartial position" (John Rawls) when it comes to the distribution of benefits and burdens arising from the social interaction of all individuals constitutes an expression of the idea of moral equality.

A communitarian concept of justice assumes that different communities have different concepts of justice which, consequently, only apply within these communities and whose reach is limited to the members of the community concerned. In a Kantian-style Universalist moral concept, on the other hand, questions of justice transcend the boundaries of communities, societies, cultures and generations.

In the Kantian tradition, justice is not just one good among others, but the supreme interpersonal norm that is applied to reach a decision when there are conflicts between various rights and when different interests have to be weighed against each other. Justice claims universal validity. Since the term "justice" is initially only formal in nature and void of any substance, it must be substantiated with principles of social ethics in order to serve as a guideline for actions by public bodies. In other words: justice is the general principle of social ethics, and this principle must be substantiated by means of particular principles of social ethics.

[62] Rawls 1975, p. 19.

In this sense, public bodies must be committed in their actions to observing particular principles of social ethics or "criteria of just politics" (Otfried Höffe). From the perspective of human dignity, these principles must be derived from subjective fundamental rights. The three basic forms of fundamental rights are: personal liberty rights, rights to social claims and political rights of participation. The Study Commission believes that, from the perspective of social ethics, this corresponds to the principles of freedom and self-determination, equal rights and non-discrimination, solidarity and political participation. However, these principles do not directly prescribe or prohibit actions; instead, they are normative guiding principles for political decisions with regard to the development of institutional and structural order of society. The guiding principles of social ethics are aimed at establishing just institutions and pursuing an "ethics of liberation" from structural violence in social systems.[63]

2.2.2.4 Freedom and self-determination

The principle of human dignity also implies the protection of an individual's personal self-determination and the right to the free development of an individual's personality. From the perspective of social ethics, this entails the obligation to design social institutions at all organisational levels in such a way that individuals are given as much room for manoeuvre for their personal freedom as possible and that their capacity for self-determination is promoted as much as possible. On the one hand, this leads to rights designed to protect the individual against interventions by the State; and on the other hand, this obliges the State to intervene wherever an individual's personal room for manoeuvre is excessively restricted by the actions of third parties or wherever the protection of the fundamental rights of some individuals is jeopardised by the acts of third parties. However, the obligation under social ethics to observe an individual's right to self-determination not only means that the room for manoeuvre for the behaviour of individuals must be protected against restrictions of their freedom; this obligation also includes a duty to actively support an individual's capacity for self-determination (e.g. through education, free access to information, etc.).

Hence, an individual's personal liberty rights are closely connected with rights to social claims because all human beings depend on the support of others to exercise their personal liberty rights, at least in many phases of their lives (e.g. childhood, sickness, old age).

[63] Mieth 1998, pp. 244 ff.

2.2.2.5 Equal rights and non-discrimination

The postulate of equal rights is based on the precept that equal regard should be paid to the subjective fundamental rights of all human beings. No-one may claim privileges by virtue of their colour, sex, role in society, health or any other – from a moral perspective – arbitrary aspects. Every individual should be free to choose his or her own lifestyle; it should not be imposed from outside through economic dependence or cultural constraints.

If political action is to be guided by the socio-ethical principle that all human beings are to be granted equal rights, regardless of ownership of property, sex, sexual orientation, colour, cultural origin, age, health and individual capabilities, it is necessary to counteract direct and indirect discrimination against specific groups in society. Direct discrimination means morally unjustified, unequal treatment or exclusion of individuals by other individuals or institutions. This includes, for instance, discrimination against employees, insured persons or disabled persons on grounds of genetic tests. Indirect discrimination is constituted by social values and norms that reflect contempt for certain individuals. This includes, for instance, the establishment of social norms such as "ascribing a certain (lower) value to the lives of individuals" because of chronic disease or disability.

The socio-ethical principle of equal rights, which is enshrined in Art. 3(3) sentence 2 of the German Constitution, makes it imperative to fully integrate persons with disabilities into society. Excluding persons with disabilities from social life is direct discrimination. In addition, the lack of opportunities for encounters between disabled and non-disabled persons paves the way for prejudices and indirect discrimination. The socio-ethical principle of equal rights also calls for equal treatment of men and women in public and in family life (see Art. 3(2) of the German Constitution).

2.2.2.6 Solidarity

Quite generally speaking, solidarity is also related to equality. Solidarity can either stand for equality of social conditions, or equality in terms of belonging to a certain group, society, nation, etc., or the moral equality of all human beings. The latter meaning is primarily relevant for the normative substance of the socio-ethical principle of solidarity based on human dignity. Solidarity means taking action in situations that are perceived to be injust in

order to establish or restore justice. Calls for solidarity are therefore often also calls for justice. Nevertheless, solidarity is not identical with justice.[64]

As a guiding political principle in the context of social ethics, solidarity is based on the precept of the interdependence of human beings living in partnerships or communities, emphasising that rights to social claims are subjective fundamental rights. What is meant here is the welfare and support that an individual can claim vis-à-vis the community in case of financial plight, disease, disability or old age. At the level of society, this points to the need to provide institutional backing for such rights to social claims. The fundamental rights of individuals and the relevant duties of the State to protect the individual go hand in hand with the welfare state principle (Art. 20(1) of the German Constitution), from which it is possible to derive, *inter alia*, the principle that those who are weak must be protected and that justice must be ensured in the distribution of income. On the other hand, individuals are not entitled to claim any and all medical care that is feasible or desirable, but only "adequate" care in the framework of the services that the public health care system is able to provide.

Solidarity is closely linked to the concepts of charity and empathy with other human beings, i.e. an appeal to help and support others in need. The labour movement extended the scope of the concept of solidarity to include the goal of a society or world order based on solidarity.[65]

Various groups within the community are affectd by injustice in various ways. The principle of solidarity reckons with such inequalities and expects them to be evened out or eliminated – providing that they are unjust – while respecting the specific identity of others. In this context, the justified resistance against injustice is strengthened if the members of underprivileged groups think and act in solidarity with each other and if others show the requested solidarity with underprivileged groups.

Hence, the socio-ethical and political principle of solidarity is aimed at establishing a practice in society that promotes public welfare, i.e. it is aimed at establishing binding rules for individuals who live together in a society – rules that protect the rights of the individual, while allowing for a plurality of lifestyles. There is a dichotomy between solidarity and individualism, competition and performance orientation, which suggests that there is need to shape societal structures and institutions through regulation in such a way that human beings can live in society as free and independent beings.

[64] Hübenthal 2000.
[65] Zoll 2000.

2.2.2.7 Participation

Participation – i.e. the ability of parties affected by decisions to participate in the decision-making processes, and participation as an expression of political freedom – is an indispensable element of any democratic society. Within this meaning, politicial participation as a guiding principle of social ethics is "the greatest possible involvement of the individual in the establishment and implementation of humane norms" (Otfried Höffe).

Political participation may be organised in two different forms: it can be either direct (through community involvement) or representative (through elected representatives). Direct political participation – more so than representative participation – serves the purpose of controlling the influence of pressure groups, as well as preventing exclusion and manipulation. Based on the principle of participation, the guiding ideal for political communication is the common search for political solutions that can be generalised because all the parties concerned can agree to these solutions.[66] If necessary, these solutions can also be compromises if they can be accepted by all the parties concerned. This is particularly relevant for the ethical and legal issues in modern medicine that are subject to a highly controversial public debate. In the field of health policy, the principle of participation also calls for adequate participation of patients and all the professional groups concerned in health policy decision-making.

The possibility for an individual to enjoy political participation presupposes the protection of personal liberty rights and rights to social claims, as well as social integration and equal rights. This implies the participation of the social groups concerned (e.g. persons with chronic diseases or disabilities) in political decisions on medical research and practice that will affect them.

2.3 Law and ethics

The relationship between law and ethics varies with a view to regulatory problems in modern medicine. Since there are different ethical convictions within society, the task of law is limited to introducing binding rules concerning those questions that touch upon claims that are protected by the Constitution or that affect indispensable common interests. Positive law is related to common ethical convictions where this law is guided by the statutory provisions on fundamental rights in our Constitution in which these ethical convictions have found their expression. The law applying to the medical profession is based on the ethos developed within

[66] Habermas 1983, pp. 53 ff.

this professional group and is reflected by the medical profession's self-image. Since the rules of the professional code are drawn up on the basis of a statutory mandate and put into force by Germany's state-level governments, the professional ethos is also translated into positive law.

The relationship between law and ethics poses particular problems when the regulation of new developments in the field of medicine requires an interpretation, further development and particularisation of certain norms in terms of fundamental rights, and when the interpretation and further development of these norms lead to ethical dissent in society. In the past, this happened, for instance, in connection with the discussion of the criteria to be applied when taking organs from deceased persons ("brain death" criterion and concept of death), and it is now happening with regard to the question of the moral status of the embryo *in vitro*.

If there is a fundamental ethical dissent, various approaches can be adopted to find a regulatory solution that meets with approval: going back to the constitutional norms and, in the light of these norms, limiting statutory provisions to the absolute minimum required and leaving any decisions beyond this to the individual's ethical responsibility; distinguishing between acts that are ethically and legally inadmissible, on the one hand, and acts that are liable to prosecution under (criminal) law, on the other. The debate on the problems posed in this context has not yet been concluded.

C Issues

1 Preimplantation genetic diagnosis

1.1 Introduction

This chapter focuses on preimplantation genetic diagnosis (PGD), a diagnostic method which permits the removal of cells from embryos produced outside the womb and the examination of these cells for certain genetic characteristics or chromosomal disorders. The embryo is only implanted in a woman's uterus if no chromosomal disorders have been detected or if the genetic findings comply with the wishes and expectations of the future parents. While PGD has been applied in the United States since 1990 and today is also performed in most European countries, it is banned in Germany under the Embryo Protection Act. The fact that a number of scientists and some couples urge politicians to permit PGD in Germany prompted the Study Commission to address the issue of PGD.

Since PGD can only be performed in conjunction with in-vitro fertilisation (IVF), this latter technique had to be included in the Commission's deliberations as well. It was neither intended nor necessary to cover the entire area of in-vitro fertilisation. Instead, the Commission elected to restrict its considerations to those aspects of IVF that are specific to PGD. This decision is reflected, among other things, in the IVF recommendations which are less detailed and less extensive than the PGD recommendations.

The frequent comparison between preimplantation genetic diagnosis on the one hand, and prenatal diagnosis (PND) on the other, made it necessary for the Study Commission to address the issue of PND as well. To develop a deeper understanding, the Commission was above all interested in this method's history of development and application. What can be learnt from 30 years of PND practice for the possible approval and use of PGD? And in particular, what wrong developments must be avoided? Since this issue, too, is considered to be complementary to the main theme of PGD, the concluding recommendations are again limited to a minimum.

Recommendations regarding both IVF and PND were based on a consensus among Commission members. In the case of PGD, however, this was not possible. The members' diverging views are expressed in positions A and B.

1.2 *In-vitro* fertilisation and preimplantation genetic diagnosis

1.2.1 Definition of the subject for the Study Commission's deliberations

The Study Commission on Law and Ethics in Modern Medicine feels that it is indispensable for a well-informed and qualified discussion of PGD to highlight some aspects of assisted reproduction:

The use of the various "assisted reproductive techniques" (ART) is motivated by the wish of a couple to have a biologically related child. This is why the discussion on ART also touches upon the important issue of involuntary childlessness.

This stocktaking exercise also includes the description of treatment results, possible associated stressors and risks and their documentation as well as quality assurance measures to be taken in the context of IVF or ART.

Issues that go beyond the link between PGD and IVF and are associated with techniques of reproductive medicine in the narrow sense of the term and with assisted reproduction in a wider sense cannot be discussed here in detail or can only be touched upon. They include

– problems of access to assisted reproductive technologies,

– heterologous sperm donation, which is not subject to any legal regulation[67], or the donation of egg cells[68], which is banned under the Embryo Protection Act, and the associated medical, technical, psychological, ethical and legal problems,

– surrogacy[69],

– fundamental issues such as changes in the perception of sexuality, fertility and pregnancy as well as questions relating to the role of woman or the child and the significance of the family seen in the context of medically assisted reproduction, and

– the question of a suitable concept for counselling before, during and after medically assisted reproduction

[67] So-called "heterologous insemination", i.e. fertilisation with (anonymous) donor sperm, is not subject to a special law in Germany, but has been performed to assist the conception of more than 70,000 children. Cf. Günther/Fritsche 2000, p. 249.

[68] Unlike the donation of an egg cell (Sec. 1(1), Embryo Protection Act), the donation of (so-called "supernumerary", cryopreserved) embryos is not explicitly regulated under the Embryo Protection Act. Cf. C1.2.3.3 Egg cell donation.

[69] Sec. 1(1), Nos. 1, 2, 6 and 7, (2) No. 2, Embryo Protection Act. Cf. C1.2.3.3. Egg cell donation.

1.2.2 Assisted reproduction

1.2.2.1 Historical development of assisted reproduction

The first child conceived outside the body of a woman (*in-vitro* fertilisation, IVF) was born in 1978. Edwards and Steptoe, the "technical" fathers, had used the knowledge on interventions in (human) reproduction that had become available since 1963.[70]

The different techniques required for the successful practical performance of artificial fertilisation were described in the 20th century: IVF and embryo transfer were successfully performed in animals, defined solutions for embryo cultures and quick hormone assays were available. Since the 1940s superovulation (simultaneous maturation of several egg cells) has been hormonally induced in various mammalian species. In 1968, a woman was delivered of sextuplets by caesarean section after having undergone hormonal stimulation. The phenomenon of sperm maturation (capacitation) in the female organism was identified as early as 1951.[71]

Table 1: Establishment of Extracorporeal Fertilisation

Event	Test object	Year	Author
First successful artificial fertilisation of a mammal	Dog	1780	Spallanzani[72]
First extracorporeal fertilisation experiments in mammals	Rabbit, guinea pig	1878	Schenk
First successful embryo transfer (without prior IVF)	Angora rabbit	1890	Heape
Beginning of the development of a technique for the successful cultivation of egg cells and embryos	Rabbit, house mouse	1930, 1949	Pincus, Hammond
Hormonal stimulation to produce multiple mature follicles (superovulation)		1940	Pincus
First embryo transfer in farm animals	Sheep	1944	Casida
Not clearly verified IVF in humans	Human	1944	Rock, Menkin
Observation of sperm maturation (capacitation)	Human	1951	Chang
Freezing of fertilised oocytes	Rabbit	1952	Smith
Defined culture solutions for eggs and embryos	Mouse	1956	Whitten
First clearly verified IVF (transferred embryos carried to term)	Rabbit	1959	Chang
Rapid LH[73] and estradiol determination by means of RIA (radioimmunoassay)	Human	1962	Berson, Yalow
Possibly first IVF in a human	Human	1962	Edwards
Birth of the first IVF baby	Human	1978	Edwards
ICSI (intracytoplasmic sperm injection)	Human	1992	Palermo et al.[74]

Source: Ottmar 1995, p. 6 (modified)

[70] See Ottmar 1995, p. 1 ff.

[71] Sperm become "fertilisation competent" only after exposure to the female genital tract, where they undergo biochemical changes termed "capacitation", which are not yet fully understood. Under in-vitro conditions sperm can be capacitated by centrifugation and subsequent incubation in a culture medium containing albumin (sperm washing or sperm preparation). According to No. 3 of the criteria applying to medical artificial fertilisation services submitted by the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers, "the husband's health insurance scheme has to pay for measures taken to examine and prepare and – if necessary – capacitate male sperm (...)." See also C1.2.4.2.2.2 Guidelines of the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers).

[72] Precht 1999, p. 167; Encyclopaedia Britannica 2001.

[73] LH = luteinising hormone.

[74] Palermo *et al.* 1992.

In 1973, a working group headed by DeKretzer had produced the first pregnancy after IVF treatment which, however, ended in a miscarriage. After some failures Edwards and Steptoe succeeded in inducing a full-term pregnancy "after laparoscopic retrieval of an oocyte on 10 November 1977, in-vitro fertilisation and normal cleavage in the culture medium and transfer of the 8-cell embryo into the uterus two and a half days later".[75] As a result, the world's first IVF baby, Louise Brown, was born on 25 July 1978.

1.2.2.2 Definitions

1.2.2.2.1 Reproductive medicine and fertility disorders

Reproductive medicine is concerned with all aspects of human reproduction (development, functions, dysfunctions, diagnosis and therapy). Above and beyond the developmental biology issues regarding the development of male and female sexual organs, reproductive medicine focuses in particular on the reproductive phase in humans. This includes studying and understanding the (hormonal) regulation and function of male and female reproductive organs as well as different diagnostic and therapeutic measures to treat dysfunctions, e.g. in the case of involuntary childlessness.

The medical causes of involuntary childlessness are more or less equally distributed between the sexes. It is estimated that male fertility disorders account for 40 per cent of infertility cases, female fertility disorders for another 40 per cent and the remaining 20 per cent of cases are "idiopathic", i.e. unexplained.

In medical terms, *sterility* describes "the failure of gametes to unite"[76], i.e. the inability to conceive[77], which according to the World Health Organisation's (WHO) definition applies "when a couple have not conceived after two years of regular unprotected intercourse".[78] Today sterility is frequently diagnosed after one year.[79] This definition[80] disregards both the

[75] Cited in Ottmar 1995, p. 5.
[76] Mettler *et al.* 2000, p. 194.
[77] Tinneberg 1995a, p. 45.
[78] Hölzle 2001, p. 1.
[79] Sterility after two years see Stauber 1996; Runnebaum/Rabe 1994; Felberbaum/Diedrich 1994. Sterility after one year see Breckwoldt 1994.
[80] Moreover, a distinction is made "between primary sterility, i.e. when a woman has never been pregnant, and secondary sterility, i.e. when after at least one pregnancy – regardless of whether or not the child was born – the woman does not conceive any more" (Nave-Herz *et al.* 1996, p. 18). In a sample survey commissioned by the *Bundeszentrale für gesundheitliche Aufklärung* (*BzgA* – Federal Centre for Health Education) 1.7 per cent of the women interviewed were affected by involuntary childlessness (according to the above definition they suffered from "primary sterility", termed "primary infertility" by the *BzgA*) and 1.8 per cent suffered from "secondary sterility" or "secondary infertility" after they had had at least one child. 15 per cent of the women interviewed in this study had experienced an infertile phase at some time in their lives. Cf. *Bundeszentrale für gesundheitliche Aufklärung* (Federal Centre for Health Education) 2000, p. 14.

causes of and the prognosis for the fertility disorder. In reproductive medicine, *infertility* is described as the inability to carry to term and give birth to a viable child.[81]

1.2.2.2.2 Assisted reproduction

"Assisted reproductive technologies" (ART) comprise all medical treatments and procedures which involve the surgical retrieval of oocytes from a woman's ovaries and the subsequent fertilisation of the egg cells with male sperm. These procedures currently include[82]:

- in-vitro fertilisation (IVF) with subsequent embryo transfer (ET)[83],
- intracytoplasmic sperm injection (ICSI)[84] into the egg cell with subsequent ET,
- gamete intrafallopian transfer (GIFT)[85],
- zygote intrafallopian transfer (ZIFT) and embryo intrafallopian transfer (EIFT)[86],
- cryopreservation of fertilised egg cells at the pronuclear stage or the use of such "impregnated" frozen egg cells for the purpose of assisted reproduction.

In fact, IVF-ET is conception bypassing the fallopian tube passage. After hormonal stimulation of the ovaries mature oocytes are retrieved, mostly by means of transvaginal ultrasound-assisted aspiration, and fertilised outside the body. About 48 hours after successful fertilisation the embryos are transvaginally emplaced into the uterus. The details of IVF are described in section C1.2.3.

All other procedures may also be seen as special cases or variants of IVF. They differ from classical IVF at the stage of fertilisation (ICSI) and/or the stage of retransfer into the woman's body (GIFT, ZIFT, EIFT). Cryopreservation is essentially a technological step to preserve either fertilised pronuclear-stage egg cells or embryos (in Germany[87], permissible only in

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[81] Cf. Mettler *et al.* 2001, p. 194. Compared with the average population, infertile couples have a reduced ability to conceive. This phenomenon can be subdivided into cases where conception is not possible without treatment, and cases where, even though fertility is reduced (hypofertility), conception is possible without treatment. Cf. European Society of Human Reproduction and Embryology (ESHRE) 2000, pp. 723-732.

[82] *Bundesärztekammer* (German Medical Association) 1998b, A 3166-A 3171.

[83] In-vitro fertilisation ("fertilisation in a test tube") describes the union of egg cell and sperm cell outside the body (which is why the procedure is also referred to as "extracorporeal fertilisation"). The emplacement of the embryo into the uterus is called embryo transfer.

[84] Fertilisation of the oocyte by injecting a single spermatozoon. Spermatozoa can be recovered from the ejaculate or extracted directly from the epididymis or the testes.

[85] Transfer of egg cells and sperm cells into the fallopian tube by means of a catheter (gamete intrafallopian transfer). As only a resulting pregnancy is proof of successful fertilisation, it is also possible to transfer the fertilised egg cell or the embryo into the tube.

[86] Transfer of the fertilised oocyte (zygote) or the embryo into the fallopian tube (zygote intrafallopian transfer, ZIFT, or embryo intrafallopian transfer, EIFT).

[87] According to data provided by the *Deutsches IVF-Register* (DIR – German IVF Registry) a total of 406 embryos were frozen in Germany between 1998 and 2000 "for emergencies". 335 of these were thawed and implanted in their genetic mothers as part of the IVF treatment (Felberbaum 2001). See also *Deutsches IVF-Register 2000*, p. 26. For further details, see C1.2.3.2 Cryopreservation.

special cases). Spermatozoa can also be frozen. In the case of some still unresolved problems oocytes or testicular and ovarian tissues are also cryopreserved on a trial basis.[88]

A common characteristic of all reproductive techniques is that they require medical procedures to be performed on a woman's body: hormonal stimulation of oocyte maturation and surgical retrieval of the egg cells and finally the transfer of embryos or gametes into the uterus.

Today, these procedures are also performed if the woman's fertility is not compromised at all. In other words, the woman is treated for the man's inability to induce pregnancy. In contrast to the beginnings of ART in the 1980s when IVF was recommended exclusively for the treatment of women whose oviducts were missing or blocked, these procedures have also been performed since the late 1990s to treat male infertility.[89]

1.2.3 *In-vitro* fertilisation[90]

Strictly speaking, in-vitro fertilisation (IVF), as the "core" of the various methods of assisted reproduction or – in a broader sense – of reproductive genetics, only refers to the union of egg cell and sperm cell outside the body in a test tube where the actual fertilisation process takes place and where (if it is successful) the first cleavages occur.

However, a complete IVF treatment cycle includes some additional steps and takes several weeks:

– hormonal stimulation of a woman to induce multiple oocyte maturation and ovulation,
– retrieval of egg cells and collection of sperm,
– fertilisation,
– embryo culture,
– embryo transfer,
– follow-up controls.

[88] See C1.2.3.2 Cryopreservation.
[89] E.g. by means of intracytoplasmic sperm injection (ICSI), cf. C1.2.4.2.3.1 Intracytoplasmic sperm injection – a special case.
[90] Cf. Tinneberg/Ottmar 1995. See also http://www.familienplanung.de/kinderwunsch/daten/f3_02.htm (as of 27 March 2002) (Website of the *Bundeszentrale für gesundheitliche Aufklärung* (BzgA - Federal Centre for Health Education).

1.2.3.1 The various steps of the in-vitro fertilisation treatment cycle

1.2.3.1.1 Hormonal stimulation to induce multiple oocyte maturation and ovulation

As a rule, only one egg per menstrual cycle matures in the ovaries. In assisted reproduction hormonal regulation is stimulated and the cycle controlled in such a way that several oocytes mature at the same time to improve the chances of successful test tube fertilisation and subsequent embryo transfer:

– **Preparatory treatment** with oral contraceptives[91] about one month prior to the actual IVF treatment cycle, i.e. a daily dose for a minimum of 15 days and a maximum of 22 days after the beginning of the normal period; this will be followed by a drug to be injected two or three times to suppress the release of endogenous LH[92], a hormone inducing follicle maturation.

– **Stimulation of oocyte maturation** (follicle stimulation): After menstruation, hormones (e.g. follicle-stimulating hormone, FSH) are administered several times to stimulate the ovaries and ensure that several follicles mature at the same time. This will increase the chances of retrieving several egg cells that can be fertilised. Follicle development will then be monitored with a combination of ultrasound scans and hormone analysis (blood tests).

– **Ovulation induction** by intramuscular hCG[93] injection about one week after initiation of ovarian stimulation. Ovulation will only be induced when regular ultrasound scans show that the largest follicle has reached a diameter of about 18 to 20 mm and when blood hormone levels also indicate adequate oocyte maturity.

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[91] For oocyte stimulation (follicle stimulation) required for IVF different treatment regimens can be applied, e.g. "ultra-long protocol", "ultra-short protocol" und "low-dose protocol". According to the BZgA various hormone preparations are used for hormonal stimulation, depending on the treatment regimen applied (http://www.familienplanung.de/kinderwunsch/daten/f3_02.htm) (as of 27 March 2002) The following approaches are commonly used:
- Exclusive direct stimulation of hormone formation in the ovaries by administering drugs to stimulate the release of hormones from the pituitary gland;
- indirect stimulation, followed by injections of FSH (follicle-stimulating hormone) and hMG (human menopausal gonadotropin) for direct stimulation of the ovaries to induce multiple oocyte maturation;
- combination of stimulation with a GnRH (gonadotropin releasing hormone) analogue or GnRH antagonist to ensure better control of subsequent egg cell maturation and the time of ovulation.

Due to different drugs and dosages administered, the number of days cited will vary depending on the treatment regimen applied. The example chosen here represents a so-called "ultra-short-protocol".

[92] LH = luteinising hormone.

[93] hCG = human chorionic gonadotropin.

Since hormonal stimulation and superovulation "involve an increased risk for some patients to develop ovarian hyperstimulation syndrome"[94], alternative methods are currently being investigated, e.g. foregoing hormonal stimulation either completely or in part prior to retrieving the egg cells,[95] harvesting immature oocytes and letting them mature in vitro (so-called in vitro maturation, IVM).

1.2.3.1.2 Retrieval of egg cells and collection of semen

By administering a certain hormone, the time of egg retrieval can be scheduled with great precision. The collection of semen is timed in such a way that male and female gametes can be optimally prepared for the subsequent fertilisation process.

– **Oocyte retrieval:** About 35 hours after hCG has been administered, oocytes are surgically retrieved, using a long, thin aspirating needle. Basically, there are two oocyte retrieval (follicle puncture) methods[96]:

  – **Laparoscopic follicle puncture** (Advantage: direct visual control of the intervention by means of a so-called optical trocar which is introduced through an incision in the umbilical fossa. In case of bleeding, treatment is immediately possible; disadvantage: mostly performed under general anaesthesia, surgical risk, follicles embedded more deeply in the ovary are difficult to find);

  – **Ultrasound-controlled (usually transvaginal) follicle puncture** (Ultrasound transducer and needle are introduced into the vagina; follicles can be aspired after puncturing the vaginal wall. Advantage: Anaesthesia is rarely necessary, procedure can be performed on an out-patient basis; disadvantages: painful, risk of abdominal bleeding, possible inflammations may be overlooked).[97]

  The success rates of the two procedures do not differ substantially. Usually, eight to ten egg cells are retrieved.

[94] Seehaus *et al.* 2000, p. 105. For risks of hormone treatment to the female patient, see C1.2.3.5.1.1 Risks of hormone treatment.

[95] E.g. Nargund *et al.* 2001, pp. 259 – 262. The authors evaluate fertilisation success achieved in 52 women whose partners have normal fertility parameters, based on a total of 181 IVF cycles (equivalent to 3.5 cycles/woman). They conclude that "spontaneous IVF cycles" are safer and less stressful than hormonally stimulated IVF cycles. At the same time they stress the financial savings potential compared with conventional IVF. See also C1.2.3.5.1.1 Risks of hormone treatment.

[96] Tinneberg 1995b, p. 113ff.

[97] Tinneberg 1995b, pp. 113, 116.

– **Collection and preparation of sperm:** Semen is usually collected by masturbation. On the day of egg cell retrieval, the husband's ejaculate is analysed in an andrological laboratory, and after adding a culture medium sperm is separated from other material present in the ejaculate. Spermatozoa with the highest progressive motility are isolated from the seminal fluid and used for insemination.[98]

  In the case of male factor disorders (e.g. occlusion of seminal ducts), spermatozoa can be extracted directly from the testes[99] or epididymis[100] by surgical intervention. Intracytoplasmic sperm injection (ICSI) means that one of these spermatozoa is then directly injected into the oocyte by means of a micro-needle.

1.2.3.1.3 Fertilisation

In conventional IVF, about 100,000 spermatozoa are brought into contact with an egg cell in a culture medium about two to four hours after oocyte retrieval and one hour after semen processing, and cultivated in an incubator for two days at a temperature of about 37°C.

In addition to treating sperm maturation disorders, ICSI is also preferably used to fertilise frozen-thawed oocytes. ICSI is the procedure that the European Society for Human Reproduction and Embryology (ESHRE) wants to see established as the standard procedure used for PGD.[101] As early as 18 hours after fertilisation the success of the procedure is verified microscopically. The presence of the two pronuclei and their morphology are also verified.

Fertilisation is a continuous process, beginning with a single sperm attaching to the egg cell and ending with the union of the pronuclei (see Chart 1). For the purposes of the Embryo Protection Act, the fertilised egg remains a germ line cell as long as the two pronuclear membranes are still present and the fertilisation process has not yet been completed. Moreover, Section 8(2) of the Embryo Protection Act stipulates that

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[98] In assisted reproduction, sperm is prepared by means of various filtration and centrifuging procedures. The objective is always to separate motile spermatozoa and eliminate various other factors from the ejaculate that might compromise the fertilisation result. Cf. Tinneberg 1995b, p. 118 ff.

[99] Testicular Sperm Extraction (TESE).

[100] Microsurgical Epididymal Sperm Aspiration (MESA).

[101] The integration of the various scientific and technical development steps into reproductive medicine cannot be overlooked. ESHRE, for example, recommends that ICSI should be applied as a standard procedure in PGD in order to preclude any contamination of the embryonic cell sample with paternal DNA, thus increasing the reliability of the molecular genetic test. In normal IVF, sperm which did not succeed in fertilising the egg can accumulate at the outer layers of the egg cell. Residues of these sperm can get into the sample material and falsify the analytical result (cf. C1.4.1.1.2 Single-cell diagnosis). It is common practice for the adoption of any procedure promising to increase the chances of success or reduce any adverse effects to be discussed in the literature.

> "in the first twenty-four hours after nuclear union, the fertilised human egg shall be considered to be capable of development, unless it has been established prior to expiry of this period that it will not develop beyond the one-cell stage."

Reproductive endocrinologists criticise that the Embryo Protection Act only permits the diagnosis of the viability of the two pronuclei, but does not allow a microscopic morphological selection of embryos prior to implantation.[102]

A special scoring or assessment programme for optimised pronuclear-stage diagnosis is now being tested. "The pregnancy rate for pronuclear-stage egg cells with the highest score was 55 per cent. Moreover, a major difference in pronuclear size of at least 4 mm seems to indicate a higher risk of mosaicism and arrest at the pronuclear stage."[103]

1.2.3.1.4 Embryo culture

At present, the cultivation technique used is still considered suboptimal and hence is one of the priorities of IVF research.[104] In addition to the so-called co-culture where certain cell types from the female genital tract are added to the culture medium, the use of a blastocyst culture is being considered. This implies that embryo cultivation could be continued beyond the third day by means of newly developed culture media and would open up the possibility of emplacing the embryos into the uterus on the fifth day, i.e. a point in time much closer to implantation after natural fertilisation. The benefits cited include better assessability of embryonic development, greater chances of nidation and the resulting potential reduction in multiple pregnancy rates after IVF.[105] So far, however, it has not yet been established by comparative studies whether after five days the viability and developmental capacity of an embryo can indeed be diagnosed with greater reliability than that of an oocyte or a fertilised egg cell at the pronuclear stage. A controlled comparative study did not show any differences in terms of implantation and pregnancy rates, multiple pregnancy rates and number of miscarriages.[106] It has been criticised that after trials with laboratory mice the procedure was applied to humans too soon. It is not yet known whether the longer cultivation period will have lasting consequences. Experiments with bovine and ovine embryos indicate that there

[102] Oral communication by Professor Felberbaum at the non-public hearing on 26 March 2001. He did say, however, that if two morphologically "ideal" embryos were implanted, a pregnancy rate of 25 per cent per embryo transfer could be achieved, while in the case of two embryos that had not been previously examined the rate was only slightly more than 9 per cent.
[103] Seehaus *et al.* 2000, p. 109.
[104] Seehaus *et al.* 2000.
[105] Seehaus *et al.* 2000, p. 109.

might be a connection with malformations and developmental disorders (especially foetal oversize – large-offspring syndrome).[107]

1.2.3.1.5 Embryo transfer

When one or more egg cells have been successfully fertilised, when the microscopic assessment of pronuclear-stage egg cells has been completed and when the first cell divisions have taken place in the culture, a thin, flexible catheter is passed through the vagina and the cervix to deposit the embryos (up to three in Germany) in the uterine cavity.

1.2.3.1.6 Follow-up controls

Pregnancy can be established either on the basis of pregnancy-specific proteins in maternal serum or by means of ultrasound scans:

> "An intrauterine pregnancy can be established as early as two weeks after fertilisation based on the amniotic sac. (...) The final proof, however, (...) is the verification of cardiac activity, which is possible on day 35 after fertilisation."[108]

1.2.3.2 Cryopreservation

Oocytes, spermatozoa, pronuclear-stage egg cells, embryos, testicular tissue, ovarian tissue, spermatogones, stem cells and any kind of precursor cells of the gametes can be preserved over a long period of time by freezing at very low temperatures. So-called cryopreservation consists of a defined cooling-down process to about -180°C within one or two hours in special freezing and culture media (cryoprotective agents). Cells or tissues are then stored at -196°C in special tanks filled with nitrogen.

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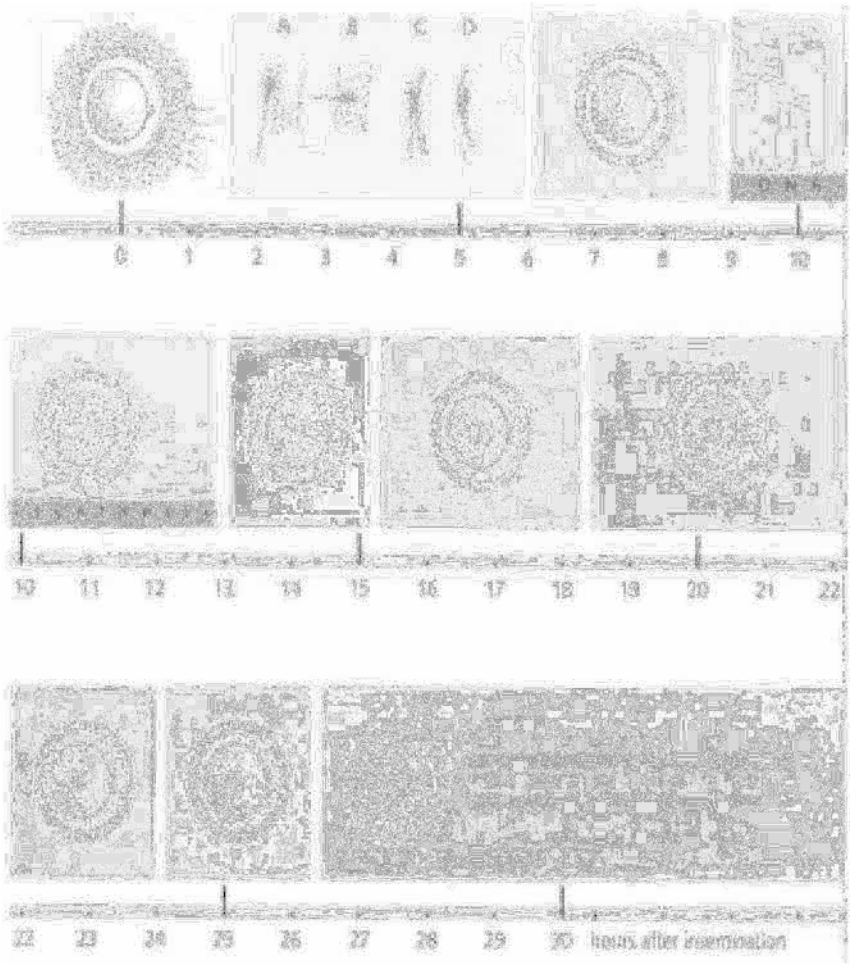
[106] Coskun *et al.* 2000, pp. 1947-1952. Cf. also Alper *et al.* 2001, pp. 617-619. So far, higher pregnancy rates could only be achieved in groups of specially selected patients (Brown 2000). See also Kollek 2000, pp. 41-44.

[107] Brown 2000, pp. 30-33, especially p. 33; Coskun *et al.* 2001.

[108] Simon 1995, p. 134.

Chart 1: Fertilisation Process



Notes on Chart 1: The time of insemination is given as zero. Sperm reach the *zona pellucida*, and after the acrosome reaction **(A)** has occurred, they actively penetrate into the zona **(B).** As soon as the first sperm has fused with the *zona pellucida*, cortical granules are released **(C),** rendering the *zona pellucida* impenetrable for other sperm. The spermatozoon is absorbed by the egg **(D).** The head of the sperm transforms (decondensation), a process which is completed after about 8 hours. The second polar body is released, and pronuclei begin to form, a process that is completed about 12 hours after insemination. DNA synthesis begins after 9 hours, peaks between hour 9 and 13 and then abates quickly. About 20 hours after insemination, the pronuclei migrate to the centre where they move towards each other. After approximately 22 hours, they begin to decondense. Gamete conjugation occurs after about 23 hours, to be followed soon afterwards by chromosome condensation and the initiation of the first mitosis.

Source: Cleine 1996, p. 140

Sperm cryopreservation is today performed on a routine basis and considered unproblematic, providing that the sperm parameters have not changed too much.[109] The first successful fertilisation with a cryopreserved semen specimen and resulting pregnancy were reported as early as the 1940s.[110]

[109] Sperm were frozen for the first time in 1938. For the scientific state of the art, see Siebzehnrübl *et al.* 1997, p. 20 ff. For sperm parameters, see also C1.2.3.4.2 Medical diagnosis of male fertility disorders.

[110] Synopses in Byrd *et al.* 1990; Kliesch *et al.* 2000; Nagy *et al.* 1995.

It has been common practice for many years also to freeze and store ovarian and testicular tissues.[111] Over time the methods employed have become more sophisticated and yield very good results.[112] Pregnancy has been achieved by injecting sperm extracted from cryopreserved tissue.[113]

Today, many working groups worldwide freeze embryos. Depending on the legal situation, this process has become an integral part of sterility management.[114] Cryopreservation of impregnated egg cells, so-called pronuclear-stage oocytes, is also possible today by using standard procedures; this process is extensively used in Germany where producing and freezing "supernumerary" embryos is banned by law. However, the literature cites strong variations in the success rate of these procedures.[115]

Over a long period of time, scientists did not continue to work on freezing unfertilised egg cells (oocytes) so that the procedure is still experimental.[116] It is controversial whether oocyte cryopreservation could damage the spindle apparatus required to distribute chromosomes during cleavage and thus lead to an increase in chromosomal damage in the children conceived.[117] It must be noted, however, that - regardless of any potential damage to the spindle - the survival rate of oocytes after thawing is variable. Freezing oocytes is more difficult than freezing embryos, partly due to the much poorer surface-volume ratio which produces a higher osmotic load on the cell membrane.[118] Quick freezing of oocytes, for instance, may result in cell damage as intracellular ice crystals form. The choice of cryoprotectants (storage media) is of crucial importance for the safe cryopreservation of oocytes. Changes in the *zona pellucida* (the outer membrane around the oocyte) are also blamed for poor fertilisation rates after thawing.[119] Finally, data provided in the scientific literature still vary and cannot be definitively evaluated because of the small number of studies currently available. In early 2000, the British Human Fertilisation and Embryology Authority (HFEA), in spite of its concerns, approved the use of frozen egg cells for IVF.[120]

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[111] Since 1994. Cf. e.g. Aubard *et al.* 1994. See also Burks *et al.* 1965; Stahler *et al.* 1976.
[112] Allan/Cotman 1997; Crabbe *et al.* 1999.
[113] Cf. e.g. Fischer *et al.* 1996.
[114] Embryos have been cryopreserved since 1983. An outline can be found in Siebzehnrübl *et al.* 1997, p. 20 ff.
[115] See Siebzehnrübl *et al.* 1997, p. 20 ff.
[116] Oocyte cryopreservation has been available since 1986. Cf.. Seehaus *et al.* 2000.
[117] Cf. also Trounson/Kirby 1989; Pickering/Johnson 1987; Spitzer *et al.* 1998.
[118] Leibo 1977.
[119] Carroll *et al.* 1990.
[120] See Human Fertilisation and Embryology Authority (HFEA) Annual Report 2000, 6. Policy update and issues for the coming year (http://www.hfea.gov.uk/frame.htm). According to this report approval was granted even though "the HFEA was not satisfied that there was enough medical research to show that their use in treatment was sufficiently safe". Reports on HFEA experience are not yet available (as of 27 March 2002).

In 1997, the first child was born after oocyte cryopreservation in combination with ICSI.[121] After more than 100 cryocycles Porcu and his team could report an average oocyte survival rate of 55 per cent, a fertilisation rate of 60 per cent and a pregnancy rate of 17 per cent.

In summary it may be said that until recently results obtained with oocyte cryopreservation were not satisfactory; this is why at present this method is not an integral part of clinical routine.

It was only recently that promising approaches have been developed. The most research results have demonstrated that under adequate storage conditions, the oocyte survival rate can be raised to more than 80 per cent. A significantly higher survival rate could be achieved especially in those cases where the egg cells were frozen at increased sucrose concentrations. Prolonged oocyte exposure to the cryoprotectant prior to freezing also seems to have a positive effect on the survival rate. Consequently, the freezing rate and the storage medium may be considered to be relevant factors in the cryopreservation of egg cells.[122] However, it should be noted that further research is needed in this area.

Originally cryopreservation techniques were developed for the benefit of men, women and children who had to undergo chemotherapy or radiotherapeutic treatment. Since these types of cancer treatment involve the risk of future infertility, freezing and storing gametes was seen as a possibility to preserve their reproductive capacity for a later point in time.

Today, cryopreservation techniques are widely used in assisted reproduction. Oocyte cryopreservation represents an alternative especially in those cases where the freezing of embryos is not possible for technical, legal or religious reasons. Reproductive medicine also offers oocyte cryopreservation with a view to evading an age-related decline in female fecundity.[123]

Unlike medically assisted reproductive techniques, measures relating to freezing and storing gametes or pronuclear-stage oocytes are not among the services paid for by German statutory health insurance schemes. This applies irrespective of the treatment purpose, i.e. costs are not reimbursed, no matter whether the procedure is performed in connection with tumour therapy or to treat involuntary childlessness. The Study Commission inquired in writing about the status of cryopreservation at Germany's leading centres of reproductive medicine and was

[121] Porcu *et al.* 1997.
[122] See, for example, Fabbri *et al.* 2000, 2001; Oktay *et al.* 2001.
[123] Oktay *et al.* 2001.

informed that the storage costs per specimen averaged between € 250.00 and € 400.00 per year.[124] Since the better part of assisted reproduction treatment – more than 80 per cent – is provided by private institutions, it is also mostly private centres that offer cryopreservation services for gametes or fertilised egg cells at the pronuclear stage.

There is no legal basis in Germany for educating and informing patients or for handling cryopreserved material. However, it is standard procedure for the male patient to be given written or oral information on the method and implementation of cryopreservation. He has to give his written consent to thawing, treatment or destruction. When pronuclear-stage egg cells are stored, the couple concerned receive written and oral information on the method and implementation of cryopreservation and the chances of a future pregnancy. Both partners sign a cryopreservation contract, and prior to thawing both partners have to confirm that they jointly wish for a transfer.[125] The customary storage time is two years for pronuclear-stage oocytes and one year for sperm.[126] Prior to cryopreservation patients are reminded that cell survival cannot always be expected.[127] Since Sec. 4(1) No. 3 of the Embryo Protection Act prohibits the post-mortal use of gametes, the preserved material will be destroyed if and when the death of the person concerned becomes known.

According to current knowledge, there are various centres in Germany that freeze and store unfertilised oocytes and fertilised eggs at the pronuclear stage. However, a precise enumeration is not possible as there is no general register providing information on the storage of cryopreserved material.

When examining the 1999 figures of the *Deutsches IVF-Register* (DIR – German IVF Registry), the extremely low rate of cryopreserved oocytes is conspicuous: In 1999, a total of 397,377 oocytes were retrieved in 43,378 cycles. Only 0.03 per cent of these (118) were cryopreserved.[128] It seems to be possible indeed that this number could be increased if the centres of reproductive medicine changed their range of services or their information policy.

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[124] *Bundesverband Reproduktionsmedizinischer Zentren* (Association of German Reproductive Centres) 2001. Although storage is not unlimited, it may well be assumed that storage is possible for decades. The following empirical values are available: sperm > 10 years, oocytes < 5 years, pronuclei ≈ nine years (clinical), embryos ≈ seven years (clinical), testicular tissue ≈ six years (clinical), ovarian tissue (only experimental so far). Cf. van der Ven/Montag 2001.

[125] Nieschlag *et al.* 2001.

[126] Katzorke *et al.* 2001.

[127] Diedrich *et al.* 2001.

[128] *Deutsches IVF-Register* 1999, p. 10.

In the years from 1998 to 2000, a total of 126,772 fertilised oocytes at the pronuclear stage were cryopreserved.[129]

1.2.3.3 Problems associated with egg cell donation

a. Legal situation in Germany

– **Egg cell donation for reproductive purposes:**

The Embryo Protection Act prohibits egg cell donations for reproductive purposes. This provision was primarily intended to prevent motherhood from being split into a genetic mother (egg cell donor) and a biological mother (recipient carrying the foetus to term), since this would involve unresolved consequences for the development of the child's identity and might not serve the welfare of the child.[130]

The ban on egg cell donation is laid down in Sec. 1(1) Nos. 1 and 2 of the German Embryo Protection Act:

"Anyone shall be punished with up to three years of imprisonment or a fine who

1. transfers into a woman an unfertilised egg cell produced by another woman,
2. attempts to fertilise artificially an egg cell for any purpose other than to induce a pregnancy in the woman from whom the egg cell originated."

Consequently, unlawful egg cell manipulations by physicians are punishable, while the oocyte donor and the recipient of the egg cell will not be liable to prosecution (Sec. 1(3) No. 1 Embryo Protection Act). This is due to personal grounds for exemption from punishment for an unlawful act[131] so that the unlawful nature of the egg cell donation as such remains unaffected.

– **Egg cell donation for non-reproductive purposes:**

When an egg cell donation does not involve any of the acts that are punishable under the Embryo Protection Act[132], the donation for non-reproductive purposes is governed by the principles of general criminal, civil and medical law. An egg cell donation constitutes an

[129] *Deutsches IVF-Register* 2001. Cf. *Deutsches IVF-Register* (DIR) 2000, p. 26.

[130] There is no male equivalent to split motherhood associated with egg cell donation (the oocyte donor is the genetic mother; the oocyte recipient is the biological mother). However, for both men and women it is possible to split parenthood into genetic and social parenthood. It should be stressed that split motherhood sets aside the historical fact of "*mater semper certa est*" (the mother is always certain).

[131] Cf. Keller *et al.* 1992, Sec. 1(2) clause 1.

[132] Also in case of "therapeutic cloning", formation of chimera or hybridisation the egg cell donor should not be considered liable to prosecution. Cf. Keller *et al.* 1992, Sec. 6 clause 14; 7 clause. 44.

invasive procedure for the benefit of a third party, which involves the risk of injuring the donor's health. It is only with major qualifications that the legal system permits medical interventions to be performed on humans for the benefit of third parties – e.g. medical trials involving humans or organ donations by living donors – even if the donor has given her consent. Even consent given after extensive medical information (informed consent) can justify an intervention only if the associated stress and discomfort are in proper proportion to the intervention's benefit for third parties. Otherwise the consent of those concerned is considered unethical and hence null and void.[133] If the consent is unethical, the bodily injury is unlawful pursuant to Sec. 228 of the Criminal Code in spite of the consent. Also in those cases where the egg cell donation is intended for unlawful purposes (such as cloning, formation of chimeras or hybridisation), the bodily injury is to be considered unethical despite the consent given.

b. Scientific assessment of the demand for oocytes for non-reproductive purposes (research and future therapy)

According to present scientific assessment a large number of oocytes are needed for so-called "therapeutic cloning". Alan Colman of PPL Therapeutics in Roslin and Alexander Kind – one of the scientific "fathers" of Dolly, the cloned sheep – calculated on the basis of animal experiments that at least 280 egg cells would be needed to clone every human stem cell line.[134] This means that the consumption of thousands, if not hundreds of thousands of egg cells is foreseeable for this kind of research. The question is still open as how this demand for egg cells is to be met. When egg cells are retrieved after hormonal stimulation, an average eight to ten oocytes are recovered.

c. Risks associated with egg cell donation

Unlike sperm donation by a male donor, egg cell donation involves major stress and discomfort for the female donor.[135] In the recent discussion on egg cell donation, attention was drawn especially to the invasive intervention required for oocyte retrieval, which is by no means without risk. Hormonal stimulation which stretches over several weeks also involves the risk of developing the dangerous ovarian hyperstimulation syndrome and is suspected of

[133] Pichlhofer *et al.* 2000, p. 42 (with further references).
[134] Colman/Kind 2000, p. 193.
[135] Cf. C1.2.3.1.1 Hormonal stimulation to induce multiple oocyte maturation and ovulation, C1.2.3.1.2 Retrieval of egg cells and collection of sperm, and C1.2.3.4.1 Medical diagnosis of female fertility disorders.

causing ovarian cancer.[136] Follicle puncture is associated with the risk of injuries, haemorrhaging and inflammation.

d. Ethical and social policy discussion of egg cell donation

Egg cell donation is an intervention for the benefit of third parties which cannot be balanced with any benefit for the health of the donor, but exclusively serves the interests of third parties (such as researchers and future patient groups). Ethically speaking, this is a violation of the fundamental principle of not doing any harm which invariably has to govern any medical intervention (*primum nil nocere*); consequently, it is difficult to reconcile this fact with the traditional medical mandate to cure which is based on individual ethics. Granting approval for egg cell donation for non-reproductive purposes would introduce a new quality to the doctor-patient relationship and imply the existence of a service contract between the physician and the donor.[137]

Law-makers should include in their considerations the notion that approval of "therapeutic" cloning for research purposes would trigger a major demand for female egg cells. This in turn could lead to developments that are considered socially problematic.

It cannot be precluded that the demand for egg cells by researchers studying "therapeutic" cloning could encourage a commercialisation of egg cell donations. Economically underprivileged women might be induced to undergo oocyte retrieval in exchange for money. It can be observed in some countries (e.g. the United States) that payment for donated egg cells is masked as "reimbursement of expenses" for travel, lost earnings etc. In some regions a market for egg cells has already developed.

There are also divergent social science and ethical views regarding altruistic egg cell donation, e.g. within a family. On the one hand, there seem to be analogies with living organ donation, which is permitted under the Transplantation Act, but limited to the group of persons close to the donor, and which is subject to scrutiny by special committees. On the other hand, it is argued that even though egg cells in a certain sense are "renewable body

[136] Cf. Pichlhofer *et al.* 2000, p. 43.

[137] Voluntary and informed consent to medical intervention is usually the legal requirement for exemption from punishment of the physician performing this intervention. If an intervention involves potential risks, these risks must be justified by a need for treatment or testing which offsets the risks, by the necessity of the intervention in question and by the expected efficacy of the therapy or the predictive power of the test. Consequently, medical procedures should not simply comply with the patient's wish, but they are governed by more general ethical and legal norms. The patient's consent does not automatically grant the physician licence to perform any medical intervention. Special conditions apply to clinical research, and in this context informed consent is a necessary, but not a sufficient prerequisite. Cf. Schneider 2002.

substances" (hence suggesting an analogy with blood donation), due consideration needs to be given to the special quality of germ cells as "substances passing on human life" and the indissoluble genetic relationship with the germ cell carrier. This is why, for example, it is hotly debated in legal literature whether germ material is a simple object, whether it can be owned, whether it can be disposed of and even be treated as valuable merchandise.[138]

International experts are also discussing the fact that, in the final analysis, any financial or other transactions promised in connection with the egg cell donation within the family cannot be monitored and verified. It has also been suggested that emotional dependencies in one's personal environment could undermine the required voluntary nature of the egg cell donation and lead to conflicting social obligations. With regard to the therapeutic use of cloning through nuclear transfer, various scenarios of developing social pressure within the family would be conceivable, e.g. a situation where pressure is put on daughters to donate egg cells for their father who is suffering from Parkinson's disease so that embryos can be produced for breeding the required, genetically matching organ replacement.

This is why in the literature legal approval of egg cell donation is described as an "act of female self-determination" on the one hand, and as "turning women into raw material suppliers" on the other.

1.2.3.4 Medical causes and diagnosis of fertility disorders and possible reproductive treatments

Apart from assisted reproductive technologies (ART) there are also other methods available for the medical treatment of female and (to a very limited extent) male infertility. Physicians should examine and exclude these methods before they perform ART[139]

Prior to any medical treatment of fertility disorders their physical causes must be diagnosed. This is why in the following the most important fertility disorders and methods to diagnose them are described before other treatment possibilities that are available are discussed.

1.2.3.4.1 Medical diagnosis of female fertility disorders

Depending on the patient's history and findings, methods like ultrasound scan, hormone analysis or invasive/surgical examinations of the oviducts or the uterus may have to be employed to diagnose female fertility disorders.[140]

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[138] Lanz-Zumstein 1990, pp. 149-158.
[139] Cf. *Bundesärztekammer* (German Medical Association) 1998b, A 3167.

The following fundamental disorders of the female sexual organs[141] may lead to transient or persistent infertility or sterility:

– functional and hormonal disorders of the ovaries,

– lesions of the oviducts,

– disorders of the uterus and the cervix,

– endometriosis[142].

1.2.3.4.2 Medical diagnosis of male fertility disorders

To diagnose male fertility disorders the testicles and epididymis and various other glands (prostate, seminal vesicles) are examined by means of palpation and, if necessary, ultrasound.

The ejaculate is examined for the presence, number, shape and motility of spermatozoa. Sperm quality is then examined under the microscope and documented in a spermiogram. As sperm quality is highly variable, this examination is usually performed twice with an interval of one month.[143] Only then will other tests be performed such as blood hormone level analysis, testicular biopsy or also genetic tests.

Disorders of the male sexual organs which may lead to transient or persistent infertility or inability to impregnate are categorised as

– sperm production disorders, and

– sperm transport disorders.[144]

Disorders of sperm production (spermatogenesis) occur when not enough healthy, motile spermatozoa are produced. Beginning at puberty, the testes constantly produce spherical spermatids, the precursors of mature sperm (spermatozoa), from the so-called spermatogones by means of hormonally regulated cell division processes. In a "highly sensitive and fragile

[140] When tubal lesions or changes are suspected, imaging and surgical procedures are applied. Imaging procedures include hysterosalpingography (HSG) and hysterosalpingo-contrast sonography. Surgical diagnostic procedures that may be considered are laparoscopy and hysteroscopy.

[141] For details, see Mettler 1995, p. 92 ff.

[142] Endometriosis is a condition where uterine mucosa is found outside the uterine cavity, e.g. in the ovaries, the fallopian tubes, on the intestines or the bladder. This may lead to adhesions in the abdominal cavity and difficulties in conceiving. A frequent symptom of endometriosis is severe pain before and during menstruation.

[143] Reference values for normal sperm quality are: sperm volume 2 to 5 ml, at least 20 million sperm per ml seminal fluid, of these at least 50 per cent with good motility and at least 30 per cent with normal morphology (head, flagellum).

[144] For spermatogenetic disorders, see Steger 2001.

remodelling process"[145] spermatids mature to form spermatozoa. It is during their subsequent migration from the head to the tail of the epididymis where they are stored that the spermatozoa acquire their fertilising capacity (sperm maturation).

Overall, the entire process of sperm formation and maturation takes at least 82 days, a fact that needs to be taken into account when treating male fertility disorders. The causes of the disruption of this process may be an inherited condition, infections, injuries of the testicles, e.g. due to an accident, environmental pollutants or excessive consumption of drugs such as nicotine or alcohol, and special environmental effects, e.g. constant exposure to excessive heat at the workplace. Disorders may be transient, e.g. caused by fever or viral infections like German measles, or persistent, e.g. caused by mumps, or undescended testicles that were not corrected in time.

Sperm transport disorders (occlusion of the deferent seminal passages, mostly in the epididymal region, or blocked spermatic ducts due to injuries or infections or after vasectomy) which prevent the spermatozoa from becoming part of the ejaculate have a lower incidence.

Before ICSI is performed, it is recommended that both partners' family histories should be checked for miscarriages and stillbirths as well as fertility disorders.

1.2.3.4.3 Treatment of female reproductive disorders

1.2.3.4.3.1 Surgical procedures

Apart from the various methods of extracorporeal fertilisation, female reproductive disorders can sometimes be treated by means of surgical intervention. Pregnancy rates of between 40 and 65 per cent have been reported after ovarian surgery (removal of ovarian cysts) and surgery performed on malformed tubal infundibula and fallopian tubes.[146]

1.2.3.4.3.2 Egg cell donation and surrogacy

Other possibilities are egg cell donation[147], which is banned in Germany under the Embryo Protection Act to prevent "split" motherhood (biological and social mother), and surrogacy, which is not permitted in Germany, either. While egg cell donation is permitted in Denmark,

[145] Schill/Haidl 1995, p. 41. In this process, DNA-containing chromatin from which the chromosomes are formed is condensed, and acrosome, which is necessary for penetrating the egg cell, and the flagella needed to ensure sperm motility, are formed.
[146] Mettler *et al.* 2001, pp. 194-200.
[147] Cf. C1.2.3.3 Problems associated with egg cell donation.

France, the UK and Spain, surrogacy is either prohibited or not regulated in Europe (except for the UK).[148] In the United States, both procedures as well as embryo donation are available.[149]

1.2.3.4.4 Treatment of male reproductive disorders

Pharmacotherapy and surgical procedures are available to treat ejaculate disorders. Sperm can be surgically extracted from the testicles or epididymis. Theoretically, immature precursor-stage sperm can also be recovered and matured in a culture medium; this procedure has already been successfully performed in animal models.

Germany and many other European countries offer the possibility of "heterologous" insemination (fertilisation with donor sperm) if these interventions are not successful or if sperm cannot be found (azoospermia). This procedure has been used since the 1970s, and up to now about 70,000 children have been born in Germany after heterologous insemination.[150] Specific legal regulations governing fertilisation with donor sperm do still not exist in this country. In its 1985 report, the working group on in-vitro fertilisation, genome analysis and gene therapy set up by the Federal Ministries of Justice and of Research and Technology (so-called Benda Commission) had advised against heterologous sperm donation and pointed out that it involved unresolved civil law issues (family law and law of succession).[151]

1.2.3.5 Medical risks of *in-vitro* fertilisation

The treatment steps mentioned above harbour a number of medical risks which can be broken down into risks for the woman and risks for the child. The surgical extraction of sperm from the testes or epididymis through biopsy or surgical exposure of the testicle is associated with the general risks of surgical interventions such as haemorrhaging, infection or tissue lesions.[152]

1.2.3.5.1 Risks for the woman

The process of assisted reproduction entails risks for the woman at the stages of hormonal stimulation of oocyte maturation, surgical egg cell retrieval and embryo transfer. Depending

[148] Koch, H.-G. 2001, p. 45.
[149] Centers for Disease Control and Prevention 1998.
[150] Günther/Fritsche 2000, p. 249.
[151] *Bundesministerium für Forschung und Technologie* and *Bundesministerium der Justiz* (Federal Ministries of Research and Technology and of Justice) 1985, p. 25 ff. Legal maternity was defined in the 1998 *Kindschaftsrechtsreformgesetz* (*KindRG* - Law of Parents and Child Reform Act), and the incontestability of legal paternity in the case of heterologous insemination by common consent was determined in the 2002 *Kinderrechteverbesserungsgesetz* (*KindRVerbG* – Children's Rights Improvement Act).

on the number of embryos successfully nidated in the uterus, other IVF-related risks may be associated with the pregnancy.

1.2.3.5.1.1 Risks of hormone treatment

Hormonal interventions in the body's regulating systems are almost never free from adverse effects. Apart from a general feeling of malaise often observed after IVF-related hormonal stimulation, the so-called ovarian hyperstimulation syndrome is one of the biggest risks involved. At worst, it leads to life-threatening breathing difficulties, enlargement of the ovaries, thrombosis and the accumulation of fluid in the abdominal and thoracic cavities. In 1997, the *Deutsches IVF-Register* (German IVF Registry) reported complications due to hyperstimulation in 3 per cent of all cases, in 1999 it was 0.8 per cent and in 2000 also 0.8 per cent.[153] A fatal outcome cannot be precluded.[154] International literature reported 18 deaths before 1990.[155] In 1999, a case of IVF-related myocardial infarction was reported in Lübeck.[156] Foregoing hormonal stimulation completely or in part as nowadays described in the literature would probably lower the risk.[157]

The drugs administered to stimulate the ovaries are suspected of causing extrauterine pregnancies. Studies have been launched to explore their carcinogenic potential.

1.2.3.5.1.2 Risks associated with oocyte retrieval

Egg cells are retrieved by surgical intervention. Complications occur in about 1 per cent of all cases.

1.2.3.5.1.3 Risks during pregnancy

Usually, several embryos are simultaneously transferred into the uterus to end involuntary childlessness.[158]

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[152] Literature references in Köhn/Schill 2000.

[153] 1997 and 1999 figures, according to oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001. Figures for 2000 calculated on the basis of *Deutsches IVF-Register* (German IVF Registry) 2000, p. 24

[154] Oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001.

[155] Klein 1990.

[156] The myocardial infarction did not lead to the patient's death, see Ludwig *et al.* 1999 and Ludwig 2000.

[157] Several approaches to retrieving egg cells from ovaries after no or only mild hormonal stimulation are currently under discussion. The maturation of the retrieved immature oocytes in the laboratory (IVM, in-vitro maturation) with the addition of various hormones and growth factors is of crucial importance for wider clinical application. IVM, however, is still at an experimental stage. Cf. Seehaus *et al.* 2000, p. 105 f. See also Rongieres-Bertrand *et al.* 1999, and Nargund *et al.* 2001.

[158] According to *Deutsches IVF-Register* 2000, p. 10 an average 2.3 embryos are transferred in IVF.

In 1999, the clinical pregnancy rate in Germany after the transfer of three embryos was 26.15 per cent, for two embryos it was 20.7 per cent and for one 8.5 per cent.[159] A breakdown of these clinical pregnancy rates by age group results in the following picture:

Table 2: Clinical pregnancy rates[160] as a function of maternal age and the number of embryos transferred

Age group	1 embryo	2 embryos	3 embryos
up to 20	0	8.33%	9.09%
20 - 24	9.28%	22.73%	31.76%
25 - 29	11.56%	27.32%	30.58%
30 - 34	10.12%	26.28%	31.10%
35 - 39	9.05%	21.15%	27.01%
40 - 44	5.71%	10.01%	18.96%
45 - 49	1.79%	0	6.67%
50 and older	0	0	0

Source: DIR 1999, p. 16 (changed)

In 1999, the general risk of spontaneous abortion after assisted reproduction in Germany was at least 25 per cent.[161] In addition, there are special risks involved in multiple pregnancies, such as hypertension, bleeding and delivery by caesarean section.[162]

While spontaneous conception results in about 1.2 per cent multiple pregnancies[163], the DIR in 1999 reported about 25 per cent multiple pregnancies; approximately 21 per cent were twins, almost 4 per cent triplets and in one case even quadruplets were born.

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[159] Felberbaum 2001, p. 269.

[160] On the significance of "clinical pregnancy/embryo transfer" rates see C1.2.4.2.4.3 What is the success of assisted reproduction – and how often does it occur?

[161] Cf. *Deutsches IVF-Register* (German IVF Registry) 2000, p. 14: The DIR cannot provide any data on the course of 1,474 of the total of 12,770 clinically established IVF pregnancies registered in 1999. The remaining 11,296 pregnancies resulted in 8,131 births and 380 so-called extrauterine pregnancies (pregnancies outside the uterus) which are not included in the 2,785 spontaneous abortions reported separately. Accordingly, the actual abortion rate is between about 25 per cent (reported abortions) and about 36 per cent (reported abortions, extrauterine pregnancies and clinical pregnancies without follow-up).

[162] Problems occurring after birth (weight and development of the children) will be discussed later.

[163] In the German-speaking regions the "natural" incidence of multiple-infant births is determined by applying the so-called "Hellin rule". According to this rule, there is one twin birth per 85 normal births (1.18 per cent),

Consequently, there is a higher incidence of premature delivery after IVF which may be accompanied by increased mortality in the first four weeks and malformations or developmental disorders in the infant.

1.2.3.5.2 Risks for the children

As already mentioned, the multiple pregnancy rate after IVF, which is 20 times higher than normal, harbours risks for the children born. In 1999, 97.7 per cent of the children born in Germany after single-embryo transfer were singletons and 2.3 per cent were twins. After the transfer of two embryos, 17.5 per cent were twins, and 0.6 per cent were triplets. The transfer of three embryos resulted in a twin birth rate of 26.5 per cent.[164]

Premature birth is one of the main risks of multiple pregnancies. After IVF, birth before week 37 occurs about twice as often as in a normal pregnancy (11.5 per cent versus 5.6 per cent).[165] As a result, the birth weight and survival chances of the neonates are lower. Multiple births are associated with considerable stress on the infants, their mothers and the relationship of the couple and in most cases entail problematic psychological and social consequences.[166]

Data provided in the literature on malformation rates after IVF or ICSI vary.[167] The numbers depend on the registration system and documentation method used. In 1998, 1.34 per cent of

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one triplet birth per 7,225 normal births (1:852 or 0.013 per cent) and one quadruplet birth per 614,125 normal births (1:853). For more details, see Fuhlrott/Jorch 2001, who also discuss premature birth and its complications, growth and mortality of and malformations in multiples. On the same subject, see Bindt 2001. The author draws attention to the fact that in western industrialised countries multiple-foetus pregnancies doubled between 1980 and 1997 and describes the special risks of multiple-foetus pregnancies before and during birth and the (long-term) psychological consequences for children, mothers and the relationship of the couple.

[164] Felberbaum 2001, p. 268.

[165] Felberbaum 2001, p. 268. A mean value for IVF twins would be birth in week 36 with a weight of 2,405 g and for IVF triplets birth in week 33 with a birth weight of 1,745 g. Singletons, on the other hand, have an average birth weight of about 3,500 g and are born after 40 weeks of pregnancy.

[166] Cf. Bindt 2001.

[167] Cf. Ministry of Labour, Women, Health and Social Affairs of Saxony-Anhalt 1997. According to this report, "about 10 per cent of all congenital anomalies (...) are monogenic, about 5 per cent are caused by chromosomal disorders and another 5 per cent by maternal diseases. In 20 per cent of the cases polygenic, multifactorial diseases are involved, while in 60 per cent the causes of the anomalies cannot be explained in the light of the knowledge available today. It has been suggested that exogenous factors also play a role in triggering polygenic, multifactorial changes with unclear aetiology" (p. 5). According to the report, it is difficult to collect realistic data on congenital anomalies. In 1993, the German Medical Association's Scientific Board recommended that a nation-wide surveying system should be set up. However, the Association estimates that "only about 10 per cent of all congenital anomalies have been registered" (p. 6). This implies that the statutory notification of anomalies that can be identified in the first three days after birth was in fact ignored. Statutory notification was abolished on 1 January 1997.
In statistics covering the years from 1990 to 1996 the 25 registries which collect data on infantile malformation rates (among them the Mainz and the Saxony-Anhalt-Magdeburg registries) and are united under the umbrella of EUROCAT, the European Registration of Congenital Anomalies, cite an average of 189.8 neonates with anomalies per 10,000 live births. This is a congenital malformation rate of 1.9 per cent. However, the data provided by the individual centres vary between 0.9 and 3.7 per cent. The two German

the children born in Germany after IVF had malformations of some kind. In the case of ICSI the rate was 1.8 per cent.[168]

1.2.3.6 Development of indications for *in-vitro* fertilisation and its variants

Originally, IVF was developed to enable women with unrecoverable tubal function or tubal aplasia (missing tubes) to become pregnant. Over the past twenty years indications for IVF were continuously extended so that today only 40 per cent of all IVF cycles are performed to treat tubal sterility.

At first, treatment availability was extended to include women who had previously undergone sterilisation. Another, rarer indication for women is endometriosis[169] which accounts for 3.4 per cent of all IVF cycles.

While in the first half of the 1980s about 3 per cent of all IVF cycles were aimed at treating male factor disorders, ten years later this percentage had risen to as much as 40 per cent. In 1999, the majority of IVF or ICSI procedures performed in Germany were intended to treat male subfertility.[170] This rapid increase is attributed to intracytoplasmic sperm injection (ICSI), i.e. the injection of sperm directly into the oocyte, a procedure which has been available since 1992. Even though female fertility may be completely normal, it is attempted to overcome male factor disorders by subjecting the woman to IVF treatment.

About 6 per cent of all IVF cycles are performed for "idiopathic", i.e. unexplained sterility, which in the view of the *Bundesärztekammer* (German Medical Association) "should only be considered for assisted reproduction after all diagnostic procedures available have been performed and all first-line therapy methods investigated"[171]. In practice, the "idiopathic" indication apparently "serves as the category where functional disorders, psychological conflicts, cases of inadequate diagnosis and persistent unsuccessful sterility treatment are lumped together indiscriminately".[172]

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registries gave rates of 2.25 per cent (Magdeburg) and 3.7 per cent (Mainz). See http://www.lshtm.ac.uk/php/eeu/eurocat/A03.html) (as of 27 March 2002).

[168] Cf. Felberbaum 2001, p. 269f. For further information on the discussion about the malformation rate after ICSI see Nowak 2001, Koch, K. 2001 and "Mehr Fertilitätsstörungen durch Spermieninjektion?" (More fertility disorders through sperm injection?) 2001. The discussion about risks associated with ICSI is described in more detail in C1.2.4.2.3.1 ICSI – a special case.

[169] The migration of uterine mucosa leads to adhesions and consequently to malfunctions of the egg cell collection mechanism, among other things.

[170] *Deutsches IVF-Register* 1999, p. 7.

[171] *Bundesärztekammer* 1998b, A 3167.

[172] Barbian/Berg 1997, p. 217.

Finally, about 0.2 per cent of all cases are due to immunological sterility. Immune responses precipitating sterility have been reported in both men and women.[173]

The fusion of therapy and diagnosis, e.g. when other measures of reproductive medicine fail, can be considered a further step in the development of IVF applications. Access to the germ cells of both sexes makes it possible to analyse the condition of the oocyte (microscopic controls or molecular genetic methods for polar body diagnosis[174]) and of the sperm cell (microscopic control in the spermiogram) and to analyse and control the entire process of fertilisation (addition of culture media, separation of sperm with the highest motility, intracytoplasmic sperm injection or the "assisted hatching" of the embryo by drilling a hole into the zona pellucida with a laser) in order to improve the chances of fertilisation, nidation and the successful development of pregnancy.

This also includes the qualitative microscopic assessment of the impregnated (fertilised) egg cells (which is permitted in Germany) before the fertilisation process is completed (pronuclear stage) with a view to selecting the oocytes with the best chances of development. If the impregnated egg cell is to be discarded, this has to be done before the fertilisation process is completed.

In principle, preimplantation genetic diagnosis (PGD) (which is not permitted in Germany) is the molecular genetic examination of an embryo prior to its transfer into the uterus. Already today the regular molecular genetic in vitro examination (PGD) of the embryo at an early development stage is discussed in Germany as another diagnostic tool to improve the success of assisted reproduction. Accordingly, PGD could be used to identify aneuploidies (chromosomal disorders) which are held responsible for a large number of spontaneous abortions and whose incidence increases with higher maternal age. According to this view, the specific selection of embryos without any aneuploidy could help reduce the number of embryos transferred, lower the percentage of multiple-infant births after IVF and thus reduce one of the IVF-related stressors for women.[175]

[173] For details, see Reinhard/Wolff 1995, p. 72 ff., especially p. 74. Usually this indication falls into the category of female fertility disorders. The causes are either an autoimmunological intolerance (between sperm and seminal fluid or between female antibodies and the zona pellucida) or antibodies contained in the secretory products of the female genital tract which immobilise sperm.

[174] For polar body diagnosis, see also C1.4.1.1.4 Alternatives.

[175] For details see Held 2001.

1.2.4 Practice of assisted reproduction

1.2.4.1 Overview of assisted reproduction in Europe and the United States

1.2.4.1.1 Europe

More than half of all IVF cycles performed worldwide are performed in Europe[176] and more than half of these are performed in France, the UK and Germany[177]. These data are not based on a European-wide or EU-wide IVF registry (there is no such thing), but rather on a monitoring programme conducted for the first time in 1997 by ESHRE, the European Society for Human Reproduction and Embryology.

According to the first ESHRE monitoring report, IVF registries exist in 16 European countries[178], but not in Italy and Greece (where data were collected nation-wide for the first time for the ESHRE monitoring report). Data could not be obtained from Austria, Ireland and Luxembourg.

Table 3: IVF Data Systems in 21 European Countries

IVF registry with obligatory notification	IVF registry with voluntary notification	No IVF registry, but national data for ESHRE	No IVF registry, no data for ESHRE
Denmark	Belgium	Italy	Ireland
UK	Germany[179]	Finland (birth statistics only)	Luxembourg
France	Iceland	Greece	Austria
Netherlands	Portugal		
Norway	Russia		
Sweden	Spain		
	Switzerland		
	Czech Republic		
	Hungary		

Source: Nygren/Nyboe Andersen 2001

[176] Cf. Nygren/Nyboe Andersen 2001, p. 384
[177] Nygren/Nyboe Andersen 2001, p. 384. Cf. Ulfkotte 2001.
[178] According to an oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001, there are 19 IVF registries European-wide. Cf. also Felberbaum/Dahncke 2000, p. 800.
[179] Fort the situation in Germany, see below. Participation in the IVF registry has been required in guidelines published by the *Bundesärztekammer* (German Medical Association) since 1998, but not all IVF centres comply with these guidelines.

Six of the 18 reporting countries have imposed obligatory notification which is monitored either by the government or an independent institution. Obligatory notification does not exist in Finland, but IVF babies are registered separately in the births statistics. 9 countries have voluntary IVF registries or registries not subject to statutory regulations, which is why the rate of participating centres cannot always be specified. Consequently, the figures cited in the following are merely approximate data.

In 1997, 203,893 IVF cycles performed at a total of 482 centres were reported to ESHRE. However, according to ESHRE, this figure is only relative since some of the individual notifications were incomplete.[180]

According to the most recent information, about 700 IVF centres are active in Europe, of which 521 reported a total of 232,225 artificial fertilisations in 1998. This is a 14 per cent increase on 1997 in the number of treatments registered by ESHRE, but it has to be taken into account that at the same time the number of contributing centres also rose by 8 per cent. The growth rates reported for Germany – which are the highest in comparison – should also be seen in a critical light, since although obligatory notification was already incorporated into the medical community's code of ethical practice in the late 1980s, the various state medical associations fulfilled this obligation at different times and in different ways. It was only in 1998 that the guidelines of the *Bundesärztekammer* (German Medical Association) called for nation-wide obligatory notification which resulted in a much greater number of centres reporting to the DIR (70 centres in 1997, 86 centres in 1998).

Related to the total number of neonates in a given country, the North European countries had the highest rate of IVF babies in 1998 (Iceland: 3.8 per cent; Finland: 2.7 per cent; Sweden 2.4 per cent; Norway: 1.7 per cent). In France and the UK, where obligatory notification exists, the rates were 1.3 per cent and 1.1 per cent, respectively. In comparison, the number of live births documented by the – voluntary – *Deutsches IVF-Register* (German IVF Registry) and comprising only about 80 per cent of existing centres was equivalent to a rate of 0.98 per cent IVF babies in 1998.[181]

[180] Nygren/Nyboe Andersen 2001, p. 390.

[181] *The Statistisches Bundesamt* (German Statistical Office) reported a total of 785,034 live births in Germany in 1998, while for the same year the *Deutsches IVF-Register* (German IVF Registry) reported 7,666 live births after IVF. However, this figure is based on the notifications of only 86 out of about 110 IVF groups in Germany; consequently, the rate should be somewhere around 1.2 per cent IVF babies of all neonates in 1998. Cf. http://www.destatis.de/basis/d/bevoe/bevoetab1.htm (as of 27 March 2002) and *Deutsches IVF-Register* (DIR) 1999, p. 19.

Most of the women undergoing IVF treatment were between 30 and 34 years old (depending on the country concerned, their percentage was between 31 and 45 per cent), followed by the age group of 35-to 39-year-old women (between 22 and 39 per cent). In Germany, just under one third of the women were between 35 and 39 years old, in the United States the rate was about 50 per cent.

In those ten European countries where all centres reported to the registry 133,215 IVF cycles were performed, resulting in 18,899 births of a total of 24,283 children. This is equivalent to a baby take-home rate of 14.2 per cent.[182]

On average in Europe 70 per cent of births after IVF were singletons, 26 per cent twins, 3.6 per cent triplets and 0.2 per cent quadruplets. At 26.3 per cent, the rate of multiple-infant births in Europe was clearly below that of North America where it was almost 40 per cent.[183] It is remarkable that in the Czech Republic, Greece, Hungary, Portugal, Spain and Russia between 35 and 57 per cent of all embryo transfers were performed with four embryos, while in the Scandinavian countries and the UK a maximum of three embryos were transferred.

1.2.4.1.2 United States

ART has been used in the United States since 1981. In 1992, the US Congress adopted the *Fertility Clinic Success Rate and Certification Act*. On the basis of this Act, the national *Centers for Disease Control and Prevention* (CDC) present reports on pregnancy rates achieved in US IVF clinics. The latest report published in 2000 presents the figures for 1998 and is addressed to the potential users of assisted reproduction.[184] The data are collected retrospectively[185], i.e. after the results of ART are known the clinics feed their data into an electronic data collection system.[186] The data are subsequently verified on site on a random-sample basis, then they are matched, and finally the report is authorised by a specific body[187]:

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[182] Nygren/Nyboe Andersen 2001. The Netherlands and Switzerland reported incomplete data on births, Germany did not provide any data on births at all. The baby take-home rate was calculated as live births per IVF cycles and not, as in the text above, related to embryo transfer. Accordingly, ESHRE reports the following success rates for 18 European countries:
- IVF: Pregnancy rate: 26.1 per cent; birth rate: 20.9 per cent. (Both figures are related to embryo transfer. Based on IVF cycles started, the pregnancy rate is 18.5 per cent and the birth rate 16.7 per cent).
- ICSI: Pregnancy rate: 26.4 per cent; birth rate: 21.5 per cent. (Both data refer to embryo transfer. Based on IVF cycles started, the pregnancy rate is 22.9 per cent and the birth rate 17.7 per cent). Unlike the baby take-home rate, the birth rate does not refer to the number of births, but to the number of live-born infants which is higher due to multiple-infant births.

[183] Nygren/Andersen 2001, p. 389.
[184] Centers for Disease Control and Prevention 1998.
[185] The *Deutsches IVF-Register* (DIR) collects the data prospectively.
[186] See Centers for Disease Control and Prevention 1998, p. 4.
[187] See Centers for Disease Control and Prevention 1998, p. 4.

– 23 per cent of the women who used assisted reproductive technologies (ART) in 1998 had previously given birth to at least one child, 51 per cent of all users were between 33 and 59 years old.

– There are a total of 390 IVF clinics in the United States, of which 360 are included in the CDC report.[188]

– In 1998, 28,500 children (that is 0.7 per cent of all live births) were born in the United States after the use of ART.

– In 1998, a total of 80,634 cycles[189] were started, with 61,650 cycles being IVF cycles using "fresh" (not donated) egg cells or embryos[190] (73.3 per cent). 11,228 cycles were started as IVF with frozen embryos (13.9 per cent) and 7, 756 cycles as IVF after egg cell donation (9.6 per cent, with "fresh" embryos accounting for 7.2 per cent and frozen embryos accounting for 2.4 per cent).[191]

– Based on the 61,650 cycles started with "fresh" egg cells or embryos, 49,837 embryo transfers[192] were performed which resulted in 18,800 pregnancies. This is a pregnancy rate of 30.5 per cent related to the cycles started. There were 15,367 births, which means that the baby take-home rate[193] was 24.9 per cent.

– 61 per cent of live births are accounted for by singletons, 28 per cent by twins and 11 per cent by triplets and higher-order multiple births.

As the data are collected retrospectively and the report does not indicate clearly whether births are exclusively related to the beginning of the ovarian stimulation cycle, the success rates cited are not comparable with the figures for Germany.

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[188] Centers for Disease Control and Prevention 1998, p. 10.

[189] According to the definition provided, "ART cycle" in the report means the beginning of ovarian stimulation, cf. Centers for Disease Control and Prevention 1998, p. 14.

[190] Although the report explicitly defines ovarian stimulation as the start of an IVF cycle (p.12), it is not clear whether the numbers given also include those cycles which are considered to begin with the presence of an embryo. The report does not give any reasons or data in this respect. If the figures were based on both "beginnings" of cycles, the resulting success rates would be more "favourable".

[191] GIFT and ZIFT together account for 3.2 per cent. Cf. Centers for Disease Control and Prevention 1998, p. 11.

[192] The highest success rates (live births) were achieved with the transfer of three embryos (35.7 per cent), followed by the transfer of four embryos (34.1 per cent). However, in both cases the multiple-infant birth rate was also the highest. Cf. Centers for Disease Control and Prevention 1998, p. 27.

[193] In the 1998 Centers for Disease Control and Prevention report referred to as "live births/cycle". The baby take-home rate always refers to the number of births (not the number of babies born). "For couples", it is the "only relevant criterion of success" (Hölzle/Wiesing 1991, p.9) and an indication of how many out of 100 women starting IVF treatment can expect to give birth to (at least) one living baby. Cf. C1.2.6.3 Baby take-home rate - the criterion of success.

The US figures given for IVF and ICSI cycles started (80,634 in 1998, 73,069 in 1997) are only slightly higher than in Germany (64,617 reported IVF and ICSI cycles in 1999), although the US population is about three times larger. This means that in relation to population figures, the number of ART treatments performed in Germany is almost three times higher than in the United States.

1.2.4.2 Assisted reproduction in Germany

1.2.4.2.1 Institutional development

In 1981, the first two IVF groups in the Federal Republic of Germany were set up at the medical centres of the universities of Erlangen and Lübeck. In April 1982, the first West German IVF baby was born, followed in October 1984 by the first IVF baby to be born in East Germany.[194] By 1984, 21 IVF teams had become established in the Federal Republic of Germany, by 1986 there were already 41 (21 teams at university medical centres, 9 at hospitals and 11 in their own independent practice).[195] In 1985, the *Bundesärztekammer* (German Medical Association) had published its first "Richtlinien zur Durchführung von In-*vitro-Fertilisation (IVF) und Embryotransfer (ET) als Behandlungsmethode der menschlichen* Sterilität" (Guidelines for in-vitro fertilisation (IVF) and embryo transfer (ET) as a treatment method for human sterility).[196] At the first nation-wide meeting of IVF/GIFT centres located in German-speaking regions which took place in Bonn in 1987, all 36 groups represented there submitted their results, beginning in 1982.[197]

In late 1990, there were 50 groups active in West Germany (23 teams at university medical centres, 11 at hospitals and 16 in their own independent practice) and six groups at East German university medical centres (Charité Berlin, Halle, Jena, Leipzig, Magdeburg, Rostock), in 1991 their number totalled 55 in East and West Germany taken together.[198]

Between 1992 and 1997, the number of centres included in the *Deutsches IVF-Register* (DIR-German IVF Registry) rose relatively slowly from 51 to 70. As a result of participation in the DIR[199] as required by the *Bundesärztekammer* (German Medical Association) in its revised "*Richtlinien zur Durchführung der assistierten Reproduktion*" (Guidelines for assisted

[194] Schneider 2001, p. 32.
[195] Barbian/Berg 1997, p. 7. This work gives a detailed description of the development of IVF in Germany.
[196] *Bundesärztekammer/Wissenschaftlicher Beirat* (German Medical Association/Scientific Board) 1985, pp. 1649, 1690-1698.
[197] Hölzle/Wiesing 1991, p. 8; Barbian/Berg 1997, p. 7.
[198] Barbian/Berg 1997, p. 5.
[199] *Bundesärztekammer* 1998b, A 3169.

reproduction), the number of reporting centres rose to 86 in 1998 and 92[200] in 1999; the latest report published in 2000 listed 103 centres[201]. As the actual number of IVF groups in Germany is estimated at 110[202], this implies that about 18 centres do not comply with the German Medical Association's current guidelines. (It should be noted, though, that the state medical associations did not consistently adopt the German Medical Association's guidelines and integrate them into their codes of ethical practice. Notification is required in all German states, but in some cases it is possible to report to the state medical association instead of the DIR). 27 of the 92 centres registered by the DIR in 1999 had been established at universities, 14 at hospitals and 51 in independent medical practices; in 2000 the number of independent IVF practices rose to 61.

Table 4: Institutional Development of IVF

	University medical centre	**Hospital**	**Independent medical practice**
1981	2	-	-
1984	14	3	4
1986	21	9	11
1990	29 (23 West + 6 East)	11	16
1999[203]	27	14	51
2000[204]	27	14	61

Successful ICSI was first reported in Belgium in 1992 and – like the cryopreservation of "impregnated" egg cells (freezing of fertilised pronuclear-stage oocytes pursuant to the Embryo Protection Act) – has been available in Germany since 1993.[205] In 1994, ICSI was performed in 32 centres and cryopreservation in 19 centres. In 1999, all 92 DIR-registered centres performed ICSI and 75 centres performed cryopreservation[206], while in 2000 ICSI was available at 98 centres and cryopreservation at 77 centres.[207]

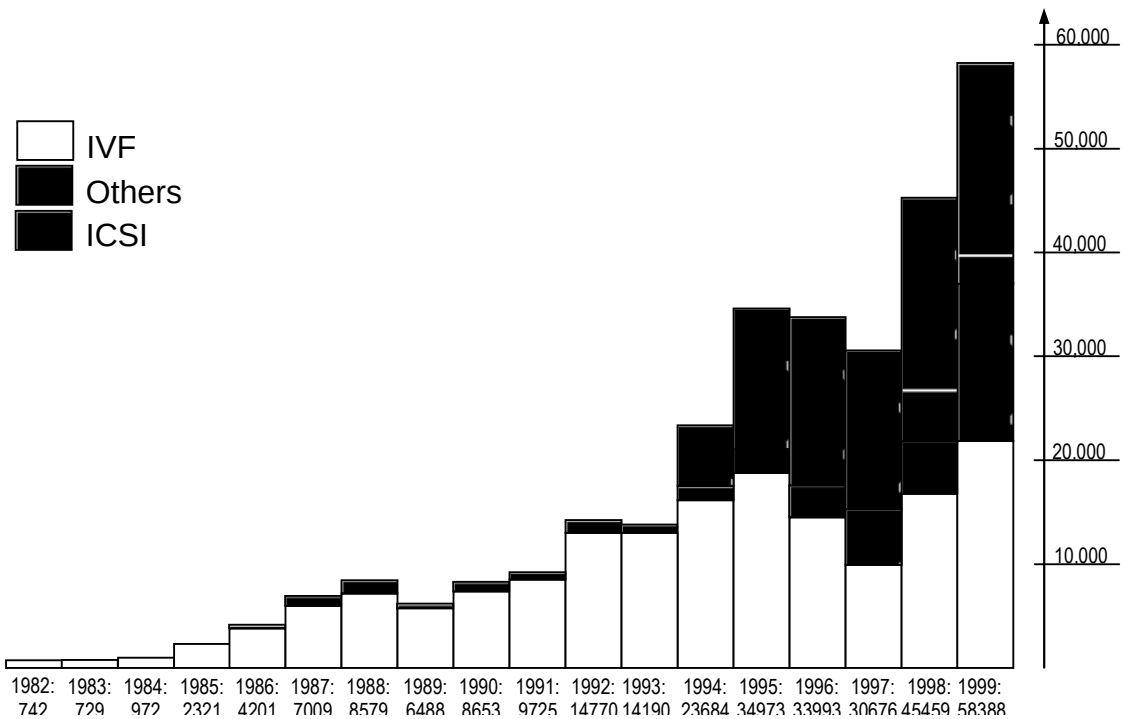
[200] For detailed figures since 1992 see *Deutsches IVF-Register* 1999, p. 6.
[201] *Deutsches IVF-Register* 2000, p.6.
[202] Oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001.
[203] According to *Deutsches IVF-Register* 1999, List of participants. Data collected before 1990 for West Germany only.
[204] According to *Deutsches IVF-Register* 2001, List of participants, p. 27ff.
[205] Oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001.
[206] See *Deutsches IVF-Register* 1999, p. 6.
[207] See *Deutsches IVF-Register* 2000, p. 6.

Table 5: Number of Treatments (IVF/GIFT/CRYO/ICSI) according to DIR

Year	1982	1984	1986	1988	1990	1992	1994	1996	1997	1998	1999	2000[208]
Reporting centres[209]	**5**	**14**	**28**	**34**	**53**	**51**	**66**	**66**	**70**	**86**	**92**	**102**
IVF	742	972	3,806	7,130	7,343	12,867	16,175	14,494	9,902	16,763	21,880	28,945
GIFT	0	0	380	1,266	985	1,283	829	420	104	11	41	25
CRYO	0	0	0	0	0	0	499	2,660	2,656	4,616	7,661	9,457
ICSI	0	0	0	0	0	0	5,856	16,233	15,365	23,578	21,244	15,752
IVF / ICSI										424	962	790
Others									2,585	67	6,600	6,562
Total	742	972	4,201	8,579	8,653	14,770	23,684	33,993	30,676	45,459	58,388	61,531

Source: DIR 2000, p. 7 (modified)

Chart 2: Reproductive Medicine 1982–1999/Number of Treatments[210]



[208] According to *Deutsches IVF-Register* 1999, p. 7, only treatments performed (completed) have been documented since 1999.

[209] Data according to *Deutsches IVF-Register* 2000, p. 6, Chart "Number of centres". The number of reporting centres is not identical with the number of all actually existing IVF centres.

[210] The *Deutsches IVF-Register* 1999 registers 64,617 cycles, 58,817 cycles are identified as "plausible cycles" registered prospectively and non-prospectively. Chart 2 is based on the data given in *Deutsches IVF-Register* 1999, p. 7.

A few years after the first reproductive centres had been established in Germany

– "numerous IVF groups called for a strong professional lobby (...) as had been the case in the fight for IVF cost reimbursement by statutory health insurers. (...) In response to this professional pressure, the *Arbeitsgemeinschaft für Gynäkologische Endokrinologie und Fortpflanzungsmedizin* (AGGEF – Working Group for Gynaecological Endocrinology and Reproductive Medicine) of the *Deutsche Gesellschaft für Gynäkologie und Geburtshilfe* (German Society for Gynaecology and Obstetrics)"[211]

was set up in 1993. In 1996, the *Bundesverband Reproduktionsmedizinischer Zentren Deutschlands e.V.* (BRZ –Association of German Reproductive Centres) was founded "which represents in particular the professional interests of IVF specialists working as independent physicians in their own practice or in private clinics"[212].

1.2.4.2.2 Legal regulations governing access to, use of, and payment for, assisted reproductive technologies

1.2.4.2.2.1 Legal access requirements

So far, legislation has addressed assisted reproduction methods in terms of social and criminal law only. In 1990, the *Sozialgesetzbuch Fünftes Buch* (SGB V – Social Security Code V) defined assisted reproductive technologies as benefits to be paid for by statutory health insurers,[213] providing that the procedures performed complied with the (exclusively) criminal law provisions of the 1990 Embryo Protection Act.

The Embryo Protection Act, which was promulgated on 13 December 1990 and entered into force on 1 January 1991, gives exclusive consideration to the criminal law aspects of assisted reproduction and regulates assisted reproductive technologies in a patchy and indirect fashion by imposing bans under criminal law. The sanctions to be imposed under the Act are addressed to the attending physicians. It was only in 1994 that concurrent legislative competence for the "artificial insemination of humans" (Article 74(1) No. 26 of the German Constitution) was transferred to the Federal Government, thus creating the possibility of adopting a national law that would cover more than criminal law aspects alone.

The discussion on whether the anguish suffered by a woman or a couple as a result of involuntary childlessness has a potential disease character has not yet been legally decided.

[211] Beier 1996, p. 50.
[212] Beier 1996, p. 50.
[213] See C1.2.4.2.3 Access to ART and payment by statutory health insurers.

Referring to the "special status of artificial fertilisation in the benefit system of health insurers", the *Bundessozialgericht* (BSG - Federal Social Court) recently ruled that "artificial fertilisation itself (...) is not considered to be treatment of a disease; it is only categorised as such" in order to make sure that pertinent regulations of the Social Security Code V are applicable and "the cost burden can be shared among the health insurers of both husband and wife".[214]

The licensing of reproductive centres (pursuant to Sec. 121a SGB V) is incumbent on the German states and, in seven states, on the state medical associations. Although Sections 121a and 27a SGB V define complex requirements for determining the demand for reproductive institutions as well as quality requirements to be met by such institutions, the Code does not provide any quantitative or qualitative indications for implementation. Laws governing chambers and health care professions do not provide any instruments for the effective enforcement of rules laid down in the profession's code of ethical practice, nor were the medical associations given the necessary instruments to enforce structural and qualitative requirements.

The provisions of the Embryo Protection Act pursue the following main objectives[215]:

- to ensure that the improper use of embryos is prevented;
- to ensure that the sole purpose of artificial fertilisation is reproduction;
- to ensure that "split" motherhood (e.g. as a result of egg cell or embryo donations or surrogacy) is prevented;
- to ensure that the development of so-called "supernumerary" or "spare" embryos is prevented;
- to ensure that the beginnings of 'eugenics' intended to breed humans are prevented;
- to ensure that the right to determine one's own way of procreation is guaranteed.

The Embryo Protection Act covers only the period up to the nidation of the embryo in the uterus. After that, the provisions of Sec. 218 ff. of the German Criminal Code apply.

Today, there are still a large number of open issues. In the context of sperm donations it was noted recently:

> "There are more than 60,000 to 70,000 children living in Germany today who owe their lives to fertilisation using donor sperm. Treatment principles governing

[214] BSG, ruling of 3 April 2001, BSGE 88, p. 62 (65).
[215] Günther 1995, especially p. 28.

> homologous insemination are available. However, some legal issues such as donor anonymity, family law and law of succession, safekeeping of files, and donor fee still need to be regulated."[216]

This applies in particular to the fact that as yet no legal basis has been created for the right of children to know about their parentage as laid down by the *Bundesverfassungsgericht* (Federal Constitutional Court).

Nor are there any legal regulations – apart from some rules laid down in the medical profession's code of ethical practice – governing quality assurance (counselling, laboratory standards, surgical interventions, handling of new methods). There is also a lack of valid and comparable statistics on success and failure rates and the health hazards associated with ART. And finally, there are no regulations regarding licensing requirements and independent quality controls of institutions performing ART.

At present, the medical profession's code of ethical practice and the guidelines of the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers) deprive unmarried and same-sex couples as well as singles of access to ART, which is another issue that lacks a legal framework. In practice, the rules of the code of ethical practice are circumvented.

When in 1994 legislative competence for assisted reproductive techniques was transferred from the state level to the Federal level, the intention was even then to adopt a comprehensive law on reproductive medicine which would regulate all issues of medical as well as public and civil law associated with assisted reproduction. Since then the public has repeatedly[217] called for the Federal Government finally to submit a bill on reproductive medicine.[218] In 1996/1997, a "Bund-*Länder*-Arbeitsgruppe zur künstlichen Befruchtung beim Menschen" (Federal/State government working group on artificial fertilisation in humans), headed by the Federal Ministry of Health, had already tried unsuccessfully to draft such a bill. In December

[216] Günther/Fritsche 2000, p. 249.

[217] E.g. unanimously demanded by the Conference of State Ministers of Health on 9/10 June 1999. See *Gesundheitsministerkonferenz der Länder* (Conference of State Ministers of Health) 1999, p. 76.

[218] In recent years, there have been public discussions about a law on reproductive medicine. The various experts involved accord special importance to a three-day scientific symposium on "Reproductive Medicine in Germany" organised in Berlin by the Federal Ministry of Health in co-operation with the Robert Koch Institute in May 2000. For documentation of this symposium see *Bundesministerium für Gesundheit* (Federal Ministry of Health) 2001.

2000, the Federal Ministry of Health submitted a "policy paper"[219] on a law on reproductive medicine.

1.2.4.2.2.2 Guidelines of the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers)

On 1 October 1990, the "*Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über ärztliche Maßnahmen zur künstlichen Befruchtung in der Fassung vom 14. August 1990*" (Guidelines of the Federal Committee of Physicians and Health Insurers on medical procedures of artificial fertilisation, version of 14 August 1990) entered into force. On 1 January 1998, it was replaced by the version amended on 1 October 1997.[220] Pursuant to Sec. 27a Social Security Code V, medical procedures for artificial fertilisation include in-vitro fertilisation (IVF) and embryo transfer (ET), if necessary, as zygote intrafallopian transfer (ZIFT) or as embryo intrafallopian transfer (EIFT). Reimbursable services are detailed under No. 12 of the guidelines and do *not* include the cryopreservation of spermatozoa, impregnated oocytes or embryos not yet transferred.

Costs will be reimbursed by health insurers on condition that

- other medical procedures aiming to induce the ability to conceive do not offer adequate chances of success and that treatment is performed in an out-patient setting,
- the partners are married to each other, neither partner has been sterilised and neither partner is HIV-positive,
- the female partner is not older than 40 years (exceptions up to 45 years are possible, if an expert opinion on the prospect of success has been submitted),
- no sperm and egg cells other than those of husband and wife are used,
- clinical pregnancy was established after the fourth in-vitro fertilisation or the second gamete intrafallopian transfer at the latest (furthermore, chances of IVF success are considered to be too slim if two fertilisation attempts have already failed and analysis of the major causes indicates that in-vitro fertilisation is not possible)[221],

[219] *Bundesministerium für Gesundheit* 2000.

[220] For the provisions quoted in the following see Bundesausschuss der Ärzte und Krankenkassen (Federal Committee of Physicians and Health Insurers) 1997.

[221] For reimbursement of IVF treatment, "cycles" are always based on the number of cycles of the woman concerned, irrespective of the individual assisted reproductive technique used.

– prior to the beginning of treatment, a physician who is not identical with the physician performing the IVF procedures has informed and counselled the couple on the medical, psychological and social aspects of artificial fertilisation.[222]

Further provisions:

The husband's health insurer is liable to pay for procedures associated with the examination and preparation – if necessary, also the maturation – of sperm and for the husband's HIV test.

If both spouses are insured by statutory health insurers, the wife's insurer is liable to pay for the couple's counselling as well as for extracorporeal measures associated with the union of egg cells and sperm.

After a child has been born, the couple will again be entitled to medical services aimed at inducing pregnancy by artificial fertilisation, provided all other conditions laid down in the guidelines are met.

If other therapeutic alternatives have been found to be inapplicable, the following are considered **medical indications** for the procedures described above:

– previous salpingectomy,

– tubal occlusion that cannot be treated with any other method (including microsurgery),

– loss of tubal function, also in endometriosis, that cannot be treated with any other method,

– idiopathic (unexplained) sterility, if all diagnostic and other therapeutic possibilities of treating sterility, including psychological exploration, have been exhausted,

– male subfertility, and

– immunological sterility.

The success criterion for the measures performed is a clinically established pregnancy.[223]

1.2.4.2.2.3 Criteria applying to reimbursable counselling services

According to No. 13 of the *Richtlinien des Bundesausschusses der Ärzte und Krankenkassen* (Guidelines of the Federal Committee of Physicians and Health Insurers), counselling services will be reimbursed which – provided all other pertinent requirements are met – are provided

[222] On the reimbursability of counselling services, see C1.2.4.2.3 Access to ART and reimbursement by statutory health insurers.

[223] Consequently, a clinically established pregnancy seems to be more important for the DIR than the baby take-home rate, which is crucial for the women or couples affected.

only after a medical indication has been established, using suitable diagnostic and possibly therapeutic procedures.

> "Counselling should specifically focus on the individual medical, psychological and social aspects of artificial fertilisation. Counselling should not only address the health hazards associated with the treatment procedures and their success rate, but also discuss in detail the physical and mental stress involved, especially for the woman, as well as possible alternatives to having a biologically related child (e.g. adoption)."[224]

The counselling physician must be either a gynaecologist or have some knowledge of reproductive medicine. In addition, he/she must be authorised to provide basic psychosomatic care. He/she will then have to issue a counselling certificate which, together with the referral form, must be presented to the physician performing the intended assisted reproductive procedures.

Psychosocial counselling going beyond the services described above that *precedes* and/or *accompanies* reproductive diagnosis or provides a *follow-up* to ART procedures which perhaps did not lead to the desired success, is offered by independent counselling institutions, but does not form an integral part of the (medical) treatment of childlessness and consequently is usually not paid for by statutory health insurers.[225]

> "A point of *criticism* would be that, to a large extent, persons other than medical professionals are excluded from providing counselling. In any case medical counselling is indicated and makes sense. However, counselling sessions that are provided by psychologists or '*counsellors*' independent of the physician performing treatment would indeed be conceivable. (…) This [would] permit a more open-ended and broad-based consideration of the issue, independent of a physician (who always also stands for a possible therapy)."[226]

Other professionals with additional psychotherapeutic training could also be considered as counsellors. These counsellors should be completely independent of the institution performing ART.

1.2.4.2.2.4 The medical profession's code of ethical practice

The current *Richtlinien zur Durchführung der assistierten Reproduktion* (Guidelines for assisted reproduction) of the *Bundesärztekammer* (BÄK – German Medical Association),

[224] *Bundesausschuss der Ärzte und Krankenkassen* 1997, No. 14.
[225] Oral communication by Professor Christina Hölzle at the non-public hearing on 26 March 2001.
[226] Kentenich 2001, p. 260.

which provide the basis for the codes of ethical practice adopted by the various state medical associations, date back to 1998 and cover the following essential aspects:

– definition of assisted reproduction as medical help to end a couple's involuntary childlessness;

– medical indications, contraindications and social requirements (married couples, otherwise a decision by the medical association is required; the resulting child must not be relinquished to a third party);

– use of intracytoplasmic sperm injection (ICSI);

– training and qualification of the IVF team in five areas of reproductive medicine and regular co-operation with a human geneticist and physician-psychotherapist;

– diagnosis, education and informed consent in writing, quality assurance (documentation in the Deutsches IVF-Register).

1.2.4.2.2.4.1 History of the German Medical Association's guidelines for ***in-vitro*** **fertilisation and embryo transfer**

In 1985, the Bundesärztekammer *(German Medical Association) presented the first* Richtlinien zur Durchführung von In-vitro-Fertilisation (IVF) und Embryotransfer (ET) als Behandlungsmethode der menschlichen Sterilität *(Guidelines for in-vitro fertilisation (IVF and embryo transfer (ET) as a method to treat human sterility)*[227] *which were revised in 1988*[228]*. In 1989, a guideline on* Mehrlingsreduktion mittels Fetozid *(Multifoetal pregnancy reduction by foetocide)*[229] *was published and in 1994 the IVF guidelines were amended and published under the title* Richtlinien zur Durchführung des intratubaren Gametentransfers, der In-vitro-Fertilisation mit Embryotransfer und anderer verwandter Methoden *(Guidelines for gamete intrafallopian transfer, in-vitro fertilisation with embryo transfer and other related methods).*[230]

Furthermore, the Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (German Society for Gynaecology and Obstetrics) has published guidelines relating to specific issues, such as the Empfehlungen zur Durchführung der Intracytoplasmatischen Spermieninjektion (ICSI)

[227] *Bundesärztekammer* 1985.
[228] *Bundesärztekammer* 1988.
[229] *Bundesärztekammer* 1989.
[230] *Bundesärztekammer* 1994.

zur Behandlung einer Sterilität (Recommendations for intracytoplasmic sperm injection (ICSI) to treat sterility)[231] which cannot be discussed here.

1.2.4.2.2.4.2 Some points of criticism with regard to the German Medical Association's current guideline for *in-vitro* fertilisation and embryo transfer

Section 4.3 on procedural and quality assurance was published for the first time in an IVF guideline in 1998, i.e. 17 years after the birth of the first IVF baby in Germany and almost 10 years after the first state medical associations had incorporated specific quality assurance provisions in their codes of ethical practice. The German Medical Association's guideline defines the *Deutsches IVF-Register* (DIR – German IVF Registry) as a joint institution of the state medical associations, but even today the DIR has not assumed this quality; it is still an institution of the centres for reproductive medicine.

All IVF groups are called upon to submit their data to the DIR. However, it seems that not all centres feel obliged to do so. In 1999, only 93 out of about 110 IVF groups reported to the DIR, and "regarding their plausibility" about 87 per cent of their data "were clearly prospectively documented".[232] Compared with previous years, this is considered a success, but at the same time it means that even the latest DIR registers plausible and prospective data of only about 74 per cent of all ART treatments performed in Germany. 102 of the 103 centres reporting in 2000 submitted their data on time, 86 per cent of their data were plausible and prospective.[233]

Regarding the necessity of quality assurance and documentation, the commentary on the German Medical Association's guideline says:

> "In concrete terms, prospectivity of the data collected means that data of the first treatment cycle need to be entered within eight days after the start of hormonal stimulation. (...) The prospective collection of data permits an evaluation for quality assurance which makes the treatment success and the importance of potential influencing factors transparent not only to the interested physician, but also to the interested patient."[234]

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[231] http://www.uni-duesseldorf.de/WWW/AWMF/ll/gyn-e002.htm (as of 27 March 2002).
[232] *Deutsches IVF-Register* 1999, p. 5. One centre reported too late so that only 92 centres could be evaluated.
[233] Cf. *Deutsches IVF-Register* 2000, p. 5: "The large number of reporting centres also implies that are only isolated cases where centres refuse to co-operate in this documentation and quality assurance scheme."
[234] *Bundesärztekammer* 1998b, A 3170.

However, the guideline does not contain a clear-cut definition of the length (beginning and end) of an IVF cycle nor does it provide binding requirements for determining or analysing and presenting the treatment success.[235]

These shortcomings have an impact on the "Education and informed consent" required in section 3.4 of the guideline which states:

> "Prior to the beginning of treatment, couples must be informed about the planned intervention, the individual steps of the procedure, its chances of success, possible complications and costs."

For when providing information on the chances of success, the attending physician has to rely on DIR data which means that the quality of information is directly linked to the quality of the data collected.

Furthermore, the code of ethical practice leaves it to the persons providing information to decide which success rates they quote. This situation is unsatisfactory for two reasons: First, because the couples' expectations of IVF success are often greater than the actual success. And second, because from the couple's or the woman's perspective the only criterion of success is the probability of having a baby after starting an IVF cycle. However, this probability is always lower than the frequently cited ratio of clinical pregnancies and embryo transfers performed.

Attention was drawn to another aspect of education and information as required by the German Medical Association regarding the qualification of IVF groups: in practice there is a lack of basic psychosomatic care. Consequently, it was criticised that the Association's guideline did not address psychological aspects in the context of education and informed consent.[236]

1.2.4.2.3 Access to ART and payment by statutory health insurers

While in 1992 about 8,000[237] couples received counselling on possible artificial fertilisation procedures and their medical, social and psychological aspects, their number had risen to as many as 46,000 in 1996. Of the 34,000 treatment cycles performed in 1996, 16,233 were ICSI treatments. ICSI was available for the first time in Germany in 1993. In 1999, more than 58,000 cycles of assisted reproduction were started.

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[235] See C1.2.4.2.4 Documentation and quality assurance of assisted reproduction in Germany.

At present, only a rough estimate can be given of the total costs of measures of assisted reproductive procedures. They consist of the cost of medication for cycle regulation and the cost of actual IVF (surgical egg cell retrieval, fertilisation and 48-hour cultivation in the laboratory plus transvaginal embryo transfer into the uterus). For ICSI, the cost of retrieving and preparing sperm and of injecting them into the egg cell will have to be added.

Based on one cycle, the following costs can be expected for out-patient treatment without any complications:

Hormone treatment	approx. € 1,300.00 to 1,550.00
IVF (oocyte retrieval, fertilisation, embryo transfer)	approx. € 1,050.00
ICSI (sperm retrieval and preparation, injection) (plus cost of hormones and IVF)	approx. € 1,250.00

This means that a normal IVF treatment cycle costs approx. € 2,300.00 to € 2,600.00.[238] A complete ICSI cycle will cost approx. € 3,600.00 to € 3,850.00.[239] The cost of cryopreservation will amount to approx. € 500.00 per year.

The reimbursement of ART costs by statutory health insurers in Germany has a chequered history which will be briefly outlined below before the essential provisions will be discussed.

Until 1988, the regulations governing the benefits provided by statutory health insurers (SHIs) in Germany did not include any special provisions for artificial fertilisation procedures.[240] However, legal courts decided that couples were entitled to payment by SHIs. At the same time, they ruled that statutory health insurers were not obliged to pay for heterologous methods, i.e. the use of egg cells and sperm of unmarried persons.[241]

When the *Gesundheitsreformgesetz* (GRG – Health Care Reform Act) entered into force on 1 January 1989, a new provision of Sec. 27a of the Social Security Code V became valid. According to this provision, measures aiming to restore a person's procreative capacity were part of the SHI benefit package. Artificial fertilisation, however, was excluded.[242]

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[236] Kentenich 2001, p. 260.
[237] Cf. Egger/Freyschmidt 2000, p. 52.
[238] Assuming that SHIs pay for up to four complete IVF cycles, costs of up to € 11,000.00 may be incurred. If couples are treated later to induce subsequent pregnancies, SHIs will again pay for up to four cycles.
[239] Figures according to *Bundesverband Reproduktionsmedizinischer Zentren* (BRZ –Association of German Reproductive Centres) http://www.repromed.de/icsigeschichte.html (as of 27 March 2002).
[240] Cf. Egger/Freyschmidt 2000.
[241] Egger/Freyschmidt 2000, p. 50.
[242] From 1 January 1989 to 30 June 1990 statutory health insurers did not have to pay for IVF procedures. The reason was a decision of the governing coalition to suspend the benefits until legal and ethical issues had been

After deliberations on the Embryo Protection Act had been concluded and the fact that SHIs paid for abortions, but not for the induction of pregnancies by assisted reproduction techniques had come under vehement criticism from some quarters, the reimbursability of artificial fertilisation procedures was regulated on 26 June 1990 in the new Sec. 27a of the Social Security Code V under the *KOV-Anpassungsgesetz* (Act on the 20th adjustment of SHI benefits under the *Bundesversorgungsgesetz* [Federal Benefits Act]). According to the new provision, couples have to be married, no sperm and egg cells other than those of husband and wife may be used, and the necessity of these procedures has to be certified by a physician. Medical and psychosocial counselling must be provided by a physician not identical with the physician performing IVF. The costs for a maximum of four attempts at IVF will be reimbursed[243], after that the chances of success are not considered sufficient to warrant continued SHI payment.

Further details were to be laid down by the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers). The *Kassenärztliche Bundesvereinigung* (KBV – National Association of Statutory Health Insurance Physicians, NASHIP) which is also represented on the Committee blames Sec. 27a Social Security Code V and the Federal Government's comments on this legislation for having made "artificial fertilisation measures the most complicated part of patient treatment in terms of reimbursement of the costs of medical services"[244].

1.2.4.2.3.1 Intracytoplasmic sperm injection – a special case

On 1 October 1997, the Federal Committee of Physicians and Health Insurers decided that, due to the risk of malformation that had not yet been conclusively explained, ICSI was not to be included in the benefit package of statutory health insurers.

It took some time until this decision had been implemented by all SHIs. However, in the course of 1999 it became generally accepted and the result was that also "IVF treatment underlying every ICSI procedure was no longer eligible for reimbursement"[245].

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settled (cf. *Bundesregierung* [Federal Government] 1990). The SHIs' obligation to reimburse the cost was restored on 1 June 1990. By adding Sec. 27a to Social Security Code V, a claim to such benefits, including the regulations governing such a claim, were explicitly laid down in the law. See Nave-Herz 1996, p. 49f.

[243] I.e. a maximum of four female cycles.

[244] Introduction to *Richtlinien über künstliche Befruchtung* (Guidelines for artificial fertilisation) on the KBV's website (http://www.kbv.de) (as of 17 August 2001)

[245] http://www.repromed.de/icsigeschichte.html The text published on the website of the *Bundesverband Reproduktionsmedizinischer Zentren* (BRZ – Association of German Reproductive Centres) relies on a paper by Professor Diedrich, Medical University of Lübeck.

The *Kassenärztliche Bundesvereinigung* (National Association of Statutory Health Insurance Physicians, NASHIP) declared that this interpretation was nationally binding as from 1 July 1999. Pursuant to No. 10.5 of the guideline, this meant for all SHIs that ICSI "was currently not a method of artificial fertilisation within the meaning of this guideline, since the documentation submitted for assessing this method was insufficient and hence the requirements for recognising this method as part of the health care services provided by SHI-accredited physicians were not met".

Before that, ICSI which had been available in Germany since 1993 had been paid for by SHIs under certain conditions. Private health insurers regularly reimbursed the treatment costs. In late 1998, the German Medical Association had included ICSI in its *Richtlinien zur Durchführung der assistierten Reproduktion* (Guidelines for assisted reproduction)[246] as an artificial fertilisation method admissible under the profession's code of ethical practice.

However, a new situation arose after the decision of the First Division of the Federal Social Court of 3 April 2001 had been handed down.[247] The Court had to decide on whether and under what conditions the claimants were entitled to ICSI benefits by their statutory health insurers.

The result of the Court's decision is that

– when the husband, who is covered by statutory health insurance, and not wife, who is covered by private health insurance, is the infertile partner, the husband's statutory health insurance will have to pay;

– when both spouses are insured by the same statutory health insurer, the wife is entitled to claim reimbursement on her own;

– when the spouses are insured by different statutory health insurers, the wife's insurance will have to pay all costs in the absence of a clear allocation rule, since the wife is the partner who wants to become pregnant.

In the opinion of the First Division of the Federal Social Court, there is no difference between ICSI and IVF as regards the fundamental risk of miscarriage, especially as it is not clear whether the procedure entailed "a substantially higher risk" for the desired offspring. Whether

[246] *Bundesärztekammer* (1998b), A 3166-3171.
[247] BSG 2001, BSGE 88, pp. 62-75.

or not the risks associated with IVF or ICSI were accepted, the Court said, had to be left to the decision of the potential parents after having received adequate counselling:

> "It is true that the risks of ICSI for the children conceived in this way are not sufficiently understood. This fact is also admitted by scientists who do not derive any higher rates of malformation from the data available so far and hence advocate this method (…)."[248]

> "According to the criteria developed by the Court's Division to prove the efficacy and assess the risk of the treatment methods to be paid for by statutory health insurers, artificial fertilisation – at least in the form of in-vitro fertilisation – might not be included in the range of health care services provided by SHI-accredited physicians. (...) Sec. 27a Social Security Code can only be interpreted to mean that these principles shall not unconditionally apply to artificial fertilisation. With in-vitro fertilisation, a procedure was included in the benefit package of statutory health insurers which - according to the supporting arguments of the Act – results in the birth of a child in 16 out of 100 attempts at most; moreover, this child is exposed to a higher mortality risk during and shortly after birth as well as to an unpredictable probability of malformation. Comprehensive surveys of malformation rates in comparison with spontaneously conceived children were not and still are not available today (…)."[249]

> "This Division does not fail to appreciate that ICSI has a quality that differs essentially from that of conventional in-vitro fertilisation if only because the process of fertilisation is not only assisted, but manipulated by penetration into the oocyte proper. Nevertheless, the law-makers' decision in the case of extracorporeal fertilisation through ICSI to describe the chances of success in terms of pregnancy, to formulate only modest requirements in terms of success rate and malformation rate, and to leave the assessment of the risks associated with hormonal stimulation to those directly affected, has to be appreciated in the same way as in the case of the standard in-vitro fertilisation method. (...) The malformation rate discussed by experts of up to twice the "natural" rate may seem to be severe (...). The merely limited importance of the medical discussion about the malformation risk is emphasised by the fact that the German Medical Association accepts ICSI in the light of its code of ethical practice

[248] BSG 2001, BSGE 88, p. 62 (69).
[249] BSG 2001, BSGE 88, p. 62 (70f).

(…) and that cautious estimates expect 6,000 children to be born in Germany and 20,000 worldwide after ICSI."[250]

The Federal Social Court was of the opinion that, as from 1 January 1998, ICSI would have had to be included in the range of procedures aimed at inducing pregnancy that had to be paid for by statutory health insurers, and decided that the claimant was indeed entitled to direct reimbursement of the cost of ICSI treatment by her SHI.[251] The board of the National Association of Statutory Health Insurance Physicians stated on 22 January 2002 that ICSI would have to be made an integral part of the SHI benefit package.

1.2.4.2.3.2 National prospective controlled multi-centre study of children born after intracytoplasmic sperm injection[252]

This study was initiated in August 1998 by the Department for Gynaecology and Obstetrics of the Medical University of Lübeck. A total of 59 IVF centres reported pregnancies after ICSI up to week 16 to the study centre in Lübeck, which contacted the pregnant women at regular intervals by telephone up to the time of delivery and collected prospective data on the course of pregnancy. All miscarriages, stillbirths and live births occurring after 16 week's gestation were registered in a standardised fashion. Standardised according to the same criteria, miscarriages, stillbirths and live births after spontaneous conception occurring in the same period were likewise registered. All data were documented in the Mainz birth registry.

Data analysis was scheduled to begin in spring 2001.

When early results were presented at a meeting on prenatal medicine in Mainz in April 2001, the malformation risk after ICSI was given as 9.4 per cent, while the same risk for naturally conceived children was 7 per cent. Presenters also reported that a retrospective analysis of the Mainz birth registry had shown that "the malformation risk after ICSI was even three times higher" and that this had led to the conclusion that every ICSI treatment had to be preceded by qualified genetic counselling and chromosomal analysis.[253]

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[250] BSG 2001, BSGE 88, p. 62 (72ff.). The data were taken from an expert opinion of 25 November 1999 by Professor Kollek that had been commissioned by the BSG.

[251] The BSG rules out the possibility of applying a decision by the *Bundesverwaltungsgericht* (Federal Administrative Court) of 22 March 2001 (DVBl. 2001, pp. 1214-1215) in which the latter – citing the risk of malformation - refused the claim of female soldiers to ICSI as part of free medical care. The BSG states that SHIs explicitly entitle couples to artificial fertilisation and leave the risk assessment to them. Cf. the passages quoted above of the BSG's decision.

[252] http://www.repromed.de/icsigeschichte.html The text published on the website of the *Bundesverband Reproduktionsmedizinischer Zentren* (BRZ – Association of German Reproductive Centres) relies on a paper by Professor Diedrich, Medical University of Lübeck (as of 17 August 2001).

[253] Lenzen-Schulte 2001.

A joint statement on the study results[254] noted with regard to the study design that

– between August 1998 and August 2000, 59 IVF centres had reported 2,687 pregnancies resulting in 3,372 children;

– after having been born in selected centres, the babies had undergone standardised clinical examinations and ultrasound scans by 25 specially trained paediatric physicians and/or human geneticists;

– based on the Mainz birth registry 6,265 children from spontaneous pregnancies in the same period had been analysed for control purposes.

The following results concerning the incidence of malformations were noted:

– 8.6 per cent of the children in the ICSI group had malformations.

– 6.8 per cent of the children from spontaneous pregnancies (population-based control group) had malformations.

– The resulting relative risk of having a child with malformations after ICSI was 1.27 times higher than in spontaneous pregnancies. While it has to be expected that after spontaneous pregnancy every 15th child will be born with a malformation, every 12th child born after ICSI will have a malformation.

  "Analysis of the ICSI group showed that there was a disproportionately high incidence of known risk factors for malformation (e.g. higher maternal age, parental malformations). After adjustment for these factors the relative risk dropped to about 1.15. This means that the difference in the incidence of malformation between the ICSI group and the control group can to some extent be explained by known risk factors unrelated to ICSI. This study has shown, however, that at present a residual risk of malformation in the children of couples who conceived after ICSI cannot be definitively excluded."[255]

An internal version of the study was available when the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committe of Physicians and Health Insurers) decided on 26 February 2002 to include ICSI in the range of SHI benefits. In its press release, the Committee said that:

[254]Ludwig *et al.* (year not indicated). This statement gives a concise summary of the study results. The complete study will probably be available in June 2002 at the earliest, i.e. after this report's press date (personal communication by Professor M. Ludwig by e-mail of 11 April 2002).

> "a study conducted by the Lübeck medical university centre covering 2,809 (sic!) pregnancies after ICSI (...) (determined) a malformation risk of 1.28. However, because there is still some doubt about this figure, the Federal Committee agreed to review its decision in the next three years."[256]

1.2.4.2.4 Documentation and quality assurance of assisted reproduction in Germany

1.2.4.2.4.1 German IVF Registry

In spite of obligatory notification as laid down in regulations at state level or in the medical profession's code of ethical practice, every fourth IVF treatment performed in Germany was reported incorrectly or not at all to the 1999 German IVF Registry. In 2000 it was every fifth treatment.

93 of the estimated[257] 110 IVF centres in Germany contributed to the 1999 edition of the DIR.[258] This is a participation rate of only 85 per cent. Just under 87 per cent of the data submitted could be used for statistical purposes. This means that in spite of obligatory notification only 75 per cent of all treatments performed in Germany were prospectively documented in the 1999 DIR. However, even this result is considered a major improvement in the notifying behaviour of, and the quality of data submitted by, the various IVF centres[259], given that in 1995 the actual coverage rate was a mere 60 per cent. In 2000, an actual prospective coverage rate of about 80 per cent was reached, because 103 IVF centres participated.[260]

At the non-public hearing of the Study Commission on 26 March 2001, Professor Ricardo Felberbaum, chairman of the board, called for a "Federal Authority for Reproductive Medicine" based on the British model "to prevent any uncontrolled development". This authority would have to be responsible for licensing the centres, documenting their results and conducting regular unannounced controls.

In 1989-90, a German registry was established, based on the model of the French central registry. At that time, more than 30,000 IVF treatments had already been performed in Germany.

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[255] Ludwig *et al.* (o.J.).
[256] *Bundesausschuss der Ärzte und Krankenkassen* 2002.
[257] Oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001.
[258] Oral communication by Professor Ricardo Felberbaum at the non-public hearing on 26 March 2001.
[259] Cf. *Deutsches IVF-Register* 1999, p. 5.

In 1996, Beier concluded that "the existing IVF registry in the Federal Republic of Germany which is based on voluntary participation by treatment centres did not manage to produce a genuinely comprehensive and standardised data collection (...)", because in 1995 only 65 of at least 80 IVF groups contributed to data collection, i.e. that "almost one-fifth of the licensed centres (...)" did not contribute to "this documentation, which is important for the general public".[261] About 24 per cent of the reporting centres were not able to submit the data in such a way that the IVF Registry could have used them in all its statistics.

In 1998, the German Medical Association – in its *Richtlinien zur Durchführung der assistierten Reproduktion* (Guidelines for assisted reproduction) - defined participation in the DIR as a measure of quality assurance, but centres are still not under a legal obligation to participate.

So far, the DIR has been compiled in co-operation with German IVF centres and jointly sponsored by (state) university centres and the association of private reproductive centres.[262]

1.2.4.2.4.2 Documentation of success and risks of assisted reproduction in the German *In-Vitro* Fertilisation Registry

In 1991, Hölzle & Wiese[263] commented on the first statistics covering the period from 1981 to 1986 and registering a total of 481 births, which is an average of 13.4 births per centre: "These extremely low figures do not permit any valid conclusions as to the efficiency of the method. Only a comparison of treatment effort and treatment result will allow a sound evaluation."

Since that time, there has been a considerable increase in treatment numbers, treatment methods, treatment centres and births.

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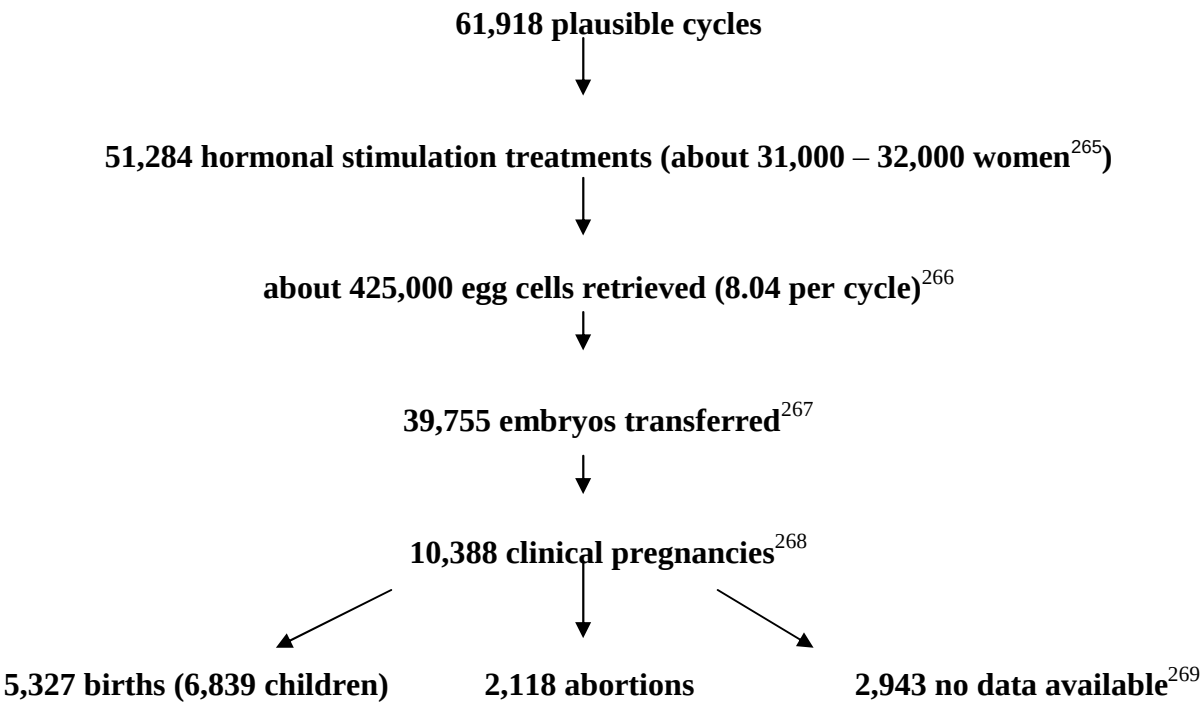
[260] Cf. *Deutsches IVF-Register* 2000, p. 5f. This figure is based on the assumption that a total of 110 centres in Germany perform assisted reproduction.

[261] Beier 1996, p. 52

[262] The *Deutsches IVF-Register* is sponsored by the *Deutsche Gesellschaft für Gynäkologie und Geburtshilfe e.V.* (DGGG – German Society for Gynaecology and Obstetrics), the *Deutsche Gesellschaft für gynäkologische Endokrinologie und Fortpflanzungsmedizin e.V.* (DGGEF – German Society for Gynaecological Endocrinology and Reproductive Medicine) and the *Bundesverband Reproduktionsmedizinischer Zentren Deutschlands e.V.* (BRZ – Association of German Reproductive Centres).

[263] Hölzle/Wiesing 1991, p. 8.

Chart 3: Assisted Reproductive Treatments and Results in Germany in 2000[264]



Source: DIR 2000

According to the DIR, 38,442 women in Germany received an average 1.65 treatment cycles in 2000. The better part was accounted for by the age group between 31 and 36 years with a rate of between 7 and 8 per cent for each of the other age cohorts. Unlike the United States

[264] Cf. *Deutsches IVF-Register* 2000, p. 11. The data are quoted from the 2000 DIR statistical summary or, if data were not available, calculated on the basis of this summary and other data of the 2000 DIR. The latter data have been marked for easy identification. The DIR statistical summary is based on both prospective and retrospective data.

[265] The number of women undergoing hormonal stimulation is not given on p.11 of the statistical summary. This number is derived from the data of the 2000 German IVF Registry, p. 8ff. and can only be used for clarifying estimates. Cf. the explanations given in the first footnote of 1.2.4.2.4.3 What is the success of assisted reproduction – and how often does it occur?

[266] Cf. *Deutsches IVF-Register* 2000, p. 10.

[267] Cf. *Deutsches IVF-Register* 2000, p. 11. These data reflect the total of all transfers after IVF, ICSI and IVF/ICSI.

[268] Cf. *Deutsches IVF-Register* 2000, p. 11. These data reflect the total of all clinical pregnancies after IVF, ICSI and IVF/ICSI.

[269] It would seem that the fate of some of the clinical pregnancies for which detailed data are not available can be explained in the future. In the 1999 German IVF Registry, p.11, for instance, the data for 3,757 of a total of 9,695 reported clinical pregnancies are missing. In the light of the data provided in the 2000 German IVF Registry, p.14, this number drops to 1,474 of 12,770 clinical pregnancies for 1999, the year under review. No explanation is given for the change in numbers, especially the increase in the total of clinical pregnancies by 3,075 over the data given in the 1999 German IVF Registry, p.11.

where more than half of IVF users are already between 33 and 39 years old, the share of this age group in Germany has so far been below 50 per cent.[270]

A total of 425,021 egg cells were retrieved in 52,857 cycles, that is 8.04 egg cells per cycle.[271] Fertilisation rates were 51.7 per cent for IVF and 54.3 per cent for ICSI. On average, 2.29 embryos were transferred after IVF and 2.39 after ICSI. The number and percentage of those egg cells whose subsequent fate is described as "unknown" more than doubled over the previous year, rising by 7.85 per cent to 33,369.[272] A total of 39,755 embryos were transferred which resulted in 10,388 clinically established pregnancies. There were 5,327 live births (with a total of 6,839 children) and 2,118 abortions. The fate of 2,943 clinically established pregnancies, that is 28.3 per cent, is unknown.

1.2.4.2.4.3 What is the success of assisted reproduction – and how often does it occur?

Absolute data on the success of assisted reproduction vary depending on the reference parameters and statistical method used. They also depend on the type of data collection (prospective or retrospective)[273] and on the start and end of a cycle as defined by the method used. Since documentation procedures and qualities differ significantly worldwide and also within Europe, a comparison of the success rates of different countries would have only limited validity.[274]

> "If you want to answer the question as to what the ultimate objective of treatment is, you will find that for the couples concerned this objective is not reached before the arrival of a baby, while the attending physicians already consider reaching individual treatment stages, e.g. successful embryo transfer, a (clinical) success."[275]

[270] Cf. *Deutsches IVF-Register* 2000, p. 8.
[271] *Deutsches IVF-Register* 2000, p. 10. Based on the data cited in the previous paragraph, it follows that these egg cells were retrieved from 32,034 women (cf. 1.65 cycles/woman) and that an average 13.26 oocytes were harvested from each woman.
[272] See *Deutsches IVF-Register* 1999, p. 10 and *Deutsches IVF-Register* 2000, p. 10. These are prospective data only, while the figures cited above consist of both prospective and retrospective data. This is why only an approximate correlation can be established between the individual data. The DIR does not provide an explanation of the difference in the type of data used as a basis.
[273] 'Prospective' data capture means that data are collected directly after the event in question, i.e. all data are immediately entered into the database irrespective of the further development of treatment. With 'retrospective' data capture on the other hand, data are not entered into the database before treatment results are available. This means that there is always the risk of data selection and hence of influencing (usually embellishing) statistics. Consequently, prospective data collection, which is practised e.g. in Germany, is considered more accurate than retrospective data capture as implemented e.g. in the United States, because retrospective data may lead to more optimistic success rates.
[274] Cf. C1.2.4.1 Overview of assisted reproduction in Europe and the United States
[275] Barbian/Berg 1997, p. 2.

Pregnancies, clinical pregnancies or live births are cited as the success criteria of IVF and its variants. There are also different points in time which are given as the start of a cycle to which the various success criteria need to be related in order to calculate success rates. For instance, the beginning of hormonal stimulation, follicle puncture, fertilisation or embryo transfer may be used as reference points.

This variance in the choice of the different reference parameters has clear consequences, given that

– of a total of 51,284 hormonal stimulations documented in Germany in 2000 about 90 per cent resulted in oocyte retrieval and 79,6 per cent or 39,755 in embryo transfer;

– 10,388 clinical pregnancies established in 2000 resulted in 5,327 births and 2,118 abortions (the outcome of 2,943 clinically established pregnancies is unknown).

What follows from this is that

– when clinical pregnancies and embryo transfers are correlated, the resulting success rate is higher than 26 per cent.[276] The figures are even more optimistic when the results are "cumulated" on the basis of three or four treatment cycles.[277]

– when births and hormone cycles are correlated, the success rate cannot be precisely determined, but it should be in the order of 11 to 13 per cent.[278]

1.2.4.2.4.4 The baby take-home rate and the contribution of assisted reproductive technologies to treating involuntary childlessness

The baby take-home rate[279] indicates the probability at the time of starting an IVF cycle with which a woman's (a couple's) wish to have a child is fulfilled. Consequently, it is the only success rate relevant for the woman (the couple) asking for treatment. The DIR gives the baby take-home rate related to "treatments performed"[280]. In 1998, this rate was 13.6 per cent after

[276] Besides, a clinically established pregnancy is the crucial success criterion for reimbursement of cost by statutory health insurers.

[277] On its homepage the *Deutsche Klinik Bad Münder* advertises a clinical pregnancy rate (related to the number of embryos transferred) of more than 39 per cent and cites a "cumulative birth rate" of 60 to 70 per cent after three to four treatments, without, however, explaining the term "birth rate" (http://www.kinderwunsch.com/seite.asp?Seite=3) (as of 27 March 2002).

[278] These figures were calculated on the basis of the data given in the German IVF Registry, p.11. The birth/hormone cycle ratio was derived from existing data and is only an approximate value, as the fate of some of the clinical pregnancies is unknown.

[279] Cf. C1.2.6.3 Baby take-home rate - the criterion of success.

[280] Cf. *Deutsches IVF-Register* 1999, p. 14; *Deutsches IVF-Register* 2000, p. 14. It seems that "treatment performed" does not begin with taking hormones (hormonal stimulation), but only with "egg cell manipulation" – after stimulation and egg cell retrieval – which is not explained in more detail. Consequently,

IVF, 15.1 per cent after ICSI, 9.37 per cent after cryopreservation, and 14.56 per cent after combined IVF/ICSI.[281] The baby take-home rate in 1999 was 14.72 per cent after IVF, 16.12 per cent after ICSI, 9.62 per cent after cryopreservation, and 16.56 per cent after combined IVF/ICSI.[282] A baby take-home rate of 13 to 15 per cent means that only every seventh woman will have a child after an IVF cycle.

Irrespective of the choice of reference parameters Mr. Kentenich, a German reproductive specialist, takes an even more cautious approach in his appraisal of the contribution of IVF to treating involuntary childlessness:

> "However, altogether it may be assumed that the majority of couples do probably not conceive as a result of treatment. Many become pregnant in treatment-free intervals or after the end of treatment. Treatment as such is probably only successful in every second case."[283]

This assessment is corroborated by a study of the success rates of IVF and psychosocial counselling in involuntarily childless couples[284]:

Table 6: Success Rates of IVF and Psychological Counselling

	Hormone treatment/ insemination	**IVF**	**Psychological counselling**
Pregnancy after treatment	17.2 %	14.6 %	15.8 %
Spontaneous pregnancy	9.5 %	7.8 %	8.3 %
Couples enrolled	125	466	38

Source: Hölzle 2001 (modified)

The study involved solution-oriented partner counselling (seven sessions of 1.5 hours each over a period of six months). Two treatment cycles of IVF were performed on average over the same period.

1.2.5 Prevalence of, and coping with, involuntary childlessness[285]

Usually, a couple notice transient or persistent infertility only when they cannot realise their wish to conceive. Up to one third of all couples wanting to have a child have to wait more

a baby take-home rate based on hormonal stimulation as the beginning of treatment should be lower than the figures given in the DIR.

[281] Professor Ricardo Felberbaum at the non-public hearing of 26 March 2001, and *Deutsches IVF-Register* 1999, p. 14.

[282] *Deutsches IVF-Register* 2000, p. 14.

[283] Kentenich 2000b, p. 41f.

[284] Hölzle *et al.* 2000.

[285] The term "involuntary childlessness" and its synonyms describe a couple's wish to have a biologically related child, i.e. a child that is genetically their own.

than one year for a spontaneous pregnancy and "according to the definitions common today, are considered involuntarily childless", while according to the European Studies of Infertility and Subfecundity (ESIS) about 25 per cent of couples European-wide conceived only after more than one year after discontinuation of contraceptives[286]:

> "The most important data in this respect can be found in the European Studies of Infertility and Subfecundity (ESIS) which were conducted in five European countries between 1991 and 1993. According to these studies, there is a lifetime prevalence of 24.8 per cent (total European sample), while the figure for Germany is 31.8 per cent, i.e. about one third of the women will at some time in their lives go through a phase of infertility, i.e. they do not become pregnant for twelve months in spite of unprotected intercourse. Only 54.9 per cent of the women in Germany turn to medical professionals for help (after a twelve-month "waiting time"). This is important to note with regard to most of the studies looking into the care of involuntarily childless couples, because they only cover medically treated patients and hence only part of those affected. It is noticeable that if medical help is sought this is done relatively quickly: in Germany, 41.1 per cent of the couples consult a doctor already after a "waiting period" of six months to become pregnant. Institutional psychosocial help, on the other hand, is sought in only very few cases: for women undergoing medical examinations/treatments the percentage is 10 per cent, for women not seeking medical help only 1 per cent."[287]

A distinction has to be made between *voluntary* and *involuntary* childlessness. Socio-cultural and economic changes have altered society's attitude towards children in many ways, and today childlessness is often a chosen lifestyle: According to a study commissioned by the *Bundeszentrale für gesundheitliche Aufklärung* (BzgA – Federal Centre for Health Education) about every fourth woman (27 per cent) between 35 and 44 years is childless, and among women with a high level of education it is even almost every second woman (47 per cent).[288] The causes of childlessness are mostly identified not as medical, but rather as social factors: "40 per cent of 35-to-39-year-old women and 43 per cent of 40-to-44-year-old women in the western part of Germany have freely chosen not to have children or have at least accepted

[286] Brähler *et al.* 2001, p. 161. The German contribution to these "European Studies of Infertility and Subfecundity" (ESIS) is the "*Deutsche Studie zur Infertilität und Subfekundität*" (DESIS – German Study of Infertility and Subfecundity). The Frankfurter Allgemeine Zeitung reported that according to this study the percentage of infertile couples in Germany was 6 per cent. 18 to 20 per cent of the women had to wait more than twelve months to become pregnant after discontinuation of contraceptives ("Infertility often overrated" 1995). Tinneberg 1995a, p. 45 assumes that 60 to 90 per cent of all couples become pregnant within a year and suggests that every fourth natural ovulation leads to a clinical pregnancy. For more detailed information see Karmaus *et al.* 1996, p. 15-26.

[287] Strauß *et al.* 2000, p. 46.

their childlessness"[289]. In the former West German states, 21 per cent of the women aged 40 and older are childless and single; in the former East German states, it is only 3 per cent.[290] The key message of a study of coping with childlessness in the long term and of its consequences for concepts of psychological care is:

> "The groups of voluntarily and involuntarily childless subjects did not differ in terms of the psychological characteristics studied (life satisfaction, partner satisfaction, psychological health)."[291]

The longer couples have to wait to end their childlessness, the greater the personal stress seems to become, especially for women.[292] This may lead to a situation where "even the most unfavourable prognosis hardly has any influence on the couples' decision" to use IVF and where their expectations "are much greater than in the case of other sterility treatments".[293]

This is the reason why every second childless couple resorts to medical or psychological help.[294] Basically, treatment of involuntary childlessness can be seen from two different therapeutic perspectives[295]:

– **Ending childlessness by inducing pregnancy**

Although there is no agreement as to whether the subjective anguish caused by involuntary childlessness can be classified as a disease, reproductive treatment aims at

[288] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 11.
[289] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 13.
[290] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 14. Moreover, 98 per cent of married women in the former East German states and half of those who never married have children. In the former West German states, on the other hand, 90 per cent of married women, but only 30 per cent of those who never married have children. The BZgA study concludes that in the "age group of 30-to-44-year-olds (...) the differences between East and West Germany are most distinct" and that the "difference in the percentage of childless women is 27 per cent". (*Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 14) According to this study, differences between east and west used to be more distinct in the younger age groups than in the older ones because women in the former East German states had their first child at a younger age. Today, the study concludes, the percentage of singles among the 20-to-24-year-olds is about the same in east and west and the difference in the percentage of childless women is only 11 per cent: "Compared with the time before German unification, the figures can be seen as an indication of approximation (at least as far as the delay of the first birth is concerned), even though more young women in the former East German states still had their first child before they were 30 years old". (*Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 14).
[291] Strauß *et al.* 2000, p. 223
[292] Usually women are the driving force when seeking psychosocial counselling. Oral communication by Professor Christina Hölzle at the non-public hearing on 26 March 2001.
[293] Barbian/Berg 1997, p. 21.
[294] Hölzle 2001, p. 1.
[295] Hölzle 2001, p. 1.

remedying this situation by inducing a pregnancy after intervening in the reproductive processes of – sometimes – both partners at different physiological levels[296].

– **Coping with (possibly irremediable) involuntary childlessness**

This perspective is usually adopted by psychological and psychosomatic experts. It does not focus on the (possibly irremediable) childlessness, but on the possibility that "the actual reason why couples present at a fertility centre is a psychological wound"[297].

1.2.5.1 Prevalence and causes of childlessness

Official data on the percentage of childless women are not available in Germany.[298] Estimates of the number of involuntarily childless couples vary depending on the source used. Robert Edwards, one of the spiritual "fathers" of the first IVF baby, recently suggested that in Europe about every sixth couple had difficulties procreating.[299] According to medical estimates, the prevalence of sterility in Germany is 10 to 15 per cent of all couples of reproductive age[300] and the number of involuntarily childless couples in this country had so far been estimated to amount to 15 to 20 per cent.[301] Recently these figures were described as much too high. "The percentage of such couples is clearly below 10 per cent in West Germany and below 5 per cent in East Germany. In contrast, the number of couples opting for childlessness is rising."[302]

Apart from temporary or permanent physiological disorders in both sexes[303], childlessness may be caused by numerous other factors which compromise reproductive behaviour and make it difficult to estimate the prevalence of involuntary childlessness:

– *Involuntary* childlessness may be transient or persistent.

– Childlessness is often voluntary at first (education, career), but may turn into involuntary childlessness at a later stage.

– The partners do not agree on having children (different ideas, limited contraception or restricted intercourse on fertile days).

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[296] According to *Bundesärztekammer* 1998b, A 3166, assisted reproduction sees itself as "medical help to fulfil a couple's wish to conceive by means of medical assistance and techniques".
[297] Kentenich 2000a, p. 17.
[298] According to Brähler *et al.* 2001, p. 157, this is due to the statistical method used which only registers legitimate live-born infants from the current marriage and disregards illegitimate children and children from previous marriages.
[299] See "*Glück aus dem Reagenzglas. Mehr Kunst-Befruchtungen*" (Happiness from the test tube. More artificial fertilisations) 2001.
[300] Tinneberg 1995a, p. 45.
[301] http://www.kinderwunsch.de/public/index.html welcomes visitors with the question: "Did you know that today about every seventh relationship is involuntarily childless? And that the number of these couples is constantly rising?" (as of 27 March 2002).
[302] Brähler *et al.* 2001, p. 157.
[303] Transient or persistent reproductive disorders.

Epidemiological estimates of involuntary childlessness due to medical causes are few and far between and refer exclusively to conjugal fertility.[304] According to such estimates, only 5 per cent of women who got married before they were 24 years old remained childless, whereas about every third woman who was between 35 and 39 years old when she married remained without child.[305] In 1989, 20 per cent of all couples of reproductive age in West Germany were childless; in 6 per cent of the cases, childlessness was involuntary, in 4 per cent voluntary and in 10 per cent transient. One estimate derived from these data puts the figure at 8.6 per cent of involuntarily childless couples in West Germany.[306]

In a study conducted by the *Bundeszentrale für gesundheitliche Aufklärung* (BzgA – Federal Centre for Health Education) 1.7 per cent of the women interviewed were suffering from "primary sterility" at the time of questioning[307] and 1.8 per cent from "secondary sterility" after they had already given birth to at least one child. Fifteen per cent of the women interviewed in this study had at least once gone through an infertile phase (lifetime prevalence). However, almost three quarters of all women with experience of infertility had children before or after that phase.[308]

It would seem that delaying childbirth in one's plan for life has a crucial influence on the probability of remaining involuntarily childless. Whereas it was perfectly normal in the German Democratic Republic to reconcile motherhood with education and training or with a job, this did not and still does not apply to the Federal Republic of Germany. A 1996 survey showed that in West Germany in the group of women between 30 and 39 about 15 per cent (women without any formal vocational qualifications) and 37 per cent (university graduates) did not have any children. In East Germany the corresponding rates were 11.4 per cent (women without any formal vocational qualifications) and 7.9 per cent (university graduates).[309]

The above-mentioned BzgA study on the lives and family planning of women arrived at the following conclusions for the group of 35-to-44-year-old women:

> "In the East German states, there are fewer single women (8 per cent) in this age group than in the West German states (25 per cent), and it is much rarer for them not

[304] The *Statistisches Bundesamt* (Federal Statistical Office) reports about 78 per cent legitimate and 22 per cent illegitimate children born in 1999.
[305] Brähler *et al.* 2001, p. 161. The authors quote a 1996 study of childlessness in Germany.
[306] Bruckert 1991, cited in Brähler *et al.* 2001, p. 161.
[307] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 14. For the terms "primary infertility" and "secondary infertility" used by the BZgA, see C1.2.2.2.1 Reproductive medicine and fertility disorders.
[308] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 14.

> to have children (6 per cent, West German states 27 per cent). In West Germany, marriage and children have not lost their importance in all groups of the population to the same extent, but very much so among women with a high or very high level of education, whereas 35-to-44-year-old women with a low level of education show a behaviour very similar to that of women in the eastern part of the country, as few of them are single and childless.
>
> In the western part of the country, the percentage of singles among women with a low level of education (figures in brackets: percentage of childless women) is 10 per cent (10 per cent), among women with medium-level education 20 per cent (21 per cent), among women with a high level of education 23 per cent (31 per cent) and among women with the highest level of education 45 per cent (47 per cent). In the eastern part of the country education does not have an influence on the percentage of single women, neither in general terms nor specifically in the group of 35-to-44-year-old women".[310]

Brähler et al. expect an approximation of the figures for East and West Germany and a general increase in involuntary childlessness as a result of delaying childbirth.[311]

In view of the widely differing figures reflecting reproductive behaviour in Europe, in East and West Germany and also in the various German states it is considered "improbable that the high level of childlessness in some European countries, such as Germany, is mostly attributable to an increase in infertility and sterility".[312]

This becomes quite evident when comparing the figures for the various German states. According to the *Statistisches Bundesamt* (Federal Statistical Office), the percentage of childless women aged 35 to 39 in West German city states in 1994 was 39 per cent (West Berlin), 35 per cent (Bremen) and 32 per cent (Hamburg). In the other West German states, between 22 and 25 per cent of the women of this age group (except for Lower Saxony with 28 per cent) were childless, but in the eastern states the rates were only between 7 and 9 per cent. At 13 per cent, the rate in East Berlin was clearly higher than in the rest of East Germany. It is remarkable, though, that in West Berlin at the same time three times as many women in the same age group as in East Berlin were childless (39 per cent vs. 13 per cent).[313]

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[309] Dorbitz/Schwarz 1996, cited in Brähler *et al.* 2001, p. 162.
[310] *Bundeszentrale für gesundheitliche Aufklärung* 2000, p. 12f.
[311] Brähler *et al.* 2001, p. 162
[312] Brähler *et al.* 2001, p. 159.
[313] According to Brähler *et al.* 2001, p. 160 (Figure 4).

1.2.5.2 Ending childlessness or coping with the situation? The demand for assisted reproduction and psychosocial counselling

Temporary infertility is quite a common phenomenon; every third woman trying to conceive has to wait for at least one year before she gets pregnant. In most cases, pregnancy is spontaneous, which is why appropriate counselling and some restraint in recommending treatment are indicated.

Moreover, delaying childbirth could lead to an increase in the demand for ART services. Perhaps there is even an interaction between planning one's life and the availability of reproductive assistance:

> "The fact that reproductive medicine raises expectations of still being able to have children at an older age might have a disastrous effect. The result may be that more and more people delay having children."[314]

It is absolutely crucial that the couple are willing to face up to their current childlessness and adopt a psychological approach to their problem if they are to be able to choose the option of coping: "However, at the beginning the majority of couples do not feel the need to discuss any psychological issues."[315]

Reducing infertility to a medical and technical problem and ignoring the social and psychological aspects of involuntary childlessness are partly to blame for a situation where couples are no longer aware of other ways of coping and "with great matter-of-factness and growing expectations turn to reproductive medicine for help".[316]

[314] Brähler *et al.* 2001, p. 162.
[315] Kentenich 2000a, p. 17.
[316] Barbian/Berg 1997, p. 1.

Table 7: Motivation for, and Attitude towards, Psychological Counselling and Medical Treatment (in %)

	Women		**Men**	
	IVF *(N=303)*	**Counselling** *N=37*	**IVF** *(N=288)*	**Counselling** *N=37*
Motivation for treatment				
1. want to take advantage of all medical possibilities	*75.6*	*47.4*	*61.8*	*44.7*
2. do not want to blame myself later	*51.5*	*44.7*	*40.6*	*34.2*
3. cannot imagine living without a child of my own	*28.4*	*47.4*	*23.6*	*7.9*
4. other		*21.1*		*10.5*
Acceptance of …				
1. psychological counselling/therapy	*58.7*	*97.4*	*54.9*	*86.8*
2. hormone treatment	*95.7*	*86.8*	*87.5*	*73.7*
3. naturopathic treatment	*51.8*	*89.5*	*61.5*	*68.4*
4. homologous insemination (partner's sperm)	*97.0*	*73.7*	*95.8*	*76.3*
5. surgical intervention	*94.7*	*84.2*	*63.5*	*42.1*
6. adopted child	*45.2*	*55.3*	*46.5*	*52.6*
7. IVF/ET	*87.5*	*31.6*	*81.6*	*34.2*
8. foster child	*15.8*	*15.8*	*17.7*	*23.7*
9. heterologous insemination (donor sperm)	*9.6*	*0.0*	*8.7*	*13.2*

Source: Hölzle et al. 2000[317]

The demand for professional help in the case of involuntary childlessness depends not only on age, but also on the level of education. IVF patients, for instance, have significantly higher educational qualifications than the average population.[318] And clients enrolling in psychosocial counselling – apart from being under greater personal stress – even have a significantly higher educational level than average IVF patients.[319]

From this it may be concluded that the threshold for seeking psychosocial counselling for involuntary childlessness is much higher than that for seeking reproductive treatment. Consequently, women receiving psychosocial counselling are under even greater

[317] Cf. Hölzle 2001, p. 6.
[318] Hölzle 2001, p. 6f.
[319] Hölzle *et al.* 2000, see also Hölzle 2001, p. 6.

psychological stress than IVF patients. 47 per cent of counselling clients claimed to be unable to live without a child of their own, compared with 28 per cent of IVF patients. For men, the ratio is reversed, with the overall stress level being lower.

Counselling clients are also slightly more open than IVF patients to the ideas of adoption, foster children and naturopathic therapies. On the other hand, they take a more sceptical attitude than IVF patients towards in-vitro fertilisation and other medical procedures.[320]

It was pointed out that IVF treatment involves a highly complex doctor-female patient relationship which may range from expectations of help to the delegation of decision-making to partner substitute projections and is subject to special emotionality, problems of detachment and responsibility on the part of the physician.[321]

1.2.6 Results

1.2.6.1 Development of assisted reproduction into "reproductive genetics"

As ever newer methods were integrated into the range of assisted reproduction technologies available it became possible to intervene at the various stages of reproduction. Today, ART makes it possible to influence the persons involved, the sequence of events and the genetic information passed on in the reproductive process. The levels of intervention that are briefly outlined below illustrate the change of reproductive medicine into "reproductive genetics" which combines methods of reproductive medicine and human genetics.

1.2.6.1.1 The four levels of intervention in human reproduction by reproductive genetics

The ever wider definition of its indications and the integration of ever newer procedures over the last two decades clearly show that assisted reproduction is losing sight of its original objective, i.e. to treat organic female infertility.

Among the various procedures that are already being used or at least discussed today, four medical levels of intervention in human reproduction can be identified[322]:

[320] Hölzle 2001, p. 7.
[321] For a detailed discussion of these aspects and the economic aspects of IVF see Barbian/Berg 1997.
[322] Cf. Koch 1998, pp. 20ff.

- **Replacing, repairing or bypassing defective reproductive organs (e.g. blocked tubes, absence of oocyte maturation, lack or complete absence of sperm) by means of**
  - IVF and its variants, such as GIFT, ZIFT, EIFT
  - IVF with ICSI
- **Replacing the persons** involved in the reproductive process ("donation") by means of
  - IVF with egg cell donation (by anonymous or known donor)
  - IVF with sperm donation (by anonymous or known donor)
  - IVF with donor egg cells and donor sperm
  - IVF with surrogacy
- **Disrupting the spatio-temporal connection between the various stages of the reproductive process by means of cryopreservation in the form of**
  - IVF with cryopreserved egg cells
  - IVF with cryopreserved sperm
  - IVF with cryopreserved fertilised oocytes/embryos
- **Influencing the genetic identity of those involved in the reproductive process by means of**
  - IVF with preimplantation genetic diagnosis (PGD)
  - IVF with modified egg cell cytoplasm[323]
  - IVF with nuclear transfer[324]
  - IVF with germ line intervention (germ line therapy)[325]

These possible interventions in the reproductive process go far beyond the treatment of organic fertility disorders. They have an impact on the personal, temporal and genetic integrity of the reproductive process. In principle, it is possible to combine the individual elements of the various levels (e.g. IVF with an egg cell which was fertilised with donor

[323] At present, changing the cytoplasm of an egg cell is still considered to be at the experimental stage. Among other things, defective oocytoplasm results in defects in protein biosynthesis, mitochondria etc. In certain cases, it is intended to improve IVF success rates by transferring cytoplasm from donor egg cells. The procedure has already been used in clinical experiments; it changes the genetic identity of the female gamete. A child resulting from an egg cell that has been treated in this way and then fertilised will have the genetic make-up of three persons. See Seehaus *et al.* 2000, pp. 109f. and Barritt *et al.* 2001.

[324] This – still experimental – method is used to place the nucleus of an embryo in which cell division has been blocked into an enucleated donor egg cell to save the embryo. Cf. Seehaus *et al.* 2000, pp. 111f.

[325] Theoretical option; currently there is international agreement not to use this procedure.

sperm by means of ICSI and frozen, whose cytoplasm was replaced and which was implanted into a so-called surrogate mother).

Consequently, it seems appropriate to use the more comprehensive term "reproductive genetics" to describe the various techniques used for assisted reproduction.

Quite apart from a host of individual ethical issues, a general problem of reproductive technologies is already emerging from the variety of possible interventions:

> "With assisted reproduction and prenatal health maintenance reproductive genetics at first seems to confirm the modern European model of the nuclear family. As it evolves, reproductive genetics permits an ever stronger individualisation of the wish to have children. However, this individualisation tends to turn against the common type of nuclear family. For in the course of this individualisation the components that are biologically required for parenthood become *freely selectable*."[326]

1.2.6.1.2 Preimplantation genetic diagnosis as part of reproductive genetics

Preimplantation genetic diagnosis (PGD) not only requires IVF, it also represents another level at which assisted reproductive technologies can intervene in the reproductive process. Within the framework of reproductive genetics PGD is an instrument for selecting embryos to meet pre-defined objectives: PGD helps to identify individual genetic risks or general (chromosomal) risks for nidation and for sustaining a full-term pregnancy.

If PGD represents the end of the process of developing reproductive genetic methods, the associated in vitro selection of embryos in particular calls for an ethical and legal appraisal.

If, however, PGD is only one step on the way to identifying genetic defects that might be curable in the future or genetic characteristics that can be changed, the discussion about germ line interventions or so-called "enhancement" (genetic "improvement" of the individual), including all the associated ethical and legal problems, emerges at the horizon of assessing PGD as part of reproductive genetics.

[326] Kettner 2001, p. 42.

1.2.6.2 Need for documenting assisted reproduction in accordance with statutory criteria

A reliable, binding and generally understandable documentation of all the procedures performed in the course of assisted reproduction (so-called "IVF cycles") is required for the following reasons:

– All variants of IVF and embryo transfer (ET) are methods that always require interventions in the physical integrity of a woman and sometimes[327] that of a man. These interventions may only be performed after patient education and information, with the aim of removing the cause of involuntary childlessness, i.e. a medically established fertility disorder, and inducing pregnancy.

– In order to comply with their obligation to educate and inform the patient as required by their code of ethical practice, physicians have to provide reliable information on the (statistical) probability of the success of IVF treatment in the counselling sessions preceding actual treatment.[328]

– The availability of generally understandable information and data on probabilities of success and on potential treatment risks is indispensable for the patients' informed consent to the planned treatment.

Statistical surveys play an important part in IVF quality assurance. In the spirit of the medical principles to relieve suffering and prevent damage they should provide reliable information on the resources needed for IVF as well as the probability of success and the risks involved in IVF treatment.

Data should be processed in such a way that all those interested in the methods of assisted reproduction have access to generally understandable information on health hazards, chances of success and (in view of the still high failure probability of the medical treatment of involuntary childlessness) also on alternatives to IVF treatment.[329]

[327] Surgical retrieval of sperm from the testes or epididymis.
[328] On the obligation to provide information as required by the code of ethical practice see *Bundesärztekammer* 1995, A 3168.
[329] Based on the model of the British HFEA. Suggestions in Beier 1996, who also cites the rates per IVF centre in the UK. See also Beier 2001, p. 497f.; Felberbaum 2001, p. 256ff.; Kentenich 2001, p. 256ff.

1.2.6.3 Baby take-home rate as a criterion of success

For the couple who hope to end their involuntary childlessness with the help of reproductive treatment the varying data available today on treatment success are confusing and difficult to understand. From the medical perspective, this information needs to be explained or justified:

– From the medical perspective, as well, it seems to be consistent to define as the beginning of medical treatment the prescribed intake of hormonal medication (pharmacological intervention in the physical integrity of a woman) and not the subsequent clinical interventions of egg cell retrieval or embryo transfer.

– The *Bundesärztekammer* (BÄK – German Medical Association) failed to provide such a definition in its "*Richtlinien zur Durchführung der assistierten Reproduktion*" (Guidelines for assisted reproduction). Hormonal stimulation and egg cell retrieval are neither mentioned in the general definition of assisted reproduction as "medical help to fulfil a couple's wish to conceive by means of medical assistance and techniques" nor discussed under No. 4.1 ("Retrieval of gametes and transfer of gametes and embryos") of the guidelines.[330]

– There is no doubt that the procedures described are medical interventions performed on a woman's body which can only be justified if voluntary and informed consent has been given.

This is why from the patients' perspective and also from the medical-ethical point of view the success of IVF has to be defined as the baby take-home rate, i.e. the probability of a live birth after medical and pharmacological interventions performed on the woman's body. Together with information on medical risks and alternative treatment methods, this rate must provide the basis for the independent counselling of couples willing to undergo reproductive treatment before such treatment is initiated. [331]

1.2.6.4 Assessment of medical risks associated with reproductive procedures

The following aspects are important for assessing the IVF-related health hazards for women:

– The reason for treatment is the involuntary childlessness of the woman (the couple). It is doubtful, however, whether this condition can be classified as a disease and whether, as a result, the need for medical intervention can be inferred.

[330] *Bundesärztekammer* 1998b, A 3166.

– A large number of the women affected are older than 30 years, at least one third are 35 years and older. Because of the higher age alone, all these pregnancies are considered to carry a greater risk than in younger women; this applies in particular to women who are past their mid-thirties.

– The various interventions in a woman's physical integrity are not exclusively performed to overcome her own medically established fertility disorder. In more than half of the cases, these procedures are performed in order to treat a male fertility disorder or because no other explanation for the couple's childlessness could be found (idiopathic indication).

– This is why counselling and information of the woman is of the utmost importance. It is only when she is aware of all alternatives, risks and the documented probability of overcoming her childlessness that a woman is able to balance risks and benefits and take an informed decision.

1.2.6.5 Counselling for involuntary childlessness

There are many causes of involuntary childlessness. Apart from physical factors, psychological and social factors play a major role.

The individual plans of men and women for their lives and careers are also influencing factors, and so are social role models and facilities offering child care for (single) parents.

Statistically speaking, data on the social prevalence of involuntary childlessness are problematic. Statistical surveys usually refer to married couples. Changes in an individual's attitude towards having children and associated phases of voluntary childlessness further complicate an analysis.

Involuntarily childless couples seeking therapeutic help have to overcome a high individual threshold. For this reason it is necessary to design counselling schemes in such a way that these thresholds are lowered. Consequently, educating gynaecologists is just as important as educating the public. Counselling staff must be expected to be experienced in partner counselling and equally familiar with both the social and psychological factors underlying involuntary childlessness and the state of the art in reproductive research and practice.

A proper counselling concept should provide for independent counselling and a three-month waiting period for couples to think things over, because studies have shown that in this way

[331] Cf. Table 2 in C1.2.3.5.1.3 Risks during pregnancy, and C1.2.4.2.4.3 What is the success of assisted

psychological and sexual disorders could be identified, which resulted in a more clear-cut and targeted patient selection for IVF.

As counselling prior to treatment has a steering function, the allocation of resources can be improved. Such a concept for physiological, psychological and social counselling should be included in the range of benefits offered by statutory health insurers.

1.2.7 Recommendations and open issues

1.2.7.1 Recommendations

1.2.7.1.1 Legal regulation of assisted reproduction ("*Fortpflanzungsmedizingesetz*" [Reproductive Medicine Act])

The Study Commission recommends that the German Bundestag should adopt a law to regulate the application of assisted reproductive technologies in detail ("***Fortpflanzungs-medizingesetz***" [Reproductive Medicine Act])

This applies in particular to the following aspects:

(1) Documentation and quality assurance

a. Documentation of all IVF treatments by an IVF registry that is independent of any reproductive centres and is equipped with the necessary human and financial resources should be made obligatory.

   Commentary:

   - Regulation of the documentation and publication of assisted reproduction data is considered necessary, because it has been demonstrated that medical self-regulation is not sufficient. The obligation of all practising IVF teams to submit data should be enshrined in a law. Improving the database is considered an urgent necessity.
   - The documentation should contain prospective data reflecting the number of procedures and successes per woman treated and/or results per indication. It should also include a specification of success rates and comprise drop-out rates and a specified breakdown by centre of the number of interventions, IVF cycles and baby take-home rates.
   - To comply with the demand for transparency, the text of the publication should be drafted so that also non-experts can understand it without difficulty.

b. Documenting and reporting the cryopreservation of gametes, pronuclear-stage oocytes and embryos on an annual basis should be made obligatory. In addition to this registration, the centres should submit annual reports to the German IVF Registry; the data should be published accordingly.

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reproduction – and how often does it occur?

c. The documentation of counselling and treatment should be made obligatory and should be regulated.

d. Quality assurance, including the introduction of new procedures and methods (such as ICSI), should be regulated. The uncontrolled adoption of new techniques should be prevented, even if these techniques have already been successfully used abroad. Possibilities of managing future development through – possibly progressive – licensing (pilot projects, pilot centres, time limits) or research funding should be improved.

(2) Heterologous sperm donation

Civil law consequences arising from assisted reproduction and from heterologous sperm donation should be regulated, always giving precedence to the welfare of the child.

Commentary:

- The child's right to know its parentage has to be protected when providing for the anonymity of the sperm donor. Any action aiming to conceal the identity of the father (mixing of donor sperm) must be prevented.
- Law-makers will also have to decide whether or not unmarried and lesbian couples and single women should be given access to heterologous insemination.

(3) Use of pronuclear-stage oocytes

(a) The donation of pronuclear-stage oocytes should be explicitly excluded.

Commentary:

- The use of pronuclear-stage oocytes for research purposes should be explicitly banned. The use of pronuclear-stage oocytes for the purpose of embryo research would amount to the production of embryos for research purposes. This should by all means be prevented.

(b) The storage period of already existing frozen pronuclear-stage oocytes should be limited. At the same time, the fate of the pronuclear-stage oocytes after expiry of the storage period will have to be decided upon.

Commentary:

- Such regulations should make a clear distinction as to whether the genetic "parents" still want to have children or whether they no longer want to exercise their rights, e.g. because their partnership situation has changed or one of the two genetic "parents" has died.

(4) Use of so-called "supernumerary" embryos

Legislators will have to decide what to do with embryos and pronuclear-stage oocytes that were conceived in vitro to produce a pregnancy, but were not used and will not be used in the future for this purpose, for reasons which were not foreseeable and did not arise from the embryos themselves, but are solely connected with the genetic "parents". The term

"supernumerary embryos" is now widely used to describe these embryos. However, the Study Commission advises against the use of this term in legal texts. These embryos have to be preserved first in order keep open the possibility of a later transfer under the Embryo Protection Act.[332] The ban on embryonic research conducted for the benefit of third parties should be maintained, even if the embryos are "supernumerary".[333]

1.2.7.1.2 Need for research

The Study Commission recommends that the German Bundestag should intensify and/or extend research in the following areas:

(1) There is an urgent need to explore **alternatives to the development of cryopreserved pronuclear-stage oocytes** in order to avoid as far as possible the cryopreservation of pronuclear-stage oocytes, since it gives rise to problems similar to those involved in the cryopreservation of embryos and those of so-called "supernumerary" embryos.

Commentary:

- For example, methods should be explored to reduce hormonal stimulation and thus permit fewer egg cells to mature.
- Freezing "supernumerary" embryos would also be a possibility, provided developmental damage through cryopreservation can be minimised and the danger of commercialising the use of egg cells can be effectively averted.
- Gamete cryopreservation is a possible alternative to storing impregnated pronuclear-stage egg cells or embryos.
- Of course, the problem of so-called "supernumerary" embryos cannot be solved completely in this way, because there will always be individual cases where a woman decides against implantation or where transfer is no longer possible due to disease or other reasons. However, gamete cryopreservation would comply more than the present procedure with the legislators' objective to keep as close to the natural reproduction process as possible.

[332] For the use of so-called "supernumerary" embryos, embryo adoption and "letting embryos die", see *Enquete*-Kommission "Recht und Ethik der modernen Medizin" 2001b, Section 3.1.1.2, p. 42 ff.
[333] See *Enquete*-Kommission "Recht und Ethik der modernen Medizin" 2001b, Section 3.2, p. 54 ff.

(2) The study of **potential late sequellae of IVF/ICSI** should be continued.

Commentary:

– Long-term systematic monitoring of women and children should be introduced.

(3) Research into the **consequences of IVF/ICSI failure** for the couple concerned should be intensified.

Commentary:

– More studies should look into the issue of how couples cope when IVF/ICSI failed.

(4) **Conclusive animal studies** should precede research designed to improve existing ART methods and/or to develop new ones.

Commentary:

– It should be noted that too little research into the action and damage potentials of IVF and ICSI had been conducted before these methods were introduced. So far, standards analogous to those applied in pharmaceutical trials (animal experiments, trial phases I-IV) have not been established for assisted reproduction.

– Obligatory consultation of interdisciplinary ethics committees, 50 per cent of whose members should be female would ensure greater transparency of and more reflection in the research process.

(5) The Study Commission feels that it is necessary to develop quality assurance criteria (e.g. reduction of multiple pregnancy rates) and to implement them (e.g. obligatory licensing and reporting, long-term studies, pilot projects etc.).

(6) The Study Commission supports the Federal Government's initiative to introduce a **UN resolution for a ban on reproductive cloning under binding international law**. It feels that all possibilities should be exhausted to win multilateral support for such a resolution and to include the ban on "therapeutic" cloning and germ line interventions, especially against the backdrop of a growing acceptance of these procedures in the United States.

1.2.7.1.3 Discourse with citizens

The Study Commission recommends that the discourse with citizens should be intensified.

In the project "*Bürgerkonferenz Streitfall Gendiagnostik*" (Citizens' Conference on the Controversial Issue of Genetic Diagnosis) and its "*Bürgervotum zur Gendiagnostik*" (Citizens' Vote on Genetic Diagnosis), **citizens were engaged** in the discourse on ethical issues involved in prenatal diagnosis and preimplantation genetic diagnosis. This project was supported by the *Bundesministerium für Bildung und Forschung* (Federal Ministry of Education and Research) and the *Stifterverband für die Deutsche Wissenschaft* (Donors' Association for the Promotion of Sciences and Humanities in Germany). The Study Commission would welcome the Federal Government's support of similar activities to promote the discussion on future new ART procedures.

1.2.7.2 Open issues requiring further deliberation and clarification and – if necessary – action

The Study Commission would like to point out that during its deliberations issues were raised which could not be conclusively answered and for which recommendations cannot be submitted.

In the Study Commission's view there is a need for further deliberation and clarification and – if necessary- action in the following areas:

(1) To **review the requirements for performing assisted reproduction** pursuant to the provisions of the Social Security Code V, the following aspects were discussed in particular:

(a) **Introduction of psychosocial counselling** which
- is independent of centres performing assisted reproduction;
- provides information on risks, damage potentials and alternatives.

There is no doubt about the need to establish low-threshold counselling schemes that can meet the existing demand and to staff psychosocial counselling centres with adequately qualified, skilled counsellors. Such counselling schemes should be offered independent of the providers of assisted reproduction. Whether such counselling provided by a psychosocial counselling centre (and not by gynaecologists, as has been

the case so far) should be voluntary or whether it should be made a condition for access to assisted reproduction, appears to be an especially problematic question.

(b) **Criteria for cost reimbursement by SHIs**

The legal consequence of making IVF reimbursable by statutory health insurers was that childlessness was treated like a disease. Members did not agree on the question whether cost reimbursement by SHIs should be subject to more restrictive conditions, such as

- **more narrowly defined indications** (e.g. established organic infertility) or
- the **introduction of a waiting period** (as e.g. in the Netherlands: one year after registration) which might lead to women becoming spontaneously pregnant in the meantime (cf. results of early studies of spontaneous "waiting-list" pregnancies and of psychotherapeutic counselling which can boast success rates similar to those of IVF/ICSI[334]), or
- limiting the eligibility of certain methods for **reimbursement** or limiting the number of reimbursable treatment attempts.

The issue of the financial accessibility of reproductive techniques or the question of a possible limitation of SHI benefits should be discussed in detail. On the other hand, there is the concern that excluding IVF/ICSI from the range of SHI benefits could lead to a two-tier health care system.

(2) Two possibilities in particular were discussed that could contribute to **reducing the rate of multiple pregnancies after IVF**:

(a) Limiting the embryo transfer by law to two embryos.

(b) Establishing the suitability or damage potential of blastocyst cultures. Results obtained so far have shown that this technique is not yet mature, but its introduction might make it necessary to amend the Embryo Protection Act.[335] For this reason the scientific discussion should be monitored and evaluated with special diligence.

(3) The Commission discussed whether a federal authority should be established to **monitor IVF centres and laboratories and implement quality assurance measures**. This authority would be responsible for regulating and monitoring operating licences, licensing procedures, controls, documentation and certification and would also define standards,

[334] Hölzle *et al.* 2000, p. 149-172. Cf. Table 6: Success rates of IVF and psychological counselling.

[335] The Embryo Protection Act is affected as it stipulates that only as many embryos as can be transferred in one cycle should be produced, and bans the transfer of more than three embryos at a time. In the case of blastocyst culture, embryos are cultivated until they reach the blastocyst stage and then selected according to their developmental capacity. To this end, it might be necessary to produce more than three embryos which will increase the risk that embryos are frozen and would later have to be considered "supernumerary". Leaving the

organise round-robin tests and, if necessary, restrict certain techniques to special reference centres.

Specialists in reproductive medicine in particular are calling for such an authority.[336] This Commission strongly advocates more in-depth deliberations, not least in the light of different conceptual notions held by some of its members.

(4) Regarding **the admissibility of egg cell donation for non-reproductive purposes** the following aspects in particular were discussed:

(a) Egg cell donations specifically for non-reproductive purposes require invasive interventions for the benefit of third parties involving major health hazards for the women concerned which could be an argument against their admissibility.

(b) So-called "supernumerary" egg cells from IVF cycles should only be used for developing and improving egg cell cryopreservation and polar body diagnosis if certain requirements are met, e.g.

- voluntary and informed consent of the woman concerned;
- hormonal stimulation of oocyte maturation in keeping with the usual standard to preclude a higher detrimental hormone dose;
- exclusion of the commercial use of the egg cells.

The Commission felt that it could make sense to take these aspects into account when drafting future legislation and perhaps include them in a possible Reproductive Medicine Act.

(5) The Commission does not recommend a specific approach to **exploring different strategies of coping with involuntary childlessness**. In its view several approaches are possible apart from IVF:

(a) medical interventions (surgical interventions; naturopathic and environmental medicine procedures like detoxication, acupuncture, homoeopathy etc.);

(b) various psychotherapeutic counselling concepts;

(c) surveys of the "success rates" of "waiting" and believing in spontaneous pregnancy (e.g. by documenting pregnancies that arose within a waiting period which might have to be introduced before resorting to ART);

(d) accepting childlessness and developing other solutions such as adoption, foster care or other forms of social parenthood.

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embryo for the purpose of observation is - under the Embryo Protection Act – a doubtful approach. See also C1.2.3.1.4 Embryo culture.

[336] Cf. e.g. Beier 1996a und 2001; Felberbaum 2001; Kentenich 2001.

1.3 Experience gained with prenatal genetic diagnosis with regard to preimplantation genetic diagnosis

1.3.1 Definition of the subject for the Study Commission's **deliberations**

The Study Commission on Law and Ethics in Modern Medicine feels that the discussion about the in vitro genetic diagnosis of the embryo (preimplantation genetic diagnosis, PGD) would be incomplete if the development of the in-utero genetic diagnosis of the embryo (prenatal diagnosis, PND) were disregarded.

In 1970, PND was performed for the first time in Germany. Since then, it has not only developed into an integral part of prenatal care, but has changed the entire system of prenatal care as such. The result is

> "that today, regardless of her age, every woman receiving prenatal care services in a gynaecologist's practice is confronted with prenatal diagnosis."[337]

In medical practice the standards of informed consent (consent after having been informed about the characteristics tested, the power and validity of the test, its therapeutic gain, possible action to be taken if the test result is positive and the risk of iatrogenic injury) have to be complied with before a genetic test is performed in order to exclude any possibility of bodily injury. However, nevertheless this diagnosis has developed into a routine procedure that usually does not meet the requirements listed here.

In the light of their deliberations on preimplantation genetic diagnosis, the members of the Study Commission consider the following questions relating to prenatal diagnosis to be important:

– How could PND develop from a narrowly defined indication when it was known that the pregnant woman carried in increased genetic risk into a routine procedure performed to identify genetic risks in all pregnant women?

– What was the impact of the following factors on the extension of the indication:

  – historical development (DFG Priority Programme, political and professional policy decisions);

  – methods available (introduction, quality assurance);

[337] Kirchner-Asbrock 2000, p. 29. Cf. also Schumann 2001, p. 2: "(Almost) every pregnant woman today is confronted with the decision for/against PND!".

- factors like supply (availability) and demand, legal framework (liability law, reimbursement)?

– Is it possible to draw conclusions for preimplantation genetic diagnosis (PGD) from the experience gathered with PND?

Going beyond these issues, the Study Commission also dealt with prenatal genetic diagnosis in the chapter on "Genetic data".[338]

1.3.2 Definitions

Currently, medical care of pregnant women in Germany is pursuing three goals:

– to protect the expectant mother's health,

– to prevent any damage to the unborn child, and

– to identify infant malformations as early and as reliably as possible.

According to the "*Mutterschafts-Richtlinien*" (Maternal care guidelines) of the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers), the expectant mother – as part of prenatal care – should be informed about "possibilities of human genetic counselling and/or human genetic tests" if there are signs of a genetic risk.[339]

> "The aim of medical care during pregnancy and after delivery is to prevent possible risks that may jeopardise the life and health of mother and child and to identify and treat any health disorders as early as possible. The primary objective of prenatal medical care is the early detection of high-risk pregnancies and high-risk births."[340]

To achieve this end, physicians can use various methods of prenatal diagnosis, among other procedures.

1.3.2.1 Prenatal genetic diagnosis

Prenatal *genetic* diagnosis aims to identify numerical or structural chromosomal disorders or single-gene defects of the embryo/foetus.

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[338] Cf. especially C2.1.1.2.1.3 Prenatal tests, and C2.3.2.4 Information, education and counselling.

[339] *Bundesausschuss der Ärzte und Krankenkassen* 1998, Section A "*Untersuchungen und Beratungen sowie sonstige Maßnahmen während der Schwangerschaft*" (Examinations and consultations and other procedures to be performed during pregnancy), No. 3.

[340] *Bundesausschuss der Ärzte und Krankenkassen* 1998, "Allgemeines" (General issues), No. 1.

Numerical chromosomal disorders are e.g. trisomy or monosomy where a usually paired chromosome in the nucleus is present in triplicate or unpaired. *Structural* chromosomal defects are e.g. translocation or strand break phenomena which result in changes in the structure or function of a chromosome.

In terms of its objectives, prenatal genetic diagnosis is similar to the methods used in PGD. However, PND and PGD differ with regard to retrieval methods and the way in which specimens to be examined are processed in the laboratory:

– Procedures primarily used to retrieve foetal cells from the womb include amniocentesis[341] and chorionic villus sampling.[342] It is also possible to take a sample of foetal cord blood (cordocentesis) and samples of foetal tissue to determine the genetic status of the unborn child.

– The sampled material can be subjected to cytogenetic or molecular genetic tests and biochemical analyses.

– For details of procedures and techniques see the chapter on "Genetic data", section C2.1.1.2.1.3 Prenatal tests. The following gives a brief overview.

1.3.2.2 Diagnostic techniques

Prenatal diagnostic procedures in a wider sense that are used in prenatal care according to the "*Mutterschafts-Richtlinien*" (Maternal care guidelines)[343] can be divided into invasive and non-invasive procedures. Only invasive procedures permit prenatal genetic diagnosis.

1.3.2.2.1 Non-invasive techniques

Non-invasive procedures include the determination of biochemical markers in maternal blood (e.g. by means of the so-called triple marker test) and imaging ultrasound scans.

Ultrasound screenings permit an unspecific prenatal diagnosis which serves "to monitor a normal pregnancy".[344] Ultrasound screening allows the visualisation of the uterus, the amount of amniotic fluid and the placenta and thus the precise determination of gestational age, the number of foetuses and their physical development and the detection of indications of

[341] Amniocentesis (AC).
[342] Chorionic villus sampling (CVS).
[343] See C1.3.3.4.2.1 Maternal care guidelines.
[344] *Bundesausschuss der Ärzte und Krankenkassen* 1998, Section A "*Untersuchungen und Beratungen sowie sonstige Maßnahmen während der Schwangerschaft*" (Examinations and consultations and other procedures to be performed during pregnancy), No. 5.

possible developmental disorders. Before 1995, prenatal care schemes routinely provided for two ultrasound screenings (between the 16th and 22nd week and between the 32nd and 34th week of pregnancy); this has now been increased to three screenings[345]: the first screening between the beginning of week 9 and the end of week 12, the second screening between the beginning of week 19 and the end of week 22 and the third screening between the beginning of week 29 and the end of week 32.

The diagnostic accuracy of imaging ultrasound scans depends on the equipment used and the training and experience of the physician performing the scan. Risks for mother or foetus have not been documented.[346]

Although non-invasive procedures can provide indications of single or multiple foetal malformations, they do not allow a diagnosis of genetic predispositions. When non-invasive diagnostic procedures provide indications of malformations, invasive procedures are mostly used to obtain more detailed information.

1.3.2.2.2 Invasive techniques

Genetic predispositions of the child can only be determined during pregnancy by means of invasive techniques such as amniocentesis, chorionic villus sampling and placental biopsy. Other diagnostic procedures include cord blood sampling and embryoscopy or fetoscopy. Foetal cells obtained with these procedures can be subjected to molecular genetic tests and examined for chromosomal aberrations and monogenic defects. The number of diagnosable predispositions to diseases is rising. While in 1992 the "Catalog of Prenatally Diagnosed Conditions" listed about 600 diagnosable predispositions[347], this number had increased to as many as about 800 in 1999.

In order to obtain the tissue samples from the embryo/foetus or the chorion/placenta that are needed for molecular genetic analysis, it is necessary to intervene in the bodily integrity of the pregnant woman, which is why such procedures are described as "invasive".

These procedures always carry a risk for the health of the mother and the unborn child and hence the danger of precipitating a miscarriage.

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[345] Parameters to be checked in the various ultrasound screenings are listed in Annex 1 to the Maternal care guidelines.
[346] Cf. Nippert 1999, p. 66.
[347] Nippert/Horst 1994, p. 1.

Chorionic villus sampling (CVS – obtaining tissue from the outer membrane surrounding the embryo), which is carried out under ultrasound visualisation between the 7th and 10th week of gestation at the earliest, usually between the 11th and 12th week, entails a risk of loss of pregnancy of 2 to 4 percent if sampling is carried out through the cervix (transcervical sampling). The risk for transabdominal sampling (access through the abdominal wall) is between 1 and 2 per cent.[348] The diagnostic accuracy of the procedure is 97.5 to 99.6 per cent, and there is a 1.9 to 3.8 per cent risk of contamination of the sample with maternal cells.[349]

Transabdominal amniocentesis[350] is mostly performed between week 15 and week 17 to puncture the amniotic sac, also under ultrasound visualisation, and to obtain 15 to 20 ml of amniotic fluid containing about 2 per cent of living foetal cells. For amniocentesis, the risk of losing the pregnancy is about 0.5 to 1 per cent, i.e. clearly below the risk involved in CVS. Diagnostic accuracy is 99.4 to 99.8 per cent, the risk of sample contamination with maternal cells 0.3 to 0.5 per cent.[351]

The sample material so obtained can be examined - either immediately or after multiplication in a cell culture and DNA isolation – for (mono)genetic or chromosomal anomalies or subjected to enzymatic studies.

The methods available for these tests are basically identical with those used for PGD.[352] The results of DNA or chromosomal analysis are usually available within two or three weeks (due to cultivation in a tissue culture prior to testing).[353]

1.3.3 Development of prenatal genetic diagnosis

As prenatal diagnosis is being more and more widely used, the public discussion about the potential of PND of creating a feeling of uncertainty in pregnant women and of selecting foetuses with genetic anomalies is becoming more heated.

> "With PND, the intentions and consequences of genetic diagnosis/testing cross the line between medical prevention and selection. This is not about preventing a disease, rather the carrier of a disease himself is not permitted to live."[354]

[348] All risk data quoted here were taken from Schroeder-Kurth 2000, p. 47. Cf. also Schmidtke 1997, p. 109ff.
[349] Nippert 1999, p. 67.
[350] Early amniocentesis is performed already between week 12 and week 14.
[351] Nippert 1999, p. 67.
[352] See C1.4.1.1.2 Single-cell diagnosis.
[353] In a so-called short-term culture a "preliminary" result is already available after one to three days, after cordocentesis it is available on day 5 at the latest. (cf. *Bundesärztekammer* 1998b).
[354] Nippert 2000, p. 130.

Originally PND was meant to be available to women with a high genetic risk only. At first, this definition only covered primary chromosomal disorders and was later extended to include neural tube defects.

Since PND entailed difficult ethical and – as Sections 218 ff. of the Criminal Code had not yet been amended in the early 1970s – legal consequences, its use was originally only permitted under the following conditions:[355]

- Medical indication (identifiable higher genetic risk; age limit for trisomy 21 38 years and older);
- introduction of the triad consisting of counselling, PND, counselling;
- guarantee of voluntary use of PND.[356]

PND was not intended to develop into a routine examination in prenatal care and should be embedded in an adequate counselling infrastructure. For this reason state governments and statutory health insurers funded the development of centres for human genetic counselling mostly in university medical institutions.

[355] For more details see Nippert 2001, p. 293f.

[356] "The assumption was and still is that informed consent can only be given if prior to the intervention the pregnant woman has received all relevant information enabling her to assess and evaluate the possibilities, limitations, risks and options for action involved in PND and to decide for or against using PND in the light of her own standards and values." (Nippert 2001c, p. 294).

Table 8: Important Events in the Process of Establishing and Spreading PND in the Federal Republic of Germany

1970	Amniocentesis performed as first invasive procedure in Germany[357]
1972	DFG priority programme on "Prenatal diagnosis of genetic defects" (Seven-year research programme involving 90 institutes which performed a total of 13,000 amniocenteses)[358]
1976	Inclusion of PND in the range of SHI benefits
1976	Reform of Sec. 218 of the Criminal Code (termination of pregnancy permissible pursuant to Sec. 218a(2) No. 1 of the Criminal Code, if "cogent reasons support the assumption that the child…would suffer irreparable damage to its *health which would be so severe that the mother cannot reasonably be expected* to continue the pregnancy.")
1975-1979	Establishment and expansion of centres for human genetic counselling and cytogenetic laboratories in several West German states
1979	Two ultrasound screenings included in the range of SHI benefits
1984	Federal Court of Justice decision on medical liability for children born in breach of contract
1984/1985	Introduction of chorionic villus sampling[359]
1987/1998	German Medical Association recommendations or guideline for the prenatal diagnosis of diseases and predispositions to diseases
1992	Introduction of triple marker test

1.3.3.1 Establishment of care and process structures

1.3.3.1.1 DFG priority programme on "Prenatal diagnosis of genetic defects"

In 1970, "a small group of gynaecologists, cytogeneticists and medical human geneticists working in university institutions"[360] had carried out the first experiments, using prenatal diagnosis on shed foetal cells recovered from amniotic fluid.

[357] Nippert/Horst 1994, p. 1.
[358] Nippert/Horst 1994, p. 2.
[359] Nippert 2000, p. 135.
[360] Nippert 2000, p. 134.

The crucial factor for the development of a care structure and for the training and qualification of diagnostic staff was the funding of clinical amniocentesis trials under a priority programme on "Prenatal diagnosis of genetic defects" that the *Deutsche Forschungsgemeinschaft* (DFG) had launched in 1972 and that extended over almost seven years.

> "Under this programme the procedures used, the associated risks, e.g. miscarriages, the diagnoses and their reliability, the decisions taken after diagnosis etc. were documented and evaluated. At the same time, this programme financed training and qualification schemes for the providers of PND services and funded the staff needed to provide these services."[361]

A total of more than 90 institutes and hospitals participated in this programme. In the end, more than 100 physicians and scientists had been trained in performing amniocentesis and the cytogenetic study of foetal cells, and more than 13,000 amniocenteses had been performed.[362]

1.3.3.1.2 Inclusion of prenatal diagnosis in the range of benefits provided by statutory health insurers

In 1976, PND was included in the range of benefits provided by statutory health insurers (SHIs). As a result, PND could be carried out as part of general prenatal care and was reimbursed by SHIs.[363]

In the first few years after SHIs had agreed to pay for PND, cost-benefit analyses were carried out from the health economics point of view. In their work on "*Genetische Pränataldiagnostik als Aufgabe der Präventivmedizin*" (Prenatal genetic diagnosis as a task of preventive medicine), which received the Hufeland Award in 1977, Passarge and Rüdiger state in the conclusions of the "Cost-benefit analysis for the partial prevention of Down syndrome":

> "Nation-wide primary prenatal diagnosis performed on all mothers older than 38 years would cost only about 1/4 of the funding required for the care of trisomy 21 children. In absolute terms, the cost of the care of these children of about 61.6 million compare with the cost of their prevention of about 13.5 million."[364]

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[361] Nippert 2001c, p. 293.
[362] Nippert/Horst 1994, p. 2.
[363] On medical prenatal care see also C1.3.3.4.2.1 *Mutterschaftsrichtlinien* (Maternal care guidelines), and C1.3.3.4.6 The German Medical Association's 1998 *Richtlinien zur pränatalen Diagnostik von Krankheiten und Krankheitsdispositionen* (Guidelines for the prenatal diagnosis of diseases and predispositions to diseases).
[364] Passarge/Rüdiger 1979, p. 23.

Another study which won the health economics award of the Federal Minister of Labour and Social Affairs in 1981 looked into "*Probleme der Erfolgskontrolle präventivmedizinischer Programme – dargestellt am Beispiel einer Effektivitäts- und Effizienzanalyse genetischer Beratung*" (Problems of success control of preventive medical programmes – based on the example of an effectiveness and efficiency analysis of genetic counselling).[365]

1.3.3.1.3 The 1976 reform of Sec. 218 ff. of the German Criminal Code

The amended Sec. 218a(2) No. 1 permitted a termination of pregnancy if "cogent reasons support the assumption that the child … would suffer irreparable damage to its health which would be so severe that the mother cannot reasonably be expected to continue the pregnancy".[366]

This had an impact on the use of PND because when genetic anomalies had been diagnosed, almost the only interventional option available was the termination of the pregnancy. So far this situation has not changed fundamentally:

> "There are still only few possibilities of intrauterine therapy, pharmacotherapy is possible via the mother. An invasive procedure that has become possible is blood replacement in the case of foetal erythroblastosis. The outcome of attempts to operate on urinary tract obstructions or hydrocephalus was not convincing."[367]

The 1995 *Schwangeren- und Familienhilfeänderungsgesetz* (Pregnancy and Family Assistance Amending Act) lead to the deletion of Sec. 218a(2) No. 1, the so-called embryopathic indication, from the 1976 of the Criminal Code. According to the reasons given for the Amending Act, this indication was to be covered by the newly worded medical

[365] Von Stackelberg 1980.

[366] Before Sec. 218a Criminal Code had been amended, killing a foetus inside the womb was a punishable offence in the former Federal Republic of Germany under Sec. 218 of the Criminal Code. However, following a decision of the *Reichsgericht* (Supreme Court of the German Reich) in 1927, in the case of a so-called medical indication law courts recognised necessity as a justification of an unlawful act according to the principles of weighing duties and interests. Accordingly, the act was no longer unlawful if there was a serious danger to the life or health of the pregnant woman which could not otherwise be averted, provided the intervention was performed *lege artis* by a physician with the consent of the pregnant woman. These requirements for the termination of pregnancy for medical reasons were legally established in Sec. 14(1) of the *Gesetz zur Verhütung erbkranken Nachwuchses* (Prevention of Offspring with Hereditary Diseases Act) of 25 July 1933 as amended on 26 July 1935. After 1945 this provision continued to exist in some German states. In other states which had abolished the Act because of its Nazi character, the requirements listed therein had to be complied with – according to a decision by the *Bundesgerichtshof* (Federal Court of Justice) of 15 January 1952 (BGHSt 2, p. 111) – as they constituted the minimum requirements for the permissibility of a termination of pregnancy according to the principle of necessity as justification of an unlawful act.

[367] *Bundesärztekammer* 2000b.

indication under Sec. 218a(2) of the Criminal Code.[368] Consequently, this also obviated the need for a 22-week time limit which had been defined as prerequisite to exempting from punishment the termination of pregnancy by a physician. It seems, however, as if the amendment of the criminal law provisions did not have a restrictive effect on the practice of pregnancy termination.[369]

1.3.3.1.4 Establishment and expansion of genetic counselling centres by state-level governments

Between 1975 and 1979, seven state governments undertook to expand the centres of human genetic counselling and cytogenetic laboratories, mostly at universities, with the result that the infrastructure built by the DFG could continue to exist, for this could not have been guaranteed by independent office-based physicians.

In 1994, there were 84 institutions in Germany offering genetic counselling services and/or laboratory diagnostic services. In the western part of the country, there were 27 university institutes specialising in human genetics which offered both genetic counselling services and laboratory tests. Then there were at least eight other institutes in public health departments or urban hospitals and more than 30 physicians in private practice or private laboratories also offering prenatal diagnostic services.[370]

At the same time, there were a total of 19 institutions in the former East German states which offered genetic counselling and cytogenetic diagnostic services. Nine institutes were co-located with universities.[371]

In 1997, there were 106 institutions, 45 at universities, hospitals or public health departments and 61 physicians in private practice or private laboratories that offered genetic counselling services and/or prenatal diagnostic services and/or cytogenetic tests.[372]

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[368] Sec. 218a(2) in the version of 1 October 1995 reads: "A termination of pregnancy carried out by a physician with the consent of the pregnant woman shall not be unlawful, if in the light of medical knowledge and considering the current und future living conditions of the pregnant woman the termination of pregnancy is indicated to avert a danger to the life, or risk of a serious impairment of the physical or mental health, of the pregnant woman, and if this danger cannot be averted in any other way that would be acceptable to the pregnant woman."

[369] Although it says in the arguments supporting the amended Act (recommended resolution and 1995 report of the Committee on Family Affairs, Senior Citizens, Women and Youth, on Sec. 218a (2) (3), p.26) "that a disability can never lessen the obligation to protect of human life". On criticism of the 1995 amended Act cf. Beckmann 1998a, p. 155ff.

[370] Nippert/Horst 1994, p. 7.

[371] Nippert/Horst 1994, p. 143.

[372] Cf. Schmidtke 1997, p. 327ff, List of genetic counselling centres in Germany.

1.3.3.2 Conceptual considerations governing the introduction and development of prenatal diagnosis

> "The early infrastructure was primarily characterised by the integration of prenatal diagnosis into interdisciplinary university institutes and the linking of PND with in-depth genetic counselling before diagnosis and in-depth counselling after positive findings had been established."[373]

Gynaecologists and human geneticists agreed that the new possibilities opened up by chromosomal diagnosis should be included in prenatal examinations. At first, this applied in particular to identifying foetuses showing signs of trisomy 21.[374] Compared with other chromosomal disorders, trisomy 21 is observed quite frequently and the at-risk group can be easily identified.

As PND developed, the application of diagnostic possibilities was extended to other numerical and also structural chromosomal disorders.[375]

1.3.3.3 Extension of indications for prenatal diagnosis

Early medical indications for PND established a correlation between the intervention-induced risk[376] (miscarriage, infection of the mother) and the risk of expecting an affected child.

Indications themselves were subject to continuous development. Compared with the beginnings of PND in the early 1970s, the following indications existed as early as in the first half of the 1990s[377]:

– increased risk of infantile chromosomal disorders when maternal age is higher, when there is a previous child with a chromosomal disorder or when there is a familial chromosomal disorder (age-related risk);

– increased risk of X-linked hereditary diseases;

– increased risk of neural tube defects (with amniocentesis);

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[373] Nippert/Horst 1994, p. 3.

[374] According to Nippert/Horst 1994 and. Nippert 2001, the reason given was that trisomy 21, a numerical chromosomal disorder where chromosome 21 is present in triplicate, occurred relatively frequently, that the risk was dependent on maternal age and that it was a serious irremediable disability of the child. It was also argued that the at-risk group in question (38 years and older) could be easily identified. Cf. Nippert 2001, p. 294.

[375] Structural chromosomal aberrations are missing or extra chromosomal segments as a result of strand breaks, translocations etc.

[376] Cf. C1.3.2.2.2 Invasive techniques.

[377] Nippert/Horst 1994, pp. 3 f. In this context, the authors refer to the development of a "list of indications" which in 1994 "defines (…) the applications of invasive PND" mentioned in the text. It remains open, however, who established this definition.

– increased risk of identifiable metabolic disorders, haemoglobinopathies or other identifiable monogenic diseases.

A particularly remarkable fact is that the age limit of 38 years[378] for the risk of chromosomal disorders which was defined when PND was established, was abolished by the German Medical Association's Scientific Board in its "*Empfehlungen zur pränatalen Diagnostik*" (Recommendations for prenatal diagnosis) and lowered to 35 years.[379]

The revised update of the 1987 recommendations, the currently valid "*Richtlinien der Bundesärztekammer zur pränatalen Diagnostik von Krankheiten und Krankheits-dispositionen*" (1998 Guidelines of the German Medical Association for the prenatal diagnosis of diseases and predispositions to diseases) also abolishes the 35-year age limit:

> "The strict observance of a lower limit for maternal age as a defined medical indication for invasive prenatal diagnosis which was based on the mothers' age-related risk of infantile chromosomal anomalies has been abandoned today."[380]

In fact, undermining the age-related indication for PND results from a development that began in the 1980s, when by way of a so-called "psychological indication" PND was made available to women who were younger than 35 years and did not have an identifiable increased risk of infantile chromosomal disorders.[381]

Thus age as a yardstick for indication tended to be replaced by the determination of specific risks.

Today, indications can be broken down as follows[382]:

age-related indication (women aged 35 and older)	78 per cent;
psychological[383] indication (fear of giving birth to a disabled child)	18 per cent;
abnormal ultrasound findings or triple marker test results	4 per cent.

It is estimated that about 3 per cent of all indications are based on an identified "familial risk". In about 2 per cent of all cases, PND is indicated because there already is a child with a chromosomal anomaly in the family. [384]

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[378] Cf. Nippert 2001, p. 294.
[379] *Bundesärztekammer* 1987.
[380] *Bundesärztekammer* 1998c.
[381] In this context Nippert/Horst 1994 make reference to an intensive discussion among human geneticists (p. 4).
[382] Kirchner-Asbrock, 2001, p. 1f.
[383] Another term used in the literature is "*psychisch*" (mental).
[384] Hennen *et al.* 2001, p. 72. Consequently, about 5 per cent of all PND procedures are carried out as a result of a so-called "high-risk" parental situation.

Table 9: Use of Invasive PND in the Federal Republic of Germany

Year	Number of PND procedures carried out
1970	6 Amniocenteses
1971	16 Amniocenteses
1972	49 Amniocenteses
1973	112 Amniocenteses
1974	308 Amniocenteses
1975	893 Amniocenteses
1976	1,796 Amniocenteses
1977	2,648 Amniocenteses
1987	33,535 Amniocenteses and 3,100 chorionic villus samplings
1995	61,794 Amniocenteses / chorionic villus samplings (former East German states)

Source: Nippert 2001, p. 135, and Nippert/Horst 1994, p. 2

1.3.3.4 Other factors underlying the development of prenatal diagnosis into a routine procedure to identify genetic risks in all pregnant women

PND originated in specialised interdisciplinary university institutes and gradually spread to general gynaecological practice.

There are various factors which are responsible for the increase in the use of PND in prenatal care; these factors will be discussed in the following.

On the one hand, there are factors that boost supply and on the other hand, there are events which have an impact on the demand by women; in the latter case, a distinction should be made between primary demand and supply-induced demand.

1.3.3.4.1 The 1983 decision of the *Bundesgerichtshof* (Federal Court of Justice) on medical liability

A decision handed down by the *Bundesgerichtshof* (BGH –Federal Court of Justice) in 1983 turned out to be a crucial signal for the extension of PND. According to this decision, a physician commits a breach of duty if he fails to inform a woman with a high-risk pregnancy of the possibility of having an amniocentesis to preclude the risk of trisomy 21.

In its decision, the German Federal Court of Justice states:

> "1. Wrong or incomplete information and education of the mother during pregnancy regarding possibilities of early detection of foetal damage, which might have justified the mother's wish to terminate the pregnancy, can also substantiate the parents' claim against the physician to reimburse the cost of maintenance of a child born with physical or mental disabilities.
>
> 2. The burden to prove that, after detailed and correct information, the mother would not have opted for a prenatal examination of the foetus for possible damage and, in case of unfavourable findings, would not have decided in favour of a termination, shall lie with the physician.
>
> 3. The physician shall reimburse the total cost of maintenance of the injured child; however, the claim for compensation shall not be valid, if the risk of an irremediable, serious damage to the child which according to the principles of criminal law would have allowed the mother to terminate her pregnancy did not materialise."[385]

The woman concerned had already given birth to two healthy children when, almost 39 years old, she became pregnant with her third child in 1977. In the 14th week of gestation she asked her attending specialist "whether in view of her age she might run the risk of giving birth to a mongoloid child and whether for this reason a test of the amniotic fluid (amniocentesis) might not be indicated. Referring to her two healthy children and possibly also to the absence of any hereditary diseases, the defendant [physician] answered that he did not (or 'not necessarily') see any need for that. After that, the parties did not take up this point again."[386]

The woman was awarded damages. Gynaecologists responded to this decision by informing patients more often of the possibilities of PND without considering existing indications and by asking patients to confirm in writing that they had received this information.

[385] German Federal Court of Justice, decision of 22 November 1983, BGHZ 89, pp. 95-107.
[386] BGHZ 89, p. 95ff. For more court rulings on liability law and prenatal diagnosis, see Franzki 1999.

> "During the period in which the proceedings passed through the stages of appeal and after the decision had been handed down, the number of PND procedures performed doubled. In this way invasive PND was offered by physicians as a defensive service to prevent claims for damages arising from the birth of a child with trisomy 21."[387]

With the decision outlined above, adjudication by the highest courts on so-called wrongful birth under a medical consulting or treatment contract began. The consequences of this ruling, especially the associated violation of fundamental rights (in this case the right to protection against discrimination and the child's right to live (Article 3(3) sentence 2 and Article 2(2) of the German Constitution) triggered a fundamental review of the situation by the legislator (cf. C1.3.3.5 Wrongful birth).

1.3.3.4.2 Payment of prenatal diagnosis by statutory health insurers

In 1975, prenatal diagnosis was included in the range of services and benefits provided by statutory health insurers. One year later, 1,796 prenatal genetic diagnostic procedures were performed, and subsequently PND figures in West Germany rose continuously to 36,000 (1986), 40,000 (1991) and 60,000 (1995).[388]

In 1986, SHIs stepped up their payment for diagnostic laboratory tests after amniocentesis so that amniocentesis performed in a gynaecological practice combined with subsequent analysis in independent laboratories became financially more attractive. Between 1991 and 1995 alone, the cost of procedures performed rose by 44.4 per cent to reach a total of DM 32.7 million. In 1991, only 56 per cent of all services were provided by independent physicians, while by 1995 the figure had risen to 71.8 per cent. As more and services were provided by self-employed physicians, the range of services offered widened. Thus services were steadily moved out of university institutions and into the offices of independent physicians.[389]

[387] Nippert 2001c, p. 295.
[388] For figures, cf. Nippert 2001c, pp. 294 and 305.
[389] Cf. Nippert 2000, p. 135.

**Table 10: Number of prescriptions of selected prenatal diagnostic services.
Item 112: Amniocentesis. Prescriptions by SHI-accredited physicians, 1990-1998,
(former) West and East German states,
primary health insurers and secondary insurance funds**

Year	Primary SHI West	Secondary funds West	Total West	Primary SHI East	Secondary funds East	Total East	Total West +East
Item 112: Amniocentesis							
1990	12,593	15,505	28,098				28,098
1991	14,009	18,076	32,085				32,085
1992	15,550	21,103	36,653				36,653
1993	17,627	24,624	42,251				42,251
1994	18,449	27,734	46,183				46,183
1995	19,951	29,845	49,796				49,796
1996	22,121	32,318	54,439	1,773	1,974	3,747	58,186
1997	23,555	34,695	58,250	2,053	2,364	4,417	62,667
1998	24,286	33,825	58,111	1,964	2,344	4,308	62,641

Source: Feuerstein et al. (in the process of being published), p. 46

According to Feuerstein[390], 49.6 chromosomal tests per 1,000 live births were carried out in 1990 after amniocentesis or chorionic villus sampling, in 1993 the figure was 78.8 and in 1996 85.7. In 1998, this figure rose to 95.7, which means that within ten years the use of prenatal diagnostic procedures had almost doubled so that in 1998 in virtually every tenth pregnancy the foetus was subjected to invasive diagnosis. Related to the total of 785,034 live births in 1998, 75,255 foetal chromosomal analyses were performed.

PND as an integral part of medical prenatal care services

In the Federal Republic of Germany, a definitive list of medical prenatal care services developed step by step after an amendment to the *Reichsversicherungsordnung* (RVO – Reich Insurance Code) in 1965 had established a pregnant woman's legal claim to medical care during pregnancy and after delivery. Since 1966, the *Mutterschutzgesetz* (Maternity Protection Act) and the fact that prenatal care had been enshrined in Volume V of the *Sozialgesetzbuch* (SGB - Social Security Code V) had contributed to improving prenatal care. The *Mutterschafts-Richtlinien* (Maternal Care Guidelines), which the Federal Committee of Physicians and Health Insurers first developed in 1966, form the basis of the *Mutterpass* (pregnancy passport), which has been issued since 1968 to every woman, once her pregnancy had been medically established.

[390] On the figure cited see Feuerstein *et al.* (being published), p. 49.

Table 11: Reimbursable Prenatal Diagnostic Services (Uniform Assessment Standard 1999)

Medical fee schedule, Item	**Section/Service**	**Score** (July 1999)
Basic services, prevention: prenatal care		
112	Amniotic fluid sampling by amniocentesis, ultrasound-guided	600
115	Chromosomal analysis of amniotic cells or chorionic villi, including analysis of at least two cultures and evaluation of at least one culture. The service under item 115 is billable only once per material sampled.	8,000
121	Transcervical sampling of chorionic villus tissue or transabdominal sampling of placental tissue, under ultrasound visualisation.	1,000

Source: Feuerstein et al. (in the process of being published), p. 46

1.3.3.4.2.1 Maternal Care Guidelines

The amendment of 23 October 1998 to the so-called Maternal Care Guidelines (*Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung* – Guidelines developed by the Federal Committee of Physicians and Health Insurers for medical care during pregnancy and after delivery), which were first issued in 1966[391], has been valid since 27 January 1999.

These guidelines are meant to "ensure medical care of the insured woman during pregnancy and after delivery which, according to the rules of the medical profession and the generally recognised state of medical art, should be adequate, efficient and cost-effective".[392]

Prenatal care as laid down in the maternal care guidelines comprises the following:

[391] Pursuant to Sec. 92(1) sentence 2 No. 4 SGB V to be read in conjunction with Sec. 196 RVO (Reich Insurance Code) and Sec. 23 KVLG (Farmers' Health Insurance Act).
[392] *Bundesausschuss der Ärzte und Krankenkassen* 1998, Preliminary remark.

– Examinations and consultations during pregnancy;

– early diagnosis and special monitoring of high-risk pregnancies;

– high-risk pregnancies are pregnancies which involve an increased risk for the mother and/or the child.[393] Risk factors include familial reasons[394], personal reasons[395] and the course of pregnancy and/or the time of birth.

– in the case of high-risk pregnancies, regular examinations may be necessary at shorter intervals and additional examinations may be indicated. These include specific ultrasound scans, amnioscopy, amniotic fluid analysis after amniocentesis, chorionic villus sampling, recording labour activity (tocography) and the baby's heart rate during birth (cardiotocography);

– serological tests (i.e. determination of specific antibody levels in the serum) for infection;

– blood group serology tests after birth or miscarriage and anti-IgD prophylaxis;

– examinations of and providing advice to the new mother,

– medication and prescription of bandaging material and remedies;

– records, notes and certificates.

Three ultrasound screenings are obligatory prenatal care services to be provided for all pregnant women. They are not based on a particular indication. All additional sonographic examinations as well as amniocentesis and chorionic villus sampling depend on a specific indication (after a high-risk pregnancy has been diagnosed).

If such an ultrasound scan is considered to be already an integral part of or the lead-in procedure to PND, the billing modalities of physicians and SHIs could conflict with the interests of the pregnant woman: Since all three screenings have to be charged as a lump sum[396], the pregnant woman's freedom of decision which also extends to the application of

[393] Cf. the definition in *Bundesausschuss der Ärzte und Krankenkassen* 1998.
[394] These include diseases, genetic risks, risk of infection.
[395] These include e.g. the mother's age (younger than 18, older than 35 years), risk of infection, genetic risks, complications during previous pregnancies, habits such as alcohol consumption, smoking, use of other drugs.
[396] Pursuant to Sec. 87(1) SGB V, the so-called *Einheitlicher Bewertungsmaßstab* (EBM – uniform assessment standard) of the *Kassenärztliche Bundesvereinigung* (National Association of Health Insurance Physicians) provides the binding basis for charging statutory health insurers for medical services. According to the EBM, version of 1 October 2001, Chapter B IX No. 1 (Chapter B IX: "Prevention according to the guidelines of the Federal Committee of Physicians and Health Insurers" Item 1 "Prenatal health care services for pregnant women"), the following services are paid for under Item 100: "Provision of prenatal health care services according to the guidelines of the Federal Committee of Physicians and Health Insurers for medical care during pregnancy, including ultrasound monitoring with imaging documentation plus documentation in case of treatment. Pregnancy counselling and examinations to be carried out according to the maternal care guidelines are paid for on a quarterly basis when billing item 100. (...)" (http://www.kbv.de/publikationen/764.htm) (as of 27 March 2002) Cf. oral communication of Dr. Claudia Schumann at the non-public hearing on 18 June 2001: "If a pregnant woman refuses to have ultrasound scans, the SHI-accredited physician must not bill item 100, the lump sum for prenatal care, because the pertinent service was not provided in full."

the maternal care guidelines and permits her to decide which medical services she wants to use and which she wants to refuse[397], is in fact considerably restricted.

For if not all services provided for in the maternal care guidelines have been rendered, e.g. because the pregnant woman refused an ultrasound scan, the attending physician can only charge the remaining individual items, which is usually financially less favourable for the physician. In practice this situation causes considerable uncertainty as to the rights and duties of both the physician and the pregnant woman under the maternal care guidelines and the associated billing rules. A clarification incorporated in the maternal care guidelines themselves could remedy this situation.

1.3.3.4.2.2 Pregnancy passport

In 1968, the "pregnancy passport" was introduced in the Federal Republic of Germany and has since been amended several times.[398] This passport is a nation-wide standardised twelve-page document which is issued after a pregnancy has been established and in which all information gained during medical prenatal care is documented as laid down in the maternal care guidelines outlined above.

Apart from the various documented examination and test results, the pregnancy passport does not contain any easily comprehensible information on prenatal care in general or PND in particular.

For the expectant mother the pregnancy passport is largely useless as a medium of information. It does not explain the various examinations and abbreviations used nor does it indicate the possibility of consulting a midwife for prenatal care (and having the SHI pay for it) or the different kinds of counselling available.

1.3.3.4.3 1987 Recommendations of the German Medical Association

In 1987[399], eleven years after PND had been established as a service to be provided by SHI-accredited physicians, the Scientific Board of the *Bundesärztekammer* (BÄK – German Medical Association) published the first so-called "*Empfehlungen zur pränatalen Diagnostik*" (Recommendations for prenatal diagnosis)[400], which explicitly provided for a triad approach

[397] See the expert opinion by Francke/Regenbogen 2001 commissioned by the *Netzwerk gegen Selektion durch Pränataldiagnostik* (Network against selection through prenatal diagnosis).
[398] For the 1996 revised edition, see *Kassenärztliche Bundesvereinigung* 1996.
[399] In 1987, more than 33,000 amniocenteses and over 3,000 chorionic villus sampling procedures were carried out in West Germany
[400] *Bundesärztekammer 1987*.

consisting of counselling prior to PND, the performance of PND as such and counselling after PND and "which at the time focused on diagnosing chromosomal aberrations, congenital metabolic disorders and neural tube defects"[401]. The age limit given was 35 years.

Although many people had again and again called for a nexus of counselling before and after PND[402], the gap widened between PND services offered and performed by an increasing number of independent gynaecologists in collaboration with private laboratories on the one hand, and previous counselling on the other. This development which was "solely to the detriment of pregnant women"[403] is reflected in the fact that the number of PND procedures carried out in West Germany between 1991 and 1995 rose from 40,000 to 60,000, while over the same period the number of genetic counselling sessions increased only from 17,000 to 21,000.[404]

1.3.3.4.4 Greater demand by pregnant women: The "psychological indication"

In the early 1980s, it was mostly educated upper-class and upper-middle-class women, usually well-informed about the availability of PND, who availed themselves of prenatal diagnosis.

As a result of the pressing demand, especially by younger women from these social strata, the so-called psychological indication emerged at that time which blurred the existing limit of the age-related indication. The psychological indication was always resorted to in those cases where the pregnant woman insisted on a test even though an increased risk of infantile chromosomal aberration that would have justified the risk of invasive PND could not be identified.

> "Until the triple marker test was introduced in 1992, the 'psychological indication' held an unchallenged second place among the indications for PND. 10 to 15 per cent of all PND services were provided as a result of this demand. (...) Adapting the indication for PND to demand in a certain sense undermined the concept of medical indication which focused on the size of the risk involved."[405]

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[401] *Bundesärztekammer 2000b*.
[402] In addition to the German Medical Association, e.g. the Study Commission on Prospects and Risks of Gene Technology of the German Bundestag in 1987, *Berufsverband Medizinische Genetik* (Association of Medical Geneticists) in 1990, the working group on genome analysis of the Federal and state governments in the same year and the *Bundesminister für Forschung und Technologie* (Federal Minister of Research and Technology) in 1991. Cf. Nippert/Horst 1994, pp. 5 f.
[403] Nippert/Horst 1994, p. 6.
[404] For figures cf. Nippert 2001c, pp. 294 and 305.

Compared with other European countries (France, UK, Netherlands), which limit access to PND through lists of strict indications, the "psychological indication" is more widespread in Germany. Nippert attributes this phenomenon to the fact that such a primary demand for PND was made possible by the German health care system, because PND was paid for by SHIs and served the interests of health care providers, especially independent, self-employed gynaecologists.[406] The strict limitation of PND indications established in neighbouring countries is based on medical service requirements which are not at all comparable with those in Germany. In Germany, the doctor-patient relationship is based on liberal civil rights and protected against government intervention. SGB V does not contain any lists of indications. The government can prevent undesirable misallocations only by means of indirect control measures, but not by imposing bans. In keeping with the principle that only a physician's indication for medical intervention within the framework of the medical health care mandate will oblige statutory health insurers to pay for the service provided, recommendations for a limitation of indications – which would be justifiable in both medical and ethical terms – will have to be implemented under a structural policy for the health sector; the parliamentary Health Committee will have to be asked to look into the matter as well.

1.3.3.4.5 Increased supply – induced demand: Ultrasound scan, triple marker test and the consequences

While in the wake of the 1984 liability law decision of the German Federal Court of Justice, self-employed gynaecologists had increased their supply of PND services, mainly for "defensive" reasons, technical developments have since then led to an increased use of prenatal genetic diagnosis.

In the 1990s, the gradual improvement of routine ultrasound scans – which are now part of the SHI benefit package - and the introduction of tests measuring biochemical markers in maternal blood substantially increased the possibilities of diagnosing risks of infantile (chromosomal) developmental disorders in a non-invasive way.

Improved ultrasound scans made it possible not only to determine the precise gestational age and detect twins, but also to identify anomalies of the baby's organs, its body shape or size development. Between the 11th and 14th week of pregnancy "nuchal translucency"[407] is

[405] Nippert 2001c, p. 295. Also providing further references regarding this aspect.
[406] Nippert 2001, p. 295. Also providing cost-benefit analyses of PND in different health care systems.
[407] Dorso-nuchal edema (neck fold).

measured. A thickness of the neck fold of more than 3 mm is closely associated with an increased risk of trisomy 21 and usually leads to invasive PND.

Since 1992 the so-called triple marker test has been used in prenatal care "without any previous verification of reliability - in terms of reproducibility of the test with identical results - and validity of the measuring procedures used, and against the recommendations of professional organisations"[408].

The triple marker test is usually carried out between the 14th and 16th week of pregnancy to measure three markers in maternal blood whose levels are combined in a computer programme with other variables (maternal age, gestational age etc.) to calculate the *individual* risk of infantile chromosomal defects.[409] The calculated risk level is meant to help the mother decide for or against invasive procedures to establish an exact prenatal chromosomal diagnosis.

In fact, this test is (was) often done without previously informing the expectant mother, it often produces false positive results[410] (i.e. it indicates a risk which does not exist at all, thus needlessly worrying the mother) and hence leads to invasive procedures:

[408] Nippert 2001c, p. 296. In 1992, the following bodies advocated a moratorium: the *Gesellschaft für Humangenetik* (German Society of Human Genetics), *Bundesverband Medizinische Genetik* (Association of Medical Geneticists), *Deutsche Gesellschaft für Gynäkologie und Geburtshilfe* (German Society for Gynaecology and Obstetrics) and *Deutsche Gesellschaft für Perinatale Medizin* (German Society for Perinatal Medicine). Development was totally different in the Netherlands where so far screening methods like the triple marker test have not been a regular part of prenatal care paid for by SHIs. On 7 May 2001, the Health Council of the Netherlands, complying with a request by the Dutch Ministry of Health, submitted a statement entitled "Prenatal screening: Down syndrome, neural tube defects, routine ultrasound screening" which, among other things, arrived at the conclusion that the following criteria had to be met when a triple marker test was done:

- Quality assurance guidelines of the health care providers involved for testing and counselling;
- quality assurance of counselling by training all those involved in prenatal care who want to carry out screening programmes;
- quality assurance of laboratory work based on international standards and a minimum routine of 10,000 to 20,000 tests per year;
- ensuring informed consent which is to be given on a step-by-step basis.

In this context see Health Council of the Netherlands, 2001.

[409] The markers are alpha-fetoprotein (AFP), human chorionic gonadotropin (hCG) and unconjugated estradiol.

[410] For the problem of triple marker test reliability, see Sancken/Bartels 1999 in particular, with the evaluation of more than 33,000 triple marker tests. See also C2.1.1.2.1.3 Prenatal tests and C2.3.2.1.1 Approval of new genetic tests.

> "In the first two years after the triple marker test had been 'launched in the market', demand for invasive diagnosis in the old German states increased by more than 33 per cent. (...) Premature introduction without a clinical trial phase and the excessive spread of this test in medical practice were clearly not attributable to demand by pregnant women. Instead, this development was primarily the result of a provider-induced demand, which was boosted by the fact that the test was often paid for by SHIs as a gesture of fairness and goodwill."[411]

Today triple marker test and nuchal translucency scan are common routine procedures and so widespread that they are available in virtually every gynaecologist's practice. Women are asking for these tests, because they promise to turn the mothers' wish that "the main thing is that it's a healthy baby!" into a certainty. This demand in turn puts pressure on gynaecologists.[412]

The development and trial of such tests, which can be carried out at the earliest time possible in a pregnancy, are progressing. The purpose of these tests is to determine the individual risk of infantile chromosomal aberrations by means of a special computer programme (so-called "first trimester test").[413] The target group comprises all women regardless of their age, because all women run a small risk of giving birth to a child with a physical and/or mental disability.[414] Definitive clarity after such screening tests would have to be obtained by invasive prenatal genetic diagnosis.

According to sociological studies, invasive and non-invasive PND procedures have fundamentally changed the experience of pregnancy in western societies. The possibility of having PND, these studies suggest, produces a feeling of "fear, stress and uncertainty"[415] in many women. Possible signs or unclear findings after ultrasound scan, triple marker test or nuchal translucency scan trigger a cascade of subsequent tests and lead to invasive PND all of which are felt to be very stressful.[416]

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[411] Nippert 2001, p. 297.
[412] Schumann 2001.
[413] Cf. Hahn/Holzgreve 1998, pp. 143-147. The authors suggest that "further significant breakthroughs in prenatal diagnosis are on the horizon after foetal cells isolated from maternal peripheral blood have made it possible to detect aneuploidy and more recently also single-gene diseases. This raises hopes for non-invasive prenatal diagnosis in the near future" (summary, p.143). At present, however, there are numerous difficulties, including the problem of reliably distinguishing foetal from maternal cells so that, if these problems can be solved, "such methods will most probably be used to complement" (p. 146) existing reliable invasive procedures.
[414] Cf. Baldus 2001, p. 24.
[415] Nippert 1999, p. 68; cf. also Weiß 2000.
[416] Cf. Pieper 1998; Schücking 1994 and 2000; Schneider 2001.

> "The actual unacceptable demand that PND makes on the mother is to resolve the conflict between the demand to protect the pregnancy and the child on the one hand, and on the other, to be potentially faced with the decision – depending on the test results – to terminate her pregnancy. The potential dependency of the pregnancy on the test result imposes on the mother a virtually intolerable detachment from the pregnancy and the unborn child."[417]

The author suggests that a pregnancy which is in fact welcomed by the woman is thus turned into a revocable pregnancy right up to the second trimester, a situation for which the term "pregnancy subject to recall"[418] was coined. The mothers' detachment from the foetus is also expressed in the fact that before they know the result of a PND test many women do not tell others about their pregnancy, do not buy any maternity clothes and begin only much later to feel foetal movements.[419] The possibility of using PND procedures results in a new allocation of responsibilities to women. The decision on a possible selective termination of pregnancy after PND may also be influenced by social pressure, because "in our society, there is a latent tendency to apportion blame to pregnant women who do not avail themselves of PND and quite consciously accept the risk of giving birth to a disabled child"[420]. However, a woman's freedom of choice is limited by a tendency "to expect the use of PND as a type of behaviour during pregnancy that conforms to social norms", a tendency "whose signs can already be detected in our society"[421]. However, it is suggested that in spite of the relief arising from a normal test result, the change in the experience of pregnancy due to PND could also exact an invisible price:

> "Sometimes a process of alienation triggered by the mechanisation of pregnancy interferes so strongly with the body experience (...) that consequences can still be felt after the end of pregnancy, even in those cases where no foetal anomalies were detected: The mother's feeling of detachment turns into an independent phenomenon in its own right which cannot be abandoned even after the child has been born (...), and there is a lasting loss of the mother's own body competence and a sense of moral guilt after the baby has been born for not having shown the child fundamental maternal solidarity and for having questioned its very existence."[422]

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[417] Nippert 1999, p. 70; cf. also Baldus 2001.
[418] Katz-Rothman 1989.
[419] Cf. Katz-Rothman 1989, p.104; Nippert 1999, p. 70; Schindele 1995 and 1998.
[420] Nippert 1999, p. 77; cf. also Katz-Rothman 1989; Griese 1999; Beck-Gernsheim 1991 and 1996; Rapp 1999 and Wolbring 2001.
[421] Nippert 1999, p. 74; cf. Nippert/Horst 1994, Graumann 2001b.
[422] Pieper 1998, p. 244.

1.3.3.4.6 The German Medical Association's 1998 "***Richtlinien zur pränatalen Diagnostik von Krankheiten und Krankheitsdispositionen***" (Guidelines for **prenatal diagnosis of diseases and predispositions to diseases)**[423]

After the 1987 "*Empfehlungen zur Pränataldiagnostik*" (Recommendations for prenatal diagnosis), the German Medical Association in 1998 published the "*Richtlinien zur pränatalen Diagnostik von Krankheiten und Krankheitsdispositionen*" (Guidelines for the prenatal diagnosis of diseases and predispositions to diseases) which go beyond the aim and purpose of PND and focus in particular on the requirement of extensive medical information and counselling of the pregnant woman *before* and *after* prenatal diagnosis which should comply with the principle of being non-directive. Two long and detailed sections, section 3.2 "*Risiko-Ermittlung*" (Risk determination) and section 3.3 "*Mögliche Gründe für eine gezielte, insbesondere invasive pränatale Diagnostik*" (Potential reasons for selective, especially invasive prenatal diagnosis), are dedicated to discussing the scope of PND beyond the early detection of risk factors. The triple marker test is cited and explained as a useful example of risk specification methods.

The guidelines address follow-up, conservative and surgical intrauterine therapies as well as the physicians' qualifications and finally the ethical and legal aspects of PND. Concerning the latter, the guidelines state with regard to the treatment contract between the pregnant woman and the physician which results from the physician's consent to provide prenatal care: "This contract covers not only maternal care but also the care of the unborn child. Under this treatment contract, the physician is obliged to draw attention to the possibilities of diagnosing foetal damage. If he fails to do so (…), he may be liable for damages."

The preface to the guidelines gives the following reasons for updating the 1987 Recommendations:

> "The past ten years have seen an extraordinarily successful development in medicine and medical technology. In the field of prenatal diagnosis, this development has generated knowledge of an increasing number of monogenic clinical pictures and has led to the introduction of molecular techniques into chromosomal diagnosis and high-resolution ultrasound diagnosis as well as – in the therapeutic area – intrauterine blood exchange transfusion if there is an Rh incompatibility between mother and foetus.

[423] *Bundesärztekammer* 1998c.

> It had become necessary to publish this first update of the 1987 Recommendations, because not only medical tasks have expanded and diversified. The legal and ethical framework, too, has been adapted to modern requirements in the light of legal changes and decisions by the highest courts and as a result of growing patient autonomy which led to the demand for informed consent regarding all medical interventions. Consequently, pregnancy counselling has moved into the centre of prenatal diagnosis.
>
> In addition to sound knowledge of genetic issues and of diagnostic and therapeutic risks and possibilities, counselling also requires sympathetic and understanding talks and a discussion of the parents' decision-making options. This highly sensitive interaction in the doctor-patient relationship is the reason why the original recommendation in the first version of this paper has now been changed to a guideline."[424]

The German Medical Association considers this guideline as complementary to the Maternal Care Guidelines.[425]

1.3.3.5 Wrongful birth

As of the mid-1980s, if a disabled child is born in Germany as a result of "failed family planning", parents will sue their attending physician for damages.[426] The parents' claim is based on the allegation that as a result of medical malpractice a child was born which, according to the parents' will, should not have been born at all (failed sterilisation) or not in this condition (missed abortion due to faulty counselling or prenatal diagnosis during pregnancy, or birth of a child with a hereditary disease after faulty genetic counselling prior to conception). In such cases, civil courts have awarded damages for pain and suffering during pregnancy and birth to the mother, and they have awarded damages for child maintenance to the parents, if the physician failed to comply with his duties under the medical counselling and treatment contract, or if performance of the contract was defective.

Decisions by the supreme courts on faulty counselling or prenatal diagnosis during pregnancy had so far been based on Sec. 218a of the Criminal Code and its provision regarding the infantile or embryopathic indication or the (financial) emergency indication as justification of the termination of pregnancy. In the view of the *Bundesgerichtshof* (BGH – Federal Court of Justice), the crucial question regarding the physician's liability was whether the protective purpose of the contract also implied that a termination of pregnancy protected the parents

[424] *Bundesärztekammer* 1998c, A 3236.
[425] Cf. *Bundesärztekammer* 1998c, A 3236.
[426] Cf. the outline of the jurisprudence in Degener 1998b and Beckmann 1998b.

from economic disadvantages arising from child maintenance[427]. The Court affirmed this for those concrete cases to which the former model of indications had applied. How the Federal Court of Justice would decide today in the light of the amended version of Sec. 218a is an open question.[428] Apart from the criminological indication, Sec. 218a of the Criminal Code in its new version of 1 October 1995 provides only for the medical indication as justification of a termination of pregnancy (provided the cases concerned are not unlawful, yet non-punishable terminations within the 12-week time limit; this limit, however, will usually be exceeded in the case of termination after prenatal diagnosis). It is doubtful to what extent the Court's requirement, i.e. the prevention of economic disadvantages as a protective purpose of the medical contract, can be applied here. The medical indication does not aim to prevent economic disadvantages, but rather to avert serious risks to the health of the mother.

The First Division of the *Bundesverfassungsgericht* (Federal Constitutional Court), which had to review the decisions of the Federal Court of Justice from the constitutional perspective, did not find any fault with this jurisprudence according to which the maintenance of a child born after failed sterilisation or faulty genetic counselling prior to conception may constitute a damage to be compensated for.[429] Regarding the former case, the Court explained that awarding damages did not violate the human dignity of the child because it was not the child that was to be considered a "loss" in the legal sense, but rather the burden of maintenance imposed on the parents by the child's birth, which was unplanned, and the result of defective performance of the contract. Regarding the latter case (faulty genetic counselling), the First Division of the Federal Constitutional Court upheld the Federal Court of Justice's previous decision, explaining that the objective of the medical counselling and treatment contract, i.e. preventing the conception of a child carrying a genetic disease, was lawful. Not even moral concerns would be appropriate in such a case, for the parents' wish to make the conception of a child contingent on the result of genetic counselling reflected a high level of parental responsibility. The Court rejected the complainants' view that the decisions previously handed down by the Federal Court of Justice degraded human beings and turned them into objects, i.e. into fungible goods in contractual relations or in legal relationships under tort law. It ruled that the application of the law of damages did not turn a human being as a person or his inalienable rights into tradable merchandise. The recognition of the child as a person was

[427] Federal Court of Justice, judgement of 15 February 2000, BGHZ 143, pp. 389-397.
[428] Proceedings on an appeal from a decision passed by the Munich Higher Regional Court – Augsburg Division (2 U 363/00) which had awarded damages for the entire maintenance of the disabled child plus damages for pain and injury for the mother pursuant to Sec. 218a new version, are pending.
[429] *Bundesverfassungsgericht* (BverfG – Federal Constitutional Court), decision of 12 November 1997, BVerfGE 96, pp. 375-407.

not based on the parents' acceptance of the obligation to provide child maintenance. The Court stated that under civil law, too, the existence of a child was only a factual precondition for the resulting burden of maintenance. The obligation to provide maintenance and parenthood could be two separate things.

In its 1993 decision on the non-punishable termination of pregnancy during the first three months of pregnancy, however, the Second Division of the Federal Constitutional Court had ruled that a legal qualification of children as a "loss" was unconstitutional.

> "The legal qualification of the existence of a child as a source of damage (…) is ruled out by the Constitution (Article 1(1) of the German Constitution). The obligation of all state authority to respect every human being for their own sake makes it impossible to perceive child maintenance as a loss."[430]

When the First Division of the Federal Constitutional Court handed down its decision in 1997, the Second Division felt that, in view of the fundamental significance of the issue, both Divisions should get together in a plenary session and jointly decide on their diverging interpretations.[431] However, the First Division rejected the proposal that a plenary decision should be taken by the entire Constitutional Court.

Had the First Division assumed a different attitude, the result would have been greater legal certainty regarding this highly controversial issue. In legal literature and among the public a discussion is still going about "wrongful birth" and about the extent to which modern reproductive technologies and the possibilities of prenatal diagnosis in combination with the court rulings on medical liability increase the pressure to give birth to a healthy child. Human geneticist Traute Schroeder-Kurth, for instance, warned that jurisprudence forced the members of her profession to provide "directive" counselling. In the case of above-average risks they would have to urge a couple not to conceive any more children, even if the risks seemed very small.[432]

The decision of the Second Division referred to the legal provisions for the non-punishable termination of pregnancy during the first three months, whereas the rulings of the German Federal Court of Justice, which had preceded the First Division's decision, were related to cases of failed sterilisation and faulty genetic counselling prior to conception. The cases that involve medical errors after conception, i.e. during pregnancy, are particularly problematic

[430] BVerfG, judgement of 28 May 1993, BVerfGE 88, p. 203 (official headnote 14 and p. 296).
[431] BVerfG, judgement of 22 November 1997, BVerfGE 96, p. 409-414.
[432] Cf. Schroeder-Kurth 1994, p. 398f.

because they concern the protection of human life. The more prenatal diagnosis progresses, the greater the pressure on the medical community, but also on the mother, to use all knowledge available in order to make a decision on whether or not to terminate the pregnancy. In contrast to cases of medical malpractice prior to conception, the question is still open and needs to be answered whether the objectives of such a counselling and treatment contract during pregnancy as such and under the amended Sec. 218a of the Criminal Code are lawful. It is also questionable whether such contractual obligations are null and void because they violate morality.

Regardless of this unresolved situation, the current legal view of "wrongful birth" can be seen as one of the causes of the dramatic increase in the use of prenatal diagnosis.[433] Physicians providing prenatal care feel considerable pressure to offer possibilities of selective diagnosis to protect themselves against subsequent claims for damages. More often than not this means that counselling and information of the pregnant woman is given short shrift, and it is too little known that also under the medical treatment contract the pregnant woman has the possibility not to avail herself of specific treatment procedures, thus allaying the physicians' fears of potential liability claims which in the light of prevailing circumstances and the legal situation are often unreasonable anyway. Even today many pregnant women are not adequately informed about the purpose, benefits and risks of the various prenatal diagnostic methods and about their right to refuse individual tests provided for in the pregnancy passport. It cannot be overlooked, either, that often such prenatal diagnostic tests are forced on them for economic reasons.

According to the jurisprudence in Germany, the child as such is not entitled to any damages, because there cannot be a right to non-existence. However, this barrier imposed by jurisprudence is no longer unconditionally supported by a solid consensus within the legal community.[434] Some people even hold the view that a child has a right to be born normal and that if this right is violated the child should be awarded damages.[435]

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[433] Hennen *et al.* 2001, p. 71; Nippert 2000, p. 135f.

[434] Cf. the documentation of this discussion in Degener 1998b, p. 45.

[435] In 2000, the highest French court of appeal (cour de cassation) had awarded damages for wrongful birth to a boy whose severe disability had not been diagnosed during pregnancy due to medical malpractice; the court had upheld this decision in two other cases. After there had been protests against this decision the Assemblée Nationale and the Senate adopted a bill (Article 1 Act No. 2002-303 of 4 March 2002) which precludes, as a matter of principle, a person's claim for damages for having been born. Persons who were born with a disability may claim damages if medical malpractice during pregnancy directly caused or aggravated this disability or prevented suitable measures to mitigate it. In such cases parents can claim damages for disadvantages they suffered themselves. The Act explicitly stipulates that these disadvantages do not include the life-long special burden resulting from the child's disability which has to be compensated for out of the general risk pool.

An attitude seems to prevail in society that can be summed up in the question: "Who would want to have a disabled child anyway?" Given the development of medical liability law, it is very difficult nowadays to enforce the right not to know in the field of family planning. Based on practical experience, representatives of the associations of nurse-midwives in particular confirm the momentum of such a development which tends to get out of control and virtually imposes a moral obligation on pregnant women to know. Late mothers who want to exercise their right not to know are confronted with a considerable lack of understanding on the part of society. Interest groups and disabled associations fear that this is the breeding ground on which discrimination against the parents of disabled children and against disabled persons themselves will grow.

While preventing the birth of a child, thus thwarting the parents' family planning, remains unpunished because no financial loss is incurred, the opposite applies to keeping the foetus alive. In this way, a hostile attitude to life has been introduced into medical practice as a result of an - alleged - legal necessity. Parents who decide against the life of a disabled or sick child are advantaged, because they can either opt for a termination of pregnancy or obviate any material consequences for themselves by making the physician liable. On the other hand, parents who in full awareness of the consequences decide for the life of a disabled or sick child are disadvantaged, because to a large extent they themselves will have to carry the financial burden of the child's nursing care. Liability law which seems to be hostile to life could be replaced by a different model, e.g. an insurance taken out by the patient, or a fund solution which would provide compensation for the additional financial burden caused by the child's disability, or this task could be regarded as a task of society, with support by the general public helping those parents who quite consciously accept this burden, and likewise helping all those parents who already have disabled or sick children. Current social insurance schemes do not adequately fulfil this function. For it must not be overlooked that in most cases the only reason why parents claim damages is the justified concern for the well-being of their disabled or sick child and for a sound financial basis for its care. If in such cases the government ensured a fair equalisation of family burdens, the problem of liability for "financial loss due to child maintenance" would arise less often.[436] This aspect, too, should be included in the law-makers' considerations.

However, nevertheless, it must still be possible to hold a physician responsible for services that are not in keeping with medical standards. The issue of imposing penalties in the case of

[436] Cf. Beckmann 1998b, p. 1, 4f.

faulty medical care should be settled by tying the payment for medical services to quality assurance schemes. Under a system that provides incentives for high-quality services, faulty counselling and treatment could be subjected to severe financial punishment. In this context, this applies in particular to the necessary quality of medical information and counselling prior to prenatal diagnosis. Such a system would not only ensure a better protection of unborn children, but also improve the quality of medical services as a whole.

Against the backdrop of this legal and actual situation, statutory regulation seems to be necessary, at least in the context of prenatal diagnosis.

1.3.4 Results

Experience gathered with PND shows that the attempt to restrict PND to specific indications, the attempt to use the severity of certain diseases for orientation, and the attempt to use PND on the basis of quality assurance in a triad of initial (human genetic) counselling, performance of PND and follow-up (human genetic) counselling have failed. The reasons for this failure are complex:

– Recommendations or guidelines, e.g. by the German Medical Association or professional organisations, seem to have too little effect to be able to control scientific and technical dynamics and economic constraints in medical practice.

– The German health care system favours a wider range of services on both the supply and the demand side.

– In the case of PND, the two crucial quality assurance problems could not be solved either by the Bundesausschuss der Ärzte und Krankenkassen (Federal Committee of Physicians and Health Insurers) (maternal care guidelines, pregnancy passport) or by the instrument of medical self-government (guidelines by the German Medical Association, professional code of ethical practice under state law or issued by state medical associations, professional organisations):

  a) poor counselling services before and after PND provided by counsellors not qualified for this task, including lack of associated documentation; lack of quality assurance schemes for the *content* of patient education and counselling and neglect of the requirement for informed consent;[437]

[437] On issues regarding suitable counselling for predictive genetic diagnosis see C2.3.2.4 Information, education and counselling.

b) lack of an approval procedure for predictive tests only after adequate trials and lack of ensured expert performance and interpretation of tests (see triple marker test).

– When PND was introduced, various developments in the fields of technology, adjudication and social policy[438] could not be foreseen which, taken together, led to the development of PND over the last 30 years from a special procedure to be applied in specifically justifiable, individual high-risk cases into a routine procedure used generally to identify or confirm risks.

– It cannot be precluded that this use of PND as a "risk-screening method" forming part of the prenatal care services in every pregnancy will also be fundamentally reinterpreted in the future. PND in general and invasive prenatal genetic diagnosis as its still most reliable instrument in particular would then no longer be regarded as a selection tool to identify and prevent individual carriers of certain traits, but would be used above all to help expectant mothers to prepare for life with a disabled child.[439]

Whether the previous or current development of PND and the shift in its importance could have been stopped by external, statutory quality control exercised by an institution created by the German Bundestag is a moot point. This institution would be responsible for licensing and monitoring clinics/medical practices and test procedures, for the documentation and evaluation of counselling services and their content and for ensuring easy access to information and counselling. Likewise, it will remain open whether such an institution would bring about a different type of prenatal care.

Even if certain historical circumstances, which cannot be directly applied to PGD and its assessment, have influenced the development of PND, it can still be stated that:

– the "harsh day-to-day reality of medical practice" undermines the high quality standards defined early in the process of introducing an ethically and/or legally controversial method;[440]

– in the course of the technical improvement of this method new indications or new procedures were very quickly used in medical practice – without adequate clinical testing – and established as a service paid for by SHIs on a goodwill basis.

[438] E.g. progress in the field of imaging ultrasound diagnosis, the development and combination of non-invasive diagnostic tools with computer-based statistical "risk profiles" or the decisions by the highest courts on medical liability or the integration of prenatal genetic diagnosis into regular SHI-financed prenatal care.
[439] Cf. Baldus 2001, p. 46f.
[440] Nippert 2001c, p. 302.

In the light of the experience gained with prenatal genetic diagnosis, it would seem to make sense to address in the discussion all possible applications of PGD that are already foreseeable or discussed today, including routine chromosomal screening of embryos in vitro, and not to narrow them down to an indication applying to so-called high-risk couples, as the German Medical Association did in its draft guideline for PGD.

1.3.5 Recommendations

The increasing use of prenatal diagnosis (70 to 80 per cent of pregnancies are defined as high-risk pregnancies) has to be seen in a critical light, not only from a deontological perspective but also in terms of women's policy and health economics. The provision of PND without any preventive or therapeutic benefit and/or specific indication is to be limited through prior counselling, the guarantee of explicit informed consent and a deontological review of the medical services offered.

The Study Commission recommends:

1. The following should be ensured as prerequisite for all prenatal diagnostic procedures:

   – Methods of risk specification (selective PND) have to be excluded from regular prenatal care and used only in individual cases, but not a routine basis.

   – The voluntary and informed decision of women or couples as a result of timely and extensive education and counselling before every prenatal diagnostic procedure designed to identify malformations.

   – Adequate medical, human genetic and psychosocial counselling services providing information on possible consequences of the test results in both medical and psychosocial terms before and, if necessary, after diagnosis. In counselling a distinction should be made between curable and incurable anomalies and information should be provided on concrete assistance through therapeutic intervention, measures offering relief for the family and through contact with self-help groups.

2. As regards the general setting for PND services,

   – it is recommended that the bodies of self-government within the health care system should revise their guidelines with a view to restricting PND and to ensuring the provision and quality of human genetic counselling services as part of their mandate to guarantee health care services;

- it is recommended that the Federal Committee of Physicians and Health Insurers should look into the practice of PND and ensure that there is no surplus provision of PND services.

3. The following political measures can contribute to creating a social climate which makes it possible/easier for parents also to give birth to disabled children:

   - The Maternal Care Guidelines should be reviewed. A preamble should be included, explaining the legal framework of medical prenatal care provided according to the maternal care guidelines[441].

   - Statutory health insurers should extend and improve patient information especially in this field. The pregnancy passport should explain the various options of prenatal care services, e.g. offered by nurse-midwives.

   - Concepts for qualified counselling should be developed and implemented as part of prenatal care.

   - The *Bundeszentrale für gesundheitliche Aufklärung* (Federal Centre for Health Education) should initiate a broad-based campaign providing information on the rights of patients, the conditions of prenatal care and the risks associated with PND, and especially on the required informed consent.

   - A statutory regulation for late abortions (so-called partial-birth abortions) should be drafted.

   - More research should be performed to look into therapeutic procedures to be performed when symptoms or syndromes are diagnosed which after PND most frequently lead to a termination of pregnancy.

   - Equal treatment of disabled children and enabling them to live with their families should be supported.

[441] This preamble should make it clear that medical prenatal treatments and especially prenatal ultrasound scans are contingent on adequate medical information and the resulting informed consent of the pregnant woman to the test in question; it should explain that this also applies to procedures covered by the maternal care guidelines which only define the legal requirements for benefits to be provided by statutory health insurers and do not impose an obligation on the insured to undergo such procedures. It should also be made clear that if the expectant mother refuses ultrasound scans after adequate information, the physician is invariably obliged to continue to provide prenatal care unless this refusal has upset the confidential relationship between doctor and patient. This may be the case when a test is urgently required for concrete medical reasons to avert risks to the life and health of the mother or the foetus, see the proposal by Francke/Regenbogen 2001.

– The Study Commission recommends that the German Bundestag should regulate by law that physicians cannot be held liable for the existence of a child if the birth of the child was not prevented through a termination of pregnancy and if they did not – on their own initiative – offer the mother any prenatal tests which did not offer any preventive or therapeutic benefit for the unborn child or did not draw her attention to such tests. It is also recommended that compensation should be provided through an insurance or a fund solution or through improved public benefits for children with a disease or congenital disability so as to support parents in their decision to give birth to a sick or disabled child.

1.4 Preimplantation genetic diagnosis

Preimplantation genetic diagnosis (PGD) is a procedure comprising in-vitro fertilisation (IVF), genetic diagnosis and embryo transfer (ET) or the "discarding" of the embryo. Genetic diagnosis encompasses all procedures carried out in a laboratory on embryos cultivated in a culture medium with a view to identifying individual gene defects and chromosomal anomalies.

1.4.1 Current situation

1.4.1.1 Description of the method

Preimplantation genetic diagnosis (PGD) requires in-vitro fertilisation (IVF) to be performed (see 1. IVF and preimplantation genetic diagnosis).[442] As a rule, several egg cells are harvested for in-vitro fertilisation (according to the 1999 *Deutsches IVF-Register* [German IVF Registry] nine oocytes on average). On day 3 after fertilisation, one or two cells are usually removed from each embryo for PGD, i.e. to examine them for certain genetic or chromosomal anomalies. The purpose of this test is to select those embryos for transfer which do not have the genetic or chromosomal defect in question.

Even experts consider PGD still to be at the experimental stage.[443] For instance, the usual laboratory standard of validating test results by duplicate analysis or control tests is not possible with PGD applied to a single cell so that its diagnostic accuracy (sensitivity and specificity) is limited.

[442] In contrast to the classical indication for IVF, couples who would be most eligible for PGD today are usually not infertile.

[443] Written communication of 28 November 2000 by Professor Klaus Diedrich to Professor Linus Geisler, an expert witness: "As long as a method still needs to be confirmed by a second test procedure (PND) it is not yet mature and – in my view – still experimental."

The essential characteristics of PGD as compared with prenatal diagnosis are as follows:

– The embryos to be examined are produced in the laboratory.

– The embryos are examined outside the womb.

– Prior to the transfer into the uterus, a selection is made among several embryos after genetic diagnosis; in the case of autosomal dominant genetic defects, there is a statistical probability that embryos with a certain genetic defect will be produced.

– The embryonic cells retrieved for diagnosis can be "totipotent", depending on the time of sampling.

1.4.1.1.1 Embryo biopsy

Usually one or two cells are retrieved from the embryos on the third day of development (4-cell to 10-cell stage).

Harvesting the cells at the 32- to 64-cell blastocyst stage has been suggested as an alternative. This would entail the advantage that a larger number of cells could be sampled, thus improving diagnostic reliability, and most probably, the cells would no longer be totipotent.[444] However, attempts to examine embryos at this developmental stage have so far not led to clinical success.

It seems that biopsy performed on the third day after insemination (i.e. at the 4- to 10-cell stage) can best meet practical requirements.[445]

It is assumed today that biopsy for PGD will lead to a loss of embryos.[446] Since potential damage to the embryo as a result of biopsy would probably be fatal, possible damage in children after birth is considered improbable. So far empirical data have not been available to support a conclusive assessment of this issue.

1.4.1.1.2 Single-cell genetic diagnosis

Depending on the diagnostic intention, either the polymerase chain reaction (PCR) method or fluorescence in situ hybridisation (FISH) is used for molecular genetic diagnosis. Microscopic chromosomal examination as in routine prenatal diagnosis for a general study of the

[444] The issue of totipotency of the removed cells is important for the legal and ethical assessment of the method, see also C1.4.1.1.6 Totipotency.
[445] Cf. Kollek 2000, p. 44.
[446] Data given in a study conducted by the European Society of Human Reproduction (ESHRE) in 2000 suggest a loss of embryos after biopsy. Detailed studies of this problem are not known. Cf. C1.4.1.1.5 Application.

chromosomes (determination of the karyotype) is not possible. This means that it is always necessary to look for a specific defect. [447]

With PCR, it is possible to determine a specific gene sequence in no more than a single cell by replicating this sequence about a thousand times by means of so-called amplification and labelling it either with fluorescent dyes or radioactive markers. In this way, it is possible to identify individual genes as well as structural changes in individual genes.

FISH permits screening for chromosomal abnormalities and single-gene defects by using fluorescent gene probes that attach to either specific gene sequences or entire chromosomes. It can also be used to determine sex chromosomes. If several differently coloured fluorescent gene probes are used simultaneously, it is possible to examine up to ten chromosomes in a single cell or embryo. However, interpretation can be a problem as there may be a superposition of signals.

Biopsy and DNA analysis by means of PCR or FISH can be performed within eight hours so that the embryo can be transferred into the uterus on the same day.

Validity of diagnostic procedures:

PCR can yield incorrect results due to contamination of the sample (e.g. by genetic material of the examiner) and the so-called allelic drop-out[448] (ADO, where one of the two alleles present in a blastomeric nucleus is not amplified).[449]

The advantage that FISH has over PCR is that contamination by foreign DNA is a smaller source of error. However, "mosaicism", which occasionally occurs in embryos, may lead to different chromosome sets (karyotype) in some embryonic cells (blastomeres). Consequently, it is not possible to infer with absolute certainty from the diagnostic result of one embryonic cell without any chromosomal disorder that all other cells will also not be affected by a chromosomal defect.

[447] Analysis is carried out with specific gene probes which can only identify single changes. Karyotype determination is not possible.

[448] "Alleles" are alternative forms of the same gene. For every gene two alleles are present in the cell nucleus which may be either identical (homozygous) or different (heterozygous).

[449] In spite of the technical amplification of the material the volume available does not permit a repetition of the analysis to validate the result. If there are two blastomeres present, they will be studied in parallel. Subsequent review is not possible for lack of material. The blastomeres and/or the entire DNA are "used up" in the process of genetic diagnosis.

Quality assurance/diagnostic errors:

The diagnostic uncertainties and problems of interpretation involved in single-cell genetic analysis as outlined above result in a relatively high diagnostic error rate. This is why today PGD results are usually reviewed and validated by means of prenatal diagnosis once pregnancy has resulted.

The data on error rates cited in literature vary widely. PCR error rates for sex determination vary between 2 and 21 per cent, those for single-cell defects such as cystic fibrosis or sickle cell disease between 7 and 36 per cent.[450]

Analysing two cells apparently improves the robustness and reliability of the test significantly. The average error rate cited for the analysis of two blastomeres is 2 to 5 per cent.[451] Consequently, it has to be assumed that every twentieth to fiftieth foetus considered genetically normal after PGD using two blastomeres nevertheless carries the undesirable genetic trait.

Given the overall error probability of this method, it has also been suggested that in theoretical terms the probability of not identifying a carrier with PGD had to be estimated to be just as high as the probability of wrongly identifying a healthy embryo as a carrier. Both probabilities therefore had to be added up to get an idea of the reliability of the method. In the above example this would mean that, all in all, every tenth to twenty-fifth embryo was misdiagnosed.

If only one cell is available for genetic diagnosis, a correspondingly higher error rate has to be expected. Comparable error rates were also found in polar body diagnosis which is described in C1.4.1.1.4 Alternatives. In this case, the probability of misdiagnosis is significantly higher, when only one polar body and not two are analysed.

1.4.1.1.3 Indications

There are four different target groups for PGD. However, the basis for indications in all cases is the desire to end involuntary childlessness by means of IVF and PGD, albeit for different reasons:

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[450] Findley *et al.* 1995. Other sources and a more detailed discussion in Kollek 2000, p. 51.

[451] According to an oral communication by Professor Diedrich at the public hearing on 13 November 2000, the rate is about 2 per cent; according to an oral communication by Dr. Henn at the public hearing on 13 November 2000, the rate is 1 to 5 per cent.

(a) couples with normal fertility whose genetic make-up suggests that there is a relatively high probability that they will have a child with a serious hereditary disease or disability (so-called high-risk couples);

(b) couples with normal fertility where, because of advanced maternal age, there is a statistically higher probability that they will have a child with a chromosomal disorder (especially Down syndrome) (so-called age-related risk);

(c) couples who, because of a fertility disorder, wish to use IVF and increase the chances of success (intended improvement of IVF success rates);

(d) couples who want to have a child with a particular genetic characteristic which, however, cannot be considered a disease (diagnosis of specific healthy genetic traits).

(a) High-risk couples:

The most common indication for PGD at present is a high probability of giving birth to a child with a certain genetic disease or disability. In such cases, advocates of PGD consider the cost and effort of IVF justified even though these couples usually have normal fertility. There is a high probability of passing on a gene mutation if both partners (in the case of autosomal recessive diseases) are carriers or one partner carries a defective gene (in the case of autosomal recessive and X-linked diseases).

In the case of autosomal dominant diseases, either one of the partners is suffering from the disease or the disease in question is an adult-onset disease (e.g. Huntington's disease) in which case the familial predisposition became known when a parent of the affected partner developed the disorder.[452]

In the case of recessive diseases, the parents themselves do not show any symptoms. The family history is usually known because a genetic disease has already occurred in the family. In most cases, the familial predisposition is diagnosed after an affected child has been born and subsequent genetic tests have been carried out. This means that there is a risk of repetition if the couple have more children.

In the case of recessive diseases (e.g. cystic fibrosis[453]) – in statistical terms – every fourth child and in the case of dominant diseases (e.g. Huntington's disease) every second child is affected by the condition.

In the case of most X-linked diseases, the female is the healthy carrier (e.g. haemophilia A). Statistically speaking, every second son is affected, whereas all daughters are healthy. If the

[452] Most dominant diseases are caused by de novo mutations. In such cases there is no risk of repetition.
[453] Cystic fibrosis is usually referred to as "Mukoviszidose" in German.

male carries the mutation, he is affected himself; all his sons will be healthy and his daughters will be healthy carriers.

PGD also identifies healthy carriers of a gene mutation. In the case of recessive diseases this applies to every second embryo and in the case of most X-linked diseases to every second female embryo. It may be assumed that if a sufficient number of embryos is available such heterozygous embryos will be excluded from embryo transfer.[454]

There are also hereditary diseases with a high probability of inheritance which have a more complicated mode of inheritance (e.g. fragile-X syndrome) and genetic chromosomal disorders (e.g. translocation trisomy) where the parents themselves are healthy.

In practice, genetic indications for PGD include Duchenne muscular dystrophy, haemophilia A (classic haemophilia), Charcot-Marie-Tooth disease[455], beta thalassaemia[456], osteogenesis imperfecta (brittle bone disease), pigmentary retinopathy[457], sickle cell disease and cystic fibrosis. These diseases carry a high risk of inheritance (25 to 50 per cent).

However, PGD also permits the identification of predispositions to diseases which have a much lower probability of manifestation. The presence of a BRCA-1 gene, for instance, only indicates a higher risk of developing hereditary or partly hereditary breast cancer than the average female population. The variability of data cited in the literature regarding the lifetime risk of BRCA-1 mutation carriers (between 56 and 85 per cent) and BRCA-2 mutation carriers (between 37 and 84 per cent) to develop breast cancer points to the very limited *individual* predictive power of such genetic tests.[458]

(b) Age-related risk:

With increasing maternal age there is a higher probability of giving birth to a child with a chromosomal disorder (especially Down syndrome). From the medical point of view, age-related risk would not be a "normal indication" for PGD because of the stress on women

[454] According to an oral communication by Dr. Henn at the public hearing on 13 November 2000, some centres discard heterozygous embryos in case of doubt because of the technical risk of misdiagnosis associated with these embryos, and only transfer homozygous healthy embryos.

[455] Mostly dominant, chronic progressive degeneration of peripheral nerve cells; identifiable partly in early childhood, partly in adulthood as bilateral paralysis of distal muscle groups leading to limb deformities.

[456] Homozygous (thalassaemia major or Cooley's anaemia) or heterozygous (thalassaemia minor or thalassaemia trait) haemolytic anaemia, i.e. a reduced haemoglobin quantity in the blood caused by a globin formation disorder (globin: protein component of haemoglobin in red blood cells which is required for oxygen transport). Thalassaemia minor does not require treatment. In thalassaemia major, early bone marrow grafts result in considerable improvements in 90 per cent of the patients.

[457] Mostly hereditary degeneration of the retinal vessels of the eye with pigment deposits and degeneration of the optic nerve; this can result in severe scotoma and even loss of eyesight.

associated with IVF. However, PGD could be an option for older women undergoing IVF treatment anyway, because in that case PGD does not entail any additional physical stress, apart from possible stronger hormonal stimulation.

(c) Intended improvement of the success rates of in-vitro fertilisation:

Chromosomal disorders occur relatively frequently in embryos and are lethal in many cases.[459] Diagnostic detection of numerical chromosomal defects which exclude embryonic viability (lethal aneuploidy) might contribute to improving the success rate of IVF. Many US IVF centres provide such services. The UK plans to extend the indications for PGD accordingly. [460]

(d) Diagnosis of healthy genetic traits:

PGD has already been performed to identify healthy genetic traits. In September 2000, the first case of this type became known in the United States. In the case of "Adam Nash", PGD was used to select one embryo out of 16 which was suited as a blood and bone marrow donor for the sister who was six years older and suffering from Fanconi's anaemia. The final successful cycle had been preceded by four failed IVF/PGD cycles so that a total of about 80 to 100 embryos had been produced before an immunologically "matching" child was born. A similar case in the UK prompted the HFEA to amend its approval criteria. Since August 2001 it has been possible in the UK in well-founded, exceptional cases to perform PGD to select an embryo as blood or tissue donor for a diseased sibling.

In Scotland, a family went to court to get permission to have a girl by means of PGD ("Masterton" case). The family had four sons and one daughter. After the death of the daughter, they wanted to restore the "female dimension" in the family. This indication is discussed in the literature under the key word "family balancing". In the UK, sex selection by means of PGD has so far only been permitted in the case of X-linked diseases. Internationally, sex selection for family balancing is already being offered by at least three clinics.[461]

Well-defined and clear-cut indications for PGD have not yet been established at international level.

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[458] Ries *et al.* 1998.

[459] According to Professor Karsten Held, embryos with autosomal aneuploidy usually have no chance of nidation in the uterus or they are spontaneously aborted between week 6 and week 12: "This applies to all monosomies and - with the exception of chromosomes 13, 18 and 21 – also to all trisomies. However, even with trisomies 13, 18 and 21 an intrauterine loss rate of 60 to 80 per cent has to be expected." (Held 2001, p. 2).

[460] Supp 2002, Striegler 2002a.

Possible future indications:

The procedures that are currently available will presumably be developed and improved in the foreseeable future. It is also conceivable that procedures will be developed and used to test for diseases, disabilities, impairments or predispositions caused by several genes and environmental factors (polygenic and multi-factorial diseases). Furthermore, new procedures like the so-called gene chips will open up the possibility of testing a large number of genes and traits simultaneously.[462] These procedures could also be used for purposes of PGD.

Technically, PGD permits not only "negative identification" but also "positive selection" of embryos with desirable genetic traits as an "indication". Further applications of PGD are conceivable in the areas of cloning and so-called germ line therapy.[463]

1.4.1.1.4 Alternatives

There are various alternatives to preimplantation genetic diagnosis.

Alternative medical technologies

The various prenatal diagnostic procedures (amniocentesis and chorionic villus sampling) are available to so-called high-risk couples.[464]

If the increased risk of passing on a genetic defect is fully (dominant inheritance) or partly (recessive inheritance) attributable to the prospective father, heterologous insemination could be performed using sperm of a donor not carrying the genetic defect; this possibility involves ethical and - for the child to be conceived - also psychological and legal problems.[465] This method prevents a transfer of the genetic defect from the male to the prospective child and spares the woman additional stress through IVF.

If the increased risk of passing on a genetic defect is fully (dominant inheritance) or partly (recessive inheritance) attributable to the prospective mother, polar body diagnosis can be performed on the egg cells. This option would be legally possible in Germany, but has so far

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[461] For an ethical assessment of PGD for selecting stem cell donors, cf. Boyle/Savulescu 2001.

[462] For more details, see C2 Genetic data.

[463] At hearings held by the US Congress, members of the Raelian sect stated that they used PGD in this way for their cloning experiments based on the method employed for cloning the sheep Dolly. Cf. Maak *et al.* 2001. For Gregory Stock's far-reaching visions regarding PGD and germ line manipulation, see also Stock 2001. For the biological risks of germ line manipulation (e.g. aneuploidy), cf. Geisler 2001.

[464] See also C1.3 Experience gained with prenatal genetic diagnosis with regard to preimplantation genetic diagnosis. The medical, ethical and legal discussion on abortion cannot be addressed here.

[465] See also C1.2.3.4.4 Treatment of male reproductive disorders, and C.1.2.7.2 Open issues requiring further deliberation and clarification and – if necessary – action.

not been provided. Polar body diagnosis, like PGD, requires IVF. However, in this case the oocytes are studied even prior to fertilisation. Shortly before ovulation, an asymmetrical oocyte division occurs. In addition to the mature egg cell, the first polar body is produced which contains the same genetic material as the oocyte nucleus. This polar body is removed and genetically studied. Only egg cells without the genetic defect sought for will be used for fertilisation in the laboratory. After the sperm has penetrated into the egg cell, the oocyte undergoes a second division before the male and female pronuclei unite. In this process, the haploid female nucleus is first duplicated, then it divides and one half is deposited as the second polar body between the actual oocyte and the zona pellucida. This second polar body can be used to verify the diagnostic result obtained from the first polar body.[466] In this way, it would be largely possible to prevent the transfer of the genetic defect from the mother to the future child. As late as 1997, internationally "more than 70 per cent of all PGD procedures were performed on polar bodies and not on embryos or embryonic cells".[467] It cannot be denied that the notion of selection also arises in the context of polar body diagnosis, but in this case embryos are not affected, and ethical questions regarding the status of the embryo do not arise.[468]

Social alternatives

In addition, there are the following social alternatives:

– abandoning the wish to have genetically related children;
– adoption and foster care;[469]
– unreserved acceptance of a child and its genetic make-up.

1.4.1.1.5 Application

By May 2001, 693 children worldwide had been born after PGD.[470]

The international survey of the experience gained by PGD centres, which was published by the European Society of Human Reproduction (ESHRE)[471] in 2002, cites a total of 1,565

[466] Cf. Kollek 2000, p. 31ff.
[467] Second International Symposium on Preimplantation Genetics 1997, cited in Kollek 2000, p. 32.
[468] Detailed information on the current status of polar body diagnosis in Buchholz/Clement-Sengewald 2000.
[469] However, the focus of these alternatives is on the welfare of the child.
[470] Diedrich 2002, p. 6.
[471] European Society of Human Reproduction (ESHRE) 2002. The data used in the following are taken from this study. Data from the previous study, European Society of Human Reproduction (ESHRE) 2000, which are also cited are identified as such.

couples or women who started 2,074 treatment cycles between 1994 and 2001.[472] 26,783 egg cells were retrieved und resulted in 309 pregnancies, which in turn led to 215 births and produced 279 children.

The following primary reasons were cited in 2001 for performing PGD (in brackets: 2000):[473]

– genetic risk and refusal of abortion 36 per cent (44 per cent);
– genetic risk and previous abortion 21 per cent (28 per cent);
– genetic risk in conjunction with subfertility or infertility 25.6 per cent (29 per cent);
– age-related aneuploidy 14.2 per cent (5.4 per cent).

About 60 per cent of the patients had previously been pregnant once or several times. About one fifth of all couples had at least one healthy child and about one quarter had already one or several affected children.[474]

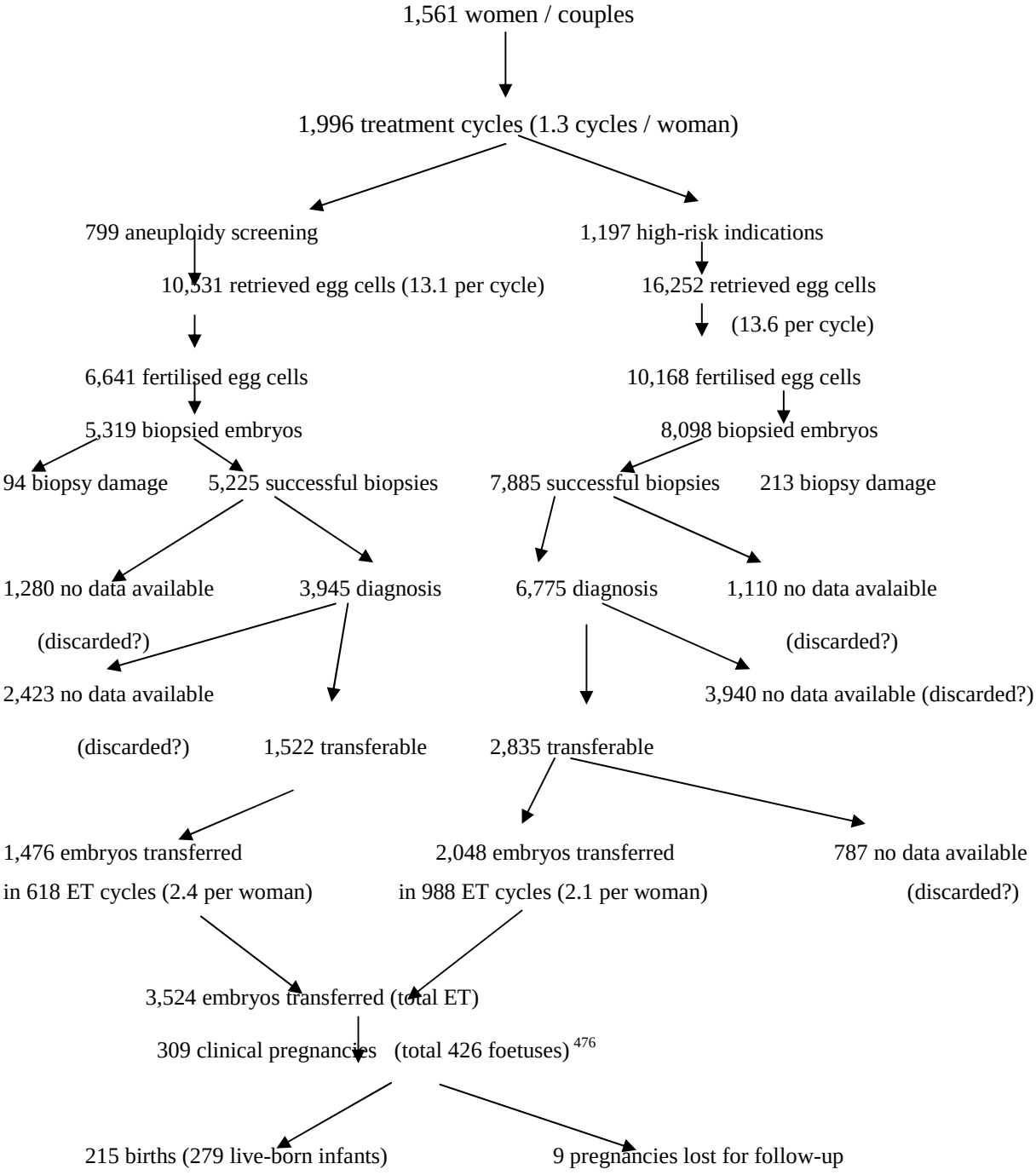
In 2001, the most important indications for PGD were (figures in brackets: 2000)[475]:

– Chromosomal aberration (numerical and structural) 41 per cent (33 per cent);
– X-linked gene mutation 19 per cent (25 per cent);
– autosomal recessive gene mutation 18.5 per cent (24 per cent);
– autosomal dominant gene mutation 16 per cent (17 per cent).

The indication for 60 per cent of PGD procedures (1,197 cycles) was a diagnosed single-gene disease ("high-risk" indication). In 40 per cent of PGD cycles, the aim was to identify chromosomal defects, usually in order to increase the probability of success of IVF ("aneuploidy screening"). Compared with the previous year, the percentage of aneuploidy screening rose by 5 per cent. From 1999 to 2000, this indication had already doubled.

[472] In 2001, for the first time 78 cycles were accounted for by social sexing. Cf. European Society of Human Reproduction (ESHRE) 2002, p. 236 (Table VIII), p. 241 (Tables XII and XIII).
[473] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 235 (Table II) and European Society of Human Reproduction (ESHRE) 2000, p. 2674 (Table II). The tables do not indicate whether several reasons could be given in a single case. A total of about 11 per cent of the reasons came under "Other" or "Not known". One per cent cited "genetic risk and sterilisation".
[474] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 235 (Table I). This table also includes 74 couples with two or three and even one couple with five healthy children. Furthermore, 65 couples were documented with two or three affected children and again one couple with five affected children.
[475] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 235 (Table III) and European Society of Human Reproduction (ESHRE) 2000, p. 2674 (Table III).

Chart 4: Results of the Application of PGD in 25 Centres Worldwide, 1994 – 2001



Source: European Society of Human Reproduction (ESHRE) 2002[477]

[476] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 242 (Table XIV).

[477] Except for separately identified numbers, cf. European Society of Human Reproduction (ESHRE) 2002, p. 236 (Table VIII) and p. 241 (Table XII).

The 309 clinical pregnancies can be broken down into 212 singleton, 78 twin, 54 triplet and 4 quadruplet pregnancies:

– 266 women were still pregnant at the end of the first trimester, another 10 pregnancies were lost during the second trimester, 32 pregnancies still continued, and there were no data available for 9 pregnancies. Finally, 215 pregnancies resulted in 279 live-born infants.

– To verify the PGD result 42 per cent of all foetuses were studied during pregnancy by means of invasive prenatal diagnosis, using amniocentesis or chorionic villus sampling[478]. Seven diagnostic errors were identified which led to 4 abortions.

– A total of 15 selective fetocides were performed in 9 higher-order multiple pregnancies.[479]

– Health data are available for 180 out of 279 live-born infants, indicating that 12 out of 180 (6.6 per cent) were born with malformations and 76 (42 per cent) suffered neonatal complications of which 3 babies died.

The following success rates were determined:

– If clinical pregnancies are related to embryos transferred, the success rate is 8.7 per cent (309 clinical pregnancies/3,524 embryos transferred).[480]

– If live births are related to the total of cycles started (so-called baby take-home rate), the success rate is 10.7 per cent (215 births/1,996 cycles).[481]

On average, about 60 egg cells were fertilised per live-born child (279/16,809), about 48 embryos biopsied (279/13,417) and 12.6 embryos transferred (279/3,524).

1.4.1.1.6 Totipotency

The question of the potentiality of early embryonic cells plays an important role for the admissibility of PGD, especially in the light of the legal situation prevailing in Germany.

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[478] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 244 (Table XIX). For more information on the various methods of prenatal diagnosis, see 2.2.2 Diagnostic techniques.

[479] Cf. European Society of Human Reproduction (ESHRE) 2002, p. 242 (Table XIV).

[480] In comparison, the data for 2000 cited in the 2001 German IVF Registry result in a success rate of more than 26 per cent (see C1.2.4.2.4.3 What is the success of assisted reproduction – and how often does it occur?).

[481] There were a total of 279 live-born babies, another 32 pregnancies with 43 foetuses had not yet been completed, and for 14 foetuses data were not available. The rate determined is below those of the 2000 DIR for 1999 (about 16 per cent). See also C1.3.2.4.3 What is the success of assisted reproduction – and how often does it occur?

There are at least four different definitions of totipotency[482]:

– the ability of cells to differentiate into all three embryonic germ layers;

– the ability of cells to differentiate into all cell types of an organism;

– the ability of cells to colonise the germ line when injected into foreign blastocytes;

– the ability of a single cell to develop into a viable individual.

Only the fourth definition should be pertinent with regard to legal regulation; it corresponds to Sec. 8 of the German Embryo Protection Act.

Most empirical studies, however, are based on one of the first three definitions. For this reason alone, caution is advisable when referring to such data. Furthermore, most findings were obtained in experiments with murine or primate embryos so that it is difficult to make inferences as to humans.

Specialist literature provides many statements as to the exact point in time when all cells lose any form of totipotency: It is often suggested that certainly at the end of the 8-cell stage not all cells are totipotent any more. Other studies emphasise that all embryonic cells have this characteristic up to the 16- to 32-cell stage, i.e. up to the so-called morula stage. It is only afterwards (70- to 100-cell stage) that a certain differentiation begins, with the mulberry-like morula developing into a spherical body (blastocyst) whose surface consists of cells that are no longer totipotent, whereas some of the inner cells in the hollow sphere can still be totipotent.[483]

It is not possible for the time being to make any definitive statements on the totipotency of the individual cells for lack of (human) embryological knowledge. An empirical verification of totipotency in human embryos (in the sense of a single cell's ability to develop into a viable individual) is not possible for legal and ethical reasons.

1.4.1.2 Statutory provisions (national/international)

At present, PGD is not used in Germany.

The majority view of the legal community is that the legal situation prevailing in Germany precludes the performance of PGD on embryos. Under Sec. 1(1) No. 1 of the *Gesetz zum Schutz von Embryonen* (EschG – Embryo Protection Act) of 13 December 1990, it is

[482] Badura-Lotter 2000, p. 60.
[483] Cf. Denker 2000a, see also Kollek 2000, p. 64ff.

prohibited "artificially to fertilise an egg cell for any purpose other than to induce a pregnancy in the woman from whom the egg cell was retrieved". Furthermore, Sec. 2(1) makes any action a punishable offence that serves any purpose other than to preserve the extracorporeally produced embryo. [484]

Legal arguments are discussed in detail in C1.4.2.2 Legal discussion.

The reader is also referred to the Digression: Ethical criteria applying to the use of human embryos in vitro.[485]

Table 12: Current PGD legislation in Europe and the United States[486]

Country	PGD permitted	Legal regulation	Notes
Austria	No	1992 The *Fortpflanzungs-medizingesetz* (FmedG – Reproductive Medicine Act) permits testing of cells capable of development only if this is necessary to induce a pregnancy (Sec. 1(1)).	PGD performed on "cells capable of development" is not permitted; testing "cells not capable of development" is not explicitly prohibited. The number of egg cells that may be fertilised is limited to the number necessary for promising and reasonable medically assisted reproduction.
Belgium	Yes	Royal decree of 1994. PGD must be approved by local ethics committees, PGD centres are subject to licensing.	Only in the case of medical indication (chromosomal anomaly and/or serious genetic condition) and after proper counselling; number of oocytes to be fertilised not limited.
Denmark	Yes	Law of 1997 Only for couples with a substantial risk of passing on a serious genetic condition.	Compulsory counselling, written consent, number of oocytes to be fertilised not limited

[484] Cf. *Enquete*-Kommission "Recht und Ethik der modernen Medizin" (Study Commission on Law and Ethics in Modern Medicine) 2001a.
[485] See Chapter B Ethical and legal landmarks.
[486] *Sozialministerium des Landes Baden-Württemberg* (Baden-Württemberg Ministry for Social Affairs) 1999, and *Bundesministerium für Bildung und Forschung* (Federal Ministry of Education and Research) 2001.

Finland	Yes	1999	PGD for serious hereditary diseases is already being performed in some laboratories.
France	Yes	1994 PGD admitted in licensed institutions for couples with untreatable serious hereditary predispositions or for chromosomal anomalies.	3 centres are currently licensed. Egg cells may only be fertilised for the purpose of inducing pregnancy, number of oocytes to be fertilised not limited
Greece	Yes	No. PGD centres must be licensed like PND centres. Requirements: counselling and informed consent.	
Ireland	No	No (prohibited by provisions in the Constitution)	
Italy	Yes	No (No statutory ban, provisions in professional code of ethical practice) Bill on assisted reproduction adopted by Lower House of Parliament and currently discussed by Upper House; does not explicitly refer to PGD, but imposes general ban on "every form of selection of embryos and gametes for eugenic purposes".	So far, no known case of PGD.

Netherlands	Yes	No Since 1995, PGD has been performed as a research project at Maastricht University. Health ministry plans to make PGD available in no more than two academic hospitals, and initially for research purposes only.	There must be an indication for PGD, and a serious untreatable genetic condition has to be expected. Review by Governmental Ethics Committee (KEMO). Biopsy is performed at 8-cell stage, with urgent recommendation to perform PND.
Norway	Yes	1994 Act has to be evaluated every 5 years. Proposal for amendment is being expected.	PGD only permitted in the case of incurable genetic conditions if there is an indication for IVF.
Portugal	?	No (Constitutional mandate in Article 67 to regulate reproductive medicine; a 1999 bill was intended to permit PGD if it was conducive to the child's welfare. No discussion at present).	
Spain	Yes	1988 Use of genetic engineering methods for prenatal diagnosis permitted, hence PGD also permitted.	PGD only permitted to assess viability or diagnose genetic diseases with a view to treating them, if possible, or advising against transfer. Approval required.[487] Non-medical selection is prohibited.
Sweden	Yes	1991 Guidelines of the Swedish National Council on Medical Ethics (SMER)	PGD only for suspected serious hereditary diseases leading to early death and for which treatment is not

[487] *Max-Planck-Institut für ausländisches und internationales Strafrecht* (Max Planck Institute for Foreign and International Criminal Law) Freiburg 2001, p. 7.

			available, for sex selection only in the case of sex-linked untreatable hereditary diseases.
Switzerland	No	2001 (*Fortpflanzungs-medizingesetz* [Reproductive Medicine Act]) Additional constitutional provisions.	Article 5 of the Act stipulates the indications for reproductive procedures: "3. Removal of one or more cells from an embryo in vitro and the study of such cells shall be prohibited."
United Kingdom	Yes	1990 (Human Fertilisation and Embryology Act) The Human Fertilisation and Embryology Authority (HFEA) is responsible for licensing and regulating PGD and embryo research.	PGD is permitted at 4 licensed centres to identify genetic or chromosomal anomalies. No PGD for sex selection without medical indication.
Canada	No	No Moratorium by the Canadian government	
United States	Yes Banned in some states.	1996 Public Health Service Act (Federal law). There is no comprehensive nation-wide regulation of PGD. PGD is prohibited in only a few states. In the majority of states, PGD is permitted and restricted to medical purposes or not regulated at all. There PGD may also be used for selective purposes, e.g. sex selection, but also to select other characteristics.	PGD is available in 6 laboratories. The ethics committee of the American Society for Reproductive Medicine (ASRM) has opposed the use of PGD for non-medical purposes. However, it has to be expected that people will avail themselves of the possibility of selection, see case of "Adam Nash".

In summary, it can be said that PGD is prohibited in Switzerland, Ireland, Canada, Austria and some US states. In Belgium, Denmark, France, Greece, Italy, the Netherlands, Norway, Spain, Sweden and the UK, PGD is currently permitted under certain circumstances. The UK and France have adopted specific laws and implementing regulations for the authorities in charge of overseeing the handling and use of embryos; embryo research is permitted within the first 14 days after fertilisation with a view to improving reproductive techniques; in the UK, it is also permitted if it serves to achieve ambitious top-priority research goals.

According to experts, there are only relatively few explicit regulations at present; in some cases, there is also a lack of implementing regulations which would be needed to give the required substance to the relevant legislation (e.g. in Norway).

1.4.2 Current state of the debate

As far as the ethical and legal assessment of PGD is concerned, the following medical and scientific facts were identified as being problematic:

– the production of so-called "supernumerary" embryos;

– the decision taken prior to establishing a pregnancy on what kind of children should be the result of conception;

– the removal of possibly totipotent embryonic cells for diagnosis;

– the health risks IVF carries to the woman and the future child;

– the limited reliability of the diagnosis.

From an ethical perspective, a distinction has to be made between ethical issues that affect the individual and ethical issues that affect society at large.

From a legal perspective, PGD raises both constitutional and criminal law issues.

1.4.2.1 Ethical discussion

1.4.2.1.1 Protection of embryos and individual rights

1.4.2.1.1.1 Interests and rights of the couples/women concerned

For many people, starting a family and having children is an essential part of a fulfilled life.

The argument put forward **in favour of PGD approval** is that it widens the range of choices in terms of reproductive decisions, thus extending procreative freedom.[488]

This position implies that potential parents should have the freedom to decide on using PGD based on their own value system. In this light, PGD and IVF would have to be seen as services of modern medicine that should be offered to so-called high-risk couples to give them the same reproductive opportunities as couples without increased hereditary risks.

It has also been argued that a couple's wish to become the biological parents of a child by means of assisted reproduction, including PGD, should not be regarded as a "claim vis-à-vis society". In any case, this is true in those cases where a couple do not require the statutory health insurance scheme to pay for this kind of medical help. For this reason – it is suggested – the question is not whether society permits such options, but whether prohibiting them would be legitimate. Against this backdrop, it is considered controversial whether the State has the right to deny affected couples access to PGD by imposing a ban. Furthermore, the proponents of PGD claim that it is questionable whether society has the right to expect a couple to forego biological parenthood if the couple only accept parenthood on condition of genetic testing of the embryo. Simply referring the couple to alternatives (foster care or adoptive parenthood or even heterologous insemination) does not justify a ban on PGD. Such alternatives – it is suggested – should be presented in psychosocial counselling, which should also draw attention to the stress that a couple, especially the woman, would have to face in the course of medically assisted reproduction.

On behalf of affected couples or women, it is argued *in favour of* PGD approval that couples that are predisposed to serious genetic conditions have the same right to medical help as couples with fertility disorders in order to fulfil their wish to have a child of their own. In addition - the argument runs - PGD is a lesser burden on the woman's health and creates less psychological stress than PND. It is being suggested that is particularly relevant in those cases where the termination of pregnancy is considered permissible in the light of the future occurrence of a serious disease or disability.[489]

Opponents to the approval of PGD argue that affected couples are *not* in a hopeless conflict situation and that they have to consider life without having biological children. Life without children does not necessarily have to be an unfulfilled life. Involuntary childlessness, it is

[488] Cf. Birnbacher 1999; Schöne-Seifert 1999.
[489] Cf. *Bundesärztekammer* 2000a; Ludwig/Diedrich 1999.

suggested, is not primarily a condition requiring medical treatment in the usual sense, but an issue of unfulfilled expectations in life, which at the same time also encompasses societal and personal values. Although "at-risk couples" who want to have children have to be taken seriously, a right to have a (healthy or genetically tested) child of one's own cannot be conclusively substantiated. After all, it is argued, other people wishing to have children (e.g. singles, homosexuals or persons whose partner does not want to have children for whatever reason) are not conceded such a claim vis-à-vis society, either.[490]

Opponents point out that there are alternative procedures to PGD such as heterologous insemination (generally applied in the case of recessive disorders and in the case of dominant diseases if the male is the carrier) and polar body diagnosis of the unfertilised egg cell as well as adoption and foster care, which both raise issues of child welfare.[491]

It is also argued that given the health hazards associated with hormonal stimulation and interventions, given the heavy psychological stress on the woman comparing with relatively low success rates even after repeated IVF, which could even result in psychological sequelae requiring professional treatment, and given the necessary "verification of success" through PND it is doubtful whether PGD is really less stressful for women than PND.[492]

From this perspective, it is not possible to identify any protective legal rights of the parents which could prevent Government from restrictively regulating PGD. On the contrary, Government would even have the duty to develop a regulatory regime, taking into account the wishes, interests and rights of all those affected by PGD approval.[493]

1.4.2.1.1.2 Interests and rights of the children conceived

In order to legitimate PGD and PND reference is often made in international debate to the child's right to bodily integrity. This view is reflected in the US court decisions on wrongful life.[494] This position is based on the assumption that the child's expected quality of life – if it can be determined by means of PGD or PND – has to be justified vis-à-vis the child.[495]

However, it is doubtful whether, from the child's perspective, the parents can be held responsible for its genetically determined physical constitution. After all, the child would not

[490] Graumann 1999.
[491] Cf. Kollek 2000.
[492] Cf. *Deutscher Ärztinnenbund/Ausschuss für Ethikfragen* (German Association of Women Physicians / Committee on Ethical Issues) 2001.
[493] Mieth 1999a.
[494] Cf. C1.3.3.5 Wrongful birth.

even exist if its parents had prevented the development of a child of such genetic predisposition. Such "arguments of compassion" in favour of PGD approval are rejected with a view to the realisation that all children and all human beings depend on being unconditionally accepted by their parents and by society as a whole. Making allowance for the perspective of the children conceived would be reduced to absurdity by questioning the claim of all human beings for recognition and care (prevention of their existence).[496] It is doubtful whether the "argument of compassion" can be seriously put forward in Germany.

Another argument presented against PGD approval while invoking the rights and interests of the child conceived is that high expectations on the part of the parents vis-à-vis a child born after IVF/PGD could add a problematic twist to the parent-child relationship. The fact that the child knows that his or her acceptance by the parents was contingent on a certain genetic make-up might burden the relationship with the parents.[497]

Of all the diseases and disabilities described as severe, the largest part by far (about 80 to 90 per cent) is not attributable to genetic make-up, but caused by complications during pregnancy and birth, as well as by diseases or accidents that occur later in life. Against this backdrop, it is suggested that couples who make their willingness to be considerate parents contingent on a guarantee of a healthy child without disability should subject their motivation and suitability to thorough scrutiny. Not even PGD can guarantee that the child will be healthy and without disability.

Another aspect is that injuries to the child may be caused by PGD and IVF. Long-term consequences of PGD for the child (as a result of cell retrieval at very early developmental stages) have not yet been identified. However, in the final analysis, they cannot be completely ruled out. In addition, there might be possible damage due to the consequences of IVF (e.g. in the case of multiple-foetus pregnancies), for which parents and physicians would be accountable to the child.[498]

1.4.2.1.1.3 The embryo's right to protection

For several reasons, the performance of PGD is associated with the "consumption" of embryos.[499]

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[495] Neidert/Statz 1999.
[496] Haker 2001.
[497] Cf. Habermas 2001.
[498] Kollek 2000.
[499] Schroeder-Kurth 1999.

Unlike conventional IVF, where all fertilised oocytes – at least if they are kept in a culture beyond the pronuclear stage – are transferred into the uterus, PGD in high-risk couples is deliberately geared toward the selection and non-transfer of embryos with genetic impairments.

In addition, it cannot be precluded that biopsy might lead to the loss of embryos. This is why the demand for embryos per IVF treatment might rise in connection with PGD (sometimes up to ten fertilised oocytes are reported, whereas for conventional IVF only one to three embryos are needed per treatment). If the cells used for biopsy (depending on the time of removal) are totipotent, they can also be regarded as embryos (artificially produced monozygotic twins). However, the period of transition from totipotency to pluripotency is the subject of controversial debate within the scientific community.[500]

There are two ways in which PGD can lead to "consumption" of embryos.[501]

Whether embryo "consumption" in the context of PGD is considered ethically justifiable, depends on the moral status accorded to the embryo. Such normative foundations of the various positions adopted in the debate are not always explained, which is why they have to be reconstructed in part.[502]

Philosophical concepts which assume that human dignity is indivisible and derive from this assumption a right to life for all human beings immediately after conception do not consider it possible to weigh the "right to life" of the embryo against any other legal interests. For the proponents of this philosophical concept, it is the foundation of the current legal situation in Germany. They argue that, as a consequence of this concept, PGD cannot be admissible because no inalienable rights of the future parents are at stake.[503]

It is controversial whether, like in a pregnancy conflict, PGD may affect relevant rights of the woman concerned ("anticipated pregnancy conflict").[504]

Some of those who are in favour of PGD approval under certain conditions also assume that indivisible and unconditional dignity must be accorded to all human life at its early developmental stages. However, in their view the respect of human dignity and the basic right

[500] Cf. Denker 2000b, Beier 1999.
[501] Cf. Schroeder-Kurth 1999.
[502] See B1 Human dignity/human rights; Digression: Ethical criteria applying to the use of human embryos in vitro.
[503] Haker 2000.
[504] Wiesemann 2000.

to life are not equivalent. They argue that - unlike human dignity - the right to life can be weighed against other legal interests, but it can only be restricted for the benefit of other top-priority interests. Human life, they maintain, must not only not be injured, but it must also be protected against third parties and, if necessary, against the child's own parents.

They suggest that there is both an ethical and a legal obligation to protect human life. The legal system's duty to provide protection applies to both born and unborn life. As regards prenatal human life, they argue that the legal system's duty to afford protection gains in intensity as the development of the foetus advances. At a very early stage (e.g. prior to nidation or in the first few months of pregnancy), the life interests of the mother can have such a weight that the obligation to protect human life takes second place.

Another position links a graduated concept of protection of life with the notion that human dignity is only gradually acquired as a human being develops. This position, too, permits the weighing of legal interests, which could lead to the conclusion that the protection of human life has to take second place behind other high-priority legal interests. In this case, it is argued that PGD can be considered admissible, if the wishes and interests of the future parents are accorded great importance (gradual or relative protection of human life). Yet another position suggests the use of procedures to weigh the protection of human life against other high-priority legal interests (procedural protection of human life).[505]

Other philosophical approaches make the accordance of rights and the claim to protection of human beings contingent on empirical characteristics which are not present in embryos, such as the ability to suffer and feel anguish, consciousness, self-awareness or the ability to develop self-esteem. For the proponents of this view, the human embryo's right to protection is not the key criterion for the assessment of PGD.[506] When such opinions are expressed in the German debate on PGD, it is pointed out again and again that these views are not compatible with the German Constitution (and its concept of the dignity of the human being). It is also suggested that such definitions are always more or less arbitrary and that they lead to other ethically problematic consequences. Other people to whom the characteristics mentioned do not apply would also be excluded from the community of those accorded human dignity.

Irrespective of all other ethical considerations, most proponents of the concept of absolute or substantive protection of human life find PGD inadmissible because, logically, it includes the

[505] Mieth 2000.
[506] Singer/Dawson 1993.

possible killing of embryos. Conversely, not all proponents of other concepts feel that PGD should be permitted. Taking into account other considerations, supporters of the procedural or relative protection of human life in some cases arrive at the conclusion that PGD should not be permitted.[507] This is why it would be unacceptable to narrow the issue of the ethical legitimacy of PGD down to the controversy over the use of human embryos.

1.4.2.1.1.4 Inconsistent assessments of preimplantation genetic diagnosis and prenatal diagnosis

In the debate on PGD, it is often pointed out that current social practice reflects contradictory value judgements: it is argued that it is inconsistent to have, on the one hand, a social practice involving broadly-based establishment of PND and the use of contraceptive methods that begin to act after fertilisation, and on the other hand, a ban on PGD. In view of such inconsistency, it is argued that a general ban on PGD can hardly be justified. Given the social acceptance of IUDs, the pill for the morning after and the early termination of pregnancy, critics suggest that this inconsistency should be resolved in favour of approving PGD.[508]

Proponents of women's issues, in particular, repeatedly asked that it should be borne in mind whether the embryo was in a Petri dish in a laboratory (as would be the case with PGD) or in a woman's body (as would be the case with IUDs, the pill for the morning after, abortion). They suggested that, based on a woman's right to physical and psychological integrity and her right to self-determination, a woman could refuse to develop a relationship of loving care with the embryo growing inside her. They argued that if the embryo was in a woman's body, the State could only intervene to protect it at the price of forcing the woman to carry her pregnancy to term and give birth. In the case of PGD, however, they maintained that the woman was not yet pregnant and hence her right to physical integrity and self-determination was not directly affected. They felt that, given this situation, their views and assessments were not inconsistent.[509]

The argument in favour of approving PGD, however, is that in the case of PGD an "anticipated pregnancy conflict" has to be expected. The reason cited is that the assumption of a pregnancy conflict as a result of a medical indication (i.e. if the child is expected to be disabled) also calls for a prognosis regarding the situation after the child's birth. This

[507] Cf. Düwell 1998.
[508] Cf. Woopen 1999.
[509] Cf. Graumann 2002.

prognosis, however – it is reasoned – can already be made before an embryo is implanted, and a woman cannot be forced to tolerate the implantation of "damaged" embryos.[510]

Proponents of a position that contradicts the arguments claiming that there is an inconsistency in the assessments of PND and PGD generally suggest that, in the case of a termination of pregnancy, the protection of the embryo's life may be disregarded only because of the predicament in which the pregnant woman finds herself. However, in the case of PGD, the existence of such a predicament is disputed. The intentional production of embryos and their selection according to genetic criteria – it is asserted – are based on rational considerations. It is argued that the alleged conflict is only brought about by medical intervention (IVF and genetic diagnosis), and that – against this backdrop – the *in-vitro* production of embryos with a view to selection is an action that cannot be ethically justified by invoking the rights of the woman concerned. Consequently, it is felt that it is inadmissible to speak of an "anticipated pregnancy conflict".[511]

1.4.2.1.2 Societal consequences

1.4.2.1.2.1 Possibilities of limiting indications

It may be assumed that there is a consensus in the German debate to the effect that, if PGD is approved, it will be necessary to limit its indications in order to make sure that the establishment of PGD in society will not gain momentum of its own which might produce questionable social consequences.

Several possibilities of limiting indications are currently being discussed:

– A list of indications defined by the legislator or the medical community could limit PGD to particularly severe cases of genetic diseases. This proposal has been questioned, however, in the light of Germany's historical experience. It is argued that a list of indications would be equivalent to stigmatising persons affected by the diseases or disabilities listed, and make targeted eugenic selection a legally established component of the physicians' mission to treat patients. A list of indications, it is claimed, would be strongly suggestive of questionable judgements made in the past on people "not deserving to live".[512]

[510] Cf. Knoepffler *et al.* 2000.
[511] Braun 2001a.
[512] Müller 1999.

– A *general clause*, e.g. referring to a high "risk" of developing a known severe genetic condition, is also considered to be problematic. It opens up considerable scope of interpretation for the attending physician or the couple concerned. This is why – among other suggestions – it has been proposed that an interdisciplinary committee should be set up to review, on a case-by-case basis, whether PGD is indicated and justified. It has also been pointed out, however, that this is a paternalistic attitude vis-à-vis the couple concerned which can hardly be justified. For this reason, it is felt that a general clause cannot effectively restrict the extension of PGD indications in the long term.

PGD is a procedure which is not only relevant for so-called high-risk couples, but also for "normal" patients who want to have children. PGD can possibly help to improve *IVF success rates*, when embryos which are not viable due to chromosomal anomalies are identified and excluded from being transferred into a woman's uterus.

It could be argued in favour of this indication for PGD that involuntarily childless patients are entitled to the best possible therapeutic support to end their childlessness. The non-transfer of embryos diagnosed as abnormal, it is suggested, does not raise any moral issues because the selected embryos would not be viable anyway. This view is supported by the argument that the only intention underlying this indication for PGD is to increase the chances of conception, and not to prevent the existence of a disabled child. So far, however, it has been considered difficult to legitimate, in the eyes of society, the use of PGD in Europe aimed at increasing IVF success rates. In this context, participants in the debate on PGD in Germany have warned against an uncontrolled extension of indications for PGD.

Conversely, the extension of indications for IVF through PGD has also become an issue. It has been suggested that the only hitherto legitimate indication for IVF was a couple's fertility disorder and not the analysis of a child's genetic make-up. Special legitimation would be required for IVF with a view to performing PGD.

PGD can also be used to select a child's sex. Some participants in the international debate accord great significance to a couple's wish to have children of both sexes. In this context (especially in spectacular cases such as the loss of an only daughter or an only son due to disease or an accident), PGD is sometimes considered acceptable ("family balancing"). As demonstrated by a recent case in the USA, PGD can also be used to select embryos with a view to conceiving a child who, after its birth, can serve as a blood or bone marrow donor for

a diseased sibling ("designer baby"). In the German debate, such an obvious exploitation of children for a particular purpose has so far been consistently rejected.

1.4.2.1.2.2 Physicians' treatment mission

With regard to PGD, the question of a shift in the medical community's self-image arises. Medical intervention in the case of PGD aims to prevent the existence of a child with a genetic predisposition to a disease or disability rather than to prevent, mitigate or cure this child's disease.

In this context, the argument is controversial that "in strictly defined exceptional cases and for overriding reasons the community can reasonably expect the individual to forego life". This argument was cited in justification of PGD in the report of the Bioethics Commission of Rhineland-Palatinate of 20 June 1999 and was derived from the exceptional situations of national defence and disaster control.[513]

The counterargument is that such wording as well as the "selective practice" of PND and PGD itself are reminiscent of the fact that once before German physicians – in the name of overriding values and objectives – violated human rights to a fatal extent. We have to learn from this historical experience – so the argument runs – that preventing the existence of disabled persons cannot be reconciled with the medical community's mission to heal.[514]

The objection raised to this is that, if PGD were approved, the physicians' mandate would only apply to the couple or woman concerned. Any medical intervention could only be legitimised by the expected burden for the couple or woman in having a disabled child.[515]

1.4.2.1.2.3 "Reproductive tourism"

To support the case for PGD it was also argued that, if PGD were not approved, couples would obtain treatment in countries where PGD was already established.

Two objections have been raised to counter this argument:

– First, the fact that German couples use medical services abroad does not permit any inferences to be made as to the ethical legitimacy of such services and procedures. The

[513] Ministry of Justice of the State of Rhineland-Palatinate 1999, p. 77.
[514] In Nazi Germany, the prevention of the existence of disabled persons ranged from measures such as forbidding individuals to get married (based on medical opinions) to forced sterilisation and murder masked as "euthanasia".
[515] Cf. Ludwig 2001.

most a reference to "reproductive tourism" can do is to cast doubt on the efficiency of a legal ban.

– Second, empirical data available so far do not indicate that German couples have engaged in "PGD tourism" on a large scale. According to these data, about 45 German couples asked for PGD in Brussels over the past five years.[516]

1.4.2.1.2.4 Freedom of choice and new social constraints

The argument expressed *in favour of* PGD is that reproductive autonomy will increase as new options evolve, and that this is why the approval of PGD should be welcomed as a positive societal development.

The argument used *against* PGD is that it would entail new social constraints for parents-to-be or expectant mothers. In view of society's expectations and the social pressure for perfection brought to bear on parents-to-be, the question arises whether the decision to use reproductive technologies can really be taken in isolation. If parents did not use the diagnostic possibilities available and if a disabled child were born, they would have to expect comments along the lines of "nowadays this is really not necessary any more!" It is suggested that PND has already triggered such a development within society. If, in future, PGD should be considered the "morally better" alternative (prevention of abortions) compared with PND, the pressure on would-be parents and especially on "high-risk" couples might increase even more.[517]

Some have expressed their fears that this development might support the trend to increase individual responsibility for a disabled child.[518] From the socio-ethical perspective, however, societal developments are not acceptable if they limit the possibility of taking individual and responsible decisions autonomously in the face of serious moral problems.

1.4.2.1.2.5 Stigmatisation of, and discrimination against, persons with disabilities

Arguing *against* PGD, associations for the disabled and the disabled self-help movement claim that PGD would lead to or further the social marginalisation and stigmatisation of, and discrimination against, persons with disabilities.[519]

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[516] Oral communication by Dr. Giselind Berg during the public hearing on 13 November 2000.
[517] Cf. Mieth 1999b.
[518] Wegener 2000; Finke 2000.
[519] *Deutscher Behindertenrat* (German Disability Council)2001.

Countering this argument, it is conceded that it is understandable that people with disabilities feel offended when would-be parents use PND and PGD to prevent the birth of a disabled child. Nevertheless, there is no empirical evidence of a causal link between the use of PND and PGD and an increase in the stigmatisation of, and discrimination against, disabled persons. It is suggested that – quite to the contrary – the disabled self-help movement has achieved an ever increasing social integration of disabled persons in recent years in spite of the broad-based social acceptance of PND. It is claimed that for this reason, stigmatising and discriminating tendencies would not increase, even if PGD were to become an integral part of medical practice.[520]

This argument, in turn, is countered with the assertion that the stigmatisation of people with disabilities is an inherent characteristic of the practice of PND and PGD. According to this line of reasoning, although at present the practice of selective PND and the integration of disabled persons are simultaneous processes, the willingness to integrate the disabled can quickly turn out to be fragile if the use of PND becomes more widespread and PGD is introduced as well. It is pointed out that, after all, it is the objective of genetic diagnosis in the case of PND and PGD to prevent the birth of disabled children. Previous experience with PND, the reasoning follows, also shows that individual decisions can be expressions of internalised views of society as to "what value should be attributed to different kinds of human life" or that such decisions are even taken under the direct pressure of a person's social environment.

It is suggested that it is not the individual decision of a couple or a woman in favour of PND and PGD that is to be considered discriminating, but rather a certain attitude of society which is expressed in the interplay of many individual decisions, social expectations and associated "views as to what value should be attributed to different kinds of human life". Some fear that in this process of changing values within society, increasing discrimination against the disabled and their families and a growing lack of solidarity with them may become socially accepted. This is why on behalf of the disabled persons affected and their families one should refrain from approving PGD.[521]

The argument brought forward against this position is that it is not possible in this respect to detect a relevant difference between PND and PGD and that, after all, PGD is established

[520] Cf. Maio 2001.
[521] Cf. Graumann 2001b.

social practice. The fact that this is so, however, does not at the same time mean that it is also ethical. Such naturalistic fallacies should be avoided when debating this issue.

1.4.2.1.2.6 Positive eugenics

In contrast to PND, a new quality of genetic "selection" is attributed to PGD.[522]

It is suggested that as the knowledge of genetic predispositions increases, it will be possible to select from a group of embryos those that come closest to meeting the parents' expectations. In this context, criteria such as gender, but perhaps also certain predispositions may play a role in the future.

Preimplantation genetic diagnosis, it is argued, makes effective positive eugenics possible for the first time, and permits a *positive selection* among several embryos produced specifically for this purpose, while PND only offers the possibility of *negative selection*. A new quality of options, it is maintained, is accompanied by a new quality of social values.

1.4.2.1.2.7 Paving the way for embryo research and germ-line therapy

PGD is a prerequisite for the development of germ-line therapy. In addition, as already mentioned, so-called "supernumerary" embryos are produced in the process. Against this backdrop, objections to approving PGD are raised on the grounds that it would open the door to "embryo-consuming" research and germ-line therapy.

Such slippery-slope arguments are countered with the defence that there is no empirical evidence that the establishment of PGD practice inevitably leads to specific further developments (embryo research, cloning, germ-line therapy).[523]

Furthermore, it is argued that the potential ethical reprehensibility of any further development (e.g. germ-line therapy) does not permit any inferences to be made to the ethical reprehensibility of the underlying practice (in this case PGD).

It is claimed that, if PGD were approved, the legislator would still have sufficient latitude to ban any undesirable developments.

These objections, however, do not apply to more complex slippery-slope arguments. These arguments claim that the actual possibility of further developments – resulting from the

[522] Testart/Sèle 1995, 1999.
[523] Cf. Maio 2001.

establishment of PGD together with a change of social values as the practice of PGD becomes legitimised – points the development of biomedical practice in a certain direction. This development, it is asserted, tends towards an increasing control of the genetic make-up of offspring and towards an increasing exploitation of human life to fulfil the wishes and interests of third parties. It is stated that such a development is not desirable, but that it is doubtful whether law-makers can curb such a development with the means available to them after PGD has become established practice.[524]

1.4.2.2 Legal discussion

The legal debate on preimplantation genetic diagnosis focuses on three thematic areas:

– the current legal situation under the Embryo Protection Act;

– the compatibility of an approval of, or ban on, PGD with other areas of the protection of prenatal life ("inconsistent assessments"), and

– constitutional issues.

1.4.2.2.1 The legal situation under the Embryo Protection Act

Legal scholars agree that the Embryo Protection Act bans the use of totipotent[525] cells for diagnostic purposes in the process of PGD. Since pursuant to Section 8(1) of the Embryo Protection Act these cells are equivalent to an embryo, their separation comes under the ban on cloning laid down in Section 6(1) and their "consumption" for diagnostic purposes comes under Section 2(1) of the same Act (use for a purpose other than that of preservation). However, if cells that are no longer totipotent are used for genetic analysis, assessments of the legal situation vary.

In some cases it is argued that the use of cells that are no longer totipotent does not conflict with Section 1(1) para. 2 of the Embryo Protection Act, since in the end PGD is aimed at inducing a pregnancy. The potential discarding of genetically abnormal embryos – according to this argument – is merely an undesirable side-effect. It is suggested that Section 3 of the Embryo Protection Act which permits sex selection by singling out specific spermatozoa with a view to preventing a serious sex-linked disease, shows that a selective orientation of reproductive procedures is not precluded *a priori*. It is also argued that in the case of PGD the egg cell is indeed fertilised with the intention to induce a pregnancy with exactly this egg cell,

[524] Cf. Graumann 2001c. In this context the warning – often expressed in the discussion on the introduction of PGD – should be taken into account that a ban on PGD could legitimise germ-line therapy. Preimplantation genetic therapy as an optional procedure in the process of PGD is also being discussed.

[525] For the concept of totipotency, see also C1.4.1.1.6 Totipotency.

albeit with the proviso that the feared genetic defect is not diagnosed. According to the general rules of criminal law, an objectively qualified intention is equivalent to an unqualified intention. It follows from this that in the case of PGD criminal liability pursuant to Section 1(1) para. 2 of the Embryo Protection Act does not apply.

To support the argument that PGD and the Embryo Protection Act are incompatible, it is maintained that inducing pregnancy at the time of artificial fertilisation with exactly that produced embryo is not intended. Consequently, the purpose required in Section 1(1) para. 2 does not exist. It is claimed that at the time of artificial fertilisation there is no specific intention regarding the use of the embryo – either to induce pregnancy or to "discard" it – (not even an objectively qualified intention). At this point, it is still unknown whether or not the embryo has a genetic defect. Therefore, following this line of reasoning, the will of the physician cannot be directed at either of the alternatives for action. It is exactly the intention to perform a genetic diagnostic procedure, it is suggested, that shows that in the case of artificial fertilisation the decision to induce a pregnancy has not yet been taken. Otherwise, the embryo could be transferred without such a genetic test.

It is argued that the protection of human life, as intended by the legislator when adopting the Embryo Protection Act, quite clearly refers to an individual human life and hence to an individual embryo. This is why in its ruling of 28 May 1993[526] on the Abortion Act, the Federal Constitutional Court stated in head note 2:

> "The obligation to protect unborn human life refers to an individual's life, not only to human life in general."

It is claimed that the reference to Section 3 of the Embryo Protection Act only applies to the selection of spermatozoa to *prevent the development* of genetically damaged embryos, but does not justify "discarding" embryos which *already exist*.

1.4.2.2.2 Inconsistency of the norms enshrined in the Embryo Protection Act and other legal regulations

In the debate on PGD, it is felt that there is a contradiction between the extensive protective provisions of the Embryo Protection Act and other legal regulations applying to unborn human life

[526] German Federal Constitutional Court 88, p. 203ff.

It is suggested that, while the Embryo Protection Act imposes very restrictive rules on the use of artificially produced embryos, the level of protection for embryos that have developed naturally in the womb is much lower, since prior to completion of the nidation process, naturally conceived embryos are not protected at all under criminal law (Section 218(1) sentence 2 of the Criminal Code). It has also been pointed out that in the ensuing weeks of embryonic development, the provision on counselling makes it possible to perform abortions on a large scale with impunity (Section 218a (1) of the Criminal Code), and that, if any genetic or other prenatal damage is diagnosed, a termination of pregnancy for embryopathic reasons is possible as part of a medical indication even without a time limit (Section 218a(2) of the Criminal Code). It follows that, if embryos or foetuses at much more advanced stages of development can be killed *in utero* legally or without impunity, it is not possible to justify a ban on PGD without contradictions and inconsistencies.

Above all, an analogy is drawn to the admissibility of abortions for embryopathic reasons.

It is argued that the existential conflict that is presumed to arise from a medical indication and which confronts a pregnant woman in the case of the birth of a disabled child, can be "anticipated"; in the case of artificial fertilisation, it has therefore to be taken into account even before the transfer of a genetically abnormal embryo.

Consequently – the argument continues – PGD has to be equated to an anticipated prenatal diagnosis. If PGD is referred to as "conception subject to recall", this is merely in keeping with the "pregnancy subject to recall" which is already made possible by prenatal diagnosis in conjunction with Section 218a (2) of the Criminal Code.

This line of argument is challenged by the statement that in different situations and contexts different legal consequences are justified.

The proponents of this position insist that this view does not prejudice the fundamental valuation of unborn human life in terms of its constitutional status and protectability. It is put forward that the provisions governing the termination of pregnancy are primarily based on the assumption that there is a unique physical tie between the embryo and the pregnant woman (the Federal Constitutional Court describes this as a "duality in unity"); this tie, however, does not exist in the case of *in-vitro* fertilisation and hence not in the case of PGD, either.

In the case of a natural pregnancy, it is maintained, the protection of the embryo can only be enforced with the co-operation of, and not against, the mother. The use of assisted

reproductive techniques permits greater possibilities of intervention in favour of the embryo. The State in particular, it is suggested, could effectively influence physicians (e.g. using measures of criminal law) to refrain from performing *in-vitro* fertilisation with the aim of selective diagnosis.

It is also claimed that there is a difference between an existing pregnancy conflict and an "anticipated" one. In the case of PGD, people do not respond to an existing conflict, but the conflict is quite consciously taken into account right from the beginning, and the conflict as such would not have arisen in the first place without *in-vitro* fertilisation.

Under current law, it is maintained, a "pregnancy subject to recall" is possible *de facto*, but the law does not approve. In 1995, law-makers abolished the "embryopathic indication" under Section 218 of the Criminal Code. This is the reason, it is pointed out, why there can be no such thing as a right to "conception subject to recall".

It is argued that if there is indeed an inconsistency in the assessments of the substantive protection of embryos, on the one hand, and the provisions governing the termination of pregnancy, on the other, this alone will not support the case of PGD, for the decision on which level of protection should be realised in the case of PGD – the level of protection laid down in the Embryo Protection Act or that laid down in the Criminal Code – requires a justification in its own right.

1.4.2.2.3 Discussion of constitutional law issues

In the discussion of the constitutional aspects of PGD the following arguments in particular are put forward to support the case of PGD:

– An embryo produced outside a woman's body is not yet a carrier of human dignity (Art. 1(1) of the German Constitution); this would require the embryo to be recognisable, to a certain extent, as a human being. Nevertheless, even if the embryo were accorded human dignity, it is doubtful whether discarding the embryo after PGD would constitute a violation of human dignity in addition to violating the right to life.

– The embryo is entitled to the protection of its life (Art. 2(2) sentence 1 of the German Constitution). However, the legislator can restrict the right to life in favour of other legal interests and concerns (Art. 2(2) sentence 3 of the German Constitution). Regarding PGD, protectable third-party rights exist, especially the rights of the future parents, which justify

discarding genetically damaged embryos. At least there is no compelling reason why a ban under criminal law should be imposed.

– Article 6 of the German Constitution (protection of marriage and family) – alternatively also Art. 2(1) of the German Constitution (general personal freedom) – also grants the right to procreation. Couples cannot be denied the right to take advantage of the medical possibilities offered by PGD in order to conceive genetically tested children.

– As regards the demands to ban PGD, the freedom of research and science (Art. 5(3) sentence 1 of the German Constitution) and the freedom to practice the medical profession (Art. 12(1) of the German Constitution) also have to be taken into account.

– When weighing conflicting basic rights, it must be considered that not only the embryo's right to life and physical integrity is affected, but also that of the mother. A potential misuse of PGD or the danger of its extension beyond strictly limited indications cannot serve as arguments against the approved use of this technique. Statutory limitation has to be given priority over a ban under criminal law (principle of proportionality).

– Another aspect to be weighed is that as the embryo is developing, its protectability increases. At the first stages of development, the level of protectability of the embryo conceived outside the womb is low and hence can take second place to other legal interests.

– Finally, it must be taken into account that in the end only the woman concerned can decide on the transfer of embryos. If this decision-making competence (Art. 2(1) and (2) sentence 1 of the German Constitution) is accepted in the case of artificial fertilisation, it also has to apply in the case of PGD.

The opponents of PGD submit the following arguments **against its approval:**

– At its earliest stages of development the human embryo is protected under Art. 1(1) of the German Constitution. "Conception subject to recall" violates the principle of human dignity guaranteed in the Constitution; the human embryo is not considered to constitute a value in itself, but rather seen as an object and a means to an end. At least, PGD violates the right to life (Art. 2(2) sentence 1 of the German Constitution) in an unjustified manner. When totipotent cells are used to establish a diagnosis and to decide on whether or not an embryo should be discarded, it is human life that is being disposed of. Restricting the right to life of innocent, non-aggressive human beings violates the essence of a basic right

whose protection is guaranteed under Art. 19(2) of the German Constitution. Furthermore, the objective of PGD, i.e. to identify genetically damaged embryos and exclude them from embryo transfer, constitutes a violation of Art. 3(3) sentence 2 of the German Constitution (selection and destruction – not "prevention" – of offspring with a hereditary disease.

– The right of couples to procreate (Articles 6 and 2(1) of the German Constitution) and the freedom of science and research (Art. 5(3) of the German Constitution) do not provide sufficient justification of PGD. The right to reproduce does not include the right to select the genetic make-up of a child. The use of PGD in the process of assisted reproduction does not affect the freedom of science and research. These rights are limited by the overriding right to life and the protection of human dignity. If the State prohibits the possibility of discarding genetically abnormal embryos prior to implantation, it fulfils its constitutional obligation to provide protection.

– Furthermore, a ban on PGD complies with the principle of proportionality. It is not possible to limit PGD to a particular group of people or specific undesirable characteristics on the basis of criteria that are effective in practice. If the indication for PGD is defined in a kind of general clause, a limitation in practice cannot be guaranteed; a limited list of indications stigmatises certain characteristics as "not worthy of life" or "undesirable".

– There is no rationale for an "incremental right to life"; this concept is also at variance with the decisions of the Federal Constitutional Court. It is not possible to determine without any arbitrariness why certain stages in the development of human life should have a "stronger" right to life than others. Following this line of argument, there would also be a "diminishing right to life" as human life draws to a close.

– The analogy drawn by the proponents of PGD with the refusal to perform an embryo transfer after IVF does not apply. In the process of IVF, the refusal to transfer embryos is an absolute exception which has no legal approval, but must be tolerated (non-enforceable statutory obligation of embryo transfer). In the case of PGD, however, it is highly likely that embryos will be discarded; this is taken into account right from the beginning and is inherent in the method applied.

– However, even if after a process of weighing legal interests according to Section 2(1) and (2) of the German Constitution the killing of embryos is considered admissible, and even if it is found that a ban on PGD affects the basic right to self-fulfilment, this does not

necessarily lead to the approval of PGD. Even then PGD will have to be banned or restricted by law, if this is in keeping with the public interest.

– A comparable legal situation exists with regard to the ban on assisted suicide. In spite of the impunity of suicide and the basic right to self-determination of the patient concerned, Section 216 of the Criminal Code makes killing at the request of the person killed a punishable offence. The reason is that the approval of assisted suicide is not in the public interest:

– "If assisted suicide were permitted, every patient in need of devoted and very costly nursing care, but without any prospect of improvement of health, might feel exposed to – at least – an indirect pressure or the unexpressed expectation to relieve their relatives or the general public or both by asking for deadly medication."[527]

1.4.3 Need for regulation and action

The considerable public interest in the use of PGD in Germany and the debate on this subject, which goes far beyond the expert community, highlight the need for regulation.

At present, PGD is not performed in Germany mainly for two reasons:

– According to current opinion, PGD is not compatible with the German Embryo Protection Act.

– In addition, both the proponents and some of the critics of PGD hold the view that clear norms have to be defined and established to avoid any legal uncertainty.

1.4.4 Regulatory options and proposals

Regarding the regulation of PGD, the following options exist whose preference, above all, depends on what legal status the human embryo is accorded, whether a conflict of interests will arise with the potential parents that might possibly have to be settled by way of legislation, and which regulation on PGD is in the public interest.

The members of the Study Commission hold the unanimous view that PGD can only be regulated by the legislator. They feel that the theoretical possibility of non-statutory regulation of PGD is not a feasible solution. PGD is a procedure which at least affects the individual protection of human life as enshrined in the German Constitution (Art. 2(2) sentence 1). PGD

[527] Kutzer 2001.

must be regulated by the German Bundestag, if only because, according to the established practice of the Federal Constitutional Court, issues affecting basic rights must be decided upon by the legislative body. The State has the obligation to define the conflicting basic rights mentioned above by way of legislation, weigh them against each other and, if necessary, grant one precedence over the other.

Consequently, there are two *fundamentally* different alternatives, depending on the appraisal of the basic rights of the embryo:

– If human life is accorded human dignity right from the beginning, there is a legislative necessity to ban PGD.

– If discarding an embryo is considered an encroachment upon its right to life, but not an encroachment upon its human dignity, or if it is considered possible that the guarantee of human dignity will become effective at a later stage in the development of human life, the *legislature has the obligation to put a regulation in place, but at the same time it also has the possibility to balance* the various basic rights affected.

1.4.4.1 Statutory ban on preimplantation genetic diagnosis

Since human dignity is "inviolable" and hence cannot be weighed against the fundamental liberties of third parties, the legislator would have to impose a ban on PGD if, from the very beginning, the developing human embryo could claim human dignity as defined in Art. 1(1) of the German Constitution.

The Supreme Court in Germany has not yet handed down any decisions on this issue. The rulings by the Federal Constitutional Court on the issue of abortion do not contain any binding statements as to whether the human embryo *in vitro* benefits from the protection of human dignity. Nevertheless, the Federal Constitutional Court considers it natural to define the point in time when oocyte and spermatozoon unite as the beginning of human life.[528]

The Federal Constitutional Court does not feel that the ability to reflect upon oneself and to show self-respect is a prerequisite for according dignity to human life.

The above comments lead to the obligation for the State to protect human dignity from the very beginning of human life.

[528] Cf. German Federal Constitutional Court 88, p. 203 (251).

If discarding an embryo is not only an encroachment upon its right to life, but at the same time violates its human dignity, the legislator has the obligation not to approve PGD.

It would also be possible to impose a statutory ban on PGD if this were in the public interest. It is in the public interest to avoid a situation in which parents-to-be feel forced to guarantee the health of their offspring, and in which the chronically ill and the disabled find that their right to exist is questioned.

1.4.4.2 Statutory approval of preimplantation genetic diagnosis

Most proponents of a statutory approval of PGD also agree with the assumption that human life which enjoys constitutional protection begins when the male and female cell nuclei unite.

Some of them, however, do not share the view that human dignity has to be accorded to human life at its earliest stages of development. They consider that it is possible to leave room for weighing and balancing processes in the phase prior to implantation. Consequently, they postulate graduated protection of human dignity, which becomes stronger as embryonic development advances. This protection, they argue, is a modification of the "absolute" protection, independent of development, which the Federal Constitutional Court accords to the embryo after nidation.

They insist that diagnostic procedures to identify serious risks (e.g. diseases or disabilities of the developing embryo, or health risks for the potential mother) do not violate the dignity of the embryo as a potential "person". The focus, they maintain, is rather on the pregnant woman's vital interests that are protected by basic rights; this view is also reflected by the Federal Constitutional Court's ruling on the approval of medically indicated abortions.[529]

As a result, the proponents of this position feel that it is possible to weigh the basic rights of parents and physicians against the embryo's right to life. At the same time, they believe that this situation obliges the legislator to create legal norms.

Some advocates of this position hold the view that if PGD uses non-totipotent cells from the blastocyst for diagnostic purposes and if its final aim is to induce pregnancy, it is compatible with the Embryo Protection Act.[530] Others, however, feel that PGD violates the provisions of this Act.

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[529] German Federal Constitutional Court 88, p. 203 (251 ff.). The argument put forward is in keeping with comments by Herdegen 2001.

[530] On embryo biopsy, see also Section C1.4.1.1.1 Embryo biopsy.

In the latter's view, it would have to be clarified whether a complete ban on PGD procedures – even when cells are used that are no longer totipotent (as defined in Section 8(1) of the Embryo Protection Act) – is unconstitutional; this applies to those cases where risks for the life or physical integrity of a woman that result from pregnancy are to be identified, or perhaps also risks of a serious condition or disability for the developing embryo, and where similarly effective, alternative diagnostic procedures are not available.

Some advocates of statutory approval want the use of PGD to be limited to those couples for whose offspring there is a high risk (at least 25 per cent) of developing a known serious genetic disease due to the parents' genetic predisposition.[531]

They suggest that in order to protect the embryo's vital interests the legislator could impose a complete ban on the attempt – when performing PGD – to realise a potential interest in controlled sexing, in preventing "atypical" or "unsightly" external characteristics or in selecting certain abilities. This should also apply to adult-onset disorders.

They suggest that again there are several options for the statutory approval of PGD:

– One conceivable option is approval under restrictive conditions which could apply to the access to, indications for, and the practical performance of, PGD.

– Another possibility is an institutional solution, such as an ethics committee which would have to review each individual case on an obligatory basis, as well as obligatory counselling for couples and the introduction of licences for performing PGD which are only granted if objective and verifiable quality criteria are met.

– Finally, it is possible to grant approval for a limited period of time only, after which the German Bundestag will have to discuss the issue again on the basis of a report.

– Unrestricted approval of PGD can only be justified if not only the embryo's dignity, but also its right to life increase in the course of embryonic development. In this case, there would be no obligation, and possibly not even a legal basis, for the legislator to restrict any of the parents' basic rights at the earliest stages of embryonic development.

[531] Experts estimate that there are about 80 to 100 couples in Germany every year, cf. oral communication by Professor Klaus Diedrich at the public hearing held by the Study Commission on 13 November 2000.

1.4.5 Appraisals and recommendations

1.4.5.1 Appraisals

1.4.5.1.1 Interests, wishes and rights of couples

The wish to have a genetically related and, if possible, healthy and able-bodied child is quite understandable. For some couples who want to have children this wish apparently has a very high priority. However, this strictly personal decision does not necessarily *oblige* the legislator to approve methods like PGD in order to fulfil this individual wish.

Preimplantation genetic diagnosis of the embryo is a procedure which in certain cases enables couples to reduce the probability of giving birth to a chronically ill or disabled child.

For this reason, some couples regard preimplantation genetic diagnosis as an alternative to prenatal diagnosis. However, because of the relatively great strain on the woman as a result of the necessary *in-vitro* fertilisation and the also relatively high rate of iatrogenic damage to the children due to multiple pregnancies, PGD cannot be considered to be the better alternative. A situation similar to the medical indication of abortion (e.g. risk for the health and life of the woman which cannot be prevented in any other way) does not exist because medical and social alternatives are available. Yet, not every couple is prepared to accept these alternatives.[532]

A person's "right to reproductive autonomy" (Art. 2(1) of the German Constitution) makes it impossible for the State to impose sanctions with a view to preventing individuals from reproducing (e.g. forbidding individuals to get married, forced sterilisation, coercion to terminate a pregnancy). However, this fact does not entitle a couple to *demand* from the legislator that it should provide all medical and technical means to fulfil their wish for a genetically related and, if possible, healthy and able-bodied child or permit the medical profession to provide such means.

A child is not an asset that can be claimed, but a holder of basic rights whose interests must be protected in a special kind of loving and caring relationship. A ban on PGD merely denies couples the possibility of fulfilling their wish for a child *by discarding genetically defective embryos after conception*. So-called high-risk couples can have children of their own through both natural and artificial conception (IVF).

[532] Cf. C1.4.1.1.4 Alternatives.

Desexualised conception as a technical solution to fulfil the wish of individuals to shape their lives in a particular manner opens up a cultural dimension that goes beyond the scope of legislative action. The realisation of this particular wish is no longer a decision taken by individuals or a couple alone in intimate closeness, but it requires the involvement of third parties (extension of the medical mandate).

The right to self-determination may also be restricted if this is in the public interest. This could be the case, for instance, if socially undesirable consequences cannot be prevented even if restrictive rules are introduced.[533]

1.4.5.1.2 Protection of the embryo

The members of the Study Commission agree that the legislator is called upon to guarantee adequate protection for the embryo *in vitro* from the time of karyogamy to embryo transfer.

1.4.5.1.2.1 Protection of the life of the embryo *in vitro*

From the beginning, the human embryo develops as a human being. All criteria used to accord the embryo the right to life at a developmental stage later than the union of oocyte and sperm reveal a certain arbitrariness.

It is not justifiable to make a distinction according to the type of conception (natural or *in vitro*) because in either case the result is human life with the same development potential. The naturally conceived embryo and the embryo conceived "*in vitro*" only differ in terms of their different need for protection:

– A naturally conceived embryo that is present in the woman "*in vivo*" travels through the fallopian tube for about seven to nine days prior to nidation in the uterus and is thus protected by the mother's body right from the beginning.

– An embryo "produced" with the help of ART that is present "*in vitro*" in the laboratory is exposed without any protection to the actions of third parties right from the beginning.

1.4.5.1.2.2 Protection of the dignity of the embryo *in vitro*

Human dignity always has a higher constitutional status and greater weight than any other interests warranting protection. Human dignity cannot be weighed against any other legal

[533] Cf. C1.4.1.1.3 Indications, and C1.4.2.2.3. Discussion of constitutional law issues.

interests. The members of the Study Commission do not agree on whether the human embryo is to be awarded human dignity from the beginning.

A woman is not yet pregnant when the decision is taken to perform PGD. One could only speak of an anticipated pregnancy conflict, if otherwise the woman concerned deliberately started a pregnancy "subject to recall", *with a view to having it terminated* after PGD *in case a medical predicament due to damage that cannot be prevented otherwise has been established by a physician.*

Consequently, the right of a woman to bodily integrity and self-determination cannot be cited as reasons for restricting the protection of the human embryo. There is no dilemma here as in a pregnancy conflict.

In the case of PGD, conception, diagnosis and transfer (or possibly non-transfer) are all in the hands of the attending physician. Taken together, they have to be treated as an object of ethical considerations regarding the legal regulation of PGD.

1.4.5.1.3 Limitation of indications

The establishment of PGD entails the risk of an uncontrolled spread of its use. The instruments discussed above to limit its indications, such as a list of indications or case-by-case decisions taken under deontological control, will hardly be able to prevent an extension of PGD indications in spite of the best intentions of all those involved.

Compared with an already existing pregnancy conflict after PND, the issue underlying PGD is that there is an anticipated situation with which the woman or couple cannot reasonably be expected to cope with.[534]

1.4.5.1.4 Physicians' treatment mission

The request to perform PGD conflicts with the objectives of a physician's mission to treat patients.

The treatment mandate in prenatal care encompasses the prevention of any harm to the health of the expectant mother and her baby. In the case of IVF, the treatment mandate is to overcome (male or female) sterility by means of medical intervention in the woman's bodily integrity with the aim to end childlessness.

[534] Detailed proposals are presented under C1.4.5.2 Recommendations.

In the case of a genetic indication, a woman's or a couple's wish to have a healthy and, if possible, able-bodied child leads to PGD performed by a physician. Physicians perform this procedure in an attempt to avoid a burden on the woman or the couple caused by the relatively high risk of having a diseased or disabled child.

For the analysed embryos this procedure may result in death. The physician does not have a mandate to act for the benefit of the embryo. To anticipate the potential wishes of a child that is possibly born against its will goes beyond the competencies of a physician and also of the potential parents on whose behalf the physician could act.

This implies therefore that in the case of PGD one can hardly talk about a "physician's mission to treat a patient".

1.4.5.1.5 Societal consequences

Making PGD available to so-called high-risk couples possibly involves the risk of arousing the unrealistic expectation of a "guarantee for having a healthy child". It is to be feared that social pressure will be brought to bear on high-risk couples, in particular, to prevent the birth of a disabled child. The parents of disabled children might come under increasing pressure to justify why they did not make use of the diagnostic possibilities available to prevent the child's birth, yet claim public resources for the benefit of their child. There is the concern that for fear of potential liability for the birth of a disabled child, physicians will habitually draw attention to the possibility of PGD, thus triggering an additional demand for PGD services.

The approval of PGD entails the risk of increasing trends in society to stigmatise, marginalise and discriminate against the disabled and the chronically ill.

One particular problem in this context is the interaction of individual decisions and social values which may eventually lead to kind of "voluntary eugenics".

The associated "views as to what value should be attributed to different kinds of human life" can altogether result in furthering developments directed against the disabled. This trend is supported by the media's presentation of the supposed possibility of a guarantee for a healthy and able-bodied child, by the dynamism created by the issues of liability law ("wrongful birth") and economic developments.

1.4.5.2 Recommendations

On 25 February 2002, the Study Commission discussed the recommendations regarding the section on PGD in this report. On that day, 19 members participated in the vote on the recommendations.

1.4.5.2.1 Opinion A of the minority of Study Commission members on limited approval of preimplantation genetic diagnosis

The minority of Study Commission members recommend that preimplantation genetic diagnosis should be approved for couples seeking help due to a demonstrably high genetic risk, subject of the following restrictions.

The question as to whether couples with a high genetic risk should be granted access to preimplantation genetic diagnosis under restrictive conditions depends on whether the legal system can ban this method or whether it must ban it. Under our liberal constitution every statutory ban needs to be legitimised. A ban can only be justified if there is no other way in which higher-priority legal interests can be protected from damage (principle of proportionality). The principle of non-under-regulation compels the legislator to guarantee legal protection of high-priority interests also by means of penal measures if this is necessary to ensure effectiveness.

The advocates of statutory approval of PGD also accept the view that human life as protected under the German Constitution (Art. 2(2)) begins when the male and female pronuclei unite. Views differ on the question as to whether the human embryo is a carrier of human dignity right from the beginning. But even if it is accepted that this is so, it must nevertheless be taken into account that by no means is every encroachment upon the right to life automatically also an encroachment upon human dignity.

Preimplantation genetic diagnosis performed in the process of medically assisted reproduction accepts that human embryos are produced and discarded after their genetic predisposition has been analysed. In this way, human life can be destroyed because it does not meet the expectations and standards of the parents. Arbitrary selection is a violation of a top-priority constitutional right, i.e. at any rate a violation of the right to life of early forms of human life and perhaps even a violation of human dignity. The law cannot accept such a situation. It must always protect and support human life. In addition, protection by way of penal measures is imperative here because the law must clearly show its disapproval of a conscious disregard of human dignity and the right to life.

In the light of these arguments, the Commission recommends that a legal regulation should be put in place which imposes a general ban under criminal law on preimplantation genetic diagnosis as a method of medically assisted reproduction, but which at the same time keeps the option open to forego the enforcement of criminal law in specific cases. In such cases, impunity can be achieved in different ways. The Commission does not submit any definitive recommendations in this respect.

There is a broad consensus in society that there are cases where a mother – especially in view of otherwise foreseeable adverse effects on her (mental) health - cannot be reasonably expected to carry a pregnancy to term and give birth to a child that will presumably have a severe disability.

As demonstrated by the regulation governing the termination of pregnancy which was upheld by the Federal Constitutional Court, the legislator is not denied the possibility of granting impunity in severe conflict situations in spite of the absolute recognition of the human dignity and right to life of prenatal human life.

Consistent answers will have to found to the questions as to whether discarding the embryo after PGD or whether a termination of pregnancy at a later stage due to a conflict situation which would already have been identified by PGD, in each case constitutes an encroachment upon the embryo's constitutional rights. The fact that PGD requires the detour via IVF does not lead to a different appraisal, since the predominant opinion is that IVF is an established method and not ethically reprehensible.

In some cases it is possible even prior to the implantation of an embryo to foresee that a medically indicated termination of pregnancy will be necessary as soon as the embryo has been implanted. This applies in particular to those cases where a previous pregnancy was already terminated due to a conflict situation.

Establishing a medical indication as defined in Section 218a(2) of the Criminal Code requires a hypothetical assessment of the mother's health after the birth of the child. In those cases where a later abortion seems highly probable, discarding the embryo prior to implantation would appear to be the method that causes the least pain for both the embryo and the mother.

Consequently, the approval of prenatal diagnostic procedures conflicts with the ban on PGD in so far as simply by communicating diagnostic results a psychological dilemma is created which results in a pregnancy conflict.

It cannot be disputed that a conflict situation prior to the implantation of the embryo is not identical with a pregnancy conflict. Nevertheless, the severity of the conflict confronting a couple who in the case of natural conception would be faced with a high probability of giving birth to a severely disabled child is identical with the severity of a pregnancy conflict. The couple are confronted with the option of either to forego having children by birth, or to accept the risk of the psychological burden imposed by becoming parents of a disabled child. PGD, on the other hand, can considerably reduce this risk – but it cannot provide a guarantee for a "healthy child". To deny such couples the possibility of PGD means to make it much more difficult for them to realise their wish to become parents.

PGD is an additional indication for medically assisted reproduction. Many people fear that the resulting spread of its use could lead to negative consequences for the couple concerned or for society as a whole.

When these consequences affect the individual couple, they should play a major role in the counselling process prior to IVF. Nevertheless, the decision as to whether they accept such risks in order to have a biologically related child will have to be taken by the couple alone. It is not for the legislator to tell them what to do.

When negative consequences of the increased use of IVF have to be expected, it is the task of the legislator to prevent them. A ban may be considered only if milder means of preventing risks will not be effective in the foreseeable future.

At first glance, the concern may seem plausible that preimplantation genetic diagnosis would adversely affect the position of the disabled in our society. However, there is no empirical evidence that this is really so. In fact, there is no evidence whatsoever that in those countries where PGD is available the disabled are more discriminated against than elsewhere. It is also remarkable that in Germany, after nearly ten years of an almost nationwide practice of prenatal diagnosis, such a development could not be identified. It will be the permanent task of the legislator to make sure that the situation of families with disabled children and the situation of the disabled in general improves. As the practice of predictive medicine expands, it will therefore be an ongoing task to prevent any discrimination against persons with future or already manifest disabilities.

It is not for the legislator to judge whether the renunciation of natural parenthood is to be considered a major or a minor burden. The legislator must be guided by Art. 2, and especially Art. 6, of the German Constitution in which the fundamental constitutional decision was taken

to grant people the freedom to start or expand a family. This freedom is the only basic right in the Constitution that is referred to as a "natural" right.

Article 6 of the German Constitution cannot be construed to grant the right to have a biologically related child, let alone a "healthy child". Of course, nobody must be prevented from fulfilling their wish to become natural parents. Even though the conflict of so-called high-risk couples after PGD is not identical with a woman's pregnancy conflict, it deserves to be taken equally seriously, as outlined above.

From the point of view of legal ethics, it is doubtful whether couples with a high genetic risk may be made the addressees of a ban under criminal law: Since they find themselves in a severe conflict situation, it might increase the strain intolerably if in this way they were put under additional pressure. Bans under criminal law that are necessary to protect human dignity and the right to life of human embryos and to comply with the principle of non-under-regulation ensure a minimum of ethics in a society. As the sharpest weapon of the State, this instrument should be used exclusively for this purpose and not to force a special ethical performance.

Irrespective of more far-reaching ethical obligations resulting from an individual's personal philosophy of life or religious beliefs, criminal law has to make concessions – as in the case of Section 218 of the Criminal Code – which in exceptional cases also imposes clear limitations on law enforcement. Otherwise, the State would knowingly accept that in these cases the law is often violated or intentionally evaded. In such a situation, the law would only be of symbolic significance and would lose the power to shape reality.

In this respect – but in this respect only – the legislator must take into account that some of our neighbouring countries have approved preimplantation genetic diagnosis. Especially when passing criminal regulations, the legislator must be careful to ensure that they are indeed instrumental in providing guidance for the behaviour of affected individuals. When considering the legal systems of neighbouring countries, it is not a question of simply copying them, but of perceiving the reality in which people are living today.

It is only in serious, exceptional cases that it is possible to depart from the general ban on PGD. Furthermore, nobody must be placed under an obligation to participate in PGD. The law must ensure that the fact that in the process of PGD an embryo was *not* discarded, but implanted does not open up the possibility of claiming damages from those involved.

The same applies to a lack of, or incorrect, counselling regarding the actual possibility of being able or permitted to perform PGD.

Should PGD be approved, the indication for that use of PGD which is at issue here has to be strictly limited to those cases where without PGD there is a high probability that the pregnancy will be terminated as a result of a medical indication.

It is imperative to prevent a slippery-slope situation where it could be possible to select embryos in the absence of a conflict situation. Likewise, the number of embryos which are possibly discarded after PGD must be limited to a minimum.

Experience gathered in countries with different legal systems indicates that PGD may involve an increased hormonal stimulation of the women concerned and an increased production of embryos.

The legislator has to make it quite clear that also in the case of a lawful use of PGD the provisions laid down in the Embryo Protection Act must be complied with. PGD must not be approved without such restrictions. Under no circumstances should the relevant statutory provisions be mere "symbolic" legislation; instead, they must be able to develop and shape general practice effectively. As long as such statutory provisions have not been developed yet, no exception to the general ban on PGD must be permitted because its spread – similar to that of prenatal diagnosis – could not be stopped. This, however, could bring about a change in society's general attitude towards the value system regarding the relationship between parents and children. These statutory provisions, which in exceptional cases do not impose any sanctions on PGD, must at the same time provide for a regular review of the effects of such provisions.

In the context of PGD, too, the general risks of IVF have to be taken into account. This applies – among other things – to the issue of handling so-called "supernumerary" embryos.

The minority of Study Commission members recommend that neither a mere list of indications nor just a general clause should be put in place to provide a legal specification of the conditions under which PGD is to be permitted. A mere list of indications could, above all, create the impression that the objective goal of the legislator is not to have to admit into society individuals affected by disabilities of a certain severity. In addition, such a list would not meet the requirement of assessing each individual case, as is the practice with abortions based on a medical indication.

Furthermore, the minority of the Study Commission members recommend urgently that – in view of the expected increase in genetic tests performed in humans before and after birth – all possible efforts should made in the areas of social, health and legal policies to increase the social acceptance of the disabled and chronically ill. In particular, the effect on the behaviour of individuals of the ban on discrimination between private parties should be intensified, a process that has already begun in the areas of private health insurance law (regarding persons entitled to allowances) and tenancy law.

The access to, and performance of, PGD as well as the possibility to review its practical effects should be regulated by law. In order to respond to the risks mentioned above, such law could comprise the following elements.

A.1 Conditions of access to preimplantation genetic diagnosis

Compulsory counselling

Human genetic and psychosocial counselling has to be provided in each individual case, independent of the institution performing PGD. All alternatives to PGD that are less problematic have to be explained and discussed.

Defining the right of access

Preimplantation genetic diagnosis can only be exempt from punishment in particularly serious cases that can be reliably identified. The crucial criterion is whether the conflict situation of those concerned appears to be as hopeless as that of a pregnant woman who would not be obliged under criminal law to carry her pregnancy to term. There are two options that could be used to determine such constellations:

– In order to set clear limits for such cases, a law could define both general and individual conditions of access. General criteria should consist of a list of severe conditions that can be diagnosed by means of PGD. In addition, it should be possible to identify a concrete social predicament comparable to a serious pregnancy conflict in the context of a medical indication for abortion.

– The benefit of such regulation is that, on the one hand, a restriction of the number of serious genetic conditions could contribute to safely limiting the use of preimplantation genetic diagnosis. On the other hand, the requirement that a concrete individual psychosocial predicament should exist emphasises the fact that the impunity of

preimplantation genetic diagnosis is not derived from the genetic defect of the future child, but from the recognition of exactly that predicament.

– However, it is unmistakable that such a regulation also involves major drawbacks: For instance, in spite of the combination with a concrete appraisal of the parents' individual predicament, the list of genetic conditions could give rise to the misunderstanding that the legal system approves of PGD for the purpose of eugenic selection. In addition, it could lead to a stigmatisation of people living with one of the conditions listed.

– This is why another option would not be based on such a list of hereditary disabilities. The necessary limitation could be achieved by combining a general clause, worded as precisely as possible, with a counselling and reviewing procedure. The law in force provides a number of models for this approach.

– However, the problem of every general clause is that its extension in practice does not seem to be impossible. The example of PND, which contrary to the original intentions has now developed into a routine procedure of prenatal care, must not be repeated. At the time, however, the indications defined for PND were not enshrined in a law, but were based on guidelines developed by the German Medical Association. A law will have to ensure that its wording prevents such a development.

A.2 Performance of preimplantation genetic diagnosis

PGD may only be performed in licensed centres. A license will be granted for a limited period of time, based on clearly defined quality criteria that have to be met by the centre in question. Quality assurance measures include obligatory documentation based on a scheme defined by the licensing agency.

Each centre must be obliged to produce not more than three embryos per cycle for the purpose of PGD. The associated disadvantages have to be justified in the light of an extremely complicated process of weighing and balancing.

It must be ensured that PGD is limited to a maximum of three cycles.

Due to the particular sensitivity of the molecular genetic diagnostic procedures to be performed and the expected low number of requests for PGD, it would seem to be appropriate – in order to ensure the greatest possible diagnostic safety – that only one institution should be entrusted with performing the diagnostic procedures.

A.3 Reviewing the practice of preimplantation genetic diagnosis

An appropriate agency, co-located with the responsible federal government department, should be set up to grant and review PGD licences. This agency will monitor and collect the reports to be prepared by ethics committees and PGD centres. After two years, a report will have to be submitted to the German Bundestag, containing all the information necessary to judge whether or not the practical use of PGD has adequately met the objective of the legislator's constitutional mandate.

For the practical implementation of the key points mentioned one should – if appropriate – draw on detailed proposals, e.g. those of the German Medical Association.

Aside from the immediate impact of PGD, particular attention should be paid to societal effects because the selection potential of PGD is a special challenge for everyone.

Prior to potential approval of PGD, the legislator must ensure that legal regulations governing medically indicated abortions are practicable. Concerns that such regulations are applied in a way not conforming to the law were expressed especially with regard to so-called late abortions. If necessary, this situation has to be remedied by means of supplementary regulations. In any case, an approval of PGD would have no basis whatsoever without truly practicable regulations.

The legislator cannot be indifferent to the question as to whether its regulations really shape reality in Germany or whether they are evaded because people go abroad to take advantage of methods that are prohibited in Germany. German citizens will only continue to respect our value system, if our legal code is really enforced. This is why it is of great importance that couples have access to PGD in most EU member states – albeit at their own expense. However, this does not imply at all that we "have to do what others are doing" or "because they are doing it". Rather, we have to prevent the imminent decline of the values we recognise and create a legal system which is socially stable and sustainable even in the face of easily accessible opportunities in other European countries. Otherwise the consequence might be that society develops a cynical attitude towards decisions on constitutional values.

It is up to the legislator to prevent this consequence, i.e. the divergence of legal system and legal reality.

At the vote taken on 25 February 2002, the minority within the Commission consisted of: Margot v. Renesse, Professor Edzard Schmidt-Jortzig and Professor Klaus Tanner.

1.4.5.2.2 Opinion B of the majority of the Study Commission members on the rejection of preimplantation genetic diagnosis

The majority of the Study Commission members recommend that the German Bundestag should not approve PGD in Germany and should specify – explicitly with regard to PGD - the ban on *in-vitro* fertilisation for diagnostic purposes as laid down in the Embryo Protection Act.

B.1 Protection of the embryo

Preimplantation genetic diagnosis cannot be reconciled with the protectability of the human embryo which derives from human dignity.[535] In the process of PGD, human embryos are deliberately produced *in vitro* with the proviso of discarding them, if the genetic test identifies an undesirable genetic trait. This procedure therefore leads to the destruction of human embryos, even if the diagnosis is performed on cells that are no longer totipotent. If totipotent cells are used for diagnostic purposes, an artificially produced "twin" is used and consumed as diagnostic material. For this reason, the majority of the members of the Study Commission are of the opinion that PGD violates both human dignity (Art. 1(1) of the German Constitution) and the right to life (Art. 2(2) sentence 1 of the German Constitution).

B.2 Rights of the woman or couple

All couples have the freedom to start a family by producing offspring. This "right to procreation" must be generally recognised under Art. 2(1) (general freedom of action) and Art. 6(1) (protection of marriage and family) of the German Constitution. It is perfectly admissible to take advantage of medical help to achieve the end of reproduction. The State must not arbitrarily impose a ban on certain reproductive techniques.

Nevertheless, the use of *in-vitro* reproductive techniques does not entitle the parents after conception to deal with the embryos at their discretion. The right to life, as protected under Art. 2(2) sentence 2 of the German Constitution, and the obligation to protect human dignity, as laid down in Art. 1(1) of the German Constitution, must be observed also with regard to embryos showing a predisposition to a disease or disability. The ban on discrimination must be complied with as well (Art. 3(3) sentence 2 of the German Constitution). The State has the right and the duty to prevent the production of human embryos, if they are produced with the proviso possibly not to use them for inducing a pregnancy.

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[535] As far as the debate on the protection provided by the guarantee of human dignity is concerned, cf. B1 Human dignity / human rights, especially 1.4.1 To whom does the protection of human dignity apply?

There is a fundamental difference between selection prior to implantation into a woman's uterus and the situation prevailing in the case of an already existing pregnancy. Pregnancy is the most intensive bodily and social relationship of a woman as an expectant mother with the child growing inside her body. In case of a conflict, a woman's right to physical integrity and self-determination is diametrically opposed to the protectability of the embryo. An abortion is only exempt from punishment if there is a genuine situation of conflict where a decision has to be taken, weighing the embryo's right to life, on the one hand, and the mother's right to life and to physical and psychological integrity, on the other, and where otherwise the legal consequence would be tantamount to forcing the woman to give birth.

In the case of PGD, however, conception is planned subject to recall and performed by means of artificial reproductive techniques. Especially in view of the "anticipation" of a conflict situation, the legislator should intervene by way of regulation and demand that embryos "to be disposed of at discretion" should not be produced in the first place.

The rules applying to the medical indication under Section 218a of the German Criminal Code also show that the search for acceptable alternatives is to be given preference over the destruction of embryos. Pursuant to Section 218a (2) of the Criminal Code, a termination of pregnancy is only justified if the conflict "cannot be averted in any other way that would be acceptable to the pregnant woman". So the primary task is to find other acceptable ways out of the dilemma. Naturally, this is more difficult when a pregnancy already exists and the child is growing in the mother's womb, and especially so, when there are circumstances which directly affect the mother's health and which in the worst case might even threaten her life. In the case of PGD, however, it is possible to avoid the actual occurrence of this danger by not artificially producing any embryos in the first place.

Consequently, there is no inconsistency in the regulations governing a termination of pregnancy and a ban on PGD. This also applies to the analogy which is drawn with the actual possibility of a "pregnancy subject to recall" in the case of PND. Of course, a woman could become pregnant several times and possibly, after PND, each time claim a medical indication due to the burden caused by a disabled child, until the desired able-bodied child has been conceived. This approach, however, is not in keeping with the intention expressed in the current version of the rules governing the medical indication. Instead, this constitutes an abuse of the current legal provisions. Even though it will hardly be possible to prevent such – certainly rare – behaviour, this fact cannot have a positive normative effect in favour of PGD.

The wish of so-called high-risk couples to have children has to be respected and supported within the limits of what is possible and justifiable. The majority of the Study Commission members recommend that the German Bundestag – by way of a legal regulation – should create an environment where these couples are granted priority access to counselling regarding the possibilities of adoption, foster care, heterologous insemination or polar body diagnosis with IVF, and where they are offered psychological counselling on a priority basis, with a view to assisting them in coping with involuntary childlessness.

B.3 Rights of the physician

Although a ban on PGD affects the free exercise of a profession (Art. 12(1) of the German Constitution), it does not affect its core area, i.e. the physician's mission to cure. This mission does not include the mandate to select embryos conceived *in vitro* because in the case of PGD a "patient" in the narrower sense of the term does not exist as beneficiary of the mission to cure. At most, a mandate to perform PGD can be defined as the parents' request for services. In the final analysis, though, restricting the freedom of practice of the medical profession in favour of the protection of the life of human embryos is justified.

The constitutional obligation to try and reconcile conflicting basic rights in the most considerate way possible means, in the case at hand, that the protection of the embryo has to be given priority. On the one hand, life as "the vital basis of human dignity and the prerequisite to all other basic rights"[536] is at stake; on the other hand, basic rights are affected which are of much less existential significance.

To the extent that psychological problems associated with involuntary childlessness can qualify as a disease, parents can reasonably be expected to accept such impairments in favour of the protection of the embryo.

The physicians' freedom to practice their profession is only marginally affected by the ban on PGD and also has to take second place when being weighed against the right to life.

B.4 Social policy considerations

It is the task of the legislator to promote equal rights of men and women and thus improve the position of women in society (Art. 3(2) of the German Constitution). Chronically ill or disabled children can impair a woman's career prospects and constitute an additional poverty risk especially for women because in most cases women bear the main responsibility for child

[536] German Federal Constitutional Court, decision of 25 February 1975, BVerfGE 39, p. 1 (42).

care, and nowadays marriage and family no longer provide adequate social protection. However, the belief that preimplantation genetic diagnosis could prevent ill or disabled children entails the risk that women will be burdened with even more individual responsibility and that they will come under social pressure to use this technique in order to ensure the birth of a healthy child. This will trigger a negative social development. In this light, preimplantation genetic diagnosis is a technical solution to a social problem which due to this very fact could be aggravated even more. Instead, priority should be given to easing the burden on women by introducing adequate social policy measures.

The hazards to a woman's health caused by IVF, which in turn is a prerequisite for PGD, are quite considerable and out of all proportion to the use of the procedure in women who are in fact fertile. Social policy considerations should also take into account the low success rates of PGD with IVF as well as quite a substantial number of diagnostic errors and an increased rate of multiple pregnancies involving additional risks for mother and children.[537]

Based on the principle of non-discrimination against persons with disabilities, as enshrined in the German Constitution (Art. 3(3) sentence 2), the legislator is obliged to create an institutional framework that prevents discrimination against persons with disabilities.

If the legislator approves the establishment in medical practice of procedures to "select and discard" embryos with genetic defects, negative effects have to be expected on people's attitude towards the disabled. Approval of PGD therefore entails the risk of encouraging tendencies in society to stigmatise, marginalise, and discriminate against, persons with disabilities. The availability of prenatal selective procedures can change the social climate and increase the expectation of society that people with certain genetic risks should only have children if they make use of these procedures.[538] This attitude is accompanied by a latent trend to apportion blame and require a justification when children with the genetic trait in question are born. Couples with "a high genetic risk" could be denounced as "negligent" when they conceive children without PGD. There is the risk that in the light of such attitudes private insurers or public agencies might deny these couples any benefits and instead point to their "individual responsibility".

[537] The most recent international survey on PGD documents 1,561 cases (couples) of which 156 couples became parents of singletons, 108 parents of twins and 5 parents of triplets. Accordingly, the baby-take-home rate is only 10.7 per cent. In addition, the study documents 8 diagnostic errors, 4 children were born with diseases, 4 pregnancies were terminated after PND. See European Society of Human Reproduction (ESHRE) 2002, pp. 233-246. See also C1.4.1.1.5 Application.

[538] Cf. e.g. the results of surveys in Nippert 1999, p. 78.

For these reasons, the approval of PGD would have a negative impact on both the position of women in society and the integration of persons with disabilities. The majority of the members of the Study Commission recommend that in order to respond to the above-mentioned risks of poverty and career disadvantages for women and men living with disabled persons and nursing sick people, the German Bundestag should take adequate measures to ease their financial burden, relieve their psychosocial stress and reduce the demand on their time. In addition, appropriate measures have to be taken to enable persons with disabilities, impairments and chronic diseases to lead independent, autonomous lives. The integration and equal status of persons with disabilities should be promoted through an anti-discrimination law.

B.5 Impossibility of imposing a precise limitation on indications

In the German debate, only very few voices call for unrestricted approval of PGD. This goes to show that PGD is a procedure which even its proponents consider to be problematic, and in fact, in need of restrictions. Realistically speaking, however, proposals for a "restrictive approval" of PGD are doomed to fail:

– Restricting PGD to "couples whose offspring are greatly at risk of developing a known serious genetic condition"[539] would not result in a clear limitation and would permit too much scope for interpretation. In addition, even human geneticists cannot agree on what a "serious" condition really is.[540] A "general clause" describing the applications of PGD is therefore considered to be unsuitable to limit the use of PGD.

– The criterion of acceptability to the woman concerned[541] is based on an analogy with the medical indication as defined in Section 218a of the Criminal Code[542]. The birth of a child with a certain impairment is considered an unacceptable burden on the parents and an impairment of the woman's health. This "anticipated unacceptability", however, cannot be judged objectively, but in the end can only be left to the woman's or couple's subjective

[539] Cf. Bundesärztekammer (German Medical Association) 2000a.
[540] See Nippertc, pp. 299 and 318 (Table 15).
[541] Cf. Bundesärztekammer (German Medical Association) 2000a.
[542] Section 218a (2) of the Criminal Code: "A termination of pregnancy carried out by a physician with the consent of the pregnant woman shall not be unlawful, if in the light of medical knowledge, and considering the current und future living conditions of the pregnant woman, the termination of pregnancy is indicated to avert a danger to the life, or risk of a serious impairment of the physical or mental health, of the pregnant woman, and if this danger cannot be averted in any other way that would be acceptable to the pregnant woman."
Draft discussion paper for a guideline on preimplantation genetic diagnosis: "The severity, therapeutic possibilities and prognosis of the disease in question are of crucial importance. The crucial factor is that this disease could lead to a serious impairment of the health of the woman seeking to become pregnant or of the expectant mother". (Bundesärztekammer 2000a, A 526, 2. Indikationsgrundlage).

discretion. The institution of deontological review committees would therefore not be a suitable means of limiting the range of PGD indications.

– A binding list of indications would lead to the stigmatisation of certain diseases and would establish views as to what value should be attributed to different kinds of human life that conflict with the constitutional principle of equal treatment. In addition, there are historical reasons speaking against a list of indications.[543]

The problems inherent in each of these models cannot be resolved by combining various preconditions to access, either.

It can be observed in other countries that PGD is also used in the process of IVF as a screening method to identify chromosomal anomalies.[544] This extension of the range of indications cannot be prevented in the long term, if PGD – at first in exceptional cases only – becomes an approved procedure. If PGD is made available to couples with a "high" genetic risk, those couples who undergo IVF treatment anyway and who, for instance, have a statistically higher risk of having a child with a chromosomal disorder due to the mother's age, will also insist on a genetic analysis of their embryos. An extension of PGD practice to include its use as a screening method to be applied in the IVF process can only be prevented by a complete ban on PGD.

Major concerns are also raised by the use in some countries of PGD for "social sexing" and for producing a tissue donor for diseased siblings.[545]

Consequently, a lasting limitation of PGD indications is either improbable or even impossible; if PGD were approved in Germany, a gradual extension of indications – as already observed internationally – would have to be expected.

The quantitatively increased possibility of selecting from several embryos can turn into a new quality in PGD because social or aesthetic criteria can be applied when choosing among the embryos produced. Furthermore, no compelling logical arguments will be left to argue against

[543] Cf. Maranto 1998, pp. 109 and 119. The Prevention of Offspring with Hereditary Diseases Act adopted in 1933 contained such a list.

[544] Today, 14.2 per cent of indications internationally are accounted for by so-called aneuploidy screening. Cf. European Society of Human Reproduction (ESHRE) 2002.

[545] Today, there are at least three centres in Europe that offer PGD services for social sexing. In addition, two requests have been documented for PGD for the purpose of HLA tissue-typing with a view to conceiving a child that could act as a blood and bone marrow donor for a sibling suffering from Fanconi's anaemia. See European Society of Human Reproduction (ESHRE) 2002. In the UK, the HFEA has meanwhile extended the list of criteria for PGD by including the conception of an immunologically matching blood or tissue donor. See Human Fertilisation and Embryology Authority (HFEA) 2001; Supp 2002; Striegler 2002b.

an interest in additional uses of human embryos (e.g. germ-line experiments, general "embryo-consuming" research), once the "embryo-consuming" use of embryos has been approved. In this context, the inevitable production – due to PGD – of so-called "supernumerary" embryos which perhaps will not be implanted (any more) must be considered an ethically problematic development, since it could pave the way for "embryo-consuming" research for the benefit of third parties.[546]

B.6 The ban on preimplantation genetic diagnosis currently in effect

The majority of the members of the Study Commission hold the view that PGD is not permitted under the law currently in force.

The Embryo Protection Act provides an extensive concept for the protection of embryos. PGD violates this concept because the production and transfer of embryos into a woman's uterus are contingent on conditions. If PGD were approved, the protection of embryos could be weighed against other high-priority legal interests. A pregnancy conflict cannot be compared with the decision-making situation in the case of IVF/PGD.

The Embryo Protection Act takes into account "the value decisions made in the constitution in favour of human dignity and human life".[547] From the constitutional point of view, the protection of human life invariably applies to each individual life.[548] Related to the *individual* embryo *in vitro*, however, PGD does not aim to induce a pregnancy with exactly this embryo because its genetic make-up is still unknown. This decision is taken only later, after a genetic test has been performed. The legislator's decision to permit the use of *in-vitro* fertilisation techniques exclusively for the purpose of inducing pregnancy must be upheld.

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[546] For more details, see Study Commission on "Law and Ethics in Modern Medicine" 2001b, 3.1.1.2 Problems of cell retrieval from so-called "supernumerary" embryos, p. 42 ff. In international practice, an average of six to ten embryos are produced by IVF which are then biopsied for PGD purposes (cf. ESHRE 2000). One reason to produce this number of embryos is that both cultivation and biopsy could cause damage to, and a loss of, embryos. In addition, it has to be expected that some of the diagnosed embryos will carry the undesirable genetic characteristic in question and therefore will not be transferred, but discarded. This practice, however, also increases the probability that embryos will be produced that are not transferred and (for the time being) are frozen and stored. If the couple decide against another IVF cycle and the implantation of these cryopreserved embryos, the latter become so-called "supernumerary" embryos. Embryonic stem cell research relies on the use of such "supernumerary" embryos for the retrieval of stem cells. In Germany, the Embryo Protection Act provides for the production of only as many embryos as will be implanted into a woman's uterus; the maximum number of embryos to be transferred is three. It is questionable whether, if PGD were performed regularly on three embryos, one embryo would be "left" and available for transfer. For this reason, it is assumed that it will be impossible with PGD to uphold the maximum number of three embryos to be produced per IVF cycle, as laid down in the Embryo Protection Act.

[547] German Federal Government 1989, p. 6.

[548] Cf. German Federal Constitutional Court 39, p. 1 (58 f.); 88, p. 203 (252).

Consequently, PGD violates Section 1(1) para. 2 of the Embryo Protection Act which "without any exception prohibits the artificial fertilisation of human egg cells for any purpose other than to induce a pregnancy".[549] The object of inducing a pregnancy must be pursued with each individual embryo produced and held *in vitro*. A different interpretation of the law, based merely on the possible final result of PGD, is not in keeping with the *individual* protection of human life as enshrined in the constitution.

Consequently, a ban on PGD ensues from Section 1(1) para. 2 of the Embryo Protection Act, irrespective of the totipotency of the cells retrieved through biopsy and consumed in the diagnostic process.

There are no superior third-party basic rights that conflict with the protection of human embryos and demand the approval of PGD.

There are limits to the State's obligation to reconcile conflicting fundamental rights by way of "practical concordance": these limits are reached when one of the fundamental rights concerned must be given priority. The majority of the Study Commission members feel that the State's duty to protect the embryo demands that the current ban on PGD should be upheld.

The majority of the members of the Study Commission recommend that the German Bundestag – if necessary, by means of a new law on reproductive medicine – should retain the essence of the Embryo Protection Act and uphold the ban on PGD in more concrete terms.

B.7 International agreements

The justified high level of protection for human embryos in Germany should receive attention at the European level and beyond. For this reason, the majority of the Study Commission members recommend that the German Bundestag should try to ensure by way of international agreements that other countries refrain from approving PGD or from continuing its practice. In future, negotiations at the European or international levels must focus in particular on finding alternatives to PGD that are generally acceptable in ethical terms.

At the vote taken on 25 February 2002, the majority of the Commission consisted of: Rainer Beckmann, Professor Linus Geisler, Dr. Sigrid Graumann, Hubert Hüppe, Werner Lensing, Professor Ernst Luther, Dr. Otmar Kloiber, Helga Kühn-Mengel, Professor Johannes Reiter, Ulrike Riedel, René Röspel, Dr. Ingrid Schneider, Dr. Ilja Seifert, Dr. Margrit Wetzel, Dr. Wolfgang Wodarg, Dr. Michael Wunder.

[549] German Federal Government 1989, p. 8.

2 Genetic data

2.1 State of the art

2.1.1 State of the art in science

2.1.1.1 Historical development, development of methods

2.1.1.1.1 Definitions

In the following, the term "genetic data" means all the information available about the genetic make-up of a human being.

The term "genetic analyses" is used below as a collective term for all examinations directly aimed at obtaining information about the genetic make-up of a human being. The terms "DNA analyses" and "molecular genetic analyses" mean methods used to determine the structures of individual genes. For the sake of simplification, the term "genetic test" is also used. "Cytogenetic analyses" are analyses used to determine the number and structure of chromosomes.

In this report, the term "tests for medical purposes" is used for examinations that relate to medical practice.

These tests have to be distinguished from genetic tests aimed at establishing a person's descent (paternity tests), identifying persons (criminological analyses), as well as tests designed to establish characteristics without any pathogenic impact on the person concerned and/or his or her relatives and any offspring. At present, however, these tests are of no major relevance. Since such tests are applied outside the realm of medical practice, it is necessary to deal with data privacy protection, the protection of the personal rights of the individuals concerned, etc. within the context of the sector of society involved.

Genetic tests for medical purposes are performed for various reasons. More specifically, it is possible to distinguish between the following categories:

– "Disease-related tests" in the narrower sense of the term are tests conducted to substantiate a presumed clinical diagnosis (e.g. if a neonate is suspected of having a chromosomal disorder or a hereditary metabolic disorder). In this process, however, information about the hereditary predisposition of biological relatives is also gathered.

– The term "predictive genetic tests" is used for examinations performed to identify genetic structures that provide information on the risk, the probability or the certainty of a future disease or handicap. Sometimes, these tests are also referred to as "presymptomatic tests". Predictive tests may contribute to disease prevention provided adequate action can be taken (changing one's lifestyle, preventive medical treatment). With this in mind, a test exclusively aimed at deciding about whether possibly to prevent the birth of a probably handicapped child is not seen as a preventive test.

– "Pharmacogenetic tests" are conducted to identify genetically induced sensitivities to certain active substances of drugs. In the future, they might enable individually adjusted drug dosage and selection.

– Tests for the presence of a heterozygotic genetic predisposition in a person not directly affected by the disease are referred to as "tests for heterozygosity". They may contribute to determining the risk that a couple's common child may have a certain disease (such as cystic fibrosis), with the corresponding impact on family planning.

– A genetic test is termed "postnatal" if the genetic material obtained for the genetic analysis comes from a human being after birth.

– A genetic test is termed "prenatal" if it is performed to identify genetic features of an embryo or of a foetus during pregnancy.

These differentiations show that genetic tests tend to broaden the scope of medical action, which has previously been limited to diagnostic, preventive and therapeutic procedures in an individual, and thus change the disease concept that medical practice is guided by.[550] In addition, it has to be taken into account that the terms introduced here are not used consistently in medical literature and that the definition of terms used in the field of genetic tests has not yet been completed.

2.1.1.1.2 Historical development

The "hour of birth" of molecular biology was in 1941, when Avery *et al*. reported that it is the DNA and not the molecular-level protein that carries the genetic information. Another important milestone was the discovery of the double-helix structure by Watson and Crick in 1953. A major impetus for the further development of molecular medicine and, in particular,

[550] Cf. Lanzerath 2000a; 2000b; Lanzerath/Honnefelder 1998.

genetic diagnosis will come from the "Human Genome Project", the first phase of which has now been concluded with the establishment of a detailed map of the genetic make-up of human beings.[551]

Table 13 below lists examples of a number of important developments in molecular biology and of genetic tests and screening methods:

Table 13: Timeline of the Historical Development of Molecular Biology and of Genetic Tests and Screenings

Year	**Development of molecular biology and of genetic tests and screenings**
1944	DNA discovered as the genetic material
1948	A gene codes for a protein
1953	DNA is a double helix
1961	(universal) genetic code is deciphered
by 1960	Establishment of fundamentals of cytogenetic chromosome diagnosis
1961	Introduction of an ultrasound imaging procedure in obstetrics
1963	Introduction of a postnatal test for phenylketonuria (PKU)
approx. 1965	Introduction of amniocentesis, initially for prenatal diagnosis of foetal erythroblastosis
1966	Launch of a postnatal PKU screening programme in the United States using the Guthrie test
1967/68	Restriction enzymes and ligases discovered by several teams of researchers
1968	First localisation of a human gene on an autosome
1969	Band staining for chromosome identification
approx. 1970	Introduction of prenatal diagnosis by amniocentesis as well as cytological and biochemical analysis of an amniotic fluid puncture specimen. Introduction of screening for heterozygosity in hereditarily tainted minorities in the United States
1973	Establishment of fundamentals of recombinant engineering (Cohen-Boyer patent)
1975	Southern blot hybridisation as a basis for molecular genetic analysis
1977	DNA sequencing

[551] More details in: Winter 2001, p. 13.

from 1980	Development of molecular genetic analysis as a means for prenatal and postnatal screening
1981	Sickle-cell anaemia can be detected prenatally by restriction fragment length polymorphism analysis
1983	The gene for Huntington's chorea can be diagnosed by means of linkage analysis using a DNA marker (indirect genetic diagnosis)
1985	The gene for cystic fibrosis can be diagnosed by means of linkage analysis using a DNA marker (indirect genetic diagnosis)
1986	Identification of a gene for Duchenne's disease (direct genetic diagnosis)
1989	Identification of the gene for cystic fibrosis (direct genetic diagnosis)
1993	Identification of the gene for Huntington's chorea (direct genetic diagnosis)
1995	Approx. 400 hereditary diseases can be diagnosed by means of direct analysis of the gene (direct genetic diagnosis)
1999	DNA sequence of chromosome 22 in man
2001	Detailed map of the human genotype

Source: Kröner 1997, p. 36 f.; Winter 2001, p. 19

However, a fundamental problem of genetic diagnosis is that progress in prevention and therapy is far from keeping pace with the increase in diagnostic options. In spite of some promising approaches, there is no prevention strategy that has been developed on the basis of a disease-related gene variant and whose safety and effectiveness has been proven by scientific evidence.[552]

2.1.1.2 Application and use

Knowledge about a person's genetic make-up can be obtained (directly or indirectly) by using a variety of analyses. Generally speaking, four different levels of analysis can be distinguished:

– phenotype analyses (overall appearance, including family history),
– protein chemical analyses (gene product analyses),
– cytogenetic analyses (chromosome analyses), as well as
– DNA analyses.

[552] Holtzmann/Marteau 2000.

The number of diseases and pathological predispositions that can be diagnosed by means of cytogenetic and molecular genetic tests is increasing constantly (see Chart 5 below).

Chart 5: Number of Entries in "Mendelian Inheritance in Man" (McKusick Catalogue)

Source: http://www.ncbi.nlm.nih.gov/Omim/Stats/mimstats.html

In recent years, there has also been an increase in the number of providers and in the use of genetic diagnostic services. The number of postnatal chromosome analyses, for example, more than doubled between 1991 and 1997.

Table 14: Human Genetics Procedures Performed in West Germany (as of 1995, incl. East Berlin)

Procedure	Year	Number of procedures		Percentage of office-based physicians as part of the medical community
		All service providers	Office-based physicians	
Amniocentesis or chorionic villus sampling (CVS) (Fee schedule no. 115)	1991	42,745	23,957	56.0
	1992	49,233	30,666	52.3
	1993	56,598	36,778	65.0
	1994	58,499	40,797	69.7
	1995	61,794	44,374	71.8
	1997	68,267	52,386	76.7
Chromosomes from blood analyses (Fee schedule no. 4872/4972)	1991	12,981	4,093	31.5
	1992	13,385	5,471	40.9
	1993	14,583	6,150	42.2
	1994	16,317	8,343	51.1
	1995	27,601	19,076	69.1
	1997	30,786	20,447	66.4
Genetic counselling (Fee schedule no. 173)	1991	21,830	5,985	27.4
	1992	24,172	9,519	39.4
	1993	26,872	12,845	47.8
	1994	29,226	17,804	60.8
	1995	32,777	19,094	58.3
	1997	40,561	25,910	63.9

Source: Hennen *et al*. 2001, p. 51

According to a survey conducted in 1999 by the *Bundesverband Medizinische Genetik* (German Association for Medical Genetics), which covered a total of 104 laboratories, tests

for a total of approx. 300 disease-related gene and chromosome variations are currently performed in Germany, Switzerland and Austria.[553]

Today, numerous diseases and pathological predispositions can be attributed (at least in part) to a chromosome change or variation affecting single genes and their regulation. Hence, cytogenetic and molecular genetic analyses are becoming increasingly important. Compared with traditional diagnostic tools, they often facilitate the diagnostic process because the test can usually be performed using a blood sample from the patient. In addition, these analyses sometimes also provide a more precise diagnosis (e.g. compared with family tree analyses), allow a more detailed demonstration of heterozygosity and help detect pathological predispositions.

Cytogenetic and molecular genetic testing procedures are applied in medicine in different contexts and for different purposes, both within the field of human genetics and outside (see Chart 6 below). These include in particular:

– confirmation of the diagnosis in clinically manifest hereditary disease (diagnostic genetic testing),

– diagnosis of a predisposition for a given disease before its outbreak (predictive genetic testing),

– prenatal diagnosis of conspicuous chromosomal features and specific single gene changes allowing conclusions to be drawn concerning possible disabilities or diseases of the expected child (prenatal genetic analysis),

– diagnosis of specific conspicuous chromosomal and molecular genetic features in embryos produced in vitro before their transfer to the uterus (preimplantation genetic analysis),

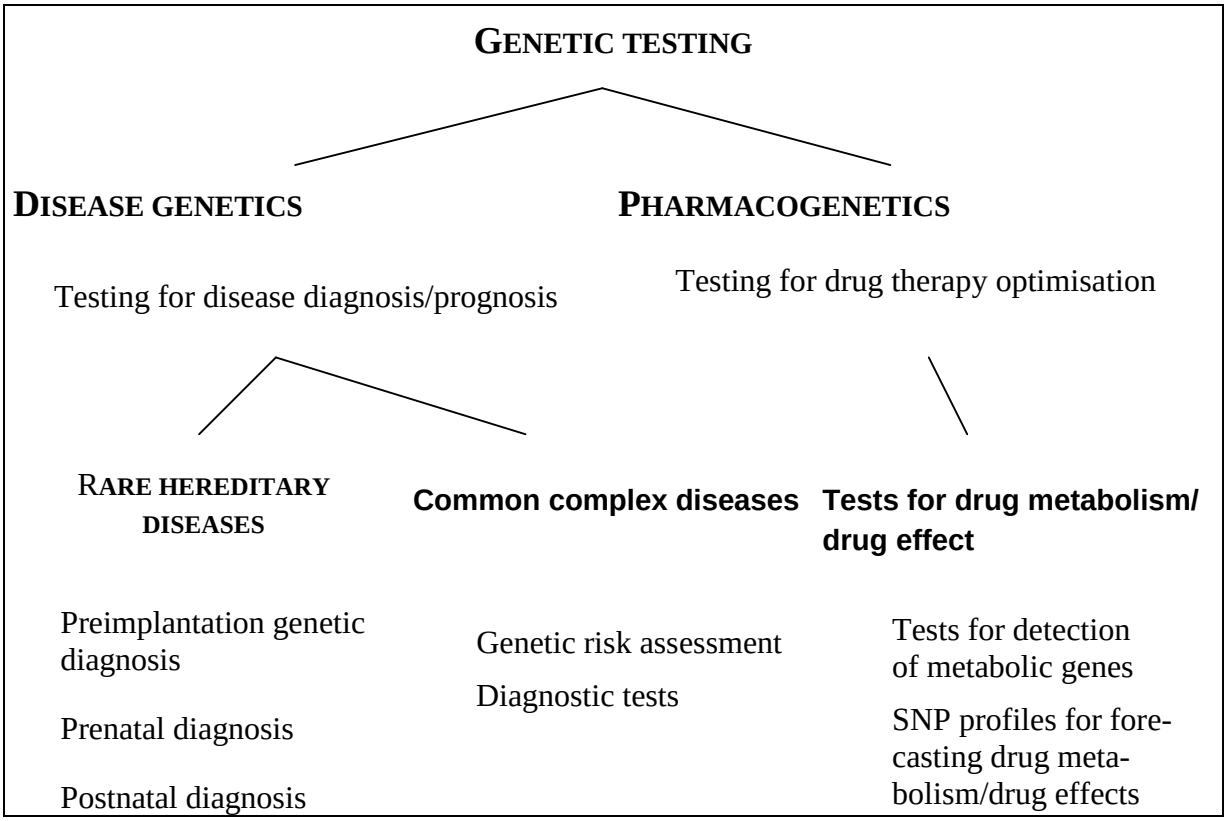
– examination of female germ cells before their fertilisation (preconceptional diagnosis),

– screening not just of individuals but of the entire population or of sections of the latter (genetic screening),

– assessment of genetically induced differences in the response of patients to active drugs (pharmacogenetic diagnosis).

[553] Quoted in Hennen *et al*. 2001, p. 52.

Chart 6: Types of Medical Genetic Analysis



(according to Cope/Border 2001, p. 48)

2.1.1.2.1 Individual genetic tests for diagnostic and predictive purposes

2.1.1.2.1.1 Cytogenetic and molecular genetic testing methods

Chromosome analyses are performed in cells capable of division, e.g. leukocytes, connective tissue, bone marrow or amniotic cells. They may help to detect numerical or structural chromosome changes. These include, for example, chromosome losses (monosomia), supernumerary chromosomes (trisomia) or crossing-over (chromosome translocation). Today, in-situ hybridisation methods – e.g. FISH (fluorescence in-situ hybridisation) – are available, in particular for diagnosing chromosome translocations (which can be very small and hard to detect), and will supply diagnostic results within a few hours.

Certain chromosome changes are associated with diseases or disabilities. Trisomia 21, for example, in which chromosome 21 is present three times instead of twice, leads to the characteristics of Down's syndrome. However, not all chromosome changes are significant for their carriers.

Cytogenetic analyses have been used for years in prenatal diagnosis. As a rule, no precise forecast of the probable severity of a disease is possible on the basis of chromosome analysis.

Molecular genetic tests can be subdivided into direct and indirect genetic tests.

Direct genetic tests require the gene (co)responsible for the occurrence of a disease to be known and available for direct analysis. Using different techniques (DNA sequencing, polymerase chain reaction, Southern blotting, the DNA chip technology under development) it is possible to detect variations of a gene from the normal condition at the molecular level; such variations may include crossing-over (deletions), insertions or an exchange of individual elements (point mutations). For numerous monogenic hereditary diseases – and increasingly for cases of congenital pathological predispositions – such a direct analysis of mutations is nowadays possible.[554]

An *indirect genetic test* has to be used if the approximate chromosomal location of a genetic defect (co)responsible for a disease is known, but has not (yet) been identified. For this purpose, a method called linkage analysis is used. Genetic defects frequently occur together with a certain DNA polymorphism and are in that case passed on to the offspring. Both are relatively close to each other on the DNA strand in the chromosome and can thus be used as a marker for the genetic defect to be detected. Detection is all the easier the closer the marker polymorphism is localised with respect to the genetic defect. Using an indirect genetic test always requires examination of several family members because it has to be ascertained that the linkage of a given marker polymorphism with the relevant genetic defect is also found in the family concerned.

2.1.1.2.1.2 Diagnostic versus predictive tests

It is important to distinguish between diagnostic and predictive tests. *Diagnostic tests* are used to confirm a diagnosis. The purpose of diagnostic tests is to try to determine the causes of a clinically manifest disease at the germ line or somatic level. In the former case, the change is hereditary according to Mendel's laws, whereas in the latter case it is not, as is true for most malignant tumours. Molecular genetic tests performed to confirm a diagnosis may replace traditional diagnostic tools or can be used as complementary analyses. In some genetically heterogeneous diseases, only the use of molecular genetic methods will allow detection of the

[554] Schmidtke 2001b, p. 412f.

underlying cause.[555] Diagnostic tests always include a predictive element as regards family members.

Predictive tests are aimed at identifying genetic changes for which there is a high probability or a probability close to certainty that they will lead to disease in the subsequent life of the person tested.

A particular problem of predictive diagnoses is that, even if it is possible to identify genetic changes which are demonstrably associated with certain diseases, it is often not possible to predict with certainty whether a given disease will occur at all during the later life of the person concerned or when and with what severity it will occur.[556] For reasons of scientific theory, a linear causal relationship between a genetic change and the severity of a given condition is frequently negated today.[557]

Tests used to diagnose genetic changes that will almost certainly lead to the occurrence of a disease in later life are sometimes also referred to as *predictive deterministic tests*. One example of a congenital disease with total "penetrance" is Huntington's chorea. Penetrance indicates the probability for a genetic change within a population to lead to the appearance of a pathological phenotype. However, it has to be added that maximum predictability of Huntington's chorea has so far only been based on statistical data because the causal link with this disease has not yet been elucidated.[558] *Predictive probabilistic tests*, on the other hand, identify genetic changes with lower – in some cases much lower – penetrance. For this reason, predictive probabilistic tests only allow individual predictions regarding the more or less high probability of the occurrence of a disease in later life. Invariably, the more complicated the characteristic to be predicted, the less accurate the prediction will be.

The specific problem of predictive genetic tests can be illustrated using the example of breast cancer diagnosis.

[555] Friedl/Lamberti 1997, p. 83f.
[556] Feuerstein/Kollek (2001, p. 27) underline that, for example, 3-5 per cent of homozygotic carriers of the gene for cystic fibrosis simply do not develop this disease.
[557] Wolf 1997.
[558] Bartram *et al*. 2000, p. 41.

> "In Germany, this cancer is the most frequent cancer in women and often leads to death. Until the age of 75, the cumulative risk is about 7 per cent; 43,000 women per year develop this disease (German Medical Association 1998a). Approx. 5 per cent of breast cancer cases are probably due to a congenital mutation. They are characterised by a relatively early onset of the disease. The two tumor suppressor genes BRCA1 and BRCA2 have been described as predisposing genes. Women with a hereditary mutation at the level of the BRCA1 gene show a highly increased risk of disease (up to 85 per cent until the age of 70, as well as a risk of up to 60 per cent for an ovarian carcinoma), the magnitude of which depends on the type of mutation involved. More than 450 different mutations have been described for the BRCA1 gene, more than 250 for the BRCA2 gene (Meindl/Golla 1998). The BRCA gene analysis, which has been commercially available in the United States since 1996 and which is also performed in Germany, can inform the tested women on whether they carry the genetic trait or not. At present, an individual probability of disease can be determined only with a high degree of uncertainty (or within a wide range of scatter) because no reliable clinical and epidemiological data are available as yet. Since the only other prophylactic option – besides more frequent preventive examinations – is the extremely distressing breast amputation (which does not offer any absolute protection, either), performing a genetic analysis is highly problematic and is therefore a procedure applied by the medical community with great caution and continues to be intensively debated. A large-scale multi-centre research study on breast cancer diagnosis, which is financed by the German Research Foundation (GRF), was initiated in 1997 (Wagenmann 2000)."[559]

Among the currently known diseases, relatively few are mainly or exclusively caused by genetic disorders. Only about 3-5 per cent of the adult population, for instance, fall ill with a late-onset *monogenic* congenital disease (see Table 15). The most frequent conditions are familiar breast cancer, familiar intestinal carcinoma, and certain forms of Alzheimer's disease, which, taken together, already represent approx. 2.5 per cent of all diseases. The vast majority of diseases are of polygenic or multifactorial origin (see Table 16 below).

[559] Hennen *et al.* 2001, p. 39.

Table 15: Common Monogenic Disorders (Selection)

Disorder	**Frequency**	**Heredity**	**Brief description**
Colour blindness (several forms)	1 : 12 ♂	X chro-mosomal (X chr.)	Colour-vision deficits of differing intensity
Alzheimer's disease (several familiar forms)	1 : 100	autosomal dominant (a. d.)	Presenile dementia
Hereditary breast cancer	1 : 200 ♀	a. d.	Breast cancer, often before the menopause, in part also ovarian carcinoma
Hereditary non-polypous colon cancer	1 : 200	a. d.	Carcinoma of the colon and of other organs
Thrombophilia (factor V deficit)	1 : 200	a. d.	Venous thrombosis, tromboembolism
Ichthyosis vulgaris	1 : 300	a. d.	Ichthyosis (alligator skin)
Juvenile diabetes	1 : 400	a. d.	Diabetes due to inadequate release of insulin
Familiar hypercholesterolemia	1 : 500	a. d.	Atherosclerosis, coronary heart disease
Cystic fibrosis	1 : 2,500	autosomal recessive (a. r.)	Formation of viscous mucus in the lungs, the pancreas and other glands. Lack of function of these organs.
Duchenne's disease	1 : 3,500 ♂	X chr.	Muscular atrophy
Haemochromatosis	1 : 5,000	a. r.	Eisenablagerung in inneren Organen
Familiar colonic polyposis	1 : 6,000	a. d.	Colonic polyps, predisposition for malignant tumours
Adrenogenital syndrome	1 : 10,000 – 1 : 18,000	a. r.	Impairment of the water and electrolyte balance, virilisation
Marfan's syndrome	1 : 10,000 – 1 : 20,000	a. d.	Connective tissue malformation
Huntington's Chorea	1 : 10,000 – 1 : 12,000	a. d.	Involuntary motor disturbances, personality degradation
Phenylketonuria	1 : 10,000 – 1 : 20,000	a. r.	Mental retardation, proneness to cramps
Retinoblastoma	1 : 14,000 – 1 : 20,000	a. d.	Retinal tumours, bone tumours

Source: Schmidtke 1997, p. 198ff. (abbreviated)

The term *polygenically* transmitted causes of disease is used for cases where several genes play a role which cannot be attributed specifically to any one of them, i.e. cases in which a disease occurs due to the "interplay" between several genetic changes. The term *multifactorial* is employed whenever it is assumed that the interaction of several genes with environmental

factors is the cause of a disease. However, the terms "monogenic disease", "polygenic disease" and "multifactorial disease" merely denote a simplified model of disease occurrence. Today, it can no longer be assumed that genes "control" diseases from a higher level. The occurrence of diseases always comprises different – genetic and non-genetic – factors. In this respect, there is no hierarchy that would justify attributing to genes a "privileged" position, even though there are cases in which specific genes quite evidently are highly dominant in their impact.[560]

Table 16: Common Multifactorial Disorders (Selection)

Disease	**Frequency**
Congenital malformations	
Neural tube closure defect (spina bifida = open back)	1 : 200 – 1 : 1,000
Pyloric stenosis (obstruction of the gastric outlet)	1 : 300
Cheilognathopalatoschisis (cleft lip, jaw, and palate)	1 : 500 – 1 : 1,000
Other disorders	
Coronary heart disease, stroke	1 : 3 bis 1 : 5
Cancer	1 : 3
Type II diabetes (late-onset diabetes)	1 : 20
Cataract (clouding of the lens)	1 : 250
Type I diabetes ("early-onset diabetes")	1 : 500

Source: Schmidtke 1997, p. 214 (abbreviated)

The performance of predictive genetic tests, in particular, is associated with a number of risks, which have become more serious with the widening of the gap between increasing knowledge, on the one hand, and the limited scope for action, on the other hand.[561] These risks include not only medical risks (in some cases, e.g. in breast cancer diagnosis, preventive interventions whose benefits have not yet been adequately demonstrated can have serious effects) but also psychological and social risks. It is particularly the prognostic character of genetic information that is "likely to burden the persons concerned with too much information

[560] Wolf 1997.
[561] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Advisory Board attached to the German Federal Ministry of Health) 2000, pp. 5 f.

requiring interpretation, which makes them feel insecure"[562]. Test results, for instance, may cause major psychological problems, such as anxiety and depression, and have a major impact on their lifestyle and plans for the future.[563]

2.1.1.2.1.3 Prenatal tests

Generally speaking, cytogenetic and molecular genetic analyses can be used both for postnatal (following delivery of the newborn) and prenatal diagnosis (before birth). In particular in prenatal diagnosis, the number of cytogenetic and molecular genetic tests performed has increased considerably in recent years:

> "While in 1990, 49.6 chromosome analyses per 1,000 live births were performed following amniocentesis or chorionic villus sampling, this figure had risen to 78.8 by 1993. The rate went up to 85.7 in 1996 and to 95.7 chromosome analyses per 1,000 live births in 1998. Within the past ten years, the frequency of prenatal diagnostic interventions has thus almost doubled. With 785,034 live births and 75,255 foetal chromosome analyses performed in 1998, this means that an invasive examination of the unborn was performed almost in one of ten pregnancies."[564]

A distinction can be made between invasive and non-invasive prenatal diagnoses.[565] As opposed to *non-invasive* procedures, where imaging or indirect methods provide information about potential disabilities or diseases of the expected child, *invasive* prenatal diagnostic procedures include a physical intervention for the purpose of obtaining foetal tissue material.[566] Hence, they always pose a health risk both for the pregnant woman and for the child to be born.

Non-invasive procedures include not only ultrasound, for instance, but also the so-called *triple test*. This test is based on the observation that certain proteins found in the blood of pregnant women whose foetuses present chromosomal variations (especially Trisomia 21) show deviations relative to pregnancies with foetuses exhibiting normal chromosomal findings. In order to perform these tests, all that is required is to take a blood sample from the woman between weeks 6 and 8 of her pregnancy. According to Jörg Schmidtke, a triple test is

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[562] Hennen *et al.* 1996, p. 42.
[563] Ethics Advisory Board attached to the German Federal Ministry of Health 2000, p. 5.
[564] Feuerstein *et al*. (forthcoming); additional evidence is presented in this paper. Feuerstein *et al*. underline that no information is available about the number of molecular genetic analyses performed in the framework of prenatal diagnosis because this figure is not recorded separately.
[565] Cf. also Schüler/Zerres 1998 for the following statements.
[566] Schmidtke 1997, p. 108.

performed in 25-50 per cent of all pregnancies.[567] The triple test is not a diagnostic tool, but merely helps to specify the risk. In a paper published by Sancken and Bartens, the authors point out:

> "[u]nder optimum laboratory conditions and taking into account the data to be supplied by the gynaecologist concerning the pregnant woman's body weight und above all the gestational age carefully determined by ultrasound (...) and for a risk limit of 1:380 (age risk of a 35-year-old pregnant woman to have a child with Down's syndrome), about ¾ of all foetuses with Down's syndrome were detected with approx. 8 per cent false positives. These data refer to the average German age distribution for pregnant women. However, the detection rate and the percentage of false positives vary considerably depending on the pregnant woman's age (detection rates ranging from less than 50 per cent in 20-year-olds to almost 100 per cent in pregnant women above 40 years; false positive rates ranging from less than 4 per cent in the 20-year-old women to more than 60 per cent in pregnant women above 40 years)."[568]

In some cases the interpretation of these test results can be very difficult and hard to explain. Even those who offer these tests are often not clear about their complexity and interpretation.[569] It is standard practice to automatically proceed to invasive prenatal diagnosis if the findings of the triple test remain unclear.[570] As early as in 1992, the *Gesellschaft für Humangenetik* (Society for Human Genetics), the *Berufsverband Medizinische Genetik* (Professional Association for Medical Genetics), the *Deutsche Gesellschaft für Gynäkologie und Geburtshilfe* (German Society for Gynaecology and Obstetrics) as well as the *Deutsche Gesellschaft für Perinatale Medizin* (German Society for Perinatal Medicine) demanded a moratorium on triple screening – among other things in view of the fact that "in many cases", because of inadequate information, test results were "incorrectly interpreted (by the persons concerned) as a dramatically enhanced risk", which tended to cause "considerable alarm among pregnant women".[571]

The invasive methods used in prenatal diagnosis include above all chorionic villus analysis and amniocentesis. In order to perform *chorionic villus analysis*, chorionic tissue is obtained from a pregnant woman – as a rule between weeks 9 and 12 of pregnancy. Since chorionic villi are embryonal cells, chromosomes can be analysed microscopically for numerical or structural changes. In addition, chorionic cells can be examined by means of biochemical and

[567] Oral communication by Dr. Schmidtke at the non-public hearing held on 26 March 2000.
[568] Sancken/Bartels 1999, 283.
[569] Schmidtke 1997, p. 119.
[570] Zerres, quoted by Hennen *et al*. 2001, p. 73.

molecular genetic methods. Specific metabolic diseases and hereditary disorders, e.g. cystic fibrosis or haemophilia, can be detected, in this manner. For molecular genetic tests, chorionic villus analysis is more appropriate than amniocentesis.[572]

In the case of *amniocentesis* – normally performed between weeks 15 and 17 of pregnancy – amniotic fluid is obtained from the pregnant woman's uterine cavity using a puncture needle. The cells retrieved from the amniotic fluid mainly come from the amnion (amniotic cells), in part also from the external skin and mucosa of the foetus (foetal cells). The foetal cells cultured after retrieval can be subjected to biochemical, cytogenetic and molecular genetic analyses. Cytogenetic analysis reveals chromosomal variations (e.g. Patau's, Edwards', and Down's syndrome, major chromosome deletions, etc.), while biochemical analysis indicates the presence of neural tube closure defects (spina bifida). These are the limits for "routine" diagnosis. If there is a known risk of a specific – possibly hereditary – change at the molecular genetic or chromosomal level (e.g. cystic fibrosis), it is also possible to perform an appropriate molecular genetic diagnostic procedure. This is done only if there is a specific problem.

While chorionic villus analysis and amniocentesis are nowadays largely routine tests, *umbilical cord puncture* (which is feasible approximately from week 19 of pregnancy and which is performed to obtain foetal blood cells) and *foetal skin biopsy* (which can be performed between weeks 18 and 20 of pregnancy) are only applied in specific cases.[573]

Invasive methods of prenatal diagnosis not only involve health risks for the pregnant women themselves (bleeding, labour-like pains, infections), but they are also associated with a risk of injuring the foetus as well as a risk of miscarriage due to the intervention, which is estimated at approx. 0.5 per cent for amniocentesis and 2-4 per cent for chorionic villus analysis.

2.1.1.2.2 Genetic screening

The term "genetic screening" is used for genetic tests performed systematically for the following purposes: early detection or exclusion of genetically induced disorders, identification of a predisposition for, or resistence to, genetically induced diseases, and identification of genetic carriers for a given genetically induced disorder.[574] Another common definition of genetic screening reads as follows: "Within a symptom-free population, a search

[571] Public Relations and Ethics Committee of the Society for Human Genetics 1992.
[572] Schmidtke 1997, p. 111.
[573] Stengel-Rutkowski 1997, p. 58f.
[574] European Society of Human Genetics/Public and Professional Policy Committee 2000a.

for genotypes that lead to increased risks of genetically induced diseases for their carriers or the latter's offspring."[575]

Unlike the tests available for individuals, the initiative to perform genetic screening tests is not triggered by individuals seeking advice but by the health care system. Genetic screenings may cover the entire population or be limited to specific population groups. In the latter case, individuals are made an offer to be tested, not because there is no individual indication for them, but because they carry a statistically higher risk than the overall population to develop a genetically induced disease.

How exactly a test may become part of a screening programme, depends primarily on the organisational structure of the health care system concerned. In a public health care system, screening programmes can be established by the institutions in charge; however, screening offers can also "trickle in", as it were.[576] This is borne out by the experience gained with prenatal genetic analyses in Germany, which have *de facto* developed into a kind of screening programme.

Generally speaking, it is possible to distinguish between various types and methods of screening programmes.

Table 17: Types and Methods Used in Screening Programmes

Time	**Type/Method**	**Objectives**
Before birth	– Foetal cells in the blood of pregnant women[577] – Serum markers in the blood of pregnant women – Ultrasound screening – Foetal karyotyping – Preimplantation genetic diagnosis	Detection of genetically (and non-genetically) induced disorders in early pregnancy; treatment *in utero*; improved perinatal management; contribution to decision-making about abortion
After birth	– Screening of neonates – Screening of adults – Carrier screening during pregnancy or before conception	Detection or exclusion of genetic characteristics that have a health impact on the test person herself; detection or exclusion of genetic risks in the test person's offspring

Source: European Society of Human Genetics/Public and Professional Policy Committee 2000b

[575] National Academy of Sciences, United States, 1975, quoted from Schmidtke 1997, p. 231.
[576] Schmidtke 2001a.
[577] This technology is not yet ready to be launched.

The neonatal genetic screenings mainly under discussion at present include the testing of neonates for cystic fibrosis – with pilot projects underway in France, the United Kingdom and Italy – as well as neonatal tests for Duchenne's disease. As for the latter disorder, no therapeutic options are presently available; testing is not done in the child's interest but only for future family planning purposes. With respect to tests to be performed in adults, screenings discussed at present concern familiar hypocholesterolaemia and haemochromatosis as well as tests for genetic carriers of the fragile X syndrome, cystic fibrosis and other recessive disorders. A number of screenings are being performed as pilot studies.[578]

In various countries, such as Israel, Australia and the United States, screening programmes have been implemented for years. They include genetic carrier tests for certain diseases that occur with particular frequency among specific ethnic groups. These test programmes are offered – sometimes at national level – to pregnant women or before conception (see Table 18).

Table 18: Tests for Heterozygosity

Disease	Ethnic groups	Test procedure
Thalassaemia	Inhabitants of Mediterranean countries	Haemoglobin analyses; molecular genetic tests
Tay-Sachs disease	Ashkenazy Jews	Biochemical test
Sickle cell anaemia	Populations belonging to African groups	Haemoglobin analyses; molecular genetic tests
Cystic fibrosis	Populations of European origin	Molecular genetic test

Source: Schmidtke 1997, p. 247

In Germany, genetic screening for haemochromatosis is currently performed in a pilot project launched by the statutory health insurance fund *Kaufmännische Krankenkasse Hannover* (KKH) and the Hanover Medical School (MHH). This is the first screening ever performed among adults in Germany on a molecular genetic basis.

This screening for haemochromatosis has been initiated not only for medical reasons but also with economic aspects in mind:

> "On the one hand, haemochromatosis – with a prevalence of 1:400 – is one of the most common metabolic disorders in Europe. It can be diagnosed readily and reliably, comprises a very long asymptomatic phase, and its treatment is both effective and free

[578] For an overview see: European Society of Human Genetics/Public and Professional Policy Committee 2000b.

> from side effects. There is a consensus to the effect that homozygotic carriers should regularly undergo a bloodletting therapy at the first occurrence of clinical symptoms. Such treatment is not only particularly inexpensive because it requires no drugs at all, but it also benefits the national economy, since the blood collected in this manner can normally be used as blood donations. In the framework of a study recently conducted on health economics, the financial expenditure involved in performing a screening programme for haemochromatosis in non-selected groups of test subjects was calculated and estimated at approx. DM 8,900 (€ 4,400) per additional life-year gained in this way. In comparison with other studies, for which cost-effectiveness studies are also available, this is a very good result."[579]

With a prevalence of approx. 2.5:1,000 in Northern and Central Europa, haemochromatosis is a very common metabolic disorder with autosomal recessive heredity. In the patients concerned, increased gastrointestinal absorption of iron from food can, with age, produce an unphysiological excess of iron in the organism (in particular in the liver, the pancreas, the heart, and the skin). Without adequate treatment, various organ injuries may develop over the years and frequently lead to premature death of the patients. In 1996, the mutation causing the disease was identified in the HFE gene on chromosome 6, and a direct genetic test is now available. This direct genetic test allows a presymptomatic diagnosis to be performed and the disease to be treated by means of a bloodletting therapy. This simple, regular treatment prevents symptoms from occurring or has a positive influence on the course of clinically manifest haemochromatosis. In patients with a suspected diagnosis, it is possible to do without the use of invasive methods (liver biopsy) to confirm the diagnosis.

In the framework of the pilot project carried out by the Hanover Medical School (MHH) in co-operation with the KKH health insurance fund, 10,000 members insured with KKH will be tested (minimum age: 18 years). Interested persons will receive from MHH a letter of information as well as filtering paper to be used as carrier for the blood sample. It is sufficient for the general practitioner to collect a few drops of capillary blood on the filtering paper and to return the sample to MHH for analysis. After analysing the blood sample in the laboratory, MHH will inform the G.P. about the result in writing. Identified genetic carriers will be offered human genetic counselling and a clinical examination. In addition, the test persons will also be interviewed in detail in order to evaluate the psychosocial effects of the screening. Critics have drawn particular attention to the following problematic aspects of the pilot project:

[579] Galas 2001, p. 70.

– The participants in the pilot project are not necessarily informed by means of human genetic counselling before or after the test; instead, they may under certain circumstances only be informed by means of an information sheet sent to them by mail. Will this guarantee adequate informed consent?

– Possibly a large proportion of the persons tested with positive genetic findings might get worried unnecessarily, because they would possibly never have been affected in terms of their phenotype.

– What happens to the data about relatives that will inevitably be obtained?

– The performance of a genetic test for haemochromatosis is subject to a controversial international debate among scientists because its significance remains unclear. It is argued that such screening is ethically problematic because it includes too many healthy persons who would not develop any clinically relevant organ injuries without such medical intervention, or only in a few decades. Furthermore, it is argued that such screening also circumvents the principle of expediency laid down in the German Social Security Code (SGB V).[580]

The use of genetic screening programmes is currently restricted by the limited technical and financial resources available. On the one hand, genetic tests can detect only relatively few hereditary diseases and risk factors; on the other hand, there are tight financial limits to screening programmes because of the considerable expenditure associated with a mutation analysis using conventional molecular genetic procedures.[581]

2.1.1.2.3 Pharmacogenetic diagnosis

Pharmacogenetics describes genetically induced factors that lead to individual differences in the response of patients to drug administration. Its main goal is to increase the safety and efficacy of drugs by "adjusting" them to the patients' genetic constitution. While pharmacogenetics is related to certain pharmacologically interesting genes, pharmacogenomics comprises the totality of all the different sequences within the genes. In the United States, pharmacogenomics is often considered as the new "miracle drug" in the manufacturing of pharmaceuticals. According to a study conducted by the international management consulting firm Frost & Sullivan, for instance, the United States market for

[580] Steindor 2001; 2002.
[581] Henn 1998, p. 130.

pharmacogenomics is heading for enormous growth. In the year 2000, gene-based diagnostics, the service part of pharmacogenomics and the so-called orphan drugs generated approx. US$ 1.7 billion; the management consultants estimate that sales could increase to more than US$ 6 billion by the year 2005.[582]

For the time being, pharmacogenetic research is still in its infancy. Today, pharmacogenetic studies "… mostly (serve the purpose of) application-oriented basic research".[583] Nevertheless, high hopes are pinned on them by some people: The implementation of pharmacogenetic methods in drug development and therapeutic practice is expected to contribute to safer drug use, to increase the efficacy of pharmaceuticals and, last but not least, to have positive economic effects.[584] Broder and Venter even think it that it is probable that, in the long run, pharmacology, toxicology, bioinformatics and genomics will converge to become a new branch of medical science dedicated to researching and developing drugs from the molecule to the sickbed.[585]

More specifically, the primary objectives of pharmacogenetic research are:

– to optimise the efficacy of drugs in individuals,
– to adjust drug dosage as much as possible to an individual's needs,
– to avoid adverse reactions caused by drug administration, and
– to better control the activity of drugs in the organism.

It is known today that the lack of drug efficacy in individuals and the occurrence of adverse drug reactions are due not only to environmental conditions, patient compliance and other causes but also to genetic factors; however, the weight of the genetic component may differ from case to case.

Generally speaking, it is possible to distinguish between three mechanisms for pharmacogenetic factors to influence drug effects:

– changes in genes that control the synthesis of enzymes which break down drugs;
– mutations that influence binding to target structures at the cell surface or in the cell itself;

[582] Frost & Sullivan 2001.
[583] German Association of Research-Based Pharmaceutical Companies (VFA) 2001.
[584] Bayertz *et al*. 2001, p. 287ff; Feuerstein *et al*. (soon to be published); Kurth 2000, p. 224.
[585] Broder/Venter 2000, p. 97.

– mutations that lead to reduced expression of transporter proteins or that influence their transport function.[586]

Extensive research is still required to identify genes that are responsible for the uptake, efficacy and breakdown of active substances in the human organism. To this end, use is made of findings from molecular biology and different genetic tools and procedures such as gene maps, population analyses, family trees and expression studies. In this context, an important role is played by search algorithms that rely on so-called SNPs (single nucleotide polymorphisms).

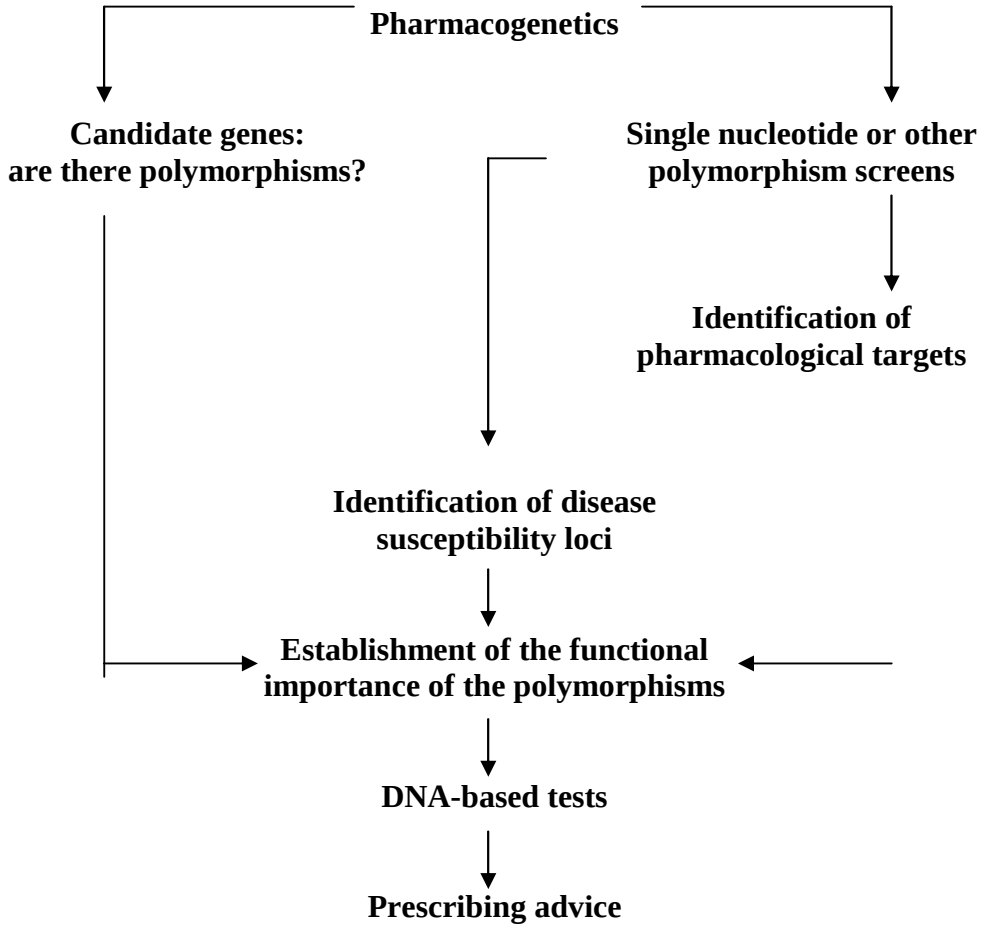
SNPs are the most frequent genetic variation, in which a single DNA building block (a nucleotide consisting of a sugar molecule, a phosporic acid molecule, and a base) is modified. 99.9 per cent of all nucleotide pairs in the human genome are the same for everyone. It is the remaining 0.1 per cent that probably accounts for differences between people. A variation in a single base – i.e. a SNP – is estimated to occur every 1,000 bases. SNPs are found everywhere in the genotype. At present, it is assumed that there are roughly 3 million SNPs of which, however, only 15,000 to 20,000 are probably of functional importance.

In 1999, leading drug companies, university research laboratories, and the Wellcome Trust jointly established an "SNP Consortium". The objective of the SNP Consortium is to sequence SNPs and to publish them in a database.[587] Knowledge of SNP markers is expected to allow systematic association studies covering the entire genome:

> "That is, SNP patterns from a target population such as patients who suffer from a particular disease or who respond poorly to a particular drug can be compared with SNP patterns from unaffected populations to find genetic variations shared only by the affected group. It is from these association studies that disease-specific genes may be identified, and from which novel therapeutic avenues and even tailor-made therapies are expected to evolve."[588]

[586] Eichelbaum 2001.
[587] On 15 February 2001, a map with 1.4 million SNPs was published in *Nature*.
[588] Press release of the SNP Consortium of 15 April 1999, quoted from Bayertz *et al.* 2001, p. 287.

Chart 7: Pharmacogenetics



Source: Wolf *et al.* 2000, p. 989

It is expected that "in the relatively near future, increasing numbers of drugs will be marketed in combination with test kits for differential genotyping of patient populations."[589] The purpose of these test kits, which are also referred to as "prognostics", is not to predict diseases but the therapeutic success of a particular drug. One example of possible pharmacogenetic treatment strategies is the use of herceptine, a drug that is only effective in a very specific type of mammary carcinoma. This type of carcinoma is caused by genetically induced overproduction of certain growth regulators. A test can therefore help to determine whether it is possible to detect the specific gene, which makes the use of herceptine reasonable in the first place. The United States Food and Drug Administration (FDA) makes the use of herceptine contingent on previously performing the test and has thus integrated pharmacogenetic diagnosis into the clinical trial protocols.

[589] Bayertz *et al*. 2001, p. 289; Feuerstein *et al*. (forthcoming); Wolf *et al*. 2000, p. 988.

Herceptine is the first drug for the treatment of breast cancer that is based upon the results of genomic research, that is target-specific, that attacks a damaged signalling system and that is used in a well-defined group of female patients (personalised therapy). "This splitting-up into more and more specifically adjusted therapies will continue", predicts Dr. Axel Ullrich of the Max Planck Institute of Biochemistry at Martinsried near Munich.[590] If this is true, the problem, however, is who will pay for such therapy because the fewer the number of patients with the same cancer, the higher the price per drug. More than in the past, the health care systems of the industrialised nations would then be confronted with the question of how to guarantee a fair allocation of medical services in the future.

2.1.1.3 Expected future developments

2.1.1.3.1 Extension of tests

Owing to increasing genetic knowledge – gained in particular in the framework of the human genome project – as well as technological developments, DNA tests will be available for a much larger number of disease-relevant mutations and genetic polymorphisms in the next few years than today. At the same time, test procedures are becoming more and more efficient, easier to use and less expensive. Both trends will lead to an increase in the number of tests performed.[591]

As a result, an increasing number of genes that are involved in the causation of autosomal recessive and autosomal dominant diseases will be identified and lead to the development of diagnostic and predictive genetic test methods for these disorders. An increase in the number of genetic tests for chronic diseases can be expected for a subgroup of these diseases for which high-penetrance predisposing genes have been identified. These include, for example, breast cancer (BRCA 1/2), intestinal cancer (FAP, HNPCC), type-II diabetes, and Alzheimer's disease (APOE, ADP, PS1, PS2). However, this subgroup accounts for less than 5 per cent of all diseased cases.[592]

[590] Quoted from Koch 2001b, p. 65.
[591] Bayertz *et al*. 2001, p. 271; Feuerstein *et al.* (forthcoming), Chapter 1.3.
[592] Nippert 2001b. According to Feuerstein *et al*., the exploration of polygenic and multifactorial diseases is likely to become an "exploding market for genetic analyses" (Feuerstein *et al.* (forthcoming)).

2.1.1.3.2 The gap between diagnostic and therapeutic options

The development of effective treatments for these diseases will probably not keep pace with this trend, so that the gap between diagnostic and therapeutic options will become wider and wider.[593]

In the relatively near future, however, it will probably be possible at least in some areas – such as in the choice of therapy and in the dosage of drugs – to achieve a closer combination between genetic diagnosis and therapy. This applies, for example, to hereditary tumours, certain autoimmune diseases, endocrinopathies and rheumatoid conditions.[594]

Originally, great hopes were pinned on somatic gene therapy for genetically induced dieases. However, experience in clinical trials and basic research has shown that the idea of healing genetically induced diseases by some kind of "gene correction", was – scientifically speaking – too naive.[595]

2.1.1.3.3 DNA chip technology

As far as new technological diagnostic options are concerned, the development of DNA chips will probably prove to be particularly important in the future. The scope of application of the chip technology will go "far beyond the field of human genetics".[596] The applications currently discussed for DNA chips include research and agriculture, food monitoring, environmental research, medical diagnosis, drug manufacturing and the checking of genetic fingerprints in forensic medicine.[597]

The DNA chip technology is a rapid and inexpensive technology that is suitable for identifying gene sequences. In addition to "rough-and-ready" sequencing of genes, analysing expression patterns (research, therapy monitoring, checking of metabolic reactions, medical prognoses), identifying microorganisms and performing environmental and food analyses, DNA chips are also suitable for applications in clinical research and diagnosis (identification of hereditary diseases, polymorphisms, markers, pathogens).[598]

The combination between molecular genetics and computer technology allows samples to be evaluated much faster, so that a large amount of genetic information can be analysed

[593] Nippert 2001b.
[594] Bayertz *et al*. 2001, p. 275.
[595] Graumann 2000.
[596] Toder 2000, p. 19.
[597] Schwerin 2000, p. 16.
[598] Wess 1998, p. 4; Feuerstein *et al*. (forthcoming).

simultaneously. Compared to the currently available methods of DNA diagnosis, procedures will be considerably accelerated, which will be significant not only for genome research itself but also for clinical genetic diagnosis. Even if microarray analysis of constitutional gene mutations has not yet been introduced in medical practice,

> "diagnostic chips for genes such as BRCA1 or CFTR, which already exist on a scientific laboratory scale, leave no room for doubt that, within a few years, DNA mutation chips will become available on a large scale. This will continue to accelerate the developments already underway towards an increase in parameters, a reduction of costs, and automation."[599]

According to experts, the introduction of DNA chip technology will also bring about major changes in human genetic diagnosis. Wolfram Henn, for example, assumes:

> "that in five or ten years from now, technologies will be available that will enable any medical laboratorory to use a blood or chorionic villus sample in order to analyse almost any number of genomic sections for variations of standard DNA sequences – at a fraction of the current cost of such analyses. Since integrated procedures that range from automatic DNA extraction to online matching with sequences defined as normal will be available, the analysers will no longer require any competence of their own with regard to the methods employed in human genetics."[600]

According to a publication by the German Federal Ministry of Education and Research, the extent to which DNA chips will be used in the future and the areas in which they will be used "will depend on a large number of factors such as the patients' interests, the economic benefit for suppliers and users, as well as the social acceptance of certain applications, and is therefore not foreseeable."[601]

2.1.2 Statutory provisions (national/international)

In Germany, there are currently no specific statutory provisions that deal with genetic counselling and diagnosis.

The provisions in the Genetic Engineering Act, which was adopted in 1990 and amended in 1993, govern the use of genetic engineering techniques in plants, animals, and micro-organisms and stipulates safety precautions that must be taken when genetically modified organisms are used in laboratories and at production sites. The use of genetic engineering

[599] Henn 2000, p. 342.
[600] Henn 2000, p. 342.
[601] German Federal Ministry of Education and Research 2000.

techniques in human beings as well as human genetics are excluded from this Act's scope of application. The only Act that currently contains relevant provisions is the *Strafverfahrensänderungsgesetz* (Criminal Proceedings Amendment Act) of 1997, which deals with the use of molecular genetic tests in criminal prosecution and criminal proceedings.

In Germany, fragments of indirect statutory provisions were introduced on prenatal diagnosis and counselling via jurisprudence and directives in health insurance law as well as in medical practitioners' liability law. In the early 1970s, for instance, methods for prenatal diagnosis such as amniocentesis were included in the benefits catalogue of the statutory health insurance funds. According to the so-called "wrongful birth" jurisprudence in Germany, which dates back to the early 1980s, medical practitioners may be liable for damages on account of a violation of their consultancy and treatment agreement if children are born with disabilities following incorrect genetic counselling or prevented or faulty prenatal diagnosis.[602] In the law of criminal procedure, the use of the "genetic fingerprint" for the taking of evidence in criminal investigations was regulated by the Criminal Proceedings Amendment Act in 1997 (Code of Criminal Procedure, Section 81e). In labour law, the first decision by a superior court on the use of DNA analyses was handed down in 2001.[603]

In-vitro diagnostics which, according to the manufacturer, are designed for genetic testing are subject to European – and hence, also to German – medicinal products law.[604] The European Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in-vitro* Diagnostic Medical Devices applies to *in-vitro* diagnostic medical devices and their accessories. According to this Directive, an *in-vitro* diagnostic medical device is any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state or concerning a congenital abnormality. As a rule, genetic diagnostics and genetic test kits are covered by this EU Directive. In Germany, the Directive was implemented by the *Zweite Medizinprodukteänderungsgesetz* (Second Medicinal Products Amendment Act), which entered into force on 1 January 2002. According to the provisions of the EU Directive and of the German Implementing Act, all necessary measures have to be adopted in Germany in

[602] Degener 1998b. However, the jurisprudence on liability following a missed abortion or faulty prenatal diagnosis only applies to the indications specified in Section 218, which had been in force until 1995. Cf. the relevant comments in the chapter on preimplantation diagnosis in this report.
[603] Cf. C2.2.1.3 The principle of voluntary participation.
[604] Schorn 2001.

order to ensure that only products carrying the so-called "CE mark" ("conformité européenne") will be placed on the market. This means that products have to be designed and manufactured in such a way that their application does not jeopardise – directly or indirectly – the clinical condition or safety of the patient when the products are used for the intended purposes. As its name indicates, the (amended) Medicinal Products Act (*Medizinproduktegesetz* – MPG) refers exclusively to product safety and product quality criteria. With regard to genetic testing, this means that issues relating to the medical practitioner's reservation ("*Arztvorbehalt*") or the linkage of genetic testing to medical purposes are not covered by this Act.[605] In this respect, the national legislator is free to adopt rules of its own.

Unlike Germany, Austria introduced statutory provisions on genetic diagnosis with the adoption of its Genetic Engineering Act of 1994.[606] In Switzerland, there is a "Preliminary Draft of a Federal Act on Genetic Testing in Human Beings".[607]

At European level, the Council of Europe's "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine"[608] devotes a separate chapter to the issue of the protection of the human genome. In its Article 11, the Convention deals with the question of discrimination based on an individual's genetic heritage and states:

> *Art. 11: Non-discrimination*
>
> "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited."

In Article 12, it deals with predictive genetic tests for diseases and makes their performance contingent on the presence of "health purposes" and on genetic counselling. However, these two criteria are not explained in greater detail:

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[605] In two points, the provisions in the Directive on *in-vitro* Diagnostic Medical Devices go beyond dealing with product safety and product quality: According to Article 1(4), the removal, collection, and use of tissues, cells, and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and by any Member State's regulations on this matter. According to Article 1(6), the Directive shall not affect national laws which provide for the supply of devices by a medical prescription. The power vested in the German Federal Ministry of Health under Article 37 of the Medicinal Products Act to issue ordinances provides for the possibility to make certain medicinal products available on prescription only or to prescribe specific distribution channels, however, only to the extent that this is imperative for reasons of direct or indirect health protection or in the interest of the safety of the patient, the user or third persons.

[606] Gentechnikgesetz (GTG – Genetic Engineering Act) of the Republic of Austria 1994.

[607] Swiss Justice Department 1998a.

[608] Council of Europe 1997.

Art. 12: Predictive genetic tests

"Tests which are predictive of genetic diseases oder which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling."

These provisions are the starting point for a Human Genetics Protocol that is currently being prepared. This protocol deals, among other things, with issues of genetic diagnosis. In addition, guidelines for the use of human biological material and of personal data are being prepared, also involving the use of genetic data.

In Germany, the provisions contained in Article 12 have led to a controversial debate because the term "health purposes" needs to be interpreted and defined more precisely. Since this debate has not yet been concluded in Germany, the German Federal Government has not yet signed the Convention.

The UNESCO Declaration of 1997 on the Human Genome and Human Rights also prohibits discrimination on the basis of genetic characteristics and lays down, in several articles, fundamental rights and principles for the performance of genetic tests for research and diagnostic purposes.[609]

Since the 1980s, the opportunities and risks associated with the application of genetic diagnostic procedures in human beings have been discussed intensively in Germany by numerous commissions and working groups established by the German Federal Government and state-level governments. In 1985, for instance, a joint working group of the former Federal Ministry of Research and Technology and the Federal Ministry of Justice – the so-called Benda Commission – dealt with questions of *in-vitro* fertilisation, genome analysis, and gene therapy.[610] In 1987, the 10th German Bundestag's Study Commission on "Opportunities and Risks of Genetic Engineering" submitted its report[611]; and the "Genome Analysis" Working Group[612] of the German Federal Government and the state-level governments published its findings in 1990. In November 2000, the Ethics Council of the Federal Ministry

[609] United Nations Educational, Scientific and Cultural Organisation (UNESCO) 1997.
[610] Federal Ministry of Research and Technology and Federal Ministry of Justice 1985.
[611] Report of the *Enquete*-Kommission "Chancen und Risiken der Gentechnologie" (Study Commission on "Opportunities and Risks of Genetic Engineering") 1987.
[612] Federal Ministry of Justice 1990.

of Health presented a position paper ("*Eckpunktepapier*") designed to provide ethical and legal guidance with regard to the use of predictive genetic tests.[613]

In position papers, statements, and guidelines, the World Medical Association, the German Medical Association, the state-level medical associations, as well as specialist societies have commented – in some cases, extensively – on the fundamental principles to be applied when dealing with genetic diagnostic procedures and various concrete problems.[614]

2.2 Current status of the debate and assessment

2.2.1 General aspects

2.2.1.1 Particularities of genetic information

Information obtained from molecular genetic tests shows a number of particularities that justify the special position accorded to such information in medicine as compared with information obtained from conventional medical examinations.

Genetic information:

– has a much higher predictive potential than other types of medical information;

– provides presymptomatic data on diseases or predispositions for certain disorders;

– maintains its predictive value over long periods;

– is of great importance for reproductive decisions;

– establishes links with ethnicity and hence, involves the risk of racist discrimination;

– has implications, beyond the tested individual, also for family members;

– as a rule is fraught with prognostic uncertainty with regard to the onset or severity of a disease;

– may provide a pretext for social stigmatisation (employers, insurance companies, partnership bureaus),

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[613] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Advisory Board attached to the German Federal Ministry of Health) 2000.

[614] World Medical Association 1964/2000; 2000a; 2000b; *Bundesärztekammer* 1998a; *Berufsverband Medizinische Genetik e.V.* and *Deutsche Gesellschaft für Humangenetik e.V.* 1998.

– may lead to considerable psychological unease as well as fears and depressions of the person concerned. Persons who are healthy and may stay healthy, may perceive themselves as being sick or at risk;[615]

– involves the risk of eugenic discrimination.[616]

However, the fundamental difference between conventional and molecular genetic tests is not related to individual characteristics of the DNA analysis; instead, it is the interplay between the conditions for application and the range of validity of the results.[617] Hence, genetic data must be seen as particularly sensitive "identity-relevant" data, which therefore require a particularly high level of protection.

Another "feature" or particularity of genetic information is that its informative value is often highly overrated.[618] This frequently leads to a distorted perception of multifactorial situations because – due to the alleged clarity of the genetic data – other aspects of the overall context, which are just as important but harder to assess, may be ignored.[619] Hence, there is a risk that less importance may be attached to psychological and social factors when examining the genesis of a disease or even character traits of individuals; and there is a risk that the complexity of individuals and their pathologies may be reduced to the mere genetic substrate.[620] Some authors even use the term "genetification" of society to describe this process:

> "This process, which is one aspect of the even more comprehensive process of medicalisation, constitutes a redefinition of the individual in terms of the DNA code, a new language that describes and interprets human life and behaviour by means of a genetic vocabulary of codes, designs, features, predispositions, and genetic make-up, as well as a genetic concept of disease, health, and the human body."[621]

Predictive tests supply information about diseases that persons who are still healthy today are certain or likely to develop in future. This knowledge creates a new group of people – the "healthy sick".[622] In the debate on genetic diagnosis, emphasis is therefore often put on the risk that predictive genetic tests might lead to individualisation of responsibility and a

[615] Feuerstein/Kollek 2001, p. 28f.; Scholz 1995, p. 48.
[616] Bartram *et. al*. 2000; Feuerstein/Kollek 2000; Schmidtke 2001b, p. 422. Cf. also Rose 2000.
[617] Scholz 1995, p 37.
[618] Cf. also Rehmann-Sutter 1998.
[619] Bartram *et al*. 2000, chapter 2.
[620] Bayertz 2000, p. 452.
[621] ten Have 2000, p. 334.
[622] Scholz 1995, 48.

decrease of solidarity in society.[623] It is feared that "genetically challenged" persons might eventually be expected to adjust their lifestyle to their genetic make-up in order to remain productive as long as possible so as to minimise the cost they cause for the shared-risk community and possibly refrain from having children with the same "genetic challenge".[624] In addition, this may lead to social pressure to perform a predictive test, to disclose genetic data or to participate in screening programmes because such behaviour would be defined as socially responsible.[625] There may be a risk of social pressure even if the principle of voluntary participation is formally laid down in legislation.[626]

2.2.1.2 The right to know and the right not to know

The fundamental rights, in particular the guarantee of human dignity and the right to free development of one's personality (Articles 1 and 2 of the German Constitution), provide the basis for the right to know or not to know, the principle of voluntary participation, the principle of non-discrimination as well as to right to informational self-determination.[627]

What follows from the above-mentioned norms in particular is the right of a human being to be given information about his or her state of health and to decide what other persons should be given this information. Aware of this information, individuals have the right to design, pursue or reject plans for action or for their future lives. This also applies to information about an individual's own genetic make-up, which may be of great importance as a basis for his or her life design or family planning. As a general rule, any restrictions imposed on this *right to know* have to be justified. The right to know is limited in particular where it affects the personal rights of others.[628]

Another right that – like the right to know – is derived from the general personality rights is the *right not to know*.[629] Any encroachment on the right not to know also has to be justified. The right not to know protects individuals from information about their physical condition that they do not want to obtain or have. Due, especially, to the particularities of predictive

[623] Oral communication by Prof. Hillary Rose during the public hearing held on 16 October 2000.
[624] Feuerstein/Kollek 2001; Lemke 2001.
[625] Damm 1999, p. 448.
[626] Neuer-Miebach 1997.
[627] Concrete risks for the basic rights mentioned below – i.e. the right to know and the right not to know (Art. 1(1) and Art. 2(1) of the German Constitution), the right to act voluntarily and to enjoy data privacy protection (Art. 2(1) of the German Constitution) and the right to be protected against discrimination (Art. 3 of the German Constitution) – can only be identified with regard to concrete applications of genetic diagnosis. The jurisprudence on "wrongful birth" can be seen as a concrete example of basic rights being jeopardised by liability law in connection with the application of genetic tests in prenatal diagnosis. Cf. the relevant comments in C1.3.3.5 Wrongful birth.
[628] Chadwick 1997a.
[629] Chadwick 1997a; 1997b; Taupitz 1998.

tests, the right not to know is of particular importance because these tests lead to a presymptomatic diagnosis and usually allow only probabilistic statements.

> "Against this background, only the right not to know can pre-empt the risk of losing one's natural, unbiassed behaviour, one's openness and, ultimately, one's freedom with regard to one's own future. (...) Individuals, acting on their own responsibility, have the right to decide not to know, irrespective of any negative effects that this may have on their health."[630]

However, another particularity of genetic testing methods is that they are not restricted to the tested individual but also affect family members. On the one hand, there are some examinations where family members have to be included in the tests. This is invariably true, for example, for indirect genetic tests. On the other hand, the findings of a genetic test often also reveal information about the genetic status of family members who were not examined. Both situations lead to particular problems with regard to the right not to know.

This may be the case, for example, when a genetic test is requested whose result would directly also provide information about the genetic status of another relative. If a young adult woman whose paternal grandmother had suffered from Huntington's chorea requests a predictive test in order to be able to plan her own life, a positive test result would inevitably also disclose the relevant genetic status of her father. In this case, the right to know clashes with another person's right not to know.[631]

In addition, the right not to know is affected by the fact that, generally speaking, genetic data may also imply additional information other than what had been known when the test was performed.

A particular problem is also posed by data obtained from genetic tests that were performed with blood from the umbilical cord of neonates. These data are usually available when this blood is used to obtain stem cells. In particular in heterologous use, the mother or the parents have to decide not only whether to consent to genetic tests that go beyond what is required for a transfer but also whether they would like to know the test results. In addition, they have to decide whether they want to be informed about such test results even if the analyses are performed at a later time, e.g. at the time of use. In these cases, the right to know or not to know could be made use of in a graduated manner, e.g. if the parents limit the use of this right to the results obtained up to a given period of time, or to certain diagnostic fields.

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[630] Simon 2001, p. 115.

2.2.1.3 The principle of voluntary participation

The performance of a genetic test encroaches upon the integrity of the tested person. This encroachment has to be preceded by personal consent given by the individual concerned following extensive information (informed consent). In fact, informed consent is the only justification for such encroachment. Exceptions to this principle have to remain within narrow legal limits and must not violate the test person's dignity. More specifically, the use of genetic tests must never be brought about by direct or indirect coercion.

The most important instrument to ensure, as much as possible, the voluntary use of genetic tests is the principle of *informed consent* laid down in medical ethics. In connection with genetic diagnosis, informed consent has to meet particular ethical requirements.

An instructive example of ethical guidelines that are aimed at ensuring informed consent in connection with genetic diagnosis is found in a document of the World Health Organisation (WHO):

"Proposed ethical gui*delines in regard of self-determination as well as informed consent*

A. As applied to clinical practice:

In clinical practice, genetic tests should be performed voluntarily on the basis of a comprehensive genetic counselling programme including a valid process of informed consent with respect to the following aspects:

- aim of the test,
- probability of a correct prognosis,
- impact of the test results on the individual and his or her relatives,
- options and alternatives for the tested person,
- potential risks and benefits of the test (also as regards social and psychological matters),
- social risks of being discriminated against by insurers and employers (even if this might be illegal) and

[631] Schäfer 1998, p 211.

– no risk for the individual and his or her relatives, whatever their decision, of not receiving adequate health care.

B. As applied to reasearch and quality control:

A valid informed consent process includes providing information about the following aspects:

Experimental character and objective of the study,

– reason for inviting the person concerned to participate and explanation of the voluntary character of his or her participation,

– procedure,

– unpleasant effects and (possible) risks of the test for the individual as well as for his or her family members,

– uncertainty of test results as regards their predictive value and adequate genetic counselling,

– possible benefits for other persons and for science,

– confidentiality of the documents concerning the test subject's identity,

– person to be contacted for questions about the study or in case of study-related damage,

– right of the individual participant to withdraw from the study at any time,

– right of the individual participant and of his or her relatives to receive unrestricted health care even after his or her withdrawal."[632]

However, in a number of fields of application of genetic diagnosis, the principle of informed consent is not sufficient to ensure the voluntary use of genetic diagnosis. Whenever there is a real imbalance of power in a society that actually thwarts the freedom of contract and the principle of voluntary consent, the persons concerned have to be protected from a more or less coerced "voluntary abandonment" of their informational self-determination. This applies in

[632] World Health Organisation (WHO) 1997 (translation)

particular to employment and insurance contracts.[633] In these cases, preventive measures may be required to prevent individuals, as much as possible, from being exposed to indirect pressure to perform genetic tests.

In this connection, one particular problem is that it is possible to perform a DNA analysis without the knowledge and consent of the person concerned. In one case, which was published by the Administrative Court of the State of Baden-Wuerttemberg in February 2001, a bank employee had been dismissed without notice. The man had been suspected by the bank's board of management to be the author of an anonymous letter, which the top executives of the bank considered to be insulting. To look into this suspicion, the employee was invited to a business meeting where food and drinks were served. The DNA snippets thus obtained were then sent to a centre of forensic medicine for analysis without the employee knowing about this. On the basis of the data thus obtained, the man was dismissed without notice by his employer. The Stuttgart Administrative Court as well as the the Administrative Court of the State of Baden-Wuerttemberg as the appellate court ruled that the requirements for a dismissal on the basis of a strong suspicion of an offence had not been met and therefore held that the dismissal had been unlawful in this case. In its decision of 28 November 2000, the Administrative Court of Baden-Wuerttemberg made it clear that the result of a DNA analysis performed without the knowledge and consent of the person concerned cannot be used as a reason for dismissing an employee without notice based on a strong suspicion of an offence on account of the distribution of insulting anonymous letters in an office. DNA tests performed without the consent of the person concerned – the judges ruled – are only admissible in order to clear up serious crimes. In this case, however, the DNA test had been performed secretly, which – according to the judges – was an inadmissible encroachment on the individual's protected personal rights.[634]

In a resolution adopted at their 62nd Conference, the data protection commissioners of the German Federal Government and of the state-level governments demanded, among other things, that:

[633] Data protection commissioners of the German Federal Government and state-level governments 2001a.
[634] Press release of the Administrative Court of Baden-Wuerttemberg of 20 February 2001.

> "a fundamental provision should be introduced in the Penal Code that will prevent genetic testing without legal authority or the consent of the person concerned – consent which is generally only valid for purposes of medical treatment or research."[635]

2.2.1.4 Non-discrimination

"Genetic discrimination" means unjustified unequal treatment of persons on account of their genetic make-up. Genetic discrimination relates to actual or presumed genetic differences in individuals and their relatives, who are healthy or show only mild symptoms due to their genetic make-up, so that their health and their functionality are not impaired.[636]

The term "genetic discrimination" summarises unequal treatment of individuals or their relatives on account of their actual or presumed genotypic characteristics and hence differs from the concept of discrimination that relates to phenotypic differences which can change an individual's performance and functionality.[637] However, genetic discrimination has several things in common with discrimination against persons with disabilities; this applies in particular to aspect of the "medicalisation" of social problems. In the context of discrimination against disabled persons, this refers to the prejudice according to which a disability will automatically lead to functional restrictions and impaired performance due to physical characteristics of the disabled person. This is then interpreted as an objective justification for the unequal treatment of disabled people. One example is the exclusion of disabled persons from public places, buildings, modes of transport and communication media or their exclusion from living in normal buildings. For a long time, the refusal of equal participation in the use of these public facilities had been justified with the fateful inability of the individuals concerned to climb stairs, to open heavy doors, to read texts not written in Braille, to indulge in audio communication or to master the cultural techniques of reading, writing and arithmetic. Today, the international consensus view is that the participation of disabled people in societal life is not a medical but a social problem which can only be solved by means of a variety of structural measures that promote integration, and by means of anti-discrimination laws.[638]

The question as to what forms of unequal treatment must be considered "unjustified" can only be answered in the context of specific applications. In the field of occupational medicine, for

[635] Data protection commissioners of the German Federal Government and state-level governments 2001.
[636] Boyle 1995. A distinction can be made between direct and indirect discrimination (cf. Chapter B2.2.2.5 Equal rights and non-discrimination).
[637] Geller *et al*. 1996.

example, there may be a case of genetic discrimination if general conclusions are drawn with regard to an employee's productive and functional capabilities on the basis of a certain genetic predisposition.

Discrimination and stigmatisation may occur in connection with

– the generation of knowledge and insights,

– the assessment and use of knowledge, and

– the distribution of benefits and access opportunities.[639]

Data collected in the framework of predictive genetic diagnosis may relate to both the level of individuals (determination of an individual's genetic risk of developing a disease) and the level of populations (screening of high-risk groups or of entire populations). Hence, both individuals and population groups may become victims of "genetic discrimination" on account of their genetic make-up.

Stigmatising or discriminating attitudes and behaviours may be directed both against persons with a hereditary disease or with a predisposition for such a disorder and against individuals carrying a hereditary or somatic risk (e.g. of developing breast cancer). In addition, genetic discrimination may be caused not only by making available information about genetic defects (which predispose for certain diseases) to third parties but also by providing information about a genetic carrier status, genetic "abnormalities" or genetically based sensitivities to certain substances or drugs.

Hence, there is a general risk of "genetic discrimination" for patients or users of genetic analysis methods – in particular with regard to a few specific disorders or test results. This discrimination may take the form of, for instance, individuals being excluded from certain occupational activities or from certain insurance benefits or being socially stigmatised. Various examples of genetic discrimination by insurance companies, employers or adoption agencies in the United States and in the United Kingdom demonstrate that these risks are very real.[640] In a 1996 survey, for instance, which was conducted in the United States among persons with an increased risk for a genetically based disorder, the 917 respondents reported

[638] Degener/Quinn 2000.
[639] Neuer-Miebach 2001, p. 55.
[640] Cf. the references given by Wolbring 2001.

more than 200 cases of genetic discrimination by insurance companies, employers or other institutions.[641]

In various countries, including Austria and Belgium, genetic discrimination of human beings is forbidden by law. In the United States, genetic discrimination is partly covered by the American Disabilities Act (ADA). Other legal provisions designed to prohibit genetic discrimination are currently being prepared. In addition, there are also various international documents that call for a ban of genetic discrimination. Under Art. 11 of the Council of Europe's *Convention on Human Rights and Biomedicine*, for instance, any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.[642]

In Art. 7, UNESCO's *Universal Declaration on the Human Genome and Human Rights* also prohibits any discrimination of individuals on account of their genetic features:

> *Article 7*
>
> "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity."

2.2.1.5 Data privacy protection

The point and purpose of data privacy rules is to protect individuals against violations of their personal and fundamental rights by preventing or at least limiting inadmissible processing of personal data. Hence, the term "data protection" is misleading. The primary purpose of data privacy protection is to protect the personality of individuals whose data are processed; and hence, data privacy protection is the "protection of personal and fundamental rights in connection with the processing of personal data".[643]

Genetic data have a number of properties as a result of which it is particularly difficult but also very necessary to protect them from improper use in order to prevent violations of personal rights − ranging from stigmatisation to exclusion from employment or insurance cover.[644] These properties include, among other things, the following features:[645]

– Genetic data are highly sensitive because the information they provide is often unknown to the carriers themselves. The genetic make-up of individuals affects their personality and

[641] National Human Genome Research Institute 1998.
[642] Cf. C2.1.2 Statutory provisions (national/international).
[643] Grand/Atia-Off 2001, p. 530.
[644] Rodotà 2000.
[645] Cf. also Bayertz *et al.* 2001, p. 300 f.

identity, which are protected by the fundamental right to informational self-determination. This also includes the right to decide what should be disclosed to whom, for what purpose and under which circumstances. When individuals decide to disclose genetic data, they often do not to know themselves what will be disclosed.

– Genetic data are easy to obtain. As a matter of principle, absolute protection of genetic data from unauthorised access by third parties is not possible because theoretically methods of genetic analysis can be used to obtain genetic data from a person without the latter knowing it. Since an individual's genetic make-up is stored in every single cell, in principle all biological material of an individual − whether it is hair left at the hairdresser's or residual saliva on the back of a postage stamp − contains the genetic information of this person and could basically be analysed for all kinds of characteristics.

– In future, genetic data will anyhow be produced by an increasing number of suppliers. Increasing amounts of genetic data will be obtained, gathered and stored by various centres and institutions. This is a problem, among other things, because the data available can also be analysed for other purposes. In other words, there is a risk that genetic data may be *analysed a second time* for purposes to which the tested person has not given his or her consent.[646]

– In addition, genetic data may also be of interest to third parties. Genetic information may possibly be of interest not only for the person from whom such information has been obtained, but also for a wide variety of other individuals and institutions (family members, private companies, employers, insurance companies, law enforcement agencies, the armed forces, scientific institutions, etc.).

In German law, there are no specific data privacy rules on the use of personal genetic data, except for the DNA provisions contained in the Code of Criminal Procedure. As early as in 1987, the Study Commission on "Opportunities and Risks of Genetic Engineering" recommended to the German Bundestag "to ensure that the data privacy rules provide sufficient protection for the genetic data gathered during genetic counselling and prenatal diagnosis".[647]

[646] The fact that this risk is very real is demonstrated by the example of a company in the United States which even offers second analyses of stored gene sequences directly to private individuals in order to enable them to obtain information about newly discovered genes in their personal genetic make-up and about possible genetic defects (cf. Bayertz *et al.* 2001, p. 301).

[647] Report of the Commission of Enquiry "Risks and Prospects of Genetic Engineering" 1987, p. 153.

In recent years, the data protection commissioners of the German Federal Government and the state-level governments have repeatedly commented on the consequences of genetic analyses in the field of data privacy law, stating that there are a number of different aspects that call for legislative action.[648] In a statement presented by an ad hoc working group on data privacy, the data protection commissioners of the German Federal Government and the state-level governments point out that it is necessary to introduce separate data privacy rules that deal with the use of genetic data:

> "Current findings suggest that it is both possible and useful to introduce a single 'Genetic Data Protection Act' because, for all areas in which genetic data are used, a sufficient number of common principles and rules that are in keeping with constitutional requirements, can and should be formulated; as in the Federal Data Protection Act, they should be complemented by only a few specific provisions to deal with specific sectors. Such an Act is also preferable to professional ethics rules introduced by the medical associations in their statutes. Especially in view of the growing trends in other countries towards commercialising genetic data (…), it seems necessary to introduce such a formal 'Genetic Data Protection Act'. Such an Act will mainly offer advantages in areas where individual fields of application converge or overlap, thereby avoiding uncertainty with regard to the applicable rules. A separate Act would also lead to more transparency and accord more importance to the fundamental right to informational self-determination than codification in a single article. However, such a 'Genetic Data Protection Act' could also be incorporated into a more comprehensive 'Genetic Diagnosis Act'."[649]

At their 62nd conference held in October 2001, the data protection commissioners of the German Federal Government and state-level governments presented comprehensive "Proposals to Safeguard Self-determination in Genetic Testing" with a view to introducing relevant statutory provisions. These proposals mainly dealt with provisions on the reliability of genetic testing in human beings, the use of specimens, and the collection, processing and use of genetic data.[650]

The data protection commissioners primarily called for improvements regarding the monitoring opportunities currently available. They felt that while there was no lack of monitoring bodies, these would have to be informed by the various institutions on relevant

[648] Cf. for example the Resolutions on Genome Analysis and Informational Self-determination 1989; Genetic Engineering and Data Protection 1997; Legal Consequences for Data Protection of the Decyphering of the Human Genome 2000.
[649] Data protection commissioners of the German Federal Government and the state-level governments 2001a.
[650] Data protection commissioners of the German Federal Government and the state-level governments 2001b.

cases of genetic data processing; furthermore, they should mobilise the necessary expertise in genetic engineering, be given clear legal yardsticks for monitoring and counselling, and they should also be adequately staffed to be able to check and enforce compliance with the provisions on site. The commissioners felt that it should therefore be considered whether research applications submitted to ethics committees should at the same time be presented to the independent data privacy monitoring bodies, which some ethics committees were already obliged to do today. The commissioners pointed out that the data privacy rules currently in force did not provide for any participation of the data privacy monitoring bodies in research projects based on informed consent. They also stated that it was unclear what monitoring options were available under data privacy rules with regard to the use of carriers of biological information (blood samples, hair roots, but also isolated DNA). Finally, the data protection commissioners pointed out that data privacy monitoring bodies should be involved in the licensing or approval of genetic laboratories for analyses of human genetic material in order to guarantee the necessary technical and organisational data privacy measures.[651]

One of the key data privacy safeguards is the individual's right to informational self-determination. Except for well-defined specific segments, this safeguard protects the individual's right to decide on the disclosure and use of his or her personal data.[652] For this reason, the fundamental principle of a statutory regime must be that no third party must be given access to an individual's identity-disclosing DNA samples or genetic information unless the individual has explicitly authorised (in writing) the taking of the sample for the purpose of genetic analysis, and the analysis itself, and unless it is guaranteed that the individual has access to, and control over, the use and disclosure of this information. This also implies that genetic data must not be used for commercial purposes without the specific free and self-determined decision of the persons concerned. The question as to how this principle should be translated into reality in society will have to be discussed with a view to adopting concrete provisions in specific areas.

[651] Data protection commissioners of the German Federal Government and of the German state-level governments 2001a.
[652] Grand/Atia-Off 2001, 532 f.

2.2.2 Specific fields of application and problem areas

2.2.2.1 Genetic testing and occupational medicine

2.2.2.1.1 Examinations in occupational medicine

In occupational medicine, examinations are performed on employees (both within and outside the scope of industrial safety legislation) for various reasons (pre-employment and aptitude examinations, specific and general examinations in occupational medicine, screening for illicit drugs, expert opinions, etc.). Generally speaking, a distinction must be made between two types of examination: on the one hand, examinations that are performed in occupational medicine, in accordance with the German Industrial Safety Act, for early detection of work-related disorders of employees in connection with certain exposures and risks that occur in plants or workplaces, with a view to taking specific safety precautions; and on the other hand, there are other examinations of employees such as pre-employment examinations that are usually not performed for preventive reasons. In addition, there are examinations that are performed in order to prove that specific injuries were caused in the workplace.

2.2.2.1.2 Use of genetic testing in occupational medicine

To the knowledge of the Study Commission, DNA analyses are currently not being used in occupational medicine in Germany. At present, there is virtually no evidence suggesting that prospective employees are obliged to present or perform a genetic test as a condition for their employment, or that individuals are asked to perform such tests during their employment.[653] Likewise, there is no evidence suggesting that job seekers might try to obtain an advantage with regard to their recruitment by presenting a genetic test to their prospective employers. And – again as far as the Study Commission knows – genetic diagnostic procedures are not applied in connection with the preparation of expert opinions, either.

This finding is in line with international experience. The *British Human Genetics Advisory Commission* (HGAC), for instance, states in its report entitled "The Implications of Genetic Testing for Employment" that in practice there is no evidence suggesting that employers make use of the results of genetic tests performed on employees. According to the HGAC's report, the only exception is the Ministry of Defence (MOD). The MOD only allows candidates to join the air force if their test results for sickle-cell anaemia and other disorders are negative.[654]

[653] There was only one exception where a young man in Bavaria allegedly was not recruited by the police force because he had refused to be tested for the mutation in the gene for Huntington's Disease (Engel 2001, p. 293).

[654] Human Genetics Advisory Commission 1999.

In the United States, however, there have been several reports about genetic discrimination in the workplace. A survey conducted by genetic diagnosis counsellors identified 550 persons who had been denied insurance contracts or employment contracts because of their genetic predisposition to a given disease.[655] Under US federal law, it is generally admissible in the United States to use genetic testing for employment.

According to experts, no genetic testing methods are currently known that could be used for predictive purposes.[656] It is at least questionable whether there is a genetic test that can be effectively used in order to protect third parties from considerable harm. The main reason why genetic testing is currently not used in occupational medicine is that, at present, molecular genetic or cytogenetic tests do not provide any advantage versus other testing methods used in occupational medicine. Tests that would be relevant for occupational medicine would primarily be tests that could help diagnose predispositions to multifactorial diseases, i.e. diseases that are caused by several genes and in addition by various environmental factors. Currently, however, there are no valid or practicable tests that could be used as routine procedures to identify such diseases.[657] Evidently much more progress will have to be made with regard to the understanding of common diseases and the genetic tests themselves before the use of DNA analyses might become a major practical problem in occupational medicine.

Unlike diagnoses at DNA level, a number of testing methods that are performed at the level of gene products and chromosomes are already standard procedures in occupational medicine today. The purpose of most of these tests or corresponding research projects is to identify acquired chromosome changes or gene mutations. Such exposure analyses can be used, for instance, to monitor workplaces (bio-effect monitoring) or to identify the causes of diseases in retrospect (ex-post analyses).

It is true that there has been a considerable increase in examinations and screening tests performed in the context of occupational medicine in the past few years. Generally speaking, occupational medicine has access to genetic tests at all four levels of testing (phenotype analyses, protein chemical analyses, cytogenetic analyses and DNA analyses) as well as the analytical methods developed to diagnose both genetic changes caused by an individual's predisposition and genetic changes that occur later in life, i.e. that are acquired. In the past, however, the vast majority of genetically based, individual risks and sensitivities were

[655] National Human Genome Research Institute 1998.
[656] Bayertz *et al*. 1999, pp. 180 ff.
[657] Hennen *et al.* 2001, p. 103.

diagnosed by means of clinical procedures such as family history and medical examinations. Between 80 and 90 per cent of all the examinations currently performed in occupational medicine are phenotype analyses. Overall, however, it is difficult to answer the question as to the extent to which each of the various testing methods is used in occupational medicine because relevant data are not available. This applies in particular to pre-employment medical examinations which employers may request prior to concluding an employment contract.

2.2.2.1.3 Statutory provisions

In Germany, the application of genetic tools and procedures in occupational medicine is not subject to any statutory provisions – with very few exceptions.[658] As regards examinations performed in occupational medicine in general, various provisions apply, depending on the time, the reason and the purpose of an examination. More specifically, there is no legal basis currently for introducing compulsory genetic testing in the framework of preventive care in occupational medicine.[659]

In other countries, there are diverging views with regard to the use of genetic test methods in occupational medicine. Only very few countries have adopted specific provisions to cover this area. In Austria, for instance, employers are prohibited under Section 67 of the Austrian Genetic Engineering Act from obtaining, requesting, accepting or otherwise utilising results of genetic tests from their employees or job seekers. In Switzerland, a Genetic Diagnosis Act is currently being prepared which will also cover the use of genetic analysis methods in occupational medicine. In the Netherlands, the use of genetic testing is covered by the Health Tests Act (*Wet op de medische keuningen*) which applies to medical information in general and which defines genetic information as a specific sub-type of medical information. The Act, which was adopted in 1997, generally restricts the performance of medical examinations in connection with the employment of individuals to a situation in which "the fulfilment of the tasks associated with an employment in the private sector or recruitment in the public service imposes particular requirements on an individual's suitability in terms of his or her state of health."

[658] The exceptions apply to specific preventive examinations prescribed by the German employers' liability insurance associations as well as bio-monitoring performed in the context of the German Hazardous Substances Ordinance (*Gefahrstoffverordnung*).
[659] Kohte 2000.

Within the meaning of this Act, "medical suitability for the task" relates to the protection of the health and the safety of the person to be examined and of third parties in connection with the performance of the work concerned. Article 3 of the Act generally prohibits examinations

– where the interest of the employer is not greater than the risks associated with these examinations for the person to be examined. This includes examinations that are specifically designed to obtain knowledge about a potential future serious diseases for which there is no cure or whose progression cannot be prevented or stopped by medical interventions, or to obtain knowledge about a current serious disease that cannot be treated and that will probably become manifest only after a longer period of time;

– that for other reasons involve a disproportionately severe burden for the person to be examined.

At European level, the member states that have acceded to the "Convention (of 4 April 1997) for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine" have made the approval of predictive genetic tests for diseases contingent on the presence of health purposes and genetic counselling.[660]

2.2.2.1.4 Purposes of tests

The benefit of genetic findings in occupational medicine is ambivalent. On the one hand, there are hopes that the application of genetic testing methods in employees will improve prevention and occupational medical care. On the other hand, however, there are fears that these procedures may be abused for the purpose of selecting employees, and that they may undermine the protection of the employees' health.

With a view to the assessment of genetic testing methods – or any other tests – used in occupational medicine, it is necessary to ask who requests such tests, for what purposes they are performed and for what other purposes the test results may possibly be used. In addition, however, it is also necessary to consider any other specific consequences and risks that may be associated with the application of genetic analysis methods.

For several reasons, tests performed on individual genes with the objective of identifying specific inherited characteristics might be of (considerable) interest in the framework of examinations in occupational medicine. Test results might perhaps reveal information on:

[660] Cf. C2.1.2 Statutory provisions (national/international).

– an individual's genetic characteristic or predisposition that might lead to a higher rate of disease-related absenteeism,

– a genetic characteristic as a result of which the employees concerned might not be able to perform their duties properly in the workplace and thus expose themselves or others to a risk in the workplace, or

– higher susceptibility of an individual to toxic or other hazardous substances or other specific circumstances prevailing in a workplace.

Like other test methods used in occupational medicine, molecular genetic tests can generally be performed at the request or for the protection and in the interest of employees, at the request and in the interest of employers, or for the protection of third persons.

2.2.2.1.4.1 Molecular genetic tests performed at the request of employees

Genetic tests may provide information to an employee on whether it is necessary to adopt protective measures with regard to a specific workplace, and if so which ones, or whether a certain workplace may perhaps be unsuitable for the individual involved. Early identification of an individual's risk would make it possible to protect a job applicant or an employee preventively from being exposed to hazardous substances to which the individual concerned is particularly sensitive, or to adopt necessary protective measures in good time. Suitable genetic tests would make it possible, for instance, to detect in advance an individual's predisposition to allergies (bricklayer's eczema, baker's asthma). It is also known that persons with alpha-1-antitrypsin deficiency often develop pulmonary emphysema at an early age when they are exposed to polluted air. Knowing the acetylation status of a job applicant or an employee might help prevent many cases of urinary bladder carcinoma.

Generally speaking, molecular genetic test methods could also be used to determine injuries acquired in connection with an occupational activity. More than in the past, occupational medicine could thus help, for instance, to compensate for damage that has occurred by means of indemnification schemes because genetic tests will provide new opportunities for retrospective exposure assessment.

In addition, better identification of genetic differences between individuals with regard to their susceptibility to certain substances and greater validity of the assessment of an individual's risk could also be used for preventive purposes. As a result, it may perhaps be possible to determine in advance whether new substances used in workplaces are hazardous to

the health of certain groups of persons and, if necessary, to eliminate or neutralise such substances. It may also be possible that a better understanding of pathogenic mechanisms will help identify hitherto unknown workplace risks.[661]

2.2.2.1.4.2 Molecular genetic tests performed at the request of employers

One of the most important examinations performed at the request of employers is the pre-employment examination. There is a clear dichotomy here because the primary purpose of the data generated is not to improve the workplace but to select employees.[662] From the employee's perspective, predictive tests can serve the employers' interest if employers try to use pre-employment and/or preventive examinations in order to identify employees with genetically based sensitivities to certain hazardous substances or in order to determine whether an employee is capable of tolerating particular workplace requirements that are detrimental to human health. However, predictive genetic tests performed in the framework of pre-employment examinations could also be used by employers to obtain information on a job applicant's productive capacity or employability in certain, challenging workplaces or to find out before concluding an employment contract whether the job applicant has a genetic predisposition that could lead to a higher rate of disease-related absenteeism, so as to avoid costs that would otherwise be incurred due to the continuation of his or her wage payments or due to the employment of a substitute during the employee's absence due to illness. Finally, it may perhaps also be in the interest of an employer to examine before concluding an employment contract whether a job applicant is the carrier of a genetic trait that might lead to an inadequate performance in the workplace as a result of which other persons (colleagues or customers) could be jeopardised.

Overall, however, it should be borne in mind that the use of genetic tests must not be allowed to prepare the ground for genetic determinism in occupational medicine, which would mean that the genetic information available on an individual would be used to draw conclusions with regard to the commitment, the productive capacity and the risk which that individual would pose for other persons, because the whole human being is more than his or her genes. Again it is possible to draw a comparison with the medicalisation of disabilities. Information on existing disabilities must not be used alone to draw medical conclusions with regard to the qualification of employees. An employee with a disability must be appraised individually and

[661] Bayertz *et al*. 1999, p. 200.
[662] Kohte 2000.

in concrete terms. This applies even to so-called dangerous disabilities or diseases such as epilepsy.

Once again, the US anti-discrimination law is exemplary in this context:

> "An employer may include a requirement that an individual shall not pose a direct threat to his or her own health and safety or to that of other individuals in the workplace. However, the employer must comply with very specific and very strict requirements under the ADA (Americans with Disabilities Act) in order to be able to determine that an individual poses a direct threat. The term "direct threat" means a significant risk to the health or safety of the individual or others that cannot be eliminated or reduced by reasonable accommodation. (…) The mere possibility of future invalidity cannot be cited as a reason for deciding that an individual poses a threat. (…) An employer cannot refuse to hire a disabled person solely because of a slightly higher risk or a purely speculative or very improbable risk. (…) If a medical examination shows that a person has epilepsy, however, without having any seizures or if that person can feel early enough that a seizure is imminent, it would be unlawful to refuse to assign this person to a workplace at a machine because of the fear or speculation that this person may pose a risk for himself/herself or others."[663]

2.2.2.1.4.3 Molecular genetic tests performed for the protection of third parties

Another idea that is currently being discussed is the use of molecular genetic testing on employees for the protection of third parties. This idea is based on the assumption that it would be possible by means of a predictive genetic test to predict the outbreak of an employee's disease that could lead to a sudden slip and might therefore pose a considerable risk for third persons. Examples that have been cited include persons with seizure disorders of neurological or circulatory aetiology; such persons should not be employed in safety-relevant occupations (e.g. aircraft pilots). For technical reasons, genetic tests are currently not capable– and will not be in the foreseeable future – of predicting, with sufficient certainty, the onset and the severity of diseases that might cause a sudden slip and that could therefore pose a considerable threat for third parties.

2.2.2.1.5 Development prospects

Since there is a common belief in occupational medicine that, as a general rule, all diagnostic procedures should be applied during medical examinations that are performed in the framework of the occupational health service's mandate, and since no rules have so far been

[663] Golden *et al.* 1993 (translation of German translation).

adopted for genetic tests, it must be assumed as a general rule that in future all laboratory tests that are introduced in the market – consequently also DNA tests – can be used in examinations of employees. In this context, it should generally be borne in mind that effects observed in connection with pharmacogenetic research can often also be relevant in the workplace. What types of genetic tests will be practically applied in occupational medicine in future, and to what extent, will largely depend on the evolution of the relevant scientific research and technological developments. It is currently hard to estimate how long it will take until practical tests become available to make valid predictions with regard to an individual's health risks and susceptibilities. In addition to continuous improvements in the knowledge of the human genome, new testing technologies (DNA chip technology, automatic sequence analysers) will also play an important role for the development of new application options.[664] Generally speaking, it must be assumed that the – already wide – gap between diagnostic options on the one hand, and industrial safety options on the other, will probably become even wider in the future with the availability of genetic diagnostic procedures.

2.2.2.1.6 Fundamental principles to be protected

2.2.2.1.6.1 The principle of voluntary participation

The use of genetic testing methods in occupational medicine might jeopardise the principle of voluntary participation mainly insofar as job seekers might try to obtain an advantage over their competitors with regard to their recruitment by presenting a genetic test to their prospective employers. The principle of informed consent is not sufficient in this case to ensure the voluntary use of genetic diagnosis.

2.2.2.1.6.2 Objective industrial safety versus selection of employees

On the one hand, the identification of genetically based sensitivities to hazardous substances in the workplace or of injuries caused in connection with an occupational activity can be an important and effective instrument for employees to protect their health in terms of choosing a suitable workplace, protecting (an individual's) health, or safeguarding claims for damages.

On the other hand, however, in conjunction with this potential benefit, there is a risk that objective industrial health and safety standards may be undermined. Molecular genetic test methods could be used by employers, for instance, not to reduce health hazards in the workplace but to avoid recruiting, or to terminate the employment contracts of, particularly

[664] Hennen *et al.* 2001, p. 105.

high-risk employees, or generally to select job applicants with a view to their genetic make-up, which practically may be tantamount to excluding employees from employment opportunities because of their genetic make-up. For this reason, it is necessary to adopt specific rules that will ensure that the primary function of occupational medicine – which is to improve objective industrial safety – will not be pushed into the background by subjective industrial safety options that are made available by the application of genetic testing methods. Preventive measures adopted from an objective technical perspective must take precedence over individual measures. Otherwise, the consequence would probably be that more efforts would be made to select employees without having to remedy the relevant injuries to health.[665]

At the same time, there is a risk that approved limits for hazardous substances and for working conditions with adverse health effects might be relaxed. The risks might be increasingly passed on to each employee. For this reason, genetic tests should only be used in occupational medicine if it is guaranteed that important principles of industrial safety law will not be put into question. One principle to be upheld in particular is the principle that whoever poses a threat by establishing a business operation will be accountable for the associated health risks. Employers are obliged to protect their employees' health in the workplace, but not only under public law rules: under private law, employers are also obliged to protect the health of each individual employee (Section 618 of the German Civil Code). This duty to protect the individual's health must not be undermined by the introduction of genetic testing in occupational medicine. Introducing provisions to this effect in Section 618 of the German Civil Code or in the German Industrial Safety Act (*Arbeitsschutzgesetz*) of 1996 would be an obvious choice to clarify this matter.

2.2.2.1.6.3 The principle of non-discrimination

In our society, having a job is vitally important for most people. Denying access to gainful employment to an individual because of his or her genetic predisposition severely curtails that individual's opportunities for personal and economic development. Hence, the application of molecular genetic test methods in occupational medicine involves a particular risk that these procedures might be abused for the purpose of selecting employees. A negative prediction may entail the risk that a job applicant will not be recruited or that an employee will be dismissed.

[665] Hennen *et al.* 1996, p. 182.

In the context of occupational medicine, there is also a high risk that individuals may become or may remain excluded from employment because general conclusions are drawn from a certain genetic predisposition with regard to their performance and functionality.

In order to avoid these and similar disadvantages, the *Americans with Disabilities Act* – which is the US anti-discrimination act for persons with disabilities – prescribes a multi-stage right for employers to make inquiries:

> "Under the ADA, an employer's right to make inquiries or request a medical examination in connection with a disability is examined in three stages: prior to extending an offer of employment, after extending an offer of employment and once the applicant has been hired. During the first phase (**prior to extending an offer of employment**), the ADA prohibits all disability-related inquiries and medical examinations, *even* if they are related to the workplace. During the second phase (**after a conditional offer of employment has been extended to an applicant but before the individual begins work**), an employer may make inquiries and have medical examinations performed in connection with a disability, irrespective of whether these inquiries and examinations are related to the workplace or not, as long as this applies to all newly recruited employees of the same professional category. During the third phase (**once the applicant is hired and begins to work**), an employer may make inquiries and request medical examinations in connection with a disability only if the information to be obtained is job-related and consistent with business necessity."[666]

To what extent elements of the ADA can be applied to the situation prevailing in Germany will have to be examined.

2.2.2.1.6.4 Data privacy

Genetic data are particularly sensitive data and therefore warrant particular protection. This also applies in particular to the use of genetic tests in occupational medicine because genetic data gathered by a company may be abused both internally and externally and may be used, for instance, by employers for the purpose of selecting employees. For this reason, it is particularly important that data privacy rules are observed in the context of occupational medicine.

[666] U.S. Equal Employment Opportunity Commission 2000, p. 3 (translated from German translation).

According to the data protection commissioners of the German Federal Government and state-level governments, the individuals concerned should themselves have the right to restrict the use of genetic data:

> "In view of the particular nature of genetic data (…), a job applicant should be protected against having to undergo a 'voluntary' genetic test – at the employer's 'suggestion' or not – in order to improve his or her chances. This could be achieved by clearly prohibiting employers from requesting *and accepting* genetic tests from applicants."[667]

For this reason, the data protection commissioners of the German Federal Government and the state-level governments have proposed the following "principle" in their "proposals aimed at safeguarding self-determination in genetic testing":

> "Employers and insurers shall be prohibited by law from performing or having others perform predictive genetic tests on applicants for employment and insurance contracts as a condition for the conclusion of such contracts, or on employees and policy holders after the conclusion of such contracts, or from requesting, accepting or otherwise using results of genetic tests. As a matter of principle, employers or insurers shall not be able to claim any rights from untruthful answers."[668]

In addition, the data protection commissioners have proposed the following provisions:

> "If, despite prior industrial safety measures, a workplace continues to be associated with a higher disease or accident risk (where the state of the art in science suggests that a certain genetic structure of the individuals concerned is significant for the occurrence of the diseases or accidents), the employer shall draw a job applicant's attention to this fact. The factory's medical officer shall advise the individual concerned with regard to a suitable genetic test and recommend doctors who are qualified for this purpose."[669]

2.2.2.2 Genetic testing and insurance

For several years now, there has also been a discussion concerning the use of genetic testing in the insurance sector. Private insurers might use the results of genetic tests *prior* to the conclusion of an insurance contract in order to improve their risk selection or to ward off anti-

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[667] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001a.
[668] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001b.
[669] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001b.

selection risks. The genetic make-up of a person who wants to take out insurance may be particularly interesting for life insurance, occupational disability insurance and health insurance policies. In addition, genetic tests might also play a role *after* the conclusion of an insurance contract. It would be conceivable, for instance, that policy holders might be obliged to carry out genetic tests in the framework of preventive examinations (screening programmes) or with a view to providing care and treatment geared specifically to the needs of an individual.

2.2.2.2.1 Genetic testing and risk assessment

In the Federal Republic of Germany, there are two basic types of insurer that provide insurance cover for health risks: social security institutions and private insurance companies. In the case of the social security institutions, an insurance relationship is established by operation of the law and without assessing an individual's risk. The purpose of such insurance is to cover elementary risks in life while upholding social justice. In the case of private insurance companies, on the other hand, the establishment of the insurance relationship is not imposed by mandatory statutory provisions; instead, the relationship is created by means of a contract. Private insurance policies are risk-related and subject to an assessment of the risk.

Private insurers calculate the premiums on the basis of the policy holders' individual risks. For this reason, private insurance companies – unlike social security institutions – assess a prospective policy holder's risk prior to concluding a contract. Premiums for private insurance policies vary in accordance with the level of the risk assumed by the insurance company. "The purpose (of risk assessment) is to ensure that the risks assumed are in line with the targets set by the insurers in their general operational plans for their business operations and that they do not overtax the company's ability to pay out benefits. This means that its purpose is also to ensure that the company will be able to fulfil its obligations vis-à-vis the policy holders in the long term."[670]

The use of genetic testing methods could be of particular interest to private insurers. However, Schöffski believes that it is also conceivable that the insured persons' duty to co-operate, which is codified in social security law, might one day be interpreted as an obligation to perform genetic tests.[671]

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[670] Lorenz 2000, p. 21.

[671] Schöffski 2001, p. 546. Generally speaking, it is also conceivable that genetic tests might play a role in the insurance sector *after* the conclusion of an insurance contract, e.g. with a view to the coverage of diagnostic or

Private health or life insurers could use the results of genetic tests prior to concluding a contract in order to improve their risk assessment. This could enable them both to calculate more risk-adequate premiums and to select risks. Insurance companies might also be interested in the use of genetic tests in order to ward off an anti-selection risk which may possibly arise if prospective policy holders gain a "genetic information advantage" over the insurance company on a larger scale and use this advantage deliberately against the company. De facto, the German insurance industry currently not only abstains from using genetic test methods to specify risks but largely also abstains from using other diagnostic procedures that could help obtain risk-relevant findings. Usually, it is the information provided by the applicant that is relevant for the assessment of the risk. Currently, approx. 99 per cent of all life insurance contracts in Germany are concluded without a prior medical examination. However, the insurance companies have the right to challenge the validity of a policy if it turns out when the insured event occurs that the policy holder has concealed a relevant diagnosis.

2.2.2.2.2 Use of genetic test procedures in the insurance sector

Currently, genetic testing procedures do not play a major role in the insurance sector worldwide. In an international survey conducted in 1997, the respondents "mentioned only isolated cases where applications had been submitted together with molecular genetic test results (most frequently Huntington's Disease)."[672]

To the knowledge of the Study Commission, DNA analyses are currently not being used in the insurance sector in Germany. Private insurance companies do not request the submission of a genetic test in the framework of their risk assessment as a requirement to be met prior to the conclusion of an insurance contract; nor do they explicitly ask for the results of genetic tests obtained elsewhere in the framework of their risk assessment.[673] At the end of 2001, the members of the Association of the German Insurance Industry (*Gesamtverband der Deutschen Versicherungswirtschaft* – GDV) have made a voluntary commitment "not to make predictive genetic tests a prerequisite for the conclusion of insurance contracts." They went on to state that

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therapeutic benefits by health insurance policies, or with a view to their use in prevention, or additional premiums for high-risk lifestyles, etc. This aspect will be disregarded in the following considerations.

[672] Regenauer 1997, p. 630.

[673] Bayertz *et al.* 1999, p. 29; pp. 234 ff.; Hennen *et al.* 2001; Gesamtverband der Deutschen Versicherungswirtschaft 2001.

> "for private health insurance and for all types of life insurance including occupational disability, general disability, accident and nursing care annuity insurance up to a sum insured of less than 250,000 euros or an annuity of less than 30,000 euros, they will not request their customers to present to the insurance company prior to the conclusion of a contract any predictive genetic tests carried out voluntarily for other reasons. Within these limits, the insurers *waive* the proposer's obligation, as enshrined in the German Insurance Contract Act (*Versicherungsvertragsgesetz*), to disclose all risk-relevant facts to the insurer prior to the conclusion of a contract."[674]

In addition, the members of the GDV have stated that they would not make use of any genetic findings nevertheless submitted by customers in such cases. The voluntary commitment made by the GDV will be valid until 31 December 2006.

There are various reasons why the insurance companies are reticent to use genetic testing: in addition to legal reasons, which play a role in various countries, these are mainly technical and actuarial reasons. Currently, there are only very few predictive genetic tests that supply clear information. These tests relate to rare (single-gene) hereditary disorders with a low prevalence in the population.[675] However, when it comes to disorders that are very common in the population and whose diagnosis would be interesting for actuarial reasons, reliable genetic diagnostic procedures are not yet available.[676] In 1997, the British Human Genetics Advisory Commission (HGAC) arrived at a similar conclusion:

[674] *Gesamtverband der Deutschen Versicherungswirtschaft* (Association of the German Insurance Industry) 2001.
[675] Regenauer 1997, p. 630.
[676] Hennen *et al.* 2001, p. 118.

> "For certain single-gene (monogenic) disorders, actuarially significant associations between genetic factors and specific diseases or premature death are known to exist. (…) There are a few late onset monogenic disorders, for example Huntington's Disease, and here genetic test results may provide a basis for relatively precise prediction. However, it is not possible precisely to predict the age at which the disorder will become manifest or its probable severity. (…) In the vast majority of cases of ill health, however, not enough is known about the interaction between different genes, or between genes and the environment, or genes and life-style factors. Nor is this degree of knowledge likely to be available for a significant time. One of the basic misunderstandings of genetics is the notion that it will lead to an immediate increase in general predictive power. These expectations seem unrealistically high, and for the foreseeable future, genetic tests may have little real predictive value for insurance purposes, except for a few relatively rare diseases."[677]

In addition, it has been argued that the availability of genetic tests actually did not contribute to calculating more risk-adequate premiums or to optimising the risk selection because if the individual's probability of developing a specific disorder was known too precisely, so that the "insured community would be split up into groups in accordance with their risk characteristics", the "law of large numbers would no longer be applicable and the concept of insurance would ultimately come unhinged".[678] It has also been suggested that if risks were too differentiated, at the end of the day insurance cover would only be sought by individuals "who expect to develop a disorder; however, a prudently calculating insurer would have to charge such high premiums to these individuals that they would have to finance their own diseases in the final analysis."[679] However, the two latter actuarial reasons cited for the cautious approach adopted by insurance companies are controversial, even in the insurance industry itself.[680]

2.2.2.2.3 Statutory provisions

In Germany, there are no specific statutory provisions that restrict the options of insurance companies to make use of the results of genetic tests for the calculation of risks.[681] For this reason, various bodies have suggested that there is need for legislative action (e.g. Report

[677] Human Genetics Advisory Commission 1997, pp. 10 f.
[678] Sahmer 1995, pp. 7 f.
[679] Sahmer 1995, p. 7.
[680] Cf. the comments made by Bayertz *et al.* 1999, pp. 237 f.
[681] According to the General Insurance Conditions, however, if one parent of a new-born child has been insured for at least three months and if an application is filed for the new-born child within two months after birth, the child is entitled to the same insurance cover without the insurance company being allowed to charge an additional premium, e.g. for a disability (Sahmer 1995).

submitted by the Study Commission on "Opportunities and Risks of Genetic Engineering" (1987)[682]; the "Genome Analysis" Working Group of the German Federal Government and the state-level governments (1990); resolution of the *Bundesrat* (Upper House of the German Parliament) to prevent the use of genome analyses in private insurance (November 2000); Ethics Council of the German Federal Ministry of Health (November 2000).

To the Study Commission's knowledge, insurance companies in Germany do not make use of genetic testing; however, they do insist on the disclosure of facts prior to the conclusion of a contract. Under Section 16 of the German Insurance Contract Act (*Versicherungs-vertragsgesetz* – VVG), insurance prospects are obliged "to disclose all risk-relevant facts that may influence the insurer's decision to conclude the contract as such or with the agreed terms." In its current version, the Insurance Contract Act does not distinguish between predictors analysed at phenotype level or at genotype level; whether results of genetic tests are risk-relevant or not, and if so which ones, is controversial.[683] Outside Germany, the use of genetic tests in the insurance sector is subject to varying statutory provisions.[684] In this context, it is worth noting that managers of social insurance systems make less use of the risk selection opportunity provided by genetic diagnostics than their counterparts in competitively organised insurance systems. In *Denmark*, *France* and *Austria*, for instance, the use of results of genetic tests in the insurance sector is prohibited by law. In Austria, for example, Art. 67 of the Genetic Engineering Act of 1994 states:

> "Section 67. It is unlawful for employers and insurers to collect, request, accept or otherwise utilise results of genetic analyses from their employees, job applicants, policy holders or insurance buyers."

Provisions contained in the preliminary draft of federal bill on genetic testing in *Switzerland* have a similarly restrictive effect:

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[682] *Bericht der Enquete*-Kommission "Chancen und Risiken der Gentechnologie" (Report submitted by the Study Commission on "Opportunities and Risks of Genetic Engineering") 1987. In its report, the Study Commission recommended that the German Bundestag should "call upon the German Federal Government to make every effort to ensure that the insurance industry will maintain its current cautious approach with regard to the use of genetic testing. In order to protect the applicants against being genetically sounded out, which would be contrary to public policy, the Government should convince the insurance companies, by way of the competent supervisory authorities, to make statements in their general operational plans that reflect the principles developed (...) by the Study Commission. If it proves to be impossible to limit the use of genetic tests in this way, an amendment to the Insurance Contract Act should be considered." (Report of the Study Commission on "Opportunities and Risks of Genetic Engineering" 1987, p. 175).

[683] Präve 1992; Sahmer 1995; Schmidtke 1998.

[684] Comprehensive overviews can be found in Berberich 1998, Simon 2001 and European Society of Human Genetics/Public and Professional Policy Committee 2001.

"Art. 22 Principles

1 Insurance institutions shall not request pre-symptomatic or prenatal examinations from applicants as a condition for establishing an insurance relationship.

2 They shall not request applicants, prior to concluding an insurance contract, to disclose results of earlier pre-symptomatic or prenatal examinations or of examinations performed for family planning purposes, and they shall not use the results of such examinations.

3 Applicants shall not, on their own accord, disclose the results of earlier pre-symptomatic or prenatal examinations to insurance institutions.

Art. 23 Exemptions

1 Applicants may disclose to insurance institutions results of earlier pre-symptomatic or prenatal examinations if they want to use this information to demonstrate that they have been wrongfully classified in a high-risk group.

2 Based upon well-founded requests submitted by the insurance associations or individual insurance institutions, the federal agency appointed by the Executive Federal Council (*Bundesrat*) shall determine for certain non-compulsory types of insurance the pre-symptomatic examinations about the results of which insurance institutions may make inquiries vis-à-vis applicants. The agency may make it mandatory for applicants to answer relevant questions by fiduciary doctors if:

the examination concerned was found to be reliable by the Swiss Commission for Genetic Testing (*Eidgenössische Kommission für genetische Untersuchungen*); and

the scientific value of the test results for the calculation of the premiums has been demonstrated.

3 The fiduciary doctor shall merely tell the insurance institution whether the applicant should be classified in a particular risk group.

4 Paragraph 2 above shall not apply to occupational provident institutions or to insurance covering continued pay in case of sickness or maternity leave."

In the *Netherlands*, the Act on Medical Examinations (*Wet op de medische keuningen*), which was adopted in 1997, prohibits insurance companies from asking any question during the risk assessment that constitutes an unreasonable encroachment on the privacy of the person to be insured. Under no circumstances may medical examinations be performed where the

informative value to be expected for the insurance company is disproportionate, relative to the associated risks for the person to be examined. However, these restrictions only apply up to certain "question limits" that depend on the maximum limit of a given insurance. The "question limit" for life insurance is currently HFL 300,000, which is adjusted every three years to reflect the cost of living index. The Act does not prohibit voluntary genetic tests and the subsequent submission of the results to insurance companies. In various other countries such as *Italy*, *Spain*, *Portugal* and *Sweden*, there are no statutory provisions.

In the United Kingdom, the use of results of genetic tests is primarily regulated by rules and codes adopted by associations. According to the Genetic Code of Practice[685] of the Association of British Insurers (ABI), results of genetic tests may be used providing that the recommendations of the UK Government's Genetics and Insurance Committee (GAIC) are observed and providing that the tests are reliable and relevant for the insurance contract. In October 2000, the first test that the GAIC declared to be reliable and relevant was a genetic test for Huntington's Disease.[686]

Table 19: Conditions and Genetic Tests Relevant for Insurance Purposes, as Recommended by ABI

Condition	Tested Genes
Huntington's Disease	HD
Early-onset familial Alzheimer's Disease	APP, PS1 and PS2
Hereditary breast/ovarian cancer	BRCA1 and BRCA2
Myotonic dystrophy	MDPK
Familial adenomatous polyposis coli	APC
Multiple endocrine neoplasia	RET
Hereditary motor and sensory neuropathy	PMP22

Source: House of Commons 2001, p. 14

In a "Government Response to the Report from the House of Commons Science and Technology Committee: Genetics and Insurance", the UK Department of Health suggested in

[685] Association of British Insurers 1999.

October 2001 that the composition of the GAIC should be reconsidered and at the same time recommended

> "that, prior to the publication, the reformed GAIC should reconsider its decision to allow the use of the genetic test for Huntington's Disease by insurers, together with an extensive review by experts of both the data provided by the insurers and its own decision."[687]

Also in October 2001, the Association of British Insurers agreed with the British Government to a five-year moratorium. This agreement includes

- "a five-year moratorium on insurers' use of predictive genetic test results, beginning on 1 November 2001, except for the circumstances mentioned below;
- the continuing use of genetic test results by insurers only if these have been authorised by the Government's Genetics and Insurance Committee (GAIC), for policies above £ 500,000 of life insurance or above £ 300,000 and for other insurance policies;
- a review of the financial limits after three years;
- an impartial and independent complaints mechanism;
- monitoring of the companies' compliance with the ABI's code and moratorium by the ABI, with the ABI publishing an annual public report on compliance."[688]

At European level, the Council of Europe's *Convention on Human Rights and Biomedicine* of 1997 provides in Art. 12 that tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.[689] According to the prevailing view, this wording cannot be interpreted to mean that genetic testing is prohibited in the insurance sector.[690] Other views suggest that it must be assumed – because of the Convention's clear purport – that the conclusion of an insurance contract should not be made dependent on the performance of a predictive genetic test.[691]

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[686] Genetics and Insurance Committee 2000.
[687] Department of Health 2001, p. 10 (translated from German translation)
[688] Association of British Insurers 2001.
[689] Cf. C2.1.2 Statutory provisions (national/international).
[690] Degener 1998a; Simon 2001, p. 81; Rudloff-Schäfer 1999, p. 36. Dissenting view: Spranger 2000.
[691] Simon 2001, p. 82.

2.2.2.2.4 Development prospects

It is currently difficult to predict whether genetic tests will play a major role in the insurance sector in the foreseeable future. This will depend on several factors, including

- "the number of genetic tests available for relevant genetic predispositions,
- the possibility to have genetic tests performed anonymously, e.g. by means of an anonymous source combined with the use of so-called home test kits for self-testing at home, or by means of anonymous tests performed in private laboratories,
- the population's willingness to be tested in the first place."[692]

While the two latter aspects might primarily increase the risk of anti-selection to the disadvantage of insurance companies – which in turn might try to use the results of genetic tests in order to restore the "the genetic information balance" – the development of a variety of new testing methods and in particular of tests for polygenetic or multifactorial hereditary disorders might also lead to the use of genetic tests for a more risk-adequate calculation of premiums or a more efficient risk selection by insurance companies. The German Bundestag's Office of Technology Assessment came to the same conclusion in its Genetic Testing Report:

> All in all, we cannot rule out a development in which, on the one hand, *competitive pressure* will build up *in the insurance industry* because some insurers will try to use genetic testing in order to calculate more adequate premiums for various risk groups in order to gain a competitive advantage in the market. On the other hand, it is conceivable that the *use of genetic testing by insurance prospects* might force the insurance industry to use genetic test procedures in order to avoid the economic disadvantages involved. Both trends *could* mutually amplify each other and promote a *widespread use of genetic testing in the insurance industry*."[693]

Since the introduction of competition in Germany's statutory health insurance system, there has been a greater incentive for individual health funds to provide their services to low-risk individuals. In the Health Structure Act (*Gesundheitsstrukturgesetz*) of 1992, the legislator tried to make allowance for this selective acquisition of customers by introducing a so-called "risk structure compensation" mechanism (*Risikostrukturausgleich* – RSA). However, this RSA reflects the morbidity of the insured persons only indirectly (age, sex, income). Currently, the health funds are already able to use morbidity profiles of the persons insured by them (diagnosis, prescribed drugs) in order to gain an advantageous competitive position. In response to this development, the legislator is currently planning to introduce an improved

[692] Berberich 2001, p. 313.
[693] Hennen *et al.* 2001, p. 122 f.

RSA; the goal is to reflect the morbidity risks as precisely as possible as a basis for the financial compensation among the health insurance funds. In this context, there is a risk that assessing the risks by means of genetic data may also become relevant for the German statutory health insurance sector. The principle of solidarity, which is currently applied, might be reduced to absurdity by the attribution of specific morbidity risks to individuals. As far as the specific issue of genetic data is concerned, it must therefore be ensured that genetic data will not be made available, collected or used in a personalised form when a morbidity-based RSA is introduced.

2.2.2.2.5 Consequences of a widespread use of genetic testing in the insurance sector

2.2.2.2.5.1 The right to informational self-determination and the right not to know

The main problem associated with the use of genetic testing procedures by insurers is often that it is believed to violate the insurance prospects' right not to know and their right to informational self-determination. In its 1987 report, the Study Commission on "Opportunities and Risks of Genetic Engineering" already noted:

> "The freedom to refuse to have genetic information about one's own future collected in the first place is one of the key elements of an individual's self-determination. This freedom must probably be classified as being part of the core area of an individual's personality which, according to the formula developed by the German Federal Constitutional Court, is an "inviolable area of individual's private life' and as such out of reach for public authorities. In the framework of private contracts, this area should not automatically be accessible to influence from outside, either.[694]

In this context, it is necessary to distinguish between two situations: There is a controversial debate about whether the right of insurance prospects to informational self-determination is affected when they are obliged to disclose already available results of genetic tests performed earlier.[695] On the one hand, prospects are only compelled to update knowledge that they already have; hence, there is no violation of their right not to know. On the other hand, however, it can be argued that the disclosure obligation conflicts with the right to informational self-determination because it violates the right of individuals to decide

[694] *Bericht der Enquete*-Kommission „Chancen und Risiken der Gentechnologie" (Report submitted by the Study Commission on "Opportunities and Risks of Genetic Engineering") 1987, p. 174.
[695] Cf. on this discussion Berberich 1998, p. 184.

themselves how their personal data should be used.[696] Informational self-determination also means being able to determine *to whom* information should be disclosed.

The situation is different if insurance companies make the conclusion of an insurance contract dependent on the performance of a genetic test. In such a situation, prospects might be confronted with the choice of either having a genetic test performed and in this way gaining knowledge of their own genetic make-up, which they may not want to do, or doing without insurance cover. The argument sometimes put forward to counter this position is that private insurance contracts are usually concluded voluntarily and that their purpose is not to provide for the individual's future but to provide "well-being to the individual".[697] However, there are cases of insurance prospects who do not have any access to Germany's social insurance system. In addition, it must be borne in mind that life insurance is an essential component of an individual's choices in providing for the future (protecting the family, providing for old age, home ownership) and a key instrument for coping with financial burdens during old age.[698] This applies in particular after the German legislator's reorganisation of the old-age pension system, which involves the compulsory inclusion of private insurance elements. Generally speaking, one can say that the less choice prospects have to decline insurance cover offered to them, the more the pressure put on them to obtain and disclose predictive data looks like coercion.

2.2.2.2.5.2 Genetic discrimination

Some people also fear that the use of genetic testing by insurers may lead to "genetic discrimination" against prospects because of their genetic status. In the event of unfavourable genetic test results, it may be that prospects could obtain insurance cover only at higher premiums or that they might be considered to be altogether uninsurable. Various studies have shown that such forms of "genetic discrimination" occur in the United States.[699]

In the event that a genetic test produces negative results for a given prospect, the latter may be confronted with additional forms of discrimination because, in Germany, insurance companies are authorised to transmit data to a relatively large group of persons (insurance intermediaries, re-insurers, other insurance companies, trade associations).[700]

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[696] *Bundesaufsichtsamt für das Versicherungswesen* (German Federal Supervisory Office for Insurance) 2001, p. 15; Simon 2001, p. 116.
[697] Lorenz 2000, p. 28; Taupitz 2000, p. 24 f.
[698] Schmidtke 1997, p. 147. For diverging views, cf. Taupitz 2000, pp. 23 ff.; Lorenz 2000, p. 28.
[699] Cf. the evidence presented by Simon 2001; Wolbring 2001.
[700] *Bundesaufsichtsamt für das Versicherungswesen* (German Federal Supervisory Office for Insurance), p. 11.

However, in response to the accusation that the use of genetic tests by insurers may lead to "genetic discrimination", it is argued that discrimination, as defined in law, is only constituted if a person is treated in a different way than other persons without any acceptable objective reason. The advocates of this position suggest, however, that a risk-relevant genetic predisposition is such an objective reason for differentiated treatment.[701]

Cases where – for certain risk factors – insurance premiums are increased to a level not justified by the risk itself, or where – for certain risk factors – insurance cover is decreased to a level not justified by the risk itself, are clear evidence of "genetic discrimination". Another reason for "genetic discrimination may be improper application of genetic tests or improper interpretation of the results of such tests by insurance companies.[702] Another particular problem is "genetic discrimination" against persons who exhibit a genetic change that is the factor (one of the factors) responsible for a disorder but who are completely free of symptoms and whose only "abnormality" is their genotype.[703] Billings *et al.* refer to such individuals as "asymptomatic sick".[704] Refusing to grant such individuals insurance cover, or only on tougher terms, constitutes a blatant case of genetic discrimination because there is no objective reason for such unequal treatment.

2.2.2.2.5.3 Effects on testing in practice

There are also fears that the use of genetic testing by insurers might have adverse effects on the testing practice. Because of their fear of the detrimental consequences of unfavourable test results, individuals concerned may be less willing to undergo a genetic test, even in cases in which such a test would make medical sense. Persons carrying a higher risk of developing a hereditary tumour, for instance, may decide not to have a test done, for fear of subsequent disadvantages.[705] Several studies have shown that this fear is widespread. In a telephone survey conducted among 1,000 persons in the United Kingdom in 1997, for instance, as many as 63 per cent of the respondents stated that they would not carry out any genetic tests if insurance companies or employers were given access to the results.[706] Genetic diagnosis counsellors as well as various self-help groups already recommend today that "insurance matters should be settled prior to such tests".[707]

[701] Taupitz 2000, p. 31.
[702] Berberich 1998, pp. 129 f.
[703] Berberich 1998, pp. 127 f.
[704] Billings *et al.* 1992.
[705] Human Genetics Advisory Commission 1997, p. 7.
[706] National Human Genome Research Institute 1998.
[707] *Ärzte-Zeitung* of 22 May 1997, quoted by Hennen *et al*. 2001, p. 126.

In addition, there is a risk that the individuals concerned might make greater use of anonymous testing opportunities in order to avoid disadvantages that might result from unfavourable genetic test results. This will be all the more likely as more private testing laboratories provide such services and more tests become available without prescription via the Internet or "over the counter" (home test kits). This would pose problems in particular in view of the lack of counselling.[708]

2.2.2.2.5.4 Effects on statutory insurance schemes

Finally, it is also argued that the use of genetic tests by private insurers may have adverse effects on statutory insurance schemes. While private insurers might use genetic tests to segment their risks in order subsequently to try and retain so-called "good risks", the statutory health insurance funds may be obliged to take the "bad risks". This could bring about an accumulation of bad risks in the statutory health insurance schemes, which would lead to a "two-tier health care system"[709] or even jeopardise the very existence of the social security system.[710]

2.2.2.2.5.5 The risk of anti-selection

The insurance industry's most important fear with regard to the use of genetic testing methods is concerned is directed at the risk of anti-selection (also referred to as adverse selection), i.e. the risk "that insurance prospects – although, or perhaps because, they are aware of their risk-relevant genetic predisposition – take out personal insurance policies in order to obtain insurance cover either for themselves or for beneficiaries determined by them"[711]. Prospects could try to have themselves tested, to withhold unfavourable test results from the insurer and to obtain insurance coverage on better terms than those warranted by their individual risk. For insurers, the consequences would be "a greater intake of higher risks, an increase in the premium level, and reduced demand by normal-risk individuals – a repetitive process with steadily growing effects."[712] Once again, however, it is necessary in this context to distinguish between life insurance and (private) health insurance. Unlike health insurance, which is indemnity insurance, life insurance policies are fixed-sum insurance policies.[713] Since it is

[708] Hennen *et al.* 2001, p. 126.
[709] Schmidtke 1997, p. 147.
[710] Feuerstein *et al*. (forthcoming); Uhlemann 2000.
[711] Lorenz 2000, pp. 34 f.; cf. also *Gesamtverband der deutschen Versicherungswirtschaft* (Association of the German Insurance Industry) 2000.
[712] Rupprecht 1999, p. 98.
[713] Simon 2001, p. 25.

generally possible for prospects to take out life insurance for any sum, there is a much greater risk of anti-selection.

2.2.2.2.5.6 Actuarial versus moral fairness

For the reasons mentioned above, Bayertz *et al.* come to the conclusion in their study that an extensive use of genetic tests by insurers – especially under the condition of asymmetrical information – would pose serious problems and violate the principles of *actuarial fairness* on the one hand and *moral fairness* on the other:

> "An extensive use of genetic test methods by insurers would create major ethical problems and, in the final analysis, be morally unfair because it would violate fundamental moral rights such as the right to informational self-determination. On the other hand, more intensive use of genetic tests by insurance prospects would unhinge the very concept of insurance and violate the principle of *actuarial fairness*. The consequences cited above are particularly likely to occur if there is a genetic information imbalance between insurers on the one hand and policy holders or prospects on the other. Hence, the fundamental problem seems to be that it is not possible to lift the 'veil of genetic ignorance' unilaterally without bringing about serious consequences that, in the final analysis, are not desirable for any of the parties involved."[714]

Once again, however, a distinction must be made between health and life insurance. Unlike life insurance coverage, obtaining cover against personal disease risks in the framework of a health insurance policy is vitally important for the individuals concerned and guarantees that policy holders will be able to cover vital basic needs in terms of security. Health insurance is a key instrument for an individual to provide for the future. This currently applies to life insurance contracts to a limited extent only. However, the importance of life insurance policies for individuals making provisions for the future will grow as specific benefits – e.g. in the field of pension insurance – are removed from the scope of statutory insurance and transferred to the individual's responsibility.

2.2.2.2.6 Regulatory options

Three regulatory options are currently being discussed with regard to the use of genetic test methods in the insurance sector:

[714] Bayertz *et al*. 1999, pp. 266 f.

– "The first option is *to admit the use of genetic tests in the insurance sector* and to allow insurers to oblige applicants, prior to the conclusion of an insurance contract, to have a genetic test performed or to implement such a test themselves as a routine procedure.

– A second option is not only *to prohibit insurance companies from requesting a genetic test* prior to the conclusion of an insurance contract but also to rule out that an insurance prospect may disclose to the insurer the results of a test performed elsewhere.

– The third option is to allow *limited use* by insurers and prospects *of genetic information* obtained from genetic tests."[715]

The latter model could perhaps be modified in terms of defining specific sums insured as of which it would be admissible to use genetic tests for the purpose of risk selection, or in terms of differentiating the insurance cover on the basis of the results of analyses of the genome.[716]

In a recently published opinion, the German Federal Supervisory Office for Insurance rejected a regulatory option that would allow insurers to request prospects to have a genetic test performed prior to the conclusion of a contract, and the Office recommended that insurers should not be allowed to accept or use the results of such tests. However, the Office did insist that, as a matter of principle, prospects should continue to be obliged to disclose all risk-relevant factors to insurers prior to the conclusion of a contract:

> "If voluntary tests were performed in the past, prospects (...) would undoubtedly have an information advantage that they could use unfairly against the insurers. This anti-selection risk cannot be denied and should not be underestimated. It is in this context – but only in this context – that one needs to see the insurer's right under Articles 12 and 14 of the German Constitution to exercise their entrepreneurial freedom in the way they conduct their business."[717]

For this reason, the Federal Supervisory Office for Insurance proposes that, with a view to the disclosure of all risk-relevant factors prior to the conclusion of contracts, insurers should start asking prospects if they have performed any voluntary genetic tests elsewhere in the past. The wording proposed of this purpose is as follows:

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[715] Hennen *et al.* 2001, p. 129.
[716] Hennen *et al.* 2001, p. 129.
[717] *Bundesaufsichtsamt für das Versicherungswesen* (German Federal Supervisory Office for Insurance), p. 15.

> "Have you, or has the insured person, had a genetic test performed in the past 5 years, or have you, or has the insured person, performed such a test yourself/himself/herself, and has this test revealed any disease that is already manifest or any genetic predisposition which, in the near future, will certainly lead to the onset of a disease or to premature death?"[718]

Another option, which has also been discussed occasionally, is the introduction of a national insurance scheme for the entire population based on the principle of solidarity, i.e. a scheme that would provide insurance cover irrespective of any risk assessment, and hence, irrespective of the genetic status of prospects.[719] On the basis of this guaranteed basic insurance coverage, it would be conceivable to add private supplemental insurance cover for the acquisition of which it would be admissible to disclose the results of genetic tests performed elsewhere or to have genetic tests carried out. A similar solution would also be conceivable for life insurance, e.g. the introduction of an obligation to contract up to a certain sum insured while at the same time prohibiting multiple insurance cover.[720] The argument that can be put forward against such a two-tier insurance system is that it would not eliminate the problem of genetic discrimination; instead, it would merely limit it to the attractive supplemental insurance policies. In terms of supplemental insurance cover, genetically challenged persons would be structurally at a disadvantage in comparison with individuals who are not genetically challenged.

2.2.2.3 The use of human genetic material in research

Now that the first phase of the human genome project has been concluded with the successful sequencing of a basic or reference human genome, research into genetic changes that are relevant to disorders will become much more important in the next few years. In the near future, such research will probably become an integral part of pharmacogenetic studies and many clinical trials.

The Ludwigshafen Heart Centre, for instance, has built up a data base since 1997 in which detailed data are collected on patients who have given their consent. In the letter of consent in which patients are given information, they are given the assurance that no-one outside the hospital will be able to link the anonymised data with their personal data. Patients are asked to fill in an extensive questionnaire, which covers their medical history data. Subsequently, they are thoroughly examined. A total of up to 1,600 data and measured values are collected.

[718] *Bundesaufsichtsamt für das Versicherungswesen* (German Federal Supervisory Office for Insurance), p. 17.
[719] This option is also referred to in the study by Bartram *et al.* 2000, p. 187.

These data contain information on diseases of the patient's parents but also details on the condition of the coronary vessels. The bulk of this information was obtained from genetic tests and laboratory measurements. Blood counts, hormone levels, characteristics of defence cells, etc. The Heart Centre plans to contact the test subjects again after one and five years. The pharmaceutical manufacturer Aventis pays DM 6.2 million (DM 1,800 per person) to have access to the data of the approximately 3,500 patients. As part of the co-operation between Aventis and the Ludwigshafen Heart Centre (which is referred to as LACORM), the pharmaceutical company will expand the data base by adding data from studies of its own. Frozen blood and cell samples will be genetically tested by the company's scientists to study questions of interest to the company. These data will then be incorporated into the data base. Aventis expects that this register will enable the company to estimate – earlier than in the past – for which groups of patients it might be worthwhile to develop a new drug.[721]

Generally speaking, it is possible to distinguish between two different approaches to research. Studies can either selectively focus on the analysis of samples taken from persons suffering from diseases or – more like a "data catch" – they can be aimed at collecting the largest possible amount of genetic information, with the objective of subjecting the data captured, where possible, to a multivalent evaluation in order to detect statistically relevant correlations.[722]

One example of the latter method is a project that is currently being carried out in Iceland, which is designed to combine health data, as well as genetic and genealogical data in a single data base. The purpose of this project is to combine the genetic data of individuals with the medical records and the register of the Icelandic health system, and with data on the descent and kinship of living and deceased Icelanders. The goal is to cover, where possible, the entire Icelandic population in this way. The intention is to use the data for research designed to facilitate the development of disease diagnoses and therapeutic options, or to make such diagnoses and options possible in the first place, and to improve the quality of health care for the Icelandic population. The Icelandic government has issued a licence to a company called deCODE Genetics for a period of twelve years to build up, manage and use this data base. A co-operation agreement concluded, in turn, by deCODE Genetics with the pharmaceutical manufacturer Hoffmann LaRoche allows the latter company to use the health data of the

[720] Hennen *et al.* 2001, p. 133.
[721] Written communication by the *Klinikum der Stadt Ludwigshafen am Rhein gGmbH* of 26 November 2001.
[722] *Berliner Beauftragter für Datenschutz und Akteneinsicht* (Berlin Commissioner for Data Privacy Protection and Inspection of Records) 2001.

Icelandic population in order to investigate the genetic causes of twelve widespread diseases, and grants this company the exploitation rights for any patents, diagnostics and drugs resulting from this research.[723] However, it is not yet possible to predict whether the planned database will produce any medical or economic results at all.[724] A similar project is currently also being implemented in Estonia. However, while the subjects in Iceland are automatically presumed to have given their consent to the use and storage of their genetic data ("presumed consent"), the subjects in Estonia first have to be asked for their consent ("informed consent").

In these and similar studies, large amounts of genetic data are collected, processed, merged and stored – usually pseudonymised. Providing that certain additional information is available, stored DNA data can always be related to individuals, although they are not directly personal data.[725] This makes it necessary to make a particular effort to safeguard the privacy of genetic data in connection with scientific research projects.

From the perspective of data privacy protection, it should therefore be examined, for instance, whether it is useful:

– to prescribe a multi-tier pseudonymisation procedure, possibly with the key bridge placed in the custody of trustees, as a standard for research with human genetic material,

– to safeguard the right of the persons concerned – by means of pseudonymisation – to demand the destruction of their samples and the deletion of other data,

– to lay down by law a maximum period for which samples have to be preserved, and

– to oblige companies that do research to use the depseudonymisation pathways if they have discovered anything conspicuous in order to inform the persons concerned about their discoveries – even after longer periods of time – because these discoveries may affect the personal state of health of the persons concerned.[726]

The core problem associated with this research in terms of data privacy protection is not only the anonymisation or pseudonymisation of the samples and the results but – also the impact of

[723] Wagenmann 1999.
[724] Sigurdsson 2001.
[725] *Berliner Beauftragter für Datenschutz und Akteneinsicht* (Berlin Commissioner for Data Privacy Protection and Inspection of Records) 2001.
[726] Cf. *Berliner Beauftragter für Datenschutz und Akteneinsicht* (Berlin Commissioner for Data Privacy Protection and Inspection of Records) 2001.

the consent given.[727] Unlike conventional data collection projects, the subjects of research involving human genetic material often do not know what data will be used by the investigators and what these data contain. This poses particular challenges with regard to the subjects' informed consent. To ensure that a subject can give his or her informed consent to a research project, he or she must have been given concrete information not only about the survey but also about any additional data processing purpose. The subjects must be given an opportunity to refuse the use of their samples for each (additional) research purpose. In addition, they must also have a choice of either giving or refusing their informed consent to the storage or the exploitation of unintended results.

In their "Proposals aimed at safeguarding self-determination in genetic testing", the data protection commissioners of the German Federal Government and the state-level governments suggest that, prior to giving their consent to genetic research projects, the individuals concerned should be informed in particular about:

– "the institution responsible for the research project or the collection of data,

– the objective of the research project, or in the event of data collection, the potential research institutions,

– their rights in the event of patent applications and commercial exploitation,

– the period of time for which samples will be preserved and genetic data will be stored,

– the time and type of pseudonymisation of samples and genetic data, and the possible restoration of their ascription to the person concerned,

– their right – except for pseudonymised processing after the end of the research project – to demand the destruction of the sample and the deletion of the genetic data or the elimination of the traceability of the data when they revoke their consent,

– their right not to take note of the results of investigations or not to be informed about them by means of a depseudonymisation procedure to be developed,

– their right to request information about stored genetic data on them,

[727] Metschke/Wellbrock 2000, p. 47.

– The information should be provided both in writing and orally."[728]

The Commission members feel that this proposal points in the right direction.

This applies in particular to research done on individuals who have already developed a disease. From a scientific perspective, this type of research is also necessary because the investigation of many genetic disorders requires the involvement of both patients and family members. However, experience has shown that persons who have already developed a disease often feel more strongly obliged than individuals who do not suffer from a disease to participate in research projects from which they will not benefit themselves.[729]

Genetic investigations that are designed to test several genetic characteristics at the same time are particularly problematic with regard to the informed consent required. Oral (or written) information is usually not sufficient for medical lay persons to grasp the full impact of the consent they are expected to give if their sample is to be used for many tests at the same time. Under the data privacy legislation currently in force, it would therefore not be admissible to obtain consent for an unlimited number of future research projects or for non-specified research projects about which the persons concerned cannot yet be given any information.[730]

In order to protect the subjects' right to informational self-determination, it is also very important in connection with research involving the use of human genetic material that the genetic tests must be performed exclusively for the purpose specified. This is all the more necessary since progress in scientific findings and the emergence of new questions make it harder to resist the temptation of collecting surplus information and of using samples and genetic data for purposes other than the ones specified. The data protection commissioners' experience has shown that investigators are not always aware of the relevant data privacy legislation and that the practical implementation of these rules sometimes causes problems.[731]

What the data protection commissioners lack in particular is sufficient monitoring opportunities to prevent the unlawful use of genetic data for other purposes or their deanonymisation through a comparison with other data, or to ensure that data are actually deleted if that is requested by the subjects. The main reason why effective monitoring fails is that data protection commissioners are often not informed about the processing of genetic data

[728] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001b.
[729] Metschke/Wellbrock 2000, pp. 47 f.
[730] Metschke/Wellbrock 2000, p. 29.
[731] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001a.

in the first place. Under the legislation currently in force, investigators are not obliged to submit research projects involving genetic data to the data protection commissioners.[732] For this reason, data protection commissioners postulate that such research projects should be regularly submitted to the data protection institutions in charge.

Finally, a particular problem of research involving the use of human genetic material relates to the question of counselling. Generally speaking, the more serious the potential consequences of a test result for the person concerned, the more urgent the need for counselling prior to the performance of a test. However, it is in the very nature of scientific research that it is not possible to predict at the beginning of a project whether the results will be of importance to the subjects at all, and if so, to what extent.

2.2.2.4 Genetic testing on persons not able to consent

Genetic testing on persons who are not able themselves to give their consent to the performance of a genetic test poses a particular problem. This group of persons includes both adults and children. Performing a genetic test is an encroachment on the integrity of the tested person, which has to be preceded by the individual's personal consent following comprehensive information, and as a rule, such encroachment can only be justified by this consent. However, it is exactly this personal consent that such persons are unable to give.

Nevertheless, a genetic test may be necessary for the benefit of the person concerned if such a test may have a positive effect on that person's state of health because the test may be used to derive preventive, prophylactic or therapeutic consequences.

For this reason, various documents do not generally rule out the possibility of performing genetic tests on persons not able to consent, but they impose restrictions on such tests. In its policy paper, for instance, the Ethics Council of the German Federal Ministry of Health recommended that the performance of predictive genetic tests on adults not able to consent should be made contingent on consent given by a custodian, who may have yet to be appointed, and to allow the performance of predictive genetic tests only if:

– "without such a test, the persons concerned are at risk of developing disorders or suffering detrimental effects on their health, and

[732] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001a.

– effective preventive or prophylactic treatments are available and if, based on reliable evidence, there are concrete prospects of recovery (attempted cure), and

– the risks of the genetic diagnostic intervention required are smaller than the expected benefit for the persons concerned, and

– the custodian has been given information (the requirements under item 5 apply here as well)."[733]

In the United States, the authors of the Genetic Privacy Act also formulated recommendations for genetic tests to be performed on minors and on adults not able to consent. The bill will prohibit taking or analysing identifying DNA samples of minors under the age of 16 if the purpose of the test is to detect the existence of a gene that, according to medical wisdom, is unlikely to produce any signs or symptoms before the person concerned is 16 years of age. Exemptions will be admissible only if effective interventions are available, interventions that are capable of preventing or delaying the onset or reducing the severity of a disease and that take effect before the person concerned turns 16 years of age.

As far as genetic tests on adults not able to consent are concerned, the Genetic Privacy Act recommends that such tests should only be allowed for the following purposes:

(A) "Diagnosis of the cause of incompetence or

(B) Diagnosis of a genetically induced condition that, according to expert medical judgement, can only be effectively improved, prevented or treated as long as the sample source is incompetent or

(C) diagnosis of a hereditary disease of a parent, sibling, child or grandchild of the sample source, providing that, according to expert medical judgement, the disease can be effectively improved, prevented or treated."[734]

According to the bill, the test (to which a representative of the person concerned must have given prior consent) must be limited to those aspects that are required for diagnosis.

Genetic tests performed exclusively for the benefit of third parties on persons not able to consent are for the most part rejected. The Swiss draft of a federal law on genetic tests in human beings provides for exceptions to this rule. According to the bill, the legally authorised representative of the person concerned can also consent to a genetic test to be performed in

[733] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health) 2000, p. 11.

the interest of third parties if there is no other way to identify a serious hereditary disorder in the family. However, the performance of such a test in the interest of third parties is always inadmissible according to the bill if this poses risks for the person concerned that are not negligible, i.e. if the test goes beyond merely collecting saliva or blood specimens.[735]

Tests on minors for late-onset disorders such as Huntington's Disease, for which recognised, medical interventions related to the health of the person concerned are not available, are generally also considered to be particularly problematic. Such a test usually violates the right of the minor concerned not to know. The respect for the autonomous decision of the person concerned must therefore take precedence over potential wishes of third parties. With this in mind, the *Kommission für Öffentlichkeitsarbeit und ethische Fragen der Gesellschaft für Humangenetik* (Public Relations and Ethics Committee of the Society for Human Genetics), for instance, recommended that such tests should be postponed until the person concerned could comprehend not only the genetic facts but also the emotional and social consequences of the various potential test results. Such comprehension, the Commission argued, is usually not present before the age of 18.[736]

Unlike other fields of medical research, genetic research encroaches more on the psychological integrity of patients and test subjects than on their physical integrity. Investigators are not always sufficiently sensitive to this fact. For this reason, applicants should be generally obliged when they submit genetic research projects to the responsible ethics committee to explain what measures they will adopt to ensure that the personal rights of subjects will be protected in the research project.

Research into the genetic causes of disabilities poses a particular problem when the persons concerned live in homes or other closed institutions. The experience with unauthorised genetic research done by the Institute of Human Genetics of the University of Würzburg in a nearby home for mentally disabled persons has shown that the investigators' awareness of the problems involved in encroachments on the personal rights of mentally disabled persons was limited. For this reason, particular attention should be paid in the context of genetic research to protecting the personal rights of mentally disabled persons who live in homes or other institutions.[737]

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[734] Annas *et al.* 1995, part E, sec. 144 (translated from German translation).
[735] *Bundesamt für Justiz (Schweiz)* (Swiss Federal Office of Justice) 1998b, p.28.
[736] *Kommission für Öffentlichkeitsarbeit und ethische Fragen der Gesellschaft für Humangenetik* (Public Relations and Ethics Committee of the Society for Human Genetics) 1995.
[737] Dörner/Spielmann 2001; Dörner 2001b.

2.2.2.5 Genetic screening

2.2.2.5.1 Opportunities and risks of genetic screening

There is a controversial debate about the benefit of genetic screening programmes for the test subjects and for society, as well as the risks involved. The main benefits associated with genetic screening programmes by advocates of this approach are:

– pre-symptomatic detection of hereditary disorders or predispositions, with the objective of prevention, early diagnosis, health care and treatment,

– detection of genetic sensitivities to environmental factors, with the objective of avoiding injuries or lesions, and

– detection of genetic carriers, with the objective of allowing the individuals concerned to make reproduction and life-style decisions.

Potentially negative consequences ascribed to genetic screening programmes include primarily:

– the fear that may be provoked in the test subjects by information that does not leave them any personal choices in terms of therapeutic options or preventive measures, or that is very hard to understand and to interpret,

– unacceptable pressure put on the test subjects,

– social stigmatisation of persons with a higher genetic risk,

– social stigmatisation of persons who refuse to participate in a screening,

– disclosure of information on family members who did not participate in a screening,

– abuse of information and discrimination based on test results by third parties such as insurance companies and employers.[738]

For this reason, the implementation of genetic screening programmes in the entire population or in specific population groups is an extremely problematic exercise which would have to be carefully prepared. It must be tied to compliance with fundamental ethical standards if the risks involved in screening programmes are not to outweigh the potential benefits.

[738] Cf. European Society of Human Genetics/Public and Professional Policy Committee 2000a.

According to the recommendations of the European Society for Human Genetics (ESHG), genetic screening programmes are only justified under the following conditions:

> "III. Criteria for the introduction of genetic screening programmes
>
> III-1. A screening program should only be contemplated if there is general agreement among experts, patients and the public at large about the benefits to be expected from the programme, if there is a major health problem with regard to the number of persons affected or the severity of a disorder, if – depending on the test results – screened persons will actually undergo an intervention, or if a decision will have to be made by the persons concerned, and if a suitable predictive test is available.
>
> III-2. Since genetic screening is associated with potential harm, a programme should only be contemplated if the benefits clearly outweigh the harm. The first aspect to be examined is the benefit and harm for the screened person before considering the relatives, especially when screening neonates and children. Benefits and harm should be assessed and interpreted in the framework of pilot programmes and while taking their cultural dimension into consideration.
>
> III-3. Before initiating broadly-based screening programmes, all other alternatives must be examined."[739]

2.2.2.5.2 Restriction to tests used for medical purposes

In view of the particular risks associated with screening programmes and the particular sensitivity of genetic data, there is a common belief that genetic screening programmes can only be justified if they are – at least also – in the test subject's own best health interest. Screening programmes that are designed to achieve eugenic objectives and to "improve" the genetic make-up of the population, in particular, are rejected.

Another reason given for restricting genetic screening programmes to disease-relevant characteristics for which preventive or therapeutic options are available is that the availability of disease-specific prevention is the only acceptable justification for actively offering genetic tests to a group of persons for whom there is no personal test indication.[740]

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[739] European Society of Human Genetics/Public and Professional Policy Committee 2000a (translated from German translation).

[740] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health) 2000, p. 12.

2.2.2.5.3 Information and counselling

If one assumes that participants in genetic screening programmes are persons for whom there is no personal indication to be tested, and if one applies the principle that the requirements in terms of information and counselling will be all the greater the less such a test is indicated, information and counselling for such genetic screening programmes must meet particularly high standards.

However, the complexity of genetic issues, the relatively limited knowledge of these issues in the public, and the limited availability of information and counselling give reason to doubt whether the information usually made available is actually sufficient in order to enable the persons concerned to give their consent to the programme, or whether extensive information can be guaranteed in the first place. At any rate, experience gained with screening programmes to date has shown not only that the willingness to participate in such programmes depends on the scope and quality of the counselling provided beforehand, but also that in many cases adequate information and counselling is not guaranteed.

> Merely providing information is not sufficient; instead, it must also be ensured that this information is understood and that decisions can be taken, based on the individuals' own personal biographical context, their own personal design of life. All genetic screening programmes suffer from the fact that they are accompanied by inadequate counselling programmes."[741]

However, differences in information standards between routine tests and individual (diagnostic or predictive) tests are rejected, in particular by data protection commissioners in Germany. They argue that it is irrelevant for the person concerned how often a genetic test is (routinely) also performed on other persons because it retains its potentially drastic effects on each individual irrespective of the number of persons tested. However, they emphasise that the information provided must be related to the object of the test, which may vary in terms of its importance for the test subjects. In addition, they point out that the information provided for routine tests can – additionally – be supported by standardised instruction leaflets and written information that could hardly be produced for individual tests. However, the Commissioners insist that the information standard must not be reduced and that it must be ensured in any case that the test subjects understand this information.[742]

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[741] Schmidtke 1997, pp. 250 f.

[742] *Datenschutzbeauftragte des Bundes und der Länder* (Data protection commissioners of the German Federal Government and the state-level governments) 2001a.

The fundamental importance of qualified information and counselling prior to implementing a genetic screening programme is underlined by the fact that the rate of acceptance, and hence the willingness to participate, to a large extent also depends on the way in which the information is provided. The experience gained with screening programmes to date has shown that acceptance rates increase "the more effort the test suppliers put into offering their programmes and the scantier the information accompanying the programme."[743]

As far as the justification of screening programmes is concerned, the fact that it must be assumed that the participants are not (cannot be) given optimum information is a particular impediment. The problems indicated above are often also put forward as an additional argument for limiting genetic screening to programmes that are associated with a substantial and clearly identifiable *benefit* for the persons tested.[744]

The problem which arises from a data privacy perspective is that screening programmes could generate extensive collections of specimens and genetic data bases with personal data. The data protection commissioners of the German Federal Government and the state-level governments recommend that this should be prohibited by law.

2.2.2.5.4 Screening for heterozygosity

The same applies in particular to programmes that are designed to screen individuals for several characteristics at the same time, and to group programmes designed to identify heterozygous carriers of recessive disease alleles. In both cases, it is hardly possible to guarantee reliable information. In its 1996 position paper, the *Gesellschaft für Humangenetik e.V.* (GfH – Society for Human Genetics), for instance, therefore rejects the implementation of screening programmes for heterozygosity under the currently prevailing conditions:

[743] Schmidtke 1997, p. 249.
[744] Oral communication by Prof. Schmidtke at the non-public hearing held on 26 March 2001.

> "There are several prerequisites to population screening programmes: is it not only necessary to provide comprehensive and appropriate information to the population but also to ensure the subjects' voluntary participation in screening programmes and their ability to understand the implications of their decisions and to verify the qualifications of the persons responsible for counselling and testing, and to assess potential risks prior to screening subjects. The GfH rejects such population screening at the current point in time because the general conditions required for this purpose are not met. This applies both to the information to be provided to the public and to the provision of the required qualified counselling and to the implementation of scientific projects to serve as a basis for further decision-making."[745]

Another argument put forward against screening programmes for heterozygous disease alleles which do not lead to a disorder in their carriers is that the purpose of these tests is not to prevent the development of a disease in the tested subjects.[746]

It should also be borne in mind that genetic screening for non-treatable disorders in the following generation always also includes a eugenic component insofar as that the societal objective of such screening programmes is to persuade individuals to use the genetic test results, *inter alia*, as a basis for their family planning.[747]

2.2.2.6 Pharmacogenetic diagnosis

Drug therapy is an essential part of medical care. On average, each general practitioner prescribes approx. 12,000 drugs annually. Doctors in private practice prescribe approx. 400 to 600 different drugs.

Drug therapy is in particular confronted with two major problems: What can be said for all drug groups is that they fail to have a therapeutic effect in some of the patients, despite an accurate diagnosis, the right indication and the correct dosage. Between 15 and 20 per cent of the patients, for instance, do not respond to treatment with beta receptor blockers. The second problem is adverse drug effects. Approx. 6 or 7 per cent of all hospitalisations are due to such effects; adverse drug effects rank number 6 to number 4 in the mortality statistics. A study conducted in the United Kingdom comes to the conclusion that one of 15 hospitalisations is due to adverse drug effects. According to a US study, some 106,000 patients annually die in the United States due to adverse reactions following the administration of drugs; approx. 2.2

[745] *Kommission für Öffentlichkeitsarbeit und ethische Fragen der Gesellschaft für Humangenetik e.V.* (Public Relations and Ethics Committee of the Society for Human Genetics) 1996.
[746] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health) 2000, p. 12.

million patients suffer injuries.[748] Adverse drug reactions are often due to overdosage or underdosage because patients are usually administered a standard dosage with limited variability. It is currently not possible to make precise statements about the extent to which pharmacogenetic effects actually play a role in adverse drug reactions.[749]

The implementation of pharmacogenetic methods in the development of drugs and therapeutic practice is designed to increase treatment safety, efficacy and tolerance by providing personalised and risk-adapted treatments. Patients who are sensitive to side-effects of drugs, for instance, could be informed early on and protected. A high efficacy of therapeutic interventions could perhaps already be achieved at the beginning of the treatment by finding the right drugs for patients at an early point in time and in an optimum dosage. This could perhaps permit a considerable reduction of monitoring for potential toxic effects of administered drugs. It might also be possible to avoid costs caused by the prescription of inefficacious drugs (and by the treatment of side-effects brought about by such drugs). It might also be possible to reduce the number of medical consultations required.[750]

Registration authorities as well as the pharmaceutical industry might insist in future – as they already do in the case of Herceptin – that a drug may only be prescribed if appropriate molecular genetic diagnostic procedures have shown that the therapy seems promising. As a result, so-called "blockbuster" drugs could become less important because the target groups for certain drugs could become smaller.

On the other hand, however, there is a substantial economic potential that might make the development of "custom drugs" attractive for the pharmaceutical industry.

– "It would be possible to predict, and hence avoid, failures (which can be extremely expensive) in drug development in clinical trial phase III.

– It would be possible to "save" drugs that failed in earlier clinical trials if there was pharmacogenetic evidence of their suitability for certain patients.

– It would perhaps be possible to "revive" "old" drugs that are no longer protected by patents if actions can be described based on pharmacogenetic specifications.

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[747] Cf. Schmidtke 1997, p. 247.
[748] Cf. the evidence presented by Wolf *et al.* 2000.
[749] Eichelbaum 2001.
[750] Bayertz *et al.* 2001, p. 289; Feuerstein *et al.* (forthcoming).

– It would be possible to simplify the development of drugs for small patient populations, and hence, to make such drug development economically profitable in the first place. In ethnically correlated sensitivity studies, it would be possible, on the one hand, for population minorities to benefit from such developments, and on the other hand, it would be easier for pharmaceutical companies to obtain approval for a drug in additional countries with a relevant population majority."[751]

How realistic these expectations are, is currently hard to assess.

However, pharmacogenetics is not only expected to have positive effects; instead, it is also associated with a number of problems and risks. These relate primarily to the safety of the drugs developed by means of pharmacogenetic methods, the reliability of the informed consent to be obtained from persons to be tested, the problems of data privacy and the protection of an individual's personal rights, as well as the risks of stigmatisation and discrimination. However, Feuerstein *et al.* have criticised that currently there is a "dramatic deficit with regard to studying and discussing the potential implications" of pharmacogenetics. They point out that there are "virtually no studies (…) in which the specific consequences of identifying and using individual pharmacogenetically relevant differences in medicine and the health sector are analysed in greater detail."[752] The Study Commission feels that there is still considerable need for clarification.

2.2.2.6.1 Safety

Experts hope that the implementation of pharmacogenetics in drug research and development might accelerate clinical trials and reduce the number of subjects recruited for clinical trials by excluding individuals whose genetic tests suggest that the drug to be tested is likely to provoke adverse side effects or a negative treatment outcome. As a result, clinical trials could not only become smaller, faster and more cost-effective but the risks associated with the participation in clinical trials for subjects would be minimised.

On the other hand, however, a reduction of the number of subjects required for clinical trials could also mean that very rare adverse reactions to drugs that only occur when a drug is administered to a large number of patients would remain "invisible". The sub-division of subjects into diagnostic sub-groups, which is part of *pharmacogenetic profiling*, could reduce

[751] Hennen *et al.* 2001, p. 44.
[752] Feuerstein *et al*. (forthcoming).

the probability of discovering such adverse side-effects in clinical trials and thus increase the risk of marketing drugs that will have rare, but potentially dangerous side-effects.[753]

2.2.2.6.2 Voluntary participation and informed consent

In pharmacogenetic studies, it is important to ensure that sample donors have given their informed consent to the collection and use of the genetic data beforehand. This informed consent must meet the requirements for genetic tests, as specified in C2.2.1.3 The principle of voluntary participation.

This currently applies in particular to the participation of subjects in pharmacological epidemiological studies that are designed to identify genes that are responsible for the uptake, efficacy and breakdown of active substances in the human organism. One question that arises in this context, for instance, is how "narrow" or "wide" the wording of the consent must be to be valid. Another question that needs to be clarified is whether it is admissible to analyse the DNA of individuals for new genes or mutations without the express consent of the persons concerned. This problem arises because extensive DNA tissue banks are established in the framework of this research. However, German ethics committees usually give their approval to studies only if they are limited to defined genes. Since only some of the genes are known or have been analysed with regard to their functions and mutations, it is not possible to have recourse to existing banks. According to some scientists, this means that there is considerable wastage of resources. In addition, these scientists argue that it is often very difficult to obtain the necessary samples for very rare disorders.[754]

When pharmacological diagnosis is applied in medical practice, it is necessary – as in all other DNA tests – to ensure that the subjects participate voluntarily and that they have given their informed consent to the tests to be performed. This presupposes that both the suppliers and the users of pharmacogenetic tests must have (at least) fundamental knowledge of the use, the interpretation and the implications of pharmacogenetic tests. In practice, this could give rise to problems if a large number of pharmacological tests is routinely carried out in doctors' surgeries or in pharmacies. In such a case, it may no longer be possible for pragmatic reasons alone to ensure that the subjects are properly given complex genetic information. This would apply in particular if it was possible to develop pharmacogenetic DNA chips that could be used to obtain a wide variety of pharmacologically interesting information simultaneously.

[753] Parliamentary Office of Science and Technology 2000, p. 72.
[754] Eichelbaum 2001.

2.2.2.6.3 Data privacy and protection of personal rights

In connection with both research and applications, pharmacogenetics poses problems with regard to data privacy and the protection of personal rights. Extensive DNA tissue banks are established and large amounts of genetic data are produced in the context of pharmacogenomic and toxigenomic or pharmacogenetic and epidemiological research. The data collected are usually effectively anonymised data that do not permit any reference to other data of the sample donors. In this context, it is necessary to comply with fundamental requirements of data privacy protection. It must be ensured, for instance, that there is no supplementary knowledge that would be sufficient for re-identification (and that it is impossible to do a reference analysis). According to the *Verband Forschender Arzneimittelhersteller* (German Association of Research-Based Pharmaceutical Companies), there is "considerable need for action at European and international level because the rules and recommendations that currently apply in the various countries are very different and in some cases even conflicting."[755]

The implementation of pharmacological diagnosis would lead to a massive increase in the amount of testing and to the production of large volumes of genetic data. This would be true in particular if the administration of a drug like Herceptin was tied – already during the registration procedure – to the prior implementation of a genetic test. The data collected in this way are personal data that provide information on the test subjects' polymorphisms that are relevant for the intended drug action. The availability of these data raises the question of their exposure to third-party access because the data obtained by pharmacogenetic diagnosis may at the same time be superimposed by information on genetically induced predispositions to disorders; in the case of enzymes and transporters that break down drugs, for instance, certain mutations – when exposed to carcinogenic substances – are associated with a greater cancer risk.[756] For this reason, information obtained from pharmacogenetic diagnosis may be of interest for third parties (insurance companies, employers). A question that arises in this context, for instance, is whether certain results of pharmacogenetic tests – that may also contain indications of a greater predisposition to a given disorder – may be subject to the obligation to disclose all risk-relevant facts to the insurer prior to the conclusion of a life or health insurance contract. In this case, the implementation of a test may be advantageous for the person concerned in one area (such as employment), but in another area (e.g. insurance),

[755] *Verband Forschender Arzneimittelhersteller* (German Association of Research-Based Pharmaceutical Companies) 2001.
[756] Eichelbaum 2001.

they may be associated with serious disadvantages. In addition, the data privacy problems that exist in connection with pharmacogenetic diagnosis would be compounded by the development of test kits that could be used to test several characteristics at the same time.

2.2.2.6.4 Stigmatisation and discrimination

In addition, the implementation of pharmacogenetic methods in therapeutic practice involves the risk that specific population groups may be subject to stigmatisation and discrimination. First of all because it is possible to identify ethnic differences in terms of gene frequency that may be relevant from a pharmacogenetic perspective. Secondly, there is a risk that "genetically-based non-responders to therapy" may form a new high-risk group. In the course of the application and establishment of pharmacogenetics, it may be possible:

> "to develop normal standards of treatment tolerance and to define curability limits based on which certain patients (so-called "poor metabolisers") will be regarded as general problem cases for medicine – merely due to their genetic make-up, which is within the range of non-disease-relevant genetic variability. As in the case of genetically-based disease risks, genetic polymorphisms may be subject to "pathologisation" and the starting point of social discrimination."[757]

Feuerstein *et al.*, for example, assume that predictions based on pharmacogenetic tests "will become as relevant for health insurance funds as findings based on predictive genetic tests to identify specific disease risks."[758]

2.2.2.6.5 Distribution equity

In addition, critics fear that, first of all, pharmacogenetic research in the long term will primarily develop drugs for persons whose genetic predispositions are either in line with the "mainstream" or who can afford a personalised genetic treatment. Unequal access to health care services would thus create a social problem. Secondly, the critics argue that there is a risk that the logic of drug research would be twisted around, as it were: "While the current purpose of research is to find the right drugs for many people, the future purpose may be to find the genetically "right" individuals for a drug."[759] As a result, this could lead to a new form of "two-class system of medical care".

[757] Feuerstein *et al.* (no year cited), p. 12.
[758] Feuerstein *et al*. (forthcoming).
[759] Riewenherm 2001, p. 7.

2.3 Regulatory needs, options and proposals

2.3.1 Need for regulation and action

The question as to whether it will be possible to take advantage of the opportunities provided by genetic diagnosis, while at the same time minimising the associated risks, will primarily depend on the prevailing ethical, social and legal conditions.

Except for the provisions specified in C2.1.2 Statutory provisions (national/international), there are currently no specific statutory provisions in Germany that deal with genetic counselling and diagnosis.

Genetic testing is an area that is characterised by very rapid developments. Bearing this in mind, it is at least questionable whether the current instruments of self-regulation under the code of ethical practice are sufficient in order to prevent misguided developments. In addition, the principle of the rule of law implies a statutory proviso according to which important decisions must be taken by the legislator itself.

Currently, there is need for action and regulation with regard to a number of fields of application and application problems of genetic diagnosis:

- For years, there have been considerable quantitative and – to some extent – also qualitative **shortcomings with regard to competent prior as well as follow-up human genetic and psychosocial counselling**. This applies to both prenatal and postnatal genetic diagnosis. In practice, access to qualified information and counselling is currently available to a limited extent only in Germany.

- Guaranteeing the availability of qualified providers of genetic tests is a prerequisite to a sensible and responsible use of genetic diagnosis. It is therefore necessary to **develop and implement quality assurance and quality control instruments** in order to

  - prevent a premature introduction of genetic tests that are not guaranteed to be safe, effective and beneficial,

  - ensure the quality of laboratory services, and to

  - guarantee that test results will be interpreted and communicated in accordance with the state of the art in science and technology.

– In order to protect the personal rights of individuals whose genetic data are processed, it is indispensable to have common **statutory data privacy rules as well as effective monitoring of compliance with these rules**. These rules should be codified either in a separate "Genetic Data Protection Act" or in the framework of a more comprehensive "Genetic Diagnosis Act".

– As far as **research involving human genetic material** is concerned, it is necessary to adopt clear rules on consent and purpose (collection, surplus information, ulterior exploitation or use of samples for other purposes) in order to protect the subjects' right to informational self-determination.

Potential applications are emerging which make it seem sensible to introduce a *preventive scheme*. The fact that currently genetic tests are hardly applied in practice in either the employment or the insurance sector enables the legislator to intervene by setting the course through proactive legislation instead of having to respond to practical constraints. This could help prevent the often criticised problem that legislation lags behind the development and application of technology by adopting legislation in time in this particular area. This could and should be seen as an opportunity for legal policy.

– As far as the **application of genetic testing in occupational medicine** is concerned, it is necessary to develop rules that will make it possible to make use of the potential preventive benefit of genetic testing methods in this particular area, without giving rise to fears in terms of employee selection, discrimination and undermining objective industrial safety.

– With regard to the potential **use of genetic testing for insurance**, it is necessary to take precautions that will prevent any violation of the insurance prospects' right to informational self-determination and the genetic discrimination of individuals, on the one hand, and that will avoid the potential risk of anti-selection that may ensue from asymmetrical information.

– The **implementation of human genetic screening programmes** and the **area of pharmacogenetic diagnosis** should be governed by statutory provisions. What is needed first and foremost is rules that will ensure adequate prior information and counselling, that will rule out any stigmatisation or discrimination of individuals, and that will guarantee the protection of data privacy and of the personal rights of the individuals concerned.

– Finally, it is also necessary to have an international debate about regulating the **marketing of genetic tests via the Internet**.

In view of the ethical and political issues associated with the research on and development of genetic tests and in view of the societal challenges associated with a broadly-based application of genetic diagnostic procedures, there is a considerable **need for conducting a debate and for reaching an understanding** on these issues **in society**. Suitable instruments should be developed for this purpose and implemented.

2.3.2 Regulatory options and instruments for social implementation

2.3.2.1 Quality assurance

Guaranteeing the availability of qualified providers of genetic tests is an important prerequisite to a sensible and responsible use of genetic diagnosis. The question as to whether the implementation of a genetic test is medically sensible and ethically acceptable largely depends on the validity of the test methods, the qualifications of the individuals performing the tests, the reliability of the test results (also under the conditions of every-day application in practice), the quality of the interpretation of the test results, and an adequate integration of the testing practice into (human) genetic counselling.[760] Hence, quality assurance is also a major reference point for statutory provisions.

In this context, it is necessary to distinguish between quality assurance of the product (i.e. the genetic test) and quality assurance of the process (i.e. conditions and rules for the application of the test).[761] When genetic tests are manufactured, used or marketed in a professional and commercial context for purposes of medical analysis, the quality requirements to be met by the product are subject to the provisions of the *In-Vitro* Diagnostic Medical Devices Directive.[762] However, this Directive does not cover genetic tests that are produced within health-institutions laboratories for use in the same environment without being marketed.[763] As far as the quality assurance of the process, the definition of the prerequisites and procedure for the application

Because of the wide variety of suppliers and the broad spectrum of genetic test methods available, the situation is already "confusing", as pointed by the German Research Foundation

[760] Feuerstein *et al.* (forthcoming), Chapter 1.4; Bayertz *et al.* 1999, p. 132.
[761] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health) 2000, p. 4.
[762] Recital 11 of the European Parliament's and the Council's Directive on In-Vitro Diagnostic Medical Devices of 27 October 1998.

(*Deutsche Forschungsgemeinschaft* – DFG) in its opinion on human genome research.[764] Genetic tests are performed in laboratories of hospitals, doctors' surgeries, laboratory physicians in private practice, and private companies. A wide range of genetic test methods are available today, which differ in terms of their goals, their accuracy, the informative value of their test results, their scope of applications, their reliability and the effort associated with testing. Many of the test options currently available still involve considerable methodological uncertainties. The scope of application of molecular genetic tests is increasingly expanding beyond the "traditional" scope of application of human genetics.

More specifically, it is necessary to introduce quality control measures in order to:

– prevent a premature introduction of genetic tests that are not guaranteed to be safe, effective and beneficial,

– ensure the quality of laboratory services,

– guarantee that test results will be interpreted and communicated in accordance with the state of the art in science and technology.[765]

2.3.2.1.1 Licensing of new genetic tests

The research on, and development of, genetic tests involves a number of medical, societal and ethical risks. It is an illusion to believe that it is possible to pursue something like "pure" research in the field of the investigation of genetic testing methods. In particular, the development of genetic tests that are intended to be used for racist purposes and that are conducive to revitalising a biological racial construct, for example, would have to be rejected. Scientific research on, and the development of, genetic tests therefore amplify serious issues of research ethics and politics create a need for conducting a debate and for reaching an understanding on these issues in society.

However, the considerable momentum of technological innovations in the field of genetic testing methods and the growing confusion associated with these innovations can lead to problems not only in the field of research itself but also – and primarily – in the implementation of new methods in clinical practice. In order to prevent such problems, it

[763] Recital 10 of the above-mentioned Directive.
[764] *Deutsche Forschungsgemeinschaft* (German Research Foundation) 1999, p. 19.
[765] Cf. in this context for the United States Holtzman/Watson 1997, p. 7.

would be necessary to subject the purposes, the efficiency, the effects and risks, and the ethical acceptability of the tests to an in-depth examination.

While the so-called "triple marker test" is not a genetic test, it can still serve as a paradigmatic negative example of the premature introduction and unregulated diffusion of a test in practice. Studies have shown that this prenatal test, which is designed exclusively to specify risks, is often misinterpreted in practice as a diagnostic test, which has not only created uncertainty in pregnant women but also to an increased use of amniocentesis and chorionic villus samplings.[766] Nippert argues that the example of the introduction of the triple marker test in prenatal diagnosis demonstrates that:

> "in most cases, the women were neither asked whether they wanted the test to be performed at all, nor were they sufficiently informed about the implications of the test *before* the test or *after* the availability of the test results. This led to strong feelings of anxiety and uncertainty among pregnant women after positive findings; in many cases, these anxieties could only be remedied by means of amniocentesis, which the women originally did not want. The fast diffusion of the triple marker test in practice (a) without any prior clinical verification of its reliability and validity and (b) against the recommendations of the relevant scientific professional organisations has demonstrated how much the interests of suppliers can influence the introduction of tests in practice without giving any regard to informed consent or the patients' autonomous decision-making."[767]

The triple marker test is at the same time also an example of how difficult it is to restrict the use of a test once it is in the market – even if experts and professional organisations have pointed out that it is problematic or even medically not useful. As early as in 1992, the *Gesellschaft für Humangenetic* (Society for Human Genetics), the *Berufsverband Medizinische Genetik* (Professional Association for Medical Genetics), the *Deutsche Gesellschaft für Gynäkologie und Geburt*shilfe (German Society for Gynaecology and Obstetrics) as well as the *Deutsche Gesellschaft für Perinatale Medicine* (German Society for Perinatal Medicine) called for a "moratorium on triple screening of foetal chromosomal

[766] Hennen *et al.* 2001, p. 73; cf. Also Neuer-Miebach 1999, pp. 75 f.
[767] Nippert 2001a, p. 692.

aberrations from maternal serum".[768] In the final analysis, this call for a moratorium by and large failed.[769]

According to Nippert, past experience has shown – in particular in the field of prenatal genetic tests:

> "that the high quality standards which apply initially when a new, ethically controversial method is introduced cannot withstand the harsh reality of everyday medical practice, that the implementation of guidelines and recommendations cannot always be guaranteed, and that quality-assuring measures and basic documentations are not necessarily standard common practice. Experience has also shown that new methods find their way into medical practice relatively easily even if they have not been evaluated sufficiently in clinical trials, especially if they are supported by the statutory health funds' good will or if there is a sufficiently large number of users who are willing to pay for them."[770]

In order to reduce the risks resulting from an introduction of not yet fully developed, unreliable or superfluous tests and to avoid misguided developments as in the case of the triple marker test, various experts have called for the development and application of progressive evaluation and assessment strategies prior to the introduction of genetic test methods.[771]

[768] *Kommission für Öffentlichkeitsarbeit und ethische Fragen der Gesellschaft für Humangenetik* (Public Relations and Ethics Committee of the Society for Human Genetics) 1992.
[769] Cf. Chapter C1.3.3.4.5 Increased supply – induced demand: Ultrasound scan, triple marker test and the consequences.
[770] Nippert 2001c, p. 302.
[771] Cf. for example Nippert 2001a, p. 689.

Table 20: Introduction of Genetic Test Methods (according to Nippert)

Evidence-based Model		**Ad-hoc Introduction**
- Clinical trials / pilot studies - Evaluation of studies - Evaluation of normative criteria → objectives of measures → priorities relative to other measures → information content - Quality standards are established in agreement with the medical community and the "public" - Quality standards determine the reimbursement of cost and use	versus	- Market mechanisms - Court rulings - Interests of suppliers - Demand patterns → determine the introduction - Quality standards are determined by reimbursement of cost and use

Source: Nippert 2001c, p. 321.

The criteria developed by the *Task Force on Genetic Testing* of the National Institute of Health/Department of Energy Working Group on Ethical, Legal, and Social Implications of Human Genome Research in its report "Promoting Safe and Effective Genetic Testing in the United States", for instance, could be among the conditions that a test must fulfil before it can be cleared for use in clinical practice:

> "The Task Force strongly recommends that the following criteria be satisfied:
>
> (1) The genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of a disease. The observations must be independently replicated and subject to peer review.
>
> (2) Analytical sensitivity and specificity of a genetic test must be determined before it is made available in clinical practice.

(3) Data to establish the clinical validity of genetic tests (clinical sensitivity, specificity, and predictive value) must be collected under investigative protocols. In clinical validation, the study sample must be drawn from a group of subjects representative of the population for whom the test is intended. Formal validation for each intended use of a genetic test is needed.

(4) Before a genetic test can be generally accepted in clinical practice, data must be collected to demonstrate the benefits and risks that accrue from both positive and negative results."[772]

2.3.2.1.2 Quality assurance with regard to the implementation of tests, as well as the interpretation and communication of their results

Currently, the participation of laboratories in programs designed to assure the quality of molecular genetic tests is exclusively voluntary in Germany. Only standardised tests kits are subject to binding quality assurance measures, even after the entry into force of the second Amendment to the Medical Devices Act (*Medizinprodukteänderungsgesetz*).[773] The quality of genetic diagnostic tests performed by laboratories is currently reviewed by means of round-robin tests regularly organised by the Society for Human Genetics (*Gesellschaft für Humangenetik*). Nearly all laboratories that are members of the Professional Association for Medical Genetics (*Berufsverband medizinische Genetik*) are included in these tests. The quality of the laboratory services provided by the round-robin test participants varies. In fact, experts have described deficiencies – in some cases serious deficiencies – in their reports.[774]

Unlike the services provided by laboratories of human genetics institutes, molecular genetic tests performed by private laboratories or by laboratory physicians in private practice are subject to hardly any review at present. Against this background, experts have emphasised that it is necessary to develop and implement comprehensive and effective quality assurance and quality control systems.

A systematic review of laboratory capabilities and services is particularly necessary when tests are used to identify risks for rare diseases (so-called orphan diseases) because such tests are not commercially available and their implementation requires particular skills on the part of the laboratory.

[772] Holtzman/Watson 1997, p. 9; cf. also Nippert 2001b.
[773] Cf. C2.1.2 Statutory provisions (national/international).
[774] Cf. the comments made by Bayertz *et al.* 1999, p. 146.

Occasionally, experts have also found problems with regard to the interpretation and the communication of test results.[775] Quite often, for instance, laboratories fail to draw attention to the limitations of the tests performed, e.g. when they definitely rule out the suspected diagnosis on the basis of normal findings.[776]

According to the Swiss preliminary draft of a Genetic Diagnosis Act, the implementation of cytogenetic and molecular genetic tests will be subject to approval by the responsible federal agency, in which the aspect of quality assurance also plays a key role:

"Art. 6 Approval of the implementation of genetic tests

1 Anyone wishing to perform cytogenetic or molecular genetic tests shall require authorisation by the responsible federal agency.

2 Such authorisation shall be granted to laboratories and physicians if it is guaranteed that:

a. that they will perform the tests carefully and in conformity with the law;

b. they will implement the test in accordance with the state of the art in science and technology;

c. they will comply with statutory data privacy provisions.

3 The *Bundesrat* (Swiss Executive Federal Council) may make other genetic tests also subject to compulsory prior authorisation if they impose the same requirements on quality assurance and interpretation as cytogenetic and molecular genetic tests.

4 The *Bundesrat* may exempt from compulsory authorisation certain genetic tests whose implementation does not require any special qualifications and may clear such tests for use by laboratories and physicians.

5 The Bundesrat shall enact implementing provisions concerning the granting and the withdrawal of authorisation, as well as supervision.

Art. 7 Tests for genetic analyses

1 Marketing genetic tests for general use shall be prohibited.

2 Whoever wishes to introduce or market genetic tests for laboratories or physicians shall require authorisation from the responsible federal agency, as determined by the *Bundesrat*.

[775] Bayertz *et al.* 1999, p. 146.
[776] Cf. Müller-Reible 1997, pp. 43 f.

> [3] Authorisation shall be granted after hearing the Swiss Committee for Genetic Tests (*Eidgenössische Kommission für genetische Untersuchungen*) if it can be demonstrated that the test will supply reliable results that can be clearly interpreted.
>
> [4] The *Bundesrat* shall adopt the necessary implementing provisions."

In this context, there have occasionally been calls for an accreditation or certification of laboratories in which genetic tests are performed in order to support the professional organisations' self-regulation by establishing framework conditions defined by law. In Germany, there are no general statutory provisions that require medical laboratories to be accredited or certified.[777]

2.3.2.2 Linkage to medical purposes

There are many national and international documents and opinions which call for a restricting genetic tests to so-called "health purposes" or "medical purposes". Article 12 of the Council of Europe's *Convention on Human Rights and Biomedicine*, for instance, stipulates that tests which are predictive of genetic diseases may be performed "only for health purposes or for scientific research linked to health purposes". However, the terms "health purposes" and "linked to health purposes" are not clearly defined.[778]

As already discussed under C2.2.1.1 Particularities of genetic information, a number of reasons have been put forward (especially points 6, 8, 9, and 10) for restricting the use of genetic tests to health purposes. One question that arises in this context is whether there are predictive tests that do not imply the risks mentioned in these points.

Terms such as "relevant to health", "health-related" or "serving medical purposes" are often used to refer to goals that go beyond the preventive measures and treatments for the person concerned. The Swiss preliminary draft of a Genetic Diagnosis Act, for instance, also describes tests as medical tests that are relevant for an individual's life design or family planning.

However, such a wide definition of "health-related" or "health-relevant" purposes involves serious problems:

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[777] Hennen *et al.* 2001, p. 99.
[778] Cf. on this discussion Lanzerath 2000a; 2000b; Lanzerath/Honnefelder 1998.

– It makes it difficult to make a clear distinction between disease-related and non-disease-related genetic tests.

– It mixes the terms "disease" and "disability" with each other; individuals with disabilities are defined as being "sick", and hence stigmatised.

– It is not conducive to preventing genetic tests performed with the intention of "enhancing" the human being.

– It involves the risk that genetic tests – in particular prenatal genetic tests – may be used for selective or eugenic purposes.

– It leads to a situation where– providing that medical genetic tests are linked to the proviso that they must be performed by a doctor – it is largely left to the medical profession to interpret what medical purposes are.

– And it contributes in a questionable way to the medicalisation of phenomena and areas of life. This is associated with the risk that the medical community might develop a professional interest in a wider use of genetic tests in practice, which might encourage them to keep promoting the use of such tests.

Hence, linking genetic tests to "health purposes" is not an efficient means of preventing an arbitrary increase in the use of genetic tests in practice. There are no bounds to the interpretation of the term "health". Hence, there is a risk that society and the health care system may be confronted with an oversupply of genetic tests, which last but not least would overtax the capacity of the health care system. For this reason, the Study Commission proposes that instead of linking genetic tests to "health purposes", they should be tied to "medical purposes". Tests performed for "medical purposes"[779] are tests which

– are disease-related in the narrower sense,

– are performed with the objective of identifying genetic structures that provide information on the risk, the probability or the certainty of a future disease or disability,

– are conducted to identify genetically induced sensitivities to certain active substances of drugs,

– are conducted to identify a heterozygotic genetic predisposition to a disease.

[779] Cf. C2.1.1.1.1 Definitions.

This means that the term "medical purposes" is related in one way or another to the term "disease". Hence, non-medical tests are not only tests performed to establish a person's descent or identity but also so-called life-style tests, i.e. tests designed to establish characteristics without any pathogenic impact.

2.3.2.3 Proviso that genetic diagnosis must be performed by a physician

In order to ensure the quality of both counselling and diagnosis, various voices have called for a proviso that genetic diagnosis should be performed exclusively by physicians. In its opinion on human genome research, for instance, the German Research Foundation's *Senatskommission* (Senate Committee) argues that it is necessary to link the performance of genetic tests not only to medical purposes but also to the doctor/patient relationship.[780]

The authors of a study on human genetic diagnosis, which was conducted at the *Europäische Akademie zur Erforschung von Folgen wissenschaftlich-technischer Entwicklungen* (European Academy for Research into the Effects of Scientific and Technological Developments) in Bad Neuenahr-Ahrweiler, call on the legislator to introduce a limited doctor's proviso in the event that "there are signs indicating (e.g. in the context of international developments) that it will not be possible to control the risks associated with genetic tests by means of voluntary commitments by all the parties involved". The wording that the authors propose for the doctor's proviso reads as follows:

> "Tests that are capable of, or are offered with the objective of, predicting genetically based diseases, disabilities or disorders, or of identifying in a person either the presence of a gene responsible for a given disease, disability or disorder, or a genetic predisposition or susceptibility to a disease, disability or disorder (genetic diagnostic procedures), may professionally or commercially only be requested by a physician for preventive, diagnostic or therapeutic purposes relative to a given individual, and the test results may only be interpreted and communicated by the physician involved."[781]

Under Section 65 of the Austrian Genetic Engineering Act, genetic tests may be performed only "at the request of a physician trained in human genetics or of a physician specialised in the area of indications concerned". The Swiss draft of a Genetic Diagnosis Act also includes a doctor's proviso with regard to genetic tests intended for medical purposes. According to the draft bill, pre-symptomatic tests, as well as prenatal tests and tests to be performed for reasons of family planning may only be requested by properly trained, specialised physicians.

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[780] *Deutsche Forschungsgemeinschaft* (German Research Foundation) 1999, p. 12.
[781] Bartram *et al*. 2000, p. 187.

2.3.2.3.1 General and limited doctor's proviso, specialist's proviso

Generally speaking, it is possible to distinguish between three options with regard to the call for a doctor's proviso: The proviso that genetic tests must be requested or performed by a physician may be general and comprehensive, it may be limited, or it may be tied to specialised physicians. Making genetic tests subject to a general doctor's proviso means that only physicians are authorised to request any kind of cytogenetic and molecular genetic tests and only for medical purposes.

On the other hand, introducing a limited doctor's proviso means that only certain tests will be tied to the doctor/patient relationship. The advocates of the latter position argue that genetic tests as such are not dangerous and that obtaining information about an individual's genetic make-up does not always require a complicated test.

Making genetic tests subject to a specialist's proviso means that the authorisation to request or perform certain or all kinds of genetic tests is limited to properly trained, specialised physicians. One argument in favour of introducing a specialist's proviso – at least for some genetic tests – is that not every physician is qualified to select patients for, and interpret, all genetic tests.

2.3.2.3.2 Pros and cons with regard to a doctor's proviso

A number of objections have been raised against making genetic tests subject to a doctor's proviso:

– It is argued that the introduction of a doctor's proviso encroaches on the general personal rights of persons who would like such a test to be performed on themselves. Such encroachment, it is said, needs to be justified.

– If the doctor's proviso is linked with a limitation to genetic tests performed for medical purposes – as, for example, in the opinion prepared by the German Research Foundation – some argue that this raises the question as to what moral or legal grounds there can be to justify a restriction of an individual's right to know by denying access to life-style tests.

– In addition, it is said that the consequence of introducing a doctor's proviso and tying genetic tests to medical purposes may be that life-style tests may be declared as medical tests in order to be able to request or use them. It is believed that this would lead to a highly problematic broadening of the scope of the definition of the term "disease" and of a physician's medical treatment mandate.

– If there is no such linkage with medical purposes – i.e. if physicians are also authorised to obtain medically irrelevant findings – the question arises why only physicians should be authorised to obtain findings that, by definition, are medically irrelevant.

– In addition, it is argued that the introduction of a doctor's proviso for the performance of genetic tests also restricts the freedom of occupation of those who want to perform genetic tests including counselling without having a license to practise medicine.

On the other hand, however, there are also considerable advantages to making genetic tests subject to the proviso that they must be requested and implemented by a physician: As a result of the introduction of such a proviso, the implementation of genetic tests could remain limited to the established system of medical care and would thus be subject to the medical profession's code of ethical practice. Last but not least, this would also largely preclude the development of a "free test market" in which genetic tests would be made available in accordance with purely commercial aspects.[782]

A doctor's proviso will also prepare the ground for a proper implementation of the tests by qualified staff and for adequate counselling. For this reason, the introduction of a doctor's proviso is an important instrument to ward off the risks that may be associated with genetic tests because errors made in obtaining, interpreting or evaluating the findings of genetic tests may cause problems that may be as serious as problems due to wrong treatment. This applies in particular to the protection that needs to be provided to relatives of the person who undergoes a genetic test. It is therefore justified to restrict the freedom of occupation of those who want to perform genetic tests without having a licence to practice medicine.

In this way, the individual's self-determination is supported more effectively than this would be the case without the introduction of a doctor's proviso. Genetic information is so highly complex that it is usually not adequately understood by lay persons, and it involves a high risk potential that is often not sufficiently recognised by lay persons. Hence, the introduction of a doctor's proviso may protect the individual from improperly using findings obtained from genetic tests.

Finally, genetic tests performed by physicians (or under their direction) would be subject to professional secrecy. This would private a relatively high standard of data privacy.

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[782] *Ethikbeirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health), in particular pp. 7 f.

2.3.2.3.3 Regulatory proposals by the Study Commission with regard to the introduction of a doctor's proviso

It cannot be assumed that all genetic tests available today and possibly in the future will be intended for medical purposes. Tests that are performed to establish a person's descent or identity as well as possible future life-style tests cannot be seen as tests that are intended for medical purposes.

If a general doctor's proviso was introduced for all kinds of genetic tests, this would mean that physicians would also assume a function that is not part of the genuinely medical activities. If a general doctor's proviso was introduced, "physicians (…) would also have to 'appropriate' – according to their own rules – information that relates to general questions of life-style or life design, irrespective of medical issues. This goes beyond the – at least currently accepted – scope of activities reserved to physicians."[783]

2.3.2.3.4 Doctor's proviso and prenatal genetic tests

Prenatal genetic tests pose a particular problem. It is conceivable that it will be possible in future to develop tests that can be used to identify specific healthy characteristics or predispositions in a future child. Currently, only the determination of the sex falls into this category, providing that sex determination is not relevant for the diagnosis of a sex-linked disease. In the case of prenatal tests, it could also be argued that introducing a general proviso to the effect that prenatal tests can only be performed by a physician and only for medical purposes is an encroachment on the personal rights of individuals when pregnant women are denied access to this type of knowledge. However, in prenatal tests – unlike postnatal tests – the unborn human being is always involved, too. One of the consequences of this test may also be a termination of pregnancy. More specifically, it cannot be ruled out that an unrestricted availability of non-medical prenatal tests may pave the way for positive eugenics, i.e. selection of future children based on desirable genetic traits. The risk for the unborn human being and the risk of positive eugenics justify a general proviso to the effect that prenatal genetic tests can only be requested by physicians and must therefore be combined with compulsory information and optional counselling.[784]

Another question that arises specifically in connection with prenatal genetic tests is whether the shared-risk community should also bear the cost of tests whose results do not provide any prospects of curing or preventing a disease. In prenatal care, pregnant women are routinely

[783] Bartram *et al*. 2000, p. 157.

offered tests today that leave no other option than terminating the pregnancy (e.g. tests for Down's syndrome or "open back"). The fact that these tests are routinely offered and that their cost is borne by the statutory health insurance funds suggest that these tests are part of the regular prenatal care services. In pregnant women, this creates the impression that making use of all the tests available is responsible behaviour of future parents. The women often do not realise that these tests cannot help their future child at all; instead, they jeopardise the child's existence.

One way of counteracting this development would be to remove such prenatal tests from the services available in the context of regular prenatal care.[785] Doctors should not offer these tests to pregnant women on their own accord, but only if a woman asks about them explicitly. In any case, it is necessary to obtain the explicit consent of the woman concerned.[786]

Another option for limiting the use of prenatal tests would be to remove any tests that do not provide any prospects for treatment or prevention from the list of services financed by the statutory health insurance funds. These tests would then have to be paid directly by the users themselves. In addition to stopping the encouragement resulting from the current payment of the tests by statutory health insurers (see above), there is another argument in favour of such an action: Since the purpose of these tests is to be able to prevent the birth of human beings with certain traits and characteristics, persons who belong to such groups perceive this testing practice as indirect discrimination because these tests suggest to them that their existence is actually undesirable. However, even those individuals who feel discriminated by the tests are obliged to co-finance the testing practice if they are members of the shared-risk community. It is impossible for them to avoid participating in a practice that they perceive as being discriminatory.

One argument against removing prenatal genetic tests from the list of services financed by statutory health insurers is that this would represent one step on the way towards a "two-class system of medical care". The effect might be that financially well-off women would continue to use the tests so that their use would be restricted only among women with lower incomes.

To refute this counterargument, it can be argued that the impact of such a measure should not be underestimated. The message that preventing the birth of a disabled child is not a collective task of society could already have a limiting effect on the testing practice.

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[784] Cf. C2.3.2.4.1 Information, education and informed consent.
[785] Kirchner-Asbrock 2001.
[786] Cf. in this context Chapter C1.3.5 Recommendations.

Doctors provide their services within the framework of medical science. The question as to which of these services are financed by the shared-risk community is determined by the *Bundesausschuss der Ärzte und Krankenkassen* (Federal Committee of Physicians and Health Insurers). The advantage of a general statutory regime on genetic tests in this framework would be that it would be possible to use already existing institutional structures. However, the disadvantage is that these structures are not very transparent for citizens.

In order to achieve better transparency, it would be desirable to introduce statutory provisions – e.g. within the framework of a future Genetic Testing Act – which specify the tests that are subject to the proviso that they may only be performed by a physician. This Act would have to exactly define the criteria according to which a test is subject to such a proviso. It is the belief of the Study Commission that these criteria should be as follows:

– tests performed for medical purposes,
– prenatal tests,
– tests that may pose a threat for the person concerned.

This means that most of the genetic tests in use today and introduced in the future would be subject to the proviso that they may only be performed by physicians. However, it must be expected that in future some life-style tests will also become available in the market. From a perspective of constitutional law, it seems hardly possible to prohibit such tests under criminal law – at least as far as prenatal tests are concerned – because this would encroach on the constitutional right of individuals to live their lives as they see fit. This means that in future there may also be tests that will not be subject to a doctor's proviso. However, for reasons of consumer protection, these tests will also have to go through a legally defined registration procedure and checked in terms of their product quality.[787] In addition, a potential Genetic Testing Act could also prescribe a separate distribution channel or distribution via pharmacies only for such tests.

In order to prevent the development in the long term of a practice according to which life-style tests will be declared as medical tests, which would overtax the capacity of the health care system, it is necessary to develop a system for monitoring the practice of prescribing genetic tests. This task could be assigned to a future Genetic Testing Commission. This Commission should monitor the extent to which specific tests are requested, implemented and prescribed and the effects that this practice might have on society. The Commission should

regularly report its findings to the public. In order to be able to fulfil this task, the Commission's composition would have to be multidisciplinary and balanced. The fields of expertise covered by the Commission's members should include in particular sociology, philosophical and theological ethics as well as law. Since the Commission's task would be to monitor the medical profession, the majority of its members should not be doctors. The Commission should be transparent in its work and involve the public in a suitable manner (e.g. by holding hearings, organising discussion forums, and accepting petitions).

2.3.2.4 Information, education and counselling

Scientific and political discussion often draws no explicit distinction between information, education, human genetic counselling and psychosocial counselling. There is a tendency to use the term "counselling", or even "genetic counselling", as a generic concept to cover all of these.[788]

Counselling in this general sense is regarded by some as indispensable – at least with a view to the predictive and prenatal tests available – before and after taking a test.[789] The professional organisations (both national and international) consider detailed genetic counselling prior to and following a genetic test to be an essential component of human genetic service provision, and the *Deutsche Gesellschaft für Humangenetik* (German Society for Human Genetics) sees counselling as a "binding framework for any kind of genetic diagnosis".[790] The Council of Europe's *Convention on Human Rights and Biomedicine* also provides in Art. 12 that tests which are predictive of genetic diseases are subject to appropriate genetic counselling, although it does not call for counselling to follow these tests.[791]

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[787] Cf. C2.3.2.1 Quality assurance.

[788] The *Bundesverband Medizinische Genetik* (Professional Association of Medical Genetics), for example, states that genetic counselling "should help an individual or a family to understand the facts of medical genetics, to consider the options and to select individually appropriate forms of behaviour". (Bundesverband Medizinische Genetik 1996).

[789] *Ethikbeirat beim Bundesministerium für Gesundheit* (Ethics Council of the German Federal Ministry of Health) 2000.

[790] Cf. e.g. *Kommission für Öffentlichkeitsarbeit und ethische Fragen der Gesellschaft für Humangenetik* (Public Relations and Ethics Committee of the Society for Human Genetics) 1996.

[791] The Study Commission on "Opportunities and Risks of Genetic Engineering" recommended to the German Bundestag back in 1987 that it "call upon the Federal Government and state-level governments as well as professional medical associations to adopt appropriate measures in order to adapt counselling practice to the broader opportunities now presented by genetic testing, to expand staffing and technical capacities and the number of locations providing counselling and diagnosis, and to improve staff skills in these locations, where necessary. The principles applied to genetic counselling should be retained in the future, especially if greater use is made of genetic tests at DNA level in prenatal diagnosis" (Report submitted by the Study Commission on "Opportunities and Risks of Genetic Engineering 1987, pp. 152 f.).

However, it would be more accurate to distinguish between information, education, human genetic counselling and psychosocial counselling.

2.3.2.4.1 Information, education and informed consent

"Information" is taken here to mean providing or passing on factual information. "Education" means providing a framework which enables people to consider and evaluate the issues themselves. Information and education about the genetic and medical aspects of the tests are essential prerequisites to ensure that the persons concerned are able to give their free, informed consent. Such information must be provided by professionally qualified persons prior to the test; if this is not the case, the conditions of informed consent have not been observed. In order to satisfy these conditions, the physician requesting the test must, prior to its performance, at least instruct the person to be tested about the nature, substance and purpose of the test and also how reliable it is, how indicative the findings are, what error rate and risks pertain, and whether there will be any consequences or options to consider as a result. Education must also be provided about any alternative options with regard to the performance of the test itself. In addition, the conditions of informed consent are only met if the subject has been told about any possible psychological conflicts or stress which might be triggered by the findings of the test and has been offered psychosocial counselling or information about available counselling services.

This information and education must meet specific requirements if genetic tests are to be carried out on persons unable to consent or on minors. As a general rule, minors should only be subjected to predictive tests if these are necessary at this early age in order to open up prospects of therapy or prevention for the individual concerned. In exceptional cases, tests may be permissible as a substitute for diagnostic methods that would expose the child to severe strain.[792] The child's decision should be taken into account in a manner befitting his or her stage of development.

Predictive tests should only be performed on adults not able to consent if the test is necessary to open up prospects of therapy or prevention, or if there is a risk that not taking the test would be to the detriment of their health or lead to suffering. In this case, the information, education and counselling should be offered to the custodian. The custodian's informed consent must be recorded. The documentation should also describe how the above-mentioned requirements regarding the necessity of the test have been met.

In the case of prenatal testing, education must also draw attention to the fact that there will be no therapeutic options and that the choice will rest entirely between allowing the pregnancy to run its course or terminating it. Attention must also be drawn to the manner in which termination would occur (induced delivery) and, if appropriate, the unlikely but real possibility that the child could survive termination at an advanced stage of pregnancy. It is also essential to explain whether the test procedure poses any risks for the unborn child. It is particularly important in the case of prenatal tests to draw attention to their limited informative value; the physician must make it clear that, while certain predispositions, diseases and disabilities can be ruled out (with a certain probability), the test cannot produce a positive guarantee that the child will be born healthy or without impairments.

In the case of particularly problematic predictive tests where findings may place the subject under an extreme strain, there is an argument for suggesting that informed consent implies a period of several days for reflection between education and performance of the test in order to ensure that the information received can be digested at leisure. The same applies to prenatal tests that merely open up the option of terminating a pregnancy.

It should also be considered whether a gene carrier test to be carried out for family planning purposes should be subject to human genetic counselling, given that interpretation of the findings calls for specific qualifications.

Information and education must be binding on both the physician requesting the test and the person to be tested. Records should be kept in every case of how the conditions of informed consent have been met.

Information and education must be non-directive in order to permit a genuinely free informed decision.[793]

2.3.2.4.2 Human genetic counselling

Education in the narrower sense should be distinguished from "human genetic counselling". The latter includes the calculation of risks, medical history taking, genealogical analysis and

[792] *Ethik-Beirat beim Bundesministerium für Gesundheit* (Ethics Council of the Federal Ministry of Health) 2000, p. 10.

[793] The great majority of human genetic specialists in Germany feel bound to provide non-directive education or counselling. According to a survey, over 91.4 per cent of the human genetic specialists interviewed stated that the non-directive approach was an essential ethical standard; 79.1 per cent regard it as a viable strategy for the responsible management of genetic knowledge; and 81.8 per cent take the view that no physician should provide genetic counselling without appropriate counselling qualifications (Nippert/Wolff, quoted in Wolff 1998, p. 174.).

possibly clinical examination. It may involve not only the person seeking advice, but also his or her family. If it can be assumed, for example, that relatives of the person seeking advice may carry a genetic predisposition which can be treated or prevented, human genetic counselling should include a recommendation to advise these relatives of their testing options.

Human genetic counselling must be non-directive at all times. In practice, however, the non-directive principle makes major demands of the counsellor's reflective skills. He or she must refrain from any explicit or implicit value statements, avoid even the subtlest attempt at exercising influence and be able to distinguish precisely between his or her own opinions and values and those of the person to be tested. Specially designed (further) training is required to foster the necessary reflective skills.

To ensure that counselling remains non-directive, it would be helpful to separate it institutionally from the performance of the test. The person providing the human genetic counselling should not subsequently carry out the test, as there is a risk that economic pressures might lead the counsellor to advise in favour of the test.

2.3.2.4.3 Psychosocial counselling

Human genetic counselling should be distinguished from "psychosocial counselling". This addresses specifically psychological conflicts and embraces the life context and plans of those concerned. It serves to help those seeking advice to order their emotions about their situation and the decisions they are taking.[794]

Providing qualified psychosocial counselling, which embraces the emotional and social situation the advice-seeker is in, including family relationships and partnerships, and enabling him or her to take the right personal decision in the light of this background, calls not for medical and genetic competence, but for psychological skills. It should, therefore, only be provided by persons who have been properly trained. If physicians wish to provide psychosocial counselling, they should be able to demonstrate an additional qualification in this field.

Psychosocial counselling also differs from information and education in that it will not be successful unless the advice-seeker comes to it of his or her volition. Psychosocial counselling must, therefore, be sought on a voluntary basis, and unlike information and education, it should not be compulsory.

[794] Cf. on these distinctions *Pränataldiagnostik und Beratung* 1999, pp. 4 f.

Unless there is pressure to act immediately for clinical reasons, psychosocial counselling, assuming the person concerned wishes to receive it, should begin *before* diagnosis in order to enhance the conditions for free, informed decision.

Experience with genetic tests such as those for BRCA 1/2 and Huntington's Disease has shown that a positive result can prove extremely stressful for those concerned. In the light of this experience, it is worth considering whether such tests should only be made available in conjunction with integrated psychological support.

2.3.2.4.4 The link between obtaining information, education or counselling and taking the test

The fundamental importance of qualified genetic information, education and counselling is highlighted by the link which exists between making the former available and the use made of tests. Well informed people, as empirical studies have shown, are more likely to decide not to use certain genetic tests than people who are less well informed. Studies on the introduction of the test for cystic fibrosis carrier status, for example, have shown that take-up rates rise and fall depending on how the test is offered. In the UK, meagre education combined with an immediate offer to test led to a take-up rate of over 80 per cent, while detailed education combined with a period to reflect saw the rate fall to below 10 per cent. In Germany, take-up rates vary, depending on the institution involved and the format, from 99.8 per cent to 15.5 per cent.[795]

Provisional findings from a multi-centre evaluation study currently in progress in Germany on predictive BRCA 1/2 tests suggest a similar pattern. They demonstrate that

> "under strict compliance with defined formal 'informed consent' procedures, which include intensive education with regard to the predictive scope and limits of the test and of the therapy options available at present, along with a period for reflection, more than 50 per cent of the women counselled to date have decided *not* to take the test (take-up rate of 40 per cent). These provisional data reflect the findings of other studies undertaken abroad on the take-up of BRCA 1/2 testing."[796]

2.3.2.4.5 Lack of capacity

In practice, the provision of qualified information, education and counselling in Germany is subject to limitations. In 1997, for example, about 40 per cent of all genetic tests were carried

[795] Nippert 2001a, p. 693.
[796] Nippert 2001a, p. 693.

out without genetic counselling.[797] Besides, it can be assumed that, due to the inadequate training of physicians, most of those who do undergo a genetic test have only limited access to state-of-the-art information, as recommended by the German Society for Human Genetics.[798] The problem of ensuring informed, autonomous decision-making could be exacerbated in future by the spread of genetic test options, notably the introduction of chip-based multiplex arrays.[799]

Table 21: Physicians in Germany with Qualifications in Human Genetics Acquired in Standard Further Training

Qualification	**active in the profession**	**of which:**			
		non-residential	residential	authorities/ agencies	other
Physician fully specialised in human genetics	181	52	97	16	16
Additional qualification in medical genetics	292	135	123	16	18

Source: *Bundesärztekammer* (German Medical Association) 2001

There is currently no systematic overview of how much qualified psychosocial counselling is available to support personal decision-making and to what extent these services are used. Various academic experts and associations, such as those in the field of psychosocial work, have given conceptual thought to new counselling structures beyond the realm of human genetics.[800] Some of these projects, such as the Cara counselling service in Bremen and the *Evangelische Konferenz für Familien- und Lebensplanung* (Protestant Conference for Family and Life Planning) in Berlin, have already been launched to provide counselling around prenatal genetic diagnosis.

The field of prenatal genetic diagnosis is particularly affected by these deficits in the provision of prior or subsequent information, education and counselling by qualified specialists. There has been a huge increase in prenatal genetic tests in recent years, and it is on the way to becoming a routine procedure. This implies a growing risk that women will "slip"

[797] Hennen *et al.* 2001, p. 54.
[798] Nippert 2001b, p. 695; oral communication by Prof. Zerres during the public hearing held on 16 October 2000.
[799] Nippert 2001a, p. 145.
[800] *Bundesministerium für Familie, Senioren, Frauen und Jugend* (Federal Ministry of Families, Senior Citizens, Women and Youth) 2001; Haker 1998; Heinkel 2000; Dederich 2000.

into prenatal tests without giving adequate thought to the procedure or its possible consequences. The risk of "supply-driven" demand for genetic testing is particularly evident in the field of prenatal diagnosis.[801]

The quality of information, education and counselling before and after the performance of a prenatal genetic test has been the subject of persistent debate for some years.[802] Even today, however, it is evident that provision remains inadequate, both of qualified genetic and medical counselling on the frequency of genetic abnormalities, pathologies and risks related to prenatal tests and also of psychosocial counselling for women confronting the difficult decision for or against prenatal diagnosis. Most pregnant women who make use of prenatal genetic tests are not offered education or counselling prior to taking the test.[803] In practice, this means that the informed consent requirement is often not fulfilled. According to a study conductd by the Federal Ministry for Families, Senior Citizens, Women and Youth, pregnant women are rarely aware that they can obtain psychosocial counselling around prenatal diagnosis outside the medical context, or indeed where to find it. Only exceptionally do hospitals and registered gynaecologists draw their attention to these services.[804]

Various studies have demonstrated that physicians with no additional training in human genetics are especially likely to display deficiencies with regard to qualified information and education:

– A study on attitudes to education and the information skills of physicians in private practice who requested genetic tests from commercial laboratories in order to establish carrier status for the APC gene (Polyposis coli/intestinal cancer) – 88 per cent of the individuals tested were asymptomatic for intestinal cancer – revealed that in 17 per cent of cases there were no grounds for testing, that written consent had only been given in 16.9 per cent of cases and that in 31.6 per cent of cases the interpretation of test results that the physician was asked to supply had been wrong.[805]

– Studies by Geller on the introduction of predictive tests for familial mammary cancer showed that only 5 per cent of the women asked, all of whom were from high-risk

[801] Nippert 2000, p. 144.
[802] Cf. for example *Bericht der Enquete*-Kommission "Chancen und Risiken der Gentechnologie" (Report of the Study Commission on "Opportunities and Risks of Genetic Engineering") 1987, pp. 147 ff. Baldus 2001 offers a recent summary of the debate about counselling for prenatal genetic diagnosis.
[803] Nippert 2001b.
[804] *Bundesministerium für Familien, Senioren, Frauen und Jugend* (Federal Ministry of Families, Senior Citizens, Women and Youth) 2001, p. 32; 40.
[805] Holtzman/Watson 1997, quoted in Nippert 2001a, p. 693.

families, did not think informed consent prior to the test was important. By comparison, 28 per cent of the male doctors who were asked believed that informed consent prior to the test was not important. Whereas only 6 per cent of the women asked said they would consider prophylactic mastectomy if the result was positive, 28 per cent of the doctors would recommend surgery a priori if the result was positive; when these medical professionals are subdivided into specialist fields, 50 per cent of surgeons would recommend surgery.[806]

– A British study showed that physicians not qualified in human genetics were particularly likely to rate counselling and informed consent prior to prenatal genetic diagnostic procedures as unimportant.[807]

– A survey among doctors in private practice in the United States indicated that the majority of the respondents believed "trisomy 52" (a chromosome disorder which does not exist since there is no human chromosome number 52) could be identified by prenatal genetic diagnosis.[808]

– Data from the BIOMED 2 project on "Decision-making after the diagnosis of a foetal abnormality" (DADA) reveal that the rate of pregnancy terminations following a positive test for a chromosome disorder (47, XXY), which is usually not very severe, varied from 0 per cent to 76.9 per cent, depending on the centre involved. Pregnant women counselled after a positive result by a physician with some training in human genetics terminate their pregnancy in 35.5 per cent of cases; and pregnant women counselled by a physician with a different qualification terminate their pregancy in 71.9 per cent of cases. The likelihood of continuing the pregnancy is 2.4 times higher after talking to a doctor who is a qualified genetic counsellor. These differences can probably be attributed to varying educational styles and varying knowledge of the syndrome on the part of the physician providing the information. They demonstrate how dependent the woman making the decision is – if she has no personal experience with the disorder – on accurate, qualified information.[809]

In general, it must be observed that in practice the conditions for a free, informed decision by the person concerned are frequently not ensured.

[806] Geller 1997, quoted in Nippert 2001a, p. 694.
[807] Dodds 1997, quoted in Nippert 2001b.
[808] Wertz 1997, quoted in Nippert 2001a, p. 694.
[809] Marteau *et al.* 2001, quoted in Nippert 2001b.

In Germany, there is currently a lack of physicians who have received qualified training in genetics and who are also qualified to provide counselling. At present, there are only a few hundred doctors who are qualified to provide complex genetic information and education, and it is unclear how many of these possess a counselling qualification. This means that most genetic tests will continue to be requested and interpreted by physicians who do not work in human genetics. The German Society for Human Genetics estimates that some 450 additional specialists in human genetics are needed to satisfy the current need for counselling, assuming a general concept of genetic counselling that does not differentiate between information/education and psychosocial counselling.[810]

Another important reason for this dissatisfactory overall situation, apart from the lack of human resources, is seen by experts to reside in the fact that genetic counselling – again in the general sense – holds little economic appeal for the person providing it, in view of the current rules for invoicing this service.[811]

2.3.2.4.6 Quality of information, education and counselling

The Genetic Counselling Guidelines issued by the *Bundesverband Medizinische Genetik* (Professional Association of Medical Genetics) in 1996 state that genetic counselling embraces:

> "5.1 The provision of information about
>
> – the medical background to congenital or late-onset, genetically-based or partially genetically induced disorders and disabilities, including aetiology, prognosis, therapy or prevention, and prenatal and postnatal diagnosis and its limitations;
>
> – the role of genetic factors in the development of disease and their impact on the likelihood of relatives or the person counselled contracting the disease. A calculation of the risks of onset must be carried out if possible. If not, an estimate of these risks must be attempted;
>
> – in the case of exogenous strains, possible impact mechanisms, teratogenic and/or mutagenic risks and options for prevention or therapy and prenatal diagnosis.

[810] Wolff 2001; oral communication by Prof. Zerres during the public hearing held on 16 October 2000.
[811] Oral communication by Prof. Wolff during the non-public hearing held on 5 March 2001.

5.2 Assistance to the individual in making his or her decision in the light of his or her personal and family situation. It is particularly important to note and respect individual values, including religious attitudes and the psychosocial situation of the person seeking advice.

5.3 Assistance in coping with existing problems or those triggered by genetic diagnosis."[812]

It is essential, when providing education and counselling, to remain open-minded as to the outcome, especially if it concerns diseases and disorders that cannot be treated or avoided and that are of significance to family and life planning.[813]

The concept of non-directive counselling, which is not a counselling method in the strict sense, has been developed in past few years through patient-oriented and client-oriented counselling towards an "experience-oriented counselling", in which the counsellor is essentially guided by jointly defined counselling objectives and by the needs of the patient or client. This also places new demands on training for counsellors who work in genetic diagnosis and imposes new requirements for quality assurance in genetic counselling.

For some years, particularly in the field of prenatal genetic diagnosis, there have been calls for human genetic counselling to be complemented by improved psychosocial counselling, since it is by no means rare for the diagnostic services available to confront a woman or a couple with serious conflicts around the decision. The idea is that psychosocial counselling services should support women in their difficult decision on whether or not to take the prenatal test and – if the result is positive – whether or not to terminate pregnancy. Psychosocial counselling in the context of prenatal diagnosis also entails information and education, but it is more than this. It offers help in dealing with the diagnosis and ensures support for women and couples making their decisions. Psychosocial counselling is not just counselling about the measure itself, but also about its psychological, social and ethical dimensions. It also addresses the question as to how the women seeking advice experience their pregnancy, their expectations and perspectives, and the problem of accepting responsibility; and moreover, it seeks to open up new perspectives for the women and couples seeking advice (e.g. on their perception of disability). Many proponents of psychosocial counselling also stress that it should challenge the underlying assumptions of selective diagnosis.[814]

[812] *Bundesverband Medizinische Genetik* (Professional Association of Medical Genetics) 1996.
[813] Wolff 2001; cf. also Wolff 1998; Hartog/Wolff 1997.
[814] Oral communication by Ebba Kirchner-Asbrock during the non-public hearing held on 5 March 2001.

In the framework of a pilot project on the "Development of criteria for counselling pregnant women carrying children expected to have a disability", which was funded by the Federal Ministry for Families, Senior Citizens, Women and Youth, counsellors formulated, among other things, the following overarching objectives for the counselling process:

1. "Build a relationship between the client and the counsellor.
2. Strengthen the intrinsic competence of the resources available.
3. Provide comprehensive information and education around PD [prenatal diagnosis]. Permit a critical attitude.
4. Allow time, space and possibly words so that anxieties, fantasies and fears are rendered conscious and can be addressed.
5. Show ways of (give encouragement for) accepting the child as it is.
6. Practise crisis intervention for the current conflict.
7. Help women perceive and accept personal feelings.
8. Support women in their bereavement and when they make a fresh start.
9. Provide counselling that specifically meets female needs.
10. Involve the partner."[815]

2.3.2.4.7 Who should provide information, education and/or counselling? The qualifications and institutional structures required

Counselling and information/education in the medical context are criticised – especially by women's health centres and other bodies – for reducing the content to medical information and risk issues. Furthermore, they are perceived as non-neutral, firstly because human genetic counselling is seen as exhibiting a tendency towards encouraging individuals to take the tests available, and secondly because it is not seen to challenge the selective practice associated with prenatal genetic diagnosis. Besides, many regard independent psychosocial counselling outside the medical or at least human genetic context as desirable.[816]

The argument put forward to counter this proposal for an institutional segregation of genetic diagnosis and counselling is that if qualified counselling within human genetics remains open-minded about the outcome, it will not necessarily be conducive to an expansion of genetic

[815] *Bundesministerium für Familie, Senioren, Frauen und Jugend* (Federal Ministry of Families, Senior Citizens, Women and Youth) 2001.

[816] Oral communication by Ebba Kirchner-Asbrock during the non-public hearing held on 5 March 2001; *Pränataldiagnostik und Beratung* (Prenatal Diagnosis and Counselling) 1998.

diagnosis or an increased use of genetic testing. Instead, it is observed, the studies show how hard it is for suppliers to stimulate demand for genetic tests of spurious value when the offer of testing is preceded by soundly qualified education or counselling. It is especially desirable for high levels of expertise to be available for the critical assessment of existing genetic test procedures. At present, however, the requisite expertise often resides with the same qualified experts who would also be able to perform the tests.

In the view of the Study Commission, these are good reasons for establishing proper co-ordination between diagnosis, information and education, but not for embedding counselling directly within the institutional context of human genetics. A specific qualification or competence in the field of human genetic knowledge does not automatically entail a qualification or competence for psychosocial counselling, and vice versa. There are sound arguments for also offering psychosocial counselling outside the human genetics community, the requirement being competence in social education or psychology rather than in human genetics or medicine. Whatever the case, psychosocial counselling skills must be acquired in training designed specifically for this purpose.

Information and education can on principle be offered not only by physicians specialised in human genetics, but also, as long as they have received appropriate additional training, by physicians from other specialist fields. Information and education on genetic tests could equally be provided by non-physicians with proper training, e.g. human geneticists or individuals with a master's degree in Genetic Counselling (United States/UK, not available in Germany). In the UK, this service is also provided by specially trained "genetic nurses" and midwives who are also qualified in genetics.

By the same token, it would be desirable if those who performed the test – be they physicians or members of another profession – also held an appropriate (further) qualification which prepared them for psychosocial counselling. If this is not the case, those seeking advice should be given another address where they can obtain qualified counselling.

A number of projects are now underway in Germany to improve the range of psychosocial counselling services available for pregnant women in the context of prenatal genetic diagnosis. In particular, concepts are being developed to permit co-operation between different professionals (e.g. midwives, counsellors, pastoral workers, gynaecologists) so that

pregnant women obtain better information about the psychosocial counselling services available.[817]

2.3.2.4.8 Monitoring the quality of information, education and counselling

Currently, there are neither clearly defined criteria for assessing the quality of information, education and counselling nor fully fledged quality assurance models. At present, quality is above all controlled by means of further and continuous training or supervision. To a certain degree, quality control is also ensured in human genetic counselling by the duty to keep records and to provide a comprehensible written summary of each counselling session.

To implement an instrument of quality control, there have been proposals from various quarters to organise quality circles for human genetic counselling centres – similar to the round-robin tests applied in cytogenetic and molecular genetic diagnosis – and to have these quality circles participate in monitoring exercises. In this manner, the entire process of services could be reviewed in accordance with the principle of continuous quality improvement. However, the requisite quality assurance models still need to be developed. There is also support for a spot-check follow-up of the decisions taken by advice-seekers, including both medical and social components.[818]

2.3.2.4.9 Compulsory counselling versus duty to provide counselling services

There is controversial debate about whether human genetic or psychosocial counselling (unlike the duty to provide information and education) should be a binding prerequisite prior to having a genetic test (compulsory counselling) or whether the suppliers of tests should be obliged to offer counselling services without the person concerned being under any obligation to accept this offer (duty to provide counselling services).

The German Bundestag's Study Commission on "Opportunities and Risks of Genetic Engineering" recommended compulsory counselling at least for prenatal genetic tests. According to this Commission, genetic counselling should:

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[817] *Bundesministerium für Familien, Senioren, Frauen und Jugend* (Federal Ministry of Families, Senior Citizens, Women and Youth) 2001.

[818] Nippert 2001b; Wolff 2001.

> "be a binding prerequisite for prenatal diagnosis and take place a few days before the removal of cells for the purpose of a prenatal test. This should provide the parents with information and time to consider the risk posed by the cell removal to the embryo and the mother and the conflict that could potentially emerge following the collection of the genetic data."[819]

Under the Genetic Engineering Act in Austria, a physician requesting a genetic test to establish a predisposition to a hereditary disease or a gene carrier status must first of all provide detailed counselling. The Swiss draft Act on Genetic Testing also provides in Art. 12 that pre-symptomatic and prenatal tests and tests to be performed for family planning purposes must be supported before, during and after the implementation of the tests by non-directive genetic counselling.

However, one argument lodged against compulsory counselling is that experts regard the voluntary nature of counselling as crucial to ensuring its open character. Another is that any compulsory counselling would require justification because it encroaches upon the self-determination of the person concerned. Rather than a regulation that coerces individuals into counselling, these critics would prefer an obligation to be placed on the suppliers of prenatal tests, in the sense that they may not offer or perform tests without comprehensive counselling taking place previously. This could, for example, be achieved by obliging test suppliers to pay fees into a governmental fund, which could then be used to provide independent counselling services.[820]

However, the information and education would have to be binding on both parties, since the requirements of free, informed consent or refusal would otherwise not be met.

2.3.2.4.10 Need for information and education in society

Various parties believe there is a need for improved public information and education about the (limited) deliverables that genetic diagnosis can provide. A survey conducted back in 1988-1990 on behalf of the German Bundestag's Office of Technology Assessment already registered a "lack of information about methods of genome analysis and the ethical and social problems involved".[821] There is no reason to assume that the situation has improved substantially since then. Public knowledge of genetic matters remains inadequate.

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[819] *Bericht der Enquete*-Kommission "Chancen und Risiken der Gentechnologie" (Report submitted by the Study Commission on "Opportunities and Risks of Genetic Engineering") 1987, p. 153.
[820] Neuer-Miebach 1999, p. 90f.
[821] Hennen *et al.* 1996, p. 257.

This observation is borne out by empirical research into similarities and differences in the attitudes of human genetic specialists and their patients. These studies show that human geneticists usually display a greater sensitivity to the ethical and social conditions and consequences of genetic tests than do the general public. For example, patients are much more willing than human geneticists to test a child for an adult-onset disease. The same applies – with the exception of sex selection – to the use of genetic tests for purposes that are not related to a disease. Moreover, the idea of "responsible parenthood" is received more warmly by patients than by human geneticists.[822] It is worth noting, however, that the control group consisted of patients who had already opted for prenatal genetic diagnosis and thus represented a pre-selected segment of the population.

In terms of information, education and counselling, especially in the context of prenatal genetic diagnosis, this finding is significant for several reasons:

– Both a conscious decision in favour of prenatal genetic diagnosis and a conscious rejection of its use assume that those concerned are sufficiently informed and educated. Even women who turn down the test must know what they are refusing.

– Information and education about the fundamental problems of genetic diagnosis frequently arrive too late, i.e. not until a person visits a human genetic counselling service for advice. It should be noted, especially with regard to prenatal genetic tests, that pregnancy is not the best time to thrash out these issues in their entirety.

– Patients making decisions are extremely dependent on accurate information. If the test suppliers provide deficient information and education, the patient's opportunity to make an informed decision will be thwarted. While patients can identify and evaluate opinions such as "I would recommend this", they are not in a position to recognise faulty information for what it is. This results in a higher take-up rate for tests and increases the likelihood, for example, that pregnancies will be terminated following fairly trivial findings.[823]

[822] Nippert/Wolff 1999, p. 106. The word "responsible" is used here to denote an individual's responsibility for the genetic make-up of future children. This concept of "responsible parenthood" has been criticised; Haker confronts it with a different concept of "responsible parenthood", which entails unconditional acceptance by parents of their children (Haker 2001).

[823] Nippert 2001a, p. 695.

– There is a risk that, if society does not adequately discuss the issues associated with tests, assessments will be based entirely on the "image" (severity, frequency, fatefulness) of the disease for which they – rightly or wrongly – promise medical aid.[824]

That is why proper factual, non-directive information and education are a minimum requirement for a free, informed decision about whether to accept or refuse the offer of a test. However, before decisions can be free in the full (and not just formal) sense, the social discrimination and cultural stigmatisation of children who do not correspond to the norm would have to be overcome, and women would need to be freed of any pressure – however subtle or indirect – to give birth to "normal" children.

2.3.3 Genetic Testing Commission

A number of countries have established national commissions (to deal with genetic engineering or genetic testing) in order to monitor establishments that perform genetic testing, to develop binding standards for test licensing or to give advice the public agencies entrusted with these tasks.

Section 80 of Austria's Genetic Engineering Act, for example, provides for the establishment of a Genetic Engineering Commission composed of representatives from various ministries and civil associations alongside a number of experts with the relevant expertise. In pursuit of this Act, the ministry responsible will set up several scientific committees under this Commission, including a Committee for Human Geneting Testing and Gene Therapy. This committee is responsible for reviewing applications for the performance of genetic tests. In other words, the committee is also authorised to decide on the admissibility of new tests. To date, it has focused primarily on evaluating tests that are already established in medical practice.[825]

The preliminary draft of September 1998 for Swiss Federal Act on Human Genetic Testing also provides for the establishment of a commission to oversee genetic tests. The tasks of this commission, in which "the relevant scientific disciplines and practitioners shall be represented appropriately", are described as follows in Art. 33 of the draft:

> "*Art. 33 Tasks*
>
> It shall be the task of the Commission to:

[824] Hennen *et al.* 1996, p. 257.
[825] Hennen *et al.* 2001, p. 146.

a. develop standards for controlling the quality of laboratories with a view to licensing and supervision (Art. 6);

b. express an opinion on applications from the licensing authority with regard to specific applications;

c. participate in inspections of laboratories on behalf of the licensing authority;

d. submit recommendations for the execution of screening programmes (Art. 10);

e. give advice to the authority responsible, if requested, on requests for exemption from professional secrecy rules under Art. 15(3);

f. verify the reliability of genetic tests and examinations pursuant to Articles 7, 19 and 23;

g. monitor scientific and practical developments in genetic testing, submit relevant recommendations and identify gaps in legislation;

h. contribute alongside the National Ethics Commission to shedding light on ethical issues related to genetic testing;

i. give advice to the Swiss Parliament, the Federal Government and the Cantons, if requested."

The members of the Genetic Testing Commission envisaged in Switzerland are to be selected for their professional expertise in the relevant medical and scientific fields. The brunt of the Commission's work will consist in reviewing from the perspective of (natural) science. Apart from its scientific tasks, the Commission will also be entrusted with "certain tasks of policy consultancy"[826]. Unlike the National Ethics Commission in Switzerland, for example, it has been conceived exclusively as an expert panel where lay representatives have no voice, and it is not itself directly concerned with ethical issues.

> "There is, of course, no strict dividing line between the fields of 'science' and 'ethics'. If a genetic test does not supply reliable results, for example, there is also no ethical justification for performing it ('bad science is bad ethics')."[827]

Back in 1993, the Nuffield Council on Bioethics in the United Kingdom, in its report on the ethical and social aspects of genetic tests, also recommended setting up a national body to assess genetic screening programmes and monitor their implementation. In 1996, the British Government appointed two commissions to deal with the assessment of new procedures used in human genetics. The task of the Human Genetics Advisory Commission (HGAC) is to

[826] *Bundesamt für Justiz* (Federal Ministry of Justice) 1998b, p. 62.

monitor developments in the fields of medical and human genetics and to assess their social and ethical implications, i.e. primarily their impact on public health, employment, insurance and patents. This commission reports to the government health and trade departments. The terms of reference of the Advisory Committee on Genetic Testing (ACGT) are to advise ministers and to develop guidelines designed to guarantee the safe use of genetic testing.[828]

Clarification is needed with regard to medical and legal questions and the assessment of the social implications of existing and foreseeable genetic tests, as well as the concomitant issues of licensing, the doctor's proviso, evaluation, monitoring and control. The existing public bodies are not capable of performing this task.

2.3.4 Genetic Testing Act

Unlike Austria, for example, Germany does not have a specific statute that deals with the performance of molecular genetic tests on human beings. In Switzerland, a federal Act on Human Genetic Testing is in the pipeline.

Since the 1980s, the opportunities and risks associated with the use of human genetic testing have been debated in depth in Germany in numerous committees and working parties set up by the German Federal Government and state-level governments. These bodies have repeatedly emphasised that any regulation of the use of genetic testing should be geared towards creating conditions that will enable individuals to take personal, informed and autonomous decisions for or against genetic testing. No clear positive or negative recommendations have been forthcoming with regard to legislative intervention.[829]

In 1999, the *Deutsche Forschungsgesellschaft* (DFG – German Research Foundation) published an opinion on human genome research and predictive genetic testing, in which it opposed new legislation and recommended leaving the responsibility for compliance with scientific and ethical standards in the hands of the scientific community and the relevant professional associations.[830]

However, there are more and more voices in Germany now calling for the broadest possible legislation on human genetic testing. During the 14th legislative period, the parliamentary party of *Bündnis 90/Die Grünen* tabled its own "Draft Statute for Regulating Analyses of the

[827] *Bundesamt für Justiz* (Federal Ministry of Justice) 1998b, p. 62.
[828] Rohdewohld 1997, pp. 496 f.
[829] Hennen 2001, p. 140.
[830] *Deutsche Forschungsgemeinschaft* (German Research Foundation) 1999.

Human Genotype", or "Genetic Testing Act".[831] During the same legislative period, the parliamentary party of the CDU/CSU also tabled a motion calling on the German Federal Government to present a bill on the "Use of Genetic Testing in Medicine and Insurance", essentially based on the key points in the CDU/CSU motion.[832]

Three arguments in particular are cited in favour of broad legislation on genetic testing:

– Given the tremendous momentum underlying developments in the field of genetic testing and the expected future increase in the use of genetic tests, it is doubtful whether the instruments of professional self-regulation will prove adequate to prevent undesirable developments. It should be borne in mind that misguided developments and problems can already be observed within the established medical system, such as inadequate counselling and the use of dubious diagnostics like the triple marker test.

– Furthermore, it must be borne in mind that recommendations made by professional associations on the implementation of genetic counselling and testing are not binding unless they are incorporated into the medical profession's codes of ethical practice. Even then, they are only binding on those who provide counselling and genetic tests, but they do not enshrine the rights of recipients or the standards they can await.

– Finally, genetic testing can be expected in the near future to spread to numerous different fields of application. This will also include an increase in non-medical tests available outside the established medical system.

2.4 Views and recommendations

The Study Commission recommends that the German Bundestag, guided by the following recommendations, should adopt a comprehensive Genetic Testing Act that will deal with the performance of genetic tests on human beings.

The Study Commission recommends that the German Bundestag should guarantee the individual's right to informational self**-determination in the field of genetic testing by including pertinent statutory provisions in a Genetic Testing Act and by adopting other suitable measures. The right to informational self-determination includes not only the**

[831] *Entwurf eines Gesetzes zur Regelung von Analysen des menschlichen Erbgutes (Gentest-Gesetz), Fraktion Bündnis 90/Die Grünen im Deutschen* Bundestag (Draft Statute for Regulating Analyses of the Human Genotype (Genetic Testing Act), Parliamentary Group of *Bündnis 90/Die Grünen* in the German Bundestag) 2000.

right to know the results of one's own genetic tests but also the right not to know them. **Particularly high standards of protection are required with regard to the performance of genetic tests on minors and persons who are not able to consent to such tests. Genetic tests performed exclusively for the benefit of third parties on persons not able to consent, as well as genetic tests performed on minors for adult-onset disorders should be prohibited by law unless they are necessary during this stage of life in order to draw conclusions with regard to therapeutic or preventive measures.**

Commentary: As a matter of principle, the performance of a genetic test shall only be admissible if the person to be tested has given his or her free and informed consent. The fundamental objective of all pertinent rules must therefore be to safeguard the right to informational self-determination according to which it is invariably up to the individual to decide if information concerning his personal life can be disclosed and within which limits.

The Study Commission calls on the German Bundestag to make the performance of secret genetic tests (which violate an individual's personal life and privacy) a punishable **criminal offence.**

Commentary: The collection or exploitation of the results of a DNA analysis which was performed without the knowledge and consent of the person concerned should be prohibited by law and a punishable offence. A suitable place for the introduction of relevant provisions would be Chapter 15 of the German Penal Code (Sections 201 ff.).

The Study Commission calls upon the German Bundestag to adopt suitable measures such as amending the first sentence of Art. 3(3) of the German Constitution by adding the term "genetic characteristics" and introducing effective non-**discrimination rules in regular legislation in order to prevent stigmatisation or discrimination of individuals on grounds of their genetic make-up.**

Commentary: This also means in particular that individuals who, for whatever reasons, do not want to make use of genetic test methods, must be protected against being stigmatised in any shape or form.

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[832] *Antrag der Abgeordneten Katherina Reiche et al.* (Motion tabled by Katherina Reiche and other Members of Parliament) 2001

The Study Commission recommends that the German Bundestag should adopt statutory provisions that will make it unlawful for insurance companies to request, accept or use the results of predictive genetic tests.

Commentary: There is only one conceivable exception: prospective policy holders who are aware of the result of their predictive genetic test may have to disclose this test result upon request if they apply for a life insurance policy with an unusually high sum. The amount of this sum would have to be specified by law.

The Study Commission recommends that the German Bundestag should adopt statutory provisions that will oblige business enterprises to take all necessary precautions in order to prevent any genetic risks or lesions in the workplace. It should be prohibited by law for employers to request molecular genetic or cytogenetic tests or to ask for the results of genetic tests performed earlier or to make use of such tests in connection with pre-employment examinations or during the employment of individuals. In addition, the Study Commission recommends that it should be prohibited by law for employees to inform an employer about the results of a genetic test performed earlier in connection with pre-employment examinations or during their employment.

Commentary: Employees cannot be denied the right to undergo a voluntary genetic test in order to protect themselves against workplace-related risks. However, such tests should be performed by a service provider other than the occupational health service. It would be worth considering the establishment of interdisciplinary teams in human genetic counselling with the involvement of expertise in occupational medicine. Before beginning to work in a new workplace, job applicants should be informed about potential risks associated with this workplace, and it should be brought to their attention that they can have relevant molecular genetic or cytogenetic tests performed outside their new company. Such counselling should be optional; it must not be compulsory. The duty to protect the individual's health must not be *undermined by the introduction of genetic testing in occupational medicine. The Study Commission recommends that this should be clarified by introducing relevant provisions in Section 618 of the German Civil Code or in the German Industrial Safety Act (*Arbeitsschutzgesetz*) of 1996.*

The Study Commission recommends that the German Bundestag should adopt statutory provisions that will deal with genetic screening programmes. In addition, the Study Commission recommends that group programmes designed to identify heterozygous

carriers and tests designed to screen individuals for several characteristics should be prohibited by law.

Commentary: As a matter of principle, genetic screening programmes should only be admissible if voluntary participation or non-participation is guaranteed, if the programmes are justified by the considerable and clearly identifiable contribution that they make to the well-being of the tested persons by providing preventive and/or therapeutic options, if the participants have been adequately informed and instructed prior to the test, and if data privacy requirements are met. Only physicians should be allowed to initiate genetic screening programmes, and only after prior approval by the relevant data privacy protection institutions. Their implementation should be contingent on authorisation to be given by a central Genetic Testing Commission.

The Study Commission recommends to the German Bundestag that prenatal genetic tests, as well as genetic tests intended for medical purposes and genetic tests that may pose a threat for the person concerned should be subject to a statutory proviso that such tests may only be performed by physicians.

Commentary: Because of the direct threat posed by prenatal genetic tests for the unborn human being, they should generally be subject to the proviso that they may only be performed by physicians. The criteria according to which genetic tests should be subject to such a proviso should be specified in statutory provisions. Genetic tests that are subject to this proviso should only be performed by physicians who can prove that they are properly qualified and who continuously participate in specific quality assurance programmes.

The Study Commission recommends to the German Bundestag that physicians requesting a predictive or prenatal genetic test or a test to be performed for family planning purposes should be obliged by law to ensure that the conditions for a free and informed decision are met before any such test.

Commentary: Before, during and after the use of a prenatal or postnatal genetic test that is subject to the proviso that it may only be performed by a physician, the requesting physician should be obliged to provide comprehensive information to the persons to be tested. More specifically, the treating physicians should be obliged to inform the persons to be tested prior to the test about the reliability, the informative value, the error rate and the risks of the test, as well as potential consequences and options for action that may result from the test, and potential alternatives. Furthermore, the treating physicians should be obliged to offer human

genetic or psychosocial counselling prior to each test and after a problematic test result, or to provide explicit information about relevant counselling services. The affected persons' r*ight not to know must be respected. The fact that the conditions of informed consent have been fulfilled must be documented. In the case of prenatal tests, there should perhaps be a waiting period of a few days between the oral information and the performance of the test.*

The Study Commission calls upon the German Bundestag to adopt the necessary statutory provisions and provide the required funding for the establishment of a nation-wide, community-based network of easy-access, comprehensive and high-quality human genetic and psychosocial counselling services in Germany.

Commentary: It is the duty of the physician to draw the test persons' attention to the *availability of qualified human genetic and/or psychosocial counselling services. This can be done either by the physician requesting the genetic test proving that he or she has the necessary qualification to provide human genetic or psychosocial counselling, or by drawing* the test person's attention to a qualified counselling service. For the person seek*ing advice, the use of such counselling services is voluntary. In the event of a positive test result, the person concerned should also be offered psychosocial counselling after having been informed about the test result. The network of counselling services could be financed to a certain extent by levying a compulsory charge on the test manufacturers.*

The Study Commission recommends that the German Bundestag should adopt suitable measures to help remove genetic tests that do not provide any preventive or therapeutic benefits for the persons tested from the list of standard services financed by statutory health insurers.

Commentary: Non-disease-related genetic tests which do not provide any preventive or therapeutic benefit for the person tested should be removed from the list of standard services financed by statutory health insurance funds; instead, they should be paid directly by the persons concerned.

The Study Commission recommends that the German Bundestag should adopt statutory provisions that will deal with the licensing of genetic tests and the implementation of cytogenetic and molecular genetic tests. In this context, particularly stringent requirements will have to be met by the licensing of DNA chips. It will be particularly important to ensure that DNA chips may only be used to examine genetic changes that are relevant for specific conditions and their treatment. DNA chips that are capable of

identifying several disorders must meet the same requirements in terms of information, education, counselling and data privacy as individual tests - for each specific disorder.

Commentary: Without prior examination, genetic tests must not be released to the market. Above and beyond the fundamental requirements to be met by in-vitro diagnostics (safety, quality, efficiency, labelling, etc.), the testing criteria should also provide proof that the test furnishes reliable results that can be clearly interpreted, that it does not disclose more data than promised, and that it provides a clearly identifiable benefit for the test person. Such quality control should be repeated at regular intervals. When genetic tests are licensed, it is necessary to determine at the same time what "counselling intensity" is required with regard *to the test concerned. Only tests whose manufacturers or vendors pay an appropriate portion* of their revenues into a "Counselling Fund" yet to be established should be eligible for *licensing. Only laboratories that are accredited or certified for this purpose should be authorised to perform cytogenetic and molecular genetic tests.*

The Study Commission recommends that the German Bundestag should adopt separate statutory data privacy provisions that will prevent improper use of genetic data.

Commentary: Such provisions should be incorporated into the Genetic Testing Act. One of the particular aims should be to ensure that persons who – while not being physicians – perform or interpret genetic tests (e.g. counsellors or employees of diagnostic laboratories, who deal with genetic tests in a professional context) will also be included in the group of persons (listed in Section 203 of the German Penal Code) who can claim protection against seizure and a witness's privilege to decline to answer questions. In addition, these persons must also *be bound by professional secrecy. When implementing this recommendation, the German Bundestag should make use of the institutions and the experience of existing organisations for the protection of data privacy and strengthen their powers.*

The storage of genetic data on patient chip cards involves a considerable risk of abuse. Should patient chip cards be introduced despite these substantial doubts, the Study Commission recommends that the German Bundestag should adopt detailed statutory provisions concerning the type and scope of storage – especially with regard to genetic data – in order to prevent abuse.

Commentary: Individuals have a right of access to "their" medical information. Care must *therefore be taken to ensure that disease-related data – and hence also disease-related genetic data – will not be stored in a form that is not comprehensible for the patient.*

The Study Commission recommends that the German Bundestag should appoint a national Genetic Testing Commission.

Commentary: The members of the national Genetic Testing Commission should be made up of representatives of the various relevant scientific disciplines. The independence of the members as well as the interdisciplinary nature and the pluralism of the Commission's make-*up must be guaranteed. More specifically, the terms of reference of the Genetic Testing Commission should include the following tasks:*

- *Development of binding standards for the licensing of genetic tests and development of criteria for making genetic tests subject to the proviso that they may only be performed by physicians;*
- *Development of binding standards for the supply and the implementation of genetic tests, as well as relevant quality assurance measures;*
- *Development of standards for the approval of screening programmes;*
- *Development of criteria for the certification of laboratories and their quality control measures;*
- *Evaluation of the development of supply and demand and the broader implications for society;*
- *Collection and documentation of cases of genetic stigmatisation and discrimination.*

The Commission should be obliged to submit regular reports to the German Bundestag.

The Study Commission recommends that the German Bundestag should adopt suitable measures in order to promote a discourse in society about the ethical, social and cultural issues associated with the application of genetic diagnostic procedures.

Commentary: In view of the ethical, social and cultural issues associated with the development and application of genetic tests, there is a considerable need for conducting a debate and for reaching an understanding on these issues in society. To this end, it is necessary to develop and implement suitable instruments and to strengthen already existing approaches. One major objective of these discussions and the efforts made to reach an understanding should be to reject the notion of "genetic determinism" and to create awareness of the problems associated with a potential "genetification" of medicine and of the *image of human beings.*

D Discourse and Participation

1 The requirements of democracy

Developments in modern medicine are posing a number of new challenges and problems to the traditional institutions of the democratic constitutional State.

These problems are generated in particular by

– the rapid pace of advances in science and technology: highly specialised knowledge which is fully abreast of technological developments in science is often required to describe a problem and identify solutions in an informed manner. A high degree of specialist knowledge in various disciplines is essential for assessing the risks and dangers and the conceivable successes, failures and side effects of new medical developments. How stable, for example, are embryonic stem cell lines? Will they truly, once established, provide an endless source of new cells? What medical potential might adult stem cells offer? To assess these questions and others of a similar nature, politicians must rely on the advice of competent experts.

– the complexity of advances in scientific techniques: developments in modern medicine are an integral part of the complex scientific developments that are exerting an impact on many spheres of society. Their consequences can be health-related, social, economic, cultural, ethical, legal and possibly even environmental. Given the interaction between these fields of impact, which cannot always be grasped in their entirety, there may be unintended consequences and side effects that not even the experts can necessarily foresee.

– the revolutionary new character of many outcomes of medical development: many of the new developments are difficult to express using the conventional categories of our language and thinking, but they must nevertheless be articulated in words and evaluated in moral terms. This applies, for example, to human embryos in vitro. Do they have "parents" and "siblings"? Or is it better to speak of "sperm donors" and "egg donors" or "gamete originators"? What is the embryo in vitro: a "mass of cells" or a "human being"? Appropriate language needs to be developed for dealing with these new developments. At the same time, it is vital to bear in mind that terms used are almost never objective, but always charged with normative intent or linked in debate to certain connotations and significations.

– the diversity of values and ethical dissent within the population with regard to issues raised by modern medicine.[833] In a modern society, marked among other things by cultural diversity and religious tolerance, it cannot be assumed a priori that there is a consistent set of norms and values that are binding for all members. People's very understanding of the problems and conflicts will be different.[834] Will the aim be to weigh up the opportunities and risks or to create moral taboos? To shore up "economic attractiveness" arguments or to draw moral boundaries that may not be transgressed? To grant individual freedom of choice or to promote social cohesion? People also hold wide-ranging views of what it means to be human and to lead a good life. No doubt, it is possible and necessary to begin with a framework of binding norms, enshrined in legal form, to govern the way we live together. Nevertheless, how these norms are fleshed out and interpreted in specific cases will depend greatly on cultural and moral orientations. Politics cannot prescribe these orientations but must work with them. However, by promoting a democratic culture of debate, politics can help to build a viable cultural basis within the population for the principles of democratic rule of law. Indeed, those who hold political responsibility have a duty, given the ethical and legal problems raised by modern medicine, to develop new formats for the culture of debate in order, on questions of legal ethics, to reach the most viable decisions possible within the bounds of the Constitution.

The specifics of modern medicine described above mean that politicians have a greater need to consult, and this in two respects. First, there is a need to seek advice from people who have the knowledge required. This is the traditional form of political consulting, whereby experts place their knowledge at the disposal of politicians. But there is also a need to consult with one another. It seems expedient, especially in the light of possible unintended side effects, but even more given the existence of pluralistic values and dissenting ethical views, to engage in intensive processes to establish common ground. The classic institution envisaged for such processes is parliament. At the same time, however, many believe that these processes of debate and reaching a common understanding should not be confined to the established political institutions. Many citizens are calling for the right to participate in these processes, arguing that matters of concern to all must be decided by all. They maintain that it is almost beyond dispute that the social and ethical implications of modern medicine concern every citizen, and that ethical assessments should not be left to experts but are matters for citizens

[833] Cf. e.g. B. Düwell 2000; Gill 1997; Honnefelder/Rager 1994; Bayertz 1994.
[834] Cf. Braun 2000a.

themselves. As a result, the need to provide politicians with informed consultancy has been accompanied by a public need for debate in society at large.

It is the view of the Study Commission that democratic policy-making should respond to both these demands: it should seek competent advice from experts *and* build and support wherever possible processes of debate and common understanding among politicians, among citizens and also between the two.

The Study Commission believes that continuing the discussions that have taken place between parliamentarians and citizens at public hearings (e.g. on the termination of pregnancy, medical transplants or stem cell research) is fundamental to drawing on the competence of those concerned. The same will apply to an even greater degree in future to using the Internet for discourse and participation, especially with regard to young people. It is of fundamental importance to involve the collective positions of the Churches, associations and self-help groups.

In this context, a wide range of initiatives and institutions have developed in many democratic countries to cater for the dual need to consult. Numerous new institutions have sprung up since the 1980s, especially in Europe and North America, whose task is to support the articulation of informed opinion and the process of decision-making in the legal and political response to the new challenges posed by medicine. They vary considerably in their structure and composition, their remit and scope, the nature and extent of their democratic legitimacy and ultimately their ability to influence.

By and large, one can distinguish between institutions with close links to political decision-makers and those with their roots in civil society with little or no connection to decision-making bodies. Between these two poles, however, there are various hybrid forms and combinations.

National ethics councils or committees tend to have close links with the political decision-makers, i.e. in particular governments and parliaments.[835] They have been appointed by a constitutional body of the legislative or executive arm for the purpose of advising political decision-makers. A further distinction can be drawn between ad-hoc and standing committees.

Ad-hoc committees are set up for a certain period and for a more or less specific reason. Sometimes they have a clearly defined remit for the content of their work, such as preparing a

[835] An overview of this type of institution will be found in Fuchs 2001.

particular law. Well-known examples are the *National Commission for the Protection of Biomedical and Behavioral Research*, which was created in the United States in 1974 and addressed issues of research ethics. The *Committee of Inquiry into Human Fertilisation and Embryology* set up in the United Kingdom in 1982 explored problems associated with reproductive medicine. It became better known as the Warnock Committee after its chairperson Dame Mary Warnock. German examples include the *Benda Committee*, named after its chair Prof. Ernst Benda, which was established in 1984 to consider *in-vitro* fertilisation, genome analysis and gene therapy, and the Study Commission on "Opportunities and Risks of Genetic Engineering" called into being that same year by the *Bundestag*. The Study Commission on Law and Ethics in Modern Medicine is also an ad-hoc committee of this kind. Usually, the work of such ad-hoc bodies feeds directly or indirectly into major political decisions, such as ministerial recommendations on research ethics as in the case of the *National Commission for the Protection of Biomedical and Behavioral Research*. The report by the Warnock Committee was echoed in substantial sections of the Human Fertilisation and Embryology Act of 1990.

Standing national ethics committees and councils constitute a different subset. The first body of this type was the *Comité Consultatif National d´Ethique pour les Sciences de la Vie et la Santé*, which was created in France in 1983. It was followed by committees in Sweden, Denmark, Luxembourg, Italy, Norway, Portugal, the United Kingdom, Belgium, Switzerland and a number of countries outside Europe.

Table 22: A Chronology of the Origins of National Ethics Councils outside Germany

Year	Country	Committee	Institutional status
1983	France	Comité Consultatif National d'Éthique pour les Sciences de la Vie et de la Santé	Presidential initiative; enshrined in law since 1994; all major constitutional bodies have power to appoint; attached to the national research institute INSERM
1985	Sweden	Statens Medicins-Etiska Råd (SMER)	Parliamentary initiative; parliament has some power to appoint
1987	Denmark	Etiske Råd	Initiative taken by parliament and government; power to appoint lies with parliament and the health ministry; attached to the health ministry
1988	Luxembourg	Commission Consultative Nationale d'Éthique pour les Sciences de la Vie et de la Santé	Government initiative
1990	Italy	Comitato Nazionale per la Bioetica	Original initiative by parliament; head of government has power to appoint; attached to head of government
1990	Norway	Den nasjonale forskningsetiske komité for medisin	Initiated by and attached to research minister
1990	Portugal	Conselho National de Ética para as Ciências da Vida	Established by law; power to appoint rests with head of government, some ministers, local government and major associations; attached to the head of government
1991	UK	Nuffield Council on Bioethics	Initiative of private foundations
1992	Australia	National Health and Medical Research Council	Established by law; power to appoint rests with health departments at Commonwealth, State and Territory level, also with other local government units and a committee representing Aborigines

1995	Belgium	Comité consultatif de Bioéthique	Established by law; the King and governments have only partial powers to appoint
1995	Canada	National Council on Ethics in Human Research	Joint initiative by the medical profession, health ministry and research councils
1995	USA	National Bioethics Advisory Commission	Initiative and appointment of members by the President
1996	India	Central Ethical Committee of the Indian Council of Medical Research	Initiative and appointment of members by the Council of Medical Research
1998	Switzerland	Eidgenössische Ethikkommission für die Gentechnik im ausserhumanen Bereich (EKAH)	Established by the *Bundesrat* (parliament); administratively attached to the Agency for the Environment, Forests and Landscape
2001	Switzerland	Nationale Ethikkommission im Bereich der Humanmedizin (NEK-CNE)	Established by the *Bundesrat* (parliament); administratively attached to the health department

Source: Fuchs 2001

Table 23: Ethics Committees and Councils Functioning at National Level in Germany[836]

Year	Committee	Institutional status
1994	Zentrale Ethikkommission bei der Bundesärztekammer (ZEKO) (Central Ethics Committee at the German Medical Association)	Established on 18 March 1994 by the German Medical Association; members are nominated following proposals by public and scientific institutions
1995/ 1999	Ethik-Beirat beim Bundesministerium für Gesundheit (Ethics Council of the German Federal Ministry of Health)	Set up in 1995; re-instated by a new decree and members nominated by the Federal Minister of Health on 15 November 1999
2000	Enquete-Kommission des Deutschen Bundestages „Recht und Ethik der modernen Medizin“ (German Bundestag’s Study Commission on “Law and Ethics in Modern Medicine”)	Established by parliamentary decision on 24 March 2000; the members are nominated by agreement with the parliamentary parties and appointed by the Federal President
2001	Nationaler Ethikrat (National Ethics Council)	Established by a government decision on 2 May 2001; the members are nominated by the Federal Chancellor

Standing national ethics councils and committees differ from their ad-hoc counterparts not only because they have broad terms of reference and can therefore address a wider spectrum of issues, but also because they often have a freer hand in defining their thematic agenda compared with the clearly defined brief of the ad-hoc bodies. In some cases, they can be called upon not only by the constitutional bodies, but also by private individuals or establishments. They are usually attached to high-ranking organs of the constitution, such as the President, the head of government or a national ministry, although in exceptional cases, they may be attached to a national research institute (France) or constituted as a private foundation (United Kingdom). Sometimes the initiative and appointment of members rests with parliament (Sweden), the government or specific ministers or ministries (Luxembourg,

[836] Status as at 31 December 2001.

Norway), but in most cases these are the joint affair of the head of government, parliament and/or other constitutional bodies (France, Denmark, Italy). There are a few countries where local government or public associations may participate in appointments (Portugal, Australia, Canada). In many instances standing ethics councils and committees have been established by law. The National Ethics Council in Germany is the only national ethics body apart from the National Bioethics Advisory Commission in the United States for whom powers of initiative and appointment rest exclusively with the head of government. This is all the more striking in that similar advisory bodies serving the German government are usually constituted as councils of experts and not afforded the status of a weighty adjective like "national".

Many countries attach importance to pluralism in the composition of their standing committees and councils. Denmark applies a gender quota, Belgium has quotas for its regions and language communities, and France stipulates that various precisely defined religious denominations and philosophical views must be represented. A pluralistic composition is universally regarded as necessary and desirable.

There is another type of institution: those with their roots in civil society and at most an informal link with political decision-makers.[837] These above all take the form of consensus or citizens' conferences, citizens' dialogues and citizens' juries.[838] Biomedical issues have been the subject of such conferences and events in Denmark, the Netherlands and Switzerland.

Table 24: Practical Examples of Dialogues with Citizens on Biomedical Issues, by Country

Denmark	Consensus conferences: **Mapping the Human Genome (1989); Transgenic Animals (1992); Infertility Treatments (1993); Gene Therapy (1995)**
Netherlands	Consensus conferences: **Transgenic Animals (1993); Human Genetic Research (1995)**; Parallel citizens' panel: **Cloning (1998)**
Switzerland	National dialogue: **Dialogue on Genetic Diagnosis (1998);** Consensus conference: "PubliForum" on Transplantation Medicine (2000)
UK	Citizens' juries: **Health service planning (1996)**
Germany	Consensus conference: Citizens' Conference on the Dispute about Genetic **Analysis (2001)**
USA	Citizens' jury: **Organ transplants (1986); Reform of the Health System (1993)**

[837] Cf. Fuchs 2001 and Gill/Dreyer 2001.
[838] Cf. Gill/Dreyer 2001, pp. 11 ff.; Koch/Zahle 2000; Fischer 2000; Ammon 1998; Grundahl *et al.* 1996; Joss/Durant 1995.

The Citizens' Conference on the Dispute about Genetic Analysis held in Dresden in 2001 was a German example of this model.[839] Citizens' or consensus conferences can also be initiated, organised or funded by public or government bodies. But they differ from national advisory committees in that there is no explicit remit here to advise politicians. Of course, these consensus conferences and citizens' dialogues may also address their message to political decision-makers, but the general public are at least as important a target. Another difference is that citizens' or consensus conferences explicitly set out to involve lay citizens. Their purpose is less to provide political decision-makers with knowledge, although that certainly may be a desirable side effect, than to offer members of the public a chance to discuss a problem area in depth. In this way, they help citizens to broaden their competence and articulate opinions.

It is debatable whether these models of discourse founded on civic participation actually influence concrete policy-making processes. One example which is cited as a successful event in this respect is the Danish consensus conference on *Mapping the Human Genome* (1989). It triggered a vehement parliamentary debate in Denmark and ultimately contributed to the present legal ban in Denmark on companies requiring their employees or job applicants to supply a genetic health profile.[840] Nevertheless, surveying the overall spectrum of consensus and citizens' conferences and public dialogues suggests that their direct impact on political decisions can be estimated as fairly low.[841] Their democratic effect should be seen primarily in furthering processes of public discussion and awareness.

The third type which can be distinguished are those models which do not seek the participation of unprejudiced citizens but discourse to thrash out conflicts over scientific and technological policy between groups already recognised as party to these conflicts. The participants in this case are "stakeholders", i.e. players who are at odds with other groups due to their own, often specific interests and objectives. The aim is to achieve an agreement between the parties based on the most rational possible discourse. A number of procedures and models of this type have been tried in the field of participatory technology impact assessments. They include mediation procedures, planning cells and future workshops.[842] However, this approach has not yet been applied to medical questions, but has focused primarily on conflicts in the field of genetic engineering for agriculture.[843]

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[839] www.buergerkonferenz.de (19 Feb 2002).
[840] Andersen/Jaeger 1999, quoted from Gill/Dreyer 2001, p. 35.
[841] Gill/Dreyer 2001.
[842] Saretzki 1997.
[843] Cf. van den Daele *et al.* 1996; Evangelische Akademie Loccum 1996.

There are varying assessments of how institutions that provide political consultancy can be expected to contribute to the questions and problems posed by modern medicine. Some commentators hope to see greater rationality and assistance in structuring the bioethical debate[844], while others look forward to civil society evolving new antennas for sensitive issues[845]. Apart from this, there is a belief that a forward-looking review of future developments in science and technology will help in formulating timely recommendations.[846] However, reservations and fears are also expressed. Frequent references are made to the danger of a new expertocracy taking shape.[847] There are worries that expert panels could develop into a kind of informal "parallel parliament". Concern is occasionally voiced that public debate will be undermined by delegating moral issues to expert authority or that ethical discourse could be functionalised by lobbyists.[848] An even more far-reaching fear is that people's moral sensitivity might be submerged under a moral *philosophy* perspective imbued with science.[849]

Given the diversity of the institutions described and the lack of transparency with regard to the experience gained with them, it is difficult to identify direct lessons to be learnt for political life in Germany. It would be rather more helpful to begin with some fundamental conceptual considerations about the purposes which might be pursued by conceivable institutions of political consulting and the democratic expectations which might be levelled at them.

The Study Commission proposes that essentially a distinction should be made between three conceivable objectives:

a) the provision of knowledge and specialist competence for decision-makers to enable them to make better informed decisions (expert model),

b) the provision of an institutional framework for articulating conflicts between groups or interests with the aim of reaching an agreement (stakeholder model),

c) the provision of an institutional framework for citizens to develop their opinions together with the aim of formulating common ideas of the public good and/or a good life (republican model).

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[844] Catenhusen 1997, pp. 2f.
[845] Kettner 2000, p. 7.
[846] Lenoir 1997, p. 11.
[847] Kettner 2000, pp. 7f.
[848] Düwell 2000, p. 105.
[849] Kymlicka 2000.

Within this basic triangulation, various hybrids and combinations could be imagined. However, for the sake of clarity we shall begin by considering them separately. In terms of democracy, they all have specific strengths and weaknesses. It is considered desirable to draw on the strengths wherever possible and to contain the weaknesses by means of appropriate precautionary or counter-balancing measures.

a) The expert model

The strength of this model is that it is the one best suited to exploiting the resources of knowledge and competence. It serves to analyse a complex set of problems from an interdisciplinary perspective, to identify the various technical particularities which should be taken into account and to facilitate decisions on this basis. Knowledge of this kind is especially indispensable in a field which is characterised both by rapid developments in science and technology and by complex interactions between the factors. Another advantage of the expert model is that, at least in formal respects, it distinguishes clearly between the advisers and the democratically legitimated decision-makers. The decision-making remains with government and parliament, the constitutional bodies specifically legitimated for this purpose. Decisions will therefore – at least formally – enjoy clear democratic legitimacy.

One of the problems with the expert model is that this distinction is not as clear *de facto* as it is *de jure*. It is possible for an informal expertocracy to emerge in which the legitimate democratic bodies become dependent in their decisions on experts who do not possess this democratic legitimacy. This would be especially problematic because it must be assumed that experts are not simply neutral, objective observers, but that they may also have their own group interests. One must, therefore, reckon with a risk that the vested interests of specific groups of experts will be asserted in the guise of apparently universal, neutral recommendations. Finally, one weakness of the model is that it excludes civic participation. This in turn harbours a danger that the decisions taken will ignore the needs or convictions of ordinary citizens and as a result lack the basis for long-term viability.

However, various precautionary measures can be adopted to combat these risks. One important factor is the clear segregation between consulting and decision-making competence. This depends primarily on the democratically legitimated decision-makers. In forming their opinion, they should not rely purely on the experts, but must subject the latters' recommendations to independent critical review.

Another decisive counter-measure is transparency. Although the experts are chosen by the democratically legitimated constitutional bodies, i.e. a government or parliament, it is nonetheless desirable for the general public to exercise a certain check and balance – in other words, to be able to assess critically whether the composition has perhaps been influenced by particular interests. It should be stated in the press or on the Internet who selected whom. The selection bodies should give reasons for the choice of every member chosen. The members, for their part, should disclose any positions and functions they hold which might possibly be conducive to bias, prejudice or the compromising of the panel's work, such as stakes or shares in companies, positions on corporate supervisory boards, registered patents or other circumstances of this kind. Only by obtaining transparency in this manner would the public be able to review the authority of these experts critically and to draw attention to potential conflicts of interest.

Moreover, it should be a requirement of political consulting by experts that if there are matters of dissent, these should be published and that minorities should also be given an opportunity to state their case. This measure similarly furthers transparency and critical public review.

To reduce the risk of experts functionalising their position to assert vested group interests, attention should be paid to avoiding an excessively homogeneous composition. One important condition for achieving this is multidisciplinarity; in other words, the experts should come from different academic disciplines, such as philosophy, the natural and technological sciences, the social sciences, law, medicine, nursing science, psychology, theology, history, etc. Expert status need not be substantiated exclusively by academic performance, but may also be founded on relevant professional or other practical experience. The experts should, however, be distinguished on account of their own personal knowledge- and/or experience-based competence; expert status should not derive from mere affiliation to specific social groups, institutions or organisations.

Deliberately involving different perspectives on a problematic issue can help to prevent the committee being functionalised by the politics of vested interest.

The broader the remit of a body of this kind, the more discerning the requirements will be in terms of its democratic legitimacy. To the extent that it is entrusted with tasks beyond advising a specific constitutional organ, such as the government – for example, with initiating and organising public debate or representing Germany's position in the international arena –

constitutional reservations could also arise[850] about confining the right of initiative to the government and the appointment of members to the head of government. Indeed, from a democratic standpoint the most directly legitimated constitutional body – parliament – should be required to select the members. In the event of evident conflicts of interest parliament should also have the option to recall individual members.

To compensate for the lack of civic participation, the expert model should be combined with formats based on the republican model.

b) The stakeholder model

One democratic strength of the stakeholder model is that, compared with the expert model, it permits broader participation by citizens and penetrates the institutions of civil society more deeply. In the field of medicine, for example, the following stakeholders are conceivable: physicians, specific groups of patients, nurses, people with disabilities and their families, researchers, members of the counselling professions, representatives of health insurance providers and the insurance sector, the pharmaceutical industry, churches, etc. As the members concerned are representing the interests and needs of a particular social group, they must be legitimated by that group. This in turn enables other members of the group to participate indirectly in formulating a position. In this way a decision could possibly be founded on a broader social basis than in the case of the purely expert model.

However, the stakeholder model also displays serious weaknesses. The gravest problem with regard to medical law and ethics is that ethics and morality are not negotiable. Moral evaluations simply cannot be made the object of interacting interests without losing their specifically moral character. The hallmark of interacting interests is that the balance of forces is measured and taken as a basis for negotiating advantages and disadvantages for the players concerned. A negotiating party can, for example, obtain compensation for certain disadvantages and, in this way or another, compromises can be reached. This means that the objects of negotiation are to some extent tradable; disadvantage A can be exchanged for advantage B. Moral questions, on the other hand, are fundamentally different from questions of interest. Moral controversies mostly address beliefs and intuitions deeply associated with the identity and self-defined role of those concerned. That is why certain norms, values and ideas about living a good life cannot simply be exchanged or traded off against one another like advantages and disadvantages. At most the players can present their own motives and

[850] Reservations of this nature were expressed by M. Schröder 2001.

standpoints in the hope of *convincing* the others present. It would deny the very concept of a moral issue to decide it according to the balance of forces. This is presumably why the stakeholder model has not yet been used to address ethical questions and problems in the medical field.

Another weakness is that it is easier for well organised, influential and well equipped interest groups to present and assert their concerns than for groups who are socially quite weak. This can lead to strong groups being further strengthened by the stakeholder model and groups who are already weak and who have the greatest need for democratic participation becoming if anything weaker.

To some extent these risks can be contained by appropriate counter-measures. It would be necessary, for example, to provide particular support for social groups who, while they might be particularly affected by certain developments in medicine, are comparatively without influence and have relatively poor resources. Their weaker social status would have to be compensated by the provision of additional resources (e.g. opportunities to publish, funding for their own conferences and internal meetings to formulate opinions etc.).

Here, too, there is an urgent need for transparency. The public must be able to recognise which group has been selected by whom to participate and why, and also which groups have perhaps not been chosen and why. It would also be necessary to disclose what advantages each particular group could derive from participation, as in the case of the expert model.

Even so, the stakeholder model should only be used in matters which do not concern questions of basic ethics. As a consequence its scope of application is limited when it comes to the law and ethics of modern medicine. It would be helpful to encourage ad-hoc debates between stakeholders on specific, precisely defined questions. It would not, however, do justice to the nature of ethical problems if a standing ethical advisory body were to consist of stakeholder representatives.

c) The republican model

The prime strength of the republican model lies in the fact that citizens participate. This assumes that political participation is in itself a value. In addition to this, there are other major reasons for favouring the republican model. It can contribute to developing greater civic competence with regard to the ethical and legal problems posed by modern medicine. This, too, can be regarded as a value in itself. The republican model can also help to encourage

citizens to test new points-of-view, or to venture a shift in perspective, by offering them an opportunity to explore the arguments and standpoints of others. In the ideal case this can lead to what Hannah Arendt, drawing on Kant, called an "enlarged way of thinking". The republican model thereby acquires an educational dimension. And finally, it can help to foster a culture of debate founded on a search for shared ground, in which empathy and considerations of the common good are able to evolve.

However, the republican model also has its weaknesses. There are, for example, major implementation problems. It will not be feasible to provide every citizen with enough expertise, time and attention on every ethical aspect of medicine. The republican model is, therefore, inevitably based on a selection of participants. There is a risk of creating expectations of its representative character that cannot truly be met. Here again the problem arises that an informal "parallel parliament" might emerge which does not genuinely enjoy democratic legitimacy. The relationship between this model and formats for direct criticism (such as the citizens' poll, plebiscite or referendum) has been discussed with a view to how these can play an important role in strengthening public debate.

Processes of discussion and consultation within the republican model are, moreover, extremely "path dependent"; in other words, whoever decides on the selection of participants, the selection of experts and not least the agenda will substantially influence the outcome. Even if the initiators attempt to maintain the lowest possible profile, there are structural conditions which can result in a certain imbalance among the participants. After all, political participation takes time. Experience shows that the self-employed, people with a demanding job, working women with small children and people caring for elderly or sick relatives, to mention just a few groups, have extremely little time at their disposal. They will presumably be less able to participate in models of this kind than other social groups.

Another danger inherent in participatory models lies in the informal relations of power, which it is often difficult for those involved to recognise as such or to influence. In this model verbal skills of expression are a decisive resource. Those who are better able to express themselves will presumably be listened to more. However, verbal skills of expression are unequally distributed. Members of the middle and upper classes can usually express themselves better than members of the lower stratum; men are often bolder than women in a communication scenario; immigrants frequently have a poorer command of German than people whose families have lived in Germany for several generations.

If these dangers are recognised, they are easier to counter. Above all no expectations should be raised that this is a parallel or even substitute parliament. It must always remain clear that any form of republican discourse has the status of an interim finding, is never fully representative and can never aim to bring the debate to a conclusion. Republican discourse is always an incomplete process; it cannot produce a legitimate, definitive decision. Clarity about this will also alleviate the problem of certain social groups enjoying a structural advantage, especially by dint of unequal access to the resource which is free time. After all, if no claim is made that the forum is representative or that its decision is final, a certain structurally induced imbalance can cause no devastating damage.

The risk posed by informal power relations can only be contained if the participants are aware of it. However, this awareness may itself be the result of a learning process initiated by the republican discourse.

From this we see that the republican model can by no means be a substitute for democratically legitimated parliamentary decisions. But republican debate can provide a democratic complement to the expert model, thereby helping to compensate effectively for its democratic weaknesses.

2 Recommendations

The Study Commission recommends that the German *Bundestag* should advocate that:

– the democratic public debate about the ethical, legal and social questions posed by modern medicine should be promoted;

– public discussion formats based on the active participation of citizens should be particularly promoted and supported;

– a legal basis that is comprehensible for all citizens should be created for both standing and ad-hoc bodies created at national and federal state level to provide political consultancy on the ethical, legal and social questions posed by modern medicine;

– this legal foundation be informed by a carefully considered concept of the tasks and purposes of these bodies, so as to prevent them from being based on contradictory or unclear objectives;

– this legal basis contain in particular a duty to create transparency with regard to the working methods, structure and composition of these bodies;

– these bodies be given the statutory means to publish their work at any time;

– they be given the statutory means and the mandate to involve the public in an appropriate format and in particular through dialogue;

– the format for public participation also give a voice and hearing to less influential groups and those with fewer resources;

– these bodies be multidisciplinary and balanced in their composition and that the dominance of a particular gender, professional group, academic discipline or world view be avoided;

– Parliament be involved in appointing national bodies for political consultation whenever their mandate goes beyond advising government organs and includes, for example, representing Germany in international organisations or promoting public debate;

– these bodies be attached to Parliament or to the Federal President;

– all bodies whose task is to provide political consultancy, and also any models and institutions, public dialogues or citizens' conferences promoted by the constitutional organs, publicise their work in an appropriate manner;

– in so doing they substantiate their findings in a comprehensible manner, reflect upon counter-arguments and, should the need arise, disclose dissenting opinions;

– questions which fundamentally affect every citizen may not be decided either formally or informally by bodies that do not possess the constitutional legitimacy to take such decisions.

E Desiderata

The Study Commission was not able to deal in detail or definitively with all the themes on its agenda, notably the issue of organ transplants and social perceptions of health, sickness and disability. The prime reason for this was the inadequate time available during this legislative term. Moreover, it is already evident that developments in biotechnology and medicine observed over the last two years will provoke a need for further ethical clarification and legal regulation in the near future. A number of the problems that could no longer be addressed are described below, some as desiderata and some in the Annex as contributions by individual Commission members. Others could no longer be accommodated.

1 Regulatory fields

1.1 Allocation of resources

1.1.1 Outline of the issues

The distribution of resources within the health system is one of the central ethical questions of modern medicine and current health policy. Resources are taken to include both human or scientific resources and structural or economic resources. Cost considerations are exerting a growing influence on medical provision, and medical freedom of action is increasingly subjected to restrictive measures, with disturbing consequences for the relationship between doctors and patients.

Although developments in modern medicine do not automatically lead to increased costs in all fields, the allocation issue is nevertheless an inevitable side effect of innovation-driven, high-performance medicine. The issue is so acute because the health sector has been hit by declining revenues due to social and economic trends.[851] The combination of these two factors has resulted in strong pressure for the existing system of health service allocations to change.

There is a particular need for action in the nursing sector. Given that demographic change will prompt a substantial future increase in the need for nursing services, structures must urgently be developed to further needs-responsive, patient-oriented allocation.

Personal prevention will play a greater role in the future.[852] We can also assume that developments in predictive diagnosis will enhance the significance of personal prevention.

[851] Cf. Kühn 2001.

One question this raises is how resources should be distributed between classical "reactive" medicine and a more prevention-oriented approach. Another is how the potential for determining increasingly personalised disease and morbidity risks will affect the health service as a whole, given that the present compensation mechanism for structural risks is founded on estimates of morbidity risks for specific groups.

1.1.2 Views of humanity and health

The value of "health" as a social good is often considered to be that it is an indispensable precondition for achieving other purposes or obtaining other social goods (*Konditionalgut*).[853] However, this idea is an over-simplification because health is then seen one-sidedly as a means to an end rather than a good in its own right, pursued for its own sake as an important component of living a good life.

It is patently clear that "health" as a social good is of immediate existential significance, which many other social goods are not. That is why the question of fair distribution is more pressing in the case of health services than in the case of most other services or goods.

Quite a few of the rationing models currently being debated seek to resolve the problem of fair distribution on the basis of cost/benefit calculations. These models are a problem if factors such as quality of life or the number of years people are likely to continue living are taken into account when determining the "benefit" a service provides and weighing this against its financial cost. Allocating health services on this basis would be contingent on criteria such as age or personal well-being, and so there is a danger that it would undermine the prohibition of discrimination derived from the guarantee of human dignity which is enshrined in Section 1(1) of the German Constitution.

When resources are in short supply, allocation implies some degree of prioritisation. The setting of priorities must be founded on value decisions about whether certain phenomena should be regarded as illnesses at all and, if so, where they rank on a scale of gravity. In ethical and legal terms, priority setting can only be guided by value judgements of this kind. Naturally this always calls for a specific understanding of health and illness.

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[852] *Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen* (Advisory Board of Experts for Concerted Action in the Health Sector) 2001.

[853] For example Eibach 1999.

There is an important task to be achieved, therefore, by drawing on the fruits of debate about our understanding of health and illness to resolve issues about allocation. These reflections should also feed into the definition of health objectives.

1.1.3 Technology impact assessment / Technology assessment

It is broadly undisputed in debate that a reasoned approach to the issue of resource allocation should be guided by the principle of rationalisation rather than rationing. But to lay the basis for decisions about rationalisation measures we need instruments which permit a plausible evaluation of the efficacy of medical technologies.[854]

In the health system the introduction and evaluation of new technologies and procedures are currently still triggered by the assertion of particular interests. The legislator has begun to counter this by setting up a "Co-ordination" and "Hospital Committee" to complement the Committee of Physicians and Health Insurers responsible for non-hospital care and by commissioning the German Institute of Medical Documentation and Information (DIMDI) to create an information system around a database to evaluate the efficiency or efficacy and the costs of medical procedures and technologies and to award research contracts for the evaluation of medical procedures and technologies. In so doing, the legislator is also institutionalising Health Technology Assessment (HTA), one of the objectives envisaged in Book V of the Social Code.

To respond to the challenges of health care provision and to be able to appraise the consequences of medical procedures, a comprehensive technology impact assessment must also be performed. This needs to go further than the demonstration of efficiency usually provided by Health Technology Assessment and focus greater attention on the ethical, legal, social and – beyond the health service itself – overall economic impacts.

Systematic analysis of the health benefits of individual technologies or procedures is an attempt to respond rationally to the health system's constantly growing demand for resources. The aim is to identify ineffective or inefficient technologies and procedures and to document their inappropriateness for statutory health insurance schemes.

However, like evidence-based medicine the Health Technology Assessment relies on knowledge about the application, deployment and outcome of the technology or procedure at stake, which is why an evaluation can only be undertaken after the considerable delay of

[854] Feuerstein/Kuhlmann 1998, above all the paper by Höfling 1998.

several years following introduction. One essential, hitherto unanswered question relates, therefore, to the validity of the tools and yardsticks used in the Health Technology Assessment as a basis for judgements.

Moreover, the Health Technology Assessment usually only considers the short-term impact (or non-impact) of a technology or procedure. Like the ethical and legal dimensions, consequences that take effect after generations are usually excluded. Nor is it customary to adopt an overall economic perspective. With new technologies it is particularly easy to overlook or underestimate their development potential, and so Health Technology Assessment can prove a defective and even problematic procedure with regard to technological development. At the same time, a purely efficiency-oriented view ignores the ethical and also social dimensions of new technologies. Limiting the assessment of new technologies to their efficiency – mostly conceived in economic terms – can, therefore, lead to a mechanical feasibility focus that fails to take social values into account.

Virtually no assessment is undertaken of the impact of the technology on future generations. However, the implications of modern medicine have consequences for many generations, and not only in the narrower sense of reproductive medicine, but also by prolonging life, causing shifts in reproductive years, altering requirements in terms of workers' health and changing public perceptions of health, illness and disability, to mention but a few aspects. An analysis of the effects of medical action should not, therefore, be confined to assessing medical efficiency. The reverse side of the coin is also true: social changes need increasingly to be investigated in the light of their impact on health.

1.1.4 Health system structures

Apart from our methods for evaluating the efficacy of the technologies we use, there is another aspect to the allocation issue, and that is the structure of the health system, especially the role of competition within the statutory system of health insurance.

New demands on the health system (changing demographic patterns, new disease spectrums) but also the changing range of medical services (technological and scientific progress) call for continuous adjustments. Present developments, however, seem to be driven by economic models or wishful thinking rather than health objectives.

To ensure that provision is fair and efficient, structures are needed that reflect these objectives. If solidarity and subsidiarity are to remain fundamental principles of the health

system, the need will continue for autonomous health structures independent of market mechanisms. Developments over the last ten years, with an emphasis on introducing elements of competition into the health system, have caused upheaval among statutory health insurance schemes, especially with statutory funds competing for healthy policy holders. Efforts to compensate for imbalanced risk structures are merely the tip of an iceberg which flags up a permanent crisis in the statutory health insurance sector.

Competition between the providers, combined with procedural issues such as "peaceful elections"[855], has led to the ongoing alienation of fund members. The idea of self-administration founded on parity between stakeholders has very much taken a back seat. Policy holders do not feel they are represented on the supervisory bodies of their providers. The health funds talk increasingly of "customers" rather than "members".

To counter this trend a new departure in health policy is seeking to shift competition from the funds to the service providers. This aims to dissolve corporatist structures of self-administration and replace them with selective contractual arrangements between health insurance funds and health service providers. The declared objective is integrated care structures.[856] However, there has been some debate about the danger that the adverse effects of competing for money, like risk selection and a huge rise in the funds' marketing spend, might also emerge among health service providers, resulting in similarly grave upheavals.

Consequently, competing for money is increasingly seen as an inappropriate instrument for the health system. Calls are being heard, instead, for competition around quality. But any form of competition will require changes to existing institutions and organisational formats. The key question here will be whether the subsidiarity principle, and with it the system of self-administration, should be preserved or whether market structures should take effect in future.

The issue of adjusting the health system to the challenges of modern medicine also, therefore, raises questions about the organisation and structure of the health system itself.

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[855] The law governing public welfare allows that, when elections are held for the welfare bodies, "organisations with rights of proposal and individuals with voting rights who wish to put forward their own proposals for election agree on a list of proposals or, if they submit several proposed lists, nevertheless all agree that they will not nominate more candidates than the number of members that the insurance provider's statutes require to be elected to the committee. If this is done, all the proposed candidates are deemed elected without further ado (Section 46(3), Book IV, Social Code). This scenario is known as 'peaceful election'." (Plate 1998)

[856] This is the wording in Book V of the Social Code.

1.1.5 A summary of the issues

The literature distinguishes between three, sometimes four, tiers of responsibility for allocation[857]:

– the upper macro-level where decisions are taken about the overall resources to be allocated to the health system,

– the lower macro-level, where decisions are made about distributing these resources to the various segments – prevention, therapy, training, etc. – of the health system,

– the meso-level, where decisions are taken about how to distribute resources among specific indications or patient groups, and

– the micro-level, where allocation decisions are made about particular patients.

For every tier apart from the "upper macro-level", a question ultimately arises about the yardsticks used to define health objectives and determine targets and also about who has the power to formulate these definitions.

The German health system displays a particular deficit at "lower macro-level" in that, unlike in France, for example, there is no committee to establish what objectives the health system is actually pursuing as a whole. Responsibilities are divided between the federal authorities, the federal states and the self-administrating bodies in the health system itself. The Federal Committee of Physicians and Health Funds (*Bundesausschuss Ärzte und Krankenkassen*), a self-administrating body set up by physicians and health funds to undertake allocations on the basis of legal provisions, is not bound by objectives formulated by the legislator. As there are no target values, a standardised evaluation of health service performance is impossible.

An important task, therefore, would be to clarify how health objectives can be defined and implemented in a transparent, democratic and universally accepted manner. This definition of general health goals with an appropriate format for evaluation which makes it possible to ascertain whether they are being achieved would take effect at the meso- and micro-levels. Citizens would then find the decisions taken here easier to decipher and more transparent.

[857] Relevant differentiation models are found in, for example, Engelhardt 1988, p. 35.

Moreover, specific provisions could be derived from universally binding objectives and substantiated; this would overcome the "theory deficit" in the current system.[858]

However, this would also incur a need to think about the structures required at the meso- and micro-levels to facilitate meaningful, fair and efficient allocation. As outlined in the previous chapter, this also entails the question as to how competition might be structured in the health system.

1.2 Research involving persons not able to consent

In recent years research involving persons not able to consent has become the focus of often heated controversies. These began in the mid-nineties around the relevant passages of the Council of Europe Convention on Human Rights and Biomedicine.[859] These controversies are ultimately one reason why Germany has not yet signed the Convention. A draft for an additional protocol was submitted in summer 2001.

The Study Commission can merely describe the current status of the debate and the need for political action.

1.2.1 Conditions for the admissibility of medical research

According to prevailing legal opinion, any intervention for the purposes of research, and the burdens and risks associated with it, may only take place if the patient or test subject grants informed consent. Informed consent is taken to mean the voluntary consent of the patient or test subject after receiving detailed information about the nature of the experiment, its duration, its objectives, its risks and the option to withdraw during the experiment.

Moreover, the risks incurred by the research must be proportionate to the objective of the research, which shall not infringe fundamental constitutional values.

Medical experiments are rated as constitutionally unobjectionable after informed consent has been given by a patient or subject capable of granting it and following a positive risk/benefit analysis.

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[858] *Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen* (Advisory Board of Experts for Concerted Action in the Health Sector) 2001.

[859] Council of Europe 1997.

There are unresolved questions relating to the presentation of information and the risk/benefit analysis. One matter of particular dispute is the admissibility of medical research involving persons who are unable to grant consent or who have only a limited capacity to do so.

1.2.2 Unresolved questions about the presentation of information

As regards the presentation of information, the following points repeatedly generate major problems in practice and should be examined with a view to framework legal provisions:

– How much detail should be presented about risks and burdens?

– Must the information simply be provided, or must the person providing the information make sure that it has been understood?

– To what extent must new knowledge of risks and burdens be passed on quickly to subjects during and after the experiment?

– How precisely can and must the subjects of blind and double blind studies be aware of the research design?

– How is the conveying of information to be recorded?

– What does the subject's informed consent cover? To what extent may findings or body samples obtained in the course of a research project be passed on for other research purposes?

1.2.3 Unresolved questions about the risk/benefit analysis

The specification and evaluation of risks and benefits must be undertaken by ethics committees established for this purpose in compliance with current professional rules for physicians. In practice, considerable differences can be observed in the working methods of these ethics committees.

One demand that is being debated is that the work of ethics committees should be placed on a statutory footing. The following fields require examination with a view to framework legal provisions:

– approval criteria for ethics committees;

– standardisation of the documents to be submitted by the researcher for the evaluation of the research project, in particular evidence that the research is necessary and that it cannot be substituted by other investigations;

– modalities for the appointment, composition, terms of reference and working methods of ethics committees;

– clarification of how far the ethics committee's opinion has binding status.

1.2.4 Admissibility of medical research involving persons unable to consent

1.2.4.1 Definition of terms

In the debate about the admissibility of medical research, especially with regard to persons who are not or no longer capable of consent and to the validity of informed consent by third parties, there has been general acknowledgement of the distinction between *clinical research* and *non-therapeutic clinical research* introduced by the World Medical Association's Helsinki Declaration of 1964.[860]

In fact, the literature often applies further differentiations, dividing *clinical research* into therapeutic research and clinical research and *non-therapeutic clinical research* into research which can serve specific target groups and non-specific research pursued in order to expand knowledge.[861]

Therapeutic research implies the application of a non-established procedure that offers the person concerned the direct prospect of a cure, an improvement or some other benefit without measures simultaneously being undertaken to obtain insights of general validity. Clinical research implies that measures are undertaken to obtain insights of general validity and that

[860] In the new version of the Helsinki Declaration adopted in Edinburgh in October 2000, this distinction between clinical research and non-therapeutic research was dropped. This move was substantiated in the debate by the argument that the terms "clinical" or "therapeutic" research as opposed to "non-clinical" or "non-therapeutic" research were not as clear as was claimed, either in test protocols or in their real significance to patients. For example, patients participating in a "clinical" experiment might be assigned (at random) to a control group and therefore not experience the direct effects of a new treatment. At the same time, the results of non-clinical or non-therapeutic tests might very well lead to a direct improvement in their treatment. Moreover, research increasingly draws on data of patients or (in future) virtual patients simulated from the data of real patients. Accordingly it is rarely possible to distinguish a "clinical" experiment clearly from a "non-clinical" experiment, and usually the same test protocol will include features of both clinical and non-clinical research. Non-therapeutic research involving persons not able to consent is to be allowed if the legal guardian has consented and the research has been proven necessary. The declaration makes no provision for limiting research to a "minimal risk" or "minimal burden". By contrast, personal therapeutic or clinical therapeutic research is dependent without exception on the personal consent of the patient. According to Taupitz, persons unable to consent are therefore excluded from clinical research in contradiction of the legal situation which has hitherto prevailed in Germany and widespread international practice (Taupitz 2001).

[861] Cf. Freund/Heubel 1997.

the prospect of a cure or improvement for the test subject cannot by and large be realised until the experiment has been evaluated, so that the benefit for the person concerned is only indirect.

In the field of *non-therapeutic clinical research* a distinction is often drawn between studies intended to bring benefits for persons belonging to the same diagnostic group or age group as the test subjects (group benefits) and studies whose usefulness does not relate to any particular group of patients, as is the case with, for example, pure knowledge-seeking and basic research.[862]

1.2.4.2 Therapeutic and clinical research involving persons unable to consent

Reservations about permitting medical research with persons who are unable or no longer able to consent derive from the fact that the law prohibits their instrumentalisation. An argument cited in favour of permitting such research is the duty to ensure the welfare of the group concerned: it is maintained that new or better treatment for this group can often only be developed if those concerned participate in trials.

In this context, there are varying assessments of the validity of consent by the legal guardian or custodian, and the evaluation usually depends on the direct or indirect benefits to the test subject in question of the medical research.

There is no dispute about the admissibility of carrying out therapeutic research, including the requisite diagnosis, on persons unable to consent if consent has been granted by the legal guardian or custodian. As the objective of the experiment is to cure the subject or to improve his or her condition, meaning that it is undertaken for his or her immediate benefit, it is assumed that the prohibition of instrumentalisation is not thereby violated and that the test subject is not being degraded to the mere status of a tool of research.

Following this, the consent of the parent or custodian is regarded as decisive in the case of therapeutic research involving persons below the age of consent, while in the case of persons without the capacity to consent the consent of the person legally responsible for his or her care is decisive. The crucial consideration here is whether the therapeutic research is to be performed predominantly in the personal interest of the subject concerned, and in every

[862] Vollmann 2000. Vollmann distinguishes between research which has potential benefits for future patients with the same disease or of the same age and non-clinical medical research (basic research) which does not relate to the disease of the test subject.

instance the approval or rejection actually expressed by the patient unable to consent, whether minor or adult, is to be taken into account.

This situation is to be distinguished from the question of whether personal consent may be substituted in the case of clinical research which, unlike therapeutic research, entails measures for the systematic evaluation and acquisition of new insights which lend themselves to generalisation, including measures permitting comparison with existing established procedures, which are only of indirect benefit to the test subjects insofar as they offer the prospect that these insights can be applied at a later date.

There are varying assessments of the extent to which simple approval by parents, guardians or legal custodians is adequate. Although weight is again given to consideration of whether the subject's participation in the research predominantly serves his or her personal interest, there is disagreement about the extent to which a disadvantage that might be incurred for the participant as a result of the research design may be legitimated by the consent of a third party. This could be the case if the design of the trial means denying the subject an established procedure so that its usefulness can be tested against that of a new procedure.[863]

1.2.4.3 Non-therapeutic research involving persons not able to consent

There is controversial debate about the extent to which consent to medical research which will not have any direct or indirect benefits for the subject himself or herself must be given by the subject in person or whether it can under certain conditions by substituted by the consent of a third party.

1.2.4.4 The Council of Europe's Convention on Human Rights and Biomedicine of 1997

Article 17.2 of the Council of Europe's Convention on Human Rights and Biomedicine provides that research involving persons unable to consent which does not have the potential to produce results of direct benefit to the health of the person concerned may be authorised if

– research of comparable effectiveness cannot be carried out on individuals capable of giving consent,

[863] Freund/Heubel (1997) propose that persons unable to consent or with a limited capacity for consent should only be permitted to join the control group of a comparative clinical study if there are overwhelming prospects of the new procedure providing benefits; in any case of doubt persons unable to consent or with a limited capacity to consent should, in a comparative clinical trial, at least receive the established treatment and thereby be allocated to the control group. However, if persons not participating in the study may not be denied the new procedure, this would result in an unequal treatment of persons not capable of consent.

– the research entails only "minimal risk" and "minimal burden" for the individual concerned,

– the research is expected to confer major benefit to persons in the same age category or afflicted with the same disease or disorder or having the same condition,

– the person concerned does not object, and

– his or her legal representative has consented.

1.2.4.4.1 Controversy about the admissibility of non-therapeutic research involving persons unable to consent

The arguments essentially cited in favour of admissibility are as follows:

– Research interventions involving persons unable to consent are ethically justified if people suffering from the same condition or belonging to the same age group only stand a chance of obtaining a cure or improvement if research is carried out on persons from this subset, resulting in an undeniably great need for this research which cannot otherwise be met.[864]

– A research measure incurring "minimal risk" or "minimal burden" to which the legal custodian has agreed does not in essence violate the person unable to consent and is thus compatible with his or her human dignity.[865]

– It is legally admissible for the legal custodian to weigh the needs of future patients against the right of the subject to protection if this is done within a framework of comprehensive legal representation in matters of health which authorises the custodian to be influenced in his or her decision by aspects of the common good.[866]

– Furthermore, some argue that persons unable to consent have a "social duty"[867] to make themselves available for non-therapeutic research or, indeed, that there should be an "everyman's duty"[868] to participate in medical research that would apply in equal measure to persons capable and incapable of consent.

There is also some agreement with approaches described for some time now in the literature on medical law whereby the admissibility of non-therapeutic research involving persons

[864] Cf. *inter alia* Helmchen/Lauter 1995.
[865] *Bundesministerium der Justiz* (German Federal Ministry of Justice) 1998, p. 18.
[866] Elzer 1998.
[867] Wolfslast, quoted in Spranger 2001.
[868] Picker 2000; also Wunder 2001c.

unable to consent should be determined by balancing the condition, the ability to consent, the risk/benefit analysis and the patient's right to protection.[869]

This is endorsed, for example, by the Central Ethics Committee (*Zentrale Ethik-Kommission*) of the German Medical Association, who combined this opinion with a proposal for case-by-case assessment of the inability to consent linked to a procedure for approval by an ethics committee.[870]

The arguments essentially cited against admissibility are as follows:

– Research interventions involving persons unable to consent who do not stand to derive direct or indirect benefits from the research would violate the prohibition on instrumentalisation and degrade the subject to the status of a tool of research; they would thereby violate Art. 1(1) of the German Constitution. A great need for this research would not be grounds for justification.[871] It would be constitutionally unacceptable to adopt a special provision for persons unable to consent which limited their personal rights. There are good reasons for making experiments on human beings and non-therapeutic research contingent upon personal consent freely given.

– The terms "minimal risk" and "minimal burden" are highly open to interpretation and could be used to legitimate a range of interventions; moreover, they are affected by subjective experience. In particular, measures commonly regarded as posing a low burden might be regarded by those concerned, given that they frequently perceive situations intuitively, as highly burdensome and fear-provoking, and in this respect they could certainly touch the core of their personal rights and human dignity.[872]

– The law of custodianship rules out accepting the consent of the legal custodian as a substitute, as his or her decision must always be taken for the personal welfare of the person placed in his or her care and not in the interest of the common good.[873]

– An expression of rejection by the person concerned does not provide adequate security that non-therapeutic research will not be carried out against his or her will, given that persons with limited or no capacity for consent often communicate in ways that outsiders

[869] Eser 1978; Helmchen *et al.* 1989.
[870] *Zentrale Ethik-Kommission bei der Bundesärztekammer* (Central Ethics Committee of the German Federal Medical Association) 1997.
[871] *Inter alia* Spranger 2001; on the scope of possible exceptions cf. Höfling/Demel 1999.
[872] Wunder 2000b.
[873] Cf. *inter alia* Jürgens 1998.

find hard to understand and that they have their own pace of response and frequently cannot be expected to display a reaction in the immediate situation.

There is a discussion about whether to use prior consent as an instrument in the case of progressive diseases, assuming that the subject's right to protection is upheld but bearing in mind the necessity for research. There is critical debate about whether the legal custodian should be able to grant consent, if body substances had to be obtained or diagnostic procedures applied in the course of treatment, for these also to be used or evaluated for non-therapeutic purposes.[874]

The Draft Additional Protocol on Biomedical Research of 18 July 2001 to the Convention on Human Rights and Biomedicine updates the terms under which non-therapeutic research may be conducted on persons unable to consent, subject to the conditions described above, if the legal custodian grants consent. In response to criticism, however, the Additional Protocol provides for a graduated scale of participation by the subject concerned, to the extent that he or she is able, which would depend on the degree of his or her capacity for consent and on an independent review of the subjective burden that he or she might experience. However, practical reservations are expressed with regard to how the legal custodian might ascertain any resistance which emerged in the course of research.

1.2.5 Pharmaceutical law

The German Medicines Act (*Arzneimittelgesetz*, AMG) is often cited in debate as evidence showing that German law, at least in the field of medical drug trials, permits non-therapeutic research involving minors beyond the limits of "minimal risk" and "minimal burden" stipulated in the Convention on Human Rights and Biomedicine. However, this is not borne out by the wording of the provision concerned.

The Act states that minors may participate in clinical trials upon the consent of the parent or guardian, assuming an appropriate balance of benefit and risk, if the product is designed to detect or prevent disease and if the application is suitable for detecting disease in the minor concerned and protecting him or her from disease (Section 40(4) 1–4 AMG). It is a matter of dispute, however, whether this formulation rules out a minor participating as a test subject in a

[874] Schröder/Taupitz 1991; Dörner 2001b.

drug trial if he or she can derive no benefit beyond a preventive measure, as in the case of a vaccine trial.[875]

With reference to the admissibility of clinical drugs trials involving patients, Section 41 of the German Medicines Act emphasises the importance of successfully treating the test subject.

The principles governing legal proxy by parents or custodians only appear to prevent the participation of minors or persons unable to consent in exclusively non-therapeutic research. Other avenues – justified by a wide variety of reasons – are often used in practice. There is a considerable grey area.

In the light of pressing practical problems, a number of authors are calling for legal clarifications to reflect the fact that the advance of knowledge in paediatrics calls for clinical studies which do not offer benefits to the minors directly involved.

Stringent provisions are proposed with regard to

– prior determination of risk and minimisation of risk,

– a graduated approach to letting minors exercise their own capacity for decision,

– a procedural hierarchy whereby older minors are involved before younger minors insofar as the focus of research allows,

– the control to be exercised by ethics committees,

– evidence that the scientific questions addressed by the specific research can indeed only be investigated within the group concerned.[876]

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use does not make drug trials involving persons unable to consent contingent on these persons deriving benefit from them, but admits them as long as risk and burden are minimised and the following protective rules are observed:

– consent is granted by the legal representative with consideration given to the presumed will of the minor or person unable to consent;

[875] Cf. *inter alia* Taupitz/Fröhlich 1997; Walter-Sack/Haeferli 2001.
[876] Cf. *inter alia* Koch/Klug 1998.

– participation may be revoked at any time;

– no incentives or financial inducements are given;

– evidence must be provided of the necessity for the research and the unavoidable need to conduct research with the group concerned.

The Directive is without prejudice to any measures undertaken in member states to offer higher standards of protection to trial subjects (Art. 3(1)). It remains to be seen how much political pressure will develop to bring the German Medicines Act into alignment.

1.2.6 Conclusions

Given this background and in the light of the fact that the debate about signing the Council of Europe Convention on Human Rights and Biomedicine has not yet come to an end, and in view furthermore of the lack of clarity surrounding the application of the provisions of the German Medicines Act to minors, there is an urgent need for the German Bundestag to take a close look at the issue of research involving persons unable to consent. There may be an additional need for debate and action in response to Directive 2001/20/EC of the European Parliament on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

In accordance with the problems outlined above, particular attention should be paid to the following thematic areas which should, where appropriate, be subjected to statutory regulation:

– the presentation of information conveyed with regard to informed consent;

– definition of the terms “not able to consent” and “able to consent”;

– the concept of risk/benefit analysis and the limits to its application;

– framework rules for ethics committees;

– the admissibility of non-therapeutic research involving persons not able to consent;

– the admissibility of non-therapeutic clinical drugs trials based on clarification of the German Medicines Act.

1.3 Terminal care and euthanasia

The issue of terminal care and euthanasia is the source of constant debate in modern health practice. Since the middle of the 20th century, questions to do with dying and death have been radically affected by medical progress. This applies to:

– the moment of death, which – because of the opportunities for resuscitation and the artificial prolongation of life – is subordinate to medical actions and hence decisions that incur accountability,

– the place of death, which has predominantly become the hospital, as a site of professional life-saving techniques, or the nursing home,

– and the circumstances of death, which threaten to be increasingly governed by a lack of personal control due to the overwhelming power of medicine and by social isolation.

The debate has been exacerbated by the increasing potential for intensive medicine combined with the decline of paternalistic concepts in medical ethics and a greater emphasis on patient self-determination. Developments in the Netherlands have led to another wave of discussion about "mercy killing" or active euthanasia. This in turn has led to warnings prompted by historical experience that the idea of people with extremely serious conditions being helped to die at their own request is akin to the killing by third parties of people with disabilities or other human beings regarded as "unworthy" of life. This is overlaid by debates about shortfalls in nursing provision and the problem of isolation faced in homes by people in need of care and also by the issue of restricting treatment for people with extreme care needs or incurable conditions, notably patients in coma.

One can also discern a growing conflict between, on the one hand, increasing expectations of a humane death, of terminal care in an intimate environment and of understanding for the process of dying and, on the other, the demands of transplantation medicine, with the explantation of more organs than in the past and the medical measures required to preserve vital functions artificially.

The Study Commission was not able to address the multitude of psychological, social, ethical, medical, legal and political questions raised by terminal care and euthanasia in an adequate manner. For this reason, only a brief summary of the essential thematic issues and the need for action is given below.

1.3.1 Issues related to terminal care

Creating a worthy environment for the dying and being guided more effectively by their wishes and needs can be regarded as an acknowledged objective of society. However, reality is at odds with the prevalent desire to die in one's familiar domestic setting, not to be left alone and not to be obliged to suffer pain.[877] Most people today die in hospitals and nursing homes[878], and in spite of so many recognisable efforts these are barely able to meet those needs. Although progress has been achieved in recent years, the number of hospices and the provision of pain therapy must still be considered inadequate.[879]

As a consequence, most people have understandable fears, such as

– the fear of pain and of a painful death,

– the fear of not receiving dignified treatment,

– the fear of being left alone, and

– the fear that they will no longer escape the grip of medicine.

Most commentators see a connection between, on the one hand, a practice which is too unresponsive to the wishes of dying people and the fears which most people consequently harbour and, on the other, the high level of support observed for several decades for the legalisation of active euthanasia.[880]

The following sections discuss major contributions to improving the situation of dying people and combating the desire for active euthanasia in the long term, but apart from all the administrative, statutory and structural measures many are also calling for a change in

[877] Cf. *inter alia* Hausmann 2001.

[878] Cf. Bickel 1998, who suggests that 70 per cent of people in Germany die in hospitals, homes and similar institutions. See also Brockmann 1999.

[879] According to a list compiled by the national coalition group *BAG Hospiz* in 2001, services are offered in Germany by 927 non-residential and 96 residential hospices, 75 residential palliative facilities and 23 non-residential providers of palliative care. According to the German Hospice Foundation, this amounts to 8 hospice beds per million inhabitants against an estimated need for 20-30 hospice beds per million, and 7 palliative beds per million inhabitants against an estimated need for 30 palliative beds per million.

[880] Approval for active euthanasia does vary considerably, however, depending on the type of survey and the environment in which it is carried out. The Federal Health report of 2001 quotes, for example, a FORSA poll conducted in 2000 on behalf of the German Society for a Humane Death, which established 81 per cent in favour, whereas a survey by EMNID on behalf of the German Hospice Foundation that same year showed only 35.4 per cent in support (Statistisches Bundesamt/Robert-Koch-Institut 2001).

attitudes and values among sections of modern medicine and in its technical, science-driven perspective.[881]

1.3.1.1 Improved terminal care in hospitals and homes

Structural improvements have been discussed, including initial and continuous training for staff, a greater integration of terminal care into nursing provision and a reflection of this in the composition of personnel and, more controversially, greater use of voluntary hospice services. Improved financial coverage is demanded to provide terminal care in hospitals, including daily budgets for the severely sick and dying and more appropriate funding for palliative medicine.

1.3.1.2 The expansion of palliative medicine

The measures under discussion range from improving the palliative component in the initial and continuous training of physicians and nurses and creating chairs in palliative medicine to opening more palliative wards and outpatient centres and placing these on a better financial footing, something that neither the care insurance scheme nor the health insurance scheme have achieved to a sufficient degree.

1.3.1.3 Improved outpatient care

Under discussion are financial improvements to ensure more home care with greater flexibility during the final stage of life.[882]

1.3.1.4 Improved collaboration between services

The proposal is that hospitals, homes for the sick and elderly, but also social service facilities, doctors in private practice and voluntary hospices should always be able to draw on the support and skills of palliative nursing providers and palliative medical consultants.

1.3.1.5 Additional assistance for families and volunteers

The ideas being discussed here include options under labour law to take leave from work in order to provide support for dying family members[883], regardless of whether they are being cared for as inpatients or outpatients, funding for self-help groups of "family carers" and modalities for coaching, mentoring and training volunteers.

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[881] Cf. Student 1989; Hahn/Thom 1983.

[882] US provisions could provide a model. They recognise a heightened need for nursing and care when patients are in the terminal phase. Cf. also Busse *et al.* 1997.

[883] A model here might be the French Act no. 99-477 of 9 June 1999 on Provision for the Right to Services of Palliative Medicine.

1.3.1.6 Continued expansion of hospice work

The statutory provisions on financing residential and non-residential hospice work have laid important foundations. There is, nevertheless, a danger that the hitherto voluntary funding schemes implemented by federal states and local authorities are being phased out in many places. However, the diversity of hospice initiatives can only be maintained if these voluntary state and local authority schemes are preserved.

1.3.2 Issues related to euthanasia

1.3.2.1 Legal situation and ethical assessment

In Germany, professional codes which govern the exercise of medicine and jurisprudence by the supreme courts[884] permit the non-provision or interruption of life-supporting measures for the dying (passive euthanasia) and the use of palliative measures, even if these induce a more rapid death (indirect euthanasia). By contrast, there is statutory regulation on "mercy killing" (direct euthanasia), which is prohibited under Section 216 of the Criminal Code. There are no statutory provisions devoted to medically assisted suicide. There is a potential demarcation problem with direct euthanasia as a criminal offence and the failure to grant assistance under Section 323c of the German Criminal Code.[885]

Much of the debate returns again and again to the issue of statutory regulation for passively and indirect euthanasia and a reformulation of Section 216 of the German Criminal Code with the aim of legally permitting direct euthanasia in Germany.[886]

The argument against statutory regulation of passively and indirect euthanasia is that, in the judgement of the medical community, the professional code and responsibility that have hitherto applied have essentially stood the test and permitted a responsive adjustment to the practical environment, although there are recurring reports from the field that decisions to restrict treatment are taken without consulting sufficiently with the patients or the family.

Fundamental objections are raised to amending Section 216 of the German Criminal Code. These point out that there are historical reasons and a constitutional basis for the protection of life, that the introduction of active euthanasia would pervert the physician's duty to heal the sick, that legal insecurity would inevitably result with regard to indirect or assumed expressions of the request to die, and that there are implicit risks that the phenomenon might

[884] Kutzer 2001, pp. 77 ff.
[885] Eser/Koch 1991; Vollmann 2000.

spread or be abused with various consequences in practice.[887] There is a fear that one-sided emphasis of the patient's autonomy might lead to physicians neglecting their duty to provide care.[888] In the light of historical experience, there are also concerns that permitting active euthanasia might lead to a pressure of expectation being exerted on the sick, the disabled or the elderly and to a revival of the debate about who is and who is not "worthy of life".[889]

Major social groupings oppose reversing the prohibition on direct euthanasia.[890] There are nevertheless a number of questions on issues which fall short of active euthanasia such as the manner in which life-supporting measures are interrupted or not provided, especially with regard to terminally ill patients who are not dying or the interruption of treatment for patients who cannot or who can no longer express their views. Particular importance is attached here to the professional codes of the medical community.

1.3.2.2 Principles adopted by the German Medical Association

Against a backdrop of increasing discussion among the medical community, the German Medical Association published new Principles for Medical Terminal Care in 1998.[891] They were designed to address changes in jurisprudence and medical technology since the directives issued in 1993 and in response to a growing number of questions from the medical community itself about limiting treatment for severely ill patients who were nevertheless not dying.

These principles are unambiguous in rejecting direct euthanasia, but they also stress that in certain situations life-supporting measures are no longer appropriate for patients who are dying or whose prognosis is unfavourable, in spite of the physician's duty to preserve life. Rather than interrupting treatment, the objective of therapy should be amended in such cases in the direction of palliative care. This includes the non-provision or non-continuation of life-supporting measures for newborn infants with extremely severe disabilities (known to some as "early euthanasia") following consultation with the parents.

The Principles accord any patient, regardless of his or her current state, a basic level of provision that encompasses humane accommodation, attention, body care, the alleviation of

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[886] Cf. *inter alia* Baumann, J. *et al.* 1986 and numerous publications by the Germany Society for a Humane Death (*Deutsche Gesellschaft für Humanes Sterben*, DGHS).
[887] Wunder 2000a; Kutzer 2001, pp. 77 ff. with additional evidence.
[888] Dörner 1993; 2001.
[889] Süssmuth 1994.
[890] There is agreement on this between major social groupings, including the two major Christian church organisations, the German Council of the Disabled, the hospice coalition (*Bundesarbeitsgemeinschaft Hospiz,*), the German Hospice Foundation, the German Medical Association and many others.

pain, respiratory difficulties or nausea, and the satisfaction of hunger and thirst. They stress the patient's right to self-determination. The shift from life-sustaining to palliative medicine should be decided by the will of the patient. However, if the patient is no longer able to express approval, the crucial factor should be his or her assumed will, and in this case any living will that has been issued by the patient is considered fundamentally helpful.

There have been critical comments on the Principles due to the fact that they include severely ill people who are not dying and have recourse to the assumed will of this group.[892] In the particular instance of newborn infants with severe disabilities, who cannot formulate their will, the legal notion of "assumed will" cannot apply.

It is argued that the interruption of life-supporting measures for patients for whom the prognosis is unfavourable or patients with life-threatening impairments should not be equated with the interruption of such measures when patients are dying. Not prolonging the agony of a dying person, it is suggested, should be distinguished legally and ethically from shortening the survival of a severely sick person. It is risky to base such decisions on prognoses for this group of patients, as assessments usually vary considerably in practice. The argument concludes that this applies in particular to newborn infants with extremely severe deformities or severe metabolic disorders.[893]

Criticism is also levelled at resorting to assumed will when denying or interrupting life-supporting measures to patients who are not dying, such as comatose patients, and at the suggestion that the legal custodian of a person not able to consent should be asked "prior to the dying phase" to supply an order from the court of guardianship consenting to the termination of life-supporting measures.[894] The critics maintain that, by extrapolating in this manner from a judgment by the Federal Supreme Court in 1994[895] that specifically described the case in hand as borderline and spoke of the "exceptional admissibility of allowing the patient to die" and also from a controversial ruling by the Higher Regional Court of Frankfurt in 1998[896], the Principles are seeking to establish a general rule for an entire group of people.

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[891] *Grundsätze zur ärztlichen Sterbebegleitung*, Bundesärztekammer 1998d.
[892] Wunder 2000a, p. 264
[893] Cf. Zimmermann *et al.* 1997.
[894] Cf. Kutzer 2002.
[895] BGH, judgment of 13 September 1994, BGH St 40, pp. 257-272. This was the "Kempten case", where the Supreme Court ruled that it was legitimate to terminate artificial feeding for a comatose patient on the basis that this was her assumed will.
[896] OLG Frankfurt, ruling of 15 July 1998, NJW 1998, pp. 2747-2749, the "Frankfurt case", when the Regional Court declared the interruption of special feeding for an "irreversibly comatose" – and therefore not dying – patient to be admissible by virtue of a proxy decision endorsed by the court of guardianship. However,

An overall danger is perceived that including terminally ill patients who are not dying and extending the use of assumed will to this group will blur the dividing line between passively and active euthanasia, even though this is not the intention of the Principles. An evaluation of practice by hospitals and outpatient facilities since the adoption of the Principles could clarify the situation and permit a possible revision and fine-tuning of the text.

1.3.2.3 Living wills

It is undisputed that the patient's will is authoritative for the physician providing treatment. In this context, there is some discussion as to whether greater weight should be attributed to living wills as a means of establishing the patient's will with regard to the non-provision or interruption of life-supporting measures.[897] Whether living wills always represent the patient's current will is questionable. There are, besides, considerable differences in the format, management and scope of the non-treatment thus authorised and the concomitant indications. There are also differences between a disposition, which can be regarded as the non-synchronous personal will of the person concerned, and a precautionary proxy or authorisation of guardianship empowering one or more persons to take decisions in accordance with the wishes and values of the person concerned in a situation where he or she is no longer capable of giving consent.[898]

Objections are raised about living wills on the grounds that they often overtax those concerned, that one cannot verify the circumstances under which they were drawn up, that they further undermine the doctor/patient relationship by subjecting it to further legal influence and that they encourage people to harm their own interests because of anticipated cost-calculating obligations.[899]

Given that the assessment of living wills is controversial, they have so far not been seen as strictly binding on the physician. The German Medical Association's Suggestions for Physicians Regarding the Use of Living Wills[900] stipulates that treating physicians should examine any such wills to establish whether the will as expressed in the document corresponds to the current will of the patient. There is still much unresolved terrain, however, when it comes implementing this point through the professional codes of the medical

subsequent rulings dispute the competence of the court of guardianship in this field, e.g. LG Munich I, ruling of 18 February 1999, NJW 1999, pp. 1788-1789.

[897] Cf. *inter alia* Klie/Student 2001; Luther 1999; Vollmann/Knöchler-Schiffer 1998.

[898] In an EMNID poll in 1999, 88 per cent of the respondents favoured the idea of formulating one's will in advance, but in practice only 8 per cent had actually drawn up such a document. Cf. Statistisches Bundesamt/Robert Koch Institut 2001.

[899] Dörner *et al.* 2002.

associations at federal state level.[901] There is also a lack of definitive instructions for recording how the patient's will was considered when reaching decisions about the non-provision or interruption of life-supporting measures. Being guided by the patient's will makes it imperative to take the patient's will into account. If there are grounds for doubting that it is currently binding, recourse must be had to the assumed will of the patient, and in establishing this an important role is played by discussion with the family.

1.3.2.4 The Council of Europe's Report

In the context of international debate and the threatening proliferation of euthanasia, some clearly critical points were raised by the Council of Europe's report on the protection of the human rights and dignity of the terminally ill and the dying in 1999.[902] It emphasises individual self-determination, but it also calls upon member countries to ensure the individual's fundamental right to protection from being killed. The right to self-determination and a dignified death does not, states the report, embrace a right to be killed. Member countries are also advised to ensure the promotion of palliative care, in particular its anchorage in medical training and the training of any other relevant vocational groups.

1.3.3 Conclusions/Recommendations

The Study Commission believes it is necessary for the German Bundestag to examine the issue of terminal care and euthanasia in detail.

In keeping with the problems outlined here, particular attention should be paid to the following thematic areas:

– structural measures to improve the situation of the dying in hospitals and homes;

– measures to expand palliative care;

– improvements to outpatient provision during the final phase of life;

– improvements to the collaboration between residential and non-residential services;

– improvements in family and volunteer assistance;

– the further expansion of hospice work;

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[900] Handreichungen für Ärzte zum Umgang mit Patientenverfügungen, Bundesärztekammer 1999.
[901] In 1998, the Medical Association of Berlin became the first and so far only state-level association to declare in its Rules that living wills are binding under certain conditions when a patient is approaching death.
[902] Council of Europe 1999.

– clarification of custody law to ensure that any decisions by a court of guardianship on limitation of treatment be strictly confined to dying persons and only granted where there is a relationship of trust between the guardian and the ward and where the will of the ward has been unmistakably expressed.

The Study Commission sees no need for statutory regulation of the non-provision or interruption of life-supporting measures or for an amendment to the law with regard to medically assisted suicide or direct euthanasia.

A need is recognised, however, for greater critical parliamentary and public discussion. In this context support is also expressed for the call to set up a Study Commission of the German Bundestag to examine conditions in residential homes.

A parliamentary and public debate could further the process of updating professional codes on medical terminal care and on euthanasia. This process should concern both the definition of specific standards of consent for the limitation of treatment afforded to terminally sick patients who are not dying and the development of quality standards for involving the patient and/or the patient's will in all decisions taken at the end of life.

Measures should above all be supported which evaluate clinical practice relating to terminal care and euthanasia and thereby lay the foundations for updating the Principles and their implementation in professional codes.

1.4 Transplantation medicine

The Transplantation Act (*Transplantationsgesetz*, TPG) entered into force on 1 December 1997 after and long and controversial debate in the political community and in society at large. The purpose of the Transplantation Act was to regulate the essential legal aspects of transplantation medicine: time of death, consent to the removal of organs, the acquisition and distribution of organs and the use of living donors.

Transplantation medicine is a widely used, highly advanced medical technology which is simultaneously caught up in the rapid development of both the basic science and the clinical applications. Its statutory regulation in the form of the Transplantation Act merits particular attention because conclusions can be drawn from how well it has stood the test or, indeed, been able to adapt to ongoing medical developments for future statutory regulation in

comparable areas of biomedical technology given the persistence of diverging social views on fundamental ethical issues.

That is why a detailed examination would have to focus on asking how successful this statutory regulation has been in the light of medical and social developments and whether it has had any unintended effects. Particular attention should be given to the growing use of live donors. In assessing the potential problems that could be entailed by introducing other new, high-end medical technologies, questions relating to the scarcity of resources, and hence also the fair distribution of resources, the transparency of distribution and the search for medical alternatives appear just as important as questions relating to public information and education and how society should deal with divergent ethical standpoints such as those which have emerged in the case of transplantation medicine around the issues of brain death and consent.

Any such examination should reflect the fact that, even if divergent views persist, the Transplantation Act has created legal security and a viable framework for the practice of organ transplants. In this respect experience in the field of transplantation medicine and the Transplantation Act can be seen as a determining factor in fields of modern medicine requiring future regulation where divergences of many kinds exist in society but where the legislator can create legal security for the practical environment by virtue of a law which provides balance and is pragmatic, while at the same time leaving individuals scope to act in accordance with their own personal values.

From this point of view, the regulation of transplantation medicine deserves particular attention, as it enables the legislator to review the impact of law against a background of ethical divergence with the aid of a concrete example.

2 An over-arching issue

2.1 The doctor/patient relationship[903]

The relationship between doctor and patient plays a key role in the development of modern medicine and modern medical ethics. It reflects both changes in the way patients and physicians see their own role and the changing opportunities for medical treatment. It subjects the actions of physicians to binding ethical objectives and, in addition, creates the protected space that medical treatment needs in order to take effect. For these reasons, the relationship

between doctor and patient is closely linked to the physician's duty to maintain confidentiality and also his or her right of therapeutic choice.

Medical progress, demographic change and the emphasis attached to self-determination are all affecting traditional patterns underlying the relationship between doctors and patients and the way that the doctor and patient respond to each other.

The success of medical treatment depends largely on the trust that exists between the patient and the person providing the therapy. This is usually a physician or psychotherapist and – in many cases to a proportional degree – it will also apply to nursing staff and other therapists. In most cases the patient is involved in a relationship with a therapeutic team. The following observations can, therefore, be extended in many respects to other health and medical professionals.

One common hallmark of the relationship between doctor and patient is a pronounced information and competence gap. The patient is dependent on the knowledge and skills of the physician and usually has only limited scope for verifying the correctness and quality of the physician's decisions. Moreover, a patient's ability to take decisions is especially limited if he or she is seriously ill, as pain or an impaired consciousness makes decisions difficult or impossible.

The position is similar for children, the mentally ill and patients with dementia, who frequently have only limited capacity, if any, to make decisions about their treatment.

The physician's right to choose the therapy, like his or her duty of confidentiality, can be interpreted as derivative rights of the patient. They serve to grant the patient and his or her treatment a protected sphere area in the relationship with the physician where the patient may be sure that the physician will not betray his or her problems and will select the most suitable therapeutic format to meet his or her needs. In practice the decision about treatment is not taken by the doctor alone, but is usually a shared or joint decision.

For various reasons, however, the degree of patient participation has altered:

– Compared with a generation ago, considerably more importance is attached these days to self-determination. "Benevolent paternalism" has made way for patient autonomy, which

[903] Cf. on the following theme e.g.: Dörner 2001a; Francke/Hart 1999; Luban-Plozza *et al.* 1998; von Reibnitz *et al.* 2001. Cf. in addition contributions to the public dialogues held on this issue by the Study Commission in Bielefeld-Bethel and Jena: Geisler 2000; Kloiber 2001; Luther 2001a; Tanner 2001; Wunder 2000c; 2001a.

implies that patients alone have the right to make decisions. Although this is not objectively what happens, as it is still the physician who decides what treatment to undertake, simply requiring the patient's approval, patient participation is at least seen to be subjectively important by a majority of patients today.

– Higher levels and the broader reach of education have permitted deeper insights into therapeutic necessities and procedures.

– While the widespread dissemination and availability of medical information enables patients themselves to be better informed, it can place the relationship between doctor and patient under strain if the information obtained has been wrong, wrongly conveyed or wrongly understood.

Now that medical specialisation has led to a variety of disciplines, medical action has become subject to a division of labour that places the relationship between patients and doctors on a broader basis, making it harder for patients to obtain their bearings.

At the same time there has been a change in how physicians perceive their own role, at least along the margins of medical activity. In public perception, the general practitioner exercising a liberal profession has increasingly given way to the service provider fulfilling the customer's wishes in return for a fee. This also concerns the increasing medicalisation of the general lives we lead. This trend is being reinforced by a displacement or extension of the spectrum of medical activity towards the treatment of emotional disorders, cosmetic problems and lifestyle expectations. This expanded spectrum also encompasses major aspects of reproductive medicine and medically assisted enhancements in athletic performance, which are barely, if at all, compatible with the physician's traditional mission to prevent, cure and alleviate suffering.

Furthermore, a legitimate interest in legal security has gone hand in hand with greater legal regulation of the relationship between patient and doctor. This has placed a strain on the relationship and can induce other adverse effects such as the emergence of defensive medicine.

Parallel to this, medicine is increasingly subject to economic mechanisms, which has meant that medicine and the relationship between doctor and patient are seen from a market economy perspective that places greater emphasis on the customer/service provider

dimension. Physicians are also, whether mistakenly or consciously, relinquishing their traditional understanding of the profession to follow this trend.

New therapeutic procedures for the beginning and end of life are presenting further challenges for the relationship between doctors and patients. The insight that in prenatal diagnosis the foetus might itself be a patient is by no means universal. At the end of life, therapeutic decisions are sometimes overlaid by the patient's wish to die. However, euthanasia or assisted suicide is incompatible with the physician's duty to heal the sick.

There is hardly any field where patient autonomy has changed treatment and also the relationship between doctor and patient as radically as in psychiatry. The shift from closed, custodial psychiatry to open, activating psychiatry has enabled many patients to live an independent life, but to many it has posed an existential threat because they have been left to cope with their illness alone and exposed to neglect. The model of the autonomous patient taking his or her own decisions when visiting the doctor does not fit in every case.

However, even when patients are kept in custody against their will, e.g. in forensic psychiatry, during imprisonment, in establishments for asylum-seekers or during deportation procedures, the relationship between doctor and patient is under scrutiny. There has been controversial discussion of whether medical decisions should be subordinate to the instructions issued by public agencies.

The rapid development of genetic testing has also challenged the definition and boundaries of the relationship between doctor and patient, as genetic tests usually produce diagnoses that concern more than one person or even generation, thereby overstepping the narrowly described margins of a relationship between two individuals.

Since the relationship between the doctor and the patient is so pivotal, any changes or influences that affect it also display a political relevance. Hence, a number of politically significant questions arise:

– How should the economic and legal framework be designed to avoid eroding the relationship of trust between the doctor and the patient?

– Can the patient/doctor relationship, which is so crucial to treatment, be shielded from external (e.g. economic) influences and protected by organisational means, or is it already too late?

– Would the relationship between doctor and patient improve if the remuneration of physicians were to be structured differently, for example by a departure from payment per service?

– How can the doctor/patient relationship be protected or improved in cases when the patient does not consult the physician voluntarily or is unable to consent to the visit, e.g. in some categories of psychiatry or in the case of unborn or small children?

– What consequences will demographic developments have for the doctor/patient relationship in terms of the chronically sick and in particular patients with dementia, e.g. in residential homes?

– What can be done to improve medical training so that communicative skills, the ability to build trust during dialogue between the physician and the patient, and psycho-social skills are reinforced?

– Is there a need to "demedicalise" the relationship between physicians and people with disabilities, and if so, how can this be achieved?

– What role do the professional associations and organisations play in the doctor/patient relationship?

– Technological influences and the trend for commercialisation are likely to change the way physicians have traditionally seen themselves as the patient's advocate, turning the physician into a "salesman" or "saleswoman" and the patient into a "customer". Should this development be regulated and monitored and if so, how?

– Who else defends patients' interests?

– What format should living wills, authorisations of guardianship or precautionary proxies adopt in order to play their part in building trust?

– How can patient participation in the health system be improved?

– What contribution could be made by a codified charter of patients' rights, for example based on the document on patients' rights in Germany presented to the 72nd Conference of federal and state health ministers in 1999?

– What relative weight should be attached to the rights and duties of informed patients? How can an appropriate patient ethos be fostered? What scope is there to promote this?

F General Recommendations for Continuing the Ethics Debate

In pursuit of its mission to examine and describe questions and problems associated with progress in modern medicine and to offer recommendations on ethics review, on a societal response to these questions and on legislative and administrative action, the Study Commission on Law and Ethics in Modern Medicine created an interface between the scientific community, the general public and the legislator. In so doing, the Commission was able to draw on a body of experience from which general recommendations can essentially be derived in three areas. These are:

– methods and procedures;

– dialogue with the public;

– a structure for ethics debate in Germany and abroad.

1 Methods and procedures

In providing input for current legislative and decision-making procedures and drawing up recommendations on ethics review and legislative responses to controversial issues, the following proved particularly difficult as a result of institutional conditions:

– submitting required opinions in a timely and topical manner, and

– describing issues on which it was not possible to establish consensus on ethics review among members of the Commission.

1.1 Support for legislative and decision-making procedures

In order to express a timely position on issues in progress the Commission made use of interim reports and the option of submitting expert positions to the lead committee for the legislative procedure concerned.

Interim reports were published on the protection of intellectual property in biotechnology and on stem cell research. The section of the report dealing with the European Union's Charter of Fundamental Rights was made available to Germany's representatives in the Convention and discussed with them.

The Commission discussed the risk that the publication of the final report might be diluted by publishing interim reports, but this was deemed acceptable in order to make full use of relevant work by the Commission for legislative and decision-making procedures in progress.

The Study Commission recommends that the German Bundestag continue developing the concept of timely counsel for legislative and decision-making procedures and establish the requisite institutional and legal conditions where appropriate.

1.2 Voting and drafting procedures on controversial themes

It proved particularly difficult to deal with themes where consensus on evaluation evaded the members of the Commission to the end. There were three such themes:

– the protection of intellectual property in biotechnology (biopatents);

– stem cell research/imports of embryonic stem cells;

– preimplantation genetic diagnosis (PGD).

In spite of the tensions due to differing assessments, the Commission succeeded in every field in maintaining a fair exchange of arguments in the debate without the discussion breaking down or indelible trenches remaining. The Commission also believes it was an important experience that members were able to establish "boundaries of dissent" and universally shared fears about abusive trends and to mark out a framework in every case for what the law may require and what minimum ethical standards must by no means be flouted. The common ground and the reasons for the fundamental differences in appraisal that remained were described in the texts in appropriate form. The problem was nevertheless posed of how to reflect the existence and magnitude of the remaining divergences between members of the Commission.

The Commission chose various ways of doing this: the option of a dissenting minority opinion (biopatents), the submission of a "two-pronged" recommendation (import of embryonic stem cells) and an expression of opinions on two different positions (preimplantation genetic diagnosis).

The Study Commission therefore recommends that the German Bundestag debate whether and to what extent appropriate descriptive procedures can be developed and applied on this basis for instances where ethical divergence cannot be overcome.

2 Dialogue with the public

As political decisions on controversial issues of medical ethics and bioethics cannot be taken without strong public participation and as the German Bundestag expects recommendations from the Commission on how society should respond to these issues, the Commission

considered it an important task to promote and inform public discourse on the issues mentioned here. In so doing, the Commission both picked up themes from public debate and itself provided the impetus to stimulate further debate. Here again various formats were adopted. The openness of the discussion within the Commission and the manner in which opinions was formed met with a strong public echo.

Drawing on its experience with the use of these formats the Commission recommends that the German Bundestag adopt or build on the following instruments for the dialogue it needs to conduct with the public:

– topical information for the public in the form of reports, expert opinions, position papers and similar formats, including use of the opportunities presented by the Internet;

– dialogue events and public hearings;

– co-operation with committees and institutions outside parliament;

– promotion of options for dialogue within society with the aid of the Internet (e.g. online forums and conferences);

– intensive co-operation with the media.

3 Structure of the ethics debate in Germany and abroad

In order to gain an impression of the structures used for decision-making on medical and bioethical issues in European neighbouring countries, the Study Commission held a public hearing to conduct an exchange with representatives of ethics committees from the United Kingdom, the Netherlands, Denmark, the Czech Republic, France, Poland and Switzerland. This revealed a broad spectrum of options ranging from the treatment of medical and bioethical issues by state institutions via discussion by relevant bodies within a framework of professional self-administration to the promotion of opinion-forming and evaluation by independent social groups and institutions.

It emerged clearly from the experience of the Commission and an assessment of the public hearing mentioned above that the problems raised by medical ethics and bioethics require specific formats for the formation of opinion and evaluation. These relate to:

– the nature of the problem: this is usually complex and hard for even a single well-informed initiate to grasp entirely. Here it is necessary to take stock of the facts, explore them from different angles and describe the outcome in a form which is intelligible to all decision-makers. This calls for exchange with the experts (scientific contribution), an

awareness of European and international developments (European and international exchange) and translation into a language everyone understands (public understanding). It is especially important to keep abreast of developments, and this requires continuous gathering of facts and communication.

– ethics review: as this is controversial on major issues, the criteria used in evaluation must be described, common positions and differences must be established and opportunities for reaching agreement must be explored. Apart from consulting experts (on ethics and law) discussion with the relevant social groups must be sought and discussion between these groups is also necessary (dialogue with the public).

– statutory regulation and political decision: as different options are usually possible and over-arching regulatory bodies at European and international level have a role to play, a debate is required about regulation that duly reflects the substance of the issue and complies with ethical and legal value beliefs. Here, too, the debate must extend beyond experts (the law) to embrace the parties concerned, so that a solution capable of attracting consensus can be found at the authoritative level of parliamentary decision. It should be borne in mind that the various positions and options are frequently not contiguous with party affiliations.

To achieve the goals described and prepare political decisions appropriately, it is particularly important in the Commission's experience:

– to identify and stake out problematic areas in timely fashion in a dialogue between the general public, the scientific community and political decision-makers;

– to communicate the problematic areas by means of comprehensible information for the general public, decision-makers and the scientific community in collaboration with the media and by making use of the Internet;

– to stimulate and promote public debate;

– to analyse and describe this public debate for decision-makers;

– to provide consultancy for political decision-making bodies with specific regard to the problematic areas and to prepare the ground for legislative and administrative decisions;

– to draw up proposals to this end for partial consensus on ethically contentious issues and to indicate any insurmountable divergence of opinion;

– to engage in ongoing European and international exchange and to participate in European and international regulation and its preparation.

In the Commission's experience, deficits still persist in Germany[904], in spite of the institutionalisation that has taken place, with regard to the exercise of duties and fulfilment of requirements necessary to preparing crucial political decisions. These have their roots in a variety of factors, including limited fields of responsibility, a lack of democratic legitimacy, faulty competence and unnecessary duplication, failure to assign roles, inadequate co-operation and deficient institutionalisation.

The Study Commission therefore recommends that the German Bundestag address the question of a culture for ethics debate in Germany and its adequate promotion and organisation and that it create an appropriate institution that can suitably prepare and support parliamentary debate and decision-making on medical and bioethical issues in a dialogue with the public. This should echo the working methods of a study commission or take the form of a standing committee. Care should be taken that:

– the requisite democratic legitimacy is vouchsafed by a decision of the German Bundestag;

– expert competence is available;

– independent functioning is assured (attachment to the Federal President or the German Bundestag deserves consideration);

– the danger of delegating decisions which should be taken by parliament is avoided (no surrogate body for the representatives of the people);

– an appropriate exchange with parliament takes place;

– the consultation processes, the positions of the participating players and the findings are rendered transparent;

[904] The following institutions now exist at federal level in the field of medical ethics and bioethics:
- as consultative bodies in the political context and in the context of self-administration by the medical profession: the Study Commission on Law and Ethics in Modern Medicine set up by the German Bundestag; the National Ethics Council attached to the German Chancellor's Office; the Ethics Advisory Board attached to the German Federal Ministry of Health (dissolved on 10 April 2002); the Central Ethics Committee of the German Medical Association.
- as institutionalised services to support decision-making and evaluation: the German Reference Centre for Ethics in Life Sciences (*Deutsches Referenzzentrum für Ethik in den Biowissenschaften*, DRZE); the Office of Technology Assessment (*Büro für Technikfolgenabschätzung*, TAB) of the German Bundestag.
- to assist public decision-making and evaluation processes: *Bürgerkonferenz Streitfall Gendiagnostik* (Citizens' Conference on the Dispute about Genetic Diagnosis), Dresden 2001, (by way of experiment).

– adequate networking is established with public debate, with social groups and institutions, with scientific developments and institutions, with the organs of professional self-administration and existing bodies in the field of medical ethics and bioethics, and

– vital participation is ensured in European and international debate and decision-making.

G Annex

1 Minority opinions

1.1 Minority opinion of Commission members Rainer Beckmann, Prof. Dr. Ludger Honnefelder, Hubert Hüppe, Dr. Otmar Kloiber, Werner Lensing, Prof. Dr. Johannes Reiter and Dr. Gerhard Scheu on Chapter B1 Human dignity / human rights, last sentence

We do not agree with the statement made in the Study Commission's Report to the effect that "it would not be incompatible with the embryo's status of dignity that one would refrain, in *the event of a pregnancy conflict, from insisting that an embryo should be carried to term* against the woman's will, so that terminating the pregnancy may prove to be the only way to preserve the dignity and the rights of the woman" (Chapter B 1, last sentence).

The Study Commission rightly emphasises that all human beings have human dignity, irrespective of their personal characteristics (B1.3). and that, if such a broad concept of the human being is applied, "human embryos cannot be barred from the protection of human dignity" (B1.4.1). Furthermore, there is a consensus to the effect that human dignity "is not open to being weighed against other legal interests" (B1.3) and that it takes "absolute precedence" (B1.4.3).

If this is true, the statement cited above cannot be upheld. It creates the impression that it might be legitimate to terminate pregnancies on a scale that is not defined in any greater detail by invoking Art. 1(1) of the German Constitution; and this impression is created at a prominent place – the final paragraph of the chapter on "Human dignity / human rights". However, if the statement cited above is applied to the embryo as a being with human dignity, the result is the very opposite. In this case, it would "not be incompatible" (i.e. it would be compatible) with the woman's status of dignity to preserve the dignity of the embryo by obliging the woman to carry the embryo to term.

Since both statements can be justified on the basis of the concept of human dignity described in Chapter B, it is not right for the Commission merely to state that the embryo's human dignity is not violated by killing the embryo ("terminating the pregnancy"). Instead, the Study Commission should have either clarified the dichotomy between the diametrically opposed conclusions that can be drawn from the chapter on "Human dignity / human rights", or it should have refrained from making a one-sided statement that neglects the dignity of the embryo.

There was no reason to include the criticised wording in the Report since the termination of pregnancies as such was not one of the issues covered by the Commission's brief, and the Commission did not discuss this issue in connection with the constitutional conflict involved.

1.2 Minority opinion of Commission member Werner Lensing on C1.4.5.2 Recommendations in the section on preimplantation genetic diagnosis

After truly careful consideration, I have come to the conclusion that I cannot fully endorse – based on an unequivocal ethical conviction and beyond any doubt – either of the two recommendations presented by the Study Commission on "Law and Ethics in Modern Medicine" on preimplantation genetic diagnosis (PGD).

Based on the assessment that PGD is prohibited under the legislation currently in force in Germany, it will indeed take compelling reasons to justify any licensing of PGD – even within very narrow limits – while at the same time weighing the conceivable implications of a potential licensing.

Generally speaking, I can see such reasons primarily with regard to provisions governing the termination of pregnancies following medical indication. To my mind, there is indeed an irreconcilable contradiction in value judgement between the current lawfulness of a medically indicated termination of pregnancy following prenatal diagnosis (PND) on the one hand, and the rigorous ban imposed on PGD on the other.

Hence, I share the position of the advocates of a restrictive approval of PGD for so-called "high-risk couples".

However, I do have grave doubts as regards the view of those who think that they can clear up this contradiction in a responsible manner by approving PGD **under certain conditions** and thus adopt binding rules and regulations.

I have doubts because I think that it will not be possible in the long run to restrict PGD to cases in which women or couples are **objectively** in a serious conflict situation that justifies the application of PGD beyond any doubt.

This belief is based on the experience made with the practical application of the medical indication following prenatal diagnosis. Against this background, it seems to be inevitable to me that in preimplantation genetic diagnosis it will not be possible in the long run to assess

objectively in which cases the mother or the couple are actually at risk of having to bear an **unacceptable** burden.

To my mind, the **objective assessment** of whether

– there is a real risk that a child may suffer from disability or a disease that must be qualified as particularly severe, and

– taking care of this child will actually be overtaxing the woman / the couple concerned,

will certainly be superseded within a foreseeable period of time by a **purely subjective assessment of the woman / the couple** as to the burden they are **willing to bear**.

The fact that a blanket clause is not suitable to guarantee in the long term that the application of PGD will continue to be **limited** is demonstrated by the example of the medical indication for terminating a pregnancy. It seems rather doubtful to me whether transferring the assessment authority to a **body** will change anything because even in this case, there is an obvious lack of **reliable** decision-making criteria. In the past, there has been a large number of diverging assessments by physicians of what a valid conflict situation is in concrete terms. This suggests that it is likely that the criteria that will be applied to determining what a conflict situation is will primarily depend on the individual members comprising such an assessment body.

Against this background, it will be indispensable for the introduction of a reliable definition to adopt clear-cut statutory provisions that will stipulate both general and individual access requirements. The general access requirements should consist of a **catalogue** of serious health impairments that can be detected by means of preimplantation genetic diagnosis. In addition, it would be necessary to prove that the persons concerned are in a concrete predicament, comparable to a serious pregnancy conflict as in the case of medical indication.

However, such catalogue-based, statutory provisions would find no acceptance at all in society; moreover, they would not provide an ethically or medically acceptable solution.

In view of the fact that it is therefore **impossible to restrict PGD in the long term** to objectively severe cases, I cannot endorse an approval of PGD – even if it is intended to be narrowly restricted.

Against this backdrop, there is no need for any further discussion of a possible broadening of the scope of PGD – which I fear and reject – to include other fields of application, e.g. as routine procedures in the context of IVF.

To sum up, I acknowledge the fact that the advocates of a conditional approval of PGD within the Study Commission on "Law and Ethics in Modern Medicine" are against the selection of human life because their primary objective is to enable affected couples to fulfil their wish to have a child.

However, what I do not want to happen is that a couple's understandable "wish to have a child" degenerates to a wish to have a "designer child".

1.3 Minority opinion of Commission member Monika Knoche with regard to the entire report submitted by the Study Commission on "Law and Ethics in Modern Medicine"

Introduction

The submitted report reflects the consensus established in the Study Commission. Dissenting opinions were dispensed with here and there for reasons of political pragmatism. Nevertheless, opinions and standpoints strayed in some cases well beyond the deliberations described. It was not possible to fulfil the desire to embed this thematic material within a cultural history, to draw attention to international aspects and social circumstances reflecting different values in particular countries and cultures.

Much clarity and greater insight and assessment opportunities could have been obtained, had more attention been devoted to the economic interests behind much research. This is exemplified by patents derived from the findings of basic research, the "patent on life". In my minority opinion, I wish to develop some considerations of another nature.

As one of those who initiated this Study Commission, I regard its appointment as a parliamentary success. Its constitution was not tackled until halfway through the 14th legislature, testifying to the fact that the Study Commission was highly controversial. This had its impact, like the differing interests of parliamentary parties and the government, on the law-making parliament. The Act on the Import of Stem Cells (*Gesetz für Stammzellimport*) shows that the decision of the sovereign body cannot be greatly influenced by its expert panels. Contrary to the maxims defined by the Study Commission at the start of its internal constitution phase about applying gender mainstreaming criteria to grasping the political and

technical complexity of the subject-matter in hand, this was almost entirely abandoned in the course of its work.

Philosophical, feminist reflections on the concept of the body underlying human rights met with little approval in this age when biomedicine overcomes corporeal boundaries and human genetic engineering can manipulate the body. Again, no expertise was devoted to these suprathemes.

During the French Revolution, Olympe de Gouges declared that the aim and purpose of political activity should be to ensure women's natural rights; yet in the 21st century, we can only be sure that we are no longer sure where to seek orientation for the self-determination of women as humans who are physically different from male humans. The elevation of woman and simultaneous reduction of woman to the role of mother, quality controller of her body's fruit, but also the cultural status of her life-giving force, which becomes a resource for biogenetic research and production when her ripe "pre-fruit" is extracted from her, all this should form part of any contemporary discourse on "bioethics".

Liberating sexuality from procreation has always been an "emancipation issue" for women. Whereas in former days it was a question of contraception and the right to self-determination through pregnancy, the desexualisation and decorporalisation of reproduction by means of new medical techniques has plunged it into a cultural dimension the magnitude and boundaries of which society today can barely grasp.

Art, literature, philosophy – although hardly natural science itself – have confronted the significance and social, societal consequences of the humanly possible. The Study Commission also revealed that little attention had been paid to the women's and cultural issues inherent in the human rights question. In this field, justice was insufficiently done to our ambition of reflecting the "state of knowledge" in the Study Commission's recommendations.

I think it is important to add some indication of the many things, beyond those described in the report, that were thought by members of the Study Commission and said in the hope of being heard.

Additional thoughts on the chapter on prenatal diagnosis – predictive tests, genetic testing

Diagnostic procedures to identify the genetic make-up of the foetus have become a routine test for which the requirements of informed consent outlined do not as a rule appear to be fulfilled. Although in medical practice, in order to rule out an offence of bodily injury, a genetic test should not be carried out unless the standards of consent have been met, following information about what characteristics are to be tested, how robust the findings will be, what therapeutic benefits may be derived, what options will be available following a positive result and what risk of iatrogenic damage is incurred, there is much evidence to suggest that these standards are not observed in the case of pregnant women.

The strict limitation to listed indications for prenatal genetic testing, as practised in neighbouring countries, is based on requirements that are fundamentally dissimilar to the conditions prevailing in Germany.

In Germany, the patient and physician enjoy a free relationship founded on civil law, which is largely shielded from governmental interventions. Social Security Code V does not stipulate indications for testing. Government can only prevent observed misallocations with the help of indirect management mechanisms, but not by means of prohibitions.

In line with the principle that the statutory health insurer's duty to finance a medical service can only be triggered when a physician provides an indication for medical intervention in the course of his or her duty of care, any recommendations on limiting these indications to such as are acceptable in terms of medical ethics will have to be resolved on the basis of self-administration and professional codes of ethics.

To overcome the observed misallocation, it may help to refer the question to the German Bundestag's Health Committee, to revise the maternity guidelines and to refer early detection measures to the co-ordination committee of the parties participating in the health sector's self-administration.

Additional thoughts on the chapter on preimplantation genetic diagnosis

I reject the authorisation of preimplantation genetic diagnosis. This is eugenics without pregnancy. Apart from the arguments outlined in the report, my rejection of eugenic selection is nourished by the following considerations.

Preimplantation genetic diagnosis has induced a paradigm shift in the physician's duty to care and cure. So far, IVF has been confined to infertile couples. Artificial insemination is justified in terms of the entitlement to equality that it is intended to create between infertile and fertile couples wishing to reproduce.

If preimplantation genetic diagnosis were to be permitted, it would have to be accessible to all couples wishing to reproduce. *In-vitro* fertilisation would then be pried from its narrow medical indications and extended as a universal entitlement to a mode of reproduction (assisted by medical technology) of one's own choosing. This would be necessary, or rather could not be refused, because the equal treatment imperative would require facilitating the eugenic selection of offspring for fertile couples – prior to pregnancy – and not restricting the option to infertile couples.

If preimplantation genetic diagnosis, combined with the *in-vitro* fertilisation that inevitably precedes it, were to be reserved entirely for so-called "high-risk couples", the limitation would smack of arbitrariness.

Ultimately one must consider this: if "high-risk couples" are capable of conceiving, an exclusive entitlement to the provision of preimplantation genetic diagnosis that was confined to specific risks would be unacceptable. Rather, the freedom to choose one's mode of reproduction would have to be developed consistently as a new right of self-determination.

Nevertheless, major problems of legal logic would be presented, if self-determination were to be extended as outlined here in conjunction with eugenic selection by means of preimplantation genetic diagnosis as a new "upstream custodial right" of non-pregnant women with regard to non-incorporated embryos.

To perform preimplantation genetic diagnosis, the physician would require a remit to treat the embryo *in vitro*, which he/she does not have. Naturally, in the present instance, the subject of this remit could only be the embryo itself. As no pregnancy has occurred, preimplantation genetic diagnosis can only be undertaken for the benefit of third parties, especially given the possibility that the embryo might be rejected. It would have to be deemed, therefore, that the very carrier of the feature – that is, the embryo *in vitro* – wished its genetic make-up to be identified and, should this make-up prove undesirable to other parties, wished in its own interest to be destroyed, so that the action of the physician would not be criminal under the provisions of, for example, the Embryo Protection Act. In this context, after all, the physician

cannot be regarded as having a mandate from the oocyte donor. This embryopathic indication would clearly be alien to the spirit and purpose of the Embryo Protection Act.

In my view, the subjective, prospective discretion of a non-pregnant woman cannot be deemed a criterion for how to treat the embryo, and especially not for rejecting it. Furthermore, a woman engaged in an *in-vitro* fertilisation procedure would enjoy an unequal privilege enabling her to realise her eugenic interest in the reproductive process when compared with a woman who has become pregnant following an act of sexual intercourse and who would be punishable under Section 218 of the German Criminal Code.

As the reformed Section 218 explicitly does not recognise an embryopathic indication for the termination of pregnancy, and PGD is an explicit form of embryopathic indication, the law currently in force gives no grounds for discerning a contradiction of assessment in Section 218 of the Criminal Code. In fact, because of the special relationship pertaining in pregnancy, "duality in unity", protection for the life of the embryo *in vivo* is afforded priority over the woman's right of self-determination. The practice of pregnancy termination following genetic testing – the medical plight of the woman as a consequence of diagnosis subject to informed consent prior to its performance – has hitherto been applied after the twelfth week of pregnancy. At this stage of development, it is no longer possible under Section 218 to weigh up conflicting basic rights. Any action taken by the physician can only be substantiated if a physician has diagnosed a medical indication which focuses on the woman. In the light of constitutional jurisprudence, the self-determination of the woman is, therefore, simply not an issue following prenatal genetic testing.

If, however, it is left solely to the subjective discretion of the woman to be allowed to define a prospective conflict situation within herself, diagnostic measures which focus on the embryo, including its possible rejection, cannot be integrated into the remit held by the physician to treat the woman donating the oocyte. An independent remit would have to be established for the physician to treat the embryo *in vitro*, elevating its assumed undesired status following the result of a genetic test to a legally secure basis for destroying its existence.

The self-determination argument is frequently cited to promote preimplantation genetic diagnosis, but in my view wrongly. This line of argument ultimately leads to the conclusion that, for the purposes of reproductive autonomy combined with ensuring one's own "genetically sound offspring", the best thing would be to opt entirely for the new

opportunities presented by artificial insemination and to dispense with sexual reproduction, especially if Section 218 of the German Criminal Code remains unchanged.

Even if one accepts this form of eugenic selection as a potentially legitimate interest, it still has to be noted that excessive self-determination cannot be applied to progeny, in this instance and in the spirit of human rights. Self-determination is confined to one's own corporeal limits and cannot be extended to others. As the embryo *in vitro* is already in the world as an unborn being and forms part, with its own intrinsic rights, of the human social community, it must remain shielded from third parties seeking access to it for their own purposes.

I feel bound to draw attention to the fundamentally new phenomenon of "eugenics without pregnancy" that preimplantation genetic diagnosis represents.

It strikes me that the more alien interests tug at the embryo, the more urgent it becomes to establish a consistent definition of the embryo's basic rights status.

I believe that it is of no matter whether the embryo exists *in vivo* or *in vitro*, whether or not it can be screened *qua* environment, or who wishes to derive what consequences for or against it from this fact: these things cannot exert any influence on its status in terms of basic rights.

Additional thoughts on the status of the embryo

IVF has now made it possible to dedicate an embryo created in this manner to be used for a purpose other than its own intrinsic purpose. Constitutional law has not yet absorbed this early state of being outside the mother's body. The embryo's status is not defined in the Embryo Protection Act which is designed as a criminal statute. A definition in analogy to the jurisprudence issued by the Federal Constitutional Court on Section 218 of the German Criminal Code is only of very limited value in providing cohesive human rights dogma on the question of species that has been posed by life without pregnancy and birth, especially as the constitutional interpretation that was supplied merely referred to the unlawfulness of terminating pregnancy.

The observed conflict between basic rights relating to the embryo in the woman's womb and the woman's autonomy during a state of pregnancy was resolved in the judgment of the German Federal Constitutional Court on Section 218 of the Criminal Code.

In assessing the penal character and unlawfulness of abortion, consideration was given to the natural process of fertilisation by procreation and the dependence of the embryo's development on the female body.

Unlike human life engendered under natural law conditions by means of the sexuality of two individuals of disparate gender, the embryo *in vitro*, due to the desexualised manner of its genesis, is not subject to the conditions which result from being corporally bound to a woman. From the outset, the pre-conditions for its own existence depend directly on the actions of third parties. The contemplations of constitutional law have not hitherto taken explicit account of this fundamental distinction from the embryo *in vivo*.

Hence, new logical and substantive problems arise. Since the German Federal Constitutional Court was not called upon in its judgment to rule on the status of the embryo in the prenidation phase, it will prove inadequate to seek to clarify the status of the embryo by drawing on or deriving conclusions from the Section 218 judgment. Where the status of the embryo *in vitro* is concerned, it is precisely this existence prior to nidation that is of such decisive constitutional significance. Although the embryo *in utero* is assumed to enjoy basic rights in its own right, this does not automatically substantiate the human dignity of the embryo *in vitro*.

An independent classification must be undertaken within the dogma of basic rights. The German Federal Constitutional Court provides some guidance here by defining the beginning of human life as the fusion of oocyte and sperm cell.

Here again, however, it is problematic merely to refer by analogy to the reasoning in the Section 218 judgment, as this develops a biologistic line of argument, fundamentally incompatible with the approach of human rights law, which suggests that the human dignity of the embryo *in vivo* is only constituted – can only be constituted – once it has reached the womb. If one accepts this assumption that nidation creates the human dignity of the embryo and that the conflict of basic rights implied by "duality in unity" originates only then, one remains confined by the biologistic argument that human rights are bound to the uterus.

The entirely new fact that there is no need to resort automatically to the uterine bond and that it is now possible to introduce an embryo into the world *in vitro* without a woman as mother and to develop it has never been preceded in history by anything comparable.

In my view, the extra-corporal and protracted or temporary extra-uterine or substitute uterine state of being of the created embryo has not been addressed to date in its full complexity. In terms of constitutional law, it is no doubt extremely unusual, not to say unacceptable, to make the status of the embryo dependent on – or derive that status from – its mode of genesis and its prospective chances of development and life, which would hinge decisively on the decisions of third parties. The human rights issue which must be clarified, and for which the judgment by the German Federal Constitutional Court on the status of the embryo following nidation offers no adequate answer, is as follows: Is a human being human even if he/she is not born and is not intended to develop within a woman's womb?

Embryos *in vitro* possess the same intrinsic potential as embryos *in vivo* to develop as human beings. They are, however, fundamentally distinct with regard to their place of genesis and their environment.

The distinguishing feature *in vitro*/*in utero* after the 14-day deadline also dissolves in the light of new advances in reproductive technology and to the extent that transfer to the uterus will not be necessary to foster its intrinsic potential. One must note, therefore, that unlike the procreated embryo the created embryo is in the world in the most unprotected state.

The embryo *in vitro* entered the human community by the act of a human hand. It exists without being born, and physically it has not yet developed as a human being. Given that our image of humanity is constrained to be holistic, these circumstances are not cogent arguments for excluding this member of the human species from the scope of universal human dignity. Rather, it implies that the embryo *in vitro should* be deemed to be embraced by the scope of human dignity.

All attempts to establish tiers of protection for the life of an embryo *in vitro* share the hallmark that they assume that it is fundamentally accessible and that, as a consequence, others may be authorised to interfere with it.

Any statute that sought to introduce tiers of protection, leaving the life of the embryo *in vitro* unprotected, unlike the embryo *in vivo*, cannot be justified on the grounds that an embryo created by artificial insemination is essentially available for the use of third parties which have an interest in it.

Additional thoughts on criminal law in relation to the Embryo Protection Act and the import of embryonic stem cells

The fact that the Embryo Protection Act (*Embryonenschutzgesetz* - ESchG) contains no explicit provisions to regulate the import of embryonic stem cells does not permit the conclusion that the import of embryonic stem cells has thereby been legalised or authorised. This conclusion would only be justified if the failure to fill this gap in regulation was deliberate as opposed to unplanned. When this legislation was elaborated, however, developments in biotechnology were unforeseeable, and the methods used to obtain embryonic stem cells were unknown.

It is nevertheless evident from the totality of the regulatory provisions in the Embryo Protection Act that the legislator intended, by adopting this law, to achieve comprehensive protection for embryos and to permit their creation *in vitro* simply and solely for reproductive purposes within a narrowly confined framework (cf. in particular Sections 1, 2 of the Embryo Protection Act).

Obtaining embryonic stem cells is punishable under Section 1(2) of the Embryo Protection Act.

Similarly, we can rule out any claim that the legislator deliberately sought to exclude the import of embryonic stem cells from the scope of the Embryo Protection Act in order not to prevent a potential future exploitation of the embryo, given that any actions involving the embryo that do not serve the purpose of reproduction would be entirely contrary to the point and purpose of the Act. The absence of provisions to regulate the import of embryonic stem cells can be attributed entirely to the fact that, at the time the Embryo Protection Act was adopted, the legislator did not expect the opportunities which arose for trading or for using products derived from embryos for non-productive, commercial applications.

It is helpful to consider the Transplantation Act (*Transplantationsgesetz*) in this context. This prohibits and penalises the use of organs in Germany that were not obtained under the conditions of explantation ("brain death") applicable in this country. This provision indicates that regulations adopted in Germany to protect human dignity and the right to life are considered so important that their substance shall be applied irrespective of national borders.

Additional thoughts on prohibiting the import of embryonic stem cells

As a proponent of a complete import ban, I wish to stress the following:

Even if the import of embryonic stem cells were to be subjected to the strictest conditions, granting it licence would be incompatible with the substance and purpose of the Embryo Protection Act, which regulates the protection of the embryo in the course of *in-vitro* fertilisation within the context of medical practice. It would be inconsistent to authorise the import, subject to regulatory conditions, of embryonic stem cells whose production would be illegal in Germany under the penal provisions of the Embryo Protection Act.

A complete ban on imports could be incorporated by amending the Embryo Protection Act. Tolerating or licensing imports of embryonic stem cells that cannot legally be obtained in Germany under the Embryo Protection Act would circumvent public policy and implicitly redefine the scope of the Embryo Protection Act for utilitarian purposes.

If the import were to be legalised on the basis of conditional toleration, and research thereby deemed to be in the public interest and owed to scientific freedom, it would be difficult in the long term to uphold the substance and purpose of the prohibition on non-intrinsic use expressed in the Embryo Protection Act.

Additional thoughts on genetic testing

As a general rule, genetic testing can only be permitted within the framework of the physician's duty of care. This ensures confidentiality, informed consent and the identification of a verifiable medical indication for testing.

Genetic data reveal highly intimate information. Since individuals have a basic right to determine what happens to information relating to them, such data must be subject to the most effective data protection. The right to know does not in itself provide grounds for justifying universal access to genetic tests or their potentially universal prescription. The knowledge about genetic conditions obtained by means of a genetic test is not confined to those who were tested, since information about third parties who are genetically related is also obtained. This touches upon their rights of self-determination. This specific conflict between basic rights imposes narrow limits on the individual's right to know.

Apart from the need for statutory provisions, this new genetic knowledge influences human social relations as well as individual and societal ideas of a "successful" life.

As society and medicine have not yet developed adequate ethical and moral norms to deal with this completely new phenomenon in human history and culture, the only possible response is to adopt a restrictive approach to genetic testing.

Thoughts on the European Charter of Fundamental Rights

It has been the goal of all EU Member States to develop a Charter of Fundamental Rights for the European Union. In implementing and applying European law, they declared, both the EU institutions and the Member States should be bound by a common standard of basic rights. On the one hand, the texts drawn up by the Convention towards a European Charter of Fundamental Rights reflect the fact that the process was based on a post-national constellation. On the other hand, they are intended to express consensus on shared values. This touches upon the normative power of definition emanating from the guarantee of human rights in an age of biotechnology and genetic engineering.

Biomedicine and research frequently reach beyond the individual subject to address the human condition as such. The Charter of Fundamental Rights must also guarantee the inviolable dignity of human beings as a species.

In the light of unprecedented threats, the values on which our culture is founded can only grow if these norms are not transgressed.

The premises which underlie the German understanding of fundamental rights oblige us to ensure under any circumstances that the existing ban on eugenic practices is extended with binding force to eugenic selection via preimplantation genetic diagnosis and that the cloning of human embryos is prohibited. Nothing must be permitted that denies an individual who comes into being by whatever means the possibility of regarding himself or herself as belonging to the human species.

The question about human beings as both subjects and simultaneously objects of this technology is now posed in a new way. From what point and for how long is a human being the subject of human rights? This definition is at the focus of interest in any talk about universal human dignity on the basis of our Constitution.

What standard of protection are national constitutional law and the legislative expression of human rights guarantees expected to provide in future if the corpus of reference for European legislation is to be the European Charter of Fundamental Rights or a European Constitutional Treaty?

Will it be possible, or indeed legitimate, for the European Charter of Fundamental Rights to homogenise different and often opposing definitions of humanity and the tradition of basic rights that has led Germany quite consciously not to sign the Council of Europe's Convention on Biomedicine? These questions remain topical in the post-Nice context.

It is still unclear how the unbridgeable dichotomies between the Anglo-Saxon concept of life and the explicitly non-utilitarian concept of life found in guarantees of basic rights can be "safeguarded" at European and national level in order not to allow supranational jurisdiction, a catalogue of basic rights and a future constitution to erode the profound bonds incurred by values rooted in culture.

General recommendations

Unlike the recommendation made by the Study Commission, I would advise appointing another Study Commission on "Law and Ethics in Modern Medicine" during the coming legislative period.

Within the procedural framework for ensuring democratic legitimacy around issues of legislative relevance, a study commission is an appropriate body to prepare and support the parliamentary decision-making process. There will undoubtedly be an ongoing need to consult on questions raised by new technologies in biomedicine in conjunction with genetic engineering beyond the 14th legislative period.

These are the human rights issues of the modern world. In diverse ways and in particular with regard to the opportunities that society as a whole has had to participate, the manner of discourse facilitated by representative parliamentary democracy has proven to be excellent. It displays inherent advantages compared with the presidential systems of other countries.

The establishment of a body similar to the National Ethics Council should not be repeated. In terms of policies for democracy, a tendency can be discerned here to diminish the democratic process and legitimacy of parliament. Only the men and women elected by the people are sovereign. It is essential to the role of members of parliament to explore new human rights issues in a comprehensive manner and to enhance their own technical and political competence by summoning external experts.

The insights and recommendations they derive from this experience exert a fruitful influence via their own parliamentary parties on the specialist committees of the German Bundestag. No other body enjoys such unimpeded access to the state of knowledge as does the German

Bundestag. This is used for establishing legal norms, and it is needed to enable society to be sure of its case.

Beyond this sphere, the elected representatives of the people engage in discussion in their constituencies at public meetings with residents. This also presents useful opportunities to involve the public in the process of information and decision-making.

The decision-makers are chosen by universal democratic suffrage, which distinguishes them from any other body. The parties adopt positions on fundamental issues of this kind. This, too, creates a major motivation for citizens to form their own opinions.

The outstanding debates in the German Bundestag, for example on importing stem cells, on preimplantation genetic diagnosis, on implementing the Biopatent Directive and other matters of biopolicy, have demonstrated that members of parliament, unlike many experts, command the art of conveying complex issues and also that it is possible to engage the intellectual participation of the public on issues which determine our culture.

Due to specific circumstances, it was not possible to establish the Study Commission of the German Bundestag until halfway through the 14th legislature. In spite of the extreme time pressure and the great expectations expressed by Parliament and the public, this Study Commission rapidly became known for its competent, politically representative work around some highly complex questions of our time. It testifies to the quality of discourse and has set standards for dealing with similar issues in the modern era.

The Study Commission seized the opportunity to organise dialogue events, public meetings, public hearings, expert discussions, and online conferences via the Internet, entering into intensive contact with people who take an interest in these matters.

By drawing on the new media, it proved possible to offer broad public access to the consultation process.

Not only this exchange with the German population, but also the exchange with members of parliament from other countries proved useful and instructive. The input of different cultural backgrounds which this permitted influenced our biopolitical discourse. It will be helpful, moreover, to continue developing dialogue between members of different parliaments and to improve linkage into the decision-making processes of the European Parliament and the European Commission.

I believe it is essential to impose a ban on cloning human embryos under international law. Parliamentary initiatives to this effect will have to be taken before the 14th legislature is over. Only a worldwide prohibition under international law of the production of human embryos for cloning, whatever their purpose, will erect a bulwark against the abuse of human beings by means of genetic engineering. Only an international ban can guarantee across all cultures and countries that a common moral and ethical boundary will be observed against human rights violations in modern biomedicine.

This general ban on cloning human embryos should, therefore, be incorporated into the Human Rights Charter of the 21st century. Isolated calls for a ban on reproductive cloning are simply no longer enough. In the German Bundestag, there has been a broadly-based consensus to date about wishing to achieve a ban on cloning. The UN General Assembly should definitively begin talks on a global ban on cloning.

All these necessities and circumstances are arguments for establishing another Study Commission when the next government takes office.

2 Supplementary opinions of individual Commission members

2.1 Prof. Dr. Linus Geisler: The changing doctor/patient relationship: Strengthening the principle of dialogue

The change

The perception of medicine and the doctor/patient relationship have been changing since the 1970s[1], mainly due to the influence of technological achievements, as well as developments in society and economic conditions.

The traditional, primarily paternalistic perception of the roles of doctors and patients[2] has been faced with contrapuntal developments that have increasingly undermined the traditional medical mandate (care, relief, prevention) in favour of a service provider/customer relationship. In extreme cases such as in preimplantation genetic diagnosis, it is no longer

[1] Kerschensteiner, H., quoted from Wittern, R. (1991) Kontinuität und Wandel des Arztbildes im Abendland. In: Geßler, U., Pilgrim, R., & Gmelin, B. (Eds.) *Der Arzt*. München-Deisenhofen.
[2] Geisler, L. S. (1993) *Arzt und Patient - Begegnung im Gespräch*, 3rd edition. Frankfurt/Main.

possible to identify a "patient" in the narrower sense[3], and hence, there is no medical mandate[4].

The former *confidential relationship* between doctors and patients has partly been replaced by a *contractual relationship* in which the services to be provided are precisely defined. The patient becomes the customer, the doctor the service provider, and the doctor's office or the hospital becomes the "profit centre"[5]. The interaction between the two parties then often resembles the relationship between two distrustful business partners.

The "trichotomy" between customer service, scientific standards and cost containment, in which medicine increasingly has to operate, makes it more difficult for the parties involved to find their identity ("trilemma of modern medicine"[6]).

Quite often, the services requested are not aimed at solving medical problems; instead, they tend to fall into the category of "life-style medicine". The concept of health nowadays also includes categories such as "beauty" and "wellness". Patient expectations and medical interventions are increasingly also guided by new key concepts such as "quality of life", "normality" and "optimisation".

"Anthropotechnologies" are replacing an allegedly outdated humanism.[7] Manipulative interventions in the germ line are demanded imperatively by U.S. scientists (Gregory Stock[8]), although the propagated methods (e.g. insertion of artificial chromosomes) are problematic for biological reasons, alone.[9]

As the current biopolicy debate shows, definitions of concepts that are acceptable in society such as health, disease and disability are caught in a state of limbo. The subjective nature of being sick, which to a large extent is determined by the patient's "self-assessment"[10] and

[3] Geisler, L. S. (2001a) Kinder auf Bestellung. *Frankfurter Rundschau*, 10 May 2001.
[4] See C1 Preimplantation genetic diagnosis in the Final Report submitted by the Study Commission on "Law and Ethics in Modern Medicine".
[5] Kloiber, O. (2001) Der Patient als Kunde – Der Arzt als Dienstleister. Statement presented at the public dialogue event organised by the Study Commission on "Law and Ethics in Modern Medicine" on 2 July 2001 in Jena. http://www.bundestag.de/gremien/medi/medi_oef5_1.html
[6] Bauer, A. W. (2001) Das Trilemma der Medizin zwischen Wissenschaftlichkeit, Kostendämpfung und Kundendienst. In: Engelhardt, Dietrich von; Loewenich, Volker von; Simon, Alfred (Eds.) *Die Heilberufe auf der Suche nach ihrer Identität. Jahrestagung der Akademie für Ethik in der Medizin e.V. Frankfurt 2000.* Münster/Hamburg/Berlin/London, pp. 94-106.
[7] Sloterdijk, P. (1999) Regeln für den Menschenpark. Ein Antwortschreiben zum Brief über den Humanismus. Suhrkamp Verlag, Frankfurt/Main http://www.wlb-stuttgart.de/referate/philosoph/sloter.html (18 April 2002).
[8] Stock, G. (2001) Unvermeidbare Designer-Babys. *Financial Times Deutschland*, 6 December 2001.
[9] Geisler, L.S. (2001b) Designer-Babys ohne Rücknahmegarantie. *Financial Times Deutschland*, 18 December 2001.
[10] Lanzerath, D. (2000) Krankheit und ärztliches Handeln. Zur Funktion des Krankheitsbegriffs in der medizinischen Ethik. Freiburg/Munich. Cf. in this context pp. 256-263.

which is invariably also based on a disturbance of his or her familiar reality[11], conflicts with other constructs of reality (society, science).[12]

Different methods of translating scientific findings into medical practice – e.g. EBM[13], meta-analyses[14], computer-based decisions[15] or managed-care concepts[16] – are simultaneously in competition with each other. Often it is claimed that such a method is the only principle – and in fact the only legally relevant principle – to guide medical decisions and actions. However, intuitive and experience-based decision-making still plays a considerable role outside universities, especially in the offices of independent physicians. The "clinical perspective", which is mainly based on "soft", non-quantifiable data, often covers up the influence of so-called "hard" data. Today medicine is still primarily a science based on experience. Patient decisions, in turn, are not at all based exclusively on counselling support or the so-called informed consent; instead, they are based to a large extent on non-rational judgements. This system of interactions between doctor and patient leads to medical decisions and actions that, all in all, are less based on rational foundations than is generally assumed. These decisions and actions are the result of circular processes between doctor and patient. Besides, such circular interactions determine the entire doctor/patient relationship. Hence, it will be possible only in exceptional cases to change this relationship intentionally by isolated actions taken by either of the two parties. Essentially, such changes are achieved by means of a dialogue.

Paternalism – autonomy – neo-paternalism

Peter Kampits defines the doctor/patient relationship as a special, if not an extreme form of interhuman relations that involve not only a high degree of intimacy and exposure but which may also be associated with interventions and changes in human existence; in extreme cases, this can go as far as being literally a matter of life and death.[17]

This relationship is usually embedded in a changing context, so that it cannot be expected that a stable balance of power will develop between doctor and patient; instead, there will be a "floating" balance that can hardly be consistently managed with a single mode of human

[11] Pflanz, E. (1993) Krankheit als Störung einer vertrauten Wirklichkeit. *Deutsches Ärzteblatt, 90(19),* B-1023.
[12] Berger, P. L. & Luckmann, T. (1969) Die gesellschaftliche Konstruktion der Wirklichkeit. Eine Theorie der Wissenssoziologie. Frankfurt/Main.
[13] Bock, K.D. (2001) Die Evidenz (in) der Evidence-Based Medicine. *Medizin und Klinik, 96,* pp. 300-304.
[14] Maumann, M. (1999) Metaanalyse klinischer Studien: Stein der Weisen oder Stein des Anstoßes? *Medizin und Klinik, 94,* Suppl II, pp.17-20.
[15] Mazoué, J.G. (1990) Diagnosis without doctors. *The Journal of Medicine and Philosophy*, 15(6), pp. 559-579.
[16] Butzlaff, M. E. et al. (1998) Managed Care im Brennpunkt. Die Organisationsform: Folgen für Patienten und Ärzte. *Gesundheitswesen, 60,* pp. 279-282.
[17] Kampits, P. (1996) Das dialogische Prinzip in der Arzt-Patienten-Beziehung. Passau.

interaction. A one-sided preference for paternalism or autonomy can therefore certainly not be the "panacea" in the relationship between doctor and patient.

Paternalism is generally seen as an encroachment on the freedom of the patient. As G. Dworkin describes it, paternalism is an "interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests or values of the person being coerced"[18]. For T. Pinkard, paternalism is an "encroachment on the individual's freedom that is justified by an appeal to the welfare of the person concerned"[19]. Klaus Dörner describes the paternalistic attitude as follows: "As the subject, I (the doctor) subject you to myself and turn you (the patient) into my object because this is the fastest way for you to become a subject again."[20]

In American colloquial English, this is sometimes referred to as the "father-knows-best" authority. Without any doubt, there is a certain grey area between so-called "strong" and "weak" paternalism. At this point, I do not want to elaborate on other distinctions, e.g. between solicited and unsolicited paternalism.

The perception of autonomy as human self-determination has its roots in the Age of Enlightenment. According to Immanuel Kant's philosophy, it is the human being's autonomy or freedom of will that turns the individual into a person, the same way that a State becomes a State only when it has political autonomy. In this context, the individual's autonomous will stands for reason that is freed of any external or internal heteronomy. Kant perceived autonomy as "the basis of the dignity of human and every rational nature".[21]

When taken to an extreme, the patient's autonomy comes up against its limits where – beyond any reason – it acts only for its own sake and blocks any medical action. Such perception of autonomy leads to mutual isolation and introduces a certain emotional coldness into the relationship between doctor and patient. The fully informed patient finally finds himself or herself in a position of solitude, which is not necessarily offset by the patient's absolute freedom of choice. The doctor, in turn, finds himself or herself (intentionally or

[18] quoted from Kampits (1996).
[19] quoted from Kampits (1996).
[20] Dörner, K. (2001) *Der gute Arzt. Lehrbuch der ärztlichen Grundhaltung*. Stuttgart/New York, p. 71. Dörner continues: "I am so far ahead of you in terms of professional expertise, knowledge and power that you cannot catch up with me. Hence, it makes sense for you to expose and fully entrust yourself to me."
[21] Kant, I. (1980) Kritik der praktischen Vernunft. Grundlegung zur Metaphysik der Sitten. Werkausgabe. Frankfurt/Main, Vol. VII.

unintentionally!) in a submissive role, which is expressed most radically by the metaphor "I am the other's hostage"[22] used repeatedly by Lévinas.

While some suggest that autonomy with regard to one's own life is the core element of human dignity, others believe that autonomy and human dignity are constituted by caring for the other in the first place.[23] The example of living wills shows that, as the patient's will in terms of abstaining from or discontinuing treatment becomes legally binding for the doctor, the doctor/patient relationship is undermined or even destroyed.[24]

In today's perception of the doctor/patient relationship, the principle according to which "the *welfare* of the patient is the cardinal rule" has been replaced by: "the *will* of the patient is the cardinal rule".[25] This development has also been brought about by the increasing regulation of modern medicine. The patient's autonomy takes precedence over the principle of welfare. The earlier concept of paternalism, which attributed a paternally determining role to the doctor, seems to be outdated. Today's ideal patient is a "responsible" patient, i.e. a patient who – after having been informed – assumes responsibility for determining the guidelines of his or her treatment.[26] It must be added though that there can be no "responsible" patient without a "responsible" doctor.[27]

However, how sustainable and viable are patient autonomy and patient responsibility in reality when it matters? Is a patient actually capable of deciding – together with the doctor – what type of an artificial valve or pacemaker is best for him or her? Does the fully informed cancer patient really want to be autonomous in choosing between chemotherapy and radiotherapy? Under such circumstances, do patients still perceive themselves primarily as "responsible" or as sick? How rapidly can autonomy turn into a sense of being left to one's

[22] Lévinas, E. (1993) *Totalität und Unendlichkeit*. Freiburg i.Br.
[23] For an overview, cf. Dörner, K. *et al.* (2002) Patientenverfügungen: Kein "Sterben in Würde". Eine Aufwertung der Ethik der Autonomie des Einzelnen bedeutet eine Dominanz des Stärkeren über die Ethik des Schwachen. *Deutsches Ärzteblatt, 99(14),* A917.
[24] Dörner (2001).
[25] Luther, E.(2001) Chancen und Risiken der Patientenautonomie. Statement presented at the public dialogue event organised by the Study Commission on "Law and Ethics in Modern Medicine" on 2 July 2001 in Jena. http://www.bundestag.de/gremien/medi/medi_oef5_1.html
[26] Baum, E. *et al.* (1996) Erwartungen der Patienten und ärztliches Handeln in Allgemeinpraxen. In: Lang, E. & Arnold, K (Eds.) *Die Arzt-Patientenbeziehung im Wandel*. Schriftenreihe der Hamburg-Mannheimer-Stiftung für Informationsmedizin, Vol. 8. Stuttgart, pp. 137-150.
[27] Uexküll, T.v. (1994) Rückmeldung als Modell interpersonaler Beziehungen: Psychosomatische Medizin als Beziehungsmedizin. In: Hahn, P. *et al.* (Eds.) *Modell und Methode in der Psychosomatik*. Weinheim.

own devices? Schotsmans spoke of the fiction of a kind of "Olympic self-control" that a frail patient would hardly be capable of (any longer).[28]

In reality, a symmetrical doctor/patient relationship, which is often considered to be the ideal, is the exception to the rule. An analysis of consultations frequently shows a surprisingly strong asymmetry. This already becomes obvious – in purely numerical terms – if one compares the predominant share of the conversation during which the doctor speaks (up to 80 per cent) to the patients' share.[29] Bliesener and Köhle referred to the traditional consultation purely and simply as "prevented dialogue".[30] The failure of communication during consultations has even been described in novels (e.g. Thomas Bernhard[31]).

It is questionable whether a symmetrical relationship is actually what patients generally want. Clinical experience has shown that doctor/patient relationships are nearly always asymmetrical. Doctors and patients do not face each other as equals; instead, one party seeks help, and one party is qualified to provide this help.[32] Eibach and Schäfer have drawn attention to discrepancies between patient autonomy and patient wishes.[33] In view of the growing complexity of diagnostic and therapeutic interventions in the wake of high-tech advances in medicine, and the resulting increase in the decision-making powers of doctors, self-determination in the doctor/patient relationship has been referred to as a myth and described with the term "neo-paternalism".[34] Christiane Grefe[35] has underlined that this is not a proud self-image of doctors; instead, it is due to structures that the doctors suffer from themselves.

The view of French doctors in the 19th century, according to which the ideal doctor is a "père maternel" – i.e. a person who manages to combine the characteristics of a guiding father and an understanding mother – does not seem to have lost any of its validity today; instead, it

[28] Schotsmans, P.T. (2002) Der Mensch als Schöpfer. In: Herbert Quandt Foundation (Eds.) *Wem gehört der Mensch?* 17. Sinclair-Haus Gespräch. Bad Homburg v.d. Höhe.
[29] Nordmeyer, J, *et al.* (1982) Verbale und nonverbale Kommunikation zwischen Problempatienten und Ärzten während der Visite. *Medizinische Psychologie*, *8*, pp. 20-39.
[30] Bliesener, T. & Köhle, K. (1978) *Die ärztliche Visite - Chance zum Gespräch*. Opladen.
[31] "The consultation, the highlight of each day, was at the same time always the greatest disappointment." Bernhard, T. (1978) *Der Atem*. Frankfurt/Main.
[32] Tanner, K. (2001) Akzeptierte Abhängigkeit? Zur Rolle des Vertrauens in der Arzt-Patienten-Beziehung. Statement presented at the public dialogue event organised by the Study Commission on "Law and Ethics in Modern Medicine" on 2 July 2001 in Jena. http://www.bundestag.de/gremien/medi/medi_oef5_1.html (18 April 2002).
[33] Eibach, U. & Schaefer, K. (2001) Patientenautonomie und Patientenwünsche. Ergebnisse und ethische Reflexion von Patientenbefragungen zur selbstbestimmten Behandlung in Krisensituationen. *Medizinrecht, 1*, pp. 21-28.
[34] Feuerstein, G. & Kuhlmann, E. (Eds.) (1999) Neopaternalistische Medizin. Der Mythos der Selbstbestimmung im Arzt-Patient-Verhältnis. Bern.
[35] Grefe, C. (2000) "Wie geht's uns denn heute?". Das Krankenhaus der Zukunft, Teil III. *Die Zeit, 38/2000*.

seems that this notion is experiencing a revival in the course of the changes that medicine is undergoing today.

Breakdowns and shortcomings in communication

Communicative relations are the very essence of the doctor/patient relationship and what determines its "chamber pitch". There is general agreement to the effect that, in every-day practice, there are communicative shortcomings that are often not perceived as such by doctors.[36]

The *Akademie für Technologiefolgenabschätzung* (Academy of Technology Assessment) in Baden-Württemberg has recently drawn attention, *inter alia*, to this fact, and in particular to shortcomings in patient information.[37] Although the provision of comprehensive and comprehensible information was rated as "very important" by 93 per cent of the patients interviewed, only close to 30 per cent of the doctors stated that – even in their own assessment – they adequately respond to the patients' wish for information.

It has been demonstrated that communicative breakdowns and shortcomings in the doctor/patient relationship lead to a number of adverse effects, all of which affect the doctor/patient relationship, either directly or indirectly:

– inadequate compliance,[38]
– disturbed confidential relationship,[39]
– break-down of doctor/patient relationship, decision to change physicians.[40]

One major reason for the communicative incompetence of many physicians is that their education tends to be increasingly deficient. A recent study conducted at the University of Göttingen among 700 students shows that, as the body of "biological knowledge" acquired by students in the course of their studies increases, their communicative and psychosocial skills

[36] Geisler, L. S. (1988) Arzt und Patient im Gespräch. Wirklichkeit und Wege. *Deutsches Ärzteblatt, 50,* pp. 3568-3574; Geisler, L. S.(1997) Sprachlose Medizin? *Imago Hominis, IV(1).*
[37] Dierks, M.L. *et al.* (2001) *Patientensouveränität – Der autonome Patient im Mittelpunkt.* Arbeitsbericht Nr. 195 der Akademie für Technologiefolgenabschätzung in Baden-Württemberg. Stuttgart.
[38] Sakett, D. L., Hayner, B. & Taylor, D.W. (1982) *Compliance. Handbuch.* Munich/Vienna.
[39] Goedhuys, J. & Rethan, J. J. (2001) On the relationship between the efficiency and the quality of the consultation. A validity study. *Family Practice, 18(6),* pp. 592-596.
[40] Keating N. L. *et al.* (2002) How are patient's specific ambulatory experiences related to trust, satisfaction, and considering changing physicians? *Journal of general internal medicine: official journal of the Society for Research and Education in Primary Care Internal Medicine, 17(1),* pp. 29-39.

decrease.[41] This problem has often been recognised and criticised by the students themselves.[42]

Efforts made to adapt medical education in Germany to international standards go back a long time. As early as in 1989, a Medical Education Task Force ("Arbeitsgruppe Medizinerausbildung", also referred to as *Murrhardter Kreis*), which had been established by the Robert Bosch Foundation, published a book entitled "*Das Arztbild der Zukunft*" (The future skills required of physicians)[43] in which one of the recommendations made was that greater attention should be paid to the psychosocial aspects of disease.

An amendment to the Regulation Governing the Licensing of Doctors (*Approbationsordnung für Ärzte*) has been discussed in Germany for over a decade. This topic has been addressed by many professional bodies and organisations such as the *Deutscher Ärztetag*, the *Medizinischer Fakultätentag* (MFT) and the *Arbeitsgemeinschaft der wissenschaftlichen Fachgesellschaften* (AWMF). Many dedicated university lecturers who teach medicine expressed their disappointment about years of unsuccessful discussion and felt that the introduction of the "model clause" in 1999 was too small a step.[44] Some have also raised the question as to whether the limited interest in questions of medical education must be seen as a "typically German" phenomenon.[45]

The dialogical principle: Overcoming the choice between paternalism and autonomy

The dialogical approach was developed in the 1920s by the "philosophers of dialogue" such as F. Ebner, M. Buber, F. Rosenzweig, G. Marcel and V. v. Weizsäcker, who is also believed to have coined the term "*sprechende Medizin*" ("talking medicine"). Emmanuel Lévinas formulated the claim of taking responsibility for the other through the other, by way of substitution or being "hostage to the other".[46] The Austrian philosopher Peter Kampits sees

[41] "Studium: Patientengespräche immer unwichtiger". *Ärzte Zeitung*, 30 May 2001.
[42] Andres, M.-S & Gaide, P. (2001) Kein Fleisch, kein Blut. Medizinstudenten klagen über zu wenig Praxis während der Ausbildung. *Die Zeit, 52/2001*. 19 December 2001.
[43] Arnold, M. *et al.* (1995) Das Arztbild der Zukunft, Analysen künftiger Anforderungen an den Arzt, Konsequenzen für die Ausbildung und Wege zu ihrer Reform, 3rd edition. Gerlingen.
[44] Pabst, R. (2000) Steigt das Interesse an Studien zu Fragen der medizinischen Ausbildung in Deutschland? *Deutsche medizinischen Wochenschrift, 125*, p. 716.
[45] International conventions such as the annual conference of the Association of Medical Education in Europe (AMEE), which attracts several hundred participants from all parts of the world, are attended by a notoriously small number of German participants. At the Ottawa Conference on Medical Education in February 2000, for instance, only 4 of the more than 800 participants were from Germany (quoted from Pabst 2000).
[46] Lévinas 1993.

the introduction of the dalogical principle in the doctor/patient relationship as a way of overcoming the alternative between paternalism and autonomy.[47]

Kampits emphasises that the dialogical approach – though related to the traditional concept of human personality originating from Jewish-Christian philosophy – goes further by allowing this personality to develop in the first place in a dialogue resulting from the encounter and relationship between two human beings. A dialogical approach is based from the outset on reciprocity in the relationship. What is essential for the doctor/patient relationship in the dialogical approach is the basic attitude required, which includes being attentive, listening actively and being able to engage in a conversation. The inseparability of trust and paying attention to the other is seen as a key prerequisite for taking action motivated by a dialogue.

Educational objective: Strengthening the dialogical skills of physicians

From a realistic perspective, however, the application of the dialogical principle is hampered by developments that are typical of, and one of the major reasons for, the change occurring in today's medicine (e.g. economic constraints, allocation problems, and increasing regulation).

The doctor/patient relationship continues to be characterised by the often cited "Silent World of Doctor and Patient", which was described so subtly and competently as early as in 1984 by the psychoanalyst and lawyer Jay Katz[48] in his book of the same name.

On the other hand, strengthening the dialogical principle, promoting the development of communicative skills in undergraduate and postgraduate medical education, and upgrading the value of verbal communication, provides the opportunity to contain these developments and to initiate a restructuring of the doctor/patient relationship.[49]

It is worrying to see that recent analyses of the objectives of medical education ("list of reform wishes") have shown that while it is recognised that it is necessary to have good conversational skills, it is assumed at the same time that the persons most likely to be able to teach these skills (or not) are older colleagues and senior physicians by virtue of their role model function.[50] Structured training with the objective of developing and strengthening the

[47] Kampits 1996.
[48] Katz, J. (1984) *The Silent World of Doctor and Patient.* New York.
[49] Geisler, L. S. (2000) "Die Liebe verkümmert". Wohin steuert die Hightech-Medizin? *DER SPIEGEL*, 17 April 2000.
[50] Jocham, D., Schulze, J. & Schmucker, P. (2002) Medizinstudium: Wunschzettel für die Reform. *Deutsches Ärzteblatt, 99(14),* A912.

dialogical skills of future physicians is not postulated with the necessary urgency, although these skills play a key role in improving the doctor/patient relationship.

Strengthening the communicative, and hence psychosocial, skills of physicians during their undergraduate and postgraduate education is an essential and indispensable approach to improving the doctor/patient relationship and should therefore be actively supported by professional bodies, policy-makers and legislators.[51]

An editorial in the British Medical Journal of 6 April 2002 addressed the global phenomenon of "unhappy doctors".[52] The workload and inadequate pay may be important factors, but they do not seem to explain the problem entirely. A key factor identified in the analysis is a change in the relationship between the profession, the patients and society, which is believed to be the root cause for the fact that the profession today no longer corresponds to what the physicians had originally expected it to be.

One potential solution is seen in a new perception of the medical profession, in which there is a fair balance between autonomy (of the patient) and responsibility (of the doctor).[53] The dialogical principle can make a major contribution towards establishing this balance.

[51] Geisler, L. S. (2000); Stein, R.(2001) Was sollen Mediziner lernen? *Frankfurter Allgemeine Zeitung*. 18 July 2001.
[52] Edwards, N. *et al.* (2002) Unhappy doctors: what are the causes and what can be done? *BMJ*, *324*, pp. 835-838.
[53] Ham, C. & Alberti, K. G. (2002) The medical profession, the public, and the government. *BMJ*, *324*, pp. 838-842.

2.2 Prof. Dr. Ernst Luther/Dr. Ilja Seifert: The perception of health, disease and disability in society

Health and sickness as conditions of vital activity

The terms *healthy* and *sick* describe the two principal manifestations of the state of health as a condition of environmentally-related vital organismic activity at a given point in time. Patibility – the ability to become sick – is a characteristic shared by all living beings. The scale of conditions describing an individual's state of health is not limited to being "healthy" or "sick"; instead, there is also a differentiated transitional field between healthiness and sickness, and there are other forms of restricted vital activity and ailments that are associated with the development of diseases. Sickness can end with the restoration of health, a limited adjusted state of restricted vital activity, an ailment, or death. Human beings share these phenomena with other living beings. At the same time, however, there are some particularities that result from specific physical and psychological features of the human being and from the historical development of life in society that all human beings depend on, whether healthy or sick. Generally speaking, it is therefore not possible to grasp human health and disease only in scientific terms; instead, it is necessary to consider the biotic, mental and social dimensions as well as their interdependencies from an ontogenetic, ecological and historical perspective. In order to establish the correct diagnosis, it is also very important to know culturally-related expressions of disease symptoms, especially in view of the relatively high percentage of foreigners among patients in Germany. The strongest transcultural differences can be observed in mental and psychiatric disorders.[1]

Causes, conditions and patterns affecting an individual's state of health are highly diverse in their origins, ranging from the level of molecular organisation to the entire system of the human organism. Furthermore, they may be related to the human personality and the social conditions shaping this personality, as well as the resulting attitudes to the results of a society's work and the natural environment. Healthiness is an individual's ability to make conscious and systematic efforts – within the framework of the concrete historical options

[1] Cf. Engelhardt, D. (1995) Der Wandel der Vorstellungen von Gesundheit und Krankheit in der Geschichte der Medizin: Erfahrungen der Vergangenheit – Anregungen für die Zukunft. Passau; Duden, B. & Zimmermann, B. (2001) Aspekte des Wandels des Verständnisses von Gesundheit/Krankheit/Behinderung als Folge der modernen Medizin. Gutachten im Auftrag der Enquete-Kommission "Recht und Ethik der modernen Medizin"; Pfeiffer, W. M. (1994) Transkulturelle Psychiatrie. Ergebnisse und Probleme, 2nd edition Stuttgart/New York.

available in a given society – to participate actively in shaping societal life, and in doing so, to find satisfaction in enjoying the material goods. Sickness, on the other hand, means that this ability is considerably restricted by changes in physical and/or mental functions; and at the same time, sickness is a condition of human life that significantly changes and impairs the individual's social position and subjective situation.

For each of the three most important observers – the patient, the doctor and society – disease means something different, even at the level of its immediate occurrence. The behaviour of sick persons, for instance, differs relative to these three groups: "relative to the disease, they are individuals who suffer; relative to the doctor, they are individuals in need of expert assistance; and relative to society, they are individuals in need of care".[2] From the perspective of today's knowledge, the question as to what human health and disease are cannot be answered by a universal definition for all purposes but only by interdisciplinary theoretical work that critically analyses the various aspects and context-related health and disease concepts as well as their interrelations, and then synthesises the result. In the final analysis, what is at stake is a theory of the human being's state of health and its principal manifestations, i.e. healthiness and sickness. Scholarly standards and humanistic values call for the adoption of a multidimensional approach and a combination between analytical/reductive and systemic/holistic ways of thinking. The evolutionary complexity and holistic integration of the human organism, which makes the human being a being with thoughts, feelings and wants, as well as the human being's social and cultural existence in its historical dimension, and the dependence of human beings on their natural living conditions, are overarching, central themes for the theoretical understanding of human health and disease.

The concept of norms, the image of the human being and disability

The commonly used definition of disease or sickness as something that is "abnormal" – with "normal" (= complying with the norm or standard) being equated to being healthy – needs to be criticised. Medical norms or standards are not based on value judgements but on numbers that are obtained by counting, measuring and weighing, where certain numerical values that are used as criteria or indexes play a role in the diagnosis or treatment of specific diseases or in recommendations of health-promoting life-styles (e.g. the so-called normal and ideal weight). There is a wide variety of norms: minimum norms that define disease boundaries; majority norms that result from statistical averages; ideal norms that indicate maximum performance levels; and special norms that serve as yardsticks for measuring special

capabilities. Since such norms depend on schools of medical thought, which vary over time, they are also variable. While health and disease are subject to socio-cultural assessments, they are not constituted by such assessments. As a rule, health is considered to be positive, and disease is perceived as something negative. There are also positive assessments of disease – e.g. in metaphysical disease concepts (where disease is perceived as something that is brought about by supernatural forces to serve as a punishment or as an opportunity to find the meaning of life) – however, without calling into question the disease as such.

Images of the human being provide answers to questions about the position of human beings in the world, their nature and character, their origin and future, their skills of cognition and action, the meaning of life, and the conditions for living a meaningful life. In the context of the answers to these questions, it is indispensable to include statements on human health, disease and disability; otherwise, there would be considerable gaps in the answers. And conversely, any logical study of human health, disease, and disability – conducted for whatever reason – will inevitably lead to the question as to what the human being is and what role health, disease and disability play in the human being's overall character and appearance.

One of the historic achievements of humanistic images of humanity is the principle that all human beings are equal (equal value, equal rights), regardless of all their differences. And in the struggle against social inequality and oppression, against ethnocentrism and racism, sexism and other forms of ideological and practical discrimination against groups of human beings, this principle leads to calls for equal (equitable) opportunities. There are two aspects to equal opportunity: "First of all, everyone is entitled to have access to the entire spectrum of status and income levels, irrespective of the status and income of their parents or relatives. (...) The second and less obvious condition for equal opportunity is the realisation that different individuals with different genetic make-ups need different environments for their self-realisation. (...) Ideal equality would include the availability of a variety of different educational options that everyone could choose or be recommended in accordance with their own preferences and aptitudes."[3]

Both aspects of equal opportunity particularly affect persons with disabilities. Traditional attitudes – prompted by the fear and rejection of what was alien and inexplicable – that have led to the perception of persons with disabilities as "cripples" and of non-disabled persons as "normal" have not yet disappeared. Pseudoscientific concepts such as Social Darwinism and

[2] Rothschuh, K.E.: Zwei Beiträge zur Allgemeinen Krankheitslehre. Stuttgart 1973, p. 12.
[3] Dobzhansky, T. (1975) *Intelligenz. Vererbung und Umwelt*. Munich, p. 55.

eugenics/racial hygiene that provide a justification for such treatment of fellow human beings are complemented by profit-centred cost/benefit analyses.[4]

Disability has been characterised as a "process of social impairment of the opportunities of human individuals in life – a process that curtails the development of the individual's personality due to a lack of mediation processes between the individual and society. (...) Whether potential sources of isolation (e.g. injuries of organs, traumatic events in life, social exclusion from opportunities in life through unemployment, for instance) actually hamper an individual's development, and if so, to what extent, depends on the stage of development of the individual's activity and personality, as well as the wealth, scope and inner quality of social relations in this situation."[5]

According to the German Council on Disability (*Deutscher Behindertenrat*), disability is "any behaviour, action or structure that hampers, restricts or eliminates opportunities to live, develop and participate for individuals with not only temporary physical, mental or psychological disabilities".[6]

The problem of disability and of equal opportunity for individuals with disabilities is not a problem of a medical nature, but a problem of human emancipation and equality. For the sake of social equality and integration, medical, educational and other means are used in order to promote the development of the potential of individuals, thereby enhancing their opportunities. This poses specific problems for people with physical, psychological or mental disabilities or with multiple disabilities. In view of the correlation between the state of health and disability, the following statement in the Constitution of the World Health Organisation gains particular importance: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[7]

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[4] Löther, R. (1992) Der unvollkommene Mensch. Philosophische Anthropologie und biologische Evolutionstheorie. Berlin.

[5] Jantzen, W. (1990) Behinderung. In: Sandkühler, H. J. (Eds.) *Europäische Enzyklopädie zu Philosophie und Wissenschaften*, Vol.1, Hamburg; Löther (1992).

[6] Statement made by Ingrid Körner, the spokesperson of the German Council, on the occasion of the World Disability Day on 3 December 2001 in the German Federal Ministry of Labour. Quoted from Bartz, E. (2002) Welttag der Behinderten am 3. Dezember. *Leben und Weg*, February 2002, p. 7.

[7] Spröte, H. & Wünsche, R. (1976) Die Vereinten Nationen und ihre Spezialorganisationen. Dokumente, Vol.7, Die Weltgesundheitsorganisation. Berlin.

Health, disease, and life expectancy

The healthiness or sickness of individuals is part of wider social and cultural interdependencies that are integrated into the socio-cultural evolution. This is demonstrated by changes in life expectancy, the structure of morbidity and causes of death, all of which in the final analysis are rooted in society. Increasing life expectancy leads to a radical transformation of the population's age structure. As a result, chronic degenerative diseases (cardiovascular disorders, degenerative diseases of the locomotor apparatus, malignant tumours) increasingly move into the focus of medical attention and confront medical research with new problems. The mono-causal and linear-causal approach of mechanical determinism, as well as one-sided medicine with an exclusively scientific bias, has proven to be inadequate to cope with the health problems of human beings, not least in connection with the search for the causes of these chronic diseases.

There have also been major changes in the relative importance of medically relevant social factors. In the industrialised nations, the social factors related to the material living conditions are no longer of primary importance. Although their impact is far from being negligible today, they have generally been replaced by factors related to interhuman relations and the socio-cultural environment, in particular as manifested through patterns of behaviour. These factors are values and behaviours that are propagated in society but that conflict with material living conditions. Not only the pathogenesis, but also the course and the outcome of chronic diseases are influenced by social factors. For the treatment of these diseases, a change in life-style is often as important, or even more important than drug therapy. For the most part, hopes for a recovery prove to be an illusion.[8]

While communicable diseases have been pushed back in the industrialised nations, they are the most frequent cause of death worldwide, and the number of fatalities is still on the rise. Because of their connection with poverty, lack of clean water, sanitary facilities and primary medical care, communicable diseases mainly affect developing countries. However, no country is safe from them. The failure to help build up primary medical care systems in developing countries, the scant attention paid to the problem of communicable diseases in the industrialised nations, global tourism and trade, as well as the growing resistance of pathogens to drugs, can lead to a return of the great plagues to the industrialised nations, as well; such a development is also fostered by global climate change and its effects on flora and fauna. In

[8] Wunder, M. (2002) Der biomedizinische Fortschritt als Herausforderung an Medizin und Gewissen. In: Schubert-Lehnhardt, V. (Eds.) Medizin-Ethik quo vadis? Versuch einer Antwort. Storbeck 2002.

addition, deadly epidemics may be caused by the use of genetically modified pathogens as biological weapons of mass destruction, for which there are neither drugs nor vaccines. Since communicable diseases cannot be eradicated or controlled sustainably by specific drugs, combating these diseases will be an ongoing challenge.[9]

Biomedicine with its various branches (e.g. medical genetics, gene therapy, reproductive medicine, regenerative medicine and others) has proven to be particularly problematic.[10] Although the scientific development in this field is still largely at the stage of basic research with open-ended results, desirable results for diagnosis, therapy and prevention are being anticipated, and there are visions of a medical practice that can virtually do anything. A new type of eugenics ("eugenics from the bottom", "liberal eugenics") relies on genomics and genetic engineering and – with the promise of perfect offspring – on the more subtle constraints of the market and a public opinion that discriminates against people with a disease or disability. This ideology, which is inspired by genetic mythology, implies an attack on human dignity which cannot be graduated or linked to specific characteristics of human life.[11]

Since the individual's state of health is subject to a wide variety of factors that are largely beyond the individual's control, the idea of imposing a duty on the individual to stay healthy is as unrealistic as individuals believing that society owes them a right to health.[12] A negative assessment of, and discrimination against, sick persons because of their disease – whatever it may be – is as incompatible with humanism as the glorification of pain and suffering. The tendency to "desolidarise", privatise and personalise the treatment of health and disease in society and to surrender both to the market has proven to be incompatible with social welfare. There are two options for individuals to influence their state of health in a positive way: one is to modify their personal life-style, although the opportunities available for individuals in this field are limited and unreliable; and the other, more important option is to convince the business community and government through organised lobbying that they should create health-promoting living conditions, which also includes a welfare system that provides equal access to optimum medical care for all citizens.

[9] Wilson, W. O. (2002) *Die Zukunft des Lebens*. Berlin.
[10] Lanzerath, D. & Honnefelder, L. (1998) Krankheitsbegriff und ärztliche Anwendung der Humangenetik. In: Düwell, M. & Mieth, D. (Eds.) *Ethik in der Humangenetik*. Tübingen/Basle.
[11] Wade, N. (2001) Das Genom-Projekt und die Neue Medizin. Berlin.
[12] Patzig, G. (1989) Gibt es eine Gesundheitspflicht? *Ethik in der Medizin*, 1, pp. 3-12.

Conclusions

The Study Commission did not have the time to address the issue of "health, disease, and disability", although this topic warrants an in-depth debate. The following subjects would be worth examining in a future study:[13]

- What lessons can the Federal Republic of Germany learn from the world's various health care systems?
- What are the prospects of the health care system in view of conflicting political interests?
- Is our medical education system in Germany still up to date?
- What new findings in genetics will influence diagnosis and therapy?
- What new findings are there with regard to the relationship between the environment and health?
- What changes should be implemented in the administrative structures of the health care system?
- What alternative treatments should be supported?
- What are the future prospects of the hospital sector?
- What developments can be expected in the fields of information and communication technologies as well as data processing?
- How important will psychosocial skills be for older persons?
- What can be done to continue to promote equal treatment of persons with disabilities?
- What can be done to overcome child poverty?
- What will be the tasks of terminal care?
- What concepts for the prevention of diseases have proven to be effective?
- What ideas are needed to initiate change in the various medical disciplines?

[13] Some of the topics are based on the comprehensive publication by Heiß, G. (Ed.) (2000) Wie krank ist unser Gesundheitswesen? Das Gesundheitswesen in Deutschland und Europa an der Schwelle zum 21. Jahrhundert. Mainz.

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4 Glossary

adult onset — A genetic condition is an adult-onset disorder if it manifests itself in the → *phenotype* only later in a person's life, e.g. → Huntington's disease

alleles — Alleles are alternative forms of the same gene. For every gene, two alleles (one each on the maternal and paternal set of chromosomes) are present in the → *cell nucleus*; alleles may be either identical (→ *homozygous*) or different (→ *heterozygous*)

amniocentesis — "Amniotic fluid analysis"; → *prenatal* diagnostic procedure in which a sample of the amniotic fluid is withdrawn from the amniotic cavity by piercing the amniotic sac. The cells retrieved from the amniotic fluid, which mostly originate from the zona pellucida and partly also from the skin and mucosae of the → *foetus*, can be cultivated and subjected to biochemical, cytogenetic (→ *cytogenetic test*) and molecular genetic (→ *DNA analyses*) tests

aneuploidy — Any deviation from the normal number of → *chromosomes* in the → *cell nucleus*

anonymisation — Changing personal data in such a way that a connection between an identified or identifiable person and individual data on personal or factual conditions can only be established with an extraordinary effort or not at all (→ *pseudonymisation*)

anti-selection — Adverse selection; the risk of anti-selection in the insurance sector is that applicants can take out insurance cover that is not in keeping with their individual risk profile because they fail to disclose information that only they have about facts increasing the risk, thus using their knowledge in their own favour and to the disadvantage of an insurance company or the community of those insured

arrest — Here: standstill of embryonic development, e.g. when the fertilised egg cell does not develop beyond the → *pronuclear stage* into an → *embryo*

artificial fertilisation — → *in-vitro fertilisation*

assisted reproduction — Collective term covering all medical treatments and procedures (e.g. the surgical removal of egg cells from a woman's ovaries or various procedures of artificial egg cell fertilisation) that are performed with the aim of helping a couple to conceive by means of medical assistance and techniques (homologous und heterologous → *insemination*, → *intracytoplasmic sperm injection*)

autosomes — → *chromosomes* that are present in pairs in both sexes

baby take-home rate	Probability of a live birth after the beginning of medical-pharmacological procedures (hormonal stimulation of egg cell maturation) performed on a woman's body
biopsy	Removal of tissues, body fluids etc. from the living organism for testing and analytical purposes
blastocyst	An early stage of embryonic development, in humans around the fourth to sixth day after fertilisation, consisting of about 100 to 200 cells. The outer cell layer (trophoblast) later forms part of the → *placenta*, the inner cell mass (embryoblast) consists of precursor cells of the → *embryo*
blastomeres	Cells produced by cleavage of the → *zygote*
capacitation	Describing the biochemical and physiological changes not yet completely understood that sperm usually undergoes in the female genital tract and that enable it to penetrate into and fertilise an oocyte
cell nucleus	Part of the cell that contains the → *chromosomes*
chorion	Outer membrane of the → *blastocyst*
chorionic villus sampling	→ *prenatal* diagnostic procedure in which a sample of → *chorionic villus tissue* is taken from a pregnant women by inserting a cannula through the abdomen or cervix; the tissue is of foetal origin and can be subjected to → *cytogenetic* and/or molecular genetic tests (→ *DNA analyses*)
chromosomes	Structures of → *DNA* and → *proteins* found in the cell nucleus which carry genetic information and aggregate during cell divisions, a process which is visible under the microscope. The number and shape of chromosomes are species-specific. Every human body cell contains 23 pairs of chromosomes, 22 pairs of → *autosomes*, and one pair of sex chromosomes (→ *diploid* set of chromosomes); each → germ cell has only a single set of chromosomes (→ *haploid* set of chromosomes)
compliance	Here: the patient's active co-operation in the measures suggested by the physician (e.g. reliable intake of medication)
cryopreservation	Procedure to preserve fertilised → *pronuclear stage* oocytes or → *embryos* (in Germany permitted only in exceptional cases) as well as egg cells, sperm, testicular and ovarian tissue, spermatogones, stem cells etc. Cryopreservation consists in cooling down the material by adding special freezing and culture media. Then the cells or tissues can be stored over prolonged periods at –196°C in special tanks filled with nitrogen.

cystic fibrosis	Most common → *autosomal* → *recessive* and as yet incurable metabolic disorder which usually leads to severe complications as early as in childhood by congesting the respiratory and GI tract with thick mucus; the life expectancy of the persons affected is severely limited
cytogenetic test	Test to determine the number and structure of → *chromosomes* (→ *genetic tests*)
deterministic	Strictly following the rules and laws of nature; a system or – more generally, a kind of behaviour – is described as deterministic if its future behaviour strictly follows from its present condition (→ *genetic determinism*)
diploid	Having a full set of genetic material consisting of paired chromosomes. Unlike human germ cells, somatic cells have a diploid set of chromosomes. (→ *haploid*)
direct genetic test	Direct detection of a → *mutation* in the → *DNA* sequence. For direct genetic tests, the gene wholly or partly responsible for a disease has to be known and be amenable to direct analysis by means of a suitable technique such as → *polymerase chain reaction*. (→ *indirect genetic test*)
DNA	Deoxyribonucleic acid; molecule consisting of → *nucleotides* and arranged in two strands wound around each other (double helix); it carries the genetic code of an organism.
DNA analyses	Molecular genetic tests, methods to determine the structure of → *genes* (→ *direct genetic test*, → *indirect genetic test*)
DNA chip	Microbiological measuring tool, representing a symbiosis of computer technology and biotechnology. In simplified terms, a DNA chip is a carrier consisting of silicon, glass or other materials on which thousands of DNA molecules can be deposited, which then are compared with the → *DNA* of a sample (e.g. taken from a test person). It is hoped that in future any type of → *mutation* can be identified in this way
dominant	Here: unlike → *recessive* traits, dominant traits are expressed in the → *phenotype*, even if they have been passed on by only one parent (→ *alleles*)
Down syndrome	Numerical chromosomal disorder where chromosome 21 is present in triplicate instead of a pair (trisomy 21) (→ *aneuploidy*) and which leads to physical anomalies and moderate - rarely severe - mental deficiency

Duchenne muscular dystrophy	Common, sex-linked hereditary disease caused by a defective → *gene* on the X-chromosome (→ *chromosome*) which is nearly always restricted to boys. The disease is severe and cannot be cured. It is associated with progressive muscular weakness and degeneration and severely shortens the life expectancy of the persons affected
embryo	Term used inconsistently. In this report, all developmental stages of a fertilised oocyte that is capable of development up to the completion of organ formation are referred to as an embryo (→ *zygote*, → *morula*, → *blastocyst*). Sec. 8 of the German Embryo Protection Act also describes the embryo as the fertilised egg cell that is capable of development from the point of karyogamy onwards. In medical terminology, however, the embryo is often described as the product of conception within the uterus during the time of organ formation, i.e. approximately from the time of → *nidation* in the lining of the uterus up to the end of the third month of pregnancy. From the time when organ development has been completed until the end of pregnancy, the unborn child is referred to as a → *foetus*. (→ *zygote*)
embryo transfer	Emplacement of an → *in-vitro* → *embryo* into a woman's womb
enhancement	Here: strategies to "improve" the genetic material
epigenetic	Collective term used to describe all the effects on the development of an organism that are not directly encoded in the → *nucleotide* sequence and may be the result of interactions between genetic factors or between genetic and environmental factors
eugenics	Scientific study of selective breeding; the aim of eugenics is to limit the spreading of "unfavourable" genes (negative eugenics) and to ensure and encourage the continued existence of "favourable" genes (positive eugenics) within a population by applying genetic findings
evidence-based medicine	Research area of medicine which – with the aim of using only validated findings – endeavours to integrate data from clinically relevant research (research evidence) with clinical experience and expertise
exogenous	Originating outside the body, caused by external factors
exposure	Here: exposure of an organism to pathogenic environmental factors
extracorporeal	Situated or occurring outside the body (→ *intracorporeal*)

family balancing	Parents who already have at least one child have the possibility to combine a planned → *in-vitro fertilisation* or → *intrauterine* insemination with selecting the sex of the future child in order to achieve a balance of the sexes within the family
foetal erythroblastosis	Incompatibility of the rhesus blood groups between mother and unborn or newly born child. This incompatibility usually becomes manifest only in the second child and leads to increased neonatal jaundice, anaemia, possibly with dangerous to lethal complications
foetus	In medical terminology, the unborn offspring after completion of organ development (→ *embryo*)
FISH analysis	Fluorescence In Situ Hybridisation (FISH) is a technique for visualising → *chromosomes* or chromosome segments by means of → *DNA probes* labelled with fluorescent dyes (→ *hybridisation*)
follicle	Fluid-filled sac in the ovary which contains the egg cell (oocyte) and epithelial cells and is surrounded by a thin membrane
gamete intrafallopian transfer	Simultaneous artificial emplacement of sperm and egg cell into the fallopian tube with the aim of fertilisation
gametes	Male or female sex cells (→ *germ cells*)
gene	Basic functional unit of genetic material (→ *genome*). Being a sequence of → *nucleotides* at a certain point in the → *chromosome*, the gene encodes information for the production of amino acids
gene expression	Translation of genetic information into a gene product, mostly a → *protein*
gene therapy	Method to treat diseases by manipulating the genetic information of the affected cells. Unlike interventions in the → *germ line*, genetic changes relating to somatic cells are not inheritable (→ *somatic* gene therapy.). Gene therapy is still at an experimental stage; clinical standard applications do not yet exist
genetic data	Information on the genetic material (→ *genome*) of a person
genetic determinism	Clear and unambiguous determination of the → *phenotype* by the → *genotype* (→ *deterministic*)
genetic fingerprint	Molecular biological test to identify a person (e.g. paternity test)
genetic test	Collective term covering all analyses directly aiming to obtain information on the genetic make-up of a person (→ *DNA*

	analyses, → *cytogenetic tests*)
genome	Genetic material; total genetic information of a cell or an organism
genome analysis	Tests at various levels (→ *phenotype* analysis, → *protein* analysis, *cytogenetic tests*, → *DNA analysis*) which directly aim to obtain information on the genetic make-up of a living organism
genotype	Collective term comprising all genetic information that are encoded in the genes of an organism and that can manifest themselves in the → *phenotype*
germ cells	Sex cells of an organism, e.g. oocyte, spermatozoon (→ *gametes*)
germ layers	Generally: describing the three distinct types of tissue found in the early stages of embryonic development, i.e. ectoderm, entoderm and mesoderm, which can be traced throughout the further development of the → *embryo* as they differentiate to form the entire range of body structures
germ line	All cells which in one cell line lead from the fertilised egg cell to the → *germ cells* of the organism resulting from it as well as the oocyte from the point of injection or penetration of the spermatozoon until the end of the fertilisation process, i.e. conjugation of the nuclei
haemochromatosis	Iron-storage disease; with a → *prevalence* of about 1:400, haemochromatosis is among the most common autosomal recessive metabolic disorders (→ *autosomes*, → *recessive*)
haploid	A single, complete → *set of chromosomes* in which each chromosome is present only once. Unlike somatic cells, human → *germ cells* have a haploid set of chromosomes (→ *diploid*)
hereditary	Inherited, inheritable
heterologous	Different; in reproductive medicine, heterologous → *insemination* means that the couple from whom the → *germ cells* originate are not married to each other or do not live in a common-law marriage (→ *homologous*)
proof of heterozygosity	Proof of the existence of heterozygosity and hence the fact that the person concerned is the carrier of a certain recessive → *gene* that cannot be identified in the → *phenotype* (→ *heterozygous*)
heterozygous	Heterozygous for a particular gene, i.e. the two → *alleles* of a gene are not identical

homologous	Generally: identical; in reproductive medicine homologous → *insemination* means that the couple from whom the → *germ cells* originate are married to each other or live in a common-law marriage (→ *heterologous*)
homozygous	Homozygous for a particular gene, i.e. the two → *alleles* of a gene are identical
Huntington's disease	Incurable, hereditary → *adult-onset* neurological disease, usually occurring between 30 and 45 years of age and leading to jerky involuntary movements and the progressive decline of mental abilities
hybridisation	Molecular genetic procedure in which two complementary single→ *DNA* strands are allowed to interact so that double-stranded DNA is formed by base pairs (→ *FISH analysis*)
hydrocephalus	Literally: water head; hydrocephalus can occur at the → *prenatal* or postnatal stage as a consequence of a disorder of the cerebrospinal fluid system. Possible precipitants include (prenatal) malformations, cerebral haemorrhages, meningitis, injuries or tumours. The resulting intracranial pressure can only be controlled by surgically implanting a valve system. The condition is incurable. Concomitant symptoms can include developmental disorders, convulsive disorders, visual impairment and disorders of locomotor co-ordination (→ *neural tube*)
imprinting	Varying expression of a gene (→ *gene expression*) or a gene section, depending on whether the → *allele* was inherited from the mother or the father
in vitro	Outside a living organism, outside the body, in the laboratory (→ *in vivo*)
in-vitro fertilisation (IVF)	Union of egg cell and sperm outside the body (→ *in vitro*); in-vitro fertilisation is one of the established procedures of → *assisted reproduction*
in vivo	Inside a living organism, inside the body (→ *in vitro*)
indirect genetic test	Genetic test for diseases by using → *markers* in the → *DNA* sequence which mostly are passed on to offspring together with the defective gene (→ *direct genetic test*). This test is used if only the approximate position of the defective gene is known that is fully or partly responsible for the disease, but the defective gene itself has not (yet) been identified. Using an indirect genetic test always requires several family members to be tested and provides information on the statistical probability of the occurrence of the disease in question.

infaust	unfavourable; prognosis for diseases for which there is no prospect of healing
infertility	In reproductive medicine, infertility is the inability to sustain a full-term pregnancy and give birth to a viable infant
informed consent	Voluntary agreement after education and information; self-determined assent of individual patients or test subjects to treatment or enrolment in a research project
insemination	"Fertilisation"; insemination is the artificial introduction of sperm into the female genital tract, if possible at the time of ovulation, in order to enable a number of fertilisation-competent spermatozoa to reach the oocyte. A distinction can be made between → *homologous* insemination (fertilisation with the sperm of a man who is married to the woman concerned, or who lives with her in a common-law marriage) and → *heterologous* insemination (fertilisation with donor sperm)
intracorporeal	Within the body (→ *extracorporeal*)
intracytoplasmic sperm injection (ICSI)	Procedure of → *assisted reproduction* in which an egg cell is fertilised by direct injection of a single sperm
intratubal	In or into the (fallopian) tube (oviduct)
intrauterine	Located inside the uterus (womb), in or into the uterus
juvenile diabetes	Type of diabetes mellitus that is based on a genetic predisposition and occurs in childhood or adolescence as a result of insulin secretion disorders (type I diabetes, insulin-dependent diabetes)
lethal	Causing death, fatal
malignancy	Malignant tumour
malignant	Severe and tending to become progressively worse
marker	Here: → *nucleotide* sequence identifiable in the → *DNA* which is usually passed on to offspring together with genetic changes. It is assumed that when the identifiable marker is passed on, a special genetic defect is passed on as well, so that the marker can be used for the indirect identification of this defect (→ indirect genetic test)
monitoring	Long-term observation of a particular system
monogenic	Monogenic diseases are hereditary diseases caused by changes in a single → *gene* (→ *polygenic*, → *multifactorial*)

morula	Stage of embryonic development at which → *blastomeres* are no longer individually identifiable, but are present as a solid ball of cells
mosaicism	Co-existence of at least two genetically different cell lines in an individual. Mosaicism occurs after → *zygote* formation through mutations of a → *gene*, → *genome* or chromosome (→ *chromosomes*; → *mutation*)
multifactorial	Multifactorial disorders are hereditary diseases caused by the joint action of several factors (→ *monogenic*, → *polygenic*)
mutagenic	Changing the DNA (→ *DNA*, → *mutation*)
mutation	Change in the → *DNA* sequence that occurs spontaneously or is induced by environmental influences or specific deliberate interventions
neck fold	Measuring the thickness of the neck fold of an → *embryo* with → *ultrasound* (nuchal translucency scan) permits early identification of a risk to develop → *Down syndrome*. A thickness of more than 3 mm is closely associated with an increased risk of trisomy 21 and usually leads to invasive prenatal diagnosis
neonatal	Relating to the newly born baby
neural tube	An → embryonic structure from which the central and peripheral nervous systems of the child develop. This structure develops already in the second or third week of pregnancy. Neural tube defects include e.g. → *spina bifida*, → *hydrocephalus* etc.
nidation	Implantation of the → *blastocyst* into the lining of the uterus, a process that in humans is completed around the twelfth day after conception
nuclear genome	The → *DNA* of the → *cell nucleus*
nucleotide	Single → *DNA* subunit consisting of one of the four bases (adenine, cytosine, guanine, thymine), a phosphoric acid residue and a sugar molecule
nucleotide sequence	Order of → *nucleotides* in → *DNA*
oocyte	Egg cell
orphan drugs	Orphan drugs serve to treat disorders that are so rare that the pharmaceutical industry is reluctant to develop drugs for their treatment under normal market conditions
ovary	Main female reproductive organ

ovulation	Bursting of a → *follicle* in the ovary releasing a mature ovum which usually starts to travel down the fallopian tube (→ superovulation)
pathogenic	Capable of causing disease
penetrance	Indicates the probability with which a change in a gene within a population leads to the expression of a disease phenotype
perinatal	Relating to the time shortly before, during and shortly after birth
pharmacogenetics	Describes genetic factors as the cause of individual differences in patient response to the intake of drugs. Unlike → *pharmacogenomics*, which comprises the totality of all different processes in the → *genes*, pharmacogenetics refers only to certain pharmacologically interesting genes
pharmacogenomics	→ *pharmacogenetics*
phenotype	The observable expression of a trait brought about by the interaction of genetic information (→ *genotype*) and environmental factors
phenylketonuria	Rare hereditary metabolic disorder in which a defective gene prevents the complete breakdown of the amino acid phenylalanine, which can lead to severe mental retardation. A special diet can prevent symptoms from developing.
placenta	Organ within the uterus, the greater part of which consists of foetal cells and the smaller part of maternal cells; responsible for providing the foetus with nourishment (exchange of metabolic products and respiratory gases) and for the production of various hormones; expelled after delivery (afterbirth)
pluripotency	Ability of a cell or a tissue to differentiate into more than one type of cell or tissue under favourable conditions (→ *totipotency*)
polar body	In the process of egg cell maturation, two polar bodies are produced as a result of divisions. Shortly before ovulation, a first asymmetric meiotic division occurs in the egg cell. In addition to the mature oocyte, the first so-called polar body is formed as a result, which has a set of identical → *chromosomes*, even though the → *nucleotide sequences* differ. After the oocyte has been fertilised by a sperm, it undergoes a second division before the male and female pronuclei unite. In this process, the → *haploid* female nucleus is first duplicated, then it divides, and one half is deposited between the actual egg cell and the zona pellucida as the second polar body, which is genetically identical with the oocyte

polar body diagnosis	Diagnostic procedure in which the as yet unfertilised egg cell or rather its → *polar bodies* are analysed at the → *pronuclear stage*
polygenic	A polygenic disease is caused by changes and/or the joint action of changes in several → *genes* that cannot be clearly distinguished from each other (→ *monogenic*, → *multifactorial*)
polymerase chain reaction (PCR)	Molecular genetic procedure to amplify defined → *DNA* sections
polymorphism	A genetic polymorphism is the existence in a population of at least two different → *alleles* at one locus
postmortal	Post mortem, after death
pre-conception	Before fertilisation
predictive	Making a prediction
predisposition	Here: genetic inclination to express certain characteristics
preimplantation genetic diagnosis (PGD)	Specific genetic diagnosis performed on individual embryonic cells (→ *embryo*) after → *in-vitro fertilisation* prior to a possible implantation into a woman's uterus
prenatal	Before birth
presymptomatic	Condition prior to the development of a particular symptom; genetic tests are referred to as presymptomatic when they are performed with the aim of defining genetic structures that provide information on the probability of a future disease or disability
prevalence	Frequency rate of a certain disease or a certain trait at a particular time or over a stated period
pronuclear stage	Stage at which fertilisation has begun after penetration of the sperm, but conjugation of the nuclei of oocyte and spermatozoon (karyogamy) has not yet occurred
prospective	Forward-looking; the method of data capture immediately after the event in question is referred to as prospective, i.e. all data are entered into the database, regardless of the further development of treatment. In retrospective data capture, on the other hand, data are entered into the database only when the treatment results are available. This method involves the risk of data selection and hence of biasing statistics.
protein	Essential constituent of the body
pseudonymisation	In pseudonymisation, data directly identifying a person are

	changed by a project-specific code in such a way that the resulting pseudonym can only be used to identify a natural person if this code is known (→ *anonymisation*)
recessive	Characteristics which – unlike → *dominant* characteristics – are only expressed in the phenotype when they were passed on by both parents (→ *alleles*)
reference genome	The reference or basic genome describes the genetic make-up shared by all humans, thus permitting a comparison with the genomes of other organisms
reliability	Trustworthiness of a research result, a measuring instrument or a study
retrospective	→ *prospective*
RNA	Ribonucleic acid; messenger substance transporting genetic information encoded in → *DNA* from the cell nucleus into the cytoplasm
screening	Here: genetic test carried out on a specific group of the population (or even an entire population) to examine them for certain genetic traits
sequencing	Determining the order of bases in → *DNA*
single nucleotide polymorphism (SNP)	Most common genetic variation where a single → *DNA* subunit (→ *nucleotide*) is changed
somatic	Relating to the body
spina bifida	Open spine, caused by a neural tube defect which often can result in severe impairments such as extremely severe paralysis and inflammation. The exact cause is not yet known. The risk of malformation can be reduced if adequate quantities of folic acid are included in the diet of pregnant women (→ *neural tube*)
sterility	Infertility of the female or inability of the male to impregnate
superovulation	Simultaneous maturation of several egg cells in a woman's ovaries induced by the administration of hormones (→ *ovulation*) (especially in the context of → *in-vitro fertilisation*)
susceptibility	Sensitivity or lack of resistance of an organism to certain substances
teratogenic	Causing malformations
therapeutic cloning	Procedure of artificial multiple formation, limited to the → *in-vitro* phase; might be used in particular to produce genetically identical substitute cells or tissues

totipotency

The terms totipotency and → *pluripotency* are used inconsistently in scientific literature: In classic embryology, totipotency is described as the ability of a cell to develop into a complete individual. Pluripotent cells, on the other hand – as defined by classic embryology – can develop into numerous types of cells, tissues or organs, but not into a complete individual. In research into murine embryonic → *stem cells*, totipotency is the ability to participate – after injection into foreign → *blastocysts* – in the formation of all types of tissue, including the germ line. Other definitions of totipotency include the ability of a cell to differentiate into all three embryonic → *germ layers* or all cell types of an organism.

Sec. 8 of the German Embryo Protection Act defines totipotency as the ability to develop into a complete individual.

triple marker test

→ *prenatal* diagnostic method in which maternal blood is examined for three different → *proteins* originating from the foetus. Using a computer programme which takes into account other variables (maternal age, gestational age etc.), the individual risk of an infantile → *chromosome* defect is derived from the blood level of these proteins. This test is not a diagnostic tool, but merely serves to specify a potential risk

ultrasound

Here: imaging procedure of → *prenatal* diagnosis; ultrasound scans permit the visualisation of the uterus, the amount of amniotic fluid and the → *placenta* and thus the determination of the exact gestational age, the number of foetuses and their physical development, as well as the identification of signs of potential developmental disorders

validity

Measure of the robustness of a research result, of a measuring tool or of a study

zygote

Fertilised egg cell as the product of the conjugation of the nuclei of oocyte and e spermatozoon, cell from which embryonic development starts (→ *embryo*)

zygote intrafallopian transfer (ZIFT), embryo intrafallopian transfer (EIFT)

Artificial emplacement of a fertilised egg cell (→ *zygote*) or an → *embryo* into a woman's fallopian tube (oviduct), with the aim of inducing pregnancy

5 List of Abbreviations

ADA	Americans with Disabilities Act
AMG	*Arzneimittelgesetz* (German Medicines Act)
AöR	*Archiv des öffentlichen Rechts* (German Archives of Public Law)
BÄK	*Bundesärztekammer* (Geman Medical Association)
BÄK-RL	*Richtlinien der Bundesärztekammer* (Guidelines of the BÄK)
BGB	*Bürgerliches Gesetzbuch* (German Civil Code)
BGBl.	*Bundesgesetzblatt* (German Federal Law Gazette)
BGH	*Bundesgerichtshof* (German Federal Court of Justice)
BGHSt	Collection of BGH cases in criminal matters
BGHZ	Collection of BGH cases in civil matters
BMG	*Bundesministerium für Gesundheit* (German Federal Ministry of Health)
BSG	*Bundessozialgericht* (German Federal Social Court)
BSGE	Collection of BSG cases
BT-Drs.	*Bundestagsdrucksache* (Bundestag document)
BVerfG	*Bundesverfassungsgericht* (German Federal Constitutional Court)
BVerfGE	Collection of BVerfG cases
BVerwG	*Bundesverwaltungsgericht* (German Federal Administrative Court)
BVerwGE	Collection of BVerwG cases
BZgA	*Bundeszentrale für gesundheitliche Aufklärung* (German Federal Centre for Health Education)
CDBI	*Comité Directeur pour la Bioéthique* (Council of Europe Steering Committee on Bioethics)
DFG	*Deutsche Forschungsgemeinschaft* (German Research Foundation)
DIMDI	*Deutsches Institut für medizinische Dokumentation und Information* (German Institute for Medical Documentation and Information)
DIR	*Deutsches IVF-Register* (German IVF Registry)
DNA	Deoxyribonucleic acid
DÖV	*Die Öffentliche Verwaltung – Zeitschrift für Verwaltungsrecht und Verwaltungspolitik* (German Journal of Administrative Law and Policy)
DVBl.	*Deutsches Verwaltungblatt* (German Administrative Gazette)

EKAH	*Eidgenössische Ethikkommission für die Gentechnik im ausserhumanen Bereich* (Swiss Ethics Committee on Non-Human Gene Technology)
ESchG	*Embryonenschutzgesetz* (German Embryo Protection Act)
ESHRE	European Society for Human Reproduction and Embryology
EU / EC	European Union / European Community
FDA	US Food and Drug Administration
GfH	*Gesellschaft für Humangenetik e.V.* (Society for Human Genetics)
GG	*Grundgesetz* (German Constitution)
GKV	*Gesetzliche Krankenversichung* (German Statutory Health Insurance Scheme)
GTG	*Gentechnikgesetz* (Genetic Engineering Act)
HFEA	Human Fertilisation and Embryology Authority
HLA-Merkmale	Human Leukocyte Antigens characteristics
HTA	Health Technology Assessment
INSERM	*Institut national de la santé et de la recherche médicale* (French National Institute of Health and Medical Research)
KBV	*Kassenärztliche Bundesvereinigung* (German National Association of Statutory Health Insurance Physicians)
KOV-Anpassungsgesetz	*Gesetz über die zwanzigste Anpassung der Leistungen nach dem Bundesversorgungsgesetz 1991* (Act on the 20th Adjustment of SHI benefits under the 1991 Federal Benefits Act)
KVLG	*Gesetz über die Krankenversicherung der Landwirte* (German Act on Health Insurance for Farmers)
LG	*Landgericht* (German Regional Court)
LSG	*Landessozialgericht* (German Higher Social Court)
MPG	*Medizinproduktegesetz* (German Medical Products Act)
NEK-CNE	*Nationale Ethikkommission im Bereich der Humanmedizin – Commission nationale d'éthique pour la médecine humaine* Swiss National Advisory Commission on Biomedical Ethics
NJW	*Neue Juristische Wochenschrift* (Geman law journal)
OLG	*Oberlandesgericht* (German Higher Regiona Court)
PKV	*Private Krankenkassen* (German private health insurance funds)
RNA	Ribonucleic acid
RSA	*Risikostrukturausgleich* (German risk structure compensation mechanism)

RVO	*Reichsversicherungsordnung* (German National Insurance Code)
SGB	*Sozialgesetzbuch* (German Social Code)
SHI	German statutory health insurance
SMER	*Statens Medicins-Etiska Råd* (Swedish National Council on Medical Ethics)
SNP	Single Nucleotide Polymorphisms
StGB	*Strafgesetzbuch* (German Criminal Code)
StPO	*Strafprozessordnung* (German Code of Criminal Procedure)
TAB	*Büro für Technikfolgen-Abschätzung* (German Office of Technology Assessment)
TA-Monitoring	Technology assessment monitoring
TEC	Treaty establishing the European Community
UNO	United Nations Organisation
UNESCO	United Nations Educational, Scientific and Cultural Organisation
VGH	*Verwaltungsgerichtshof* (German Higher Administrative Court)
WHO	World Health Organisation
ZEKO	*Zentrale Ethikkommission* (National Ethics Review Committee)

6 The Members of the Study Commission

Parliamentary Group	Ordinary Members	Substitute Members
SPD		
Bundestag Members:	Helga Kühn-Mengel	Bernhard Brinkmann (Hildesheim)
	Dr. Carola Reimann	Eckhart Lewering
	Margot v. Renesse	Götz-Peter Lohmann (Neubrandenburg)
	René Röspel	(from Febr. 2001)
	Dr. Wolfgang Wodarg	Horst Schmidbauer (until Febr. 2001)
		Regina Schmidt-Zadel
		Dr. Margrit Wetzel
Experts:	PD Dr. Kathrin Braun	
	Prof. Dr. Barbara Duden (until Sept. 2000)	
	Prof. Dr. Linus Geisler	
	Dr. Sigrid Graumann	
	Dr. Ingrid Schneider (from Oct. 2000)	
	Prof. Dr. Klaus Tanner	
CDU/CSU		
Bundestag Members:	Dr. Sabine Bergmann-Pohl	Ilse Falk
	(Oct. 2000 to Febr. 2001 subst. member)	Dr. Hans-Georg Faust (until Oct. 2000)
	Hubert Hüppe	Claudia Nolte (ord memb until Feb. 01)
	Werner Lensing	Prof. Dr. Erika Schuchardt
	Dr. Gerhard Scheu	Matthäus Strebl
Experts:	Rainer Beckmann	
	Dr. Otmar Kloiber (from May 2001)	
	Prof. Dr. Therese Neuer-Miebach	
	Prof. Dr. Johannes Reiter	
	PD Dr. Stefan Winter (until March 2001)	
Bündnis 90/ Die Grünen		
Bundestag Members:	Ulrike Höfken	Volker Beck (Cologne)
	Monika Knoche	Hans-Josef Fell
Experts:	Prof. Dr. Theresia Degener, LL.M. (until Sept. 2001)	
	Ulrike Riedel (from Sept. 2001)	
	Dr. Michael Wunder	
FDP		
Bundestag Member:	Prof. Dr. Edzard Schmidt-Jortzig	Detlef Parr
Expert:	Prof. Dr. Ludger Honnefelder	
PDS		
Bundestag Member:	Dr. Ilja Seifert	Prof. Dr. Heinrich Fink (from July 2000)
		Angela Marquardt (until July 2000)
Expert:	Prof. Dr. Ernst Luther	

7 The Commission Secretariat

Director of the secretariat

Cornelia Beek (from 1 June 2001)

Gabriele Schmidt (until 31 May 2001)

Academic staff

Dr. Johann S. Ach

Dr. Ingo Härtel

Klaus Nawarotzky (deputy director of the secretariat)

Arnd Pollmann (from 14 January 2002)

Dr. Christina de Wit (until 31 December 2001)

Matthias Wolfschmidt

Office manager

Sabine Holthusen (until 4 February 2001)

Verena Quiel (from 5 February 2001)

Temporary staff:

Harko Benkert

Brigitta Biell

Claudia Bolz

Falko Brede

Monika Ehresmann

Martina Franzen

Silke Karas

Achim Kockerols

Susanne Lietz

Sabine Schmidt

Anja Zernecke

Ayfer Yanardöner

8 Overview of Public Hearings

5th Commission meeting on 3 July 2000	**Invited experts**
Public hearing of experts on the EU Directive 98/44/EC on the Legal Protection of Biotechnological Inventions and its implementation in national law	Dr. Friedrich Baumbach Patent lawyer Marc Fierstra Legal adviser for European law in the Dutch Ministry of Foreign Affairs in The Hague Prof. Dr. Christian Koenig Director of the Centre for European Integration Research of the University of Bonn Dr. Hans-Georg Landfermann President of the German Patents and Trademarks Office Dr. Lutz van Raden Judge at the German Federal Patent Court Dr. Christian A. Stein Director of the Patenting and Licensing Agency of the German Human Genome Project Prof. Dr. Joseph Straus Max Planck Institute of Foreign and International Patent, Copyright and Competition Law Dr. Christoph Then Greenpeace Dr. Terje Vigen Dep. Secretary-General of the Norwegian Medical Association
9th Commission meeting on 16 October 2000	**Invited experts**
Public hearing of experts on the "Implications of Genetic Testing"	
1st subject State of the art in technology and research	For 1: Prof. Dr. Klaus Zerres Director of the Institute of Human Genetics RWTH University Aachen
2nd subject Historical assessment of the technological development and debate in society on genetic testing	For 2: Dr. Dirk Lanzerath Head of the Scientific Department and Deputy Managing Director of the German Reference Centre for Ethics in Life Sciences, Bonn Prof. Dr. Hilary Rose Visiting Research Professor of Sociology, London

3rd subject Comparative law with regard to rules on data privacy and non-discrimination	For 3: Dr. Aart Hendriks Secretary of the Program on Health Law Evaluation, Health Research Council of the Netherlands, The Hague Prof. Dr. Stefano Rodotà Garante per la Protezione dei Dati Personali, Rome
4th subject Desolidarisation due to right to know?	For 4: Ute Schnur Berlin Brigitte Faber Weibernetz e.V. National Network of Women, Lesbians and Girls with Disabilities, Kassel Stephan Kruip Markt Indersdorf, Mukoviszidose e.V. Erika Benderoth Huntington-Hilfe, Berlin
5th subject Future prospects of genetic testing	For 5: Dr. Thomas Uhlemann Department of Medical Sociology I, University Hospital Eppendorf, University of Hamburg Dr. Michel Haas Federal Ministry of Social Security and Generations, Vienna Karl Panzer Association of the German Insurance Industry Helmfried Meinel Consumer Advice Centre NRW, Düsseldorf
11th Commission meeting on 13 November 2000 Public hearing of experts on the topic of preimplantation genetic diagnosis	**Invited experts**
1st subject Medical and scientific aspects	For 1: Prof. Dr. Klaus Diedrich Hospital of Gynaecology and Obstetrics, Medical University of Lübeck Dr. Wolfram Henn Institute of Human Genetics, Saarland University, Homburg/Saar Prof. Dr. Hans-Werner Denker Institute of Anatomy, University Hospital Essen

	Dr. Frank Ulrich Montgomery National Chairman of Marburger Bund
2nd subject Ethical and societal issues	For 2: Dr. Giselind Berg Institute of Ecology and Biology, Technical University of Berlin Dr. Hille Haker Catholic Theology/Theological Ethics, University of Tübingen Prof. Dr. Claudia Wiesemann Institute of Medical Ethics and History, University of Göttingen Karl Finke Commissioner for the Disabled of the State of Lower Saxony Dr. Hildburg Wegener Network against Selection by Preimplantation Genetic Diagnosis
3rd subject Regulatory proposals	For 3: Prof. Dr. Joachim Renzikowski Law School, Martin Luther University Halle-Wittenberg Prof. Dr. Karl-Friedrich Sewing Chairman of the Scientific Advisory Board of the German Medical Association, Hanover Prof. Dr. Friedhelm Hufen Institute of Constitutional, Public and Administrative Law, Johannes Gutenberg University, Mainz Prof. Dr. Dietmar Mieth Centre for Ethics in the Sciences University of Tübingen Dr. Elke H. Mildenberger Institute of Criminology, Westfälische Wilhelms-Universität, Münster
25th Commission meeting on 19 November 2001 Public hearing of experts on "European Discourse on Ethical Issues of Modern Medicine"	**Invited experts** Prof. Alexander McCall Smith Dep. Chairman of the Human Genetics Commission (UK) Prof. Dr. Ruud ter Meulen Institute of Health Ethics, University of Maastricht (NL) Prof. Dr. Linda Nielsen Former Chairwoman of the Danish Council on Ethics (DK)

	MUDr. Dagmar Pohunková Member of the Central Ethics Commission at the Ministry of Health of the Czech Republic (CZ) Prof. Didier Sicard President of the Comité consultatif national d´éthique pour les sciences de la vie et de la santé, CCNE (F) Dr. Jerzy Umiastowski President of the Ethics Review Committee of the Supreme Medical Council of the Polish Medical Association (PL) Prof. Michel Vallotton President of the Central Council on Ethics of the Swiss Academy of Medical Science (CH)

9 Overview of Non-Public Hearings of Experts in Issue Groups (TG's)

TG 1	12 Feb. 2001	Hearing of an expert on constitutional issues related to PGD Expert: Privatdozent Dr. jur. Ralf Röger, Chair of General Political Science, Constitutional and Administrative Law, University of Cologne
TG 1	26 March 2001	IVF Registry Expert: Prof. Dr. Ricardo Felberbaum, Institute of Gynaecology and Obstetrics, Medical University of Lübeck Psychosocial aspects of involuntary childlessness Expert: Prof. Dr. Christina Hölzle, Technical College of Münster Department of Social Services
TG 1	18 June 2001	Prenatal testing – Experience with the development of indications and counselling, potential implications for new types of prenatal diagnostic procedures Experts: Dr. med. Astrid Bühren, Chairman of the German Association of Women Physicians Dr. med. Claudia Schumann, gynaecologist in private practice, Chairwoman of the Arbeitskreis Frauengesundheit in Medizin, Psychotherapie und Gesellschaft e.V. (AKF) Ruth Althoff-Epting, National Secretary of the Evangelische Konferenz für Familien- und Lebensberatung (EKFuL)
TG 2	23 Oct. 2000	Clinical practice, ability to consent, problem of waiting lists, logistics, stem cell research as alternative source for organ replacement Expert: Prof. Dr. Günter Kirste, Head of the Transplantation Surgery Section, Surgical University Hospital Freiburg Criticism of the practice in transplantation medicine from the perspective of cardiology/therapy without transplantation Expert: Priv.Doz. Dr. Wolfgang von Scheidt, Hospital of Grosshadern, Munich Ethical and legal issues relevant to the regulatory practice, the waiting list problem and logistics of transplantation medicine (including living organ donations) Expert: Prof. Dr. Hans-Ludwig Schreiber, Director of the Law Department, University of Göttingen
TG 2	6 Nov. 2000	Ethical and legal issues relevant to the regulatory practice, the waiting list problem and logistics of transplantation medicine (including living organ donations) Expert: Prof. Dr. Wolfram Höfling, Institute of Constitutional Law, University of Cologne Criticism of the principle of organ replacement Expert: Prof. Dr. Klaus-Peter Jörns, Berg A patient's perspective Expert: Renate Greinert, Wolfsburg

TG 2	23 April 2001	Scientific and technological state of the art as well as therapeutic opportunities provided by stem cell research Experts: Priv.-Doz. Dr. Anna M. Wobus, Institute of Plant Genetics and Crop Plant Research, Leibnitz-Institut, Gatersleben Priv.-Doz. Dr. Oliver Brüstle, Institute of Neuropathology, University of Bonn Regulation of stem cell research in European countries, the United States and Japan and by international organisations, and the problem of imports of stem cell lines to Germany Expert: Prof. Dr. Rüdiger Wolfrum, Vice-President of the German Research Foundation and Director of the Max Planck Institute of Foreign Public Law and International Law, Heidelberg
TG 3	4 Dec. 2000	Genetic diagnosis and occupational medicine Experts: Prof. Dr. Wolfhard Kohte, Law Department, Martin Luther University, Halle-Wittenberg Eva Zinke, National Executive of the German Metal Workers Union, Social Policy Department
TG 3	12 Feb. 2001	"Pharmacogenetics / good clinical practice" Experts: Prof. Dr. Michel Eichelbaum, Dr. Margarete Fischer-Bosch Institute of Clinical Pharmacology, Stuttgart Prof. Dr. Holger Baumgartner, Office of the Ethics Commission, LKI Innsbruck
TG 3	5 March 2001	Hearing of experts: Human genetic counselling / quality control of counselling Experts: Prof. Dr. Irmgard Nippert, Institute of Human Genetics, University of Münster Dr. Angela Brand, Bielefeld Dipl. Soz-päd. Ebba Kirchner-Asbrock, Cara e.V., Bremen Prof. Dr. Gerhard Wolff, Institute of Human Genetics and Anthropology, Clinical Genetics and Genetic Counselling Group, Albert-Ludwigs-Universität Freiburg
TG 3	26 March 2001	Hearing of an expert on "Genetic Screening" Expert: Prof. Dr. Jörg Schmidtke, Institute of Human Genetics, Medical University of Hanover

10 Overview of Dialogue Events and Discussion Forums

Event	**Topic**
Dialogue event 11 December 2000 in Bielefeld-Bethel	"What should modern medicine be like? "Persons unable to consent and medical research"
Discussion forum 26 March 2001 in Berlin	"The use of genetic data"
Dialogue event 2 July 2001 in Jena	"The doctor/patient relationship in modern medicine"

11 Oververview of Expert Opinions

Topic of expert opinion	**Expert**
Ways of strengthening patient rights in German law – Status report and potential actions	Prof. Dr. Gerfried Fischer Prof. Dr. Winfried Kluth Prof. Dr. Hans Lilie (Martin Luther University, Halle-Wittenberg)
Constitutional aspects of using human embryos and "human biological material"	Prof. Dr. Wolfram Höfling (University of Cologne)
Effects of the application of genetic testing on disabled persons	Dr. Gregor Wolbring (University of Calgary, Canada)
The constitutional status of the embryo in vitro	Prof. Dr. Ute Sacksofsky M.P.A. (Harvard) (University of Frankfurt/Main)
Aspects of the change in the perception of health/disease/disability as a result of modern medicine	Prof. Dr. Barbara Duden (University of Hanover) Beate Zimmermann (general practitioner)
International overview of processes for decision-making in the event of ethical dissent (political science perspective)	Dr. Bernhard Gill Dr. Marion Dreyer (Ludwig-Maximilian-Universität Munich)
International overview of processes for decision-making in the event of ethical dissent (normative perspective)	Dr. Michael Fuchs (Institute of Science and Ethics, Bonn)

12 Overview of Press Releases

Date	Title/Subject
10 October 2000	Public hearing on "Implications of Genetic Testing" on 16 October 2000 in Berlin
30 October 2000	Online conference on the Internet "Implications of Genetic Testing" on 6 November 2000 in Berlin
7 November 2000	Public hearing on "Preimplantation genetic diagnosis" on 13 November 2000 in Berlin
14 February 2001	Online discussion forum on the Internet on "The Issue of Preimplantation Genetic Diagnosis"
13 March 2001	Preimplantation genetic diagnosis incompatible with Embryo Protection Act
16 March 2001	Public discussion form on the topic of the "Use of Genetic Data" on 26 March 2001
10 May 2001	Press conference on the occasion of the Study Commission's first anniversary on 14 May 2001
2 July 2001	Public dialogue event "The doctor/patient relationship in modern medicine" on 2 July 2001 in Jena
13 September 2001	Delegation visits the U.K. and Iceland from 17 to 22 September to have talks with local experts
13 November 2001	Study Commission sees two options to regulate imports of embryonic stem cells

14 November 2001	Public hearing on ethical issues of modern medicine with the participation of foreign experts on 19 November 2001 in Berlin
15 November 2001	Online forum on research into embryonic stem cells
27 November 2001	Commission submits report on stem cell research to Wolfgang Thierse, the President of the German Bundestag
1 March 2002	Majority in favour of prohibiting PGD – Minority regards PGD as acceptable in isolated cases

13 Detailed Table of Contents of the Interim Report Submitted by the Study Commission on "Law and Ethics in Modern Medicine" – Subreport on the "Protection of Intellectual Property in Biotechnology" (Bundestag document 14/5157)

14 Detailed Table of Contents of the Second Interim Report of the Study Commission on "Law and Ethics in Modern Medicine" - Subreport on Stem Cell Research (Bundestag document 14/7546)

15 Detailed Table of Contents

16 List of Tables and Charts

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