Preimplantation genetic diagnosis (PGD)

Report of the Bioethics Commission at the Federal Chancellery

Vienna, July 2004
The Bioethics Commission expresses its thanks to all persons and organizations who were involved in the creation of the subject report.

Vienna, July 2004
Table of Contents

Introduction
1.
The current discussion on PGD 1
2. Object of the report 1
3. The basic problem 2

I. Presentation of the scientific-medical, ethical and legal aspects of PGD 3
1. PGD as method of scientific medicine 3
1.1. Description of the method 3
1.2. Coverage and safety of the PGD methods 3
1.3. Indications for PGD 4
1.3.1. Couples with a considerable risk of giving birth to a seriously ill or seriously disabled child (“high risk couples”) 4
1.3.2. Age risk 4
1.3.3. Improved success rate of IVF treatments 4
1.3.4. Couples excluded from IVF (and the Reproduction Medicine Act respectively) with frequent early abortion 4
1.3.5. Diagnosis of desired genetic characteristics of an embryo 4
1.3.6. Determination of gender related illness 5
1.3.7. Determination of non-gender-related illness 5
1.4. Alternatives to PGD and options respectively for couples wishing to have a child 5
1.4.1. Polar body diagnosis 5
1.4.2. Examination of the genetically identical trophoblast instead of the embryoblast 5
1.4.3. Donation of sperm or egg cells, donation of embryos 5
1.4.4. Foster children and adoption 5
1.4.5. Voluntary childlessness 5
1.4.6. PND 6

2. Problem areas of PGD 7
2.1. Selection 7
2.2. Comparison PND and PGD 7
2.3. Production of redundant embryos/”usage” of embryos 8
2.4. Restricted reliability 8
2.5. Change of access indication for IVF 8

3. Ethical analysis of problems with PGD 9
3.1. Ethical evaluation 9
3.2. Perspectives of individual ethics 9
3.2.1. Arguments in favour of PGD 9
3.2.2. Arguments against PGD 10
3.3. Status and right to protection for the embryo and problems of tradeoffs between values 11
3.4. Relationship between PND and PGD 12
3.4.1. Arguments in favour of PGD 12
3.4.2. Arguments against PGD 12
3.5. Socio-ethical arguments 12
3.5.1. Selection of embryos 13
3.5.2. PGD and ethical objectives of medical activity 13
3.5.3. Indications and tendencies towards expansion 14
3.5.4. Discrimination of persons with disablements 15
3.5.5. “Treatment tourism” 16
3.5.6. From negative to positive eugenics? 16

4. Legal aspects of PGD 18
4.1. The legal situation in Austria 18
4.2. The legal environment 19
4.2.1. Prenatal diagnostics 19
4.2.2. Abortion 19
4.3. Aspects under constitutional law 20
4.3.1. Basic right to life 21
4.3.2. Constitutional protection of human dignity 21
4.3.3. The equal protection clause and the ban on discrimination 22
4.3.4. Right to a private life – women’s autonomy of decision 22
4.3.5. General aspects of the rule of law 23
4.4. Aspects under Community and International Law 24
4.4.1. Charter of Fundamental Rights of the European Union 24
4.4.2. Biomedicine Convention of the Council of Europe 24
5. Political options to make law
5.1. Maintaining the existing legal ban on PGD
5.2. Legal admissibility of PGD
5.2.1. Unrestricted admissibility of PGD
5.2.2. Restricted admissibility of PGD
5.3. The Law and its steering efficiency

II: Statement regarding limited regulatory approval of PGD
1. Basic ethical considerations
2. The moral status of the embryo
2.1. Criticism of the potentiality argument
2.2. Criticism of the identity argument and of the continuity argument
3. Ethical evaluation of PGD based on different indications
3.1. Use of PGD in order to procure a pregnancy and birth of a viable child
3.2. Use of PGD to prevent the transmission of serious genetically conditioned diseases or disablements
3.3. PGD for the purpose of positive selection of desirable genetic characteristics.
3.4. Regulatory approval of PGD and consequences for society

4. Constitutional aspects
4.1. General
4.2. The equal treatment clause
4.3. The autonomy of women to decide
4.4. The right to life
4.5. Human dignity
4.6. Ban of discrimination

5. Recommendations

Supplementary opinion by UnivProf Dr Holger Baumgartner
1. General reasons
2. Particular reasons
3. Recommendation

III. Opinion in favour of maintaining the present legislation
1. Basic considerations
2. The problem how to determine the moral status of human embryos
2.1. The problem of methods
2.2. The scope of the meaning of the word “embryo”
2.3. The moral status of man
2.4. The search for the subject of life
2.5. Chronometric impossibility to define the beginning of a human life
2.6. The human embryo in vitro
2.7. Practical consequence
3. Objectives of PGD
3.1. The wish to have children and the parenthood
3.2. The right to progeny
4. PGD as an instrument
4.1. The problem of the criteria of a selection
4.2. PGD as a solution of an (anticipated) conflict
4.2.1. Anticipated – existing conflict
4.2.2. PGD and abortion after PND
4.3. The argument of contradicting valuation
4.3.1. The logic of inconsistency
4.3.2. Admissibility of the abortion and inadmissibility of a PGD
4.4. Problem areas of PGD inherent in (conditioned by) methods
5. Consequences of regulatory approval of PGD

5.1. Door opener function and extension of IVF indications 59
5.2. Discrimination 59
5.3. Increase of undesirable tendencies of society politics 60
5.4. Extension of publicly financed services 61

6. Summary 61

7. Recommendation 61

Supplementary vote in favour of maintaining the present legislation in force with regard to PGD (UnivProf DD Dr Meinrad Peterlik) 62

Bibliography 64
Introduction

The task of the Bioethics Commission is (to advise) the Federal Chancellor “on the ethical aspects of all socially relevant, scientific and legal issues arising in connection with the development of science in the fields of human medicine and human biology.”

In this regard the Bioethics Commission at the Federal Chancellery has prepared the subject report on Preimplantation genetic diagnosis (hereinafter: PGD).

This report of the Bioethics commission on PGD basically consists of three parts:

In a Part I. the arguments brought forward in the current national and international discussion are presented – in a descriptive way. Besides the scientific-medical aspects of PGD, the report summarizes thoughts on ethical and legal admissibility of this method as well as on possible options of legal policy. This Part I. also meets the approval of all members of the Bioethics Commission.

The subsequent parts of this report contain on the one hand the opinion in favour of a restricted approval of PGD (Part II.) and on the other hand the opinion in favour of maintaining the present legislation unchanged (Part III.). The essential arguments as well as the subsequent recommendations for each one of these different opinions will be discussed. A supplementary vote of a member of the Bioethics Commission is added to each one of the opinions, supporting the recommendation, however with – in part – different reasons.

1. The current discussion on PGD

With issues such as embryonic research, research with embryo stem cells as well as reproductive cloning (to produce children) and the so-called therapeutic cloning, PGD is presently subject of worldwide discussions. These discussions reflect those complex ethical and legal challenges resulting from progress in biology and medicine.

2. Object of the report

PGD is an examination of the embryo before its transfer into the uterus aiming at ascertaining a particular genetic disposition. This way couples shall for example be enabled to have a child free of certain illnesses.

Preimplantation genetic diagnosis is only possible within the scope of IVF (In vitro fertilization). One or two cells are taken from an embryo (of eight cells) and are subject to a genetic examination in order to detect any genetic changes connected with a serious disease. Following the PGD only such embryos will be transferred into the uterus which are not affected by that particular genetic disposition for a serious disease or disablement. Embryos with genetic defects will be eliminated.
3. The basic problem

PGD raises a number of medical-scientific, social, legal and ethical problems. In judging the latter ones, discussions circle around the question whether genetic examinations of embryos are admissible for the purpose not to transfer them into the female uterus in case of a strong genetic disposition for a serious disease or disablement, but to eliminate them (see 1.1.). The ethical and legal problems concentrate on questions such as: Is the embryo entitled to human dignity and protection of his life? Is the ontologic, moral and legal status of an embryo in vitro different to the status of an embryo in vivo? Can the embryo be an object of a tradeoff with other objects of high legal protection or is it – irrespective of the consequences for couples involved – off limits to such considerations?
I. Presentation of the scientific-medical, ethical and legal aspects of PGD

1. PGD as method of scientific medicine

1.1. Description of the method

IVF is a prerequisite for PGD. Starting with the third day after fertilization, between one and two cells are taken from embryos created in IVF and examined for presence of certain genetic dispositions, in particular regarding genetic defects. Embryos not containing the defect in question can be transferred, the others will be eliminated. When taking out the cells it is possible that the embryo is damaged or dies. PGD nowadays is performed either with the PCR procedure (polymerase chain reaction) or the FISH procedure (fluorescence-in-situ hybridization).

1.2. Coverage and safety of the PGD methods

PGD can detect monogenic hereditary diseases and chromosome dysfunctions. The by far larger part of serious diseases and disabilities cannot be detected by PGD. Expectations that with PGD all genetic defects possible can be excluded are unrealistic. There are neither methods to develop so-called “designer babies” nor methods for detecting and excluding respectively all possible diseases of the embryo before birth.

While PGD can already be regarded as „state of the art“ for a number of indications, it must also still largely be regarded as an “experimental medicine”. Therefore not enough data are available to answer a number of questions, such as whether performing PGD may cause damage of the embryo or which possible consequences an extended in vitro phase – caused by PGD – may have.

Diagnoses effected in one single biopsied cell sometimes cause problems of interpretation and therefore are not yet absolutely safe at the present time. The error rate will go down when two cells are examined. Presently an error rate of 5-7% must be expected with PGD (especially wrong positive and wrong negative conclusions).

Also, because of the possibility of diagnostic errors, PND is frequently recommended after PGD for sufficient evaluation. It is to be expected that the new PGD method will improve with the further experience and knowledge gained. It is to be added that also generally accepted methods of examination of embryos during pregnancy (for example ultrasonic examination) have a limited degree of reliability. PGD can ascertain only diseases and disabilities of monogenic origin.
1.3. Indications for PGD

The following indications for PGD are under discussion:

1.3.1. Couples with a considerable risk of giving birth to a seriously ill or seriously disabled child (“high risk couples”)

Such couples are on the one hand fertile – and for this reason do not require any reproductive medical intervention – but on the other hand have, based on family anamnesis, run a high risk of having a baby with a serious disease or hereditary disablement.

1.3.2. Age risk

Fertile but also unfertile couples whose advanced age (in particular of the female partner) increases the probability of having a baby with a chromosomatic dysfunction (e.g. trisomy 21 and modifications of chromosomes not able to survive). Age related changes of the chromosomes frequently are the reason of infertility of elder persons (infertility as age progresses).

1.3.3. Improved success rate of IVF treatments

Couples with fertility dysfunction resorting to IVF and hoping to improve its success rate with PGD. PGD is effected in order to exclude the implantation of a “non-viable”embryo and to reduce the rate of (spontaneous) abortion.

1.3.4. Couples excluded from IVF (and the Reproduction Medicine Act respectively) with frequent early abortion

Couples not being infertile are excluded from IVF under present laws. Due to a high risk of a serious genetically conditioned illness or ailment of their progeny, such couples frequently had “unsuccessful” pregnancies with an accumulation of early abortion. PGD can also reduce the number of or prevent “unsuccessful” pregnancies which cause an accumulation of early abortion and consecutively considerable strain on the woman involved.

1.3.5. Diagnosis of desired genetic characteristics of an embryo

It may be interesting for couples who wish to have a child with particular genetic characteristics, for example to be available as donator of blood and medulla for brothers or sisters (immunologically "suitable" child; HLA typing).
1.3.6. Determination of gender related illness

This is – further to 1.3.1. – the ascertainment of genetic diseases which are hereditary exclusively on basis of gender.

1.3.7. Determination of non-gender-related illness

This is the determination of the gender without reference to a specific illness.

1.4. Alternatives to PGD and options respectively for couples wishing to have a child

1.4.1. Polar body diagnosis

Genetic examination with regard to certain questions can also be performed at the polar bodies formed during egg cell maturation. This examination is technically difficult (if no damage should occur in the egg cell) and offers only a restricted - pertaining to the genetic material of the mother - range of information. Changes in the chromosomes arising only after formation of the polar bodies can not be detected.

1.4.2. Examination of the genetically identical trophoblast instead of the embryoblast

This refers to the examination of the outside wall of the blastocyst (trophoblast) as opposed to the examination of the embryonic node (embryoblast). Similar, probably even bigger problems than with CVS (chorionic villi biopsy) because the examination is performed at a much earlier stage.

1.4.3. Donation of sperm or egg cells, donation of embryos

Reproductive medicine provides these options for having a child, they are however largely illegal under the FmedG (except heterologous insemination).

1.4.4. Foster children and adoption

Also foster children and adoption constitute options for having a child. It is certainly up to the persons concerned to opt for one of these alternatives.

1.4.5. Voluntary childlessness

A further alternative to PGD for risk couples is the possibility to be voluntarily without children.
1.4.6. PND

Prenatal diagnosis (hereinafter PND) is performed in vivo – during an existing pregnancy. The examination of the embryo/the fetus is performed with the traditional PND examination methods. In general, pathologic examination findings confirm a high probability of an abortion.
2. Problem areas of PGD

2.1. Selection

Both PND (in any case, to the extent a problem solving therapy is not available) as well as PGD have a selective dimension: in PGD, it consists in the subsequent failure to transfer into the uterus such embryos containing certain genetic characteristics, and in PND in the subsequent decision for an abortion in case of a pathologic finding of the examination. In both methods the embryo and fetus respectively is the “object” of a selective decision based on certain biologic characteristics. This selective dimension shared by PGD and PND however has different aspects (see 3.5.1.).

2.2. Comparison PND and PGD

In case neither a prenatal nor a postnatal therapy is not possible, PND is performed during pregnancy. The embryo/fetus is located in the uterus. Upon occurrence of a „certain indication“, a PND (amniotic liquor puncture, chorionic villous sampling, nape transparency reading, triple test screening, ultrasonic examination) is performed. In case of a pathologic finding – i.e. a diagnosis of a high probability of the fetus being affected by a disease or disablement – a situation comes up (frequently called “pregnancy conflict situation”) in which a decision will be taken whether the pregnant woman or the couple can be expected to go ahead with the pregnancy or proceed to an abortion. PND is allowed in Austria (see 4.2.1.)

PGD is made in vitro – before entering a pregnancy. The embryo/fetus is not located in the uterus. The pregnancy is planned. A “pregnancy conflict” is expected – mostly on basis of an congenital family anamnesis and specific experience (of suffering).

The ethical problems involved concentrate mainly on two questions: In the course of PGD embryos – exclusively produced within the scope of IVF by medical procedure aiming at a pregnancy – are examined with the objective to transfer them to the uterus only in case they are not affected by the genetic defect looked for (“conditioned procreation”). It is ethically and legally disputed whether this procedure is admissible or not. If the embryo in vitro is entitled to human dignity and protection of his life, such selection violates the ban on instrumentalization originating in human dignity. If this is not admitted, the issue of selection is a decision based on “good” reasons.

PND can trigger a pregnancy conflict on basis of a pathologic finding in the fetus. The moral dilemma is the right of the fetus to protection on the one hand and the rights of woman to her physical and corresponding mental and social self-determination on the other hand.
2.3. Production of redundant embryos/"usage" of embryos

The question whether PGD results in an increased number of “redundant embryos" as compared with present IVF practice is answered in different ways.

So-called „redundant embryos“ are generated by fertilization of more egg cells (in accordance with § 10 FmedG “…only such number of egg cells shall be fertilized as is required according to the state of the art of medicine and by experience for a reasonable medically supported reproduction in one cycle with chances for success”) than can or are allowed to subsequently be transferred into the uterus. „Redundant embryos“ are generated because it is either not possible to anticipate the success of fertilization for a given number of egg cells or how successfully the future embryo will develop or because in case of a serious overstimulation syndrome it is not possible to transfer embryos to the uterus in order not to subject the life of the patient to any danger. Thus however the questions for options to redundant embryos (e.g. blastocyst-transfer) and as to how to proceed with them further (e.g. cryo-[deep freeze] conservation) are on the agenda waiting for a solution. PGD – being a molecular-genetic and zytodiagnostic examination of the embryo - however changes nothing as far as the methods used and thus the justifications as well as, as the case may be, the number of so-called “redundant embryos”, are concerned.

2.4. Restricted reliability

What has been said in 1.2. above however raises a number of ethical questions: On the one hand it can be seen as a relativization of the argument that PGD is the better alternative to an abortion after a PND. On the other hand it is up to a couple whether they want to have PGD performed under such conditions and in addition want to undergo PND.

2.5. Change of access indication for IVF

IVF is a prerequisite for PGD. Under the Austrian Reproductive Medicine Act, medically supported reproduction is the last resort for treating sterility, in other words: infertility is prerequisite for access to IVF (§ 2 para 2 FmedG: Medically supported reproduction is “…admissible only if according to the state of the art of the medical science and experience all other possible and reasonable treatments for procurement of a pregnancy by sexual intercourse have been ineffective or are without chances for success”). Possible parties interested in PGD include also fertile couples whose progeny run a high risk of a serious genetically conditioned illness (e.g. due to parents’ age). Including this group of interested parties would comprise a modification and extension of the original indication for access to IVF.
3. Ethical analysis of problems with PGD

3.1. Ethical evaluation

The normative questions and their solution with regard to PGD must be considered very carefully: besides ascertaining the factual basis, questions must be asked as to the objective, the means to reach it, but also as to the context, the circumstances (e.g. concern) as well as the consequences of an act. These elements for an ethical evaluation are also essential for admission or not of PGD.

For judging PGD, questions as to the moral and legal status of the embryo and thus questions of the right for protection and of tradeoffs between values are necessary. The final evaluations regarding PGD also vary, but all varying points of view (see Parts II. and III.) also agree that the reference to the status of the embryo is a central, but not exhaustive one and must be supplemented by a large number of further ethical and legal arguments in order to enable us to arrive at consistent results.

3.2. Perspectives of individual ethics

3.2.1. Arguments in favour of PGD

It is the objective of PGD to enable couples with a high genetic risk to have a child of their own which will not be affected with such specific genetic disposition. PGD increases the reproductive autonomy (freedom of choice) and responsibility of a couple. It provides equal chances between couples with specific genetic risks and others without such risks.

Such couples most frequently have a corresponding background of experience and suffering based on this genetic disease or disablement. As these couples are most directly affected by the consequences of a life with a child with this serious genetic disease or disablement (aside from the child itself, of course), they shall be free to decide whether PGD might be an option for them, provided it were admitted: they have “the competence of the affected party” in this existentially crucial situation of theirs.

Couples who know about their risk of having a child affected by a serious disease or disablement have the same right to assistance for fulfilling their wish of having a child as infertile couples have, for whom IVF has been available for ages.

A further argument for PGD refers to the inconsistence between PND – (which is permitted) also including genetic examination (even at a later date) and subsequent legal abortion – and the ban on PGD (see also what has been said in 2.2.). In both cases human life is being destroyed, following a PND even the life of a much more developed embryo/fetus. The argument for PGD is that diagnosis of a genetic defect would be possible before entering into a pregnancy. It is ethically more justifiable to admit, in anticipation of the future conflict situation of a pregnancy, a “fertilization on trial”, in order to avoid – if the diagnosis is clear enough – a “pregnancy on trial”, which is an abortion after having undergone PND. In the case of an abortion, the psycho-physical strain on the woman is by far higher than in the case of a diagnosis effected before the pregnancy occurs. For couples with a considerable risk of giving
birth to a seriously ill or disabled child, it is possible to avoid multiple abortions after traditional PND.

PGD anticipates the pregnancy conflict, mostly based on experience of suffering (for example with abortions after PND examinations; for example with a child – eventually already deceased – with such serious genetic disease or disablement.

Comparing PND and PGD with regard to stress, punctions (AC, DVS) and possible abortions are to be compared with the use of IVF (with hormone stimulation, punction, embryo transfer). Eventually, the couple/the woman concerned should make her choice what is less physical, mental or social stress for them/her.

Other options of “fulfilling the wish to have a child” (see 1.4.3. and 1.4.4.), also voluntary childlessness (see 1.4.5.) and their evaluation, as to being equivalent and acceptable, cannot justify a legal ban and may well have to be decided eventually only by the couple affected themselves.

Studies from a number of countries with different socio-cultural backgrounds show that parents with a child affected by a serious hereditary disease, such as mucoviscidosis or thalassaemia and who give authentic information on their needs, are in favour of PGD: PGD is seen as an acceptable method with advantages and disadvantages. Resorting to PGD with a child affected by a disease for them is the (!) option for reproduction decisions. Opinions in these questions however are not consistent: Other self-help groups and lobbying groups for mucovisidosis advocate for mucovisidosis not being a reason for PGD.

3.2.2. Arguments against PGD

An unfulfilled wish for a child may present an existential problem for the couples concerned. But nobody has a right to have their own child, nor to a genetically unaffected child, and no claim to society to fulfil the wish for a child at any price. There are however claims for support by reproductive technologies within certain bounds (to be defined by social discourse) in order to have a child of their own.

Couples being candidates for PGD are not in a hopeless conflict situation because on the one hand there are alternative medical examination methods (of course with little efficiency) and on the other hand, alternative options to fulfil their wish to have a child. In view of the – from the point of view of society – not desirable, problem increasing load of consequences of authorizing PGD, these options (see 1.4.) are reasonable ones for the persons concerned. Access to the possibilities of for example an adoption or a fosterage would however indeed have to be improved.

It is not true to qualify PGD as a better alternative to abortion after PND because this levels out the difference between an anticipated and an existing conflict. When deciding for PGD, the woman is not pregnant, at best she is facing an anticipated conflict. Therefore, the right for women to their physical integrity (for example not to go ahead with an unwanted pregnancy) and for respect of her self-determination cannot serve as an argument for the intervention and thus for the restriction of the protection of the embryo. Different from a pregnancy conflict, PGD creates the conflict situation on purpose – with the involvement of others. Also, the pregnancy
situation is different from the „laboratory situation“, with regard to the emotional distance and that third parties are involved/participate in the decision on the embryos ready to be transferred. Contrary to PND – where the pregnant woman is the „guarantee of protection“ for the fetus – in the laboratory the power of definition and decision regarding the embryo lie also in other spheres of interest. A woman who is not yet pregnant has an emotionally larger distance to the embryo and therefore is only to a limited extent a candidate offering “guarantee of protection”.

The recommended check on PGD by PND puts the advantage of a PGD into perspective.

Another objection is that in the case of PGD, the risks of IVF must be taken into account. An IVF treatment comprises great physical and mental strain. Also, possible problems related to IVF, such as an increased rate of multiple pregnancies and an increased risk of damage to the embryo/fetus or ethical problems of selective fetocide, must be pointed out.

3.3. Status and right to protection for the embryo and problems of tradeoffs between values

It is not possible to judge the human embryo’s right to protection without answering the question as to the moral status it is entitled to. The basic decision in the ethical perspective is: Are embryos generally worthy of protection and thus not to be included in a tradeoff between values, or is an evaluation on values ethically thinkable when guided by the consequences for the parents involved?

Diverging positions are thinkable and possible regarding these issues – basically they can be summarized as follows:

(1) The human embryo is entitled to indivisible human dignity and as a result to the protection of his life originating therefrom, starting from the completed fertilization – irrespective whether it is an embryo in vivo or in vitro. The embryo is developing as human being from the very beginning. An attribution of the right to live at a later point in time is arbitrary. This is why the life of a human embryo is not a subject of a tradeoff of values.

(2) The respect of human dignity is different from the protection of life. The prenatal stages of the protection of life increase with the age of gestation (concept of the possibility of differentiating the protection for different stages of prenatal life). Although the embryo is entitled to human dignity from the very beginning, it is accessible to an appreciation of values in comparison with other high ranking properties.

(3) Protection of life depends on the existence of so-called morally relevant properties or their biological bases. This is why the embryo before implantation is not yet covered by the imperative of protection of life.

(4) Depending from the situation it must be different between the ontologic, moralic and legal status of embryos in vitro and in vivo. The same status for the embryo in vitro and the embryo in vivo is only applicable to the condition that its implantation is
intended and still possible. When this condition ceases to exist, the status of the embryo changes. While the question for the ontologic status of early embryos is not futile, it does depend to a considerable extent on the intentions of the persons acting.

3.4. Relationship between PND and PGD

3.4.1. Arguments in favour of PGD

Advocates of PGD point out contradicting valuations existing between the regulation of PND (admission) and PGD (ban). „Pregnancy on trial“ is admitted, while at the same time a „fertilisation on trial“ or a “conditional procreation” is rejected. The embryo in vitro is protected better than the one in vivo, which is an inconsistency in perception and evaluation of the legal and ethical consequences.

Particularly in case of an embryopathic indication not linked to periods of time, an analogy to PGD is at least admissible, while an abortion after PND may be judged to be even more serious. A tradeoff on the preferred values between the rejection of an embryo affected by a genetic defect and the decision for an abortion at a later date after PND is admissible. It must be part of the legal protection. The rejection of a genetically not normal embryo is also the lesser evil than an abortion at a higher gestational age. These differences between PGD and PND are not intrinsic, but gradual, so that the different valuation of PGD and PND with regard to the embryo/fetus is not justified.

3.4.2. Arguments against PGD

Critical objections against PGD state that the alleged inconsistency is not true because the situation between embryos in vivo and in vitro are different, something that is also reflected in the protection perspective. For the embryo in vitro the threshold for the access of third parties and their interests is reduced to a lower level. The emotional tie of the future „parents“ is less and the protection guarantee function of the parents thus also at a lower level. Due to such increased access possibilities the embryo must be given higher legal protection. There is also no comparable conflict situation, the conflict constellation have a different background: according to pathological results of traditional prenatal diagnosis a pregnancy conflict develops which presently frequently results in an abortion. PGD does not result in pregnancy conflicts.

3.5. Socio-ethical arguments

The problems of PGD is to be discussed not only from the perspective of individual ethics, but also in the socio-ethical dimension. Both points of view – characterized by different focussing – are interrelated: individual decisions are linked to narrower or wider social implications. In the doctor’s perspective the problem situation of the couple involved and its interests dominate, while from the perspective of social policy and legal aspects the effect on society attitudes must be taken into account. For on the one hand decisions taken individually are apt to change trends and attitudes of society if the respective frequency is given. On the other hand individual decisions are also co-determined by basic parameters and attitudes of society. These dialectics
between the level of the individual and of society must be taken into account if the issue is to define opportunities and bounds of self-determination.

3.5.1. Selection of embryos

3.5.1.1. Arguments against PGD

PGD results in targeted selection or “rejection” of embryos. Such targeted selection of embryos is one of the objectives of fertilization and thus integrating component of PGD. Selection is not a mere side effect of PGD, it does constitute a new quality of methods towards a further instrumentalization of human life. It advocates measures leading to selective procedure regarding human life. While PGD cannot automatically be qualified as being eugenic, it does comprise an intrinsic differentiation by criteria of “worthy of living” and “not worthy of living”. Society’s solidarity with handicapped people is being jeopardized. Admission of PGD supports tendencies in the direction „right“ to a healthy child. PGD places “normality” in a medico-scientific perspective and defines the possibilities of its viability on a social level. This might result in further discrimination of suffering and disablement. PGD not only ignores requirements of protection of embryos, it is also capable of developing a questionable selective mentality in society and of promoting an instrumentalization of embryos for the benefit of interests of third parties. Protection of life is one of the duties of the state: it therefore cannot be its duty to make available medical reproduction tools which deliberately comprise the selection of embryos. This also comprises the risk of accepting an eugenic mentality.

3.5.1.2. Arguments in favour of PGD

The individual perspective speaks for PGD. Rejecting embryos can be justified because or if it concerns constellations in which due to the risk of a serious hereditary disease a pregnancy cannot be expected to be acceptable. This individual situation is embedded in a solidarity of society with a couple, running a great risk of having a child affected by a serious illness or disablement, which approaches medicine with its wish of having a healthy child (that is, not suffering from the illness in question) being able to avoid multiple abortions after traditional prenatal diagnosis. The rejection of the embryo is only legitimate with the objective of having a healthy child, thus within the scope a tradeoff between the existence of the embryo affected with genetic defects and the objective of having a genetically unaffected child. In this regard it must also be taken into account that in the case of a natural fertilization a natural selection with respect to chromosomal aberrations and serious lethal mutation before the implantation of the embryo.

3.5.2. PGD and ethical objectives of medical activity

The measures in connection with PGD are essential object of medical activity. This activity is basically determined by the duty to heal illnesses and reduce pain and suffering. Medical activity also involves measures of prevention and rehabilitation. The answer to the question how consistent this duty is with PGD (which sometimes comprises rejecting embryos), varies:
3.5.2.1. Arguments in favour of PGD

Within the parameters of society, the medical profession is committed to its patients. PGD can be necessary as a medical service, if couples with a genetic disposition for a child affected with a serious illness or disablement (and there being no chance for a therapy for such illness or disablement in a foreseeable future) are under heavy psychological strain, but also - in spite of the high risk involved – definitely intend not to forego progeny. In such cases PGD must, if it is exclusively implanting an embryo without the respective genetic dysfunctions, be seen as medical measure to avoid suffering to be expected for the individual developing from the embryo. The doctor is committed to the couple in question in his endeavour to help giving birth to a child not affected by the genetic disposition. The doctor participating in the performance of this examination within the parameters of the admissible range of indications complies with his duty to give medical assistance, complying thus also with the ethical requirements of his profession.

3.5.2.2. Arguments against PGD

The argument against is: a request of parents to perform PGD is in contradiction to the ethical objective of the medical profession. The ethical objective of the medical profession is in the case of IVF the assistance to avoid the consequences of sterility. The selection of embryos and, as the case may be, their destruction, is not part of this ethical objective.

3.5.3. Indications and tendencies towards expansion

In this connection the developments of PND are to be pointed out paradigmatically: In the initial phase of PND – that is in the seventies – it was only accessible for women with a high risk factor of having a child with genetically conditioned illnesses or disablements. Subsequently women resorted to it increasingly because of the increase of reasons for prenatal diagnosis examinations. Altogether, a tendency was noted, from risk related cases to a “right” to a prenatal diagnosis examination. On the one hand, legal opinion emphasized the duty of doctors to inform on amniotic liquor puncture and chorionzotten biopsy, including the liability for damages in case of violation of this duty to inform. On the other hand technical factors – the triple test was introduced in 1992, leading to many wrong positive results and subsequently a cascade of invasive follow-up examinations – intensified this trend. There are also tendencies in society to put the indications of PND on a broader basis. It must however also be said that invasive prenatal diagnosis is increasingly being offered on a defensive basis.

The answer to the question how this trend could look for a - presumptive, meaning yet to be introduced – PGD, varies:

In the initial phase of PND a small group with a high genetic risk (<= 25%) to give birth to a child with a genetically conditioned illness or disablement might have to be expected. Indications would be the case in accordance with seriousness, prognosis and therapeutic possibilities of the illness or disablement (see details under 5.2.). In case of a restrictive regulation the number to be expected for Austria would certainly
not reach 10 couples per year. A more permissive regulation would cause these figures to increase.

A more optimistic position considers it basically possible to stick to the narrow parameters of indication. It is admitted anyhow that the legal possibilities to cope with this challenge juridically are not easy. However there are effective possibilities and measures to prevent tendencies of expansion. Expectations prevail that also resorting to legal experience of countries who already admitted PGD will lead to satisfactory results.

Critics observe in PGD an element of its own having innate tendencies for expansion and thus not allowing restriction to only exceptional cases of serious hereditary illnesses. It is very difficult to determine with generally binding effect what may for example be qualified as “serious hereditary illness”. The answers to this question already now vary to a great extent from each other. It may be expected – and the discussion offers such indications – that with an increase of knowledge also the concept of genetic disturbance has a tendency to broaden. This is especially true for application of PGD for illnesses which become manifest only at a late stage and others affecting only the subsequent generation. The pressure to broaden the indication parameters cannot be avoided. Especially the restriction to couples with a considerable risk factor of giving birth of a child with a serious illness or disablement (“high risk couples”) is not possible to be maintained because differentiations lose their plausibility in the specific situation of being heavily affected and are not likely to be accepted in the long run. So it is certainly possible to understand the question of parties affected why in the case of existing age risks and equivalent constellations PGD is not to be applied. Extensions of examination aiming at “tendency to a healthy child” are difficult to grasp, but rather to be expected. A danger is a certain automatic development in reproductive medicine to offer for childless couples (frequently with the female part of a higher age) a trisomy 21 diagnosis as a PGD additional option within the scope of IVF treatment. A risk is also seen towards a development from a “wish to have a child” to a “right to have a child”, to consequently maybe culminate in a suggestion of society for a “duty to have a healthy child”. Accepted babies of this kind, “conditional babies”, would “depersonalise” the parent-child relationship. What is meant by that is that children live with the knowledge that they are accepted only on condition, and embryos have been rejected prior to them because they did not comply with the condition.

3.5.4. Discrimination of persons with disablements

Opinions vary also as far as this problem is concerned.

3.5.4.1. Arguments against PGD

Lobbies of persons with disablements see in PGD a further instrument for “grid square search for disabled life” discriminating persons affected by a disablement. Parents of children affected by a disablement will in future be under increased pressure to answer the question why they opted against preventive diagnosis. PGD will create new decision pressures for expectant parents. In this connection developments of PND are to be pointed out in particular (see 3.5.3.): for diagnosis trisomy 21 there is a high abortion rate (in Germany more than 90 percent of the
pregnancies are aborted when a prenatal diagnosis indicates a down syndrome; the rate is likely to be similar for Austria which has no official abortion statistics). PGD may serve to emphasize tendencies for a right to “man to measure” and thus to undermine society solidarity with persons affected by disablements. For they promote a change in our attitude to illness or suffering, can affect our attitude towards people affected by disablements and in the long run lead to questioning the right to life of lots of people with disabilities. In times of economic shortage the question may arise how to avoid cost intensive forms of life of people with disabilities. This reduces solidarity on the part of society and might be able to exercise social pressure on the decision margin of individuals.

3.5.4.2. Arguments in favour of PGD

The argument of the other side is that the selective potential of PGD is not significant as compared with PND. Also, serious disablements – in Germany about 1.5 million persons are affected – is in less than ten percent of the cases genetically conditions, of which again only a part can be diagnosed before birth. There is no empiric evidence that PND and PGD create a climate hostile to persons affected by disablements. On the contrary it is to be stressed that for decades in all industrial countries (in particular because of the integration efforts of policies for the disabled) the rights of persons affected by disabilities have been enlarged on a continuous basis and with increased input.

3.5.5. “Treatment tourism”

Discussion points at the problems how to effectively maintain a PGD ban in view of different legal rules of national legislations. A ban on PGD in national legislation provokes a questionable therapeutic tourism which also only persons in a comfortable financial environment can afford, whereby the claim for social justice is violated.

The argument against it is that therapeutic tourism as such is no ethical argument, but only an example for the restricted value of a national ban by law. While an internationalisation of legislation is desirable, this does not authorize to abandon ethical and legal principles just for such an internationalisation.

3.5.6. From negative to positive eugenics?

International discussion largely agrees that PGD must not be abused for eugenic practices. However, the value attributed to the risk factors resulting from admission of PGD varies considerably.

3.5.6.1. Arguments in favour of PGD

The fear that PGD would tend to promote eugenic practices under criteria of individual or societal desirability exceeding the narrow parameter range of serious hereditary diseases, is met with the argument that such a development seems very unlikely. Experience with PGD so far in the British set-up have not shown any tendencies to broaden in this direction. For this purpose, the methods of PGD in connection with an IVF is too much of a strain. It is also true that present research is
far from being able to fulfil the wish for “planned children”, and this will, if ever, certainly not change in a foreseeable future. If in later future the situation will change, there are ample possibilities to react with adequate legislation to this threat.

3.5.6.2. Arguments against PGD

Such reference to the present level of science does not seem plausible to others. For, as they say, with the progress to be expected, the possibilities of positive eugenics will increase as well. Such tendencies are by no means dreams of the future, they already today determine decisions within the scope of negative eugenics of a rejection of genetically negative embryos. Also already today the concepts of the parameters of the indication have blurred edges and the borders between positive and negative eugenics - ethically not without problems - are open. The step from the selection of undesired illnesses or disablements to an optimisation of desired qualities cannot be stopped. The dialectics of individual acts and social attitudes comprises the tendency to support extremes. Scenarios of fear and expectations with respect to the guarantee of a healthy child oppose each other, the latter one being unrealistic, critics say. In such a situation risk couples get under heavy pressure, also from the responsibility to society to avoid the birth of a child, leading to a restriction of their personal responsibility, something definitely not desirable.
4. Legal aspects of PGD

4.1. The legal situation in Austria

At the present time, there is no express legislation in Austria concerning the admissibility of PGD, neither in the Reproduction Medicine Act, Federal Law Gazette 1992/275 (Reproduction Medicine Act) nor in the Genetic Technology Act, Federal Law Gazette 1994/510. There is however unanimous opinion that § 9 para 1 FmedG gives an indirect answer to the question for the admissibility of diagnosis procedures performed on the embryo in vitro.

§ 9 para 1 FmedG (in the original wording not amended so far):

*Viable cells must not be used for any other purpose than for medicine supported reproduction. They may be examined and treated only to the extent as required according to the state of the art of scientific medicine and experience to induce a pregnancy. The same thing applies to sperm or egg cells to be used for medicine supported reproductions.*

According to widespread opinion, the second clause of § 9 para 1 FmedG implies a ban of PGD because and to the extent it is not the case of an examination of viable cells which “is necessary to induce a pregnancy”. According to § 9 para 1 last clause FmedG, this ban covers also examinations of sperms and egg cells, to the extent these are to be used for medicine-supported reproductions. The so-called polar body diagnosis is however considered admissible because the polar body as such does not serve reproduction and consequently also is not subject to the examination ban of § 9 para 1.

There is however no consensus on the exact coverage of this PGD ban implied from § 9 para 1 FmedG, and the various opinions vary considerably both as far as their result as well as the reasons are concerned. There is however particular disagreement regarding the question at what point in time an examination “to induce a pregnancy” is required (and therefore admitted by the law). There are basically three alternatives of interpretation: some authors are in favour of a general ban, others assume an extensive admissibility of PGD in analogy to prenatal gene analysis in accordance with § 65 para 3 GTG. Other differing opinions can also be found in the more recent literature, which, while basically maintaining a ban on PGD, however consider pre-implantation examinations exceptionally permitted in such cases where the objective is to exclude genetic anomalies incompatible with entering a successful pregnancy.

Because of the applicability of the FmedG (Art 49 B-VG [Austrian Constitution Act]) restricted to the Federal territory of the Republic of Austria, a PGD performed abroad is not subject to the ban expressed in the FmedG. Because a violation of the FMedG is only subject to an administrative fine (up-to € 36,000), co-operation involving a PGD permitted abroad (for example by the respective medical consultation) does not constitute any aiding punishable under the VStG (Administrative Penal Act).

It is undisputed that the intention to perform a PGD per se is not a sufficient precondition to perform an in vitro fertilization. Because § 2 para 2 FmedG ties the
admissibility of medicine supported reproduction among others to the condition that “all other possible and reasonable treatment to induce a pregnancy by sexual intercourse have been futile or without chances of success”. Even if one considers therefore a PGD admissible to a certain extent, it could – because of § 2 para 2 FmedG – be performed only in such cases in which (by coincidence) infertility is also given. This makes it clear that legal admissibility of PGD would also have to be followed by a corresponding enlargement of indications for IVF because otherwise this would result in privileging infertile couples in violation of the principle of equality under the law.

4.2. The legal environment

A comprehensive ethical, legal and constitution-based evaluation of PGD must include also the legal parameters of embryo protection in general and of prenatal examinations during an existing pregnancy in particular.

4.2.1. Prenatal diagnostics

Diagnostic steps during an existing pregnancy involving the embryo in vivo (prenatal diagnosis) are – in the absence of special regulation by legislation – admissible within the scope of the general prerequisites for medical treatment (especially information, consent). For the special case of “predictive” prenatal gene analyses there is an express provision in § 65 para 3 GTG concerning the detailed prerequisites for consent, information and qualification of the specialist physician, and as regards contents, the admissibility of prenatal gene analysis is restricted only to the extent as it must be “necessary from the medical point of view.”

Different from the examination of an embryo in vitro, Austrian legislation grants to pregnant women thus an extensive freedom to decide whether and which prenatal examinations they want to have performed.

Legal admissibility of PND is independent of the consequences which may result therefrom for future decisions to be made by the woman. PND is allowed also in such cases when it serves for preparation of the decision of the pregnant woman for an abortion for an “embryopathic” indication (§ 97 para 1 subpara 2 StGB [Penal Code]). Due to Supreme Court decisions – however disputed in the literature –, diagnostic errors during prenatal examinations, based on which the pregnant woman was not able to proceed to an abortion, can basically not lead to claims for damages (OGH SZ [Supreme Court SZ] 72/91).

4.2.2. Abortion

§ 96 StGB (Penal Code) basically makes abortion performed with consent of the pregnant woman punishable. § 97 StGB provides for three groups of cases of an abortion not subject to punishment, which are

(1) within the first three months of a pregnancy (§ 97 para 1 subpara 1 StGB, the so-called “deadline-for-abortion” solution);

(2) to avert a serious danger for life which otherwise cannot be avoided or a serious damage for the physical or mental health of the pregnant woman (so-called “medical
indication”) child, of if the pregnant woman was not of age when she became pregnant (§ 97 para 1 subpara 2 StGB);

(3) in order to save the pregnant woman from a direct danger of life which cannot be averted in any other way (§ 97 para 1 subpara 3 StGB). In the first two groups of cases the abortion must be performed by a physician.

With the exception of the case of the „deadline-for-abortion solution“ (§ 97 para 1 subpara 1 StGB), the abortion is not subject to punishment even after the third month of pregnancy during the complete period of pregnancy up-to giving birth.

Regarding the issue whether in cases of an abortion not subject to punishment only the criminal liability is waived – while still being unlawful under civil law) not punishable but against the law or whether the abortion is fully allowed and justified under the law, the predominant opinion and the ruling of the Supreme Court (SZ 72/91 regarding the embryopathic indication) tends in favour of the justification doctrine.

The provisions of the penal law regarding abortion are based on the existence of a pregnancy – that is the nidation of the embryo. Interventions on the embryo in vitro or the embryo in vivo before nidation (for example by using means preventing nidation) are not covered by the penalties of this section (and also not by other elements of an offence in the StGB [Penal Code]).

4.3. Aspects under constitutional law

Austrian constitutional law does not contain any explicit provisions regarding PGD. Evaluation of PGD under constitutional law rather depends on whether and to what extent general constitutional provisions can be derived through interpretation on the admissibility or not of PGD. According to the state of discussions so far, basically the following issues are being debated in this context:

Are women entitled to a basic right, protected under Art 8 of the European Convention on Human Rights, to have access to the genetic findings possible with PGD, and if so: to what extent is this right subject to a restriction by the law, on basis of the proviso of legality in accordance with Art 8 para 2 ECHR?

Is there a protection of life according to basic rights regarding the embryo in vitro, and if so: can such protection of life be weighed against other rights and interests (in particular, of women)?

Is the human dignity of the embryo in vitro protected by the Constitution, and, if so: to what extent is such protection opposed to PGD?

Is admission or not of PGD under consideration of existing legislation for protection of embryos in the matter justified in terms of the constitutional principle of equality? And in particular: Is admission of PGD compatible with the ban of discrimination because of a disablement and with the constitutional commitment to equal treatment of disabled and not disabled persons in accordance with Art 7 para 1 B-VG?
It is to be mentioned first that most of the above questions are not answered in a consistent manner by the Austrian constitutional discussion – which regarding this item is not very extensive. This is in particular true for the basic and fundamental question as to what status basic rights grant to the early embryo in the light of human dignity and protection of his life.

4.3.1. Basic right to life

Regarding the extent of the protection of life by the Constitution, the predominant opinion of Austrian legal science is that at least the early embryonic phase (in vitro or in vivo) is not covered by the protection of life under basic rights of the Constitution (Art 2 ECHR, Art 63 para 1 Treaty of St. Germain). According to court rulings of the Constitutional Court (VfSlg 7400/1974) and of the Supreme Court (SZ 72/91) as well of a part of literature, Art 2 ECHR applies only after birth. Even such authors who are critical of this interpretation advocate a protection of life under the Constitution mostly only after certain levels of development, not however for early phases of the embryo’s growth. On the basis of this opinion, the basic right for life therefore would not be eligible as constitutional criterion for PGD. There is however also the view – put forward in connection with the criticisms on the “abortion deadline solution” under constitutional aspects – of a continuous basic right for protection of life starting with fertilization.

4.3.2. Constitutional protection of human dignity

The opinions on the constitutional protection of human dignity are more controversial. There is on the one hand agreement on the fact that the constitutionally vested basic rights are based on the guiding thought of protection of dignity expressed in the various basic right formulations. At times human dignity is addressed in Federal constitutional law also more or less expressly (ban of inhumane treatment under Art 3 ECHR, respect for human dignity during detention under Art 1 para 4 B-VG personal freedom). Controversial however is whether human dignity is an independent right – accessory to the individual basic rights and supplementing these respectively – or an object of protection at constitutional level. The Constitutional Court has recognized human dignity as a “general principle of value of our legal system (VfSlg 13635/1993).

A number of authors consider this general principle of value to be an objective principle of law possessing productive importance for interpretation procedures of the basic rights and for specifying them in the light of an enhancement worthy of creative new challenges. Especially German court rulings – to some extent also taken up in Austria – regarding the “object formula”, according to which each human being is an objective in itself which must not be graded down to be an object, offers sufficient potential for development in terms of a comprehensive ban on instrumentalization. Other authors abide by the connection between protection of dignity and (subjective) capacity to have basic rights and infer from this principle of human dignity no consequences for the protection of embryos.

Also among those authors who advocate an independent protection of human dignity on constitutional level there is no consensus on the importance of this principle for the attitude towards embryos in general and the admissibility of PGD in particular.
The opinions held in this issue vary as much as they do in Germany, also the arguments put forward hardly differ from each other. One opinion states that also under the aspect of constitutional protection of dignity PGD is admissible to the extent as by early diagnosis of genetic damages abortions can be avoided at a later stage, which would be legal in accordance with § 97 para 1 subpara 2 StGB (Penal Code), in such cases the protection of the dignity of the embryo cannot reach farther than the protection of the fetus against abortion. Other voices infer from the protection of dignity – understood as a constitutional principle and applied to the embryonic phase – a ban of PGD (or a public duty of protection to that effect). In this connection the reference to the selective character of PGD and its consequence to differentiate between life worthy of living or not, is of crucial importance.

4.3.3. The equal protection clause and the ban on discrimination

1. Under the aspects of the doctrine of equality concerns from the constitutional point of view are raised in literature against the different provisions of the law regarding prenatal diagnosis and PGD. They say that there is a contradiction in valuation which has no factual justification and hence is contrary to the Constitution, between the general admission of prenatal diagnosis for medical reasons and the subsequent possibility of a legal abortion, for embryopathic indications on the one hand and the basic ban on PGD on the other hand. The other side – to the extent it is present on the constitutional level in Austria at all – is in favour of the factual justification of this differentiation of access to the examination methods with the argument that in the case of prenatal diagnosis the pregnancy is already existing (and with it also the “conflict situation”), while by PGD this conflict will only be created subsequently.

2. Regarding the importance of the specific ban of the discrimination of disabled persons or equal treatment of disabled and not disabled human beings (Art 7 para 1 second and third clause B-VG) in connection with judging PGD, the discussion on a constitutional level is only in its very initial stages. In addition, the extent of the effect on personal ties of this ban on discrimination is by no means clear with regard to private behaviour and its effect on the private autonomy of the woman concerned. Presently we certainly cannot speak of much of a consensus of opinions regarding PGD. A determining question will be whether also the embryo as “human being” in terms of Art 7 para 1 B-VG has subjective rights through this ban on discrimination, or whether – if this is denied – it causes objective protective effects accrue from it, which would deny a legal link with the element of a “disablement” in the context of a prenatal or preimplantation diagnosis or also in connection with an abortion.

4.3.4. Right to a private life – women’s autonomy of decision

1. Under the aspect of women’s autonomy of decision (as element of their private life in accordance with Art 8 ECHR) there is no consensus how to judge PGD under basic rights. With some certainty it is only possible to state that performing PGD – as well as other procedures of reproductive medicine – is only permitted with informed consent of the woman concerned. It is however controversial whether Art 8 ECHR also contains a basic right to claim public admissibility of PGD (more precisely: a right of defence against bans under the law). Some authors do not see the ban on PGD as an interference with the subject of protection of “private life” guaranteed by Art 8 para 1 ECHR and therefore deny the applicability of this basic right. Others
state the opinion that the protection of the basic rights of women comprises, with regard to the use of methods of in vitro fertilization, also the decision on implantation, including the access to relevant diagnostic information (at least with reference to serious ailments for which there are no therapies), a ban on PGD therefore constitutes an interference with the protection under Art 8 ECHR.

2. The question raised in connection with seeing an interference with basic rights, whether this ban interfering with Art 8 para 1 ECHR is, in the light of the proviso of legality of Art 8 para 2 ECHR for protecting one of the objectives named there (in particular for the protection of health, morals or rights and freedoms of others) “necessary in a democratic society”, is mostly answered in the negative, with reference to the admissibility – however different in extent – of PGD in most European legal systems. According to this opinion, a general ban on PGD violates Art 8 ECHR.

4.3.5. General aspects of the rule of law

Finally the fundamental issue of distribution of the burden of proof and argumentation in favour and against ban of PGD is being discussed on the level of constitutional law.

One side is based on the so-called „distribution principle of the rule of law”, according to which the state and its organs have only such powers which they are granted under the law, while the individual citizens under the democratic rule of law is permitted everything that is not forbidden. In terms of a comprehensive presumption of freedom and the principle “pro libertate”, the burden of justification and argumentation always rests with those who demand or formulate bans, and not with the advocates of a permission for performing certain individual acts. Therefore it is the ban on, not the admission of a PGD which needs justification. References to the risk of eugenic tendencies, a possible selection between life worthy of living or not or contradictions with the idea of man of our rule of law are per se no carrying arguments under constitutional law. They would have normative relevance only if they could be based on existing constitutional provisions – such as the basic right to life or the ban on discrimination. The limits of the constitutional presumption of freedom therefore can be found (only) there where the constitutional protection of the embryo begins (this constitutional “status” of the embryo however is controversial under all of the aspects discussed, cf. to the right to life 4.3.1., to the ban on discrimination 4.3.3., to human dignity 4.3.2.). The use of „slippery slope“ arguments in order to justify legal bans is also questionable under aspects of the Constitution, as long as sufficiently substantiated predictions regarding the exposure of objects of legal protection or individual rights to danger are not available.

The opinion to the contrary is that on condition of being able to specify the principle of human dignity in legal terms, the striking principle of “in dubio pro libertate” can no more be a nearly unrestricted legal gateway for specific individual interests, or it rather would, in the light of the principle of human dignity, on the contrary be placed between more clearly defined limits. The arguments in favour of a differentiated admission of PGD gain a different weight if we do not let human dignity remain a general value principle of our Constitution within rules that are not binding and if we do not understand them only in terms of a background knowledge of our intellectual
history. Slippery slope arguments would in this context not remain without problems, because they are affected by the risk factors resulting from anticipation of future developments. One should however bear in mind that a statement as to when a prognosis in the future procedures available is sufficiently substantiated does not only depend on restricted prognosis possibilities. A determining role for the prognostic valuation of future developments also lies in the different ethical attitudes submitting the prognosis to a pre-interpretation.

4.4. Aspects under Community and International Law

4.4.1. Charter of Fundamental Rights of the European Union

The – legally not yet binding – Charter of Fundamental Rights of the European Union specifies in Art 1: „Human dignity is inviolable. It must be respected and protected“. Should the Charter in the future become a binding source of Community Law, Art 1 would have to be interpreted as an independent source of a principle of human dignity.

At the present point of discussions however not much of an answer can be gained for the question whether also the embryo is covered by the protection of this principle of human dignity, because exactly this issue “is neither clarified and decided on the European level nor in most member states”. Also in the course of the history of the making of the Charter any definition in the one or the other direction was avoided.

Besides that Art 3 para 2 subpara 4 of the Charter contains “the prohibition of eugenic practices, in particular those aiming at the selection of persons”. Both the history of the making as well as the explanations of the convent and the comments in literature however make it clear that this was supposed to cover only state organized coercive measures, the widely disputed issues of abortion or PGD on basis of an individual decision (“eugenics bottom up”) on the other hand were to be excepted.

4.4.2. Biomedicine Convention of the Council of Europe

Art 14 of the Convention on Human Rights and Biomedicine of the Council of Europe – not yet binding for Austria pending ratification – provides for a ban on using procedures of medicine supported reproduction to select the gender of the future child, unless it is the case of avoiding a serious hereditary illness linked to gender. Following this – provided future ratification of the Biomedicine Convention – the use of PGD for selecting children by gender would be forbidden by international law, however with the mentioned exception in favour of serious hereditary gender-linked diseases. The MRB thus presupposes that it is allowed to used PGD in principle for diagnosis of genetically conditioned dysfunctions.

Also Art 12 Biomedicine Convention points in this direction: Following that, examinations which make it possible to predict genetically conditioned diseases or ascertain for a person either the presence of a gene responsible for a particular disease or to identify a genetic predisposition or susceptibility for a particular disease, may be performed only for health purposes or for health related scientific research and on condition of a reasonable genetic consultancy being effected. The Explanatory Report however emphasizes expressly that Art 12 Biomedicine
Convention does not imply any restriction of the right to perform diagnostic procedures on the unborn child in order to identify a genetic disease.

In legal literature therefore the interpretation is dominating that the Biomedicine Convention – apart from forbidding the selection of the gender – does not contain any ban of PGD.
5. Political options to make law

1. The following political options to make law are available:

   a) the general ban on PGD; for this alternative a further differentiation could be to maintain the present legislation unchanged (including the existing ambiguities) and an express definition of a comprehensive ban;
   b) full admissibility of PGD by unconditional lifting of the ban or by a clear admissibility under the law;
   c) restricted admissibility of PGD under specific substantive and/or adjective criteria, such as certain access indications, reservation to certain institutions and a system of administrative approval and supervision.

2. The decision on the political options to make law depends on a number of criteria and the answer to a number of preliminary questions.

   a) What is the weight of the liberty of a woman to decide on the implantation of the embryo in vitro and her wish to have a PGD performed?
   b) What is the moral status and the status regarding basic rights of the embryo in vitro? Even if this question is not asked expressly, it will be receive an implied answer by the type of legislative alternative chosen.
   c) What is the weight of the wish of the woman or the parents to have a PGD performed, in relation to the protection of the embryo?
   d) Which considerations from the point of view of society as a whole (including the valuation of socio-ethical consequences and consequences of society politics regarding admissibility or ban of PGD) are for or against PGD? What is important here is the aspect of the ban on discrimination and of the question whether the legal system is in a position to keep particular indication parameters narrow and to avoid undesired enlargements of the application of PGD in the direction of a routine screening of embryos.
   e) Is it possible to insert the political options to make law chosen into the complete legal system in a manner consistent with the Constitution?

3. Depending on the value given to the status of the human embryo in vitro and the correlation between human dignity, right to life and decision autonomy of the women, there are initially two basic alternatives: ban or admissibility. The life of an embryo in vitro is included in the object of tradeoff of values or not. If the tradeoff is legitimate, its admissibility can be justified in different ways: Either by denial of human dignity and right to life, or by gradualist view of different levels of protection of life and dignity, each with or without reference to the legal position of the woman concerned.

5.1. Maintaining the existing legal ban on PGD

The reasons brought forward for maintaining and defining the legal ban are that such a ban is to express the protection of human dignity by preventing the selection and consequent rejection of embryos. Another argument for the ban is that it avoids the reference to the attribute “disabled”/“not disabled” and the discriminating aspects resulting therefrom. According to this opinion in any case such constellations could be exempted where a reliable prediction is possible to the effect that the embryo will not develop to become a live birth.
5.2. Legal admissibility of PGD

The advocates of legal admissibility of PGD relativize the legal protection during the embryo’s development and maintain a tradeoff with other rights and interests for legitimate and necessary (free decision of the woman, fulfilment of the wish for a child of her own without genetic dysfunctions). Condition for such a tradeoff is the denial or at least reduction of the protection of human dignity and right to life in the early embryonic phase (in vitro) before the implantation. This opinion is typically based on the concept of a protection of life initially not existing at all and then gradually increasing and a protection of human dignity gradually increasing during the development of the embryo.

For admitting PGD a number of legislative solution patterns can be discussed:

5.2.1. Unrestricted admissibility of PGD

As far as can be seen, nobody advocates unrestricted admissibility of PGD. The argument against is in any case that this would open unlimited access to methods of gender screening or a selection based on „desired“ characteristics, on which a broad consensus of rejection exists in society. Also those denying protection of dignity or life of the embryo in vitro or to be traded off against other rights and interests support a limited admissibility defined by special access indications.

5.2.2. Restricted admissibility of PGD

For the option of restricted admissibility a number of alternatives are thinkable with regard to wording and detailed legal definition of the basis of indication as well as of the admission procedure and control.

1. The main question concerns the formulation of the substantive admission criteria of PGD (the content). The range of theoretically possible diagnostic objectives covers, from the selection of genetically “suitable” embryos for later tissue donations in favour of third parties, the diagnosis of genetically conditioned illnesses or disablers (in each case with or without reference to a degree of seriousness, missing therapeutic possibilities, available and reliable methods of proof or the preconditition of an identifiable genetic risk) up-to a narrow restriction to serious anomalies, not likely to be compatible with the successful completion of a pregnancy and/or with a longer period of survival after birth.

2. From the point of view of legislation there is a number of ways how to word the substantive admission criteria:

2.1. A complete list (for example of such genetically conditioned illnesses of couples with a high risk factor affecting their progeny) would have the advantage that the cases where to apply PGD are precisely defined, complying thus with the prerequisite of legal certainty. Also extensions by interpretation would be difficult because the addition of new diagnoses or criteria would presuppose a new legislative act. An argument against such complete technical regulation can be that it is not flexible, that it will constantly be behind the progress of scientific knowledge and a
modification would be possible only by way of cumbersome amending of the existing laws. On the other hand there is a risk that explicit listing of hereditary diseases might result in discriminating persons who live with such diseases. The first one of the two objections (lack of flexibility) could be resolved by combining a generally worded legal norm with a specifying implementation regulation.

2.2. The description of the indication by formulating a general legal clause has the advantage of more flexibility in application and avoids discriminating effects by listing certain diseases. Such a regulation scheme for example is contained in the discussion draft of the German Federal Medical Association prepared in 2000. It states that the indication for PGD “may be given only for such couples with a high risk of having children with a known and serious, genetically conditioned disease.” Other possibilities are for example addressed in the majority vote of the comment of the (German) National Ethics Council of January 2003 (for example admissibility of PGD for couples “with a high risk of having a child with a serious genetically conditioned disease or disablement for which there is no effective therapy and who would with a child affected by it end up in a conflict threatening their existence”). Other formulations aim at the fact that “there is a risk of a serious genetically conditioned illness not compatible with life, meaning that it will lead to death either in utero, at birth or up-to a maximum of six months after birth.

The argument in favour of such a legislation technique is that it is possible to react to the requirements of reality in a more flexible manner. The disadvantage is the relative indefiniteness of definition of terminology, the legal uncertainty and differences of interpretation during practical application. In particular, the criteria for a „serious“ or “grave“ damage or disease frequently are not particularly precise, as can be seen from the considerable differences in opinions as to the extent of the embryopathic indication for abortion. Moreover, doing without a list might increase the tendency towards a creeping extension of indications. This can be expected for example for diseases identified at a progressive stage or diseases affecting only the following generation, age conditioned risks, gender selection, or selection of embryos for the benefit of third parties (e.g. whether suitable for tissue donation).

2.3. From the legal point of view a combination of both control schemes seems advisable. A more general description on the legislative level offers the basis for more detailed specification by an authority given power for this purpose, which would have to prepare a list of indications for PGD according to the state of scientific development by way of implementing regulations.

3. Irrespective of the legislation technique regarding indication chosen, collateral procedural and/or institutional parameters should be determined. This might include in particular

- an obligation for human genetic consultancy before performing PGD
- a system of approval and control by the administrative authorities for facilities authorized to perform PGD, on basis of quality requirements for the professional equipment and staff as well as the medical methods applied,
- mandatory measures of quality assurance on a regular basis regarding the qualification of the staff involved, the standards of the methods used, etc, or
- calling in ethic commissions for advice.
4. A further option for legal policy could be to test-run admission or ban of PGD initially for a limited time. After evaluation of the experience made, a decision would have to be taken after expiry of a certain period of time. Arguments against admission of PGD “on a trial basis” are however put forward stating that such temporary solutions in practice could become irreversible.

5.3. The law and its steering efficiency

As already stated in 3.5.3. on socio-ethical issues, the ability of legislation and reality to prevent tendencies for selection and extension which are not considered reasonable is judged in varying degrees. One part of the sources regards this controlling ability to be of a high level, they think it is by all means possible to ensure legislative specification of precisely described cases and protect the indication parameters against tendencies of expansion, especially aimed at positive eugenic practices, by means of adequate legal guarantees. Others doubt this ability of law and justice and hold the view that legislative restriction to narrowly defined special cases is in practice not possible to uphold. The growth of genetic knowledge would necessarily enlarge the possibilities of access to PGD, and in view of effective interests of society it would not be possible to restrain this development.

This Part I. of the report has been unanimously adopted by the Bioethics Commission on 9th June 2004. The members of the Bioethics Commission unanimously and expressly state that the option of official approval of PGD presented in I.5.2.1. is by no means endorsed.
II. Statement regarding limited regulatory approval of PGD

1. Basic ethical considerations

Evaluating PGD from an ethical point of view depends to a large extent on the answer to the question regarding the ontologic and moral status of the embryo. A scrutiny of all positions taken regarding the question of the status of embryos shows that their importance for decision making in bioethical issues is often overestimated. The supposedly strict alternative between the alleged objective borderline of fusion of nuclei as starting point for embryos to be worthy of protection and all other supposedly arbitrary definitions for the beginning of life does not convince with this razor-sharp definition, because in the first place none of the positions taken in the status question can do without supporting philosophic or theological presumptions.

Apart from that, while the clarification of the ontologic and moral status of the embryo is an indispensable element of forming bioethical judgments, it is as of yet no sufficient criterion for answering the question whether PGD is basically admissible or not. Ethical valuation on the contrary also has to consider the different indications and objectives claimed for PGD.

Attributing a certain moral status of the embryo, however, alone does not enable us to answer the question whether the protection to be given by the legal system is to be uniform for the full period of the embryo’s growth. The usual concentration of the arguments to the alternative whether morally the embryo is to be seen as a “person” (and therefore to be protected by the law like a living person) or not unduly simplifies the problem. on the one hand the legal system – albeit within the narrow scale of basic rights – can differentiate the level of legal protection of persons, and on the other hand also other objects of protection – which are not persons – can be more or less subject to the protection of the legal system. In the prevailing Austrian law such a differentiated protective scheme has been in force all the time, because the embryo, while on the one hand not being qualified as person in the legal meaning (as subject capable of having rights and obligations), he is on the other hand awarded a gradually increasing protection in line with his growth.

The result of these deliberation leads to a differentiated view of PGD:

1. A general ban of PGD cannot be justified, neither by reference to the status of the embryo, nor with the argument, PGD essentially is a method aimed at selection accepting negative eugenic tendencies, having the objective to avoid the birth of disabled persons and declaring such objective to be legitimate.

2. Basically one can differentiate between three groups of indications:

a) Use of PGD to exclude chromosomal or genetic dysfunctions which are incompatible with life, with the objective to make a pregnancy and own progeny possible;
b) PGD for the purpose of negative selection of diseases which in principle are compatible with life;
c) PGD for the purpose of positive selection of desirable genetic characteristics.

For the first group of indications, PGD can generally be recommended. For the second group this is not applicable without restrictions. In certain cases however for such a group PGD can also be justified. The situation is different for the third group of indications. Argument against using PGD for positive selection is in any case that the basically acknowledged right to reproductive autonomy is infringed and the human dignity of the offsprings concerned is violated.

2. The moral status of the embryo

What we see is always more than mere empiricism. Whether we perceive an embryo merely as a “bunch of cells” or rather a “human being in the making” depends on our intentions and interpretation patterns. This is true for the advocates of all points of view in the same manner. Critics of those who call an embryo a bunch of cells and criticize that language is used to make politics must face the argument that calling embryos and fertilized egg cells (zygotes) “embryonic human beings” is a form of politics by language as well which presupposes something as given which has to be proved yet. This is also true for the metaphoric formulation according to which the zygote or the embryo is developing, during the first days of its development, not towards man, but as man towards man.

The thesis of a continuous right to moral protection, comparable to the one of living persons, during the complete phase of embryonic development, starting with fertilization, usually tries to be justified with the argument of continuity and identity, in combination with the so-called argument of potentiality. These arguments however do not hold, neither separately nor jointly, they cannot justify the conclusions drawn from them.

2.1. Criticism of the potentiality argument

The term potentiality can be applied in two different ways. On the one hand it designates the formal “possibility”, on the other hand the “inherent capacity” of an existing being. The thesis that the embryo develops as human being from the point of fusion of the cell nuclei, alleges that the fertilized egg cell – and also an egg cell fertilized in vitro outside of the uterus, which still has to supply the necessary environment for the development of a human being – would prospectively have to be considered of having the potential (the capacity) to develop into a human individual. The statistical probability for a fertilized egg cell to become a human individual however generally is below 50 %. Only retrospectively, that is after the development actually has taken place, a safe judgment is possible on whether a zygote had the organizing power to control the process of development. The potentiality argument, however, transfers the certainty which may result from the “successful” end, to the beginning which is characterized by a substantial amount of uncertainty. Expressed in a simplified manner, each living person once was a fertilized egg cell, but not each zygote develops into a living person.
The mere potential for development therefore cannot be equalled with the possible result of the development, because the factual procedure of development, its possible success as well its possible failure depend on a number of environmental factors that the zygote itself is not able to influence. The potentiality argument misunderstands the relevance of epigenetic processes which are not already determined as such in the fertilized egg cell. In this respect the effectively existing (environmental) possibility is relevant, not only morally, but also ontologically. We must therefore differentiate in accordance with the situation between the ontologic status of embryos in vitro and in vivo. The same status for the embryo in vitro and the embryo in vivo is only applicable on the condition that its implantation is intended and still possible. When this condition ceases to exist, the status of the embryo changes not only from the moral, but also from the ontologic point of view.

In legal contexts it is still much less plausible why potential carriers of a right shall mandatorily be entitled to the same rights as actual carriers of such right. Putting potential opportunities for development on an equal footing with the „final point“ of such development is not found at any other point of the legal system either. In the context of this protection of the embryo it would also not be justifiable on a conclusive basis why especially early embryonic stages are to be treated as “potential” manhood just as living persons, if the ruling law at the same time admits a number of interventions at a later date by willful acts of third persons which may prevent the realization of the potential (in particular: the decision of the woman not to implant the embryo, an abortion).

2.2. Criticism of the identity argument and of the continuity argument

Basically, it is impossible, and not only time wise, to determine the beginning of life of an individual human being. It is therefore misleading to simply call already the fertilized egg cell after the fusion of the nucleus or the pile of cells formed by the first cleavage (morula) an embryo. Only after a number of days, when the morula has developed into a blastocyst, an early form of the actual embryo is formed (embryoblast) as well as the early stage of placenta and umbilical chord (trophoblast). This is the earliest point when it makes at all sense to speak of a new individual, although also in this stage the development of more than one child is possible.

The ontologic status of early embryos in vitro also depends to a considerable extent on the intentions of the persons involved. This becomes clear by the following mental experiment considering the procedure of PGD in the eight cell stage from the ontologic point of view: from the small pile of cells, one cell is being removed for examination purposes. Is this cell to be considered as a part of an individual or is it, starting with the moment of separation, another individual because of its totipotence? But what happens if the physician handling it changes his mind and returns the removed cell to the embryo? Where is then the second individual left? The point of this mental experiment is that in the initial stage of embryonic development it is not yet possible to speak about identity or individuality. The ontologic status of the cell separated for examination purposes thus fully depends on the intentions of the physician whether it is to be considered a part of the early embryo to be examined or a further embryo.
The thesis of the lack of definition or of the lack of definition of the beginning is as little a part of a dualist separation of the identity of a person from the physical body as of a monist biologism or a “moral false conclusion”. Referring to identity or continuity arguments rather by itself ends up in a naturalist false conclusion because this disregards that inseminated egg cells never can develop to a human being outside of the womb and because the only identifiable identity reference between an early embryo and a living person consists in the identity of his genome.

Finally, regarding the argument that all cesuras during embryo development to which a certain level of embryo growth might be linked, are arbitrary, the objection is that the absence of unequivocal biologic cesuras does not yet provide a suitable argument for not defining the legal protection of the embryo in different levels depending on the progress of the embryo’s development. The legal system rather is confronted with the necessity to determine for a continuously proceeding development such legal thresholds as to grant different levels of legal protection. Would it be true that the mere empiric finding of a continuous development would prevent any normative determination of different levels (eventually based on a social valuation) for the mere reason that, in the absence of unequivocal biological criteria, the determination of legal levels might also result in being somewhat different, then a formulation of legally prescribed deadlines would be as inadmissible as the formulation of limits of the legal capacity. Such a scheme of legal protection increasing by stages is largely also based on the present legislation for the protection of embryos, where – to quote just one example – there is no protection (under penal law) at all for the embryo before nidation and its protection after nidation increases step by step as the pregnancy proceeds and only with birth becomes a full protection of rights and basic rights of the “person”.

Trying to consistently implement the thesis brought forward in the bioethical discussion, to the effect that already the zygote is developing as a “human being” and therefore is subject to the same protection as living persons would only result in questionable consequences for the living world. Transferred to the legal system, this would also result in legal consequences as little compatible with the principles of the existing legal system as with the widespread moral intuitions of people: zygotes not achieving nidation in the course of natural procreation would then have to be handled as people who died; destroying “redundant” embryos – because not achieving nidation – following IVF would not be allowed to be accepted by the law, contraceptives preventing nidation (“spiral”) not preventing conception, but nidation, would have to be banned as killing tools, and last not least the admissible tolerance for admission of an abortion would become restricted to extreme cases of vital indications of the mother.

3. Ethical evaluation of PGD based on different indications

3.1. Use of PGD in order to procure a pregnancy and birth of a viable child

Indications for PGD would in this case be hereditary diseases and defects of chromosomes or genes which prevent a pregnancy to start at all, which result in repeated miscarriages or death already in the first few months of life after birth. (cf.
I.1.3.3. and I.1.3.4.). The objective of medical intervention in such cases is by no means to prevent the existence of a child with an illness or a disablement, but on the contrary the birth of a viable child. In case of a defective chromosome or gene identified by a reliable diagnosis for which there is no medical therapy, the use of PGD in such cases is ethically justified.

This must at the same time mean that also the use of IVF is ethically justified in these cases and not to be restricted to the fertility indication.

3.2. Use of PGD to prevent the transmission of serious genetically conditioned diseases or disablements

If so-called high risk couples wish to have PGD performed in combination with IVF, because while they do want a child of their own, they want to avoid giving birth to a child affected by an illness or a disablement, the objective of such PGD is not the viability of the child, but the negative selection. There are however ethical doubts in connection with such a procedure because in this case a difference will be made between desirable and undesirable life and the right of existence for those not yet born will depend on certain characteristics.

Before the background of these objections it must be said that childlessness as such is not an illness and that the justified wish to have a child need not be fulfilled at any price. This might at first suggest that couples threatened by the risk of a genetically conditioned disease or disablement may either be expected to enter a risk pregnancy or, if they believe not to be able to take such risk, to voluntarily resign to have children. Such a renunciation would in any case be an ethically responsible decision.

On the other hand one must bear in mind that an unfulfilled wish to have a child may be at least indirectly the cause of mental suffering. This is also true in those cases where giving up the wish to have a child is not desired as such, but the result of a serious ethical conflict. The argument against PGD that the use of IVF and PGD for so-called high risk couples is to be rejected because it is a negative selection, is also relativised by the fact that also the recommendation not to have children of one’s own eventually is based on an eugenic indication. Unconditional respect of the dignity and life of persons with serious genetically conditioned diseases or disablement are not to be mixed up with the valuation of such diseases and disablements as such. Otherwise high risk couples would in any case have to be encouraged to enter into a pregnancy instead of talking them out of it for ethical reasons.

And finally, the valuation of disablements would result in an argument for a positive selection of embryos which are carriers of a hereditary disease or a disablement. As a matter of fact members of some groups of disabled people claim such a right to a positive selection with reference on their autonomy in reproduction matters. This is for example the case of the organization of deaf-mutes in the USA. However relative the term disablement may be, so little the preferability of serious physical or mental disablement can be generally justified within the scope of a theory of values.

To the extent serious genetically conditioned diseases are not as such declared to be goods of ethical value, we have a case of an ethical conflict between the wish of high risk couples to have children and the ethically justified objective to avoid the
transfer of a serious hereditary disease, an ethical conflict which cannot be placed on an equal footing with a pregnancy conflict based on an embryopathic indication, but certainly can be considered as an analogous case. One can with good reason speak in this case of an anticipated conflict (cf. I.3.2.1.).

The criticism put forward against regulatory approval of PGD, the objective of PGD was preventing the birth of a child with a serious genetically conditioned disease or disablement is to be confronted with the argument that the couples involved might not decide for a pregnancy at all without the possibility of PGD, in particular in such cases where they reject the use of PND and a subsequent abortion for ethical reasons. This however means that also in such cases, similar to the indications discussed under II.3.1., the real objective of PGD is definitely not to avoid a childbirth, but quite to the contrary the birth of a human being which otherwise would never have been procreated.

A further objection against PGD is that physicians and professional societies of reproductive medicine recommend after each PGD to perform, after the pregnancy occurs, a PGD for making sure, which, as the case may be, may result in an abortion. This puts the argument that PGD avoids abortions and is the smaller evil of them, in a certain perspective. It can also not be excluded that already the procedure of extracting cells for the purpose of PGD carries the risk of a possible unacceptably high risk of damage for the remaining part of the embryo. Such objections however cannot convince: on the one hand is to be said that the decision for PND after previous PGD is made by the women concerned and not by the attending physicians. On the other hand, the probability of a false diagnosis during PGD, resulting in a diagnosis of a genetic or chromosomatic defect only during a subsequent PND, is not a fundamental objection against PGD. This situation must however be valued against the possibility that without previous PGD a pregnancy occurs and will be aborted after a positive (pathologic) PGD finding. This shows that the possibility of PGD clearly increases the disposition of risk couples to enter a pregnancy.

Also the argument, the embryo could be exposed to a not precisely known risk of being damaged constitutes no essential objection against PGD. Any diagnosis or therapy may be opposed with the argument of unknown residual risks. This is not a specific ethical problem of PGD, it is linked to any medical activity of man.

3.3. PGD for the purpose of positive selection of desirable genetic characteristics

PGD is ethically problematic if it aims not at procurement of a pregnancy and birth of a viable child, but at eugenic selection, no matter whether it is a negative or a positive selection. Cases have become known in the past where parents wanted to have a second child in order to serve as tissue donator for an already living brother or sister affected by a serious disease. Such cases suggest the question whether the birth of another child is desired also irrespective of the disease of the child already living. It is difficult to neglect the impression that the second child is only seen as a means for the purpose of healing the first child. This unveils an ethically not justifiable instrumentalization of a human being which is contrary to the good of the second child.
Finally an understanding of reproductive autonomy permitting parents to proceed to positive selection of disablements is also to be rejected (cf. II.3.2.).

### 3.4. Regulatory approval of PGD and consequences for society

The concern, regulatory approval of PGD favours an environment hostile to disabled persons, because legislation thus declares avoiding birth of disabled people to be justified and consequently approves of negative eugenic tendencies, is understandable especially in consideration of historic experience in the German language speaking area and to be taken serious, but after weighing all arguments it is in the final run not valid: with this objection PGD is alleged to have an undifferentiated eugenic objective which – as already mentioned – is not the case in such a general way. Regulatory approval of PGD in no way permits the conclusion that assistance for people affected by disablements is equivalent with preventing their birth. Apart from that, this conclusion would also be drawn from the recommendation of high risk couples to renounce their wish for children of their own for ethical reasons.

The objection raised against PGD, the IVF required for it produces an increased amount of redundant embryos which might arouse desires on the part of research, is already empirically false (cf I.2.3.). The argument is essentially based on the debate in Germany where inseminated egg cells are being preserved in the pre-nuclear stage and in terms of the German embryo protection act are not yet considered to be embryos. This is however not true for Austria. And it can be excluded that, of all things, embryos from high risk pairs for example are used to produce human embryo stem cells. This is already excessively expensive for embryos without pathological findings, their use for therapeutic purposes carries considerable risk, so that accepting additional risks by using embryos with genetically or morphologically pathological findings would not result conducive for medical purposes.

Finally it is not a valid argument that PGD has a „door opener“ function for genetically modified germline interventions which in Austria are forbidden. Genetic interventions in the germline are not only banned by the Austrian Act on Genetic Technology, they are also excluded by Article 13 of the Convention on Human Rights and Biomedicine of the Council of Europe. Suitable means to counteract such fears are not a ban on PGD, but the still lacking signing and ratification of the Convention on Human Rights and Biomedicine on the part of the Republic of Austria.
4. Constitutional aspects

4.1. General

Also constitutional considerations speak against a general ban on PGD. Irrespective of the fact which position is assumed with respect to the ethical valuation of PGD, each new legislation must stand an examination to the effect whether it is compatible with current Austrian constitutional law. This includes an examination in the light of the basic rights of the persons affected as well as the question whether the future legal situation regarding PGD can be inserted into the complete system of law in a consistent manner and without contradictory valuations not justified in the matter.

It is true that an ethical valuation can be made separate from constitutional law. As however the opinions of the Bioethics Commission to PGD both from the legal objectives of the Commission (cf. § 2 para 1 subpara 3 of the Regulation on the Institution of a Bioethics Commission “Preparation of proposals on necessary legislative measures”) and also from the possible effects of their resolution from the point of view of legal policy in any case also aim at future legislation, it cannot make sense to word recommendations for legislation whose implementation into legal policy would not be possible in conformity with the Constitution.

To include this constitutional perspective seems so much the more important as the ethical valuation of PGD is – worldwide – controversial, depending on the concepts of ethics it is based on and there cannot be any generally accepted system of ethics in a society based on religious freedom and Weltanschauung, which would be suitable as guideline of legal policy of the state and eventually would become legally binding for such persons who might not agree with this system of ethics. It is not the task of the law to implement valuations of ethics, more or less, to become orders and prohibitions of the law. Since not the comprehensive implementation of morality or values, but the assurance of being able to live together in peace, is the purpose of the law, the formulation of bans should be restricted to what ensures an “ethical minimum”. Especially in controversial areas of ethics and society legal bans should therefore be used in a very restrictive scale. All this presupposes on the one hand an ethical reflection on how, for purposes of legal policy, the finding should be handled that a certain technique of medicine such as PGD can be and actually is the subject of different ethical valuations. Und andererseits ist es gerade eine Funktion des Verfassungsrechts, jene (insb aus den Grundrechten ableitbaren) Eckpfeiler rechtlichen Schutzes zu formulieren, die der Entscheidung durch einfache parlamentarische Mehrheit entzogen sind. Under these aspects certain references for the solution of the subject issue can also be taken from constitutional law, as to how legal policy of a democratic rule of law is to face ethically controversial themes of bioethics and where the discretionary jurisdiction of Parliament (to be exercised by means of the majority principle) ends.

4.2. The equal treatment clause

1. On the level of the equal protection clause (Art 7 para 1 B-VG [Federal Constitution Act]) we first of all face the question for the factual justification of the present unequal treatment of (generally permitted) PND and PGD (forbidden according to preponderant view). It aims at the issue whether there are sufficiently
substantial factual differences between PND and PGD which can subjectively justify
the completely different legal parameters.

2. To start out with, both techniques are comparable as to their objectives and
consequences, being diagnostic procedures on the embryo in vivo (PND) and in vitro
(PGD) which may result in an individual decision to terminate the pregnancy (in the
case of PND) or not to implant and thus “reject” the embryo in vitro (in the case of
PGD). Both constellations thus affect the decision of a woman whether – after
obtaining certain information on the embryo – she wants to remain pregnant (PND) or
become pregnant (PGD). The cases are also comparable because the actual act of
decision against „further life“ of the embryo is already being accepted in both cases
by the legal system in effect and it is up to the autonomous decision of the woman, to
either abort the pregnancy (within the scope of § 97 para 1 subpara 1 within three
months or in accordance with subpara 2 StGB [Penal Code] possibly also up-to the
end of the pregnancy, or to revoke the consent to implant the embryo in vitro
(according to § 8 para 4 FmedG [Reproduction Medicine Act]). In the case of IVF
however she is refused by law to have access to the genetic findings – different from
the case of PND.

Factual differences between PND and PGD however exist – apart from details of the
examination techniques which however are not the point in this connection – on the
one hand in the different ages of the embryos: PND affects the embryo in vivo with a
higher age which may reach up-to birth, while PGD is performed on the embryo in
vitro during the earliest stage of the inseminated egg cell before its implantation into
the uterus. Secondly, the problem of selection among several embryos eligible for
implantation arises to this extent only with PGD, while PND regularly refers to a
specific embryo. And thirdly, the physical and personal contact relationship between
woman and embryo is closer in a pregnancy and thus possibly also the threshold for
decision in favour of an abortion higher than for the non-implantation of an embryo in
vitro.

3. For the valuation of PND and PGD under the aspect of equal rights follows that
both measures are basically comparable, both with regard to the information to be
obtained on the condition of the embryo (for example medical findings on future
diseases and/or disablments) as well as with regard to the consequences which
may result therefrom for the protection of the embryo (abortion/non-implantation) as
well as with regard to the future social consequences for the woman (living with the
child after birth). Also with reference to the decision regarding selection no essential
difference can be seen, because the problem arising with regard to selection – albeit
on a different time schedule – can also arise with PND in the case of several
subsequent pregnancies. The remaining differences (different level of growth; lower
“inhibition threshold” towards embryos in vitro) however have a contrary tendency,
because the low age of the embryo in the case of PGD can be supported with the
argument of a reduced legal protection compared with PND, and the different
“access threshold” for a stronger protection of the embryo in vitro.

Result-wise the by far predominant parallels between PND and PGD speak against a
general ban on PGD, and this has been stated also in the literature in quite a number
of instances. The factual differences mentioned do leave space for differentiating
regulations between PGD and PND and are no compelling
reason for a fully equal legislation. At least for those serious mental or physical damages which are valid reasons for permitting an abortion at a much later date, it would be necessary to permit PGD for the embryo in vitro for considerations of equality under the law. Specific needs for protection resulting from the situation in vitro can be met by collateral provisions (for example obligation to seek and give medical advice, reservation of authorization etc).

The present legal situation protecting the embryo in vitro throughout against diagnoses, while for the embryo in vivo any medically indicated examination is admitted, from the point of view of equality proves to be unqualified and thus to be a differentiation in contradiction to the Constitution. It forces women desiring PGD to undergo a “pregnancy on trial” by letting them decide freely during their pregnancy on performance of prenatal diagnoses and (within the scope of the provisions of penal law) also on a subsequent abortion, however does not permit them to shift the decision and the diagnostic steps necessary therefor into the extra corporal stage, which for them would be a reduction of strain and also the by far less consequential intervention, because of the early stage of development of the embryo also with regard to its protection.

A legal situation granting less legal protection to extra corporal insemininated egg cells in the earliest stage of the embryo than to those of the further developed embryo in vivo would also comply with Constitutional Court rulings judging a differentiating level of protection in the different phases of development expressly as in conformity with equality rights (VfSlg 7400/1974).

4. The objection, PGD lacks the „pregnancy conflict“ – typical for PGD during an existing pregnancy – is not valid in this connection, in particular because the applicable legal position for abortions does not require at all any such “conflict” as condition for permitting the abortion. The decisive reason for the regulation of abortion according to different levels and the full exemption from punishment for interventions taking place before nidation however is a different legal weighting of the protection of human life before birth, depending on the level of development. Would the ratio legis for less protection under penal law for life before birth really consist in the existence of a “pregnancy conflict”, it would not be understandable why abortion without consent of the pregnant woman (§ 98 StGB [Penal Code]) – where any kind of decision conflict as justification is excluded from the beginning – is subject to a clearly lesser punishment than offences killing a human being after birth.

5. Also the other arguments raised under individual and socio-ethical aspects against an at least limited regulatory approval of PGD do not constitute sufficient objective reasons under constitutional aspects for maintaining the present legislation:

5.1. The consideration that PGD contradicts the “ethical objective of medicine” neglects that the objective of PGD (avoiding a pregnancy in case of certain genetic dispositions) is not essentially different than the one of the (admissible) PND. The these, the „ethical objective“ of measures of reproductive medicine is restricted to medical assistance to avoid sterility, declares the present legal restriction of access to IVF according to § 2 para 2 FmedG [Reproductive Medicine Act] to be the guideline for Parliament legislation, but it is not in a position to explain why the future admission of a new diagnostic technique (and thus the expansion of the medical
sphere of activities) should not be permitted in the future. Apart from that it cannot be the duty of legislation to ban an internationally widespread method at times requested on the part of the women concerned because of a contradiction to the allegedly given objective “ethical objective” of medical activity.

5.2. The problem of formulating restrictions for the admissibility of certain behaviour patterns as precisely as possible and protect them against any abuse is for PGD not any different as for all other legislation projects. Clear legal regulations, the corresponding regulatory approval and control schemes, a law-abiding implementation and, in case of necessity, a subsequent course correction of legislators constitute proven instruments for effective implementation of legal norms. Against isolated (selective) abuse there are however no safeguards based on legal means. Who doubts the ability of the legal system to control in this regard as a whole must face the question why in particular the present comprehensive ban on PGD would constitute a much stronger protection against infractions than a differentiated regulatory approval.

5.3. To the extent that with reference to “tendencies for extension” to be expected a step by step easing of the legal parameters (and not only deficiencies in the implementation of or compliance with the law in force) and possibly even an erosion of the protection of disabled persons is the question, such an “extension” can always be only a consequence of a new decision of Parliament. Such a further correction of the legal course can not be effectively prevented anyway, whatever the design of the legal position de lege lata is, and, as the case may be – should this expectation or threat come true – would again have to be examined regarding its ethical and constitutional admissibility. The tendency for precautionary bans, supported by so-called „slippery slope arguments” , would then be in basic conflict with the presumption of liberty, if the only support it can find are vague and empirically not plausible threats. The prediction that restricting and differentiating legal regulations typically result in a progressive extension is in any case not sufficiently well based: neither did – just to name two relevant examples – the introduction of the “abortion deadline solution” question the protection of life after birth, nor are there indications that regulatory approval of PGD in other European jurisdictions jeopardized the protection of human beings born with disablements.

4.3. The autonomy of women to decide

From the point of view of the woman who for medical reasons wants to have a PGD performed, a legal ban on PGD would create an impediment to make use of a possible medical diagnostic procedure. If we presume alongside with the Constitutional Court that the use of methods of in vitro fertilization is covered by the protection of basic rights of private life in accordance with Art 8 para 1 ECHR (European Convention of Human Rights) ( VfSlg 15632/1999), then there are valid reasons for this basic protection to comprise also the decision on the implantation of an embryo in vitro including access to relevant diagnostic information (at least concerning heavy diseases for which there is no therapy). Both the strictly personal nature of this decision as well as the direct connection with the pregnancy resulting therefrom and the effect of the birth to be expected on her private and family life support this interpretation.
If the ban on PGD constitutes an infraction with the right to private life of the woman concerned, in accordance with Art 8 para 1 ECHR, this requires a sufficient justification in terms of the legal proviso of Art 8 para 2 ECHR: The ban must, with respect to one of the objectives quoted there (in particular for the protection of health, of morality or rights and freedoms of others) be “necessary in a democratic society”. As the ban on PGD serves neither the protection of health nor – as the embryo is not to be qualified as “another person” in terms of Art 8 para 2 ECHR – the protection of rights and freedoms of third parties, only the protection of “morality” can be a reason for such justification. Regarding the question whether an infraction with the basic rights for purposes of protection of morality is necessary, legislation has a considerable span of discretion. It will however be limited with the progress in emergence of a “European standard” among the ECHR member states. If we take into account that PGD is admitted in the overwhelming majority of European legal systems (albeit to different extents), there are considerable doubts regarding a general ban of PGD in the light of Art 8 ECHR. From the point of view of the basic rights legislation there are better reasons for than against the admission of PGD.

The objection raised against this fundamental decision autonomy of women, there would be no “right to a healthy child” (under the protection of basic law) is true, but it simplifies the problem in an inadmissible manner. For in the constitutional discussion regarding regulatory approval of PGD the issue is not to grant a positive right via a vis the state to make available or finance techniques of PGD, but only the question regarding admissibility of a legal impediment (for which therefore the state is responsible) against actually using the de facto possible and medically available examination methods. From the point of view of basic rights the issue is therefore not a right for benefit of social law, but the defence against a barrier to access to medical services set up by the state.

The state always has to justify such a legal restriction of access to medical services, and as long as this justification is not successful in accordance with the Constitution, the women or couples involved are entitled to a basic presumption of freedom under the rule of law, which can be claimed without any particular moral motives or specific “competence for being involved”. In this regard the freedom rights of the democratic rule of law can unfold their protection also against having to subject by law to moralic convictions of others.

4.4. The right to life

The basic right to life (Art 2, ECHR, Art 63 para 1 StV [State Treaty] of St. Germain) obviously does not stand in the way of regulatory approval of PGD, as the constitutional protection of life does, in accordance with the ruling of the Constitutional Court (VfSbg 7400/1974) and of the Supreme Court (SZ 72/91) not cover human life before birth. Also the literature on constitutional law agrees to a large extent – with some differences in details – that at least the early embryonic phase (in vitro or in vivo) is not subject to the constitutional protection of life under the basic rights. Moral convictions of a continuous protection of life – comparable with the protection of persons after birth – starting with insemination are of course to be accepted, but they do not find any expression at the level of constitutional law.
Moreover, a ban on PGD cannot be justified with the argument of protection of life also for the reason that the „life threatening“ act cannot be seen at all in the performance of a PGD, but, at best, in the subsequent failure to implant the embryo. This freedom of the woman to decide on the implantation (§ 8 para 4 FmedG) so far has never been seriously doubted. Taking a closer look, we see that the ban on PGD therefore does not aim at the protection of the embryo’s life (to this effect the freedom of decision with regard to the implantation would have to be put in doubt or at least the donation of embryos to third parties admitted), but only at accepting certain motivating factors for exercising the right of implantation. According to the existing legal situation it is not primarily the embryo’s life, but his “genetic incognito”. With the constitutional protection of life this intention to protect would therefore not be sufficiently explainable even then if the basic right to life would be intended to be applied also to the early embryo.

Thus at the same time all those arguments against PGD are put in perspective, which refer to the inadmissibility of a “selective” procedure with human life: constitutional reservations against „selective“ decisions can result from the perspective of protection of life only from such consequences to which the “selection decision” leads (here also, as the case may be: from the “elimination” of the embryo in vitro). Without this reference to its consequences, each reference to an alleged constitutional inadmissibility of “selective” decisions is futile because selective decisions per se are neutral from the point of view of basic rights. Anyway, if the legal system accepts, for respect of the freedom of decision of the woman (cf II.4.3.), the final decision on the fate of the embryo (in the form of the permitted abortion of the admissible refusal of implantation), it is not understandable why this decision cannot be made also on basis of corresponding diagnostic information (and not “blind”). In fact the selection argument therefore turns out to be rather an expression of the protection against discrimination (see below II.4.6.), but not for the protection of life.

4.5. Human dignity

From the protection of human dignity follows – even if only assuming for argument’s sake their constitutional basis to be an element of the system of basic rights – no suitable argument for a general ban on PGD.

This follows on the one hand from the fact that a protection of human dignity derived from the basic rights presupposes a personal subject of protection in terms of a “carrier” of the basic right of human dignity, which obviously is not present in the embryo in vitro. If not even objectively relevant basic rights such as in particular the right to life are applicable to the early embryonic phase, it seems then hardly justifiable why an unwritten basic right or „valuation principle“ is to have extensive indirect effect on early development stages of human life which are not at all reflected in the express provisions of the basic rights. But if there is no “subject” of basic rights entitled to human dignity, then also the “object formula” known from Supreme Court decisions and the “prohibition of instrumentalization” based on it lack the necessary point of reference to a carrier of basic rights.

But also if we dismiss a “carrier of basic rights” as subjective legal point of reference and consider the protection of human dignity to be merely an expression of an objective duty of protection of the state, the early human embryonic phase would at
best be an object of protection justifiable under constitutional law, which however would be open to a tradeoff with other objects of legal protection – in particular the rights of the woman involved in accordance with Art 8 ECHR as well as the protection of her human dignity. Insofar we would talk about an objective “impact” of human dignity comparable with the post mortal protection of a human body.

It is also true that the way the principle of human dignity is understood is particularly controversial as far as PGD is concerned as it is opposed to any interpretation of expressed constitutional arguments able to meet at least some consensus. To a large extent the lack of definition of the dignity principle turns out to be just a gateway for certain moral premises which can convince only those who share such premises. Already the circumstance that most national legal systems (including the European Community Law) contain an explicit or implied recognition of the principle of human dignity and at the same time admit PGD to a more or less large extent, casts a light on the small degree of normative capacity to derive an argument emanating from the principle of dignity.

Finally it must be considered that all those objections based on the principle of human dignity, which now are raised against PGD, would to a high extent also be applicable to other constellations of collision of the woman’s decision autonomy with the protection of prenatal life. If we look at the embryo in vitro as carrier of human dignity and conceive this protection in an analogous manner for the protection of human beings from the moment of birth, it would not be understandable why such protection should prevent only PGD and not also PND or the abortion of an embryo in vivo.

4.6. Ban of discrimination

The ban on discrimination „related to disablement“ laid down in Art 7 para 1 B-VG (Federal Constitution Act), providing that “nobody … must be discriminated because of his disability”, as well as the subsequent commitment of the Republic of Austria to “equal treatment of all disabled and non-disabled persons in all spheres of everyday life” is rightly so the center of constitutional valuation of PGD. This provision justifies not only a subjective constitutional right to a ban on discriminations specific against disabled persons, but also an objective duty of protection on the part of the state in terms of a definition of the objectives of the state with regard to equal treatment of disabled and non-disabled persons. That thus in some way “selective” and detrimental interferences into the rights of disabled persons are forbidden is self-understood and needs no tedious justification.

From the constitutional point of view, however, it is not possible to derive that Art 7 para 1 B-VG prohibits also diagnostic steps during or before the beginning of pregnancy aiming at identifying genetically conditioned diseases or disablements: as to the extent that Art 7 para 1 second clause B-VG creates a subjective right against discrimination, this right of defence - just as also other basic rights – refers to human beings as carriers of basic rights (arg „noone“). Art 7 para 1 B-VG does not demand equal legal treatment of “disabled life”, but equal treatment of “disabled and non-disabled persons”. We can, however, speak of a „person“ in terms of the constitutional law of Art 7 para 1 B-VG – just as in the case of right to life – only from the moment she or he is born. In the same way, also the duty for protection in the
third clause of Art 7 para 1 B-VG refers, already by its wording, only to human beings after birth. Measures which are to prevent future diseases or disablements therefore are not in contradiction with the above, not even in cases when this objective is to be achieved by failing to implant extra corporal embryos after PGD or by an abortion after PND.

Even if one does not agree with this restriction of Art 7 para 1 B-VG only to persons after they have been born, the binding effect of this ban on discrimination - initially aimed at the state – not be transferred offhand to decision patterns of private persons (in the subject case: to the woman involved). It is true that within certain limits legislation can, on basis of the duty of equal treatment, also be obligated to issue corresponding regulations against a discrimination also among private persons. However, within the scope of strictly personal decisions, an undifferentiated transfer of such equal treatment obligations to private persons may result in an unsolvable conflict with the private autonomy of the person concerned. For decisions affecting the strictly personal sphere of life – such as entering private or sexual relations or marriage – there is also, within the scope of private autonomy, a constitutionally protected autonomy to take decisions, especially by the possibility that on the basis of one’s own – thus also “selective” – moral view, personal valuations, experience and preferences, one can decide without having to justify such decisions by objective parameters.

The decision to become pregnant, bear a child and bring it up certainly is part of such strictly personal decisions. This freedom to decide is in no way an absolute one and must respect such limits resulting from the basic rights of others (and this is why the life of the child after birth of course is protected without any restriction also against the mother). These limits however do not directly emanate from the ban on discrimination, they must be justified also by means of other boundaries (in particular those resulting from basic rights). Because and inasmuch as the early embryo is neither protected against decisions of his mother by the right to life nor by other constitutional provisions, also the ban on discrimination of Art 7 para 1 B-VG is no obstacle to PGD or the subsequent failure to implant. But even if one rejects this point of view, the difference in treatment of PGD and PND would not be justified, as Art 7 para 1 B-VG would then also prohibit prenatal diagnosis of disablements and an abortion based on it.

To avoid misunderstandings it must be stated that this interpretation of the ban on discrimination can in no way be interpreted as an expression of reduced respect on the part of the legal system for people affected by diseases or disablements and definitely not as approval of a differentiation by being “worthy” or “not worthy” of life. Regulatory approval of PGD would therefore also not reflect a lack of esteem for people affected by disablements. It would only reflect the necessary respect for the individual decision of conscience in a truly strictly personal matter of the women and couples involved.
5. Recommendations

The aforementioned ethical and constitutional considerations result in the following recommendations:

5.1. PGD shall be granted regulatory approval for cases of recurrent failure of IVF/ICSI, i.e. for attempts to transfer nonviable embryos (i.e. in constellations not resulting in an implantation), as a method to “improve” the chances of success of IVF/ICSI.

5.2. PGD should be granted regulatory approval for such cases where due to chromosomal or genetic findings there is a risk of a serious disease leading to death either already during pregnancy, at birth or up-to at the latest several months after birth, with a reliable diagnosis and without the possibility of medical treatment.

5.3. In addition to that PGD should be admitted also for couples with a high risk of having a child affected by a serious genetically conditioned disease. In such cases also the determination of the gender is admissible with reference to the disease (cf. above I.1.3.6.). Since PND, involving more problems regarding its consequences (not in its prerequisites) (abortion at a later date, repeated abortion, is legally permitted, it is in any case inconsistent and objectively not justified to generally prohibit PGD.

5.4. The introduction of a general genetic screening within the scope of IVF is to be rejected. The decision to perform PGD shall be made separately in each single case and on the basis of an indication scheme. For this purpose criteria such as family anamnesis, age, (high) reliability of the diagnosis (without “overkill information”), the lack of therapy, etc. may be used.

5.5. Regulatory approval of PGD is to be defined as precisely as possible, both regarding the subject matter as well as the procedure. It is advisable to word a general clause, possibly containing examples for the specification of a number of individual indications. Administrative parameters are to ensure adequate quality control, for example by requiring approval of the authorized medical facilities on the basis of objective qualification requirements. For this purpose separate organizations and persons shall have the authority to perform PGD on the one hand and the preceding IVF on the other hand. PGD shall not be performed by the reproduction medicine physicians who perform the IVF, but by duly qualified specialists of human genetics, and a separate administrative approval should be required for each single indication.

5.6. From the legislative point of view, a legal regulation of PGD would be advisable to be provided either in the FmedG (Reproductive Medicine Act) or the GTG (Genetic Engineering Act) The FmedG would in any case have to be amended to the effect as IVF will be admitted not only for treatment of sterility, but also as prerequisite necessary for the use of PGD whenever PGD will be authorized.

5.7. A consultancy on human genetics in preparation of a PGD should be made mandatory.
5.8. Adequate measures of quality assurance and quality control should be required by law as well as regular evaluations and duties to notify and inform the Federal Ministry for Health and Women.

5.9. The prerequisites for admissibility and indications provided by the law are to be worded in a way as to prevent any implication for discrimination of people affected by disabilities. The objective specified by society and by constitutional law to protect people affected by disabilities as well as their relatives against any form of discrimination must not be jeopardized by the regulatory approval of PGD.

UnivProf Dr Karl Acham
UnivProf DDr Johannes Huber
UnivProf DDr Christian Kopetzki
UnivProf Dr Ulrich Körtner
UnivProf Dr Heinz Ludwig
UnivDoz DDr Barbara Maier
UnivProf Dr Christine Mannhalter
Dr Heinrich Scherfler
UnivProf Dr Renée Schroeder
UnivProf Dr Ina Wagner
UnivProf Dr Kurt Zatloukal
Supplementary opinion by UnivProf Dr Holger Baumgartner

1. General reasons

With reference to the arguments stated under II.4. (aspects under constitutional law) I support the recommendations stated to II.5. to the extent that the following additional corollary measures will be added to the recommendation.

I basically agree with Part III – opinion in favour of maintaining the present legislation unchanged – as far as III.1. through inclusive III.4.4. are concerned, but taking into account the prevailing legal and social realities I personally arrive at the abovementioned decision in favour of a recommendation in terms of II.5. My decision is therefore not based on the presentation given under II.1. through including II.3.4. because I do not share the opinion of a number of the reasons given there.

2. Particular reasons

PGD (PGD) are measures of preventive medicine of a completely new kind. Naturally the long time data decisive for the overall evaluation are not available yet, this is why PGD-IVF will have to be considered for a longer period of time to be an experimental medical procedure. Therefore a particular high degree of responsibility is involved with regard to future human beings which will be born as a result of this method. With the restrictions recommended, PGD will affect, as a special solution for individual (isolated) cases, a rather restricted number of persons, so that only close international co-operation will be able to provide the necessary number of cases for establishing high quality standards and for the necessary prospective collection of long time results on a scientific basis, therefore co-operation with other countries, especially EU member states, is urgently recommended for this purpose. The obligation for prospective coverage of interests of future human beings resulting from PGD, political and social responsibility and last not least the scientific duty of diligence, require comprehensive special organization to be subject to an accompanying process of reflection and justification.

3. Recommendation

I support the recommendations stated in II.5., however in supplement to II.5.8. I consider the following additional corollary measures to be necessary:

1) Annual duty to report to a suitable parliamentary body and mandatory publication of a report.
2) Obligation by law of the competent Federal Ministry to perform inspections at regular intervals and include the results of such inspection into the report to the Parliament.
3) In coordination with other EU member states suitable measures shall be taken in order to ensure
   3.1.) quality control and quality assurance measures of international standard and
3.2) control of results over extended periods of time (state and development of health after PGD-IVF).
4) The respective legislative regulations shall be issued for a limited period of time and require new evaluation of the situation by Parliament for their renewal.

UnivProf Dr Holger Baumgartner
III. Opinion in favour of maintaining the present legislation

1. Basic considerations

The following statement is given in the full knowledge of the existential suffering an unfulfilled wish for children or the worry resulting from a child affected by a genetic defect may in the given case mean for parents. This suffering calls for active understanding and solidarity of society. Understanding is indispensable because it makes us aware of ethical problems, but in an isolated manner it does not yet supply all aspects of judgment for responsible action and no criteria and standards of action. Ethical valuation is not only a matter of being concerned, it also implies the question of the rights of those involved and their respective acknowledgement.

Balanced moral valuation of an act includes taking into account all elements constituting its structure, i.e. its object, its objectives and intentions, the ways and means for achieving the objectives, the foreseeable consequences as well as the circumstances in their individual ethical and socio-ethical perspective. Especially in the case of such a sensitive matter as PGD, this perspective must be brought forward, because here, as also otherwise between individual acts on the one hand and attitudes and acceptance by society on the other hand, the experience is that they are mutually conditioned by each other.

A fundamental, albeit not the only, relevant problem in the context of PGD is the question who or what it is that has been inseminated extra corporally. It is dealt with under the title “moral status of the human embryo” and is related to the moment of beginning of human life and its worthiness of being protected. This is not a religious issue and not to be put in perspective by referring to “positions” of religious denominations or philosophic points of view to the effect that only pragmatic research oriented or economic interests would be in charge of deciding. It is rather an issue of philosophic anthropology which can be solved not without scientific knowledge, but not only by science alone, because of the reductionist methods it uses. It is to be addressed open-mindedly, because otherwise we have a case of a “convenience anthropology” where from the outset the objective aimed at determines the solution.

2. The problem how to determine the moral status of human embryos

2.1. The problem of methods

The problem consists in the question whether the human embryo is covered by the general prohibition to kill and the prohibition of instrumentalization of human beings and whether his life can be an object of a tradeoff of legal values or not. Though scientific knowledge is indispensable to answer this question, however it is because of the not sufficient reductionist methods being its basis. They eliminate from the start the human dimension and remain in need of interpretation. The points of view of interpretation cannot be gained from natural science, but rather from a critical method
reflexion regarding the principles of the experience which precedes scientific objectivation, an experience science will never catch up with. This is the practical experience of our life. The reflexion to the self-image we include in our practical life and to the communication of language in the context of this practical life is of a philosophic-anthropologic kind.

This reflexion must take place independently of pragmatic objectives (intention to implant or not), because otherwise its results would be circular and criteriological. It must not draw conclusions from possible options for action to the ontologic and moral status of man. A philosophic-anthropologic reflexion however by itself cannot yet provide any specific standards for actions, it can only name necessary prerequisites to ascertain sufficient precision.

2.2. The scope of the meaning of the word “embryo”

The term „embryo“ is used differently depending on the context (medical-philosophic, anthropological or ethical-legal). In medical language the term means the human germ-cell from the time of its nidation in the uterus (implantation) until completion of the development of its organs (2nd to 8th week after fertilization). For these purposes the embryonic period is subdivided into a preembryonic and an embryonic phase. Where in the philosophic-anthropologic or ethic-legal context the issue is the so-called moral status of the embryo, the term „embryo“ does comprise also the preembryonic phase. If we disregard the radical gradualist positions which tie the full protection of life to so-called morally relevant properties (either their actual presence or their organic prerequisites), the controversial question essentially refers to the first two weeks of life. There is disagreement on whether with the beginning of new human life starting with fertilization the full moral status is also given and thus the full protection of life is triggered. In the context of this controversial question the term „embryo“ means the phase of life between fertilization and completion of the development of organs – otherwise the controversy would be dismissed. If the argument is that the question for the moral status of the embryo is relative already for the reason that it is problematic to define the new human living being to be an embryo at all until a multiple birth pregnancy can be excluded or until the moment of nidation, the discussion of a problem is replaced by language use.

2.3. The moral status of man

The status of a human being on basis of which it is covered by the prohibition of being without exception instrumentalized and killed and is entitled to care and welfare, is not based on gender or certain characteristics, abilities, performances or conditions, but simply due to the fact that she/he is a human being and belongs to the species of human beings, no matter how he became a member of such species, - whether through fertilization in vivo or in vitro. Therefore all men (universality) are entitled to this status in the same way (fundamental equality among human beings from the ethical and legal point of view). Therefore it is not possible to establish the conditions for acceptance as a human being by resorting to so-called morally relevant characteristics such as the sense of pain, self-esteem, ability to communicate, for mutual recognition and future related wishes, etc. It is not the acceptance of the status as human being that need be justified irrespective of such characteristics, but the attempt to make them dependent on them.
Being a human being is not a quality that possesses something. We are not human beings because we possess certain properties, it is the other way around: it is because we are human beings that we possess properties or capabilities, and can obtain them or not. The term „human being“ constitutes in this context not a property, but in an indefinite manner the carrier of such property. Being a human being is also not a state, in which something is (This state would have to be a human condition. However, only a human being could be in such a condition). As a human being, one is in a state of health or illness, one is not in the condition of a human being as a healthy or as a sick person.

If the moral status of a human being is simply based on the fact of being a human being and being a human being means to live in a time-history frame, then this status and the worthiness of being protected following from it is given, since and during the time a human being lives. One cannot live more or live less, one can only live or not live. To live is something indivisible and permits no gradualism. As little as life increases, as little its worthiness of protection increases. That we are living by existing in one or the other phase of our life only means that we human beings exist in a time-history frame, but not, that life, as differentiated by its phases, becomes more or less worthy of protection. A gradualist concept of the protection of life therefore necessarily becomes exposed to more or less arbitrary boundaries. Phases of life are not components of life. With the first phases of life not only a part of a human being exists and the rest is yet to follow, but with them the human being itself (as a whole) began to exist.

The difficulty to determine the moral status of the human embryo concerns on the one hand the question for the subject of life and on the other hand the circumstance that the beginning of human life is out of the reach of chronometric date fixation.

2.4. The search for the subject of life

„A human being“ can refer to a phase of life and a figure or something like a figure (a grown up person or an appearance reminding of a grown up person – in a way if one says an embryo develops into a human being.) „Human being“ also is the term for the subject which is living. In order to speak about the subject which is developing, we therefore must say: the embryo, as a human being, develops further into a human being. A human being develops as such, but it is not a development from something not human to human, not a development of a potential human being to an actual one. That is one of the reasons why the differentiation between potential and actual carriers of human rights does not lead anywhere. Being a human being means being someone. It is not human life that is living, it is always someone who lives. The subject of life is someone – someone who is fathered and dies. Because one is always a physical being, the subject of human dignity or the carrier of human rights cannot be reduced to a subject conscious of itself and imply the absence of a subject to be protected as long as it is not conscious itself. One can protect a person only by protecting his/her life, there is no other way.

If we speak of living cells or organs and in this sense of the existence of “human life”, one must not suppress the only analogous meaning of such sentence. Otherwise one disintegrates the physical-personal unity of a human being, by creating a multitude of living beings from certain united cell structures and organs. The unity of one human
life is then figured by a kind of collective unit. This is not the way we recognize ourselves. We are not a complex of living beings.

Looking on his own life history, each one of us rightly says she/he has been conceived by her/his parents. (This is also true for monozygotic twins.) We ourselves have existed in the state of an embryo or of a fetus, we have already existed although at that time we have not been conscious of ourselves. My parents did not conceive an anonymous human life, they conceived me. I myself am the subject of my life, neither something different, nor somebody different from myself. We must not draw ontologically false conclusions from substantival ways of speaking. The terms “embryo”, “fetus”, “newborn” do not mean different subjects of life, but different phases of life of one and the same subject of life. Having been an embryo means to have already existed in the embryonic phase of one’s life, i.e. oneself already has been there. Therefore it can neither be said, an embryo has been before me, or I am identical with the embryo that has been before me, because my past phases of life cannot have preceded me, nor can it be said that I have arisen out of an embryo, because I cannot arise out of myself but can – under adequate conditions - only came out of myself to myself.

2.5. Chronometric impossibility to define the beginning of a human life

The arguments listed for fertilization starting the life of a new human being are: the zygote possesses a unique genome specific to the human being. It is a functional, self organizing and differentiating unit which can under adequate conditions by itself develop into a grown up human being. This development is specific to human beings from the very beginning. The various stages of development pass into one another in a continuous way. These transitions are in no way comparable with the caesura constituting the process of fertilization. Under biologic aspects the zygote possesses individuality as unmistakable time-space related self-organizing unit in interaction with its environment. The rare case of twins constitutes no valid objection. From the point of view of system theory, it can be described to be a bifurcation. As long as the embryo still comprises the choice of multiple life, it is not less worthy of protection, than when it has reduced and individualized to one single life. The laws of ethics and law gain terrain, when the laws of nature (or the natural random principle) retire. That after natural fertilization only one out of three fertilized egg cells reaches the objective of nidation, and most of them are ejected automatically, happens outside of the legal horizon of responsibility; it does not trigger for anybody a duty to intervene under the title of basic rights. It therefore also does not provide any argument for liberating human handling of artificially fertilized embryos from the obligations of law and denying the embryos the intrinsic right to life. „Selection by nature“ is no ethical guideline for a selection by man, and definitely no reason for justification. Procedures in nature do not provide standards for human action.

The arguments against fertilization as beginning of a human life are: a high percentage of all fertilized human egg cells does not succeed in implantation but comes off in natural ways, which would mean speaking senselessly of a corresponding number of human deaths. The zygote is not an embryo because it must yet be differentiated further into trophoblast and embryoblast. Before formation of the early embryonic body in the blastocyst it would not be possible to speak of a
human individual. Individuality is only given after exclusion of multiple pregnancy. Resorting to potentiality and continuity of development is said to overlook the fact that an extra corporally fertilized zygote cannot develop extra corporally into a human being. For particular single cases there is no prospective certainty for the development potential of a zygote, comparable with the retrospective certainty. It depends on the intention of third parties whether a separated totipotent cell is to be regarded as a part of the preembryo in waiting position or as newly formed preembryo.

The fact that both arguments can bring forward important reasons tells that the beginning of a human life basically cannot be exactly fixed time-wise. From this lack of possibility of the point in time it is however not possible to draw any unequivocal conclusions, neither with regard to the moral status of the embryo in vitro nor with regard to options for actions to be taken.

2.6. The human embryo in vitro

Taking the chronometric impossibility to fix the point in time in serious precludes construing a status of the human embryo with the intention to justify the admissibility of tradeoffs between legal/ethical goods (life of the embryo vs. therapeutic or preventive purposes) and the possibility of realization of certain objectives. The impossibility to define the time does not provide any legitimate basis to determine the moral status of the embryo retrospectively as far as kind of fertilization, intentions or possibilities of implantation are concerned. The kind of fertilization - whether in vivo or in vitro – does not establish any difference in status. The moral quality of the status can be traced back on the “natural quality” of the fertilization procedure only for the price of biologism. In the same way, the intention to father a child the “natural” way does not establish a moral status of what has been fathered. Genesis is not the reason for validity.

Deciding on the moral status of an extracorporally created embryo, depending on the intention to implant or not, exposes the status definition to arbitrariness. One and the same embryo would have its status only during the period in which its implantation is intended. Would this change in between, it would lose it, would it return to the original intention, it would get it back. The same is true for the recourse to the elimination of the possibility to implant. If „possibility“ means that the intention to implant exists, what has just been said is true. If “elimination of the possibility” means that due to an only restricted future viability the implantation of the embryo is dispensed with, also this form of establishment of a status falls back into biologism, because it makes the moral status of the embryo dependent on the empiric property of its ability to develop.

In the same way it is not possible to justify the admissibility of subjecting an embryo’s life to a tradeoff with the argument that the existence of development potentialities is dependent on intentions. By this principle embryos not intended to be transferred cannot be considered to be “future human beings” in the same way as others intended to be transferred, and therefore they would be subject to a tradeoff. And the fact that an embryo cannot become a human being outside of the womb also does not let us draw the conclusion that it would not have such potential, in order to infer the admissibility of tradeoffs. This objection levels the difference of real potentiality and the conditions of its realization. The reference to this difference has nothing to do
with a wrong naturalist conclusion. Depending on an opportunity to develop on adequate conditions does not mean that they constitute the real potential. It is not that with the implantation the (already living!) embryo is provided with the capacity to live, it is just that he is allowed to continue to live or not in case of non-transfer. In both cases the real potential is presupposed. The admissibility to subject the life of a human embryo to a tradeoff cannot be justified by resorting to subjective intentions.

A similar thing is true for the reference to the prospective uncertainty. According to that only the retrospective on a successful development provides certainty on the existence of a potential for development in a given individual case, and not the prospective, and this is why pragmatic interests in a given case would have to be valued higher than the continuing life of an embryo. The presence of a real potentiality however is not based on a transfer of the certainty communicating the “successful” completion of a development, to the beginning, but to the knowledge of what is typical for the species. It always can only say what normally happens under required species-related conditions if nothing goes wrong. This is what we cannot know beforehand. This lack of knowledge must not be re-interpreted into an uncertainty on the presence of a possibility of development in an individual case. Such a re-interpretation exposes the way embryos are handled to an irrational decision environment. With the uncertainty in the individual case on the presence of a potential for development it is possible to justify options for action to the contrary: confirm or cancel the development potential for a zygote – depending on the situation of interests.

The allegation that the only identifiable identity reference between an early embryo and a human being after birth consists in the identity of its genome mixes up, in biologist manner, the time-frame unity of a human life with the invariability of a physical characteristic. Apart from the fact that there is no identity relationship between phases of life, this allegation misses the point. It is not some genome, but my individual genome. The self attribution („my“ genome) is not made by my unchangeable genome, but by myself. Who transfers his identity into the unchangeability of the genome, reduces man to his genetic equipment.

2.7. Practical consequence

The discussion on when a life of a new human being begins makes us realize that by defining the moral status of a human embryo one cannot obtain any unequivocal knowledge beyond any relevant doubt and in this sense remains confined in a state of not knowing anything. One must, however, not equal a situation of not knowing whether something exists with a situation of knowing that something does not exist. Who implies from the admission of a lack of knowledge the admissibility of instrumentalized handling of human embryos, requires knowledge there where this is not possible and supports further instrumental handling of human life.

In view of the impossibility to justify the admissibility of a tradeoff between human embryos and subjective objectives, and in view of the consequences not desirable from the point of view of society, meaning an admissible tradeoff of the earliest phases of human life, the impossibility of chronometric definition of the beginning of a human life compels us to draw the practical conclusion in dubio pro embryone. This means deciding for the biologically defined beginning of new human life and to
recognize the human embryo from the moment of fertilization not as mere legal object, but as carrier of personal rights, to put him under the full protection of life and the ban on instrumentalization, withdrawing him thus from the sphere where he can be traded off with other values. From the difficulty to identify a limit we must not draw the conclusion that there isn’t any. The biologically defined beginning of new human life is the only point in time free of arbitrariness, what cannot be said about all other markings letting the protection of life begin at a later date – a circumstance which is of special importance for a legal regulation depending on clear borderlines.

3. Objectives of PGD

3.1. The wish to have children and the parenthood

Advocates of PGD argue with the increase of the reproductive autonomy, the fulfilment of the wish for a child without genetically pathological findings. Fulfilment of a wish to have children and life with a healthy child certainly enjoy a high priority for the design of a successful life. With full consideration of this circumstance it still means simplifying the question when the problem of PGD is only discussed from the perspective of the couple concerned and forgetting that parenthood is a relationship implying to recognize the subjective status of the child. Human creation is not a production method, on the contrary, under adequate conditions its result is a carrier of rights. A carrier of rights is more than a mere legal object that can be traded off against other legal values and be put in perspective by those. The carrier of rights possesses dignity not subject to tradeoffs. The circumstance that the existence of a human being depends on being created by parents does not imply a right for those parents to decide on its further right to live on the basis of certain prerequisites of being decided beforehand. This would be an instrumentalization of descent and therefore a disrespect of the self-intent character of the expected child.

3.2. The right to progeny

However much happiness may emanate from parenthood, the fact remains that – as is generally known – there is neither a right to have a child of one’s own nor to have a healthy child. The so-called right to one’s own progeny means not being prevented from having one’s own offsprings. This right does not imply the obligation of the state to make available without distinction all means of reproductive medicine. Making available such means is rather subject to restrictions of financial but especial ethical kind. These restrictions comprise the protection against instrumentalization of descent. This is the case for reproductive cloning and for selection of embryos by genetic criteria. It is not possible to argue against such restrictions that they cover up a state chaperoning practical life because we are talking here about the duty of the state to ensure protection for life. Under basic rights there is no right to claim the right to performance of diagnostic techniques that do not even serve the original purpose of IVF, that is to overcome sterility.
4. PGD as an instrument

4.1. The problem of the criteria of a selection

Whatever may be the focus of its objectives – to avoid unbearable suffering of parents exposed to the risk of repetition, support to procure the birth of a healthy child – PGD involves a selection and destruction of embryos identified by genetic defects. (Apart from that, PGD abolishes the connection between diagnosis and therapy). Different from PND, this selection is planned with the prevention from the very beginning. It cannot be justified with the fact that it is an inevitable corollary consequence of the act accepted for the purpose of realisation of goods considered to be of higher value because they constitute part of the procedure. Where a decision is taken for a PGD, embryos are produced extracorporeally with the intention to make them an object of a tradeoff (“fertilization on trial”) and not to implant them if they will be affected with the genetic defect, what subsequently means their destruction.

The decision to abstain from implantation is based on a normative idea that the embryo created is not supposed to be as it is – an idea determined also by the valuation of the (future) parents not to be able to face a life with a genetically affected child. PGD raises the question for the criteria between health and disease, according to which the right to live or not will be decided, evocating the issue “worth living or not”, to be clearly distinguished from “viable or not”.

An examination as to non-viability in the sense of restricted viability in the context of a “normal” IVF is covered by existing legislation. It constitutes an ethically acceptable border case not subject to the ban on instrumentalization and not serving the purpose to eliminate viable embryos with pathological findings. (The term restricted viability covers embryos not nidating in the uterus, fetus unable to reach the stage of birth or newborn babies dying within short after their birth.

4.2. PGD as a solution of an (anticipated) conflict

4.2.1. Anticipated – existing conflict

One of the main arguments for regulatory approval of PGD looks at it as a means one can live with in order to solve an anticipated conflict. While in the case of an intended PGD there is no pregnancy conflict, but with the situation of couples with a risk of repetition or a probability resulting from family anamnesis that the first child may already be genetically affected, a conflict is anticipated whose seriousness seems to justify PGD as means to solve it. Apart from the fact that means for realising an objective are not accepted like unavoidable collateral consequences, but are in part intended, this argument has also other deficiencies. With PGD it is not an anticipated conflict being solved (pregnancy conflicts or life with a genetically affected child), but it rather creates a conflict through third parties – the selection of human life.

Speaking of an „anticipated conflict“ inadmissibly simplifies the problem by hiding the differently based anticipative situation and thus reducing from the very start the alternatives to a gradual difference of conflict solutions. The ethical problem will then be restricted to prevent abuse and the question of use is no more asked at all. One
can certainly suffer from an anticipated conflict situation. The decisive moment for an “anticipated” conflict however is not the content of the anticipation (such as life with a genetically affected child), but the situation in which it is created (existing or intended pregnancy). The wish to have a child of one’s own without pathological genetic findings – and this is the only thing existing before asking for a PGD – is no conflict situation. It is therefore inappropriate to level out the difference between PGD and PND with the statement that both cases are cases of an anticipated conflict (life with a genetically affected child). Talking about an „anticipated conflict” suggests that the issue is only one of a better or worse solution, and distracts from the fact that the options also include avoiding the conflict by ethically reasonable alternative solutions (adoption, fosterage, having no children). PGD definitely is no means of conflict solution. Life with a genetically affected child one already has can be a conflict situation for the couple involved, but this emergency situation obviously also PGD cannot solve.

4.2.2. PGD and abortion after PND

Practically the same thing is true for the statement that PGD is in comparison to an abortion after PND the „lesser evil“. This comparison is inappropriate because it disregards the different ethical context in which the measures are positioned. It (a) disregards the incomparable situations and prerequisites existing between an abortion after PND and the decision for or against PGD (existing – not existing pregnancy, possibility to avoid a conflict). It (b) presupposes tacitly that the ethical problems would begin only after performing a PGD and not already before, and therefore concentrates (c) exclusively on the consequences of handling embryonic life in vitro and embryonic or fetal life in vivo. Only on the basis of this abstraction the consequences of actions in terms of a larger or minor evil become comparable (avoiding the problems connected with an abortion versus rejection of embryos before the stage they can feel pain). The logic of avoidance of pain overlooks however that according to its painless killing of a newborn comes to be on the side of the smaller evil.

4.3. The argument of contradicting valuation

4.3.1. The logic of inconsistency

The reference to so-called contradicting valuations or inconsistencies and the request following it to eliminate them falls short of being an argument. Acceptance by society is not a priori equivalent with ethical acceptability. Otherwise ethics will be deprived by its potential for ethical criticism and downgraded for approval a posteriori of the “normative power of factual things.” So-called contradictions of valuation are a sign of modern democratic societies. Because the possibilities and the handling of such “contradictions” are part of the untouchable bases of democratic societies, an uncritical request to cancel them touches these very bases. The request to cancel contradictions of valuation in the long run on an “everything or nothing” decision of either fundamentalist or liberalist kind. Who considers ethically acceptable under exactly defined conditions need not consider everything acceptable what A still considers feasible. The alleged contradiction in valuation between an A and a B arises only as soon as the exact context and the conditions of A on the one hand and B on the other hand are consciously set aside. Therefore the logic is not true, who
Preimplantation genetic diagnosis (PGD) – Report of the Bioethics Commission

4.3.2. Admissibility of the abortion and inadmissibility of a PGD

The admissibility of an abortion because of an embryopathic indication can also not serve as justification for approval of PGD, nor the possibility to have abortions after PND performed as many times until a healthy child is born. First, when the protection of life is not given at one point, this does not justify its being dispensed with at another point. The ethical problem is primarily not the non-admissibility of PGD, but the admissibility of an embryopathic indication until directly before birth. (Besides there is the question whether an embryopathic indication provided by law is in conformity with the Constitution.) Second, the possibility to act in contradiction to the intention of a law, that is to arrive at a successful birth after a series of abortions, is equally not an ethical argument – apart from the fact that such a possibility cannot be interpreted as an unavoidable necessity to use it, resulting from the existing legal provisions.

It is true only in part that the embryo is not qualified as a person in terms of the law. It is on the one hand certainly not a person with full legal capacity in a definite status of rights, but he is carrier of subjective rights (and obligations) under § 22 ABGB (Austrian Civil Code) as he has in particular (conditionally) the capacity to inherit. To maintain his right, a curator ventris nomine may be appointed for him as legal representative. (Only a subject of law can be represented, never a mere object of law). Within the scope of its partial (and temporary for the condition of live birth) legal capacity the embryo therefore also has the capacity to be a party in a legal proceeding involving its rights (or obligations). If we do want to differentiate between potential and actual carriers of rights, the circumstance that potential carriers of a right are not mandatorily entitled to the same rights as actual carriers of this right, does not imply that “potential” carriers of rights are to be regarded fully without rights and protection. For a legal valuation of PGD this question however is not relevant. What is decisive is the status of the embryo under basic rights. In the light of the European Charter of Basic Rights (Art 1: Respect for and protection of the dignity of man; Art 2 para 1: right to life of every person) this will have to be re-defined also in Austria.

In the absence of an objective differentiation of the contents to be regulated, the equality principle certainly does not imply a mandatory equal treatment of PGD and PND in terms of regulatory approval of both methods of diagnosis. The opinion that the “abortion deadline solution” was not intended for a pregnancy conflict as prerequisite for the admissibility of the abortion, fully disregards the political reasons...
of this regulation by the historic legislator! Because either such a conflict has been assumed as representative and typical in the regular case, or the regulation as such would already for this reason have to be qualified as arbitrary and therefore contrary to the constitution - because it presumes arbitrariness not only in negligible single cases. The same thing would then doubtless have to be held against the regulation, that the abortion without consent of the pregnant woman is not punished like killing a living person.

4.4. Problem areas of PGD inherent in (conditioned by) methods

Taking the cells necessary for the genetic test may constitute an unacceptably high risk of damage for the residual embryo. In view of the method-inherent uncertainty factors of PGD the European Society of Human Reproduction and Embryology recommends, to make sure, to have PND performed after each PGD followed by pregnancy. As this may, as the case may be, result in an abortion, the argument of PGD being the lesser evil becomes relative.

5. Consequences of regulatory approval of PGD

5.1. Door opener function and extension of IVF indications

The question whether PGD results in increased occurrence of redundant embryos has not yet been solved on an international level. The possibilities of application of PGD are not restricted to the target areas presently quoted as being reasons for its approval. As it can be used as test during gemline-interventions and cloning of embryos, it may increase the readiness for acceptance of these procedures. There is no necessity whatsoever from the point of view of medicine or of health policies for a use of PGD to improve efficiency of IVF.

5.2. Discrimination

Realistically, the only choice can be: either unlimited approval of or ban on PGD, a restricted approval cannot be maintained as it is, in view of the inherent pressure for expansion. Granting admissibility of PGD as a legal procedure, the legislator declares preventing the birth of human beings affected by a disablement to be legal and approves of negative eugenic tendencies. Both a regulation in terms of a general clause as well in terms of a list of indications forces the legislator or those who apply the law, to name hereditary diseases whose occurrence shall permit a selection. Thus discrimination is made public. Associations for the disabled are concerned that what has been technically avoidable is perceived as an unreasonable demand and prevention of disabled people will become a priority, and this concern cannot be dismissed. This concern cannot be rebutted with the argument that never before so much has been done for disabled people, because the priority of prevention is not opposed to increased support and assistance for such disabled people. The problem is the self-perception of these people. For they must realize that they live in a society for which support of disabled people ranks equally with preventing them from being born.
PGD also cannot be justified with the argument that one can presuppose the subsequent consent of the person concerned. Because the person being born as a result of the successful test is exposed to the knowledge she/he only exists because of the absence of a defect. The child must realize that it has been only conditionally accepted by its parents.

Finally in the long run social pressure to use PGD cannot be excluded.

5.3. Increase of undesirable tendencies of society politics

The evaluation of the consequences affects in the first place the socio-ethical problems of regulatory approval of PGD. This evaluation naturally is burdened by the uncertainty of future conditioned statements. However, all arguments regarding PGD face this problem, not only the against, also the in favour arguments. Wanting to trigger a decision by pleading for approval and verification of the result means misjudging the situation. The question actually is which criteria shall serve for the judgment of the future success or failure of the measure. The answer to this question cannot be put off into future, it must be given now – guided by fundamental equality of people by ethical and legal standards.

A socio-ethical reflexion is neither restricted to a mere assessment of consequences, nor is it only concerned with the so-called slippery slope arguments. It however culminates in the question what are we to intend. It is to be asked whether a society is to intend to live with drastic changes brought about in full awareness which will undermine the approach of men to health, illness, beginning and end of a human life and the social bases excluded from hypotization. The objection, only a prognosis based on sufficient experience offers strong arguments, only seems to be true, because it leaves essential questions not discussed. Which people are questioned in the opinion polls? Are they only people affected, or also others? Asking people directly affected is of course indispensable. An opinion given by somebody affected however does not guarantee that it contains all points of view relevant for an ethical judgment – especially when already the wording of the question is influenced by a simplified view of the ethical problem. The requirement of being sufficiently based on empiric experience resorts to the scientific method of trial and error. It mistakes a human society with dead objects. It is irresponsible to set up a social experiment which consciously puts at stake such basic behaviours patterns as are part of the indispensable bases of a value pluralistic society. Apart from that it is mostly too late to cancel measures when the failure is sufficiently proven by empiric experience. Approving PGD would increase a practice aiming at increasing genetic control and instrumentalization of the earliest phases of human life which is not acceptable from the point of view of the policies of society. This practice undermines the principles matured by historic experience forming the basis for the modern state with its neutral philosophy of life and its commitment to tolerance.

The reference to the practice followed for example in Great Britain cannot be a guideline for Austria, for a number of reasons. Firstly, the reference to the practice of others does not constitute any ethical justification for one’s own practice. Secondly, it presupposes what is yet to be proved: the social desirability for Austria of the practice followed there. Thirdly, it alleges that whatever is the most liberal practice followed abroad must be measure and guideline for regulations of activities at home.
5.4. Extension of publicly financed services

Regulatory approval of PGD will change the access indication for IVF. Under equality of law, an extra corporal fertilization would have to be made available for all couples, resulting in consequential problems of capacity and finance. The expanded services offered and the increased financial requirement would have to be covered by insurances. In case of being covered only by private insurance companies, this would mean a discrimination of couples with less financial means.

6. Summary

(1) By questioning earliest phases of human life, PGD violates the ban on instrumentalization.
(2) The decision rationale in a pregnancy conflict is not comparable with the decision rationale in case of PGD.
(3) A restriction on PGD both in the form of a general clause as well as also a catalogue of indications will not be able to stand the pressure for extension inherent in the matter, as analogous experience with PND shows.
(4) When admitting either one of the restrictions, the legislator would have to make extra corporal fertilization accessible for all couples in order to maintain equality before the law. This would raise the consequential problem of capacity and increase of financial benefits to be granted with public money.
(5) Approving PGD, the legislator publicly discloses stigmatisations by legalizing prevention of the birth of human beings affected by a certain genetic defect.

7. Recommendation

For the reasons named and in order not to solve problems by increasing problems, the undersigned members vote in favour of maintaining the legislation presently in force.

UnivProf Dr Richard Greil
UnivProf Dr Hartmann Hinterhuber
UnivProf DDr Josef Isensee
UnivProf Dr Gerhard Luf
UnivProf Dr Günther Pöltner
UnivProf Dr Günter Virt
Supplementary vote in favour of maintaining the present legislation in force with regard to PGD (UnivProf DDr Meinrad Peterlik)

1) The fundamental duties of the medical profession are not only diagnose and (attempt of) therapy for existing diseases, but also and above all their prevention. This does not refer to abstract entities of disease, each individual case concerns personal human life. As medical activity is in each case an interference with the physical and/or mental integrity of an individual, the relation between urgency of the indication and the risk of an intervention must be valued with reference to possible damage.

2) In connection with all consequences intended and resulting, comprising both the implantation of an embryo without the pathologic findings sought as well as the termination of life of in the preimplantation phase of embryos affected, PGD therefore must be judged by the aspects of whether being justifiable and the necessity of medical intervention.

3) If PGD were exclusively concerned with implanting an embryo not affected by serious genetic damage, it could be seen as medical method to prevent heavy suffering to be expected by the individual developing out of the embryo, which would also justify to terminate this form of living during the preimplantation stage.

It must however expressly be stated that in each case the problem of moral assessment of the fate of the „redundant embryos“ created by IVF preceding PGD remains on the table, so that also the respective ethical doubts as formulated “in extenso” in I.3.and in the opinion in favour of maintaining the present legislation in force (Part III.) remain valid, apart from medically justified exceptional situations.

4) PGD could be seen as medical help if couples with hereditary problems regarding occurrence of grave malformation and diseases for which within a foreseeable time there is no prospect of healing, are under no circumstances ready to renounce to having children and therefore are considering IVF. For this purpose the regulatory approval for access to IVF would have to be largely modified.

5) The discussion on PGD therefore must at the present time be restricted to its application within the scope of the legally admitted IVF, that means to PGD as aneuploidie-screening with the objective to prevent implantation of embryos with heavy genetic damage.

6) § 9 para 1 of the Reproduction Medicine Act presently in force contains the provision that “viable cells must not used for any other purposes than medically supported reproduction” and “be submitted to examination and treatment only to the extent as this is required in accordance with the state of the art of medical science in order to procure a pregnancy.” It is obvious that the legislator thus wants to prevent abuse of PGD, so that an extensive ban on PGD can be inferred from the wording of the law.

7) It however cannot be the case of a complete ban of PGD, because it must not be the intention of legislation to prohibit on principle possible measures of medical help by simple legal regulation, especially in such cases when the state of the art of science – twelve years after publication of the FmedG –
makes the diagnosis of genetic anomalies in the embryonic stage possible. Failure to perform PGD would in this case have to be regarded as grave misconduct of the physician.

8) „Preimplantative examinations“ must therefore – as stated in chapter I.5.1. – “be exceptionally permitted in such cases when the objective is the exclusion of genetic anomalies which are incompatible with the occurrence of a successful pregnancy” or lead to grave malformations or insupportable suffering of the individual developing from the embryo.

9) There is no medical or health policy requirement whatsoever for an extension of indications for PGD, such as for improving the efficiency of IVF, so that an explicit regulatory approval shall – also in view of the many moral doubts expressed – be dispensed with.

UnivProf DDr Meinrad Peterlik
Bibliography

A summary of literature on PGD, in no way complete (and – with full intention – not constituting a valuation). A more comprehensive presentation is – with regard to the following sources (with further sources whenever applicable) – being dispensed with.

Literature references:

Albers, Marion, Die rechtlichen Standards der Biomedizinkonvention des Europarates, EuR 2002/6, 801ff.
Bernat, Erwin, Recht und Humangenetik – ein österreichischer Diskussionsbeitrag, in: FS Steffen, 1999/5, 33ff I
Birnbacher, Dieter, Hilft der Personenbegriff bei der Lösung bioethischer Fragestellungen?, in: Schweidler, Walter; Neumann, Herbert A.; Brysch, Eugen (Hg), Menschenleben – Menschenwürde, Münster 2003, 31-43.
BMJ (Hg), Fortpflanzungsmedizin - Ethik und Rechtspolitik, Wien 2000 (Schriftenreihe des BMJ 105).
Damschen, Gregor (Hg), Der moralische Status menschlicher Embryonen, Berlin 2003.
Eder-Rieder, Maria, Kommentar zu §§ 96ff StGB, in: Wiener Kommentare zum StGB.
ESHRE PGD Consortium Steering Committee (Hg), ESHRE Preimplantation Genetic Diagnosis Consortium: Data Collection III (May 2001), Hum Reprod 2002; 17, 233-246.
European Commission (Hg), Ethical, legal and social aspects of genetic testing: research, development and clinical applications, Brussels 2004.
Geyer, Christian (Hg), Biopolitik. Die Positionen, Frankfurt am Main 2001, 10f.

Preimplantation genetic diagnosis (PGD) – Report of the Bioethics Commission
Preimplantation genetic diagnosis (PGD) – Report of the Bioethics Commission

References to preimplantation genetic diagnosis (PGD)

Government ethics commissions


“NGOs” – Austria:

Dialog Gentechnik (Ed) (Dialogue Genetic Engineering), Ethical Aspects of Preimplantation Diagnostics. Results of the activity of a work group formed subsequently to the first discussion day “Genetic diagnostics: What does it matter to me?” (2002), presented by Dialog Gentechnik, Vienna 2004.


Lebenshilfe Österreich (Self help Austria), in: Basic Statements for Ethics of Biomedicine (based on basic paper of Bundesvereinigung Lebenshilfe Deutschland, Lebenshilfe Österreich, insieme Schweiz und Lebenshilfe Südtirol, http://www.lebenshilfe.at/archiv/content.pl?id=356 (Federal association self-help Germany, self help Austria together with Switzerland and self help South Tyrol).

Aktion Leben Österreich (http://www.aktionleben.at/bildung-PID.htm) (Organization life Austria).

“NGOs” – Germany:

Federal Medical Association, draft for discussion regarding a Directive on Preimplantation Diagnostics, 2000 (http://www.bundesaerztekammer.de/30/Richtlinien/Richtlijn/PraeimpEntwurf/10Diskuss.html)


Lebenshilfe Deutschland (http://www.lebenshilfe.de/recht/Ethik/PID-Langversion.htm) (Self-help Germany)

Further addresses for your reference:

Overview regarding PGD issues at DRZE (http://www.drze.de/themen/blickpunkt/pgd).