



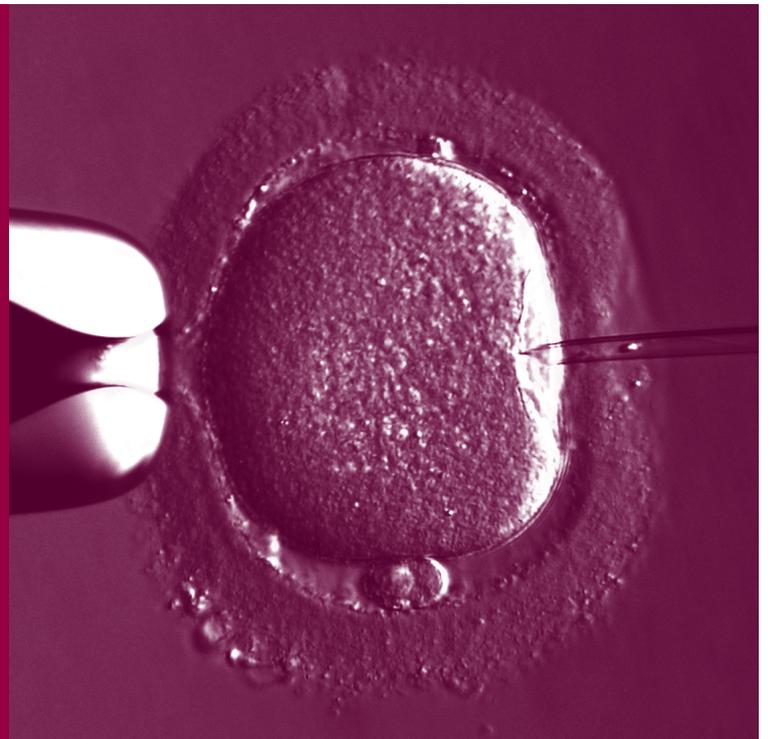
OFFICE OF TECHNOLOGY ASSESSMENT
AT THE GERMAN BUNDESTAG

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Reproductive medicine: underlying conditions, scientific-technical developments and the consequences

Summary

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SUMMARY

In general there is a growing demand for fertility treatment. On the one hand, this results from the fact that reproductive technologies are becoming established procedures and correspondingly their acceptance is increasing. On the other hand, there are indications that an increasing proportion of couples present fertility disturbances. The causes may lie in a general increase in risk factors, such as environmental burdens, an unhealthy life style, and urogenital infections and diseases. A significant reason is also, however, that couples increasingly postpone satisfaction of their desire to have children until a later phase of life, in which natural fertility (in particular of women) has declined considerably and a pregnancy is linked to increased risks to the health of mother and child. The idea that the time constraints on reproduction might be removed arises against the background of more and more frequent reports about women aged 40 and above who are apparently in the prime of life and who are expecting their first child. Two issues that are frequently not a topic of discussion are (1) that many couples have to engage the help of reproductive medicine, and (2) how many of them ultimately fail to have children despite having undergone repeated in vitro fertilization procedures.

Reproductive medicine provides the technical medical options for dealing with this unsatisfied desire to have children. Reproductive medicine (also called assisted reproductive techniques, or ART) refers to all of the treatments and procedures for handling human oocytes, sperm, or embryos with the goal of bringing about a pregnancy and the birth of a child. There have been significant developments in reproductive medicine in the last few years. In addition to in vitro fertilization (IVF), it today includes intracytoplasmic sperm injection (ICSI) into an oocyte with subsequent transfer of the embryo, as well as cryopreservation of gametes, impregnated egg cells, and embryos and their later use in assisted reproduction. Although reproductive medicine was initially directed at the treatment of infertility in women which was organic in nature, further specific techniques have been and are being developed that apply to all forms and causes of a couple's infertility.

The procedures in assisted reproduction are however also tied to various difficulties. One can name in particular the health risks to women and to the children conceived in this way as well as the psychic stress on the parties involved before, during, and after treatment (especially if the measure is unsuccessful). The most important parameter of success is the probability of the birth of a child per treatment cycle, the baby-take-home rate (BTHR). Worldwide the rate



is 20%–25% and thus of the magnitude that is assumed to be the birth rate after natural conception. The age of the woman exerts a great influence on the birth rate: the older, the lower. The current goals include especially raising the efficacy of technically assisted reproductive techniques (e.g., by means of a better targeted preselection of the transferred embryos) and lowering the risks for women and children, particularly by reducing the number of pregnancies with multiple fetuses, which always pose a health risk and often cause psychosocial stress.

ART IN CLINICAL PRACTICE: SUCCESSES AND PROBLEMS

The use of reproductive medicine in Germany is subject to the Embryo Protection Law (Embryonenschutzgesetz, ESchG), adopted in 1991. It permits only those oocytes to be transferred that stem from the patient herself. Egg donation and surrogate motherhood are not permitted, while semen donation is. Furthermore, a maximum of three embryos may be transferred to the womb at one time, and a selection among the oocytes is only possible during the initial 24 hours after impregnation, i. e., before nuclear fusion.

In European comparison, reproductive medicine treatment is conducted in Germany less frequently than the average of the other countries. The percentage of births is also below the European average. Yet if one considers the data for treatments and births for the year 2003 (before the Health Care Modernization Law took effect), Germany was above the European average. This makes it clear that the below average treatment numbers for Germany cannot be traced back to a lack of medical know-how or to missing social acceptance, but primarily to the health policy framework. After the health care reform took effect, there was a nearly 50% drop in treatment numbers in 2004. Since then there has been a slow but steady increase. This development, by the way, corresponds to the global situation, namely that the number of ART cycles carried out is directly related to the financing by the health care system.

At the same time, an increase in the age of patients can be observed even though the financing by the statutory health insurance companies in Germany is subject to an age restriction. This must be seen in the context that the average age of first-time mothers in Germany – as in almost all industrial nations – is in general increasing. The proportion of women over 35 who undergo IVF or ICSI therapy in Germany is higher than the European average (in 2005, in Germany 55.6% of the women undergoing IVF were 40 or older, while in Europe as a whole the value was 50.5%). This development must be seen critically in view of the fact –

especially for woman over 35 – that the prospects for a successful conception, pregnancy, and birth decline rapidly.

With regard to the techniques that are employed, an increased use of ICSI techniques can be seen in Germany, just as in Europe, the USA, and the world as a whole. While conventional IVF treatments still account for approximately one third of all treatments in Germany, IVF is used less frequently in many European countries. This development cannot be explained by the significantly higher success rates of ICSI since the latter only promises to be more successful than conventional IVF in cases where the quality of the man's sperm is limited. The increase in number of ICSI treatments might be explained by the fact that male infertility has today become an increased focus of attention among specialists in reproductive medicine.

A development that can be observed throughout Germany, Europe, and the world is that fewer embryos are being transferred pro cycle. This has to be seen in the context of improved technical possibilities in ART applications since the prospects of success have improved for all of the methods employed in Germany. Furthermore, the goal of treatments in reproductive medicine is increasingly to prevent a pregnancy with multiple fetuses. A policy of single embryo transfer (SET) is becoming increasingly prevalent, especially in the Scandinavian countries. Leading the way is Sweden, where predominantly only a single embryo is transferred, which is also reflected in the highest rate of singletons in Europe. Because of the partially elective character of SET, which is only permitted in Germany under specific conditions, Germany is in the middle of the field in Europe with regard to the number of transferred embryos and of pregnancies with multiple fetuses. Mainly, two embryos are transferred.

The trend to transferring fewer embryos suggests that in Germany, too, there are efforts to minimize the risk of a pregnancy with multiple fetuses, in particular one involving several embryos. The SET rate in Germany has correspondingly continued to increase (between 2003 and 2008 its relative portion of all ART treatments rose from 11% to 13.3%), although the prospects of success are significantly lower than if two embryos are transferred. The transfer of a single embryo continues, however, to be the exception. Nonetheless, the tendency for fewer embryos to be transferred has led to a decrease in the number of multiple births throughout Europe and in the USA. In this sense, the policy of SET can be considered to be a success. The rates of multiple births in Germany and in most of the European countries are still, however, clearly higher than the rate to be expected naturally. Sweden is the sole European country in which the ART singleton rate is higher than 93% (an almost natural rate).



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The success rates for the baby-take-home rate (BTHR), i.e., the birth rate per cycle, in Germany in the period from 1997 to 2005 were below the European average. In general, a comparison is difficult since there are differences in how the data are collected in the individual countries and some of the data are incomplete. If one considers the BTHR for Germany and Europe, Germany's rate of 15.4% corresponds largely to the European average of 15.0%. Yet if only those countries whose data for all ART treatments is available and complete are included in the European average, then the average BTHR is 16.8%. Of these countries, Great Britain has the highest rate of success at 20.4%, closely followed by the Scandinavian countries among others.

Overall we must recognize that use of ART to treat unwanted childlessness is being conducted more and more frequently in Germany, Europe, and the USA and that there has been a considerable improvement in the prospects of success for affected couples in the last few years. Internationally, however, the number of ART cycles that have been carried out in Germany and the number of births that result are below the European average. We must note in this context, however, that for many years the focus of assisted reproduction was nearly exclusively on maximizing the effectiveness of the treatment as reflected by the indicator BTHR. The high success rates were achieved at the expense, however, of obtaining as many oocytes per cycle as possible in order to be able to transfer as many embryos as possible into the uterus. This resulted in the danger of ovarian hyperstimulation syndrome and a high number of pregnancies with multiple fetuses with the concomitant health risks and stress. Some ten years ago, the increased use of elective SET led to a change in policy, which is currently being further developed under the designation of a »patient friendly« or »patient centered« approach to reproductive medicine. This concept includes in particular the objectives of minimizing the general stress and health risks to women, children, and men.

PSYCHOSOCIAL COUNSELING CONCOMITANT TO FERTILITY TREATMENT

The diagnosis of a fertility disorder pushes many couples to the limits of their ability to cope with emotional stress. Studies show that infertility can constitute one of the most stressful situations in life, comparable to the loss of a partner or the death of a child. It should also be noted that, as a rule, the role played by psychic causes in connection with an unsatisfied desire to have children are considerably overestimated. At the same time, the consequences of both the unsatisfied desire for children and the treatment in reproductive medicine are still

frequently underestimated. Although there have been far-reaching developments and improvements in the technical steps in the medical procedures, the psychosocial aspects of stress related to an unsatisfied desire for children during treatment and after an unsuccessful treatment have hardly changed. One can, however, understand the changes in how couples who are involuntarily childless are treated in a medical context. Emphasis can in particular be placed on the strengthening of psychosomatic forms of treatment and the depathologization of couples. What is referred to as psychosomatic primary care, which has also increasingly established itself in reproductive medicine in the last few years, has proven itself to be sensible since it integrates psychic and social factors in treatment in addition to the medical ones.

Overall, psychosocial counseling of involuntarily childless couples should offer help toward deciding about pending therapeutic measures but also support in dealing with conflicts between a couple that result from this stressful situation. It should furthermore help the couple improve its communication with one another, with physicians, and with their environment in order for it to cope with the situation in a more adequate manner. Another important aspect is to promote the acceptance of a life without biological children and to include the possibility of treatment being unsuccessful in the counseling from the beginning. Yet even if counseling is available, there are still informational deficits and anxiety about accepting help as well as anxiety about being stigmatized by their social environment if such help is accepted. This explains the fact that only a small portion of couples actually accept psychosocial counseling about their desire to have children although a large number of these couples have a positive attitude toward it. The acceptance rates are however much higher (up to 80%) when psychosocial counseling about a couple's desire to have children is an integral and accepted component of the treatment.

Counseling in connection with gamete donation

Although only semen donation is permitted in Germany, experts advise against limiting counseling to this form of gamete donation (i. e., of semen, oocytes, or embryos), precisely in the context of the increase in reproductive traveling. A more binding form of counseling should be established, introducing a requirement that participation in counseling or its rejection be documented. The reason for this is that the creation of a family on the basis of donated gametes results in specific issues that differ from those associated with the creation of a family on the basis of a couple's own gametes. The acceptance of gametes from third persons leads to biological and social parentage. This usually has far-reaching and profound consequences for all the participants: the parents who wanted a



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child, the child conceived in this manner, the donor and his or her partner, the parents of the new parents and of the donor, and any other children of these parents or the donor, regardless of whether they were born previously or later. In order to take the welfare of all the participants – especially that of the child to be conceived in this manner – into consideration as well as possible, a decision in favor of gamete donation should be based on informed consent that takes both the momentary as well as the long-term implications of this manner of creating a family into account for all of the participants. The counseling should be conducted by qualified professionals before the beginning of the medical intervention. It should be presented as a constructive process of examining a type of family that deviates from the customary norm and about which there is little educational literature available. The counseling should fill any gaps in information and support those seeking advice in their process of coming to grips with social and biological parentage.

LEGAL ASPECTS

Reproductive medicine in Germany is thoroughly structured by a dense network of various coercive rules that are scattered in different laws and regulations. The result is a degree of confusion. This confusion is however not (exclusively) responsible for the existing legal uncertainty in the area of reproductive medicine, which is rather due to the fact that certain rules possess general applicability for different areas of medicine. Even a tendency toward creating special legal rules can be noted, which contributes to the confusion and contradictions. In this situation, the question is whether a separate law for reproductive medicine is necessary and also suitable for unequivocally overcoming the uncertainties and contradictions. On the other hand, the law governing reproductive medicine is characterized in part by considerable legal uncertainty with regard to various new techniques as a result of various unclarities or ambiguities in the Embryo Protection Law. It appears necessary for the unclarities to be resolved so that state-of-the-art specialist standards can be provided in the area of reproductive medicine in the future.

The newest development and one that is also relevant in Germany is the recent decision of the European Court of Human Rights on the Austrian law on reproductive medicine. It could lead to new movement in the discussion. In its decision, the European Court of Human Rights affirms that all limiting or restricting legal regulations are subject to rigorous checks as to whether they are commensurate. In the process, this court expresses its opinion that reasons based in moral considerations or social acceptance do not on their own provide sufficient

cause to completely prohibit a technique of reproductive medicine. Fundamental for the decision were, in particular, the obvious judgmental contradictions between certain prohibited and permitted measures.

It might even be possible to clarify some of the uncertainties in the Embryo Protection Law, possibly even today, by appropriate interpretation. These possibilities are used by parts of the judiciary and law. It is possible to detect an increasing tendency on their part to take the current medical and scientific developments and the overwhelmingly positive attitude of society toward reproductive medicine into consideration and to interpret the rules in the Embryo Protection Law – where this is possible – in a more comprehensive sense. Yet the situation remains uncertain for physicians and patients as long as there is no decision from the highest court to all of the unclear legal issues.

Legal aspects in international comparison

An overview of an international comparison of the medical-technical procedures in reproductive medicine shows that – although these procedures are essentially the same – neither reproductive medicine nor couples desiring children can make use of the procedures in the same manner. Overall one can say that the regulations in Europe are very diverse. They are based on different historical developments and different cultural, religious, social, political, and economic factors. Efforts have been and are being made at the European level to harmonize these differences. The European Court of Human Rights in particular plays an important role in this context, as shown by its decision of April 1, 2010, in which the prohibition of oocyte and semen donation is called an infringement of the prohibition of discrimination. It is evident that this pushed the door wide open for the possible or necessary regulatory changes in the area of reproductive medicine not just in the Austria, the country directly affected by the judgment, but in other countries as well. After all, the European Union plays an important role in legal harmonization – as shown for example in Article 12 of the EU directive on human tissue and cells 2004/23/EU – one of the purposes of which is to coordinate medically assisted reproduction. This is of immediate relevance for preimplantation genetic diagnosis, semen and oocyte donation, and the cryopreservation of embryos. In this connection, internationally active nongovernmental organizations, such as the European Society of Human Reproduction and Embryology (ESHRE), play a role since they have been trying – some for several decades – to set scientific and professional standards and to support the policies surrounding research on and the practical implementation of the techniques of assisted reproduction as well as legal harmonization.

OPTIONS FOR ACTION

Enlightenment and prevention

Enlightening the general public about the reproductive phase and about the limitations on options with advancing age is of great significance. This enlightenment should already be initiated in school sex education. The rising age of first gravidity means not only that the probability of having a second or third child is sinking but that more and more frequently this is also true about a first child. In contrast to this is the promise held by reproductive medicine that the desire to have children can be fulfilled anytime and that reproductive medicine is better than nature. The success rates of treatments in reproductive medicine must be presented more clearly. Furthermore, the aspects represented by cost and effort and by success and general results should be communicated more forcefully.

It is possible to name the following aspects of sensible adjunctive psychosocial counseling during fertility treatment. Every couple should fundamentally be able to make use of psychosocial counseling at any time during fertility treatment, which should also act to remove thresholds. The obligatory part of the (standardized) qualification of the psychosocial counselors should include experience in couples counseling, awareness of the psychosocial factors in unwanted childlessness, and knowledge about the current state of ART. The counseling being offered should be made available independently of the reproductive medicine centers, but in cooperation with them. The psychosocial counseling should take place before the planned measures, including any time allotted for the couple to consider them. It should also as a matter of principle be available before, during, and after all the measures of medically assisted reproduction. The implementation of the directive issued by the German Medical Association (Bundesärztekammer) should be effectively guaranteed in practice in each reproductive medicine center, including with regard to the psychosocial aspects. This directive should furthermore be revised to take better consideration of the psychosocial aspects of assisted reproduction. Yet the task is fundamentally to simplify and increase the precision of the partially contradictory directives of the German Medical Association, the German social security code (SGB), and the German Society for Fertility Counseling (Beratungsnetzwerk Kinderwunsch in Deutschland, BKiD).

Integration and networking of counseling

Currently psychosocial counseling generally takes place separately from that in reproductive medicine, which leads to unnecessary duplications and disparities

between fertility treatment and psychological counseling, which in turn is an irritation to couples. This could be avoided by an improved coupling of the psychosocial counseling with the treatment in reproductive medicine, and the professional competence of the counselors and therapists could be better utilized. And the current situation that many couples either do not know about the option of psychosocial counseling or find out about it very late could be improved and the gap between need for counseling and its use could be minimized. Finally, but not least important – in particular considering the fact that reliable, highly professional quality is necessary and that these professionals must take part in ongoing training – it would be sensible to conduct a scientific evaluation of the psychosocial counseling for the desire to have children.

Risk reduction

One of the factors that currently lowers the prospects of success in Germany is that the (average) age of ART patients has increased significantly and continues to rise. For the affected couples it would be practical if ART treatment were initiated as early as possible since the chances of success are significantly better for younger women and thus in most cases a pregnancy and birth of a child could be reached with a smaller number of cycles. This would coincide with less personal stress for the couples and with lower treatment costs.

In the course of a stronger patient-oriented treatment in reproductive medicine, the future significance of the following factors (among others) would have to be examined:

- > Modification of the process organization of IVF clinics in order to lower the stress that couples experience during the treatment in reproductive medicine and to reach a stronger focus on the patients. There is clear potential for improvement by avoiding the frequent change in medical personnel during a couple's course of treatment, by informing couples better about all the details of the treatment, and by providing them stronger emotional support.
- > Optimization and simplification of the administration of gonadotropin in order to reduce patient stress; close monitoring of ovarian stimulation and oocyte maturation in order to prevent ovarian hyperstimulation syndrome. There is also a need to clarify whether the use of in vitro maturation constitutes a further option for being able to use oocytes that have not matured optimally.
- > Avoiding pregnancies with multiple fetuses by transferring only one embryo. A prerequisite for this is the availability of methods for evaluating the quality of oocytes and embryos before fertilization or transfer and before their selection.



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- > Making greater use of cryopreservation of oocytes, impregnated oocytes, or embryos is necessary to achieve cumulative pregnancy rates that are as high as possible.

In general, there is a need for evidence-based research projects on currently pending problems or on specific aspects of ART. The study of the safety, risks, and consequences of techniques of reproductive medicine has not been pursued internationally with the same dynamics and intensity as the development of existing or new ART techniques. On the basis of newly acquired information, future questions should be pursued in a more differentiated manner, and studies should be methodologically better planned. Overall, high-quality studies continue to be necessary in order to answer open questions:

- > Large-scale (representative, multicenter) prospective studies with control groups that take into consideration socioeconomic factors and the base health status of the couple considering fertility treatment (e.g., history and course of infertility).
- > Studies on the safety of new techniques and biological mechanisms that go beyond the perinatal phase, in particular cryopreservation, vitrification, in vitro maturation of oocytes, use of sperm from testicular sperm extraction (TESE), embryo biopsies, and oocyte and semen donation.
- > Studies with control groups made up of children who were conceived naturally and whose parents had to wait just as long for a pregnancy as couples undergoing ART treatment. Such studies should make possible greater differentiation with regard to the extent to which parental infertility or the ART procedure contributes to an increased risk of illness.
- > Studies on the long-term development of ART children that continue into adulthood, especially on the risks for illnesses that do not become manifest until advanced age (e.g., diabetes, cardiovascular illnesses, malignant diseases).

There is also a need for research with regard to the sociopsychological development of children and family dynamics following a successful treatment. For example, the psychological effects of higher rates of preterm births and lower weight at birth after ART, even of singletons, and the effects of secondary damage are not yet known. This should be examined in prospective studies on child and family development. Furthermore, in view of the fact that the male offspring following ICSI treatment of a father with inherited infertility will also be infertile, it is very important that prospective studies be conducted until the children reach the stage of family planning. From a psychological point of view, these

boys must be given timely information. After all, the children conceived with the aid of assisted reproduction are generally informed very late – if at all – about the mode of their conception, and those after semen or oocyte donation hardly at all. It is unknown what this means for the development of these children.

Research into adoption and on identifiable donors points so far to the importance of knowledge about biological roots. According to the current state of research, an anonymous gamete donation must be considered rather critically from a psychological point of view, and research in this area at least has to be intensified. As a rule, children conceived in connection with a gamete donation or a surrogate mother in another country do not have the possibility of getting to know their biological roots. The long-term significance of this for children and their families should be studied. In Germany in the last few years, a few isolated children have sought or even established contact to a semen donor. The objective here is initially to evaluate the experience of the children, their parents, and the donors qualitatively and also – if there are larger numbers – quantitatively. This will help create a structure of such contacts for psychosocial care.

Financing

Financing is apparently of great significance in the perception of offers for treatment in reproductive medicine. Cuts in the amounts paid for this treatment by the statutory health insurance companies have led to a clear decline in the number of treatments performed. There was an obvious decline in how many reproductive medicine measures were performed in Germany in 2004, when the statutory health insurance companies introduced a significantly more restrictive policy for covering expenses. Since then, at constant financing conditions, the number of ART treatments has been increasing slowly but constantly. Against this backdrop, it can be assumed that some of the so-called reproduction tourism does not take place only because of a country's rather »liberal« policy toward measures in reproductive medicine – for example to countries such as Belgium, the Czech Republic, and Spain – but that increasingly cost factors also play a role, such as in the case of such trips to, for example, Slovenia, Hungary, or Ukraine. This will be all the more the case if, as agreed at the European level, medical care will actually be available to all EU citizens in all the European countries.

Finally, it also appears noteworthy that the offers of psychological counseling are being accepted for payment by the statutory health insurance companies, at least for a limited number of sessions. In view of the cost issue raised in this connection, it should be pointed out that psychosocial counseling regarding a desire to have children does not have a preferred outcome. It can contribute to



stabilizing emotionally unstable couples who have a good pregnancy prognosis, so that they can undertake what is – from a medical point of view – a sensible number of treatment cycles. It can also support couples who have made a decision against (further) expensive measures in reproductive medicine.

Legal adjustments

With reference to the recent decisions of the European Court of Human Rights, some of the prohibitions contained in the German Embryo Protection Law could also be considered in violation of the European Convention on Human Rights. The European Commission on Human Rights and the relevant decisions of the European Court of Human Rights apply in German jurisdiction in the same manner that a federal law does. In interpreting the European Court on Human Rights, the administrative bodies and the courts (and even the legislature) are therefore called upon – under certain preconditions – to take the European Commission on Human Rights into account in their decisions and interpretation of national regulations. A reform of the laws covering reproductive medicine – or at least of individual norms of the Embryo Protection Law – might therefore be necessary. This view is also supported by the German Federal Court of Justice (Bundesgerichtshof, BGH). In its decision of July 6, 2010, this body noted critically that the German legislature did not determine an explicit regulation in the Genetic Diagnosis Act or the Embryo Protection Law, nor in the relevant legislative material, regarding the permissibility of preimplantation genetic diagnosis despite being aware of the conflicts about this topic that have been ongoing for many years. For this reason, the Federal Court of Justice added a reminder that an unambiguous legal regulation of the matter was still necessary. If the judgment of the European Court of Human Rights is confirmed, this would also be relevant for the German legislature.

A review of the legal situation in Germany thus appears sensible or necessary regarding the following existing unclear issues:

- > What is supposed to happen with the »extra« embryos collected for IVF (e.g., cryopreserved) or SET and that will no longer be utilized for reproductive purposes? May they possibly be donated or used for research purposes?
- > How can unwanted pregnancies with multiple fetuses be prevented? Should elective single embryo transfer be permitted?
- > From ethical and legal points of view, how are we to proceed with »extra« fetuses (where there are health or medical issues during pregnancy)?



In the context of the judgment of the Federal Court of Justice on the culpability of PGD, the review of the legal situation in Germany also appears necessary in view of the following unclear issues:

- > Should PGD also be expressly forbidden on nontotipotent cells? If not, which examinations of which genetic properties or dispositions to illnesses should be permitted in the framework of PGD of nontotipotent cells?
- > Should PGD be completely included in the applications covered by the Genetic Diagnosis Act? If yes, which changes will be necessary?

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