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## **Current problems of Preimplantation Genetic Diagnosis in the Context of Parental Aspirations**

**Abstract:** Preimplantation genetic diagnosis (PGD) is designed to assist in conception when a serious hereditary disease affects a couple and it is necessary to screen out embryos carrying chromosomal or genetic abnormalities. The procedure may therefore be lawfully applied only for medical reasons to avoid a particular risk of transmitting genetic defects to a child regardless if the couple is infertile or not. In practice, PGD raises many ethical objections as a method which – as the doctrine says – commodifies reproduction and enables unwanted practice of positive eugenics (a selection of embryos of a particular sex or carrying certain qualities, let alone particular defects (deafness, blindness, etc.). Parents may be prone to choose the features of their future child and decide, by means of PGD, to have a baby of a certain sex, genetic make-up, or to conceive a tissue match for a living sibling. The legislator should therefore intervene, establish the normative framework for the practice of PGD, and keep continuous control over its application to prevent the abuse of the child's welfare.

**Key words:** preimplantation genetic diagnosis, medically assisted procreation, embryo selection, sex selection, designer baby, saviour sibling, welfare of the child

### **1. General comments on preimplantation genetic diagnosis**

#### **1.1. The nature and objectives of PGD**

IVF (in vitro fertilisation), which in recent years has become a common and constantly enhanced and upgraded technique, allows not only to conceive a child in a laboratory and induce pregnancy<sup>1</sup> but also provides a possibility to control gametes

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1 IVF is the most common method of medically assisted procreation (MAP), as a result of which – from the birth of Louise Brown (1978) – approximately 5 million children were born. The effectiveness of this procedure is systematically increasing because of the introduction of improvements, including the use of micromanipulation (for instance ICSI – intracytoplasmic sperm injection). See more on this problem M. Nesterowicz, *Prawo medyczne*, Toruń 2016, p. 341 and following and in the foreign literature, A.B. Thomas, *Avoiding EMBRYOS “R” US: Towarda*

and select them properly in order to create an embryo characterized by specific features and genetic profile. In particular, it is possible to carry out preimplantation genetic diagnosis (PGD), i.e. the procedure of retrieving (by biopsy) one or two cells from a developing embryo (in the phase of 4-8 cell blastomere) and the analysis of their DNA as well as chromosome structure before implantation in the mother's uterus or cryopreservation (freezing)<sup>2</sup>. Blastomere's cells that are picked, as emphasized, without detriment to further undisturbed embryo's development contain genetic information of both parents that is crucial for the future child's health and condition<sup>3</sup>.

A fundamental purpose of PGD is to evaluate and select non-defective embryos (screening out), whose transfer to the woman's uterus (immediate or subsequent – after cryopreservation) assures high probability of conceiving and delivering a child free of disorders (impairments)<sup>4</sup>. Genetically defective embryos that have an improper anatomical structure or inappropriate chromosome structure are destroyed or designated for research upon the gametes donors' consent<sup>5</sup>. As a rule

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Regulated Fertility Industry, "Washington University Journal of Law and Policy" 2008, vol. 27, p. 248.

- 2 See: R. Słomski, J. Kwiatkowska, H. Chlebowska, Diagnostyka molekularna, (in:) J. Barciszewski, K. Łastowski, T. Twardowski, Nowe tendencje w biologii molekularnej i inżynierii genetycznej oraz medycynie. Tom II, Poznań 1996, p. 331 The first successful PGD procedure was conducted in the United Kingdom in 1989 to determine the sex of the child and thus eliminate the risk of transmission of a sex-linked genetic disease. After the method became popular, in the years 1990-2006 approximately 5,000 cycles of PGD were performed in the world. E. Jackson, *Medical Law. Text, Cases, Materials*, Oxford 2006, p. 840. In Poland until the mid-1990s, PGD was an experimental method; The intense development of technology in the 21st century has led to the improvement of procedures from which in the years 2000-2009 about 30 children were born. See: O. Nawrot, Diagnostyka preimplantacyjna w prawodawstwie Rady Europy, "Zeszyty Prawnicze Biura Analiz Sejmowych" 2009, No. 2, p. 43 and J. Kapelańska-Pręgowska, Preimplantacyjna diagnoza molekularna w międzynarodowych standardach wiążących i zalecanych, "Prawo i Medycyna" 2009, No. 2, p. 86.
- 3 J.K. Mason, R.A. McCall Smith, G.T. Laurie, Law and Medical Ethics, London-Edinburgh 2002, p. 194. Medicine knows also the preconception diagnostics involving the examination of the so-called the directional body of an egg cell, which allows only the genetic material from a woman to be assessed. O. Nawrot, Diagnostyka..., *op. cit.*, p. 42
- 4 Over 2/3 of the total number of PGD procedures are performed to detect chromosomal abnormalities (e.g., trisomy 21), the risk of which increases with the age of the genetic mother; the remaining 1/3 refers to the already mentioned elimination of serious sex-related genetic diseases (eg Turner syndrome, characteristic of the female sex, hemophilia occurring in the male sex) and the so-called autosomal recessive genetic diseases (eg Tay-Sachs). Cited after E. Jackson, *Regulating Reproduction, Law Technology and Autonomy*, Oxford 2001, p. 242. See also J. Kapelańska-Pręgowska, Zjednoczone Królestwo i Republika Włosa – dwa bieguny diagnostyki preimplantacyjnej, (in:) L. Bosek, M. Królikowski(eds.), *Współczesne wyzwania bioetyczne*, Warszawa 2010, p. 403 and following.
- 5 E. Jackson, *Medical...*, *op. cit.*, p. 840.

(and in compliance with the objectives of the legal systems of most countries), PGD is therefore a method allowing genetically impaired couples to conceive a child without a risk of transmitting a genetic disease or other serious defects and disorders onto their children<sup>6</sup>. PGD may be applied in such circumstances even if a couple is medically fertile and capable of conceiving a child without the need to rely on the procedures of the above-mentioned procreation. IVF, however, allows spouses (partners) not only to avoid a risk of transmitting hereditary defects and disorders onto their children but also enables them to fulfil the parent project and give birth to a child that is genetically related to both parents without the need to use donated gametes in the MAP procedures<sup>7</sup>. On the other hand, different from the so-called prenatal diagnosis carried out after inducing pregnancy and involving a genetic test of an embryo *in utero* (foetus), PGD enables to avoid the transfer if embryo's anatomical or structural irregularities are detected, and thus it prevents possible termination of pregnancy for eugenic reasons<sup>8</sup>.

PGD procedure, which is complicated and requires suitable technical equipment as well as specialist preparation and expertise (and thus it is relatively expensive<sup>9</sup>), is subject to constant improvement as it allows identification of a still increasing number of genetic mutations and chromosome anomalies while recently it has even become possible to establish a risk of developing specific types of cancer (e.g. breast or colon)<sup>10</sup>. Despite objections raised by some representatives of the doctrine, ethics

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6 *Ibidem*.

7 IVF combined with PGD and the evaluation of embryos formed from the gametes of steam is, in particular, a beneficial alternative to the procedure of artificial insemination by donor's semen (artificial insemination by donor – AID). See: M. Brazier, E. Cave, *Medicine, Patients and the Law*, London 2011, p. 367.

8 Por. P. Krajewski, *Eugeniczna selekcja embrionów*, (in:) L. Bosek, M. Królikowski (eds.), *Współczesne wyzwania bioetyczne*, Warszawa 2010, p. 69 and in the foreign literature, G. Nicolau, *L'influence des progrès de la génétique sur le droit de filiation*, Bordeaux 1989, p. 351 and following. The Authors aptly point to the fact that avoiding the need to perform an abortion in the event of fetal defect detection is important especially for the mental condition of the woman; it saves her serious suffering.

9 The procedure costs from about USD 10,000 to about USD 21,500. The literature emphasizes that these amounts constitute a serious barrier to the use and access to PGD, which otherwise could be carried out preventively in most IVF cycles due to the significant diagnostic value. J. Kapelańska-Pregowska, *Preimplantacyjna...*, *op. cit.*, p. 86.

10 Since the application of PGD for the first time in 1991 to determine the embryo's charge on cystic fibrosis (a genetic disorder unconjugated with sex but conditioned by a single gene defect), preimplantation diagnosis enables the detection of the most important chromosomal aberrations and about 30 so-called monogenic diseases (induced, like cystic fibrosis, mutations within individual genes). In the medical literature, however, it is argued that in the near future preimplantation tests are likely to include diseases resulting from the interaction of many genes and environmental factors (e.g. schizophrenia, Alzheimer's disease). J. Kapelańska-Pregowska, *Preimplantacyjna...*, *op. cit.*, p. 85. See also J. Bal, W. Wiszniewski, J. Wiszniewska, *Diagnostyka*

and Church<sup>11</sup>, PGD is currently a medical procedure commonly carried out in most countries worldwide (including Poland<sup>12</sup>) in legally and medically justified cases. Bans on the use of preimplantation diagnosis, valid only in the legislation of Germany (until 2011), Switzerland (until 2013) and Austria (until 2015) are not upheld, and they are abolished by the legislators due to the above mentioned benefits provided by PGD on the one hand, and non-compliance of the ban with the right to respect for one's private and family life guaranteed by Art. 8 of the European Convention on Human Rights<sup>13</sup>.

### 1.2. Prerequisites for the application of preimplantation diagnosis

Rules (directives/prerequisites) for the application of preimplantation diagnosis procedures have been depicted in international documents, in particular in the Council of Europe Recommendations, i.e. Ad Hoc Committee of Experts on Progress in the Biomedical Sciences CAHBI titled *Human Artificial Procreation* of 10 January

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molekularna, (in:) J. Bal (ed.), *Biologia molekularna w medycynie. Elementy genetyki klinicznej*, Warszawa 2006..

- 11 The opponents of PGD argue that preimplantation diagnosis is a manifestation of undesired eugenic practices, because it allows the selection of embryos due to their "genetic quality". Parents who use PGD can create "custom" offspring (designer baby), guided by their own subjective preferences or current social patterns. See: D. King, Preimplantation Genetic Diagnosis and the "New" Eugenics, "Journal of Medical Ethics" 1999, vol. 25, p. 178; Robertson Ethical Issues in New Uses of Preimplantation Genetic Diagnosis, "Human Reproduction" 2008, vol. 18, p. 465 and following and in the Polish literature M. Gałązka Prawo francuskie wobec embrionu in vitro, "Państwo i Prawo" 2000, No. 6, p. 71. In addition, as it is emphasized, PDG is connected with the necessity of creating supernumerary embryos which are destroyed after the procedure (which in the Church's teaching is considered a form of abortion practices). See: T. Smyczyński, Aksjologiczne i prawne podstawy dopuszczalności wspomaganej prokreacji, (in:) J. Haberko, M. Łączkowska (eds.), *Prawne, medyczne i psychologiczne aspekty wspomaganej prokreacji*, Poznań 2005, p. 92.
- 12 See: art. 26 ust. 1 of the Act of 25 June 2015 on the treatment of infertility (Journal of Laws of 2015, item 1087) [Ustawa z dnia 25 czerwca 2015 r. (Dz. U. z 2015 r. poz. 1087)]. However, PGD was carried out in a wide range before the Act came into force (INVICTA Infertility Clinic is recognized as a pioneer, since the end of the 1990s it has been tested for the identification of cystic fibrosis, Down syndrome, Patau, Turner and Edwards syndrome). Cited after: O. Nawrot, *Diagnostyka... op. cit.*, p. 43.
- 13 The European Court of Human Rights in the judgment of 28 August 2012 in the case *Costa and Pavan vs Italy* (application No. 54270/10) *expressis verbis* stated that the statutory prohibition of PGD, contained in the Italian law of 2004 on medically assisted procreation, violates art. 8 of the Convention. In the Court's opinion, the right to conceive a child free from genetic encumbrances falls within the scope protected by the Convention of private and family life (the case concerned of healthy couple who carries a cystic fibrosis who after conception of a child burdened with illness and eugenic abortion demanded the use of PGD in order choose embryos free of defects). J. Dute, European Court of Human Rights. ECHR 2013/9 Case of *Costa and Pavan vs Italy*, 28 August 2012, No. 54270/10 (Second Section), "European Journal of Health Law" 2013, No. 3 (vol. 20), pp. 315-316.

1989<sup>14</sup>, and Recommendation R(90)13 of the Committee of Ministers of the Council of Europe of 21 June 1990 on prenatal genetic screening, prenatal diagnosis and associated genetic counselling<sup>15</sup>. As a rule, the legislation of individual countries contains these prerequisites strictly and restrictively. As a desired diagnostic tool enabling identification of impairments and, at the same time, a means of their elimination, PGD may be applied solely in exceptional cases, i.e. when there is a risk of transmitting a genetic disease onto a child or/and other serious defects and impairments (e.g. one or two spouses or partners suffer from a hereditary disease or are its carriers, or they already have a congenital child). This rule is particularly reflected in Art. 2 par. 4 of the Swedish Act of 18 May 2006 on genetic integrity, which stipulates *expressis verbis* that PGD may be applied solely when due to confirmed predispositions of a man or/and woman to develop a serious hereditary disease, a risk of giving birth to a child suffering from a genetic disease or other kind of serious impairment is high. A “medical” prerequisite of PGD’s application has been similarly formulated in Art. 1455 of the Greek Civil Code (added by the Act of 27 January 2005 on the above mentioned procreation), in § 2-14 of the Norwegian Act of 5 December 2003 on the application of biotechnology in medicine, Portuguese Act on MAP of 2006 (Art. 7), and the provisions of the Spanish Act of 2006 (Art. 12)<sup>16</sup>. Moreover, most countries additionally introduce (in the practice of hospitals or clinics’ activity, or under the law) the obligation to confirm a risk of transmitting a hereditary

14 The 1989 CAHBI recommendation does not explicitly refer to PGD, but indicates that the avoidance of a genetic disease or other serious hereditary condition should be a necessary condition for the legal application of MAP procedures. The wording of Principle 17 results, however, in the admissibility of cell collection from the embryo solely for the purpose of diagnosing the disease or developmental defect and the negative selection of embryos intended for implantation (screening out). The Polish text of the Recommendation – T. Jasudowicz, *Europejskie standardy bioetyczne. Wybór materiałów*, Toruń 1998, p. 107.

15 The Polish text of the Recommendation – T. Jasudowicz, *Europejskie...*, *op. cit.*, pp. 123-127. This document, along with the Recommendation of the Council of Europe No. 1100 of 2 February 1989 on the use of human embryos and fetuses in scientific research were a breakthrough in the approach to PGD and meant a change in the policy of the Council of Europe in this area. While the previous recommendations (e.g. Recommendation No. 1046 of 24 September 1986) were to provide individuals and society with protection against threats resulting from interference in the embryo and genetic manipulation, the primary goal of Recommendation R (90) and 1100 was to create unhampered conditions access to PGD by persons (couples) at risk of transmitting hereditary diseases to offspring (see point 9 of Recommendation R (90)) and Annex (A) of the Recommendation No. 1100). More on this subject O. Nawrot, *Diagnostics...*, *op. cit.*, pp. 53-56. See also the Report of the International Bioethical Committee of UNESCO of 2006 indicating the conditions for the legal conduct of PGD. J. Kapelańska, *Preimplantacyjna ...*, *op. cit.*, p. 95.

16 About regulations relating to medically assisted procreation in individual European and world countries see Steering Committee of Bioethics (CDBI) – Replies by the Member States to the Questionnaire on Access to MAP and on Right to Know About Their Origin for Children Born After MAP, Strasbourg 9 February 2012, [www.coe.int/t/dg3/healthbioethic/Activities/04\\_Human\\_embryo\\_and\\_foetus\\_en/INF\\_2005\\_7%20e%20MAP.pdf](http://www.coe.int/t/dg3/healthbioethic/Activities/04_Human_embryo_and_foetus_en/INF_2005_7%20e%20MAP.pdf) (accessed: 23 December 2016).

disease or genetic defect by an expert. Before undertaking IVG/PGD procedures, the Portuguese Act on MAP of 2006 in particular requires a couple to obtain a written certificate issued by a unit (centre) of prenatal diagnosis confirming that due to a family situation, spouses (partners) are very likely to give birth to a child suffering from a hereditary disease recognized as incurable at the moment of diagnosis<sup>17</sup>. The French law envisages similar rules, where medical legitimacy of the application of PGD is confirmed by the opinion of the Council of Genetics<sup>18</sup> and Belgian solutions<sup>19</sup> modelled thereon. Due to emerging interpretive doubts, on the one hand (especially about the form of a serious disease justifying diagnostic intervention), and objections raised by the opponents of interference in an embryo, on the other hand, the most recent regulations depict the above mentioned PGD's prerequisites more precisely indicating exhaustively cases when this practice is admissible (the British Act on Human Fertilization and Embryology of 2000, hereinafter referred to as HFEA 2008)<sup>20</sup>, and even formulating a definition of a hereditary disease justifying PGD (the Austrian Act on MAP of 1992 in the amended reading of 2015)<sup>21</sup>. On the other hand,

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- 17 V.L. Raposo, Assisted Reproduction. Two Models of Regulation: Portugal vs Spain, "Jornal Brasileiro de Reprodução Assistida" 2012, No. 1 (vol. 16), p. 35 and following.
  - 18 M. Nesterowicz, Ochrona osobowości, prokreacja medycznie wspomagana i inżynieria genetyczna w prawie francuskim, (in:) Teoria prawa. Filozofia prawa. Współczesne prawo i prawoznawstwo. Księga pamiątkowa ku czci Profesora W. Langa, Toruń 1998, p. 204. More on this see: A. Laucle, B. Matthew, D. Tabuteau, Droit de la santé, Paris 2009, p. 633 and following.
  - 19 According to art. 67 of the Belgian MAP Act of 2007, the evaluation of the existence of therapeutic interest (medical premise justifying PDG – emphasized by K.B.R.) is done by the MAP clinic, however its final position should take into account the opinion of the human genetic research center (included obligatory in the medical records). G. Pennings, Belgian Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes, "European Journal of Health Law" 2007, vol. 14, p. 258.
  - 20 HFEA 2008 allows PGD to detect embryos of genetic, chromosomal or mitochondrial disorders (anomalies) and the selection of the future child's sex in a situation where the inheritance of a specific form of defects is gender-related, and the choice allows the conception of offspring-free offspring. On the basis of the provisions of the Act, a woman (couple) can be given preimplantation diagnosis functions, if the risk of transmission of the indicated anomalies is significant and has a specific character in a specific case and will either result in the offspring of a patient suffering from defects or even a healthy child, but disability (serious disability), illness or other form of disorder (other medical conditions) is likely to develop only later in life. More on this subject see: J. Herring, Medical Law and Ethics, Oxford 2012, p. 389 and literature given there.
  - 21 The provision of § 2a, added to the Austrian MAP Act in 2015, permits PGD only in three situations: when, after a minimum of three IVF attempts, pregnancy cannot be invoked, there are grounds to conclude that genetic defects of reproductive cells are the cause, and secondly, in the event of at least three medically proven spontaneous miscarriages or births of a lifted and potentially fatal genetic embryo and, thirdly, when there is a significant risk of miscarriage, stillbirth or a hereditary disease in one of the two parents due to the genetic predisposition of one or both parents (Erbkrankheit). Erbkrankheit was defined in the act as a disease in which maintaining a child's life is possible only with the use of complicated medical equipment or the use of devastating medical procedures significantly reducing the quality of life. The statutory

there are only few legal systems depicting the application of GPD in a general manner while the legislator is merely limited to indicate that preimplantation diagnosis is admissible *verba legis* solely for medical reasons (the same as Art. 26 par. 1 of the Polish Act on Infertility Treatment). Such formulations neither secure interests of entities engaged in the IVF/PGD procedures nor sufficiently protect embryos because, as underlined in the doctrine, they particularly evoke a risk of development of adverse (undesired) practice of positive eugenics<sup>22</sup>.

From a juridical point of view, spouses or partners must, first of all, agree for the performance of PGD. As a rule, their consent is written and embraces their will to collect (retrieve) and carry out diagnostic tests necessary to detect potential defects and impairments (the same as, e.g., the above-mentioned Art. 1455 of the Greek Civil Code)<sup>23</sup>. According to general rules referring to the legality of medical interventions, the consent is effective if it is given after the interested parties have been informed about the nature, aims, benefits and typical risks ensuing from the procedure<sup>24</sup>. As far as PGD is concerned, couples are fully and exhaustively informed about the procedure before it is performed even though it is no longer an experimental method implying a wide inclusion of the obligation of information. The obligation to provide a couple with above-standard information about the PGD's nature, purpose, risk and benefits connected with, *inter alia*, biopsy of embryo cells, their assessment and selection, is a consequence of a close relation between PGD and MAP (IVF) procedures whose application requires informing the woman (couple) about all and any medical (and legal) aspects of the undertaken interventions<sup>25</sup>. The rule envisaging a wide scope of the obligation of information has been set forth *expressis verbis* in the laws of many countries, among others in Art. 66 of the Belgium Act on MAP of 2007, which obliges a clinic/hospital performing IVF/PGD to inform a couple about these procedures with due diligence (*une information loyale*)<sup>26</sup>. A wide approach to the obligation of information is desirable and undeniably accurate. Spouses (partners) should be fully informed about the treatment before making a decision as the procedure is, in

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concept of inherited disease also refers to diseases manifested by a serious brain injury or other form of an incurable disease that does not promise improvement and causes considerable pain and suffering.

22 See: for e.g. J. Lipski, *Opinia prawna na temat rządowego projektu ustawy o leczeniu niepłodności*, "Zeszyty Prawnicze Biura Analiz Sejmowych" 2015, No. 4 (vol. 48), p. 145.

23 See also principle 6 of the Recommendation R (90) 13 13 of Committee of Ministers of the Council of Europe of 21 June 1990, according to which prenatal and preimplantation tests should be performed on the basis of conscious and free consent of interested persons. More on this subject see: O. Nawrot, *Diagnostyka...*, *op. cit.*, p. 56.

24 K. Bączyk-Rozwadowska, *Prawo pacjenta do informacji w świetle uregulowań polskiego prawa medycznego*, "Studia Iuridica Toruniensia" 2012, No. 1, p. 59 and following.

25 M. Świdarska, *Zgoda pacjenta na zabieg medyczny*, Toruń 2007, p. 324. See also principle 17 of Recommendation CAHBI of 1989.

26 G. Pennings, *Belgian...*, *op. cit.*, p. 258.

principle, undertaken upon their initiative and in order to conceive a child free of genetic defects and disorders. Awareness of potential risks or failures connected with the treatment may, in particular, impel a couple to consider other possibilities to fulfil the parent project and abandon IVF/PGD for the sake of, e.g., MAP's heterological techniques, especially AID or in vitro fertilisation with the use of gametes (embryos) *ab alieno*.

In some countries (Great Britain, France or Poland) the obligation of information has been complemented by obligatory specialist or/and expert counselling, recommended in international documents<sup>27</sup>, to be given to individuals interested in PGD. Mandatory genetic counselling (by the Council of Genetics) is in particular envisaged by the French law<sup>28</sup> as well as Polish Act of 25 June 2015 on Infertility Treatment, which encompasses genetic counselling necessary to apply PGD as an element of medical MAP counselling envisaged in the provisions thereof (Art. 26 par. 1 in connection with Art. 5 par. 1 point 1)<sup>29</sup>. On the other hand, in the system of English law, the rule envisaging obligatory counselling does not ensue from the law but the Code of Good Clinical Practice (HFEA Code of Practice, VIII ed. of 2009, § 10 par. 4-6), which complements statutory HFEA 2008 regulation and sets binding standards of MAP procedure to be applied by experts. Nevertheless, the implementation of obligatory counselling is of great practical significance – it helps explaining doubts connected with the application of IVF/PGD procedures and, in particular, as confirmed by the practice, enables to establish genetic disorders parents would like to avoid in their future child (subjectively finding them serious), and thus assess whether they are encompassed by the statutory definition of serious disability/illness/impairment<sup>30</sup>.

In some legislations (e.g. French, Swedish or Norwegian), PGD may be applied solely after obtaining a positive assessment or consent of an appropriate competent interdisciplinary body, e.g. a state committee or bioethical commission<sup>31</sup>. The adoption of such a solution, recommended in international documents (e.g. the CAHBI Recommendation No. 17 of 1989), means that each case of PGD's application is assessed *ad casum*, including an individual situation of a specific person or couple.

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27 See principle 14 Recommendation R (90) 13 of the Council of Europe of 21 June 1990, in which Member States were recommended to create conditions for easy access and dissemination of knowledge about counseling in the sphere of PGD.

28 M. Nesterowicz, *Ochrona...*, *op. cit.*, p. 204.

29 See: J. Haberko, *Ustawa...*, *op. cit.*, p. 164 and following.

30 M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 368. Por. R. Scott, C. Williams, K. Ehrich, B. Farside, *The Appropriate...*, *op. cit.*, p. 320.

31 The French law allows PGD after obtaining a positive opinion from the National Bioethics Commission (Agence de la biomédecine); under the Swedish Genetic Integrity Act of 2006, the use of IVF / PGD procedures depends on the approval of the State Social Commission, while the Norwegian Act of 5 December 2003 requires the approval of the state commission appointed by the Ministry of Health.



Arbitrariness, undeniably desirable and approvable, enables to establish real motifs of future parents to perform embryo diagnosis and selection, and may prevent too widespread application of PGD beyond indicated statutory framework and for other reasons than those envisaged by the law (e.g. a selection of gender for social reasons)<sup>32</sup>.

Due to its close relation to the procedures of medically assisted procreation (IVF), PGD requires the fulfilment of specified institutional and substantial conditions. In particular, it is necessary to fulfil a mandatory and typical of any MAP manifestation condition to provide treatment by a qualified entity or/and in an authorized centre which has obtained a state licence or permit<sup>33</sup>. On the one hand, this requirement ensues from the need to guarantee a high level of sanitary security to entities taking advantage of MAP (IVF/PGD) procedures as well as a due quality of service provided by appropriately qualified staff in required premises and under appropriate technical conditions<sup>34</sup>. On the other hand, the system of licence provides a State with a possibility of supervising and monitoring PGD practices as well as minimizing a risk of potential abuse in the sphere of medical services which, due to their nature and aim (interference in the process of procreation), should be provided solely within the limits of law.

On the one hand, the introduction of far reaching restrictions to the application of preimplantation diagnosis and its exceptional character (as a medical procedure envisaged solely for individuals affected by or carrying genetic diseases or mutations/abnormalities) result from the above mentioned necessity to counteract undesirable practices, especially positive embryo selection and unjustified manipulation in

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32 In countries where the law does not provide for the approval or opinion of a special committee, the burden of making an assessment and making a final decision on the implementation of PGD lies with the MAP clinic (see, for example, the already mentioned Article 67 of the Belgian Act on Assisted Procreation of 2007). Moreover, due to the link between PGD and IVF, the infertility treatment clinic may refuse to undergo diagnostic activities, citing the contradiction of such activities with the good of the future child. The principle of the welfare of the child is in most legislations the final criterion for verifying the legitimacy of subjecting a woman (couple) to MAP procedures.

33 Model solutions for the licensing system are provided by HFEA 2008, according to which individual authorization is necessary to conduct PGD in each of the five permitted cases. (in 2011, the Office for Human Fertility and Embryology issued about 100 permits). More on this subject see: J. Herring, *Medical...*, *op. cit.*, p. 390 and the literature give there.

34 The obligatory European standard in this regard are set in the so-called tissue directives, in particular Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJEU L 102, 7.4.2004, pp. 48-58) and the Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance) (OJEU L 330M, 28.11.2006, pp. 162-174).

human genome. On the other hand, restrictive regulation protects in vitro embryos and appears to sufficiently satisfy the postulate of treating this form of existence with due respect (human being deserving special respect) and in accordance with the adopted concept of respect<sup>35</sup>.

Yet the practice confirms that despite creating an organizational framework of PGD's application, both in recommended international standards and domestic law, undesirable cases of going beyond permitted limits do occur. Currently, there are particular aspirations to use PGD for purposes other than original, i.e. the selection of gender for reasons other than avoidance of transmitting a serious disease onto a child such as creation of a child with specific features (designer baby) including, similar to parents, designer disability, or tissue match for older siblings affected by a serious life threatening illness (saviour sibling). If the above practices occur, the legislator is obliged to evaluate them from the perspective of valid laws and principles of ethics (taking into account future parents' interest and child's welfare) and, if necessary, undertake appropriate steps aimed at potential legalization or new bans. The discussed regulation is based on the assumption according to which the performance of PGD diagnosis for health (medical) reasons is morally justified contrary to procedures pursued for other reasons than medically justified.

## 2. The so-called saviour sibling

Apart from the evaluation of embryos and selection of non-defective ones, preimplantation diagnosis provides a possibility of the so-called tissue typing (HLA typing), i.e. establishing whether a specific embryo matches the so-called HLA Antigen (Human Leukocyte Antigen) of a living child of the couple subject to PDG that is affected by a serious life threatening illness. The child born in effect of such embryo's implantation (saviour sibling) becomes a donor of stem cells contained in cord blood which are used to treat an ill brother or sister when other methods of treatment have failed or are unavailable<sup>36</sup>. Therefore PGD/IVF is performed not only

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35 The concept of dignity presupposes that a human embryo is neither a person nor an object (an object of property), but is an intermediate category (interim category), which deserves a particular respect due to the provision of a unique human genetic code and the potential to become a human (potential for human life). See for example the judgment of the Supreme Court of the state of Tennessee in the case *Davis vs Davis* of 1992 (842 S.W. 2d. 588), cited after Ch.P. Kindregan, M. McBrien, *Assisted Reproductive Technology. A Lawyer's Guide to Emerging Law and Science*, Chicago 2011 (second ed.), p. 113. See also W. Lang, *Wstępna charakterystyka problematyki statusu płodu ludzkiego*, (in:) W. Lang (ed.), *Prawne problemy ludzkiej prokreacji*, Toruń 2000, pp. 1617 and O. Nawrot, *Status prawny pre-embrionu*, "Państwo i Prawo 2009" No. 2, p. 15 and following..

36 M.W. Wolf, J.P. Kahn, *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines and Limits*, "Journal of Law Medicine and Ethics" 2003, vol. 31, p. 331 and following.

in order to legally select an embryo free of anomalies that older siblings are affected by (screening out) but it also assumes a selection (to establish HLA Antigen match) and choice of an embryo with specific features (screening in), which, as emphasized by the literature, is a manifestation of positive eugenics<sup>37</sup>.

By all means, Kant's moral imperative forbidding treating human beings merely as means (treatment of another child) but as an end itself speaks against PGD performed in order to choose an embryo that will be used to conceive a child just to become a donor of cells or tissues. Opponents of such practices argue that a child "designed" as saviour sibling (saviour embryo) may, in their future life, after finding out about the circumstances of their conception, experience serious mental torment especially if the establishment of tissue match does not succeed and donorship will eventually be excluded<sup>38</sup>. According to another important argument raised in the literature, admitting embryo selection in order to conceive "a saviour child" is a step towards the acceptance of further manifestations of positive eugenics, e.g. a choice of an offspring of a specific gender, phenotype, IQ, or other features or predispositions desired by parents (designer baby)<sup>39</sup>.

On the other hand, the performance of PGD in order to choose an embryo of a desired HLA structure is supported by the fact that this procedure may prevent death of a terminally ill child (sibling) especially if blood transfusion is the last available therapeutic method. Here benefits of preimplantation diagnosis prevail over its negative aspects, in particular crushing a fundamental argument of tissue typing opponents, i.e. quality selection. Saving sibling's life is principally perceived as a beneficial action that is positive from the point of view of a donor, or at least not harmful to him or her<sup>40</sup>. Moreover, harm that in PGD opponents' opinion may be experienced by a saviour child in his or her future life is only hypothetically possible (potential), and it should not be a barrier preventing a diagnostic procedure. As it is underlined in the literature, we cannot exclude here an opposite situation – joy and other positive feelings ensuing from helping older siblings<sup>41</sup>. What is more, the practice proves that PGD combined with tissue typing in many cases enables to counteract pregnancy termination since parents of an ill child often strive for conceiving next offspring naturally hoping for HLA match and often choosing abortion in case of failure<sup>42</sup>.

The first legislation that admitted PGD to determine tissue match due to a scientifically proven lack of a serious risk for a created child and a therapeutic

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37 See e.g. G. Pennings, Belgian..., *op. cit.*, p. 258.

38 M.W. Wolf, J.P. Kahn, Using..., *op. cit.*, p. 332.

39 See: E. Jackson, Medical..., *op. cit.*, p. 849.

40 S. Sheldon, S. Wilkinson, Hashmi and Whitaker: An Unjustifiable and Misguided Distinction, "Medical Law Review" 2004, vol. 12, p. 137 and following.

41 J. Herring, Medical..., *op. cit.*, p. 396 and the literature given there.

42 E. Jackson, Medical..., *op. cit.*, p. 849.

purpose of this method was enacted in Great Britain. Prerequisites of the legal performance of the procedure developed in connection with a landmark ruling in the case of Hashmi – Quintavalle (on behalf of Comment on Reproductive Ethics) vs. Human Fertilisation and Embryology Authority (3 All ER 257) of 2003, which is the basis of a future statutory regulation (HFEA 2008)<sup>43</sup>. The Court of Appeal ruled that HFEA (Human Fertilization and Embryology Authority) did not violate valid laws issuing a licence to perform PGD in order to select saviour embryo. The Court decided that the practice of admitting PGD combined with tissue typing should be found lawful on the grounds of the Act to the extent in which it assisted to carry a child of a couple affected by a risk of transmitting a genetic disease. The reasons to the judgment emphasized that the process of facilitating woman's pregnancy without a fear that a child will be at a risk of being affected by a serious hereditary illness lies within the limits of a statutory concept of treatment, that is assisted conception<sup>44</sup>.

In 2004, in connection with another motion for PGD combined with tissue typing (in the so-called Whitaker case)<sup>45</sup>, the prerequisites of the legal performance of embryo selection were updated. The most important change involved the extension of PGD to cover cases where a saved child (alive sibling) suffered from a serious genetic disease, not necessarily inherited from both or one parent but initiated by a self-contained genetic mutation (e.g. Diamond-Blackfan anemia). The scope of admissible interference into the saviour child's body conceived to life for a therapeutic reason also embraced bone marrow aspiration apart from the collection of stem cells from the cord blood (which occurred in the Hashmi case). On the other hand, stricter rules on tissue typing were manifested in the introduction of the prerequisite

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43 The case concerned a 6-year-old child suffering from thalassemia beta (a serious genetic disease leading to anemia and requiring frequent blood transfusions) whose parents after subsequent failures in treatment and inability to find a blood donor asked the MAP clinic for tissue typing. The clinic, after obtaining the permission of the HFEA Office, led to the creation of 14 embryos, none of which, however, met the criteria for HLA compliance with a sick child. Further attempts were halted due to ethical circles' opposition, including CORE (Comment of Reproductive Ethics) organization. In a lawsuit filed against the court, CORE questioned the legality of the clinic's activities, undermining in particular the purpose of issuing the license – immoral and unethical creation of a child “on order.” N. Karczewska, *Prokreacja medycznie wspomagana w prawie angielskim*, “PiM” 2010, No. 1, pp. 98-99 See also E. Jackson, *Medical...*, *op. cit.*, p. 850.

44 M. Brazier, E. Cave, *Medicine...*, *op. cit.*, pp. 367-368. Por. E. Jackson, *Medical...*, *op. cit.*, p. 849.

45 The application was submitted by the parents of a child affected by the severe form of Blackstone-Diamond anemia. However, unlike in Hashmi, the HFEA Office did not grant a MAP license to the surgery, justifying the refusal by the fact that the child's illness was not inherited condition, but was the result of a spontaneous genetic mutation. This decision provoked opposition from the legal doctrine and bioethics, who pointed to the unjustified differentiation of children suffering from serious genetic disorders depending on the cause of the disease. Under the influence of criticism, the HFEA Office changed the decision and allowed the clinic to carry out tissue typing for therapeutic purposes. M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 369. More on this subject see: S. Sheldon, S. Wilkinson, Hashmi..., *op. cit.*, p. 137 and following.

of a prior use of all and any therapeutic possibilities available home and abroad to help a living child before a woman or couple could be subject to PGD. In the light of 2004 instructions, HLA typing was assumed to be an exceptional as well as final method of treatment (alleviating symptoms) of a serious genetic disease (option of last resort)<sup>46</sup>.

At present, pursuant to the amended HFEA 2008, embryo selection aimed at a choice of “a saviour embryo” is one of the five admissible cases of the legal performance of PDG and requires (the same as each of these options) an individual licence granted by the Human Fertilisation and Embryology Authority. According to the provisions of the Act (Schedule 2 § 1 ZA), PGD combined with tissue typing may be performed solely for therapeutic reasons, i.e. to help the siblings of a child conceived to life provided this help shall be limited to donating stem cells of core blood, bone marrow or other tissues excluding body organs and their parts<sup>47</sup>. Deciding about the legitimacy of performing PGD in each specific case, a MAP clinic is obliged to consider precisely the circumstances of the case related to the living child, a potential donor (saviour sibling) and parents. From the point of view of the siblings, it is, most of all, necessary to consider the nature and kind of an illness, an extent/degree of mental disability, forecast for the illness progress and future prognosis. The clinic should be convinced that the parents have taken advantage of all possible and available therapeutic methods *in casu*. With regard to the child that is to be conceived as a saviour sibling under MAP (IVF) procedure, it is necessary to consider risks connected with the performance of embryo biopsy and psychological and emotional consequences of “saviour conception” in the future, and establish whether the collection of a specific type of cells or tissues does not ensue serious health problems, and whether the procedure will not be too invasive. The clinic should also verify if after birth the child shall undergo one-off therapeutic procedures or whether it will be necessary to repeat (even regularly) specific medical acts in the future. The analysis of the whole family situation of a couple wishing to perform PGD and conceive a saviour child should check, on the one hand, earlier reproductive experiences of the spouses (partners) and current conditions of applying IVF/PGD

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46 If a transplant was an available option of the child treatment (for example, bone marrow cells), firstly, parents were required to exhaust the possibility of finding a suitable donor both at home and abroad (prior to submission to PGD combined with typing tissue) (which, as emphasized in doctrine, it is possible in a short time due to the functioning of electronic registers of donors). More on the guidelines of 2004 see: E. Jackson, *Medical...*, *op. cit.*, p. 849 and following.

47 However, it cannot be ruled out that the parents will attempt to get the organ from a younger sibling, tissue-compatible with a sick brother or sister later, when all other methods of therapy are exhausted. However, this action may fail due to the requirement under the Human Tissue Act of 2004 to obtain the consent of the court to collect the organ from a minor. The doctrine emphasizes that in practice the consent of the court is unlikely because it is a manifestation of circumvention of the HFEA 2008 regulations constituting the prerequisites of tissue typing admissibility). See: M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 369.

to them (including a number of possible cycles and embryos that may be created therein), while on the other hand, a probability of achieving expected results with regard to the older siblings' therapy. What is more, the MAP clinic should also consider a risk of IVF/PGD and tissue typing failure and its potential consequences for the couple as well as verify possible social support if a conceived child proves to be genetically impaired again<sup>48</sup>.

Despite evoking continuous and numerous controversy in some representatives of legal doctrine and bioethics (as a manifestation of eugenics), cases of assessment of tissue matching in PGD procedures do occur and, as confirmed by the practice, in many countries they result in delivering children for therapeutic reasons<sup>49</sup>. The above-mentioned diagnostic and therapeutic benefits of PGD combined with tissue typing on the one hand, and the need to provide such activities with organizational framework (to eliminate potential abuse, illegal treatment or even "procreation tourism") on the other hand, have made some countries, with the support of the doctrine, adopt the relevant regulation<sup>50</sup>. The laws are most often modelled on the original British model (i.e. 2004 Recommendations and HFEA 2008), which, however, is distinct in comparison to other countries with regard to precise and exhaustive determination of tissue typing prerequisites.

The need of regulating a controversial technique of establishing tissue matching in PGD procedures was included, among others, in the Spanish Act on MAP of 2006 (Art. 12) and the provisions of the Portuguese Act on 2006, which permit tissue typing as one of the legally admissible cases of preimplantation diagnosis within the narrow framework designated by a therapeutic purpose and respect for the child's welfare<sup>51</sup>. Similar to the English law, most legislations assume that tissue-typing procedures are exceptional in their nature. Apart from the need to obtain cells (tissues) for older, seriously ill sibling (and not other persons, e.g. a parent or other relatives), special regards should support tissue typing *in casu*. It has been rightly decided that a MAP clinic should decide about the performance of these procedures while some countries conditioned it (the same as other cases of IVF/PGD) on obtaining a consent or/and positive opinion of a special committee or board (e.g. State Social Committee in Sweden, or *Agence de la biomédecine* in France). Evaluating every circumstance of a specific case, a clinic or/and committee should especially verify if actions undertaken by a couple to fulfil the parent project are not contrary to the future child's welfare,

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48 J. Herring, *Medical...*, *op. cit.*, p. 394-395.

49 The birth of a child whose stem cells were used to treat older siblings (beta thalassemia) was in Spain (2008) and France (2011), and in other genetic diseases in Belgium and the USA, O. Nawrot, *Diagnostyka...*, *op. cit.*, p. 49. See also D. Pszczółkowska, *Po pierwsze dziecko, po drugie lekarstwo*, "Gazeta Wyborcza" of 11.02.2011.

50 Acceptance for tissue typing practices is particularly evident in the Belgian doctrine and medical environments. G. Pennings *Belgian...*, *op. cit.*, p. 258.

51 *Ibidem*. See also: V.L. Raposo, *Assisted...*, *op. cit.*, p. 42.

and whether their actual motivation is not limited to saving an older brother or sister but rather aimed at MAP conception to carry a child as a purpose in itself (the same as, e.g., Art. 68 of the Belgian Act of 6 July 2007)<sup>52</sup>. However, it is difficult to verify this prerequisite in practice since, as a rule, parents continue to claim that regardless of other circumstances, they intended to undergo IVF and conceive a second child while the application of PGD was justified by a risk of transmitting genetic disorders that one or both of them have been affected by.

### 3. “Designing” a disabled child (*designer disability*)

In connection with the possibilities provided by IVF/PGD as to embryo evaluation and selection, the ensuing question is whether parents affected by a genetically conditioned disease or disability (e.g. muteness, deafness, or dwarfism), may demand implantation of impaired embryos in order to conceive a child with the same defect (designer disability). As proved by the practice<sup>53</sup>, such a choice is most often justified by peculiar understanding of the child’s welfare by parents and a desire for the child’s complete assimilation in a family or even community of people affected by the specific illness. At the same time, a demand for the transfer of a defective embryo is an expression of protest against social perception of a specific type of handicap as disability and the need to eliminate it through IVF/PGD procedures<sup>54</sup>.

The literature rightly depicts the argument against purposeful conception of a child affected by a defect, according to which such practice, as a new form of eugenics, is an undesirable and dangerous step towards commercialization and instrumentalization of reproduction (free market/laissez-faire eugenics). Parents deciding to conceive a child of a specific health condition are compared to consumers choosing a product according to their own individual needs and preferences (consumer-like choice)<sup>55</sup>. PGD combined with a positive selection of impaired embryos is undeniably contradictory to the principle of the child’s welfare, which, pursuant to the legislation of most countries, should be applied while deciding about substantive and non-substantive (personal) sphere of the child’s life. Deliberate creation of a child that is either deaf, mute or affected by inherited dwarfism, will not satisfy their welfare, just on the contrary, it is a gross violation thereof and may be perceived as a manifestation of subjective, or even selfish aspirations of parents.

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52 G. Pennings, Belgian..., *op. cit.*, p. 258.

53 See: This Couple Want a Deaf Child. Should We Try to Stop Them? “The Observer” of 9.032008 (the UK) and M. Spriggs, Lesbian Couple Create a Child Who is Deaf Like Them, “Journal of Medical Ethics” 2002, vol. 28, p. 283 and following (USA).

54 See: M. Brazier, E. Cave, Medicine..., *op. cit.*, pp. 369-370 and J. Savulescu, Deaf Lesbians, “Designer Disability” and the Future of Medicine, “British Medical Journal” 2002, vol. 325, p. 771.

55 D. King, Preimplantation Genetic Diagnosis and the “New” Eugenics, “Journal of Medical Ethics” 1999, vol. 25, p. 176 and following.

No illness (physical impairment) and mental wellbeing, which are objectively recognized as positive and highly desirable, are, by all means, much more valuable than benefits of the child's assimilation into a specific community and a sense of a lack of distinctiveness from its other members. Moreover, a deliberate conception of a child with defects does not account for the child's future interests, who, after becoming mature or independent due to commencing education, is likely to leave the family community. Life choices are particularly limited not only in a professional field (a choice of study or profession) but also personal (a risk of transmitting defects into future offspring). Even though assimilation is assumed desirable and beneficial for a child, it may evoke opposite effects and excessively bind the child with a specific environment.

On the other hand, few supporters of designer disability claim that admissibility of defective embryo selection and transfer is the right of the spouses (partners) ensuing from procreative autonomy and the right to procreate everyone is entitled to. The fulfilment of the parent project that is medically assisted does not differ from the situation when, in result of a scheduled natural conception, a woman chooses a man affected by a specific inherited defect to be a father of her child ("parental eugenics")<sup>56</sup>. Furthermore, such concepts as equality and disability discrimination ban also support the admissibility of deliberate conception of an ill child. It is emphasised that the rejection of impaired embryos by a MAP clinic as "unsuitable" for implantation manifests a lack of acceptance of specific forms of disability and conveys a negative message of medical environments and society in general towards affected disabled persons<sup>57</sup>.

The provisions of valid legislation on MAP worldwide do not regulate straightforwardly a controversial issue of designer disability. Nevertheless, non-admissibility of such kinds of activity results from the already mentioned narrow framework of PGD admissibility adopted by most countries, i.e. the rule that only embryos free of defects and impairments shall be used in implantation, and banned selection of the child's genetic features (e.g. Art. 26 of the Polish Act on Infertility Treatment). Yet the practice proves that the shape of provisions regulating the principles of transfer may evoke doubts and favour aspirations of parents to conceive a child affected by a defect. In Great Britain, pursuant to Art. 13 par. 10 of HFEA 2008, embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop serious physical or mental disability, serious illness, or other serious medical condition, must not be preferred to those that are not known to have such an

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56 See: J. Herring, *Medical...*, *op. cit.*, p. 391.

57 Por. J. Savulescu *Deaf...*, *op. cit.*, p. 771.



abnormality<sup>58</sup>. Thus, the Act does not establish an absolute ban on the implantation of defective embryos but introduces the principle of transfer priority for healthy embryos. If in one cycle both non-defective and impaired embryos are created, genetic parents may refuse to undergo implantation and undertake next IVF/PGD attempts counting on the creation of exclusively defective embryos satisfying their procreative plans<sup>59</sup>. If the choice is not statutorily regulated, it is theoretically possible, *inter alia*, to implant an impaired embryo based on the argument raised by the parents to support their aspirations, according to which the transfer is the last resort to conceive a child that is genetically related to them. The use of a defective embryo may, however, be found contrary to the child's welfare which, in accordance with general HFEA rules, the clinic is obliged to consider each time a woman (a couple) undergoes MAP procedures (Art. 13 par. 5). In such a situation, in compliance with the principle ordering a thorough analysis of each case *ad casum*, it is necessary to assess potential consequences of specific defects affecting the child and, in particular, verify whether, e.g. inherited blindness or deafness, is serious impairment justifying a refusal to carry out the transfer. If the defect is not connected with a far-reaching harm or disorder of the child, and in effect of a specific type of an illness or disability life would not be as impaired as to be not worth living, a positive selection of an impaired embryo is admissible<sup>60</sup>. However, majority of the doctrine representatives rightly believe that the principle of the child's welfare excludes a transfer of impaired embryos in each case and regardless of the nature and type of a defect. Therefore, the will of future parents to conceive a child affected by an illness may not (and most probably would not have been) considered due to the content of the above-mentioned Art. 13 par. 5 of HFEA<sup>61</sup>. Apart from that, the evaluation of the defect's burden and impact of the ensuing disability on the quality and comfort of the child's life seems impeded or even impossible if, on the one hand, the child has not been conceived yet (*pre-conceptus*), while on the other hand, there are no appropriate measures to assess a degree of both physical and mental torment evoked by the illness due to their highly individualized nature.

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58 This principle corresponds to the rule of preference for the gamete donation of this donor, for whom it is known that he is not a carrier of genetic diseases or another form of hereditary defects and burdens (art. 13 par. 9). See: J. Herring, *Medical...*, *op. cit.*, p. 391.

59 M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 370. This action would be unacceptable in countries whose laws prohibit the creation of new embryos in a situation where the couple have healthy embryos suitable for implantation (France).

60 J. Savulescu, *Deaf...*, *op. cit.*, p. 771 and following.

61 See: E. Jackson, *Medical...*, *op. cit.*, p. 843.

#### 4. The selection of the child's sex

Apart from monitoring embryo conditions, PGD enables to choose future child's sex and other features (e.g. phenotype)<sup>62</sup>. However, international documents referring to the issue of assisted procreation apparently indicate inadmissibility of such practices. A general ban on sex selection in connection with the application of MAP procedures<sup>63</sup> was expressed, among others, in CAHBI Recommendation of 1989 (Rule 17), and a basic document in the field of bioethics, i.e. the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 4 April 1997 (The Oviedo Convention on Bioethics, Art. 14)<sup>64</sup>.

The ban is founded upon the assumption according to which deciding about the child's sex and other features is excessive, undesirable and unjustified interference in the process of procreation ("playing God"), admissibility of which would be equal to the acceptance of positive eugenics practices. It is assumed that MAP techniques should come as close as possible to natural procreation (*procreatio artificialis naturam imitatur*) where such a choice is impossible<sup>65</sup>. Moreover, the exclusion of admissibility of sex selection counteracts discrimination (it fulfils the moral order to accept a conceived child regardless of its sex) as well as favours elimination of demographic threats, that is births of an excessive number of children of specific sex and a negative impact thereof on the population. Furthermore, the literature underlines that the fact that parents decide about sex of their future offspring entails a risk of evoking negative effects in the child's psyche who, learning about the circumstances of his or her conception, may suffer from serious psychological harm<sup>66</sup>.

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62 The appropriate selection of donor gametes in cases of using heterologous MAP techniques also has an impact on the traits of the future child. In many countries, the law imposes on the doctor (clinic) the right choice of the donor so that the child shows minimal although similar to the social father, for example in terms of body structure, eye color or hair. The boundary between the "matching" of traits within the created family and the selection of specific, desirable values of the child may turn out to be smooth and even difficult to determine.

63 This selection is possible by selection in PGD procedures and implantation into the uterus of the male or female embryo or the use of appropriate sperm (X or Y) for insemination or IVE.

64 The choice of gender based on insemination with selected sperm (X or Y) is, however, acceptable from 1995 in the US, on a commercial basis. In practice, about 2,000 people (couples) took advantage of this opportunity. Cited after the House of Commons, Science and Technology Committee, Human Reproductive Technologies and the Law: Fifth Report of Session 2004-2005. Volume 1, London 2005, p. 62 and the literature given there.

65 Compare J. Lipski, *Opinia...*, *op. cit.*, p. 145.

66 The ban also reflects the social attitude to the issue of gender selection, which is opposed by around 80% of respondents. Cited after J. Herring, *Medical...*, *op. cit.*, p. 392. See also: House of Commons Science and Technology Committee, *Human...*, *op. cit.*, p. 62-63.

The ban on gender selection has been adopted by most legal systems worldwide. Among others, it is expressed *expressis verbis* in Art. 53 of the Belgian Act on the above-mentioned assisted procreation and disposal of supernumerary embryos of 2007, § 2-13 of the Norwegian Act on the Application of Biotechnology in Medicine of 2003, Art. 1455 of the Greek Civil Code (in the reading enacted by the Act on MAP of 2002) and Art. 26 par. 2 of the Polish Act on Infertility Treatment. Violation of the ban is, as a rule, subject to criminal sanctions: a fine, limitation or deprivation of liberty (see Art. 82 of the Polish Act of 25 June 2015)<sup>67</sup>. The introduction of sanctions is of considerable preventive significance and, in compliance with the legislator's assumptions, it is to counteract undesirable practices and eliminate unauthorized cases of embryos selection<sup>68</sup>.

The sex selection ban, however, is not of an absolute nature. CAHBI Recommendation, Oviedo Convention and legislations of individual countries admit an exception thereof, when the choice is supported by medical considerations – the need to avoid a risk of transmitting a serious sex-linked disease (e.g. haemophilia, or Turner syndrome). In other words, if a genetic disease typical of a specific sex may affect a child, the couple may undergo PGD procedure and choose to transfer only embryos of this sex that does not inherit a given type of disorders in accordance with the rules of medical knowledge.

International documents, including the Oviedo Convention (Art. 14), do not define a serious genetic disease whose risk justifies sex selection. The literature has assumed that this term should be defined more precisely by a national legislator, who should accurately determine cases when such a choice is possible to achieve the purpose of the regulation – to counteract abuse<sup>69</sup>. The solution in the form of introducing a list of diseases (*numerus clausus*) has been found inaccurate due to the lack of flexibility and the need to systematically verify and complete this list is result of dynamic development of medical science in recent years<sup>70</sup>. Hence, each acute (serious) hereditary specific sex-linked disease may theoretically justify the

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67 However, the Polish legislator limited in art. 82 the application of sanctions provided for in breach of the prohibition in art. 26 par. 2 to unjustified gender selection, despite the fact that the ban is broader and also concerns the choice of phenotypic features of the child other than gender. This solution, as it is aptly pointed out in the literature, is unintentional and overlooked by the legislator. See: J. Haberko, *Ustawa...*, *op. cit.*, pp. 389-390.

68 In the Polish literature it was raised that the ban stipulated in art. 26 par. 2 has too narrow a scope of application, and the protection envisaged in it is illusory, which in turn poses a threat to the development, on a large scale, of the practice of medically unjustified selection of embryos and positive eugenics: J. Lipski, *Opinia...*, *op. cit.*, p. 145.

69 O. Nawrot, *Diagnostyka...*, *op. cit.*, pp. 57-61.

70 See: the Report on the Protection of the Human Embryo In vitro of 19 June 2003, [www.coe.int/t/dg3/healthbioethic/texts\\_and\\_documents/CDBI-CO-GT3\(2003\)13E.pdf](http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3(2003)13E.pdf) (accessed: 20 February 2017). Compare J. Haberko, *Ustawa...*, *op. cit.*, p. 167. See also J. Pennings, *Belgian...*, *op. cit.*, p. 258 and J. Kapełańska-Pręgoszka, *Zjednoczone...*, *op. cit.*, p. 409.

selection. In some countries (e.g. Great Britain), to eliminate doubts, the provisions of law have defined a sex-linked disease while underlying the need to determine whether specific genetic impairment (disorder) the parents applying for PGD would like to avoid actually regards one sex exclusively or overwhelming majority of cases (Art. 13 par. 11 of HFEA 2008)<sup>71</sup>. This solution eliminates doubts and is sufficiently flexible because, in accordance with HFEA 2008, each serious hereditary disease, even the new ones that have been recently described in medicine, may justify embryo selection if HFEA Authority issuing a PGD licence is convinced about the existence of the relation between the disease and a specific sex<sup>72</sup>.

Despite the restrictive regulation of PGD and explicit statutory ban on sex selection, the practice knows cases of parents demanding the fulfilment of the parent project and the conception of a child of a specific sex most often for social reasons, e.g. family balancing. Its justification is also evoked on the grounds of procreative autonomy and the right to procreate which, as it is sometimes emphasized, may also embrace the selection of a child's sex and his or her other features due to the possibilities provided by MAP. What is more, there are attempts to extend the prerequisite of medical reasons by encompassing therein a mother for whom a refusal to fulfil an intended parent project and conceive a child of a specific sex is a serious psychological threat.

The literature knows at least two cases of parents claiming their "right" to conceive a child of a specific sex (female) for social reasons<sup>73</sup>. In the first case (the so called *Mataró case*) of 1995, the Spanish government found a demand submitted to a MAP clinic for the application of IVF/PGD for the woman, a mother of four boys, to select (and consequently transfer) female embryos unreasonable. The claimant argued that a fear she would not deliver a female child in result of the next pregnancy is a source of serious mental torment for her that may lead to profound depression and nervous breakdown. She believed that her claim was based on medical considerations, which, pursuant to the then valid Act of 1988 on MAP, justified a selection of a child's sex as an exception from the relevant general ban thereon set forth in the Spanish law. Dismissing her claim, the court rightly underlined that medical considerations, which are the only prerequisite of admissibility of sex selection, refer solely to the child who is at a risk of a specific genetic sex-linked disease and not other persons (the mother or second parent) applying for embryo selection<sup>74</sup>. A failed attempt at a wide interpretation of the prerequisite of medical

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71 J. Herring, *Medical...*, op. cit., p. 392. Pojawia się jednak pytanie, czy elastyczność modelu i brak listy nie stwarza zagrożenia w postaci nadmiernego arbitralizmu ocen. Compare: J. Haberko, *Ustawa...*, op. cit., p. 167.

72 *Ibidem*.

73 However, MAP clinics in some countries (USA, China) offer gender selection services for social reasons. See: <http://www.givf.com/familybalancing/> (accessed: 26 February 2017).

74 V.L. Raposo, *Assisted...*, op. cit., p. 42.

reasons justifying PGD and a selection of a child's sex was an efficient barrier against similar claims in the future.

The application for PGD in order to select embryos of a specific sex was also rejected in the English case of *Masterton* of 2004<sup>75</sup>. Different from the *Mataró* case, the couple demanding preimplantation control of IVF embryos and a selection of solely female ones for implantation was infertile because after delivering the last fourth child the woman carried out vasectomy. Although humanitarian reasons and rules of community life supported assisted conception (a three-year-old daughter of the couple, born after fifteen years of attempted conceptions and prior births of four sons, died tragically) and the doctrine criticized limiting admissibility of embryo selection to medical reasons, a licence for PGD and embryo selection has not been granted<sup>76</sup>. The refusal was justified by the fact that sex selection is an action contrary to the Act each time it is motivated by other reasons than medical ones (social sex selection), in particular if the parent project assumes the creation of a desirable and sex balanced family composition<sup>77</sup>. In connection with the *Masterton* case, the doctrine extensively criticized HFEA solutions going as far as raising a postulate to amend the Act and mitigate the criterion of medical reasons. Nevertheless, these proposals have not brought any effect; the legislator not only remained consistent with regard to the maintenance of a medical prerequisite of embryo selection in PGD procedures, but also consequently banned other selection techniques, including sperm sorting to separate X and Y spermatozoon, and use only one type thereof for insemination (e.g. Y in order to conceive a boy)<sup>78</sup>.

## 5. Final comments

The application of PGD providing a possibility of evaluating and selecting embryos before implantation is, by all means, desirable because it helps to conceive a child when there is a risk of transmitting a serious genetic disease or other forms of disorder onto a future child. On the other hand, however, preimplantation diagnosis enables to fulfil the parent project according to parents' subjective needs and beliefs not necessarily corresponding to the interests of the child to be born. Intensive development of biotechnology and growing possibilities of medical sciences change the nature of parents' aspirations and expectations, who intend not only to conceive

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75 House of Commons, Science and Technology Committee, *Human...*, *op. cit.*, p. 63.

76 The couple eventually used the services abroad (Italy) on a commercial basis (for a price of around 30,000 USD). However, male embryos obtained in in vitro procedures have been passed on by genetic parents for anonymous donation purposes. M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 370.

77 S. Wilkinson, *Racism and Sexism in Medically Assisted Conception*, "Bioethics" 1998, vol. 12, p. 25.

78 M. Brazier, E. Cave, *Medicine...*, *op. cit.*, p. 370.

and deliver a child despite obstacles (e.g. infertility), but also expect a healthy child who even, as it has been confirmed, has specific features (sex, phenotype, HLA structure, etc.). Hence, it is not only necessary to set limits of IVF/PGD legality and grant these types of procedures appropriate organizational and legal framework (eliminating potential abuse), but also realize further instant attention of the legislator, among others, through the system of licensing MAP (PGD) practices and supervising the activities of entities providing such services. The argument presented in the 1990s, according to which regulation and system of control are excessive and undesirable interference of the State into the personal and intimate sphere of human life (“state controlled procreation”) seems to become obsolete<sup>79</sup>. State control and supervision are necessary, most of all, to prevent and counteract MAP development in already indicated and undesired directions. The application of techniques of assisted procreation leads to the conception of human life. Hence, none of the practices may be contrary to the principle of the child’s welfare encompassing his or her wellbeing in the personal (and medical) area (sphere) and appropriate security of financial interests. Consequently, each parent project opposite to the above should be inadmissible. Striving to achieve this and provide a child with appropriate protection concurrently satisfy the rule adopted in Art. 3 par. 2 of the UN Convention on the Rights of the Child of 20 November 1989<sup>80</sup>, which makes countries undertake action to ensure the child such protection and care as is necessary for his or her well-being.

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79 See e.g.: M. Safjan, *Prawo wobec ingerencji w naturę ludzkiej prokreacji*, Warszawa 1990, p. 217 and 218.

80 *Journal of Laws of 1991*, No. 120, item 526 [Dz.U. 1991, Nr. 120, poz. 526].

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