

**One model two approaches? A comparison of Preimplantation Genetic  
Diagnosis' regulation in the UK and in Germany**

by

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## EXECUTIVE SUMMARY

This thesis is a comparison of Preimplantation Genetic Diagnosis' (PGD) regulation in the UK and in Germany. PGD is a new technique, developed in the 1990s and primarily used for selecting in-vitro fertilized embryos before implantation.

Originally PGD was developed for therapeutic use to enable couples who are at increased risk of having a child with a genetic disorder, to be free from the potential burden of giving birth to a child suffering from a serious genetically inheritable disease or of the prospective termination of the pregnancy. The technology has undergone a significant development since the 1990s and current applications of PGD have also the potential to screen for such genetic conditions that are unrelated to medical necessity.

Currently no international regulation exists for PGD and different states choose different strategies based on the specific countries' moral and ethical principles. For the first sight, the regulations in the UK and in Germany appear somewhat similar and this thesis aims to clarify whether these two regulations are truly similar. I suggest at the end of the paper that labeling these two regulations differently (liberal v. conservative or pragmatic v. normative) is well founded.

After the introduction I will list several human rights arguments and ethical concerns for or against potential applications of PGD. In the third chapter European perspectives of PGD's regulations is shown. The fourth chapter is about the comparison between the two regulations in the UK and Germany and their potential effect on the technology's future development.

## **LIST OF ABBREVIATIONS**

ESchG	German Embryo Protection Law ('Embryonenschutzgesetz')
HR Act	Human Rights Act
HFE Act	Human Fertilisation and Embryology Act, 2008
HFE Authority	Human Fertilisation and Embryology Authority
IVF	In-vitro Fertilisation
PGD	Preimplantation Genetic Diagnosis
PGS	Preimplantation Genetic Screening

## CHAPTER 1: INTRODUCTION AND THESIS STATEMENT

A very interesting debate raised my attention in the German society during the summer of 2010. The issue was about the regulation of Preimplantation Genetic Diagnosis (PGD). PGD is a new technique, developed in the 1990s and primarily used for selecting in-vitro fertilized embryos before implantation.<sup>1</sup> Originally PGD was developed for therapeutic use to enable couples who are at increased risk of having a child with a genetic disorder, to be free from the potential burden of giving birth to a child suffering from a serious genetically inheritable disease or of the prospective termination of the pregnancy.

The technology has undergone a significant development in the last 20 years and current applications of PGD have also the potential to screen for such genetic conditions that are unrelated to medical necessity. These issues raise several legal and ethical concerns. In the first part of the thesis I approach this difficulty by investigating human rights arguments from the aspect whether on their basis it is more common to argue for or against PGD as a first step. However, the regulation of the technology is related not only to legal questions and human rights arguments but also to several ethical issues. Following, as a second step I am investigating ethical concerns in relation to PGD as well. Emerging ethical concerns could be for example organized, after Benjamin B. Williams, in two groups labeled as ‘risks to offspring’ and ‘risks to society’.<sup>2</sup>

Currently no international regulation exists for PGD and different states choose different strategies based on the countries’ moral and ethical principles. There are countries where no governmental

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<sup>1</sup> Norton, Vicki G.: Unnatural Selection: Nontherapeutic preimplantation genetic screening and proposed regulation. 41 UCLA L.Rev. (August, 1994) p. 1584

<sup>2</sup> Williams, Benjamin B.: Screening for children: Choice and chance in the ‘Wild West’ of reproductive Medicine. 79 Geo. Wash. L. Rev. (June, 2011) p. 1308-1310

regulation exists. In the United States for example there are no agencies or statutes with a direct control over PGD.<sup>3</sup> A contrasting example of this model is a complete ban on the technology. There are countries, for example, Switzerland, Austria, Italy, Ireland, Norway and Poland where PGD is banned through federal legislation.<sup>4</sup>

Williams also lists countries for the third example of a potential regulation. These are countries, where a regulatory framework allows for a ‘restricted use’ of the technology. In these countries, for example, UK, Canada and now also Germany a central agency exists, which oversees the application of the technology.

For this thesis I will make a comparison of Germany’s and the UK’s PGD regulation. The comparison of these two countries is adequate because firstly both UK and Germany are European countries, as a result their ethical approach to the question is fairly comparable, and secondly they both follow a somewhat similar regulatory model. Nevertheless, my research is focused around the question to what extent it is true that the two legal regulatory frameworks represent the same or two different legal or ethical model.

For the first sight the two regulations appear somewhat similar. In both cases a framework regulation was put in practice, which establishes a central agency, which is firstly responsible for the licensing of assisted reproduction clinics, and secondly reviews and considers requests made by the clinics. Still, the regulatory framework in the UK is labelled as a ‘liberal model’ while the German as a ‘conservative model’. The issue and conclusion necessarily follows from these that

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<sup>3</sup> Gortakowski, Michael: A Parent’s Choice v. Governmental Regulations: A Bioethical Analysis in an Era of Preimplantation Genetic Diagnosis. 29(85) Buff. Pub. Int. L.J. (2011)

<sup>4</sup> See supra note 2

there must be other aspects in these countries other than the regulatory framework of PGD that lead to different applications of the law.

Another interesting aspect follows from this issue. And this is the question whether human rights arguments and ethical concerns strengthen each other in this debate or whether they are present with the same function in the two regulatory models. My presumption is that mainstream human rights arguments (protection of couples' reproductive autonomy or women's right to physical integrity) in practice will rather strengthen the development of PGD's application, while those are only ethical concerns that can function as springboards to deny PGD's novel treatment procedures.

Even though PGD is a technique that requires in-vitro fertilization (fertilizing the woman's egg with the partner's sperm outside of the woman's body), Bouffard, Godin and Béviere legitimately highlight that this technique is often mixed with other technologies that primarily aim at helping infertile couples.<sup>5</sup>

There are several ways in trying to define the process of PGD; these definitions depend primarily on the scope they cover. One way to define it is to concentrate on its purpose. Many scientists emphasize that the primary object of PGD is to 'allow scientists to detect defects at a very early stage of embryonic development'.<sup>6</sup> According to one approach, PGD is a technique that enables 'to obtain

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<sup>5</sup> Bouffard, Chantal; Goden, Julie-Kim; Béviere, Bénédict: State intervention in couples' reproductive decisions: Socioethical reflections based on the practice of Preimplantation Genetic Diagnosis in France. 1(3) AJOB Primary Research (July-September, 2010) p. 22

<sup>6</sup> See supra note 1 p. 1585

a biopsy from the embryo for genetic testing before its transfer to the uterus thus allowing only the transfer of healthy embryos'.<sup>7</sup>

The second possibility is to focus on the technology it requires, and less on the outcome. According to this approach, the term 'preimplantation diagnosis' (PGD) refers to procedures that allow a diagnosis of embryos using in-vitro fertilization (IVF).<sup>8</sup>

The second definition obviously represents a broader approach, since the term 'diagnosis' may refer to more potential outcomes than simply choosing the 'healthy embryo' so that the future child is free of any serious hereditary disease. In this thesis I will use the second definition, since the research also involves questions of non-therapeutic application of PGD.

Even though many authors write about the process how PGD is applied, only some of them give such detailed analysis about it as Williams.<sup>9</sup> He gives a comprehensive description about the process of PGD in which he splits the process into five steps. The first steps in this explanation include the stimulation of the woman's eggs by drugs and their extraction. This process is followed by the fertilization and creation of one or more embryos outside of the woman's body. After a couple of

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<sup>7</sup> Mansour, Raga: In vitro fertilization for the prevention of genetic diseases In: Serour, Gamal I.: Ethical Implications of Assisted Reproductive Technology for the Treatment of Infertility. Summary of the workshop organized by The International Islamic Center for Population Studies And Research 22-25 Nov, 2000 p. 81 OR According to the opinion of the German Research Institute 'Leopoldina' 'Preimplantation genetic diagnosis (PGD) is a diagnostic procedure that enables parents who are at an increased risk of having of a child with a serious hereditary disease, to give life to a child, who is not affected by the disease'. Available at: [http://www.leopoldina.org/fileadmin/user\\_upload/Politik/Empfehlungen/Nationale\\_Empfehlungen/stellungnahme\\_pid\\_2011\\_final\\_a4ansicht.pdf](http://www.leopoldina.org/fileadmin/user_upload/Politik/Empfehlungen/Nationale_Empfehlungen/stellungnahme_pid_2011_final_a4ansicht.pdf) (last visited: 25.03.2012)

<sup>8</sup> Definition by the German Reference Centre for Ethics in the Life Sciences (DRZE) <http://www.drze.de/im-blickpunkt/pid> (last visited: 25.03.2012)

<sup>9</sup> See supra note 2 p. 1306

days the embryos are biopsied and undergo a genetic testing. The last step happens when the embryo, which the woman chooses, is implanted to her womb.<sup>10</sup>

Even though this is a highly developed technique, there are some important limitations in its application, which are highlighted in Norton's article. One of its crucial elements is the speediness of genetic testing. Waiting too long after the fertilization, scientists risk of arriving at a stage when the embryo can no longer attach to the woman's body when implanted. Another limitation of the technique is the low success rate of implantation, which is often resolved by implanting more than one embryo to the woman's body.<sup>11</sup> These critiques are important, but it could easily be argued that these limitations might be easily overcome in the future.

Preimplantation Genetic Screening (PGS) is considered as an 'advanced' form of PGD, which is used to test almost all in vitro embryos for multiple genetic characteristics providing a 'better test and information' about it.<sup>12</sup> These two are slightly, nevertheless different technologies.

One of my models in this research, the UK is probably the most advanced country in both applying and regulating PGD. This is the country where the technique was both first developed and first regulated, and is often referred to as a country with a highly regulated but at the same time very 'liberal' approach.<sup>13</sup> The Human Fertilisation and Embryology Agency, the PGD's regulatory body, has since the 2000s constantly widened the scope of PGD's treatment procedures.<sup>14</sup>

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<sup>10</sup> Ibid.

<sup>11</sup> See supra note 1 p. 1890

<sup>12</sup> King, Jamie: Predicting probability: Regulating the future of Preimplantation Genetic Screening. 7 Yale J. Health Pol'y.L.&Ethics (Summer, 2008) p. 290

<sup>13</sup> Gourounti, Kleanthi; Glentis, Stavros: Patient attitude to Preimplantation Genetic Diagnosis and counseling issues. 6(3) Health Science Journal (July-September, 2012) p. 408

<sup>14</sup> See supra note 2 p. 1312

In Germany, until 2011 a very strict regulation was in use, which put practically a complete ban on the application of the technology. The experience nevertheless proved that it is not possible to 'put the genie back into the bottle', and a discrepancy existed between the legal framework and the real practice of PGD in Germany. Finally a gynaecologist, who had applied PGD with three couples, reported his actions to the courts of justice for the purpose of finding out the regulation applied.

In July 2010, the Federal Court of Justice found him not guilty in its ruling.<sup>15</sup> After the ruling of the Federal Court in Germany, a new regulation was approved in 2011 July, which according to the law allows for a restricted use of PGD ('begrenzte Zulassung der Präimplantationsdiagnostik').

The framework provided in the new German legislation is in many aspects, as already noted, somewhat similar to the one that exists in the UK. Still, many supporters of the legislation argue that this regulation provides for a conservative approach, according to which PGD will normally be prohibited and only in certain exceptional cases allowed – which will also provide for setting limits in applying constantly novel treatment procedures in relation to PGD.<sup>16</sup>

In this paper I will first give an introduction to the potential bioethical concerns and principles at stake. These can be categorized as 'human rights arguments in relation to reproductive autonomy', 'ethical concerns I - risks to offspring' and 'ethical concerns II - risks to society'. After this I will

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<sup>15</sup> 'Germany allows for controversial PID' <http://www.scienceguide.nl/201107/germany-allows-for-controversial-pid.aspx> (last visited: 25.03.2012)

<sup>16</sup> Preimplantation Genetic Diagnosis: Opinion. Deutscher German Ethics council (8th March, 2012) p. 108-116 Available at: [http://www.ethikrat.org/dateien/pdf/Stellungnahme\\_Genetische-Diagnostik.pdf](http://www.ethikrat.org/dateien/pdf/Stellungnahme_Genetische-Diagnostik.pdf) (last visited: 29.11.2012) AND the HFEA was able to change the interpretation of the HFE Act and introduce novel treatment methods by a single press release, see further 'HFEA to allow tissue typing in conjunction with pre-implantation genetic diagnosis' on 13th December 2001 Available at: <http://www.hfea.gov.uk/961.html> (last visited: 10.12.2012)

present a functional comparison between the two regulations according to some of the most important aspects. These are: who is making the decision about PGD's application and how can it be challenged, ethical debates in Germany and in the UK in relation to PGD and legal constraints in PGD's application.

My research will suggest that similar legislation frameworks will potentially lead to different practices in different countries. One of the potential explanations to this discrepancy is that the practice will much depend not only on the given regulatory framework, but also on other aspects that influence the specific understanding and interpretation of the legislation's text. This conclusion, according to my presumption, follows from the different legal constraints and the countries' different approach to ethical concerns.

At the end of the paper I will evaluate the two regulations based on their potential to eliminate certain ethical risks or protection certain human rights mentioned earlier in the research. The hypothesis is based on the presumption that since these two models differ in several, other than only regulatory aspects, they will be able to protect different approaches, such as the protection of the couples' human rights in relation to reproductive autonomy or ethical concerns in relation to the status of the embryo and the risks to the society.

There exist a limited number of articles<sup>17</sup> which do a comparison between European regulating models of PGD but they are able to give only a limited answer to such questions as for example what is the framework for PGD's decision-making procedure and to what extent the regulatory

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<sup>17</sup> Krones, Tanja; Richter, Gerd: Preimplantation Genetic Diagnosis (PGD): European Perspectives and the German Situation. 29(5) Journal of Medicine and Philosophy (2004) AND Ziegler, Uta: Präimplantationsdiagnostik in England und Deutschland. Campus Verlag, 2004

framework is based on ethical considerations and following, how clear they are.<sup>18</sup> These answers could be key indicators to determine how consistently the regulation could be maintained in the long run and which category of risks the regulation is more capable of eliminating.

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<sup>18</sup> See for example: Asscher, Eva C. A.: The regulation of preimplantation genetic diagnosis (PGD) in the Netherlands and the UK: A comparative study of the regulatory frameworks and outcomes for PGD. 3 Clinical Ethics about the aspect of policy-making of the Authorities in the Netherlands and UK (2008) AND Aarden, Erik; Vos, Rein; Horstman, Klasien: Providing Preimplantation Genetic Diagnosis in the United Kingdom, the Netherlands and Germany: a Comparative In-depth Analysis of Health-care access, about the access to PGD in the three countries. 24(7) Human Reproduction (July, 2009) p. 1542-1547

## CHAPTER 2: HUMAN RIGHTS ARGUMENTS AND ETHICAL CONCERNS: FOR OR AGAINST PGD

One aspect to evaluate the technique of PGD is to concentrate on the benefits it is able to create. These are relatively obvious: firstly it helps to expand the scope of reproductive autonomy; secondly it plays a role in ‘eliminating’ and detecting early genetic diseases.<sup>19</sup> However, therapeutic applications of PGD is only one aspect of the technology, and non-therapeutic applications of PGD (to some extent therapeutic applications also) continue to create controversies. In this Chapter I will first give an introduction to the different applications of PGD and in the second part, reflect on ethical concerns and human rights benefits that potentially arise from them.

### 2.1 Applications of PGD

#### 2.1.1 *Therapeutic*

The original idea behind PGD was to develop a technique for couples ‘who are at increased risk of having a child with a genetic disorder’, which enables them to be free from the ‘burden of prenatal diagnosis (PND) and the possible subsequent termination of a pregnancy’.<sup>20</sup>

Following fertilization, the eggs ‘develop in an incubator’ for two to three days until the point when they ‘consist of about 6-10 cells’.<sup>21</sup> The advantage of this stage, stressed in Norton’s article, is that these cells are still ‘pluripotent’, which means that they have the potential to become any cell that builds the human body, and the procedure does not impair the cells prospective to become a normal

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<sup>19</sup> Steinbock, Bonnie; Arras, John D.; London, Alex John: *Ethical issues in Modern Medicine*. The McGraw-Hill Companies, 2003 p. 516

<sup>20</sup> Iwarsson, E.; Malmgren, H., Blennow, E.: *Preimplantation genetic diagnosis: Twenty years of practice*. 16 Seminars in Fetal & Neonatal Medicine (2011) p. 74-80

<sup>21</sup> Botkin, Jeffrey R: *Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis*. In: Bonnie, Steinbock: *Legal and Ethical Issues in Human Reproduction*. Ashgate Publishing, Burlington, 2002 p. 335

baby.<sup>22</sup> At this point, one or two cells are first removed from the embryo and after that are tested ‘for the specific genetic condition for which the embryo is considered to be at increased risk’. This procedure enables to identify the embryos from which they were removed as ‘affected’ or ‘unaffected’.<sup>23</sup> After the test, couples can choose ‘to place in the woman’s womb those embryos that are unaffected’, as predicated in the test. Those embryos that are identified with ‘genetic abnormality’ are either discarded or frozen. If more embryos were created than needed, the rest of normal embryos may be frozen for the purpose of potential transfer, donation or research.<sup>24</sup>

### ***2.1.2 Non-therapeutic***

During the last twenty years, PGD has gone through a significant development. Currently, together with the development of genetic science, there is a possibility to select a wide variety of embryo’s traits with PGS, for example its sex. This in summary means that there is possibility even today, but potentially in the future more increasingly, that embryos will not be tested only for a specific mutation, but for all potential qualities. This could lead to the possibility for the parents to ‘create children’ according their wishes and several other ethical concerns presented below.

### ***Designer Babies***

The often-quoted term of ‘designer babies’ is closely related to the technique of PGS. One of the accusations that are usually raised in this aspect is the possibility with PGS to choose an embryo designed simply to meet the desires of the parents. It is feared that choosing embryos based on other

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<sup>22</sup> See supra note 1 p. 1590

<sup>23</sup> Zhuang, G.-L.; Zhang, D.: Preimplantation genetic diagnosis. 82 *International Journal of Gynecology and Obstetrics* (2003) p. 419–423

<sup>24</sup> Ehrich, Kathryn; Williams, Clare; Farsides, Bobbie: Fresh or frozen? Classifying ‘spare’ embryos for donation to human embryonic stem cell research. 71 *Social Science & Medicine* (2010) p. 2204-2211

than medical indications (intelligence, athletic build up), could potentially lead to the ‘commodification’ of future offsprings.

### ***Late-onset disease***

There are recently examples of using PGD to diagnose late-onset diseases such as breast and ovarian cancer.<sup>25</sup> The debate around this application is deeply controversial, since affected individuals stay healthy until the onset of the disease, which usually develops in the fourth decade of life. It could be argued that this application is actually a therapeutic form of PGD, however it highlights the difficulty of defining the scope of the term ‘serious genetically inheritable disease’.

### ***Savior Sibling***<sup>26</sup>

The case of Adam Nash took PGD into a new dimension and also made his case known by the wide public. This boy was born in August 2000 after having been selected by PGD using tissue typing in order that he could become a donor for his sister, who suffered from leukemia.<sup>27</sup> In his case, no genetic risk existed that would threaten the new baby, and the PGD was carried out solely for the purpose of tissue matching and for choosing a suitable donor for the sister. Although there are clear arguments for tissue typing, including the possibility to save a sibling; Adam Nash’s born was surrounded with great controversy.<sup>28</sup> Issues such as consent and the protection of children's autonomy were raised in the discussions around.

<sup>25</sup> Noble, Ray; Bahadur, Gula; Iqbal, Mohammad; Sanyal, Arnab: Pandora's box: ethics of PGD for inherited risk of late-onset disorders. 17(3) [Reproductive BioMedicine Online](#) (2008) p.55-60

<sup>26</sup> Dickens, B.M.: Preimplantation genetic diagnosis and savior siblings. 88 *International Journal of Gynecology and Obstetrics* (2005) p. 91-96

<sup>27</sup> Pennings, Guido: Saviour siblings: using preimplantation genetic diagnosis for tissue typing. 1266 *International Congress Series* (2004) p. 311–317

<sup>28</sup> Boyle, Robert J; Savulescu, Julian: Ethics of using preimplantation genetic diagnosis to select a stem cell donor for an existing person. 24 *BMJ* (November, 2001) p. 582–586

## ***Sex Selection***

The ability to identify the sex of embryos is another application of PGD that fuels extensive debate and controversy. According to the principle of ‘family balancing’ the wish for a child of another sex, when there is one child or more of one sex in a family, has been accommodated sympathetically in the US but still remain controversial, and many question if this is a legitimate use of PGD.

## **2.2 Human Rights Arguments and Ethical Concerns in Relation to PGD**

One way of approaching PGD’s application is emphasizing the necessity to fulfill reproductive autonomy and to protect women’s right to physical integrity. One would think that even in the human rights discourse, the principles of non-discrimination or equality could function as facilitators to deny PGD’s novel treatment methods. However, as it will be proven, as a result of the complicated issues around the status of the embryo and the embryo’s right to life, human rights discourse in favor of the embryo lacks enough clarity and foundation.

As a result, in opposition of the human rights discourse and arguments in relation to reproductive autonomy, only ethical concerns can be listed – the principles of non-discrimination and equality are also only present in the form of ‘ethical principles’ in stead of real human rights attached to the embryo. Nevertheless, there are fewer controversies around PGD’s therapeutic applications.

Most of the concerns arise with the potential misuse of the technology, especially for discriminatory purposes. One of the discriminatory concerns is that there is a potential that parents will choose characteristics for their children that should be irrelevant in a free and democratic society. Sex selection or the possibility to ‘create super intelligent designer babies’ are evident examples for this

– even if the widespread application of this second category will potentially remain for long a favored topic for science-fiction movies.

In the followings I will introduce some of the most important human rights arguments and ethical concerns in three sub-groups, these are: human rights discourse in relation to reproductive autonomy, ethical concerns in relation to the embryo and ethical concerns in relation to the society.

### ***2.2.1 Human Rights Arguments in Relation to Reproductive Autonomy***

With some exceptional questions around reproductive autonomy (for example the use of contraception, abortion or techniques of assisted reproduction) the idea of ‘reproductive autonomy’ is widely accepted in the world. The basic concept of reproductive autonomy is based on the presumption that it should be under the person’s control to decide whether or not to reproduce. The issue in relation to the connection between PGD and reproductive autonomy is to decide whether the scope of reproductive autonomy includes PGD and more specifically what methods of PGD are (or will necessary be in the future) covered under the protection of reproductive autonomy.

The argument for including control over the future offspring’s characteristic is that in some people’s cases, their decision to procreate would depend on their possibility to have a healthy child.<sup>29</sup>

Glover’s logical analogous example in relation to this argument questions its legitimacy. His argument is reflected in the question whether banning cars from the part of the city where the church is located violates the freedom of religion of the inhabitants.<sup>30</sup> He says no, however one

<sup>29</sup> Krones, Tanja.: Praenataldiagnostik und Praeimplantationsdiagnostik aus der Sicht von Paaren mit einem bekannten genetischen Risiko. In: Graumann, S.; Grüber, K.: Biomedizin im Kontext. Beiträge aus dem Institut Mensch, Ethik und Wissenschaft. Lit Verlag, 2006 p. 201-221

<sup>30</sup> Glover, Jonathan: Choosing Children. Genes, Disability and Design. Oxford University Press, 2006 p. 39

could argue that the inconvenience in this case of going to the church on foot does not equate with the difficulty of having a child with a serious genetic disorder as the only chance to procreate.

Many experts similarly emphasize that what is at stake in case of PGD's application is a slightly different problem than a simple decision whether or not to procreate: 'there is the question about whether one should have control over the kind of children one has'.<sup>31</sup> The basic concern about the possibility of extending parents' choice to their future offspring's genetic characteristic is a Kantian one.

Kant proposed the 'Formula of the End in Itself'. According to him, there is a need to '[a]ct in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end and never simply as a means.'<sup>32</sup> It is feared that by allowing parents to determine their children's characteristics, children will be too much of an object to fulfill their parents' aims, which contradicts general conceptions about human dignity.<sup>33</sup>

At the same time parents' legitimate aim to have a child without a disability seems likely to be compatible with the Kantian call – since parents reasonably worry for the interests of their children. However, one could argue against this statement by questioning this altruistic form of parenthood<sup>34</sup>. Nevertheless it seems that choosing an embryo free of disability by couples living with 'serious

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<sup>31</sup> Ibid.

<sup>32</sup> Guyer, Paul: Kant, Immanuel. In E. Craig (Ed.), Routledge Encyclopedia of Philosophy. London: Routledge, 2004 Available at <http://www.rep.routledge.com/article/DB047SECT9> (last visited: 08.03.2012)

<sup>33</sup> Green lists a couple of examples in what relation there could be major concerns with 'expanded programs of prenatal choice' See further: Green, Ronald: Babies by Design: The Ethics of Genetic Choice. Yale University Press, 2007 p. 109-130

<sup>34</sup> Rabin, A. I.; Greene, Robert J.: Assessing motivation for parenthood. 69(1) Journal of Psychology: Interdisciplinary and Applied p. 39-46.

genetically inheritable diseases’ and whose decision on procreation will depend on this question, is a very legitimate reason why to allow PGD.

At the same time it must be emphasized that choosing simply an able-minded and healthy child is only one aspect of PGD’s available treatment methods.<sup>35</sup> Non-therapeutic applications of PGD raise slightly different concerns. John A. Robertson for example, a US lawyer, who made a detailed analysis about parents’ rights to select their future child’s characteristic argues that procreative rights are limited in one important aspect. He notes that procreative autonomy only protects ‘actions designed to enable a couple to have a normal, healthy offspring’.<sup>36</sup> He says that claims to produce a ‘supernormal’ or ‘supranormal’ child are illegitimate.

The question, nevertheless, remains difficult to answer how to define ‘serious genetically inheritable diseases’ or a ‘healthy offspring’ and whether parents’ perception about the seriousness of the disability and what services are available in the society should be taken into account when making decision about these questions.

A conclusion could be, however, drawn according to which our decision in deciding about the scope of reproductive autonomy in relation to PGD will much depend on, in the words of Sheila McLean ‘the ethical perspective from which we address the issue’. When one regulation follows a ‘rigid

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<sup>35</sup> The other controversy is that there is also the possibility to use this reproductive technology not to have a healthy child but one with a disability. There are people who have used PGD in order to have a child with the same disability as they have. It happened for example in 2002 that a deaf lesbian couple in order to have a deaf baby asked a friend to donate sperm who also had hereditary deafness See further: Savulescu, Julian: Deaf lesbians, ‘designer disability’ and the future of medicine. 5 BMJ. (October, 2002) p. 771–773.

<sup>36</sup> Robertson, J.: *Children of Choice; Freedom and the New Reproductive Technologies*. Princeton University Press, 1994 p. 166

autonomy based argument' (which I label as 'human rights' approach), then probably a restriction is not acceptable. From a rather 'communitarian perspective', a slightly different conclusion follows, which does not necessarily grant individual choice superiority. From this standpoint also the 'general welfare of the community' needs to be taken into account.<sup>37</sup> During the research it will be interesting to analyze which country approaches this question from which aspect.

### ***2.2.2 Ethical concerns I: Embryo protection***

What possible advantages PGD for the future offspring could have is clear. Even most ethicists agree with the use of PGD for therapeutic reasons. PGD, following this argumentation, could prevent significant emotional, physical and financial burdens for the family as well as for the future offspring, which could happen when a child with a serious or incurable hereditary genetic disease is born. However, as already noted, how seriously the family and the person understand a potential disability varies widely.

It should be added that PGD's application not only involves benefits but also risks to the potential embryo and future offspring. Williams lists three of these. First, since the biopsy is a difficult procedure and is performed at an early stage of the embryo, there is a danger that it could seriously 'impair the development of the embryo'. Secondly, the practice of multiple implantations could negatively affect the future child, resulting in stillbirth or low birth weight.<sup>38</sup>

A third risk of psychological nature could also be listed. As already noted, there is no guarantee for the result of PGD. Many scientists agree that, 'the possibility of misdiagnosis obviously has

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<sup>37</sup> McLean, Sheila: *Autonomy, Consent and the Law*. Routledge, 2010 p. 22

<sup>38</sup> See supra note 2 p. 1308

significant medical, psychological and economic implications'.<sup>39</sup> The impacts of the parents' potential disappointment could have severe impact on the future offspring. The same psychological burden is present for healthy children, who were born after such treatments, because potentially they need to live up to higher expectations by the parents.

### ***2.2.3 Ethical concerns II: Risks to society***

One of the main underlying issues in the conflict between PGD and social welfare is the presumption that what is good for the individual will not necessarily be beneficial for the society - there is always the risk that technologies will have unforeseen side effects.

From the list of ethical concerns it is easy to realize that most of the objections originate from the fear that these new genetic technologies will potentially be misused. Apart from the misuse, there is a concern from the communitarian perspective as well, according to which 'new genetic technologies may be an inefficient use of scarce societal resources'.<sup>40</sup> Social justice would require that benefits and burdens be distributed fairly. However, the use of PGD is expensive in all countries and it is highly unlikely that it would become easily accessible to everyone in the future. It might not be justified to devote resources to a technology that will grant benefits only to a few, while other projects with the possibility of delivering more general welfare become victims at the expense of it.<sup>41</sup>

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<sup>39</sup> Baruch, Susannah et al.: Genetic Testing of Embryos: Practices and Perspectives of U.S. IVF Clinics. 5 Genetics&Pub.Policy Ctr. (2006), available at: <http://www.dnapolicy.org/resources/PGDSurveyReportFertilityandSterilitySeptember2006withcoverpages.pdf> p. 4

<sup>40</sup> See supra note 19 p. 516

<sup>41</sup> Ibid p. 516

Although the therapeutic application of PGD is the least objectionable one, the question legitimately arises ‘what attitudes towards disabled people do these programs express’?<sup>42</sup> It is feared that even PGD used to avoid a genetic disease could increase negative attitudes towards the disabled. There are two main concerns in relation to this. Firstly, that the decrease in the number of people with genetic diseases may also lead to a decrease in the level of attention and resources paid to the remaining disabled people. PGD in this understanding might do harm by encumbering the maintenance and development of social structures and services that have the purpose of supporting those with disorders, and maybe also by boosting negative attitudes towards them.<sup>43</sup>

Secondly, it could also be argued that allowing PGD for therapeutic purposes would lead to difficulties of sustaining the egalitarian structure of the society, while at the same time suggesting that people with disorders need to be ‘eradicated’ from the gene pool. The underlying fear in this case is that if screening is taken for granted, then selection of the conditions, which are the basis of screening, might suggest that these conditions should be avoided and therefore, more problematically, it might suggest that a person with one of these conditions is not of equal social value.<sup>44</sup>

In summary, these opinions are labeled as ‘slippery slope arguments’ claiming that PGD might lead to a wide range of potential misuses based on the possibility of selection for intelligence and beauty.

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<sup>42</sup> See supra note 30 p. 4

<sup>43</sup> Making Babies: reproduction decisions and genetic technologies. Human Genetics Commission, Great Britain, 2006

<sup>44</sup> Ibid.

Some people go further and even argue that modern practices of PGD and other genetic diagnostic and screening services are a continuation of the previous century's eugenic practices.<sup>45</sup> They claim that current applications of prenatal screening programs have a similar aim, and this is to eliminate people with genetic deficiencies and diseases.<sup>46</sup> Others argue that eugenics is present in rather a 'passive or subtle' form in case of PGD through a 'more general social pressure' placed on women 'to have prenatal screening and diagnosis and to seek to terminate a pregnancy if a fetal abnormality is identified'.<sup>47</sup>

It seems likely that these arguments are very well grounded, however, they still do not offer a solid basis or springboard on which PGD's application can be refused. First of all, because it is unclear whether selecting between embryos equates with selecting between living humans. Secondly, it can be possibly concluded that PGD suggests that a healthy embryo is more favorable than one with a genetic disease. However, this conclusion is not specific to only the technology of PGD, there are many more social services that suggest the same conclusion.

Genetic diversity is another argument that is often raised against the application of PGD. Genes, as already noted above, function very complexly. Humans, as discussed in Williams' article, carry two copies of the gene: one from the mother and one from the father. It might happen that an individual possesses 'one normal dominant' and 'one mutant recessive allele'. In this case the individual,

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<sup>45</sup> See for example: King, D.S.: Preimplantation genetic diagnosis and the 'new' eugenics. 25(2) J Med Ethics. (April, 1999) p.176–182.

<sup>46</sup> David Galton: Eugenics. The future of Human Life in the 21st Century. Abacus, London. 2002. p. 105-117

<sup>47</sup> Krahn, T; Wong, SI: Preimplantation Genetic Diagnosis and Reproductive Autonomy. 19(2) [Reproductive BioMedicine Online](#) (2009) p. 34-42

however will potentially pass on the mutant allele to his or her offspring, will not suffer from the symptoms of the disease.<sup>48</sup>

Similarly, Norton argues very clearly for the complex nature of DNA, and uses the arguments of Darwin's theory of natural selection, according to which some of the inheritable DNA mutations have both positive and negative effects, which combination ensures the given individual's best chances of survival. Logically, beside their negative effects, 'mutant genes' bring also benefits. A good example is the 'sickle cell anemia' gene, in which case carriers of the disease will not exhibit symptoms, but at the same time have resistance against malaria. Another example is that women, who are carriers of this gene, are twenty percent more fertile on average. This means that it is not enough to realize the drawbacks of the given disease, they need to be analysed together with the potential benefits of the disease 'in the context of specific environmental condition'.<sup>49</sup>

I find it likely that the most persuasive counter argument against fears around the possibility of creating a 'designer baby' or a 'supra normal baby' is that the end effect of the genes is not 100 per cent predictable. Green legitimately points out that genes are extremely complex in nature; he compares them to words and languages, which can be 'mixed and matched to produce different meanings'.<sup>50</sup> His main argument is that 'the particular sequence of DNA that an organism possesses (genotype) does not determine what bodily or behavioral form (phenotype) the organism will finally display'.<sup>51</sup> A good example for this is the susceptibility to develop serious forms of depression.

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<sup>48</sup> See supra note 2

<sup>49</sup> See supra note 1 p. 1585

<sup>50</sup> See supra note 33 p. 86

<sup>51</sup> Ibid. p. 87

An example for the above noted argument is based on a research conducted by the King's College in London. They found that it is true that there are certain sort of genes that are responsible for the development of depression, however, this research also showed that the presence of this gene had a significant effect on individuals only if they had gone through some sort of emotional trauma.<sup>52</sup>

What this study highlights is that genes and environment work together and genes will not necessarily lead to depression, violence or other desired or undesired characteristics, without environmental factors. This argument seems to highlight also the weaknesses of communitarian arguments fearing that the technology would lead to a new form of discrimination – based on selection procedures and genetic composition.

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<sup>52</sup> Ibid. p. 88

## CHAPTER 3: PGD'S LEGAL FRAMEWORK IN EUROPE

In the next chapter I will first give a short introduction to the potential regulation of PGD at the European level and in the neighboring countries of the UK and Germany, and after that give a more detailed introduction to the regulation of PGD in the paper's two examples (UK and Germany). Examples of Germany's and the UK's neighboring countries' regulation is a good illustration for the regulations' diversity and the difficulty of finding a consensus at the European level about the general licensing of PGD. It can be argued that this difficulty originates from the fact that PGD's regulation is strongly connected to constitutional questions and to the status of the embryo in different countries' legislation. However, today's possibility of health tourism questions the efficiency of strict national regulations.

### 3.1 European Perspectives of PGD's Regulation

What are relevant at the European level are the conventions adopted by the Council of Europe and other sources of the European law. What needs to be listed in the first place is the Council of Europe's Convention on Human Rights and Biomedicine.<sup>53</sup> The legally binding Convention has been already signed by 34 out of the 47 Member States.<sup>54</sup>

Its fourth Chapter' title is called 'Human Genome' and contains several norms and provisions, which are extremely relevant for research and diagnostic of embryos. Article 12, for example says:

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<sup>53</sup> Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ETS.No. 164Oviedo, 4.IV.1997 Available at: <http://conventions.coe.int/Treaty/EN/Reports/Html/164.htm>

<sup>54</sup> both Germany and UK signed the Convention

*Tests which [...] detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling.*

It is, however, not clear whether this article covers only already born humans or it is applicable also to prenatal development stage. In the Biomedicine Convention's explanatory notes it is made clear<sup>55</sup>:

*Art. 12 as such does not imply any limitation of the right to carry out diagnostic interventions at the embryonic stage to find out whether an embryo carries hereditary traits that will lead to serious disease in the future child.*

When it comes to another application, sex selection, the Convention says in its Article 14:

*The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing the future child's sex, except where serious hereditary sex-related disease is to be avoided.*

At this place, surprisingly to many, the European Convention of Human Rights needs to be mentioned. Even though this Convention is less specific in terms of bioethical norms, a very important development happened on 28th August 2012 in relation to PGD and its European standards of application.

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<sup>55</sup> See supra note 53 para. 83

On that day, the European Court of Human Rights issued its first judgment concerning access to (PGD). In the case of Rosetta Costa and Walter Pavan v. Italy<sup>56</sup> an Italian couple, who were both carriers of cystic fibrosis, challenged the Italian regulation, according to which PGD was forbidden.<sup>57</sup> The couple had already aborted the birth of a child who would suffer from cystic fibrosis. They accordingly, asserted in front of the ECHR that the prohibition of PGD by the Italian Law 40/2004 ‘infringes their private and family life’.<sup>58</sup>

Even though, in its judgment the European Court agreed with the ‘strict interpretation of the Italian law on human assisted reproduction’, the Court reiterated Article 8 of the Convention (right to privacy), and it underlined that Article 8 entails ‘a broad concept which encompasses also the right to respect for the decisions both to have and not to have a child’, ‘the right to respect for the decision to become genetic parents’.<sup>59</sup> The Court also referred to S.H. v. Austria in which case it has been concluded that the *‘right of a couple to conceive a child and to make use of artificial reproductive technologies for that purpose is also protected by article 8 as such a choice is an expression of private and family life’*.<sup>60</sup>

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<sup>56</sup> Rosetta Costa and Walter Pavan v. Italy ECHR Ap. No.: 54270/10 (20<sup>th</sup> September 2010)

<sup>57</sup> According to this Italian law, married couples ‘may have access to assisted reproductive technologies exclusively in order to bypass infertility or sterility’ Penasa, Simone: European Court of Human Rights Declared disproportionate Italian ban on Preimplantation Genetic Diagnosis. Available at: <http://www.bioethicsinternational.org/blog/2012/09/15/european-court-of-human-rights-declared-incoherent-and-disproportionate-italian-ban-of-preimplantation-genetic-diagnosis-pdg/> (last visited: 07.01.2012)

<sup>58</sup> Puppink, Grégor: ‘European Court of Human Rights Hears Italian Bioethics Case’ available at: <http://www.lifenews.com/2011/09/14/european-court-of-human-rights-hears-italian-bioethics-case/> (last visited: 07.01.2012)

<sup>59</sup> See supra note 57 See further Evans v. the United Kingdom ECHR Application no. 6339/05 (10th April, 2007) and A, B and C v. Ireland ECHR Application no. 25579/05 (16th December, 2010) and Dickson v. the United Kingdom ECHR Application no. 44362/04 (4th December 2007)

<sup>60</sup> Ibid. S.H. v. Austria EHR Application no. 57813/00 (3rd November 2011)

Following, in the conclusion the Court extended the content of protection provided by article 8 of the convention ‘to include also the desire to procreate a child that not suffers from genetically transmissible diseases’.<sup>61</sup>

In the European Union it is more difficult to find relevant norms, which deal with the questions of PGD. However, the explicit ban on eugenics (Art.3 para.2) or the commercialization of the human body and its parts (Art.3 para.2) or articles about the protection of human dignity (Art.1), right to life (Art.2 para.1), the right to respect physical and mental integrity (Art.3 para.1) and non-discrimination (Art.21 para.1) of the Charter of Fundamental Rights of the European Union<sup>62</sup> could be mentioned as examples of norm-setting standards in relation to PGD. There are also other European Union directives that deal with in-vitro diagnostic<sup>63</sup>, the legal protection of biotechnological inventions<sup>64</sup> and setting standards for ‘the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells’<sup>65</sup>.

These norms and Conventions show that there is a will in Europe, especially by the Council of Europe, to establish a clear norm system concerning the newest technologies in biomedicine.

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<sup>61</sup> Ibid.

<sup>62</sup> Charter of Fundamental Rights of the European Union, ABI. EG Nr. C 346/1 18 December 2000 Available at: [http://www.europarl.europa.eu/charter/pdf/text\\_en.pdf](http://www.europarl.europa.eu/charter/pdf/text_en.pdf) (last visited:14.03.2012)

<sup>63</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0079:en:NOT> (last visited:14.03.2013)

<sup>64</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF> (last visted:14.03.2012)

<sup>65</sup> 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 Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF> (last visited:14.03.2012)

However, the Biomedicine Convention only in Iceland and Denmark has the same status as national laws.<sup>66</sup> The application of the Convention's norms will depend in most of the signatory countries on the adequate national legal practice.

In the neighboring countries of Germany and the UK, the regulation of PGD is very different.<sup>67</sup> In Switzerland, for example, according to the Law on Medical Reproduction<sup>68</sup> (Fortpflanzungsmedizingesetz (FMedG) Art. 33), a selection of gametes is allowed if there is a risk that a 'serious incurable disease is transmitted to the offspring'. However, PGD of embryos is technically prohibited. In-vitro fertilization of embryos is also strictly regulated in Switzerland, and it is allowed for infertile couples and only if other treatments are hopeless.

The Irish regulation is specific in the sense that there is no specific national law or directive that would deal with PGD, but the norms in relation to it come from the Constitution<sup>69</sup> itself. There is also no definition of the term 'embryo' in the Irish constitution, but Art. 40.3.3 clearly says: 'The State acknowledges the right to life of the unborn and [...] guarantees in its laws to respect [...] by its laws to defend and vindicate that right'.

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<sup>66</sup> Latsiou, Charikleia Z.: Präimplantationsdiagnostik. Rechtsvergleichung und bioethische Fragestellung. Max-Planck-Gesellschaft zur Förderung der Wissenschaft e.V., 2008 p. 104

<sup>67</sup> For an overview see: Max Planck Institute's excel file about the European regulation of reproductive medicine Available at: [http://www.mpicc.de/meddb/show\\_all.php](http://www.mpicc.de/meddb/show_all.php) (last visited: 13.03.2012)

<sup>68</sup> Fortpflanzungsmedizingesetz (FMedG) in der aktuellen Fassung (18. Dez. 1998) Available at: <http://www.human-life.ch/news/fmf/fmedg.htm> (last visited: 13.03.2012)

<sup>69</sup> Constitution of Ireland enacted by the People 1st July, 1937 in operation as from 29th December, 1937 Available at: <http://www.constitution.ie/reports/ConstitutionofIreland.pdf> (last visited: 14.03.2012)

The only question remains whether the term ‘unborn’ refers only to in-vivo or also to in-vitro fertilized embryos.<sup>70</sup> Guiding principles of the Irish Council for Bioethics and the Medical Council help in the understanding of this article, but there are still no clear legal indications about the scope of the unborns’ rights. However, according to one of the Highest Irish Court decisions, Art. 40.3.3 is clear in the sense that they have the right ‘not to be destroyed’.<sup>71</sup>

To help in clearing these norms, the Irish Government in 2000 established the Commission on Assisted Human Reproduction and in 2005 it published its Recommendations. One of its recommendations is that ‘Pre-implantation genetic diagnosis (PGD) should be allowed, under regulation, to reduce the risk of serious genetic disorders’.<sup>72</sup>

In France the application of PGD has been regulated since 1994 by the bioethics law<sup>73</sup>, which was renewed in 2004<sup>74</sup>. PGD is allowed only to prevent the transfer of a serious, and at the time of diagnosis incurable genetic disease. PGD, according to the legislation is not allowed unless it has been asserted that the mutation is present in one of the parents’ genetic composition.<sup>75</sup> Furthermore,

<sup>70</sup> Honnefelder, Ludger; Lanzerath, Dirk: Präimplantationsdiagnostik, Embryoforschung, Klonen. Ethik in den Biowissenschaften – Sachstandsberichte des DRZE. Verlag Karl Alber, November 2007 p. 34

<sup>71</sup> Ibid. p. 35

<sup>72</sup> Report of the Commission on Assisted Human Reproduction, 2005 Available at: <http://www.dohc.ie/publications/pdf/cahr.pdf?direct=1> (last visited: 14.03.2013) Recommendation 40 p. XVII

<sup>73</sup> Loi n 94-654 du 29 juillet 1994 relative au don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal bioéthique Available at: <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000549618> (last visited: 13.03.2012)

<sup>74</sup> Loi n 2004-800 du 6 août 2004 relative à la bioéthique (1) Available at: <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441469> (last visited: 13.03.2012)

<sup>75</sup> ‘Rechtliche Aspekte’ available at: <http://www.drze.de/im-blickpunkt/pid/rechtliche-aspekte> (last visited: 13.03.2012)

PGD is allowed only in specially licensed clinics, and couples applying for the technique must live together for at least two years beforehand.<sup>76</sup>

In the Netherlands on 1st September 2002 took the Embryo Act<sup>77</sup> into effect. This law does not prohibit PGD. Sex selection is, however, explicitly prohibited. Since May 2008, Parliament discussed the possibility that embryos with an increased risk for hereditary cancer, for example, could be also sorted out before implantation.<sup>78</sup> Currently, however, there is no draft legislation about this issue.

In Belgium, PGD is not explicitly regulated by law.<sup>79</sup> It is, however implied in the definition of ‘treatment’ regulated by the law on research on embryos<sup>80</sup> (Loi relative á la recherché sur les embryons in vitro) in force since May 11, 2003. PGD can be carried out only in licensed centers; and only in cases when the required medical indication is present, and after the application of bioethical norms by the Bioethics Commission. A sex-selection of embryos is prohibited with the exception when it allows screening out embryos with sex-linked diseases.<sup>81</sup>

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<sup>76</sup> See supra note 5

<sup>77</sup> Lanzerath, Dirk: Präimplantationsdiagnostik – Zentrale Fakten und Argumente. 85 Analysen und Argumente (November, 2010) Konrad Adenauer Stiftung p. 7

<sup>78</sup> ‘Rechtliche Aspekte’ Available at: <http://www.drze.de/im-blickpunkt/pid/rechtliche-aspekte> (last visited: 13.03.2012)

<sup>79</sup> For a detailed summary about PGD in Belgium see: Grüber, Katrin: Präimplantationsdiagnostik - Praxis und rechtliche Regulierung in Belgien. Institut Mensch, Ethik und Wissenschaft, April, 2003 Available at: <http://www.imew.de/index.php?id=239#c1020> (last visited: 13.03.2012)

<sup>80</sup> Loi relative á la recherché sur les embryons in vitro 11 Mai 2003 Available at: <http://staatsbladclip.zita.be/moniteur/lois/2003/05/28/loi-2003022592.html> (last visited: 13.03.2012)

<sup>81</sup> See supra note 77

The Austrian Reproductive Medicine Act allows the investigation of viable cells, only insofar as required to achieve a pregnancy according to the current state of medical science and experience.<sup>82</sup>

The Austrian Bioethics Commission dealt in July 2004 along with other issues of reproductive medicine with the PGD.<sup>83</sup> Finally, 12 of the 19 members ‘voted for a limited approval’, while seven members spoke in favor of maintaining the current legal position.<sup>84</sup>

It seems that there are several possibilities to regulate PGD and even the European countries apply different approaches. However, it seems that certain common elements are present in many countries. These include for example the establishment of licensed centers and the definition of different criteria for PGD’s application. At the same time it needs to be emphasized that the aspect (bioethical or practical) the regulations put emphasis on vary widely.

### 3.2 PGD’s Legal Framework in the UK and in Germany

Until 2006 about 100 babies were born in the UK following PGD<sup>85</sup> but in 2009 alone there were 86 live births resulting in 100 babies after the application of PGD.<sup>86</sup> Interestingly until 2004 only about 1500 babies were born worldwide after performing PGD.<sup>87</sup> The UK is the first country where PGD was applied and where the first form of regulation started dating back to the 1990s, the Human

<sup>82</sup> Fortpflanzungsmedizingesetz (FMedG) BGBl.Nr. 275/1992 idF BGBl. I Nr. 98/2001 Available at: <http://homepage.univie.ac.at/elisabeth.holzleithner/Fortpflanzungsmedizingesetz.pdf> (last visited: 13.03.2012)

<sup>83</sup> Präimplantationsdiagnostik (PID) Bericht der Bioethikkommission beim Bundeskanzleramt Available at: <http://www.bka.gv.at/DocView.axd?CobId=6415> (last visited: 23.03.2012)

<sup>84</sup> See supra note 77 p. 6

<sup>85</sup> See supra note 43

<sup>86</sup> Latest UK pre-implantation genetic diagnosis (PGD) figures – 2009 Available at: <http://www.hfea.gov.uk/1271.html> (last visited 11.03.2011)

<sup>87</sup> Krones, Tanja; Richter, Gerd: Preimplantation Genetic Diagnosis (PGD): European Perspectives and the German situation. 29 (5) Journal of Medicine and Philosophy (2004) p. 624

Fertilisation and Embryology Act (HFE Act)<sup>88</sup> which means that the country has already more than twenty years experience of regulating PGD.<sup>89</sup>

The German Embryo Protection Law (*Embryonenschutzgesetz, or ESchG*)<sup>90</sup>, earlier did not specifically cover PGD and according to that law, firstly, the destruction of embryos was forbidden and secondly, according to Art.2 Para.1 of the ESchG ‘any use of embryos for purposes other than their conservation’, was punishable with imprisonment up to three years or a fine<sup>91</sup>.

The necessity to create a legal framework for PGD became pressing, as already noted, after a ruling of the German Federal Court of Justice, which set a precedent in 2010.<sup>92</sup> According to the ruling, the application of PGD by the gynecologist was not violating the ESchG, since his principle aim was with its application, even in case of a negative result, to establish pregnancy.<sup>93</sup>

Both countries felt that it was necessary to develop legislation in response to new embryo manipulation techniques outside of the woman’s body, and the recent regulatory model in the two countries follows the same logic. Firstly, both regulatory frameworks are based on ethical considerations – however there might be a difference in their clarity and transparency. Secondly, in

<sup>88</sup> Human Fertilisation and Embryology Act, UK 2008 Available at: [http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga\\_20080022\\_en.pdf](http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf)

<sup>89</sup> Iwarsson, E.; Malmgren, H.; Blennow, E.: Preimplantation genetic diagnosis: twenty years of practice. 16(2) *Semin Fetal Neonatal Med.* (April, 2011) p. 74-80.

<sup>90</sup> Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG) BGBl. I S. 2746 (13th Dezember 1990) as amended in BGBl. I S. 2228 (21st November 2011)

<sup>91</sup> ‘*jedwede Verwendung von Embryonen zu Zwecken, die nicht ihrer Erhaltung dienen, mit Freiheitsstrafe bis zu drei Jahren oder Geldstrafe bedroht*’

<sup>92</sup> ‘Germany allows for controversial PID’ Available at: <http://www.scienceguide.nl/201107/germany-allows-for-controversial-pid.aspx> (last visited: 11.03.2012)

<sup>93</sup> Decision of the German Federal High Court of Justice for violation of the ESchG 5 StR 386/09 6 July 2010 para. 30

both countries the law delegates a significant discretionary power in relation to the technology to a central regulatory authority. Thirdly, PGD is allowed in both countries only in ‘exceptional cases’ and in ‘centrally licensed clinics’.

In the UK it is the Human Fertilization and Embryology Authority (HFE Authority) that is responsible for the licensing of the PGD and also for policy-making in relation to PGD.<sup>94</sup> The Human Fertilizations and Embryology Act 2008, the HFE Authority’s Code of Practice and ‘case law together with the interpretations of the law made for specific cases’ gives the legal framework within which PGD is licensed and conducted.<sup>95</sup>

In Germany the regulation is much newer and there are still many questions unclear.<sup>96</sup> This also means that there is a possibility that the new regulation will be further changed in order to help better its purpose. However, similarly to the UK, in Germany the new law says that the central regulatory authority will be responsible for overseeing both the clinics and licensing PGD. This central agency is called ‘Ethics Committee’ (Ethikkommission), according to the new legislation.

Nevertheless, it must be noted that there are already at this stage differences in the two regulations. In July 2011 the German MPs did not enact a completely new legislation dealing with fertilization and embryology but simply changed the old law about embryo protection (EschG). Secondly, there is a big difference in the decision making process in relation to PGD. While in the UK the HFE

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<sup>94</sup> Asscher, Eva C. A: The regulation of Preimplantation Genetic Diagnosis. 3(4) Clin. Ethics (December, 2008) p. 177

<sup>95</sup> Choices and Boundaries. Human Fertilisation and Embriology Authority, 2005 Available at: [http://www.hfea.gov.uk/docs/Choices\\_and\\_Boundaries.pdf](http://www.hfea.gov.uk/docs/Choices_and_Boundaries.pdf) (last visited: 09.01.2013)

<sup>96</sup> Hübner, Marlis; Pühler, Wiebke: Die neuen Regelungen zur Präimplantationsdiagnostik – wesentliche Fragen bleiben offen. 29(12) Medizinrecht (December, 2011)

Authority is the central agency in every aspect, and it has a great discretionary power also in policy-making, in Germany any regulation in relation to bioethical questions must first be referred to the National Ethics Council (a different one than noted in the amendments of ESchG).

### ***3.2.1 The definition of PGD in the regulation of the UK***

Interestingly there is no specific definition of PGD in the HFE Act. PGD is referred to indirectly '*as a practice designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose*'.<sup>97</sup> Before licensing PGD, the HFE Authority needs to be satisfied about the criterion that there is '*a significant risk that a person with that abnormality will have or develop a serious medical condition*'.<sup>98</sup> It follows that the HFE Authority has a wide discretionary power for the licensing of PGD, which was also clarified in the House of Lords rulings and precedent.<sup>99</sup>

### ***Conditions for genetic testing in the UK***

According to the 8th edition of the Code of Practice from 2009 on the use of PGD, it should be accessible to couples only, according to the statutory criteria, when firstly, there is a 'particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth'<sup>100</sup>, and secondly, when there is a significant risk that a 'person with abnormality will have or develop a serious physical or mental disability, a serious illness or any

<sup>97</sup> 'Choices and Boundaries' HFEA Consultation document Available at: <http://www.hfea.gov.uk/516.html> (last visited: 12.01.2013)

<sup>98</sup> HFEA 8th Code of Practice Available at: [http://www.hfea.gov.uk/docs/2011\\_OCT\\_9\\_PGS.pdf](http://www.hfea.gov.uk/docs/2011_OCT_9_PGS.pdf) (last visited 11.03.2012)

<sup>99</sup> R v HFEA, (ex p. Assisted Reproduction and Gynaecology Centre and H) [2002] Lloyd's Rep. Med 148, [2002] Fam Law 347 (CA)

<sup>100</sup> HFEA 8th Code of Practice Available at: [http://www.hfea.gov.uk/docs/2011\\_OCT\\_9\\_PGS.pdf](http://www.hfea.gov.uk/docs/2011_OCT_9_PGS.pdf) (last visited 11.03.2012)

other serious medical condition’<sup>101</sup>. There should be also a requirement of medical indication in all cases.<sup>102</sup>

The HFE Authority has further developed an Explanatory Note for Licence Committee for Pre-Implantation Diagnostic Testing, where it clarifies terms used as ‘particular risk’, ‘significant risk’ and ‘seriousness’.<sup>103</sup> In relation to ‘particular risk’, according to the explanatory note, it should be considered whether ‘the abnormality is heritable and if so, what the mode of inheritance is’.

In defining ‘significant risk’, the Licence Committee will take into account, according to the same explanatory note, the ‘penetrance of the condition. When assessing the seriousness of the disability or condition, according to the same note, the Committee will include into the consideration the following factors: 1) age of onset, 2) symptoms of the disease, 3) whether the condition is treatable, 4) what type of treatment is available for those conditions that can be treated, 5) effect of the condition on quality of life, 6) variability of symptoms

Apart from these principles, the Code of Practice also sets out two important aspects that should be taken into account when clinics make their decision. These are firstly the views of the people who are seeking treatment<sup>104</sup> and secondly the need for the use of PGD to be ‘consistent with (not necessarily the same as) current practice in the use of prenatal diagnosis’.<sup>105</sup>

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<sup>101</sup> Human Fertilisation and Embryology Act, 2008, UK Paragraph 1ZA of Schedule 2

<sup>102</sup> See supra note 77 p. 7

<sup>103</sup> Human Fertilisation and Embryology Authority Pre-Implantation Diagnostic Testing (‘PGD’) Explanatory Note for Licence Committee Available at: [http://www.hfea.gov.uk/docs/2010-10-28\\_Licence\\_Committee\\_PGD\\_explanatory\\_note.PDF](http://www.hfea.gov.uk/docs/2010-10-28_Licence_Committee_PGD_explanatory_note.PDF) (last visited: 09.01.2013)

<sup>104</sup> See supra note 98

<sup>105</sup> See supra note 97

The regulation in the UK is specific in the sense that it has indirectly produced a list of genetic conditions for which genetic testing is allowed. Not surprisingly, during the twenty years of regulations, this list has only become longer and longer. Until 2007 these permits were issued for the testing of about 70 genetic conditions, based on the three key ‘ethical principles’.<sup>106</sup> Interviews indicate that the procedure is different when the parents would like to obtain a license for an already ‘accepted disease’ (merely notifying) and for a new one.<sup>107</sup> Sex selection is strictly regulated, according to the eighth Code of Practice, it can only be allowed when there are medical indications that there is a danger of a ‘sex-related hereditary disease’.<sup>108</sup>

The HFE Authority, as one of its most debated decision, has also included the possibility of tissue typing within the available treatment methods. According to it:

*A licence ... cannot authorise the testing of an embryo, except for one or more of the following purposes:*

*(d) in a case where a person (‘the sibling’) who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling.*<sup>109</sup>

<sup>106</sup> See supra note 23 p. 1094–1105

<sup>107</sup> Aarden, Erik; Vos, Rein; Klasien, Horstman: Providing Preimplantation Genetic Diagnosis in the United Kingdom, the Netherlands and Germany: a Comparative In-depth Analysis of Health-care Access p. 1543

<sup>108</sup> See Supra note 98

<sup>109</sup> See supra note 88

Apart from ‘tissue typing’ newly applied tests for ‘lower penetrance conditions such as inherited breast cancer’ is a good example for the constantly widening scope of PDG in the UK.<sup>110</sup> However, many of the critics concern exactly the inconsistency and unpredictability of these new applications.<sup>111</sup>

### ***3.2.2 The definition of PGD in the German regulation***

After a long on-going political debate, the German Bundestag in July 2011 finally approved the amendments of the German Embryo Protection Law (ESchG) that now allows embryos to be screened for genetic diseases before implanting them to the mother’s womb. At the same time the Bundestag also imposed strict conditions. According to the new law in Germany, PGD is the genetic examination of the in-vitro fertilized embryo’s cells before their implantation in the uterus (‘genetische Untersuchung der Zellen eines Embryos in vitro vor seinem intrauterinen Transfer’). The law is strict, since it maintains the ban on this technique and allows only for exceptions where certain conditions are present.

### ***Conditions for Genetic testing in Germany***

Doctors are allowed to conduct the screening only in cases when there is a ‘strong likelihood that the parents will pass on a genetic disease to the child, or when the chances of miscarriage or stillbirth are genetically high’.<sup>112</sup>

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<sup>110</sup> See supra note 2

<sup>111</sup> Sheldon, Sally: Commentary: Saviour Siblings and the Discretionary Power of the HFEA. Quintavalle (on behalf of the Comment on Reproductive Ethics) v. Human Fertilisation and Embryology Agency. 13 Medical Law Review (Autumn, 2005) p. 403-411

<sup>112</sup> ‘bei den Eltern oder bei einem Elternteil eine genetische oder chromosomale Disposition diagnostiziert ist, die [...] mit hoher Wahrscheinlichkeit eine Schädigung des Embryos, Fötus oder Kindes zur Folge hat, die zur Tod-oder Fehlgeburt oder zum To dem ersten Lebensjahr führen kann’ ‘German Parliament Allows Some Genetic Screening’ <http://www.spiegel.de/international/germany/0,1518,773054,00.html>

The German MPs finally rejected the idea of defining a list of diseases in which cases PGD would be automatically allowed, because the German Parliament did not want to stigmatize certain diseases. At the same time, the possibility to use PGD to create ‘designer babies’ is according to Art. 3a para. 1 of the ESchG forbidden.

## **CHAPTER 4: FUNCTIONAL COMPARISON – THE REGULATION IN THE UK AND IN GERMANY – LEGAL AND ETHICAL ENVIRONMENT**

The original research question concerned the issue whether there are fundamental differences in the German and the UK system, which would set limits to applications of PGD's novel treatment methods in Germany. This was also one of the concerns raised by the German Ethics Council in its official Opinion about PGD published in 2011.<sup>113</sup> The Council itself investigates a couple of criteria and factors that might influence the development of PGD (scarce resources, restricting statutory provisions, the woman's freedom of choice and the state's obligation to protect the embryo, the question of liability, international development and socio-political aspects.)

In the following chapter the same question is going to be investigated in the light of the existing UK system that has gone through exactly the process of development in relation to PGD that the German regulators would like to avoid. The question in relation to it is whether fundamental differences compared to the UK's framework exist in the German system to guarantee this.

In this section the comparison between the two systems aims to highlight these differences and to answer the original research questions for which purpose two systems are going to be compared according to the following aspects: 1) who is making the decision about PGD's application and how can it be challenged, 2) ethical debates in relation to PGD in Germany and in the UK, 3) legal boundaries that influence PGD's application.

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<sup>113</sup> Preimplantation Genetic Diagnosis: Opinion. Deutscher German Ethics council (8th March, 2012) p. 108-116 Available at: [http://www.ethikrat.org/dateien/pdf/Stellungnahme\\_Genetische-Diagnostik.pdf](http://www.ethikrat.org/dateien/pdf/Stellungnahme_Genetische-Diagnostik.pdf) (last visited: 29.11.2012)

#### 4.1 Who is making the decision about PGD and how can it be challenged?

The HFE Authority is an independent public body, which was set up according to Section 5 of the HFE Act and began its operation on 1st August 1991. The Act has been amended several times. The last amendment happened in 2008, which had effects as well on the HFE Authority's operational work. As already noted, in the UK the HFE Authority is a centralized agency, which has three main functions that are set out in Section 8 of the Act: 1) 'to keep under review information about embryos [...and] treatment services', 2) 'to provide guidance or advice' and 3) 'to store data or to provide information'.<sup>114</sup>

Under the HFE Act and other legislations, the HFE Authority has also important regulatory functions, of which the following are of high relevance in relation to the development of PGD's and PGS's application: 1) to 'license and to monitor clinics carrying out in vitro fertilization (IVF) and donor insemination', 2) to 'license and to monitor establishments undertaking human embryo research' and 3) under Section 25 of the Act to 'produce and maintain a Code of Practice, providing guidelines to clinics and research establishments about the proper conduct of licensed activities'.<sup>115</sup>

A parallel institution in Germany is the so-called Ethics Committee set out in the new German Embryo Protection Law (ESchG) amended in 2011. According to the Regulation, PGD can be implemented only by the Ethics Committee licensed centers and only in cases when the Ethics Committee allows it. The function of this institution looks similar to the HFE Authority, however, at least one important difference becomes apparent at the first sight. While in the UK the HFE Authority is a single and centralized institution, in Germany there will not be one single Ethics

<sup>114</sup> Human Fertilisation and Embryology Act 2008 Section 8(a)

<sup>115</sup> 'Our role as a regulator' Human Fertilisation and Embryology Authority available at: <http://www.hfea.gov.uk/119.html> (last visited: 28.11.2012)

Committee established but there will be, according to the executive order published on 14th November 2012 in relation to the Law<sup>116</sup>, Ethics Committees in every German state and they will be only responsible for licensing PGD.

The regulation in Germany allowing PGD only in exceptional cases mentions in Paragraph 3(a(3)) a ‘Committee composed of members from interdisciplinary fields’, but the above-noted executive order further clarifies the short regulation and in relation to the Ethics Committee it says the followings: ‘The States are responsible for the setting up of Ethics Committees independent from the PGD-licensed centers’.<sup>117</sup> The executive order also explains in relation to the number of the Ethics Committees that there should not be just one central Committee, however, their number should be limited and several German states should be able to maintain one common Ethics Committee which is responsible for the licensing of several centres in these different states.<sup>118</sup>

Apart from this basic institutional difference, in the comparison of these parallel decision-making authorities in the UK and in Germany, I will take into account the following three aspects: 1) who are the members of the authorities and 2) what is their decision-making process or function and 3) how can their decisions be challenged.

#### ***4.1.1 Members of the authorities and their appointment***

In Germany the regulation for the composition of the Ethics Committees sets out the criterion that they should be composed of members from ‘interdisciplinary fields’, as already listed. The same

<sup>116</sup> Verordnung zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikverordnung – PIDV) Available at: [http://www.bmg.bund.de/fileadmin/dateien/Downloads/P/PID/PIDVE\\_121114.pdf](http://www.bmg.bund.de/fileadmin/dateien/Downloads/P/PID/PIDVE_121114.pdf) (last visited: 09.01.2013)

<sup>117</sup> Ibid. Article 4(1) p. 8

<sup>118</sup> Ibid. Article 4(1) p. 30

executive order further defines this aspect and maximizes the number of its members at eight. According to it, these members should come from the following fields: four persons from the area of medicine and four other persons from the area of law, ethics (possibly also from the area of theology), patient representation and a representative of a state level organization acting in the name of the chronically ill or the disabled. Two further important criteria are the followings: firstly they should dispose of the ‘required professional expertise’, and secondly they should not be at the same time related to the PGD-licensed centres. Even though Marlis Hübner and Wiebke Pühler list a number of unclear issues already in relation to these aspects, I will not cover these technical aspects in much depth.<sup>119</sup>

As opposed to Germany, where these regulations exist yet only on paper, in the UK the HFE Authority has been in existence since the early 1990s. Originally, in the UK there were proposals according to which the ‘half of the HFE Authority’s members should be composed of supporters and half of the opponents of embryo research’.<sup>120</sup> Finally Parliament refused this initiative claiming that the HFE Authority’s primary function is licensing and it should not be an institution where further discussion is provoked about the principles.<sup>121</sup>

Nevertheless, the HFE Authority has currently 22 members on its board coming from the fields of medicine, law, philosophy and religion and 85 members of staff. The members are appointed in

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<sup>119</sup> For further information see Hübner, Marlis; Pühler, Wiebke: Die neuen Regelungen zu Präimplantationsdiagnostik – wesentliche Fragen bleiben offen. 29(12) Medizinrecht (December, 2011) p. 789-796

<sup>120</sup> Zielger, Uta: Präimplantationsdiagnostik in England und Deutschland. Campus Verlag, Frankfurt am Main, 2004 p. 77

<sup>121</sup> Morgan, Derek; Lee, Robert G: Human Fertilisation and Embryology Act 1990: Abortion and Embryo Research, the New Law. London, 1991 p. 91

accordance with Schedule 1 to the Act by the Secretary of State for Health. According to the HFE Act, the majority of the board should be composed of ‘lay persons’.<sup>122</sup>

The board holds 7-9 meetings yearly and two of those should be, according to the regulation, held in public. The HFE Authority’s work is divided into the following Committees: Audit and Governance Committee, Compliance Committee, Remuneration Committee, Licence Committee, Research Licence Committee. There are two additional Panels (Register Research and Horizon Scanning). The procedures under which the HFE Authority’s Board and Committees function are set out in the standing orders.<sup>123</sup>

In addition to the above listed Committees there are two other institutions whose purpose is to give advice to the members of the board. These are: the Scientific and Clinical Advances Advisory Committee and the Ethics and Law Advisory Committee. And there is one more important institution, the Appeal Committee where applicants or license holders can challenge the Authority’s decision.

After this analysis it seems that, apart from some structural differences (the number of licensing authority and its responsibilities), their composition and main functions in relation to PGD’s application are not that much different. Further investigation will follow about their decision-making procedure and its review.

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<sup>122</sup> ‘About the Human Fertilisation and Embryology Authority’. Human Fertilisation and Embryology Authority, October, 2009. Available at: <http://www.hfea.gov.uk/Authority-members.html> p. 10

<sup>123</sup> ‘Standing orders’ Human Fertilisation and Embryology Authority September, 2012 Available at: <http://www.hfea.gov.uk/140.html> (last visited: 16.11.2012)

#### ***4.1.2 Decision-making procedure and its challenge***

In relation to authorizing PGD or PGS in specific individual cases, it needs to be made clear that the Authority in the UK is implementing this decision-making indirectly on a ‘condition-by-condition basis’<sup>124</sup>. The Authority itself is not making a decision on individual PGD or PGS applications themselves on a ‘case-by-case basis’. The Authority itself is only responsible for defining the frameworks for a decision made by licensed clinics (except for cases of tissue typing and screenings for late onset, low susceptibility diseases which are still decided on a case-by-case basis by the Authority).

Apart from these, the Authority can only influence decision-making on individual cases in the following four indirect ways: by defining the Code of Practice and giving guidance on PGD and PGS within the framework of the HFE Act, by deciding about clinic licensing and inspections, by ruling on a certain clinic’s applications for new methods and by deciding on a new policy following the required public consultation and research through a change in the Act’s interpretation.

One of the functions listed in the paragraph above is licensing, which seems to be an important aspect in relation to clinics performing PGD, and which is a common element in the function of both the HFE Authority in the UK and the Ethics Committee in Germany.

However, opposed to the HFE Authority, the German Ethics Committee will not be able to influence decisions about individual PGD applications only indirectly; the German Ethics

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<sup>124</sup> King, David: ‘[The case for case-by-case regulation of PGD](http://www.bionews.org.uk/page_53438.asp)’ 18 January 2010 available at: [http://www.bionews.org.uk/page\\_53438.asp](http://www.bionews.org.uk/page_53438.asp) last visited: 23.11.2012

Committee, according to the executive order, will be by itself responsible for making a decision on individual PGD applications directly on a ‘case-by-case basis’.

According to the executive order, ‘as a result of Article 3(a(3)) of the ESchG, the Ethics Committee is responsible for checking whether the criteria defined in Article 3(a(2)) of the EschG are present and to give its agreement to treatment in case these criteria are present.’<sup>125</sup>

After having looked at the regulation in the UK in detail, it becomes clear and the initial suspicion confirmed that the HFE Act and Authority gives a very regulated and clear framework for the decisions. This regulatory framework provides for a transparent and stable structure for a basis applications concerning PGD can be decided on.

The main parts of the regulation include: defining activities that the Act absolutely prohibits and other activities that can be carried out only with a license issued by the Authority, issuing, as already noted, a Code of Practice that gives guidance to licensed centers about the conduct of licensed activities, conducting regular inspections in the licensed centers to enforce regulations and to see whether the licensed centers are complying with them, and finally launching public consultations or conducting research in order to review policies.

Looking at the German Ethics Committees, they will have in some aspects a broader discretionary power, while in others a much narrower. Unlike, the HFE Authority, the German Ethics Committees will be solely responsible for licensing PGD on a ‘case-by-case basis’. They will not have any further function in relation to decisions about questions of research, reviewing policy, providing

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<sup>125</sup> See supra note 116 p. 31

information or advice for persons concerned. The Ethics Committees themselves will not even be responsible for storing data, which function will be implemented, according to the executive order, by a centralized institution.<sup>126</sup>

However, the Ethics Committees will have a much more direct say and a stricter surveillance on individual family requests. While in the UK, once the Licence Committee has allowed for the application of PGD for a particular disease or abnormality, any licensed clinic will be able to offer PGD for that disease or abnormality, but in Germany these requests will be decided on a ‘case-by-case basis’ directly by the supervisory Ethics Committees.

As already stated above, PGD’s regulation in the UK dates back to the early 1990s and during the past years its regulation has developed in two important aspects. Firstly, definitions, indications and licensing have become more and more detailed and precise. Secondly, it needs to be also emphasized that, as Hermann points out in her article, regulation has become a form of de-regulation.<sup>127</sup>

During the years, as a result of the regulation and the technologies’ development, newer and newer treatment services and methods have become accepted PGD practices. Examples include tissue typing, PGS and screening for late-onset diseases, which are now somewhat accepted and practiced methods in the UK - even if tissue typing and screening for late-onset diseases are still regulated on a ‘case-by-case basis’ instead of the ‘condition-by-condition’ basis, as already noted.<sup>128</sup>

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<sup>126</sup> Ibid.

<sup>127</sup> Hermann, Svea Louise: Deregulation via Regulation: On the Moralisation and Naturalisation of Embryonic Stem Cell Research in the British Parliamentary Debates of 2000/2001. 32(2) ÖZP (2003)

<sup>128</sup> Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing. Available at: [http://www.hfea.gov.uk/docs/PolicyReview\\_PreimplantationTissueReport.pdf](http://www.hfea.gov.uk/docs/PolicyReview_PreimplantationTissueReport.pdf) (last visited: 09.01.2013)

Coming to the evaluation of this process's development (which will be done in much more detail in Chapter 5), it has on the one hand the advantage that it adapts easily to new technological advances. However, on the other hand, it might lead to the negligence of other ethical aspects. This is also what Uta Ziegler emphasizes in her chapter about ethical debates in the UK in relation to PGD and about which I am going to write more in detail later.<sup>129</sup>

The next aspect to be investigated as part of the comparison is what possibilities exist to challenge a decision made by the responsible authority. Reviewing policies has two dimensions: 1) the review of specific decisions in relation to individual applications and 2) the review of the authorities' general policy in relation to novel treatment methods. In the UK, a challenge against a decision made by the Executive Licencing Panel or by a Licence Committee is regulated as well. However, it mainly concerns decisions made in relation to licensing clinics. Individual applicants may only appeal to the High Court and only on a point of law concerning the decision in specific individual cases.

In Germany individuals can challenge the Ethics Committee's decisions only at Courts and only in relation whether they properly applied the law. A change in the interpretation in the law itself is thus not as easy as in the UK. It seems that in Germany a change in PGD application's practice will only be possible by a review of law by Parliament.

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<sup>129</sup> See supra note 120 p. 85

My original research question related to the difficulty of finding the differences in the German and English regulation of PGD because they seem very similar in some aspects for the first sight. After having looked at both authorities' detailed functions and decision-making process the original question has become clearer, however, some aspects still need to be investigated. One of them is the crucial issue how the responsible Authority's general policy in relation to novel treatment methods can be reviewed and changed.

In order to answer this question, the review policy of both the HFE Authority and the German Ethics Committee discussed above need to be evaluated in order to reply to the original research question about the fundamental differences from two aspects: firstly to investigate how democratic and transparent the review process of these authorities is in relation to applying new technologies, and secondly to examine who has the authority within the two systems and under what process it is possible to change current policies in relation to PGD's novel treatment methods.

The first component is relevant because the decision-making's transparency might be a signal of how easily practices can be changed and how much control can be exercised over it. The second component is also relevant, since it concerns the acceptance of novel treatment methods.

Concerning the first question, it seems for the first sight that the English regulation is more clear-cut in both aspects. Conditions for licensing are clearly formulated and available to everyone interested, in which process the HFE Authority itself plays a very important role. According to the HFE Authority's guide to licensing '[a] standard condition of all licenses issued by the Authority is that centres must not carry out new methods of conducting a licensed activity unless they have first

notified the Authority and have been given approval by the Authority to carry out those activities.’<sup>130</sup>

Additionally, in relation to the second question, reviewing policies is listed as one of the Authority’s responsibilities officially, thus the Authority itself is responsible for policy changes. The reviews are implemented through extensive research, review of literature, open meetings, and often the commissioning of work from specialists in the field. One of its means to review policies, which is highly relevant for the analysis of the process’s democratic nature, is conducting public consultations. The information gathered through this process is summarized afterwards and policy options are presented to the Authority, which also makes the decision at the end of the investigation.

In terms of reviewing general policies in relation to PGD’s application, the German Ethics Committees’ possibilities will remain potentially very limited. Their tasks will be reduced to making decisions on a case-by case about individual applications. Similarly, as questions of research will not be part of the Committees’ daily activities, reviewing policies in relation to PGD will only be possible by changing the law, thus in case of a decision by Parliament.

In summary this means, that in the German system, the balance of power will be much easier to maintain, since two different institutions (branches) are responsible for policy-making. This also suggests that the different interests of scientists and patients will be much more balanced in Germany. While in the UK a review of a general policy can be initiated, investigated and

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<sup>130</sup> ‘Guide to Licensing’ Human Fertilisation and Embriology Authority Available at: [http://www.hfea.gov.uk/docs/Legislative\\_Guide\\_to\\_Licensing.PDF](http://www.hfea.gov.uk/docs/Legislative_Guide_to_Licensing.PDF) (last visited: 09.01.2013) p. 4

implemented by the same Authority, in Germany different and distinct institutions will do the same job. This is one of the most important fundamental differences in the two systems.

The first question in relation to the evaluation of the Authority's decision-making process was: 'to what extent the HFE Authority makes its decision in a democratic and transparent manner'. This issue needs to be further investigated from the aspect to what extent 'public consultations', as an important argument in this debate and potentially a counter argument for the above-concluded arguments, are forms of truly open public discussions. It can be easily proven that these consultations take place in limited circles of experts. Following, it means that they are similar to research and are not forms of true public consultations.

To answer this question properly, the issue needs to be investigated first how in the past ethical debates within the public have influenced the Authority's decisions. Secondly, what have been the most important arguments thrown up in the debate about the PGD's application and whether they are represented in the public consultations' end results.

## **4.2 Ethical debates in the UK and in Germany**

### ***4.2.1 UK***

Basic principles about technologies such as IVF and embryology were established already in the early 1980s in the UK as a result of growing concerns and technological development. In 1982, the so-called Warnock Committee was established for this reason and concluded after its inquiry in

1984 in the Warnock Report that ‘human embryo should be protected, but research on embryos and IVF would be permissible, given appropriate safeguards’.<sup>131</sup>

According to Sally Sheldon, the Warnock Report’s approach, similarly to the decisions later made by the appeal courts in relation to the Authority’s decisions as regards PGD’s novel treatment procedures, was ‘very pragmatic’.<sup>132</sup> She brings up an illustrative example for this – the Committee’s refusal to take a position on the moral status of the embryo:

*Although the questions of when life or personhood begin appear to be questions of fact susceptible of straightforward answers, we hold that the answers to such question in fact are complex amalgams of factual and moral judgments. Instead of trying to answer these questions directly we have therefore hone straight to the question of how it is right to treat human embryo [...].*<sup>133</sup>

According to the HFE Act, research on embryos is allowed up to 14 days following fertilization, which is also indicative of PGD’s application. This argument is based on the Warnock Committee’s argument, according to which, this is ‘the earliest possible point for development of a central nervous system’.<sup>134</sup> This decision highlights on the one hand a general avoidance of critical issues around embryos’ early development and on the other hand reassures and confirms this pragmatic approach.

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<sup>131</sup> ‘The Warnock Report’ 1984. List of Recommendations p. 80-86 available at: [http://www.hfea.gov.uk/docs/Warnock\\_Report\\_of\\_the\\_Committee\\_of\\_Inquiry\\_into\\_Human\\_Fertilisation\\_and\\_Embryology\\_1984.pdf](http://www.hfea.gov.uk/docs/Warnock_Report_of_the_Committee_of_Inquiry_into_Human_Fertilisation_and_Embryology_1984.pdf) (last visited: 25.11.2012)

<sup>132</sup> See supra note 111 p. 410

<sup>133</sup> See supra note 129 at para. 11.9.

<sup>134</sup> See supra note 131

The question is whether this pragmatic approach is present in the regulation's other aspects, such as public consultations. Previous public consultations topics have included the publication of specific clinics' IVF-success rate or recently topics on 'mitochondria replacement' and on 'reviewing multiple births and single embryo transfer policies'. Since the establishment of the HFE Authority, public consultations on PGD have taken place already three times: in 1999, in 2005 and in 2009.

According to Flora Goldhill, who had been Chief Executive of the HFE Authority until 1996, the idea of these public consultations is less to carry out a form of 'market survey', but rather to collect well grounded arguments in order to find a result. In her words '[i]t is the quality of the argument and not the numbers that the authority is interested in'.<sup>135</sup>

According to Uta Ziegler, PGD had already been practiced before this public consultation form came out and a regulation started to formulate.<sup>136</sup> She also underlines that PGD's application has never been questioned in principle, and regulations aimed simply at the improvement of the procedures while making the processes more transparent.

In 1999, Ruth Deech, chairman of the HFE Authority, said<sup>137</sup>:

*The HFEA decided it would be unacceptable to allow PGD to be used to test for any social, physical or psychological characteristics, or any conditions that are not associated with serious, often life threatening, medical disorders.*

<sup>135</sup> Goldhill, Flora; Deech, Ruth; Human Fertilisation and Embryology Authority: [Human Fertilisation and Embryology Authority Account 1994-95](#). TSO, 1996 p.12

<sup>136</sup> See supra note 120 p. 89

<sup>137</sup> 'Gene screening debate goes public' BBC 16.November 1999 available at: <http://news.bbc.co.uk/2/hi/health/521027.stm> (last visited. 25.11.2012)

However, looking at the questions and the results of the second and third public consultations on PGD in 2005 and 2009, these original principles seem to shade. The second consultation concerned the licensing of PGD application for lower penetrance cancer susceptibility conditions.<sup>138</sup> Following the consultation the Authority took the decision to allow application of PGD for lower penetrance conditions. However, these applications would be considered on a case-by-case basis, as already noted, ‘because of the difference in the way that families are affected by these conditions and also because this is a new class of PGD conditions’.<sup>139</sup>

The third consultation for PGD took place after the amendment of the Act in 2008. According to the Authority ‘[t]he new Act meant that we needed to update the Code and consent forms’.<sup>140</sup> Accordingly, following the consultation, the Code of Practice was renewed and reworded and new guidance was given how to complete consent forms.

One of the reports’ conclusion was in relation to the judgment about the genetic condition’s seriousness and returned to the guidance used in the 7th Code of Practice, according to which:

*‘The perception of the level of risk for those seeking treatment will also be an important factor for the centre to consider’.*<sup>141</sup>

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<sup>138</sup> By 2005, the HFEA has licensed over 50 single gene conditions for PGD including also late onset conditions. For further information see: Choices and Boundaries Report. Summary of responses to the HFEA public discussion. 2006 p. 4 Available at: [http://www.hfea.gov.uk/docs/Choices\\_and\\_boundaries\\_Report\\_2006\\_summary.pdf](http://www.hfea.gov.uk/docs/Choices_and_boundaries_Report_2006_summary.pdf) (last visited: 12.01.2013)

<sup>139</sup> ‘Authority decision on the use of PGD for lower penetrance, later onset inherited conditions’ Available at: [http://www.hfea.gov.uk/docs/The\\_Authority\\_decision\\_Choices\\_and\\_boundaries.pdf](http://www.hfea.gov.uk/docs/The_Authority_decision_Choices_and_boundaries.pdf) (last visited: 12.01.2013)

<sup>140</sup> See supra note 138 p. 3

<sup>141</sup> See supra note 138 p. 19

These public consultations, as already noted, should be now assessed in the light of whether they should be considered as a form of democratic debates in the society about critical questions, allowing for transparent decision-making and policy review. Uta Ziegler argues that despite all the efforts, these public consultations have not been objective enough and opponents of research have not been sufficiently represented in them. As a conclusion, the argument seems to be enough well grounded, according to her, that the negligence of ethical concerns is a price to pay for protecting research interests.<sup>142</sup>

I think that Uta Ziegler's arguments are highly relevant and I also find it likely that the previous public consultations have not provided for satisfactory procedures for transparent decision-making and an effective control over the Authority's policy reviews. A democratic control, which in my understanding would also cover an ethical review of the Authority's decision, is thus not ensured. It seems to me that the Authority's processes serve more the interests of doctors, scientists and researchers, and following the interests in the application of novel treatments is not balanced with ethical concerns or the public's opinion.

Apart from public consultations and research, previous court decisions in relation to PGD's and PGS's novel treatment methods as a challenge to the HFE Authority's discretionary power could have also played an important role in setting limits to the extension of the HFE Act's interpretation in relation to PGD.

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<sup>142</sup> See supra note 120 p. 84-85

One of the relatively recent decisions of the House of Lords, in *Quintavalle (on behalf of Comment on Reproductive Ethics) v. Human Fertilisation and Embryology Authority*<sup>143</sup>, rather than limiting, clarified and confirmed the discretionary power of the Authority to license novel treatment methods, such as tissue typing. To answer the question Lord Brown needed to go back in time as early as the Warnock Report and the White Paper, which followed the first in order to decide whether the practice in the case concerned fell within the scope of ‘suitable’.

Sally Sheldon rightly points out in her article the discovery upon this judgment the followings<sup>144</sup>:

*The wording of a statute aiming to regulate a fast developing area of medical and scientific practice has been found to provide limited or ambiguous guidance on a number of matter that were not foreseen by its drafters.*

A very important fact underlying this aspect is that PGD’s technique itself is not mentioned in the HFE Act’s text. It is only possible, as shown, to draw some conclusions from the abstract wording to the specific application.

Concerning the Authority’s discretion in licensing activities and the question of ‘black-holes’ in the regulation, Lord Brown concluded that the technique of HLA typing is not ‘[...] left unregulated. *There will be no ‘free for all’.* Rather, the licensing of this new technique is for the discretion of the Authority.’<sup>145</sup> The Court added that ‘*in an unlikely event that the Authority were to propose licensing*

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<sup>143</sup> *Quintavalle (on behalf of Comment on Reproductive Ethics) v. Human Fertilisation and Embryology Authority* U.K.H.L. 28 (2005)

<sup>144</sup> See supra note 111 p. 407

<sup>145</sup> See supra note 143 para. 58

*genetic selection for purely social reasons, [...] the court's supervisory jurisdiction could be invoked'.<sup>146</sup>*

This suspicion that ethical aspects do not play an important role in the UK's regulation is again confirmed by the Court in *Quintavalle v. Human Fertilisation and Embryology Authority*, where the Court refers to the White Paper at paragraph 14 saying:

*To ensure that the legislation is flexible enough to deal with as yet unforeseen treatment developments which may raise new ethical issues, the Bill will contain powers to make regulations (subject to the affirmative resolution procedure) to add to or subtract from the range of matters coming within the regulatory scope of the Authority.*

#### **4.2.2 Germany**

In Germany ethical debates about the regulation of PGD date back to the 1980s.<sup>147</sup> In May 1984, a working party called 'In vitro Fertilization, Genome Analysis and Gene Therapy' was set up by the Federal Ministry of Justice under the direction of the former president of the Federal Constitutional Court, Ernst Benda. The Benda Commission's main goal was in particular to handle legal and ethical questions stemming from new reproductive technologies and to make 'large numbers of suggestions for possible legal measures in its final report'.<sup>148</sup>

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<sup>146</sup> See supra note 143 para. 62

<sup>147</sup> Mayer, Stefanie: Complex Matters The Regulation of Predictive Genetic Testing and Genetic Counselling in Germany available at: <http://www.ihs.ac.at/steps/gendialog/Regulation%20Deutschland.pdf> p. 14-23 (last visited: 25.11.2012)

<sup>148</sup> Wessels, Ulla: Genetic Engineering And Ethics in Germany In: Dyson, Anthony and Hawis, John: Ethics and Biotechnology. Routledge, 1994, p. 230-259

A number of institutions were involved in the debate about the regulation and later about the amendment of the legislation.<sup>149</sup> The main regulation about reproductive technologies, the German embryo protection law ('Embryonenschutzgesetz' - ESchG) was ready and came into force in 1990. Overall the new law's evaluation was positive, however, many institutions, including the 'Bundesrat' accepted that the new law left a couple of questions unresolved.<sup>150</sup>

Debates around the ESchG, among others, included already at that point questions whether its provisions allowed for the application of PGD. This issue refers to the fact that in Germany several ethical, medical and legal concerns were involved in the debates about PGD's application and the issue of understanding the law as an indirect allowance for PGD's application – which was finally refused.

It soon became clear that even if it had been possible to solve the difficult medical and ethical issue around totipotency<sup>151</sup> with a change in the text's interpretation, there was a general refusal in the public to allow for the application of PGD through an unclear regulation and with the technique of changing the law's interpretation (that kept happening in the UK).<sup>152</sup> Much before the new law in 2011, there had been consent among professionals that this technology, which has so much potential and also brings fear, needed both a very clear regulation and control. The debate, however, continued around PGD with the main players involved being different parliamentary and

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<sup>149</sup> For further information see Lynch, John: What are Stem Cells? Definitions at the interaction of science and politics. University of Alabama Press, 2011 p. 95

<sup>150</sup> For further information see: Günther, Hans – Ludwig; Keller, Rolf: Fortpflanzungsmedizin und Humangenetik: Strafrechtliche Schranken. Entschließung des Bundesrates zum Embryonenschutzgesetz in 'Anhang IV'. J.C.B. Mohr, 1991

<sup>151</sup> See further: Van de Velde, H.: Lessons from human embryo. 20 (Supplement 1) Reproductive BioMedicine Online (May, 2010)

<sup>152</sup> See supra note 120 p. 124

governmental commissions and working groups, professional organizations, research centers and the German National Ethics Council.<sup>153</sup>

As a general characteristic for Germany, even explicit advocates of PGD have been of the opinion that PGD application's clear boundaries should be defined and made specific recommendations on how to exercise control over its practice.<sup>154</sup> The advocates of PGD in Germany have many times mentioned the aspect of reproductive autonomy. According to the supporters' interpretation, as already noted, reproductive autonomy is the highest principle, which also includes that reproductive autonomy should prevail when it conflicts with ethical judgments.

Countering arguments in the human rights discourse including reproductive autonomy, important ethical concerns, which are in general labeled as 'slippery slope arguments', have been much debated partially as a result of the previous German experience during the Second World War. Fears have included the risk that PGD would be allowed not only in cases of serious genetically inherited diseases and that potentially it would also lead to the stigmatization of a number of diseases and the protest of organizations representing people living with disabilities.<sup>155</sup>

Another interesting topic in the German debate has been brought up by PGD's supporters and is in relation with the discrepancy around PGD and prenatal diagnostic (PND). PND allows for the late termination of pregnancy in case it turns out that the unborn child has a genetically inherited

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<sup>153</sup> See supra note 147 p. 14-23

<sup>154</sup> See supra note 120 p. 112

<sup>155</sup> See supra note 120

disorder. However, PGD, where embryos that are only a few days old, is prohibited. Birnbacher, for example, makes the following comments in relation to the two somewhat similar techniques.<sup>156</sup>

*As for the similarities, both methods [PGD and PND] involve the selective destruction of human life for the sake of the reproductive freedom of parents, i.e. the freedom to have a choice concerning the children they want to bring up [...] On the other hand, the normatively relevant differences between the two methods suggest that PGD should be regarded at less, and not as more, problematic than PND.*

The German ethical debate described above seems to highlight two aspects about the German approach to PGD. Firstly, that these ethical concerns have played a very important role in the German society and also influenced the decision-making about PGD. Secondly, that those ethical arguments have long been strong enough to counter arguments in the human rights discourse, such as the issue of reproductive autonomy.

Another important element in the German system also highlights the importance of ethical concerns, among others, also in relation with PGD. Ethical concerns are not only debated sporadically by academics and professionals but also within institutionalized public frameworks. Institutionalized forms of discussing ethical concerns at national level are the Inquiry Committee and the National Ethics Council.

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<sup>156</sup> Birnbacher, Dieter: Prenatal diagnosis yes, preimplantation genetic diagnosis no: a contradictory stance? Reproductive BioMedicine Online. 14. Supplement 1 (October 2006) p. 110

Inquiry Committees are set up by the ‘Bundestag’ and function as advisory bodies for legislation, however, their decisions are not binding on the institution itself.<sup>157</sup> The Inquiry Committee for Law and Ethics in Modern Medicine was set up in March 2000 by the German lower house of Parliament. Its 26 members also included 13 members of the Parliament and other professionals.<sup>158</sup> The previous Committee for ‘Chances and Risks of Gene Technology’ in 1987 was the first in the series of these special parliamentary bodies.<sup>159</sup>

According to the Committee’s final report in 2002, two members voted explicitly for the allowance of PGD, 16 voted for an explicit prohibition and three members were of the opinion that PGD should be allowed restrictively.<sup>160</sup> The Committee justified its final voting decision among others with the command of protecting dignity, the danger of potential discriminatory tendencies against people living with disabilities and the impossible mission of limiting its application to a restricted indications list.<sup>161</sup>

The early 2000s are important also for a second reason. In 2001 the government declared the creation of a new expert body, the National Ethics Council. The Council’s main function is to draw up ‘*Opinions at the request of the Federal Government or of the Bundestag*’.<sup>162</sup> Fuchs highlights at

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<sup>157</sup> Enquete-Kommission des 14. Deutschen Bundestages ‘Recht und Ethik der modernen Medizin’ Deutsches Referenzzentrum für Ethik in den Biowissenschaften Available at: <http://www.drze.de/im-blickpunkt/pid/module/enquete-kommission-des-14.-deutschen-bundestages-recht-und-ethik-der-modernen-medizin> (last visited: 28.11.2012)

<sup>158</sup> See supra note 120 p. 120

<sup>159</sup> See supra note 147 p. 24

<sup>160</sup> Schlussbericht der Enquete-Kommission ‘Recht und Ethik der modernen Medizin’ Deutscher Bundestag 14. Wahlperiode Drucksache 14/9020 Available at: <http://dipbt.bundestag.de/dip21/btd/14/090/1409020.pdf> (last visited: 29.11.2012)

<sup>161</sup> Ibid. p. 9-19

<sup>162</sup> Fuchs, Michael: National Ethics Councils. Their backgrounds, functions and modes of operation compared. Nationaler Ethikrat, Berlin 2005 p. 43

the same time in his essay about national ethic councils that its founding decree also ‘provides for collaboration with other national ethics committees (Section 2(4))’.

Since its foundation, the Council has already published two times an official Opinion on PGD. The first in 2003 and the second, as a result of the decision by the German Highest Court, in 2011. The majority of the Council already in 2003 voted for a ‘restricted permission of PGD’. Among the reasons grounding its decision, the Council named parents’ reproductive autonomy and granted only a relative right to life for embryos existing only in such early development phase as right after an IVF treatment.<sup>163</sup> According to the position ‘in favour of the responsible approval of PGD subject to strict limitations’<sup>164</sup>:

*The argument from potentiality [...] is an insufficient basis, for those who ascribe a fundamentally different status to an embryo from that of a born human being, for explaining why a subsequent, stronger status (status ad quem) should be fully attributed to a prior stage of development (status quo).*

In 2011, the majority of the Council voted for a restricted permission of PGD again. This time they held their opinion ethically justified, because firstly PGD enables to avoid the termination of pregnancy at a later stage, which is more dangerous to the health of the woman, and secondly because of the necessity to guarantee reproductive autonomy to couples living with a risk of passing over a genetically inherited disease to the child.<sup>165</sup>

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<sup>163</sup> See supra note 113

<sup>164</sup> Ibid. p. 112

<sup>165</sup> Ibid. p. 77-84

The purpose of this chapter has been to analyze the issue how have ethical debates in the society influenced the responsible Authority's decision in Germany and in the UK in relation to PGD. The reason of this investigation was firstly, to see what extent ethical concerns have played an important role in the evolution of PGD's application. Ethical arguments' strength in the society and the decision-making can be indicative of the capability of setting limits to PGD's novel treatments and can potentially counter human rights arguments, such as the right to reproductive autonomy.

The second reason for making this investigation was to find out to what extent the decision-making process within the responsible authority in Germany and in the UK in relation to PGD policies and their reviews is transparent and how far societies' different interests and concerns are represented in this process. The presence of different interests in the decision-making process can help in exercising control over the decision-making process and can potentially limit the technique's evolution in unilateral direction.

In terms of the first issue, it is clear that ethical concerns have played a much stronger role in the German society and debate around PGD. In the UK, none of the previous reports and documents investigating issues of IVF dealt in much detail with PGD's ethical objections. This seems to be an important argument underlining why the evolution of policies in relation to PGD could in the future lead to a different end result than the current situation in the UK.

With relevance to the second issue, it seems that the HFE Authority's broad discretionary power in the UK is not so much balanced with non-scientific interests of the society. While in Germany, not only scientists and academics sporadically, but national public institutions in the form of ethics committees and ethic councils have taken part in the debate, in the UK the HFE Authority seems to

be the only competent authority responsible for decisions, such as PGD's novel treatment methods. It seems that despite its original function, public consultations do not appear to be forms of democratic consultations and the Courts have not taken up a strong review function, they only confirmed the Authority's discretionary power.

From these arguments it likely follows that not only the institutional and the legal structure in the two countries exhibit important differences, but also the society's general approach to such sensitive and ethically dubious issues as the application of PGD.

#### **4.3 Legal boundaries of PGD in the UK and in Germany**

In the analysis of my original research question about the differences in the German and the UK legal and ethical environment in relation to PGD, the last aspect is the comparison of the most important legal boundaries that potentially play a role in setting limits to the development of PGD's novel treatment procedures. This question could be approached from different perspectives, since a number of legislations, including the legislation itself providing for PGD and those ensuring human rights, furthermore legislations guaranteeing equality and criminal law also could also provide for legal constraints in PGD's application.

I chose two aspects from this broad scale, which I find the most important: analyzing firstly the German and the UK provisions clarity that allow PGD and secondly the most important human rights legislations (the Basic Law in Germany and the Human Rights Act in the UK) in the two countries and their role in PGD's regulation. The question is whether they strengthen the application of novel treatment procedures from the aspect of reproductive autonomy or on the

opposite, they strengthen ethical concerns in relation to discrimination, the embryo's right to life and equal rights of people living with disabilities.

To answer these questions firstly the German Embryo protection law (ESchG) and the HFE Act will be analyzed. With regards the second question, in the German literature about PGD, the application is usually confronted with Article 1 of the German Basic Law<sup>166</sup>. Even though previous analyses had been carried out before the ESchG was amended in summer 2010 which concentrated on the theoretical compatibility of PGD's application and the specific provisions of the German Basic Law, parallel arguments could also be used in the investigation about PGD's further novel treatment procedures.

In relation the second aspect in the UK, I chose to analyze the Human Rights Act, which is, in absence of a written Constitution, the most important piece of human rights legislation in the UK currently. Interestingly, not so much reference have been made to this piece of legislation in the debates around PGD, which question could be also relevant to investigate.

#### ***4.3.1 The German Embryo Protection Law and HFE Act***

It was earlier explained that in the German ethical debate strong voices have recommended a clear regulation with a strong monitoring system for PGD – the question is whether they have succeeded in this after having the ESchG amended.

After the amendment of the ESchG, the following aspects of PGD's application became clearly regulated. First of all, according to the law, the application of PGD is prohibited and unlawful in

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<sup>166</sup> Grundgesetz für die Bundesrepublik Deutschland GG 23.05.1949 Article 1

general and it will be allowed only in the presence of specific indicators. The following terms or criteria are presented in the new law as indicators in Article 3(2) of the ESchG: 'high risk', 'serious genetic disease', 'high probability'.

Comparing these elements with the HFE Act's provisions about PGD and especially the 8th Code of Practice, it becomes clear that these two pieces of regulations show a lot of similarities. Both the licensing construction and the indicators for PGD reflect many similarities.

According to Article 3a(2) of the ESchG PGD is not illegal:

*'If on the basis of the genetic disposition of the woman [...] or the man [...] there is a high risk of a serious genetic disease [...] with the written consent of the woman ... PGD is also not illegal [...] with the written consent of the woman [...] if a serious damage to the embryo [...] can be determined which will most likely lead to a stillbirth or miscarriage.'*

Further provisions of Article 3(a) contain principles in relation to PGD's technical implementation, counseling and licensing.

The same provisions, according to Article 1(1) of Schedule 2 in the HFE Act (as amended), are the followings to start with in relation to licenses for treatment:

*(1) A licence under this paragraph may authorise any of the following in the course of providing treatment services*

- (a) bringing about the creation of embryos in vitro,*
- (b) procuring, keeping, testing, processing or distributing embryos,*
- (c) procuring, testing, processing, distributing or using gametes]*
- (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,*
- (e) placing any embryo in a woman [...].*

Further provisions are to be found about embryo testing, according to 1ZA of Schedule 2:

- (1) A licence [...] cannot authorise the testing of an embryo, except for one or more of the following purposes:*
- (a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,*
- (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality.*

Provisions about license conditions in Articles T86-T87 contain very similar requirements. In addition to these provisions, the Authority's 8th Code of Practice contains further guidance how to interpret these Articles. However, one of the most important deficiencies in the UK's system clarity is that no matter how much PGD is regulated in the different Codes of Practice, the technique itself does not have a textual basis in the law itself.

After having looked at the legislations themselves in the UK and in Germany, it is necessary to consider the second element of the analysis – important human rights provisions and their influence on the two pieces of legislations allowing PGD. Accordingly, in the next chapter, I will discuss the provisions of the German Basic Law and its potential effects on PGD and similarly the Human Rights Act in the UK.

#### ***4.3.2 The German Basic Law and PGD***

The German Basic Law in Article 1 states that ‘human dignity is inviolable’ and according to Article 2(2) ‘[e]very person shall have the right to life and physical integrity. Freedom of the person shall be inviolable’. It needs to be answered whether this provision could alone set limits to any further application of PGD in Germany, such as licensing tissue typing or applying PGD also in case of late-onset or low susceptibility diseases. Before going into the analysis of this specific question, it is necessary to have an overview about the interpretation of Article 1 of the German Basic Law and in general in the literature.

The concept of dignity in the Constitutions has been much criticized in general by many scholars. It is in the German Basic Law that following Second World War the concept of ‘dignity’ was included. Interestingly, it is elsewhere only in the Universal Declaration of Human Rights and in the Swiss Constitution that dignity has a textual basis as a self-standing article. Many debates have taken place also in Germany itself in relation to Article 1 of the German Basic Law about how the concept

of 'dignity' itself shall be understood.<sup>167</sup> Nevertheless, some countries' High or Constitutional Courts have also chosen to include dignity in their decisions as an interpretive tool.<sup>168</sup>

The most common critique against the use of dignity either as an interpretive tool or a provision itself is that its interpretation will always depend on the specific court and judges, and thus offers only a limited tool for clear-cut and objective approach to certain rights. Murray Wesson for example writes in relation to the South African 'equality jurisprudence' that *'dignity is subject to various conceptions, limiting its usefulness as a litmus test for equality. [...] An initial issue is that dignity is amenable to both subjective and objective conceptions.'*<sup>169</sup>

Similarly, the example of *Pretty v. the United Kingdom*<sup>170</sup> and *Law v. Canada*<sup>171</sup> could be listed as an example of the above stated. While in the second case the concept of dignity is used in order to set limits to the right of equality, in the first it does not. In the second case it is used instead to extend the interpretation of the right in question. This again reflects the fluid nature of dignity's concept.

In relation to the German jurisprudence, it has been many times emphasized that the German Basic Law's Article 1 should be interpreted and applied as a 'subjective basic right' (subjektives

<sup>167</sup> See for example Geddert-Steinacher, Tatjana: *Menschenwürde als Verfassungsbegriff*. Tübingen, 1990 AND Böckenförde, Ernst-Wolfgang: *Bleibt die Menschenwürde unantastbar?* 10 *Blätter für Deutsche und Internationale Politik* (2004); Schlink, Bernard: *Die überforderte Menschenwürde: Welche Gewissheit kann Art. 1 des Grundgesetzes bieten?* 51 *Der Spiegel* (2003) Available at: <http://www.spiegel.de/spiegel/print/d-29475098.html> (last visited: 10.12.2012)

<sup>168</sup> For example the ECHR, Canada, South Africa

<sup>169</sup> Wesson, Murray: *Contested Concepts: Equality and Dignity in the Case-Law of the Canadian Supreme Court and the South African Constitutional Court*. In: András Sajó, Renáta Uitz (eds): *Constitutional Topography: Values and Constitution*. Eleven International Publishing, Utrecht, 2010 p. 281

<sup>170</sup> *Pretty v. The United Kingdom* Application no. 2346/02 (29<sup>th</sup> April, 2002)

<sup>171</sup> *Law v. Canada (Minister of Employment and Immigration)* SCR497 (1999)

Grundrecht) and will be absolutely protected without actually giving the content of it<sup>172</sup>. In addition, according to the German Constitutional Court's Mephisto judgment, the Court will decide with a balancing technique on a case-by-case basis if the provision of dignity has been violated.<sup>173</sup> Rosemarie Will mentions as a result of this that the concept of dignity *'in the German society will have as well an interpretation that is changing on a case-by-case basis'*.<sup>174</sup>

Similarly, I think its usefulness in relation to the application of PGD and the German Embryo Protection Law (ESchG) is limited – alone it would not set limits to a change in the law's interpretation as a result of dignity's subjective element. This is also among others what has been emphasized by Charikleia Z. Latsiou in her book about the legal background of PGD.<sup>175</sup>

Latsiou investigates the relevance of Article 1 in relation to PGD by segmenting the process itself into three different activities. She comes to the conclusion in relation to the 'artificial insemination', the 'cells investigation' and the 'non-implantation of the damaged embryos' that Article 1 has hardly any relevance whether the application of PGD itself is confronted with basic constitutional principles.

It must be emphasized that she investigated Article 1 only in relation to the theoretical application of PGD, since the book had been written before the ESchG was modified. However, I think the arguments she uses can be further applied as regards the potential extension of PGD's application.

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<sup>172</sup> Will, Rosemarie: Bedeutung der Menschenwürde in der Rechtsprechung – Essay Available at: <http://www.bpb.de/apuz/33162/bedeutung-der-menschenwuerde-in-der-rechtsprechung-essay?p=all> (last visited: 10.12.2012)

<sup>173</sup> Mephisto (Klaus Mann / Gustaf Gruendgens) 1 BvR 435/68 (24 February 1971)

<sup>174</sup> See supra note 172

<sup>175</sup> See supra note 66

Furthermore, in her chapter about the German Basic Law, she also investigates Article 2(2) ('right to life'). She underpins her argument that in the German literature the right to life is to be distinguished from Article 1, nevertheless, the protection of dignity is the basic principle above all and the right to life can be limited as long as it does not violate dignity. On the basis of this, she draws the conclusion that both the embryo's genetic analysis and the non-implantation represent a violation in the protection of the right to life. However, the character of Article 2(2) covets a relativization of the legally protected right.

Interestingly, on the basis of the same provisions even the complete opposite of the above explained hypothesis could be argued. It could be claimed that Article 2(2) rather than limiting it, requires the legality of any application of PGD. This is, what Latsiou also emphasizes. She further refers to the same Article 2(2) of the Basic Law as the woman's right to physical integrity and the couples' right to self-determination (including reproductive autonomy). She comes to the conclusion that the legalization of PGD should be necessary, because a call to obligatorily implant an *affected embryo* would provide for an interference with the couples' right to self-determination and the woman's right to physical integrity.

The conclusions from this part follow that in Germany one of the most important instrument for the protection of human rights, the Basic Law itself does not provide for, from the ESchG law distinct, clear boundary for the development of PGD's novel treatment methods.

#### **4.3.3 The UK Human Rights Act and PGD**

It is a well-known fact that the UK has never had a written Constitution, but in the late 1990s it adopted the Human Rights Act (HR Act), which came into force in October 2000, which is now

provides for the most important human rights piece of legislation. However, it does not mean of course that before adopting the HR Act the protection of human rights was impossible within the state. The traditional reasonableness test, applied for example in the *Ex Parte Daly* case<sup>176</sup> was widely practiced before introducing proportionality, which is used also in most of the cases in the ECHR.

The HR Act is relevant for this study, since it applies to public bodies, including regulatory bodies relevant for reproductive issues, such as the HFE Authority. It is stated at several places in the Authority's guidelines that the HFE Act and its Code of Practice need to be in line with the HR Act, and thus the European Convention of Human Rights. The most important effect of the HR Act's adoption is that 'instead of having to take a case to the ECHR in Strasbourg, litigants can enforce their rights in the UK'.<sup>177</sup>

Taking the Convention's different articles into consideration, it is easy to realize that Articles 8 (right to respect for family life), Article 12 (right to found a family) and potentially Article 6 (right to fair trial) and Article 14 (non-discrimination) are the most relevant for reproductive issues, including PGD.

To answer my original research question the following issue needs to be investigated: has the adoption of the HR Act become a 'springboard to deny novel treatment procedures' or on the opposite, it supports them. In connection to these issues, it is necessary to refer back here to the

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<sup>176</sup> R. v. Secretary of State for the Home Department, *Ex Parte Daly*, UKHL 26 (23<sup>rd</sup> May, 2001)

<sup>177</sup> Bahadur, G.: The Human Rights Act (1998) and its Impact on Reproductive Issues. *Human Reproduction* Vol.16, No.4 (2001) p. 785

previous chapter, where it has been highlighted that as a result of the fact that ‘PGD is not specifically mentioned in the HFE Act’, its limits cannot be defined by a statute.<sup>178</sup>

In light of the newest ground-braking Italian case in relation to PGD, I would also suggest that the discourse of Human Rights and the HR Act itself offers a very limited protection against the development of novel treatment procedures in the UK. As the latest groundbreaking Italian case in front of the ECHR also underpins, human rights in the arguments around PGD are rather used for the protection of the woman’s right to physical integrity and the couples’ right to reproductive autonomy.

However, it seems to be necessary to emphasize that the HR Act has not become such an integral part of the debates around PGD. This is also underlined by the fact that in the litigation in relation to PGD and cases of reproductive issues it has been appealed to the Court only a couple of times on the basis of the HR Act.<sup>179</sup>

In summary, this means that the HR Act in the UK, rather than setting limits to novel treatment procedures, could on the opposite counterweight ethical arguments and help keeping up with scientific development. This result seems to be very similar to the role of the German Basic Law and its interpretation with regards to the same question in Germany. A conclusion is likely, that the human rights discourse itself does not provide for sufficient limits against a potential extension in PGD’s application and enough safeguards against slippery-slope arguments.

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<sup>178</sup> Ibid. 788

<sup>179</sup> The Human Rights Act (1998) and its impact on reproductive issues. 16(4) Human Reproduction (2001) p. 785-789

The reason for this seems to be, that in the debates around PGD's application, the principles of equal rights of people living with disabilities and non-discrimination do not seem strong enough. One of the causes for this could be the many contested and mostly unanswered questions in relation to the status of the embryo and the embryo's right to life. Instead, the human rights discourse in the debates about PGD supports arguments based on equality of sexes, non-discrimination in terms of family status, couples' privacy and women's right to physical integrity.

## **CONCLUSION AND EVALUATION: ADVANTAGES AND DISADVANTAGES OF THE GERMAN AND THE UK SYSTEM**

At the beginning of the paper the question about the similarities and the differences between the German and UK legal framework in relation to Preimplantation Genetic Diagnosis' regulation was unclear. When looking at the two pieces of legislation and the two systems' basic construction, one might have the feeling that there are no fundamental differences in the two regulations. From the same argument the conclusion follows that arguments labeling the two systems differently are not well grounded. However, after having analyzed the decision-making process, previous ethical debates and legal boundaries of PGD's application in the two countries the conclusions presented below follow.

First of all, it seems that the initial statements about the two systems' similarities were not absolutely correct. It is true that there are some similarities, including the establishment of a licensing center and the process of licensing. However, the analysis has shown that the two responsible authorities' functions are not as similar as they appear to be. While the Human Fertilisation and Embryology Authority is a centralized institution responsible for not only the licensing of clinics and PGD itself, but for research and reviewing policies, the German Ethics Committees will have a strongly limited power and role.

The future German Ethics Committees clinics will only be responsible for deciding about individual PGD applications on a case-by-case basis. It is the German Courts that will have review power over the decisions made by the Ethics Committees, and Parliament will be responsible for any changes in the text of the German Embryo Protection Law. It needs to be emphasized here that there is a contrast between the UK practice of licensed clinics deciding about individual applications on a

case-by-case basis and the German Ethics Committees regulating on a case-by-case basis. In Germany, licensed clinics will only implement the German Ethics Committees' decision. Consequently, it seems to be more likely that the German Ethics Committees will have a stronger surveillance and responsibility in setting limits to the introduction of novel treatment method procedures than the HFE Authority.

In relation to differences in two pieces of legislations, it is also important to stress that while in the new German Embryo Protection Law (ESchG) PGD has textual basis and the conditions of its practice are also somewhat regulated in detail within the law itself, in the HFE Act they are not. The UK piece of legislation does not even mention PGD explicitly. There is only an indirect reference to its application within the text. It is likely that this is one of the main reasons why the HFE Authority could easily change its practice and introduce novel treatment methods by only changing the interpretation of the text

The same argument is linked to the issue about the checks and balances in the German system that seem to be working better than in the UK. While in the UK, the HFE Authority has by the power of law itself a stronger discretionary power, which has been confirmed by the House of Lords in several cases, the powers of the German Ethics Committees will be much under control by Parliament and Courts. Overall, it seems unlike Germany in the UK there is no well-functioning supervisory body over the HFE Authority.

Since the House of Lords' jurisdiction has only confirmed this discretionary power and withdrew from questioning the HFE Authority's decisions, only public consultations within the Authority's policy review could fulfill certain supervisory functions. However, these consultations' analysis has

proved that they do not seem to have a real control over the HFE Authority and they are not true forms of democratic procedure. Rather, they are another form of consultations within a narrow circle of relevant experts.

In contrast to Britain, in Germany apart from medical scientists, ethics councils and committees have also participated in the debate about PGD's regulation. Likewise, ethical concerns seem to have less relevance within the UK system, where as it has been shown that not single authority or body has seriously considered ethical issues in relation to PGD, such as the status of the embryo or the embryo's right to life.

In contrast to the UK, in Germany several professional organizations and ethics councils have repeatedly emphasized the importance and the relevance of ethical concerns in relation to PGD. From these arguments the conclusion follows that it is very likely that ethical concerns play a stronger role in the German society than in the UK. This also means that it is less likely that changes in PGD's application can happen as easily and are as weakly transparent as in the UK.

The arguments above seem to underline and confirm opinions highlighting the differences between the UK's past development and the German potential future development in relation to PGD. As a result of the differences in the decision-making procedures, the two responsible Authorities' discretionary powers and the whole society's approach to ethical issues and concerns around PGD applications confirm the correctness of the differentiation between the two approaches.

While the original research question has thus been answered, one question has been left unanswered. This is the issue of the advantages and disadvantages of the two systems. The answer

is implied in the above stated arguments and some reference has also been made to these issues within the analysis itself. In a nutshell, if the two systems were to be labeled somehow, the UK system could be labeled as ‘pragmatic’, while the German system as ‘normative’.

The labels imply the followings. The UK system is much more focused on following scientific development and research and on being able to easily adapt to the fast changing technological environment. This also means that as technology advances there will always be novel treatment methods and practices available. In addition, such sensitive issues as IVF and PGD – which involve embryo creation, manipulation, genetic testing and selection – will always have ethical consequences.

One way of solving this problem between advancing technology and ethical concerns is to try balancing between these two aspects. It appears that the UK has chosen to neglect ethical concerns in relation to PGD and chose rather to keep practices and novel treatment methods up to date with the changing technology.

New treatment methods and novel technologies will also have some influence on rights in possibly all aspects of life. From the analysis, it has also transpired that human rights arguments for or against PGD can be raised on both sides. However, it seems that the relevance of reproductive autonomy has triumphed in the human rights discourse in relation to PGD, and non-discrimination and the equality of people living with disabilities are only present as ethical concerns in the debate.

From the essence of reproductive autonomy it follows that the human rights discourse in relation to PGD seems to strengthen the introduction of PGD’s novel treatment methods, which is confirmed in

the ECHR's new Italian case. Without making reference to the general concept or nature of human rights, the example of PGD's application and reproductive autonomy suggest that keeping available services in harmony with new technologies allows for fulfilling new interpretations of human rights.

In contrast, the German system in relation to PGD's regulation has truly stayed much more 'conservative' and somewhat 'normative' when it comes to new technologies of reproductive methods. German decision-makers and scientists seem to have been quite reluctant in introducing new methods. Rather than easily following technologies' new trends, they chose to stay reserved in allowing for a compatibility between new technologies and available treatment methods, ethical concerns and expanding human rights interpretations.

The question about which of the two systems will remain more sustainable in the long run is open at this moment. The specific issue whether the German regulation will finally change its approach, and despite the differences and constant ethical debates and strict control over IVF-technologies in the society and within decision-makers, will eventually lead to the same outcome as what is in practice in the UK is still too early to answer.

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