Chapter 2: Preimplantation Genetic Diagnosis

A. Preimplantation Genetic Diagnosis in Germany

I. PGD in the Embryo Protection Act

1. Ethical Approach

Discussions on the possibility of a law regulating medically assisted reproduction started relatively early in Germany. As early as 1985 the German Medical Association (*Bundesärztekammer,* BÄK) published its first guidelines on IVF as a fertility treatment.[768] Moreover, an interdisciplinary working group had already been set up the previous year by the Federal Minister of Research and the Federal Minister of Justice. The Working Group on In Vitro Fertilisation, Genome Analysis and Gene Therapy worked under the leadership of the former President of the Federal Constitutional Court, Ernst Benda, and is therefore known as 'Benda Commission'.[769] The 19 members of the commission included representatives of the medical and scientific communities as well as of the two major churches in Germany, Catholic and Protestant.[770] Both the guidelines of the German Medical Association and the report of the federal Working Group mentioned that diagnosis of a genetic condition before implantation in the uterus of the future mother could be deemed acceptable if it would prevent a later abortion.[771] However, a definitive stance on the matter would have been

768 Bundesärztekammer, 'Richtlinien zur Durchführung von In-vitro-Fertilisation (IVF) und Embryotransfer (ET) als Behandlungsmethode der menschlichen Sterilität' (1985) 82(22) Deutsches Ärzteblatt p. 1691, as reported by Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 65.

769 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 65; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 41; Eberbach, 'Eine kurze Geschichte der Fortpflanzungsmedizin bis zur Eizellspende' (2020) 38(3) MedR p. 167, 168; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 97.

770 As reported by Eberbach, 'Eine kurze Geschichte der Fortpflanzungsmedizin bis zur Eizellspende' (2020) 38(3) MedR p. 167, 168.

771 Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p.40.

premature as preimplantation genetic diagnosis was still an experimental method at the time.[772]

Ethical concerns were also at the forefront of the debate with regard to fertility treatments in general. It was therefore decided to place the protection of the embryo at the core of the legislation, which was enacted in 1990 and took the title of the Embryo Protection Act (*Embryonenschutzgesetz*, ESchG).

The declared aim of this legislation was to prevent any form of manipulation of human life.[773] The ethical stance of the law is clearly stated in the document accompanying the draft legislation that was proposed by the federal government. It is claimed that the legislature must above all take into account the Basic Law's resolution to protect human life and it is specified that the draft assumes that human life already comes into being with the nuclear fusion within the fertilised egg cell.[774] As a consequence, criminal protection was provided against the "abusive use of reproductive techniques"[775] and the "abuse of human embryos"[776] during medically assisted procreation procedures. The decision to regulate the matter by means of criminal law was certainly a choice of values, since the criminal law was considered a useful tool for conveying moral convictions and the need to protect the interests of the unborn child.[777] Yet one also must mention that the choice to intervene by means of the criminal law was dictated partly by by the fact that this was an area of the law in which the federal legislature had the competence to enact legislation. A federal legislative competence in the field of reproductive medicine was lacking at that stage[778] and the fed-

772 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 67; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 97.

773 Deutscher Bundestag, 'BT-Drucks. 11/5460. Gesetzentwurf der Bundesregierung: Entwurf eines Gesetzes zum Schutz von Embryonen (Embryonenschutzgesetz - ESchG)' (25.10.1989), p. 1 <https://dserver.bundestag.de/btd/11/054/1105460.pdf> accessed 8.3.2022.

774 ibid, p. 6.

775 § 1 ESchG (author's translation).

776 § 2 ESchG (author's translation).

777 Eberbach, 'Eine kurze Geschichte der Fortpflanzungsmedizin bis zur Eizellspende' (2020) 38(3) MedR p. 167, 170; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 6.

778 It is only since 1994 that the federal legislature has had the power to regulate "the medically assisted generation of human life, the study and artificial modification of genetic information", as prescribed by the *Gesetz zur Änderung des Grundgesetzes*

eral legislature could therefore only regulate the field using its concurrent competence in criminal law.[779]

2. Initial Uncertainty

a Legislative Proposal and Public Debate

As a result of the early[780] and rather restrictive nature of this legislation there were highly uncertain consequences for the legal assessment of preimplantation genetic diagnosis. There was no explicit prohibition on the use of these techniques. Nonetheless, the performance of a preimplantation genetic diagnosis involves actions that could arguably fall under the scope of the Embryo Protection Act. For instance, § 1(1) no. 2 ESchG prohibited the artificial fertilisation of an egg cell with a purpose other than inducing pregnancy. Furthermore, § 1(1) no. 5 ESchG held that only as many cells could be fertilised as would actually be transferred into the woman's embryo. This number was assumed to be three, which would not be sufficient to carry out a PGD. Finally, § 2(1) ESchG criminalised the use of an embryo for a purpose other than the preservation of the embryo itself.[781] Regarding this, the legal consequence for carrying out a PGD could have differed depending on whether the diagnosis was conducted on a totipotent cell or merely on a pluripotent cell. In the former case the law regarded the cell to be equivalent to an embryo[782] and – being unavoidably destroyed in

(Artikel 3, 20a, 28, 29, 72, 74, 75, 76, 77, 80, 87, 93, 118a und 125a) (27.10.1994), BGBl I S. 3146, n. 75.

779 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 66; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 51; Eberbach, 'Eine kurze Geschichte der Fortpflanzungsmedizin bis zur Eizellspende' (2020) 38(3) MedR p. 167, 170.

780 Whereby the legislature was well aware that it would be impossible to predict all future developments in reproductive medicine, see Ruso and Thöni, 'Quo vadis Präimplantationsdiagnostik?' (2010) 28(2) MedR p. 74, 75; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 97.

781 On all those aspects, see Ruso and Thöni, 'Quo vadis Präimplantationsdiagnostik?' (2010) 28(2) MedR p. 74, 75-ff; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) pp. 99-ff.

782 According to the equivalence between totipotent cell and embryo, as laid down by § 8(1) ESchG.

the diagnosis procedure – its use would not serve its preservation.[783] The implications of these provisions for PGD were controversial and the resulting legal framework governing PGD remained uncertain.[784] As a result of this widespread uncertainty, doctors were prone to take the safe option and refrain from performing PGD procedures.

The described situation was soon considered unacceptable.[785] In 1999 the Ethics Commission of the Rhineland-Palatinate issued an opinion in favour of PGD's authorisation.[786] In the following year the German Medical Association produced another document in favour of PGD.[787] In its 'Discussion draft on a guideline on preimplantation diagnostics' the BÄK clearly stated the intention to contribute to the ongoing public debate on reproductive medicine. In particular, the document argues that the decision to refuse the transfer in uterus of a genetically affected embryo following a PGD is a "serious fundamental ethical decisions"[788] that belongs, firstly, to the couple involved and, secondly, to the doctor who implements the procedure. Due to the several ethical concerns raised by PGD, the German Medical Association advocated for a rather restrictive regulation that allowed PGD in more limited cases compared to traditional prenatal diagnosis. Moreover, the document suggests that PGD-commissions should be introduced. These would be in charge of examining single cases.[789] It is

783 See Ruso and Thöni, 'Quo vadis Präimplantationsdiagnostik?' (2010) 28(2) MedR p. 74, 76; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 71; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 105.

784 As pointed out by the Berlin Appellate Court (*Kammergericht*, KG) in the first relevant judicial decision on preimplantation genetic diagnosis (*KG Berlin, 9.10.2008 – 3 Ws. 139/08,* discussed later) the opinions of the legal literature were divergent. While some authors argued that PGD would be covered by criminal law under the Embyo Protection Act (see, *inter alia* Beckmann, 'Rechtsfragen der Präimplantationsdiagnostik' (2001) 19(4) MedR p. 169, 171; Böckenförde-Wunderlich, *Präimplantationsdiagnostik als Rechtsproblem: Ärztliches Standesrecht, Embryonenschutzgesetz, Verfassung* (2002) pp. 119-ff.), others claimed that PGD using pluripotent would not constitute a violation of the Embryo Protection Act (see, *inter alia*, Schneider, 'Auf dem Weg zur gezielten Selektion - Strafrechtliche Aspekte der Präimplantationsdiagnostik' (2000) 18(8) MedR p. 360, 364).

785 Ruso and Thöni, 'Quo vadis Präimplantationsdiagnostik?' (2010) 28(2) MedR p. 74, p. 78.

786 As reported by Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 62.

787 Bundesärztekammer, 'Diskussionsentwurf zu einer Richtlinie zur Präimplantationsdiagnostik' (2000) 97(9) Deutsches Ärzteblatt A525-A528.

788 ibid (author's translation).

789 ibid, A527.

foreseen that, amongst other information, the doctor would be required to include a statement on the ethical and legal acceptability of the procedure in each application.[790]

The publication of these two documents, together with several speeches and contributions by influential stakeholders, led to an intensification of public debate on PGD after the year 2000.[791]

In 2001, the first bill to regulate PGD was introduced in the Bundestag by the Free Democratic Party (FDP).[792] The draft – an almost identical version of which was later reintroduced into Parliament in 2003 – [793] argued in its problem statement that denying the possibly of PGD to couples with severe genetic conditions would be questionable for ethical and constitutional reasons.[794] In addition, the document stated the crucial need to provide couples and doctors with legal certainty on the matter. Whilst requiring that future parents undergo comprehensive medical, ethical and psycho-social counselling, as well as the approval of an ethical commission on each PGD procedure, the bill acknowledged that the decision to perform the diagnosis is ultimately a matter of conscience for the involved subjects. The ethical dimension of the procedure was reflected in the provision of

790 ibid.

791 As illustrated by Lungstras, *Der Umgang mit dem Embryo in vitro: Eine Analyse der berzeugungsstrategien in der verfassungsrechtlichen Debatte um die embryonale Stammzellenforschung und die Prïmplantationsdiagnostik* (2008) pp. 28-29, the attention for the topic increased sharply in 2001, and especially after evocative speeches given, for instance, by former President of the Max Planck Society Hubert Markl, by the former President of the German Research Foundation Erns-L. Winnakcker and by the former Federal President Johannes Rau, as well as by representatives of the Church. The Author also points out that the "contribution on genetic engineering" by the then German Chancellor Gerhard Schröderof the year 2000, calling for the removal of "ideological blinders" is regarded as the beginning of the debate on the protection of life in its early stages.

792 Parr, Leutheusser-Schnarrenberger, Schmidt-Jortzig and others, 'BT-Drucks. 14/7415. Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz - PräimpG)' (9.11.2001).

793 Deutscher Bundestag, 'BT-Drucks. 15/1234. Parr, Flach, Funke et al.: Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG)' (25.6.2003) <https://dserver.bundestag.de/btd/15/012/1501234.pdf> accessed 15.8.2022.

794 Deutscher Bundestag, 'BT-Drucks. 14/7415. Parr, Leutheusser-Schnarrenberger, Schmidt-Jortzig et al.: Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz - PräimpG)' (9.11.2001), p. 1 <https://dserver.bundestag.de/btd/14/074/1407415.pdf> accessed 15.8.2022.

a conscience clause that protected all individuals unwilling to take part in PGD procedures.

In the section on cost estimation the issue of PGD reimbursement was touched upon. The draft mentioned that the use of PGD could entail costs if it was recognised to be eligible for public subsidy. The costs of statutory health insurance would also be increased in the event that PGD was approved as a new method of examination and treatment by the Federal Commission of Physicians and Health Insurers (at the time exercising the functions of the current G-BA).

In its first examination before the Bundestag accusations were made that the draft was dealing too hastily with complicated ethical issues[795] and was subsequently no longer pursued.

During these same years a 'Study Commission on Law and Ethics in Modern Medicine' was set up by the Bundestag. It had the task of developing recommendations for the ethical evaluation of – and for legislative and administrative action with regards to – medical issues in the future.[796] The Parliament wished the Commission to participate in the discussion of legislative proposals and to contribute to deepening the public debate on issues related to the developments in modern medicine.[797]

In its final report of May 2002 the Commission outlined in detail the ethical[798] and the legal[799] discussion points on preimplantation genetic diagnosis. The Commission unanimously agreed that this issue should be dealt with by the Parliament by balancing the different constitutional interests involved. In their final vote only a minority of the Study Commission members recommended that PGD should be allowed for couples with high genetic risk, albeit with several restrictions.[800] According to this minority, criminal sanctions should only aim at ensuring minimum ethical standards

795 Deutscher Bundestag, 'Plenarprotokoll 14/209: 209. Sitzung' (Berlin 14.12.2001), pp. 20787-ff. See, in particular, the speeches given by MPs Seifert and Böhmer.

796 As reported by the final report of the Commission, Deutscher Bundestag, 'BT-Drucks. 14/9020: Schlussbericht der Enquete-Kommission „Recht und Ethik der modernen Medizin"' (14.5.2002), p. 7.

797 ibid.

798 ibid, pp. 95-ff.

799 ibid, pp. 101-ff.

800 A (partial) liberalisation of PGD under very restrictive conditions was supported only by three members of the commission, see Deutscher Bundestag, 'BT-Drucks. 14/9020: Schlussbericht der Enquete-Kommission „Recht und Ethik der modernen Medizin"' (14.5.2002), p. 107.

in a society rather than at enforcing particular ethical behaviours.[801] However, the vast majority of the commission[802] advocated for an explicit blanket ban of PGD in the law. This had the aim of protecting the life of the embryo and of creating an institutional framework that prevented discrimination against persons with disabilities. The Commission used the slippery slope argument: it argued that the conditions and restrictions initially imposed on the implementation of an ethically controversial technology would eventually be loosened.[803] The case of prenatal diagnosis was taken as an example, as its practice increased after its inclusion in the GKV. In this regard, reimbursement by the statutory healthcare insurance was seen as one of the factors expanding the scope of application of prenatal diagnosis.[804] The commission concluded that the German public healthcare system favoured the expansion of service provision on both the supply and demand sides.[805]

b Case Law

Despite the illustrated increase in public and political debate on the issue, the uncertainty over the legal framework of preimplantation genetic diagnosis was eventually only resolved by the legislature after developments in the case law. The first relevant decision on PGD came from the Berlin Appellate Court *(Kammergericht*, KG). The case concerned a doctor who, after having performed various PGD procedures on pluripotent cells, self-reported this activity to the Berlin public prosecutor's office with the intention of bringing about a clarification of the legal situation. Initially the prosecutor stated that the doctor misunderstood the prohibition,[806] which excused his behaviour. They added that it was not the task of the prosecutor

801 ibid, p. 109.
802 With 16 votes, see Deutscher Bundestag, 'BT-Drucks. 14/9020: Schlussbericht der Enquete-Kommission „Recht und Ethik der modernen Medizin"' (14.5.2002), p. 111.
803 See Chapter 1, sec. A.I.3.b.
804 Deutscher Bundestag, 'BT-Drucks. 14/9020: Schlussbericht der Enquete-Kommission „Recht und Ethik der modernen Medizin"' (14.5.2002), pp. 74-ff.
805 ibid, p. 82.
806 According to § 17 of the German Criminal Code (*Strafgesetzbuch*, StGB).

to make abstract statements on the legality of certain actions.[807] Later the case was raised by another public prosecution official whose request for a reopening of the case was surprisingly[808] refused by the Regional Court (*Landesgericht*, LG) Berlin.[809]

An appeal before the KG, however, successfully reopened the procedure and assigned the case to a different section of the LG Berlin. In its decision, the KG argued that the embryos were created by the doctor without the purpose of inducing a pregnancy, thus violating § 1(1) no. 2 ESchG. Moreover, the defendant had used human embryos for a purpose other than their own preservation in breach of § 2(1) ESchG. In the course of making these observations the court held that the intention of the legislature had to be taken into account. By referring to the original normative choice of the Basic Law in favour of life and human dignity, the Embryo Protection Act would accordingly be based on the assumption that human life exists as soon as the fertilisation process is completed. Therefore, any action that is undertaken with the purpose of benefitting others, and which does not serve the preservation of the embryo, would be prohibited. Human life cannot be instrumentalised for the benefit of others. Against this background the decision was criticised because it was solely based on a historical interpretation of the legislature's purpose and did not take into account a possible fundamental rights driven approach.[810]

The LG Berlin, to which the case was referred, ruled a second time in favour of the doctor.[811] The court stated that the historical intention of the Parliament could not be considered decisive. Indeed, the legislation of the time could not take a clear stand against PGD, since such procedures were not yet sufficiently developed to be performed in a clinical setting. Moreover, the court pointed to the fact that women have a right to abortion under § 218a(2) of the German Criminal Code in the case of a genetically affected embryo that is discovered through prenatal diagnosis. In the opinion of the judges, in light of Article 2 of the Basic Law (right to life and physical integrity), it would be unconstitutional to oblige a pregnant woman to wait until the beginning of her pregnancy to obtain information about

807 Spranger, 'Strafbarkeit der Präimplantationsdiagnostik: Anmerkung zu KG, Beschl. v. 9. 10. 2008' (2010) 28(1) MedR p. 36, 40. See, also, Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 69.

808 Frister, *Wissenschaftsrecht und Wissenschaftspraxis* (2014) p. 117.

809 LG Berlin, 14.5.2009 - (512) 1 Kap Js 1424/06 KLs (26/08).

810 Spranger, 'Strafbarkeit der Präimplantationsdiagnostik' (2010) 28(1) MedR p. 36, 41.

811 LG Berlin, 14.5.2009 - (512) 1 Kap Js 1424/06 KLs (26/08).

the embryo's state of health. The court therefore called on the legislature to provide appropriate regulation.

Eventually, the case was brought to the attention of the highest court of civil and criminal jurisdiction, the Federal Court of Justice (*Bundesgerichtshof, BGH*). In its decision of 6 July 2010, the BGH confirmed that the performance of PGD was not punishable under the current Embryo Protection Act.[812] According to the court, the defendant's action was indeed guided by the aim of inducing a pregnancy, thus not constituting a punishable offence according to § 1(1) no. 2 ESchG. In this respect, the fact that the transfer of the embryo and the actual start of the pregnancy were conditional on the result of the diagnosis did not affect the initial intention to start a pregnancy. The court observed that the entire fertilisation process had been extraordinarily stressful for the patients and would not have been completed had it not been for the purpose of the planned pregnancy.[813]

The BGH largely based the legitimacy of its decision on an analysis of the historical intention of Parliament and on the evaluative choices found in the Embryo Protection Act,[814] albeit reaching the opposite conclusion to the KG. The BGH observed that, at the time of the adoption of the Embryo Protection Act, PGD techniques were not yet sufficiently developed.[815] In this context the legislature intended to prevent the performance of a diagnosis on totipotent cells, which are actually subsumed under the legal definition of an embryo. The possibility of carrying out PGD on a pluripotent cell without harming the embryo itself had, by contrast, not been considered. In addition the Court referred to § 3 ESchG. This allows sex selection of the sperm in order to avoid a hereditary sex-related illness of the child.[816] According to the Court, this provision enshrined a choice of

812 BGH, 6.7.2010 - 5 StR 386/09.

813 BGH, 6.7.2010 - 5 StR 386/09, para. 19.

814 Indeed, the BGH focused its legal assessment of PGD around the evaluation of value choices done by the legislature in the Embryo Protection Act. As sustained by Jens Kersten, this led to an insufficient consideration of constitutional law in the legal assessment of PGD by the BGH, with negative consequences for the legitimacy of the judgment, see Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) pp. 127–130. See also comments by Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 71.

815 For a critique of the BGH's argument on this point, see Kersten in Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013) p. 100.

816 The parallel drawn by the Court has been criticised since the choice of value made by the legislature is limited to the treatment of sperm cells and, according to some scholars, could not be extended by analogy to the embryo, see Dederer, 'Zur

values and was a decisive factor for the decision at issue. A married couple could not be reasonably expected to run the risk of having an affected child when sperm selection could prevent it, especially in the light of a possible subsequent abortion.[817] Similarly, if PGD were prohibited, there would be a high risk that a non-viable or seriously ill child would be born – the right to abortion would have to be guaranteed following prenatal testing.[818] By reconciling the legislature's choices with a coherent system of values,[819] the Court held that selection must be permitted at least in cases that, in light of a possible serious genetic defect in the foetus, would fall within the scope of the medical-social indication justifying an abortion at a later stage of fetal development.[820]

Moreover, in the BGH's opinion, PGD was not in breach of the prohibition under § 2(1) ESchG to use a human embryo for a purpose other than its preservation. The court noted that the provision was intended to prevent the misuse of a human embryo for the benefit of others and that its main field of application was embryo research.[821]

In sum, the Federal Court of Justice ruled that a legislative intent to criminalise PGD could not be presumed. In its conclusions it argued that the lack of legal certainty could not be at the expense of the defendant and explicitly called for clear legislative intervention in this area.[822] As legal scholars observed, the judgment thus took a stance against the inactivity of the legislature.[823] The latter was alleged to be postponing the adoption of an explicit position on PGD while exploiting the situation of legal uncertainty

---

Straflosigkeit der Präimplantationsdiagnostik: Anmerkungen zu BGH, Urt. v. 6. 7. 2010 – 5 StR 386/09' (2010) 28(12) MedR p. 819, 820.

817 BGH, 6.7.2010 - 5 StR 386/09, para. 26.

818 ibid.

819 Schroth, 'Anmerkung zu BGH, Urt. v. 6.7.2010 – 5 StR 386/09' (2010) 63(36) NJW p. 2676.

820 Schumann, 'Präimplantationsdiagnostik auf der Grundlage von Richterrecht?: Anmerkung zu BGH, Urt. v. 6. 7. 2010' (2010) 28(12) MedR p. 848, 848.

821 BGH, 6.7.2010 - 5 StR 386/09, para 34.

822 BGH, 6.7.2010 - 5 StR 386/09, para. 29.

823 As commented by Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 130, the persistent applicability of an obsolete law in the absence of legislative intervention has, in the case of PGD, led to the transformation of the courts into "democratically non-legitimate legislative substitutes" (author's translation). A similar observation can be made regarding the Italian regulation of PGD, which in the absence of legislative intervention, eventually had to be entirely determined by the Italian Constitutional Court, see Chapter 2, sec. B.I.3.

and the resulting *de facto* ban.[824] At the same time the decision gave room to considerations of legal policy, for instance by indirectly addressing the issue of possible discrimination against people with disabilities.[825]

The decision was controversial. Some authors claimed that the Federal Court of Justice adopted a particular ethical stance as a basis for its decision.[826] This was because the Court assumed that PGD does not entail an instrumentalisation of the embryo for purposes other than those involved in the fertilisation process.[827]

3. Legislative Intervention

a Reform Preparation

i. The Introduction of Three Draft Bills

The legal vacuum and the situation of uncertainty brought about by the judgment of the Federal Court of Justice served as a driving force behind the reopening of the public and political debate on preimplantation genetic diagnosis.[828] In January 2011, the German Academy of Sciences Leopoldina published its opinion in favour of a limited authorisation of PGD in Germany.[829] A similar statement was issued by the German Medical Asso-

824 Schumann, 'Präimplantationsdiagnostik auf der Grundlage von Richterrecht?' (2010) 28(12) MedR p. 848, 851.

825 Kreß, 'Präimplantationsdiagnostik und Fortpflanzungsmedizin angesichts des ethischen Pluralismus.: Rechtspolitische Gesichtspunkte nach dem Urteil des BGH.' (2010) 43(7) ZFR p. 201, 202. See BGH, 6.7.2010 - 5 StR 386/09, para. 26.

826 As it has been noticed, the decision did not analyse the several existing counterarguments to this position, see Schumann, 'Präimplantationsdiagnostik auf der Grundlage von Richterrecht?' (2010) 28(12) MedR p. 848, 849; Kudlich, 'An den Grenzen von Naturwissenschaft und Strafrecht – Strafrechtliche Fragen der Präimplantationsdiagnostik: Keine Strafbarkeit nach §§ 1 Nr. 2, 2 ESchG durch die Durchführung präimplantationsdiagnostischer Untersuchungen (an nicht totipotenten) Zellen und anschließendes Absterbenlassen kranker Embryonen' (2010) 42(11) Juristische Arbeitsblätter p. 833, 835.

827 BGH, 6.7.2010 - 5 StR 386/09, para. 35.

828 As noted by Kersten in Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013) p. 102, the BGH judgment, by dictating its own regulation of PGD, has overstepped the boundaries of the principle of separation of powers, thus calling for an immediate reaction of the legislature.

829 Nationale Akademie der Wissenschaften Leopoldina, 'Ad-hoc-Stellungnahme Präimplantationsdiagnostik (PID): Auswirkungen einer begrenzten Zulassung in

ciation, which also advocated for a legal framework allowing PGD under certain conditions.[830] In its document the BÄK argued that the state should respect the ethical, religious and ideological pluralism surrounding the question of the status of an embryo. Against this background, the decision to perform PGD should remain an informed choice of the couple.[831]

In April 2011 three cross-party drafts for a Law on PGD were finally presented for debate before the Bundestag.[832]

The first draft, from MPs Göring-Eckardt, Kauder and others, envisaged a blanket ban on PGD.[833] According to the drafters PGD should be banned altogether for ethical and socio-political reasons. The performance of such a diagnosis and the subsequent embryo selection would allow a judgment to be made on the value of a life. This violated the right to equal dignity of all human beings and was ethically unacceptable.[834] The implementation of PGD would also endanger the acceptance of disabled persons and social diversity in general and would increase the pressure on parents to procreate a healthy child.[835] The legislature's duty to protect the life and dignity of the embryo allegedly derives from the premise that human life would begin with the fusion of the gametes during fertilisation.[836] The slippery slope argument was also brought forward in the explanatory memorandum.[837]

A second draft, submitted by MPs Röspel, Hinz and others, contained a limited softening towards PGD.[838] The document provided for the exceptional permissibility of PGD when a genetic predisposition of the parents gave rise to a high probability that the embryo would suffer from a condi-

Deutschland' (January 2011) <https://www.leopoldina.org/uploads/tx_leopublication/201101_natEmpf_PID-DE.pdf> accessed 6.9.2021.

830 Bundesärztekammer, 'Memorandum zur Präimplantationsdiagnostik (PID)' (2011) 108(31) Deutsches Ärzteblatt A1701-A1708.

831 ibid, A1707.

832 For a critical discussion of each draft, see Kersten in Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013) pp. 102-111.

833 Deutscher Bundestag, 'BT-Drucks. 17/5450. Göring-Eckardt, Kauder and others: Entwurf eines Gesetzes zum Verbot der Präimplantationsdiagnostik' (11.4.2011) <https://dserver.bundestag.de/btd/17/054/1705450.pdf> accessed 15.8.2022.

834 ibid, p. 3.

835 ibid, pp. 8 ff.

836 ibid, p. 8.

837 ibid, p. 9.

838 Deutscher Bundestag, 'BT-Drucks. 17/5452. Röspel, Hinz and others: Entwurf eines Gesetzes zur begrenzten Zulassung der Präimplantationsdiagnostik' (12.4.2011) <https://dserver.bundestag.de/btd/17/054/1705452.pdf> accessed 15.8.2022.

tion leading to miscarriage, stillbirth or death in the first year of life.[839] The admissibility of the procedure according to these criteria would have to be strictly monitored and judged on a case-by-case basis by an ethics commission.[840] In its cost assessment, the draft anticipated the possibility that statutory and private health insurance funds would have to cover the use of PGD in the context of reproductive treatments.[841]

The draft that allowed the most extensive use of PGD was the one signed by MPs Flach, Hintze and others.[842] Although it established a general ban on PGD, it provided for its use to be permitted in certain exceptional cases. That is, when a genetic disposition of the parents entailed a high probability of a serious hereditary disease in the foetus or possible serious damage to the embryo that would result in a stillbirth or miscarriage. The draft did not endorse the moral position of those who strictly rejected PGD[843] but, as a guarantee of high ethical standards, provided for compulsory counselling[844] and the possibility for doctors to refuse on conscientious grounds.[845] Moreover, PGD could only be carried out after a vote by an ethics commission and in authorised centres. The explanatory memorandum emphasised that legislative regulation of PGD was constitutionally necessary. An absolute ban on PGD would violate fundamental rights and the principle of proportionality.[846] In this way it stressed the need to weigh ethical concerns against the rights of women and couples. The draft did not mention any reimbursement through health insurance, but simply stated that, if funded through tax revenues, PGD would only entail limited costs due to an expected limited number of cases.[847]

All three bills introduced into Parliament resorted to the means of the criminal law to regulate the matter. The criminal law was already used in the Embryo Protection Act, driven by ethical concerns for the embryo as well as the need to ground a federal competence in the matter. Yet the

839 ibid, p. 3.
840 ibid.
841 ibid, p. 2.
842 Deutscher Bundestag, 'BT-Drucks. 17/5451. Flach, Hintze and others: Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik' (12.4.2011) <https://dserver.bundestag.de/btd/17/054/1705451.pdf> accessed 15.8.2022.
843 ibid, p. 7.
844 Which cannot be refused as it is a prerequisite for the procedure, see Scheffer, 'Zur Zukunft der Präimplantationsdiagnostik in Deutschland' (2011) 20(1) ZfL p. 9, 12.
845 Deutscher Bundestag, 'BT-Drucks. 17/5451. Flach, Hintze and others', 12.4.2011, p. 9.
846 ibid, p. 7.
847 ibid, p. 3.

Federal legislature had been assigned the competence to legislate on human reproductive and genetic medicine with a reform of the Basic Law in 1994.[848] However – presumably due to the ethical issues affecting reproductive rights and policies in general and to the time pressure imposed by the BGH judgment – the choice was once again made for regulation through criminal law and against a more comprehensive piece of legislation.[849] As was the case with the Embryo Protection Act, the use of the criminal law conveys a general and fundamental moral disapproval of PGD on the part of the legislature.[850] It fails to promote access to the procedure as an implementation of the right to self-determination and physical integrity of women and couples.[851]

ii. Opinion of the German Ethics Council

In March 2011 the German Ethics Council issued an opinion on PGD that was communicated to the Federal Government and subsequently taken into account in the legislative procedure.[852] Since there was no unanimous consensus, the Council members developed two different alternative recommendations for a legal regulation of PGD and one member of the Council attached a separate opinion.[853]

A narrow majority of the members (thirteen members) stated in its recommendation that PGD would be ethically justified if certain restrictions applied and that its authorisation by law would indeed be constitutionally required, albeit within certain limits.[854] In particular, the majority of the Council suggested that the termination of an advanced pregnancy might involve much greater trauma for the woman than the possibility of obtaining early information about the embryo's state of health with PGD. The same

848 As noted, *inter alia*, by Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 51.
849 ibid, p. 80.
850 Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 7.
851 Hufen in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) pp. 134-ff.
852 Deutscher Ethikrat, 'Präimplantationsdiagnostik: Stellungnahme' (2011) <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-praeimplantationsdiagnostik.pdf> accessed 6.9.2021.
853 ibid, p. 152.
854 ibid, pp. 80-ff.

would apply to miscarriages and stillbirths. The risk of serious disease, disability or stillbirth should be gauged by reference to the genetic disposition of the parents. Accordingly, the majority opinion essentially endorsed the draft by Flach, Hintze and others,[855] *inter alia* with regard to the need to conduct PGD only in a limited number of certified centres and the requirement for psychosocial counselling. Furthermore, unlike the parliamentary drafts, the Council members recommended that "an appropriate amount" of the costs of PGD should be borne by the statutory health insurance.[856]

By contrast, the minority position maintained that PGD should be subject to a complete legislative ban. According to this group of eleven Council members the ethical assessment of PGD could not depend solely on the desire, albeit understandable, to have a healthy child or avoid stillbirths and abortions. The selective intention of the procedure would make it, from an ethical point of view, fundamentally different from the conflict that arises during a pregnancy. The fear of a slippery slope was expressed, and graphically represented in a table claiming that allowing PGD to detect conditions incompatible with life would inevitably lead to the selection of embryos with other desirable characteristics such as eye colour.[857] Concern was also expressed that "funding of PGD by health insurance funds would [...] be likely to stimulate demand for it"[858].

iii. Parliamentary Debates

Because of the strong ethical concerns involved in the issue, the debate conducted in Parliament was not tied to the division of political parties and freedom of conscience was granted to each MP as an exception to group discipline.[859] Ethical and religious arguments carried great weight in

855 As noted by Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 83.
856 Deutscher Ethikrat, 'Präimplantationsdiagnostik' (2011) p. 84 (author's translation).
857 See the table 'Eskalationsstufen der Präimplantationsdiagnostik' in Deutscher Ethikrat, 'Präimplantationsdiagnostik: Stellungnahme' (2011) p. 126 <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-praeimplantationsdiagnostik.pdf> accessed 6.9.2021.
858 ibid, p. 133 (author's translation).
859 As reflected in the cross-party votes and highlighted in several speeches during the plenary session, for instance by Kathrin Vogler, Deutscher Bundestag, 'Plenarprotokoll 17/120: 120. Sitzung' (Berlin 7.7.2011), p. 13885; see also Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 77.

the plenary debate and played a very important role in the speeches made before the assembly by both supporters of a general ban and those of a limited PGD authorisation. [860]

According to the authors of the drafts containing the most favourable regulation of PGD it would be ethically irresponsible and immoral to deprive a woman of knowledge that is relevant to her physical and mental health. Sharing such information would, conversely, guarantee her self-determination in the decision to implant the embryo.[861]

On the opposite side, the ethical argument of the slippery slope was invoked several times. According to this, allowing PGD for serious hereditary diseases would inevitably lead to an expansion of the cases in which its use would be permitted until selection would be made on the basis of gender or eye colour. [862]

Explicitly religious arguments were primarily raised by opponents of PGD,[863] who argued that PGD would contradict the Christian view of humanity[864] and the religious notion of life as a gift.[865] Similarly, several members of Parliament expressed their views on the beginning of life. Proponents of Christian doctrine claimed that human life begins with the fusion of gametes and is thereafter worthy of protection,[866] while PGD sup-

860 Naturally, some participants were neither completely for nor entirely against PGD and were looking for a possible middle ground in the compromise draft. However, for simplicity, the arguments can be divided into those for and against PGD, following the classification of the debate into two compartments, as indicated by Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 82.

861 See speeches by Ulrike Flach and Peter Hintze, Deutscher Bundestag, 'Plenarprotokoll 17/105: 105. Sitzung' (Berlin 14.4.2011), pp. 11946, 11949.

862 See speeches by Günter Krings, René Röspel, Julia Klöckner, Katrin Göring-Eckardt, Maria Flachsbarth Wolfgang Nešković and Jens Spahn in Deutscher Bundestag, 'Plenarprotokoll 17/105: 105. Sitzung' (Berlin 14.4.2011), pp. 11947 ff. and by Maria Böhmer, Elisabeth Winkelmeier-Becker and Franz-Josef Holzenkamp in Deutscher Bundestag, 'Plenarprotokoll 17/120', Berlin 7.7.2011, pp. 13897-ff.

863 But occasionally also by the supporters of PGD, especially when arguing for the woman's right to procreate a child: see speeches by Wolfgang Börnsen and Jens Koeppen in Deutscher Bundestag, 'Plenarprotokoll 17/120: 120. Sitzung' (Berlin 7.7.2011), pp. 14161, 14171.

864 On the Christian *Menschenbild* see the speeches by Hartmut Koschyk, Maria Böhmer and Philipp Mißfelder in Deutscher Bundestag, 'Plenarprotokoll 17/120: 120. Sitzung' (Berlin 7.7.2011), pp. 14159 ff.

865 See arguments brought forward by Thomas Rachel and Volkmar Klein in Deutscher Bundestag, 'Plenarprotokoll 17/120: 120. Sitzung' (Berlin 7.7.2011), pp. 14171, 14176.

866 As sustained, for instance, by Günter Krings in Deutscher Bundestag, 'Plenarprotokoll 17/105', Berlin 14.4.2011, p. 11947 and by Franz-Josef Holzenkamp and Patrick

porters argued that legislation should not be based on a personal religious position.[867]

Opponents of PGD have also argued that the embryos are already entitled to have their human dignity protected and that selecting them according to desired characteristics would result in their treatment as mere objects, thus failing to guarantee this dignity.[868]

This brief overview shows how the debate on this issue in the Bundestag has been marked by strong ethical and ideological stances. In addition, ethical arguments have been used to support a specific reading of rather vague legal or constitutional concepts, such as dignity and the right to life.[869] These are attempts to give legally binding force to personal religious and ethical convictions by *de facto* transposing them into law.

On 25 May 2011 a public hearing on the three bills was held before the Committee on Health (*Ausschuss für Gesundheit*) of the Bundestag. On that occasion several experts were invited to give their opinion on PGD and answer the questions of MPs. Thanks to the wide range of disciplines represented by the experts – including constitutional law scholars,[870] medical doctors, experts in ethics and theology, and representatives of people with disabilities – the committee addressed social, ethical, medical and legal issues related to preimplantation genetic diagnosis.

The issue of PGD financing was also addressed by some of the experts in response to questions from MPs. It was maintained that funding should be provided for through the public health system,[871] but that an active intervention of the legislature would be necessary to include PGD in the statutory health insurance's benefit basket.[872] In its conclusive report the committee recommended that a decision be taken by a plenary session of

Schnieder in Deutscher Bundestag, 'Plenarprotokoll 17/120', Berlin 7.7.2011, pp. 14170, 14179.

867 See Karl Lauterbach in Deutscher Bundestag, 'Plenarprotokoll 17/120: 120. Sitzung' (Berlin 7.7.2011), p. 13900.

868 Rudolf Henke and Patrick Sensburg, Deutscher Bundestag, 'Plenarprotokoll 17/105', Berlin 14.4.2011, pp. 11965, 12119; Wolfgang Thierse, Maria Michalk, Pascal Kober, Elisabeth Winkelmeier-Becker and Hartmut Koschyk, Deutscher Bundestag, 'Plenarprotokoll 17/120', Berlin 7.7.2011, pp. 13881-ff.

869 See the analysis of the debate by Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 145.

870 And namely, Ernst-Wolfgang Böckenförde and Matthias Herdegen.

871 Deutscher Bundestag, 'Ausschuss für Gesundheit, Protokoll Nr. 17/42: Wortprotokoll 42. Sitzung' (Berlin 25.5.2011), p. 46.

872 ibid.

the German Bundestag, taking into account the recommendations of the Ethics Council.[873]

b Introduction of §3a Embryo Protection Act

In its session of 7 July 2011, the Bundestag finally voted in favour of the more permissive draft law presented by MPs Flach, Hintze and others. After approval by the Bundesrat, the Preimplantation Genetic Diagnostic Act thus entered into force in December 2011.[874] This Act adds a § 3a to the Embryo Protection Act. According to this PGD is generally criminalised but may be performed in certain exceptional cases. Namely, PGD may be conducted if either there is a high risk of a serious hereditary disease for the offspring due to the genetic disposition of the future parents or the diagnosis is aimed at detecting serious damage to the embryo that could result in stillbirth or miscarriage (§ 3a(2) EschG).[875]

When these conditions for the exceptional cases are met, PGD can still only be undertaken after compliance with certain procedural safeguards set out in § 3a(3) EschG. According to § 3a(3) sentence 1 no.1, it is necessary to provide information and counselling regarding the medical, psychological and social consequences of the procedure. Moreover, a positive assessment of the individual case must be made by interdisciplinary ethics commissions that are attached to PGD centres (§ 3a(3) no. 2). As for the latter, they must be approved and have the necessary diagnostic, medical and technical facilities to perform PGD. The performance of PGD in disregard of these procedural requirements is classified as an administrative offence by § 3a(4) EschG and is punished with a fine of up to fifty thousand euros. The law also provides for a conscience clause for doctors. Hereby no doctor is obliged to perform or cooperate with PGD and no disadvantage may arise from their refusal (§ 3a(5) EschG). § 3a(3) sentence 3 EschG specifies that all details concerning the authorisation of PGD centres and the procedure before ethics commissions are delegated to be specified in an ordinance of the Federal Government.

873 Deutscher Bundestag, 'BT-Drucks. 17/6400: Beschlussempfehlung und Bericht des Ausschusses für Gesundheit (14. Ausschuss)' (Berlin 30.6.2011).

874 Gesetz zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz - PräimpG) vom 21.11.2011, BGBl. I 2011, p. 2228.

875 See Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 423.

c Ethics and Law in PGD Regulation

In the German debate, preimplantation genetic diagnosis has been perceived as highly ethically controversial. The public, scientific and parliamentary discussions preceding the adoption of the Preimplantation Genetic Diagnosis Act were characterised by a mixture of legal and ethical arguments. As mentioned above, religious representatives also actively participated in the debate and brought forward concerns related to the Christian view of life.[876] The debate was conducted with a particularly dramatic tone[877] and it was labelled as lacking in rationality.[878] If we divide the debate into two clusters, [879] then purely ethical arguments were arguably used primarily by opponents of PGD.[880]

In various ways ethical concerns played an important role in deciding the scope of § 3a of the Embryo Protection Act. Some authors have, for instance, suggested that ethical difficulties might have been an obstacle to a more comprehensive legislation on reproductive medicine.[881] Instead of turning once again to the criminal law, the legislature could have reformed the field for all aspects requiring regulation.[882] The use of the criminal law was, however, suitable for expressing a certain moral judgment of fundamental disapproval of PGD.[883]

Ethical considerations were also reflected in the legal debate and thus largely influenced it.[884] Indeed, one of the features of the German debate on

876 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 1.

877 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440; Gutmann in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 61.

878 Herdegen in Dürig, Herzog and Scholz, *Grundgesetz: Kommentar* (2021) para. 59; Hilgendorf in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 175.

879 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 82; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 1.

880 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440.

881 Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 81.

882 As for instance the reimbursement by the GKV, later addressed in this section at para. II.

883 Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 6.

884 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 441; Frommel, 'Die Neuregelung der Präimplantationsdiagnostik

PGD is that ethical arguments have often been disguised as a form of legal reasoning; arguments grounded in the law might better achieve the aim of persuading the reader and giving an appearance of rationality.[885] This effect is reinforced by the fact that the Basic Law declares a number of principles open to interpretation through ethical standards, such as the principle of human dignity and the right to life.[886]

Especially when it comes to human dignity, the intertwining of ethical, religious and legal arguments occurs frequently.[887] The concept is difficult to grasp in purely legal terms and the use of ethical language to allege the violation of human dignity is particularly suited to conveying a clear message of disapproval with considerable persuasive force.[888] The Federal Constitutional Court has also adopted arguments that originally belonged to ethical reasoning, such as the idea that the embryo's potential[889] to develop into a human being is sufficient to establish its dignity.[890] As a result, some authors have noted that the argument of dignity and the associated statements of the constitutional court lend themselves to instrumentalisation. They open an avenue through which purely religious or ethical views can enter into the legal debate on PGD.[891] However, the Federal Constitutional Court has used this argument – admittedly criticised by

durch § 3a Embryonenschutzgesetz' (2013) 68(10) JZ p. 488, 492; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 89.

885 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 126.

886 As noted by Heun in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 104, "[c]onsequently, nowhere is the ethical debate better reflected in the constitutional debate than in Germany". See also, Gethmann and Huster in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 10; Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung: Festschrift für Friedhelm Hufen zum 70. Geburtstag* (2015) p. 46.

887 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 138; Furkel in Feuillet-Liger and Orfali, *The Reality of Human Dignity in Law and Bioethics* (2018) p. 45.

888 Gutmann in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 62.

889 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 145.

890 See BVerfG, 25.2.1975 - 1 BvF 1/74, in BVerfGE 39, 1 (41), as pointed out by Starck in Mangoldt, Klein and Starck, *Grundgesetz: Kommentar* (7th edn 2018) para. 18.

891 Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para 63; Hufen in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 129.

some authors –[892] only in relation to the embryo after its implantation in uterus and, specifically, after the beginning of the pregnancy.[893]

The very argument that PGD violates the embryo's human dignity because of the resulting instrumentalisation of the embryo[894] is also based on a purely ethical point of view. One could argue that PGD in itself is simply the diagnosis of a genetic condition that does not directly imply a diminishing of the embryo's worth.[895] Any selection of embryos for implantation is made only later, possibly on the basis of information obtained from the diagnostic procedure. Moreover, the decision not to implant an embryo is not based on the embryo being considered unworthy, but on the personal choice of the future parents as to their capacity to raise a child affected by a serious genetic disease.[896] This perspective is also endorsed by the BGH in its judgment of 2010, which holds that the practice of PGD does not constitute an instrumentalisation of the embryo. This is because the diagnosis forms an integral part of a process aimed at ensuring the successful development of a pregnancy.[897] Therefore many authors argue that instrumentalisation, and therefore violation of human dignity, would only occur in cases where future parents wish to perform the diagnosis for arbitrary, superficial or aesthetic reasons. This is not the case when the diagnosis is aimed at detecting possible health problems that threaten the development of the foetus or the future child.[898]

892 Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para. 63; Heun in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 116.

893 As noted by Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para. 63, the Federal Constitutional Court has so far explicitly affirmed the embryo's human dignity only from the complete implantation of the fertilized egg in the uterus.

894 Sustained, *inter alia*, by Starck in Mangoldt, Klein and Starck, *Grundgesetz* (2018) para. 102; Hillgruber in Epping and Hillgruber, *Grundgesetz Kommentar* (3rd edn 2020) para. 25.

895 Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para. 113; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 108.

896 Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 108.

897 BGH, 6.7.2010 - 5 StR 386/09, para. 35. See also Dreier in Dreier, *Grundgesetz: Kommentar* (3rd edn 2013) para. 97.

898 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 446; Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para. 113; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 231; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019)

Regardless of the outcome, the question of whether there is such an instrumentalisation, with a consequent violation of human dignity, appears to be one that can only be answered with an ethical approach.[899] Rather, a purely legal approach would aim at answering different questions, regarding both the interference in the women's and couples' rights that can be justified under constitutional law[900] and the coherence of the legal system.[901] In other words, posing the question in terms of instrumentalisation already sets the framework for an ethical rather than a legal answer. Within the legal system, the answer to the question of the admissibility of PGD must be found in the terms of constitutional law.[902]

Referring back to what has been amply illustrated in Chapter 1, an ethically neutral state cannot endorse one particular ethical conception and use the resulting prescriptions to substantiate principles of law that are open to interpretation, such as the principle of human dignity.[903] According to the concept of neutrality as neutrality of justification, restrictions on reproductive rights must be justifiable without recourse to an ethical or religious point of view which is not universally shared in a situation of ethical and religious pluralism.[904]

---

p. 127. Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 446

899 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) p. 166; Bögershausen, *Präimplantationsdiagnostik: Die verschiedenen Verfahren und ihre Zulässigkeit im deutschen Recht* (2016) p. 271; Gutmann in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 65.

900 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 442; Kubiciel, 'Grund und Grenzen des Verbots der Präimplantationsdiagnostik' (2013) 33(7) NStZ p. 382, 383.

901 Frommel, 'Die Neuregelung der Präimplantationsdiagnostik durch § 3a Embryonenschutzgesetz' (2013) 68(10) JZ p. 488, 490.

902 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 442.

903 See, for instance Gutmann in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 64, stating that the state must interpret constitutional concepts according to neutral, universally valid and non-ideological stances and Müller-Terpitz, *Der Schutz des pränatalen Lebens* (2007) p. 43, who warns the interpreter of the constitution against the temptation to convert their particular but legally unsubstantiated understanding of morality into positive law by invoking constitutional vagueness.

904 Kreß, 'Präimplantationsdiagnostik und Fortpflanzungsmedizin angesichts des ethischen Pluralismus.' (2010) 43(7) ZFR p. 201, 203; Bögershausen, *Präimplantationsdiagnostik* (2016) p. 274.

The problem of the coherence of the legal system is emphasised by those arguments which stress that it would be unreasonable to prohibit recourse to PGD when it is possible for the woman to resort to prenatal diagnosis after a pregnancy has already begun and to eventually obtain an abortion.[905]

Similar considerations apply to the slippery slope arguments – also widespread in the German debate on PGD –[906] according to which the initial acceptance of PGD in exceptional cases would, over time, inevitably lead to an expansion of admissible cases to a point where there is complete freedom from all restrictions. As many authors have noted, this argument hardly seems to be relevant to the law, since the mere fear of abuse cannot justify the restriction of a fundamental right. It has rather been suggested that, first of all, these concerns justify the provision of regulations that are effectively designed to avoid misuses[907] and, secondly, that the possible consequences of an exceptional authorisation could be marginally taken into account when weighing the conflicting interests in the proportionality test.[908] Concerns about a possible slippery slope would therefore not be legally relevant per se, but only insofar as they could be included in a proportionality test.[909]

Some effects of this interplay of ethical-religious and legal issues in the debate can be directly observed in the text of the PGD Act as adopted by Parliament. In particular, two provisions of the law reflect the existence of ethical concerns relating to PGD. Firstly, the law provides for the introduction of § 3a(5) of the Embryo Protection Act, according to which no

905 Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda: Eine Analyse zum AME-FMedG* (2018) p. 301. The so-called 'Augsburg-München Draft' (AME-FMedG) – a proposal issued by a group of distinguished legal scholars for a new regulation of reproductive medicine in Germany – also affirms the need for coherence in the legal regulation of reproductive medicine on this point. It thus suggests adjusting the regulation of PGD to the legal framework for abortion, Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013) p. 51.

906 Lungstras, *Der Umgang mit dem Embryo in vitro* (2008) pp. 98-ff.

907 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 64; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 94.

908 Hufen in Gethmann and Huster, *Recht und Ethik in der Präimplantationsdiagnostik* (2010) p. 150.

909 Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 448.

doctor is obliged to carry out a PGD. The inclusion of this PGD-specific conscience clause is deemed to be superfluous, as §10 ESchG already prescribed that nobody shall be obliged to perform or assist in performing any procedure of medically assisted reproduction or preimplantation genetic diagnosis.[910] As it serves no legal function, the restatement of the conscience clause merely serves to explicitly affirm the ethically problematic nature of this diagnostic procedure.[911] It therefore has a purely declaratory character aimed at conveying a certain disapproval of PGD.

Even more explicit in this respect is the provision that each case of PGD must be authorised by an ethics commission. As illustrated above, the law requires a specific medical indication as a condition for the performance of PGD. However, the exact definition of the scope of this concept is left to a commission, called the 'ethics commission', which is responsible for verifying the requirement in the individual case. Given that it mainly has to check a medical requirement, the commission's designation as 'ethics commission' is another statement of the ethical issues raised by PGD.[912] At the same time, introducing an ethics commission into the procedure has an admittedly restrictive function; the explanatory statement of the law emphasised that this measure would serve to ensure that the procedure would only be accessed in exceptional cases.[913] The need to restrict access to the procedure derives from an ethical and religious objection to it and this is therefore one of the ways in which the legislature allows ethics to silently enter the law.[914]

910 Frister and Lehmann, 'Die gesetzliche Regelung der Präimplantationsdiagnostik' (2012) 67(13) JZ p. 659, 666; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 167.

911 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 109; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 122.

912 Pestalozza, 'Eine späte und mißliche Geburt: Die Verordnung zur Regelung der Präimplantationsdiagnostik' (2013) 31(6) MedR p. 343, 345; Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung* (2015) p. 48.

913 Deutscher Bundestag, 'BT-Drucks. 17/5451. Flach, Hintze and others', 12.4.2011, p. 3. See also Hermes, *Die Ethikkommissionen für Präimplantationsdiagnostik* (2017) p. 67; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 199.

914 For a reflection on how ethics comes silently into the law via introduction of committees named 'ethics committee', see Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011).

d PGD Ethics Commissions

i. Procedure before the Ethics Commissions

The Preimplantation Genetic Diagnosis Act delegated to the federal government the task of specifying, by ordinance, the conditions for authorising PGD centres and the details of the procedure before the ethics commissions. The Ordinance issued accordingly came into force in 2014 (*Verordnung zur Regelung der Präimplantationsdiagnostik,* PIDV) and triggered again the debate on preimplantation genetic diagnosis.[915]

The Ordinance has been criticised in several regards. First, the time needed to pass the Ordinance delayed access to PGD by more than two years after the PGD Act was enacted. This resulted in a four-year gap between the BGH's warning to the legislature and its full implementation.[916] It has also been pointed out that the Ordinance has delegated the regulation of some further details to the individual State (*Land*) governments, thus causing differences in regulation between the various states and further delays in access to PGD.[917] Furthermore, the content of some provisions was considered excessively paternalistic.[918] For instance, any facility seeking authorisation to carry out PGD must comply with very strict standards, which not only serves to guarantee the high quality of the procedures but also effectively limits the number of centres that obtain authorisation[919] and thus reduces couples' opportunities to access PGD.[920] The Ordinance also allows the ethics commissions that are in charge of approving each PGD

915 Hermes, *Die Ethikkommissionen für Präimplantationsdiagnostik* (2017) pp. 31-32.

916 Schroth, 'Die gesetzliche Regelung der PID – De lege lata et de lege ferenda' (2014) 125(3) ZStW p. 627, 637-638; Pestalozza, 'Eine späte und mißliche Geburt' (2013) 31(6) MedR p. 343, 344.

917 Pestalozza, 'Eine späte und mißliche Geburt' (2013) 31(6) MedR p. 343, 346; Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 424; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 140.

918 Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1.

919 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 143.

920 A limited number of PGD centres is considered to be a factor that can bring about a reduction in the use of PGD, see Tolmein, 'Präimplantationsdiagnose – neues Gesetz schafft Wertungswidersprüche' [2011](5) GuP p. 161, 163; Wostry, 'Fünf Jahre PID-Gesetz' (2016) 28(3) Medizinische Genetik p. 299, 300; Deutscher Bundestag, 'BT-Drucks. 19/8351: Bericht des Ausschusses für Bildung, Forschung und Technikfolgenabschätzung (18. Ausschuss) gemäß § 56a der Geschäftsordnung' (4.11.2019), p. 77.

procedure to take into account ethical, psychological and social aspects, which are not foreseen under the framework of the PGD Act.

According to § 3a(3) no. 2 ESchG, the reason for the mandatory approval of each PGD procedure by the ethics commissions would be the need to assess, on a case-by-case basis, the existence of the requirements for access to PGD laid down by the legislature. In other words, the purpose would be to verify whether the future parents are affected by a genetic disposition that poses a high risk of serious hereditary disease to the embryo or whether there is a risk of stillbirth or miscarriage.[921] The commission must therefore simply ensure that the medical-legal requirements for access to PGD are met.

Nevertheless, the mandatory[922] examination by an ethics commission is highly symbolic of the legislature's reservations towards this diagnostic procedure. The very name given to the commission is questionable[923] as it conveys the impression that a couple wishing to apply for PGD would first have to appear before a commission in charge of investigating their moral standards. It seems that a state authority would be taking over the assessment of the ethical validity of a procedure whose recourse should instead be an intimate and personal decision for the couple.[924]

This perception is reinforced by the inclusion in § 6(4) PIDV of a provision according to which ethics commissions may give their positive assessment after taking into account the relevant psychological, social and ethical aspects of the specific individual case.[925] The explicit inclusion of these aspects in the commission's assessment is problematic on two levels. Firstly, because it reaffirms the paternalistic view of the role of ethics com-

921 § 3a(2) ESchG.

922 Conducting a PGD without the authorisation of the ethics commission subjects the doctor and the couple to a penalty of up to 50,000 Euro, as laid down by §3a(4) ESchG and observed by Frister, *Wissenschaftsrecht und Wissenschaftspraxis* (2014) p. 123

923 Schroth, 'Die gesetzliche Regelung der PID – De lege lata et de lege ferenda' (2014) 125(3) ZStW p. 627, 637; Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung* (2015) p. 48; Bögershausen, *Präimplantationsdiagnostik* (2016) p. 251; Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda* (2018) p. 119.

924 Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 2.

925 The provision was added to the draft by the Bundesrat upon approval of the Ordinance according to Art. 80(2) GG, Bundesrat, 'BR-Drucks. 717/12: Beschluss des Bundesrates. Verordnung zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikverordnung - PIDV)' (1.2.13), p. 6.

missions.[926] They seem to be entrusted with the task of making an ethical decision for the couple, thus violating the future parents' rights to self-determination and reproductive choices.[927] Hence, as suggested by several authors and organisations, the involvement of an ethics commission in the procedure should be avoided. This decision should rather be entrusted to the couple who can obtain all the information necessary for an informed choice in consultation with their physician. [928] The importance of performing PGD to the woman can be better assessed in the context of a personal conversation with her treating doctor.[929]

Moreover, this provision seems to imply that the ethics commission's assessment not only depends on the existence of the requirements laid down by law[930] but also on the ethical evaluation of the members of the

926 Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1.

927 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 139; Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung* (2015) p. 49; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 2.

928 The Augsburg-München Draft proposes to avoid involving an ethics commission and to rather leave the decision to the woman after consultation with the doctor, Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013) p. 52. On this point, see Schroth, 'Die gesetzliche Regelung der PID – De lege lata et de lege ferenda' (2014) 125(3) ZStW p. 627, 644; Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda* (2018) p. 305. See, also, the opinion of the National Academy of Science, Nationale Akademie der Wissenschaften Leopoldina, 'Ad-hoc-Stellungnahme Präimplantationsdiagnostik (PID)', January 2011, p. 90. As pointed out by the German lawyers association in its opinion, Medizinrechtsausschuss, 'Stellungnahme des Deutschen Anwaltvereins durch den Medizinrechtsauschuss zu den Gesetzentwürfe zur Präimplantationsdiagnostik' [2011](2) Zeitschrift für das gesamte Medizin- und Gesundheitsrecht p. 71, the introduction of an ethics commission in the PGD procedure is a sign of mistrust toward the capability of the patients and doctors to make the right 'moral' decision. That the decision should be left to the patient in their dialogue with the doctor is also argued by Bögershausen, *Präimplantationsdiagnostik* (2016) p. 278; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 141; Kersten, 'Regulierungsauftrag für den Staat im Bereich der Fortpflanzungsmedizin' (2018) 37(17) NVwZ p. 1248, 1252; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 195; Brade and Tänzer, 'Präimplantationsdiagnostik vor dem Bundesverwaltungsgericht' (2021) 40(14) NVwZ p. 1037, 1041.

929 Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013) p. 52.

930 The provision could therefore be interpreted in the sense that the approval could be denied in the concrete case although the requirements in § 3a(2) of the ESchG are met. See Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417.

commission analysing the case.[931] Yet such an expansion of the evaluation criteria available to the commission must be considered unlawful. The medical requirements that the commission has to prove are already clearly laid down in the law and the Ordinance of the executive may not go beyond what is expressly stated in the legislative mandate contained in the Embryo Protection Act.[932] For this reason several scholars correctly maintain that the ethics commission's assessment should ignore the ethical aspects and concentrate on ascertaining the medical requirement under § 3a(2) Embryo Protection Act.[933]

Irrespective of the arguably illegality of the explicit consideration of ethical aspects, it has been observed that the inclusion of an ethics commission in the procedure inevitably implies a certain exposure to ethical scrutiny, as the legal requirements for accessing PGD remain open to interpretation.[934] The composition of the ethics commission also contradicts the purpose of a mere check on medical requirements. According to § 4(1) sentence 3 of the PGD Ordinance the commissions are composed of four experts in the field of medicine, one expert each in the fields of ethics and law, and one representative each from the organisations responsible for representing the interests of patients and of persons with disabilities at the state level. Such an interdisciplinary composition and the representation of conflicting interests seem to suggest that the possibility is accepted that the assessment will not be based merely on medical criteria.[935]

931 Poscher in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013) p. 438.

932 Poscher in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013) p. 434; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 183.

933 Pestalozza, 'Eine späte und mißliche Geburt' (2013) 31(6) MedR p. 343, 347; Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 424; Frister, *Wissenschaftsrecht und Wissenschaftspraxis* (2014) p. 132; Schroth, 'Die gesetzliche Regelung der PID – De lege lata et de lege ferenda' (2014) 125(3) ZStW p. 627, 637; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 166. However, the conclusions of the legal scholarship are rejected by a part of the case law which has ruled that the psychological, social and ethical aspects of the individual case referred to in § 6(4) PIDV must be taken into account in the commission's assessment, see VG Regensburg, 24.1.2019 – RO 5 K 17.335, para 32, as discussed below.

934 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 252.

935 Schroth, 'Die gesetzliche Regelung der PID – De lege lata et de lege ferenda' (2014) 125(3) ZStW p. 627, 637.

In addition, the Ordinance requires the decision of the Ethics Commission to be reached by a two-thirds majority of its members.[936] The justification for this provision – inserted by the Bundesrat into the *Verordnung* at the time of its approval according to Article 80(2) GG – indicates that the broad consensus required stems from the weight of the ethical consequences of the decision.[937]

The possibility for the commission to take ethical and social considerations into account is also to be inferred from the provision in § 6(2) no. 4 PIDV allowing for an oral hearing of the woman who submitted the application. The only possible reason for such a summon would seem to be an investigation of the social circumstances and the personal or ethical reasons for which the couple wishes to opt for a PGD.[938] At the same time the woman is not able to request to be heard by the commission.[939]

ii. PGD Commissions before the Administrative Courts

As the evaluation by the ethics commission risks leading to a certain moral scrutiny of the couple's reproductive intentions, the ethical concerns or convictions of individual commission members might well have an influence on the commission's decisions and thus on couples' access to the healthcare treatment. A safeguard against such an outcome would be a right for couples to appeal to the administrative justice and seek a review of the unlawful decision of the commission.[940] The administrative judge would thus be in a position to remove any illegitimate interference of ethical convictions in a decision that should remain bound to legal criteria.[941]

It is possible to lodge an appeal with the administrative courts against a negative decision of a commission. This is on the grounds that such

936 Which in a commission of eight members actually represent ¾ of the board, as pointed out by Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 180; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1.

937 Bundesrat, 'BR-Drucks. 717/12', 1.2.13, p. 6.

938 Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 424; Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung* (2015) p. 50.

939 Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 184.

940 Frister, *Wissenschaftsrecht und Wissenschaftspraxis* (2014) p. 133.

941 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 254.

a decision is an administrative act of a public authority that has direct legal consequences for the rights of the applicant.[942] However, in order to understand whether courts can actually remedy an unlawful intrusion of ethical convictions into the determination of legal criteria, the extent of the judicial control over the lawfulness of the decision must be investigated.

Here it must be observed that the PGD Act does not clarify whether ethics commissions have a margin of appreciation that would prevent their decisions from being subject to a full judicial review.[943] A mention of the fact that the commissions' decisions can be challenged through administrative law is only contained in government's explanatory memorandum to the PGD Ordinance.[944]

A majority of commentators argue that the commission has no margin of appreciation and that the judicial review must therefore be full, since the requirements that the commission has to verify – i.e. the existence of a serious hereditary disease – are fully justiciable legal terms.[945]

Nevertheless, the administrative courts are divided on this issue, as is shown by a review of the main case law relating to the Bavarian PGD Ethics Commission.

Two first instance judgments by the Administrative Court (*Verwaltungsgericht, VG*) in Munich[946] and the Administrative Court in Regensburg[947] both held that the ethics commission enjoys a margin of appreciation in assessing the requirement of a serious hereditary disease and that its

942 As pointed out by Frommel, 'Die Neuregelung der Präimplantationsdiagnostik durch § 3a Embryonenschutzgesetz' (2013) 68(10) JZ p. 488, 492; Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 424; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 136; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 167; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 185.

943 And neither of the two drafts presented to the Parliament clarified this point, as noted by Scheffer, 'Zur Zukunft der Präimplantationsdiagnostik in Deutschland' (2011) 20(1) ZfL p. 9, 14.

944 Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 185.

945 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 262; Huber and Lindner, 'Rechtsschutz gegen ein negatives PID-Votum der Ethikkommission nach §3a Abs. 3 Nr. 2 ESchG' (2016) 34(7) MedR p. 502, 506; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 136; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 182.

946 VG München, 10.0.2017 – M 18 K 16.1738.

947 VG Regensburg, 24.1.2019 – RO 5 K 17.335.

decision is therefore only subject to limited judicial review. In both cases the Bavarian PGD commission had refused to grant access to PGD. The Administrative Court of Munich argued that the pluralistic and interdisciplinary composition of the commission is a clear indication of the margin of appreciation left to it.[948] The evaluation of the ethics commission could not be replaced by a judicial decision given that the commission also had the competence to take difficult ethical and social issues into account for its assessment. According to the court this was also clear from the legislature's decision to designate the decision-making authority as an 'ethics' commission.[949] On this basis the court concluded that the ethics commission had respected the limits of its margin of appreciation in the concrete case and that, therefore, the couple's appeal against the negative decision had to be rejected.

By contrast, in the case before the Regensburg Administrative Court the judges argued that the commission's margin of appreciation had been exceeded in a judicially verifiable manner. Indeed, the commission had not adequately considered the psychological, social and ethical aspects of the individual case which, according to the court, had to be taken into account according to § 6(4) of the PGD Ordinance.[950] As a result the VG Regensburg ordered the commission to reassess the application in compliance with the judicial indications.

By granting the commissions a wide margin of appreciation that cannot be legally reviewed by the courts, the above case law fails to effectively counteract the influence of the ethical convictions of commission members in assessing the legal requirements for accessing PGD.

In sharp contrast with this approach stand the courts of second[951] and last[952] instance that ruled that the Bavarian PGD commission has no margin of appreciation and that therefore its assessment on the existence of a serious hereditary disease is subject to full judicial review.

The higher Bavarian Administrative Court (*Bayerische Verwaltungsgerichtshof, Bay.VGH*) – ruling on an appeal in the case previously cited as having been decided by the VG Munich – held that the provision of

948 VG München, 10.0.2017 – M 18 K 16.1738, para. 21. See Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 168.
949 VG München, 10.0.2017 – M 18 K 16.1738, para. 23.
950 VG Regensburg, 24.1.2019 – RO 5 K 17.335, paras. 30-32.
951 VGH Bayern, 14.0.2019 - 20 BV 17.1507.
952 BVerwG, 5.11.2020 - 3 C 12.19.

the PGD Ordinance mandating the consideration of social, ethical and psychological aspects had to be deemed null and void. The Ordinance had exceeded its competence to define the procedural aspects of the ethics commissions' decisions. Given the influence that the ethics commissions' decisions have on the fundamental rights of couples, it is up to the legislature to define the essential criteria for the commissions' assessment.[953]

In the last instance the Federal Administrative Court (*Bundesverwaltungsgericht, BVerwG*) endorsed the view that the decisions of the Bavarian ethics commission are subject to full review by administrative courts. The ethics commissions are not granted any margin of appreciation regarding the assessment of whether a serious hereditary disease exists.[954] The judgment argued that this requirement could be sufficiently defined using legal methods of interpretation, also given the fact that the court can rely on experts and on the documents submitted by the couple throughout the procedure.[955] After a thorough assessment the court ordered the Bavarian ethics commission to issue a decision in favour of the couple, thereby allowing them access to PGD. The court also stated that the inclusion of psychological, social and ethical aspects cannot override the content of the statutory requirements laid down at § 3a(2) of the Embryo Protection Act.

The latest rulings demonstrate that the principle of legality in administrative law may constitute a barrier to unlawful ethical influences in the law.[956] Nevertheless, it has been observed that recourse to administrative justice may not be a feasible alternative for couples affected by a negative decision, since it imposes an additional burden on those already encountered in the procedure before the ethics commission.[957]

iii. Influence on Patients' Uptake of PGD

The possibility of a negative decision is not the only obstacle that the involvement of ethics commissions poses to accessing PGD. In addition to posing a problem for the state's ethical neutrality, the mandatory exam-

953 Huber and Lindner, 'Die Rechtsprechung der Verwaltungsgerichte zur Praeimplantationsdiagnostik (PID)' (2020) 135(12) DVBl p. 796, 799.

954 For a comment on the decision, see Brade and Tänzer, 'Präimplantationsdiagnostik vor dem Bundesverwaltungsgericht' (2021) 40(14) NVwZ p. 1037.

955 BVerwG, 5.11.2020 - 3 C 12.19, para. 23

956 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 254.

957 Frommel, 'Die Neuregelung der Präimplantationsdiagnostik durch § 3a Embryonenschutzgesetz' (2013) 68(10) JZ p. 488, 492.

ination by an ethics commission creates bureaucratic, psychological and financial burdens that also affect the couple's chances of accessing PGD.

One obvious problem arises in connection with the expenses incurred by the couple during the procedure before the ethics commission. Under § 4(3) PIDV the ethics commission charges fees and expenses for examining a PGD application. Costs vary from one commission to another. This depends on whether they are established within a medical association, such as the commission in Baden-Württemberg, or the Ministry of Health, as is the case in Bavaria,[958] as well as on whether members receive an attendance allowance.[959] However, some very high figures can be reached as the fee scales provide for a range of costs from 100 to 5,000 euros.[960] Such costs are likely to discourage the couple, as they have to be incurred in advance and in the hope that the commission will end up approving the procedure with a positive vote.[961] Moreover, these costs, as well as the costs of PGD, are not covered by the health insurance.[962]

Couples may also have to bear high travel costs to reach the PGD centre that falls within the jurisdiction of the chosen ethics commission. There are in fact only five PGD ethics commissions in Germany,[963] each of which is independent and responsible for making its own decisions regardless of the approaches of the other commissions. As a result, some of the commissions may be known to have a more restrictive or a more permissive attitude, depending on what genetic condition the applicants suffer from.[964] Couples may consequently wish to bring their case before that ethics commission

958 Gesetz zur Ausführung der Präimplantationsdiagnostikverordnung (BayAGPIDV), 17.12.2014, GVBl p. 542.

959 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 56.

960 ibid.

961 Many authors regard the couple's obligation to cover costs as problematic, see for instance Bögershausen, *Präimplantationsdiagnostik* (2016) p. 261; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 5.

962 As observed, *inter alia*, by Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 181.

963 Ethik-Kommission für Präimplantationsdiagnostik Nord bei der Ärztekammer Hamburg; Präimplantations-diagnostik-Kommission (NRW); Ethikkommission für PID bei der Landesärztekammer Baden-Württemberg; Bayerische Ethikkommission für Präimplantations-diagnostik; Ethik-Kommission des Landes Berlin, see table in Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 49.

964 Deutscher Bundestag, 'BT-Drucks. 19/8351: Bericht des Ausschusses für Bildung, Forschung und Technikfolgenabschätzung (18. Ausschuss) gemäß § 56a der Geschäftsordnung' (4.11.2019), pp. 56-ff.

that they believe offers them the best chances of a positive assessment.[965] Since the approved PGD has to be performed in a PGD centre for which the ethics commission that assessed the case has jurisdiction, couples may have to commute to a facility located far from their place of residence in order to undertake the various steps required for PGD.[966]

In addition to the issue of costs in terms of fees and expenses, the obligation to bring an application for PGD before an ethics commission implies other psychological and social costs for the couple. The prospect of having to undergo scrutiny by an ethics commission that will be questioning their moral decisions may create psychological pressures on the woman or couple.[967] The procedure involves revealing very personal health and social information – and given the couple's genetic predisposition this often includes recalling past experiences of abortion or miscarriage – that couples tend to find stressful and unnecessary.[968] In addition, the woman's past and future intentions could be questioned, also with a view to moral criteria, at the oral hearing of the applicant. This may add unnecessary stress for the woman or pressure to change her mind about her request for PGD.[969] It was also observed that the presence of representatives of people with disabilities and theologians could intimidate women and put them in a defensive situation where they feel accused or humiliated.[970]

There is also a time factor. Although there is a three-month deadline for the commission's decision,[971] the procedure lengthens the time it takes to

965 Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda* (2018) p. 119; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1, 2. The phenomenon is criticised as so-called 'commission hopping', see Duttge, 'Wider den prinzipienvergessenen Zeitgeist bei der rechtsethischen Beurteilung der Präimplantationsdiagnostik' (2014) 125(3) ZStW p. 647, 655.

966 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 58.

967 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 261.

968 Nationale Akademie der Wissenschaften Leopoldina, 'Ad-hoc-Stellungnahme Präimplantationsdiagnostik (PID)', January 2011, p. 91; Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 47.

969 As it could be targeted to inquire about the reasons why the applicant is not prepared to take the risk of severe hereditary disease, stillbirth, or miscarriage, Frister, *Wissenschaftsrecht und Wissenschaftspraxis* (2014) p. 131.

970 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 261; Kreß, 'Grenzziehung für Ethikkommissionen' (2021) 39(1) MedR p. 1.

971 As laid down in § 6(1) PIDV, see Bögershausen, *Präimplantationsdiagnostik* (2016) p. 261.

access PGD and thus affects the likelihood of its success in view of the age of the applicant.[972]

The necessity of securing an approval by the ethics commission is therefore in itself a deterrent for couples wishing to access PGD. Although the number of applications rejected by the commissions can be considered relatively small,[973] one has to take into account the number of couples who refrain from submitting an application after being informed of the various costs to be incurred in the process.[974] Moreover, it has been shown that PGD centres do a very thorough preliminary screening of couples who approach them in the first place. Doctors only recommend starting the procedure to couples that are likely to receive a positive evaluation by ethics commissions and that are likely to have a successful IVF procedure.[975] The PGD centre in Lübeck, for instance, over a period of about two years invited only 47% of the couples to a second interview.[976]

In sum, the mandatory approval by an ethics commission entails financial, psychological and bureaucratic burdens that many couples struggle to find acceptable and respectful of their personal ethical positions.[977]

II. PGD in the Statutory Health Insurance

1. Lack of Public Coverage

In the final version approved by Parliament the PGD Act does not foresee any reimbursement by the statutory health insurance for costs incurred to perform a PGD. As has been observed, this oversight was not accidental.[978]

---

972 Bögershausen, *Präimplantationsdiagnostik* (2016) p. 260; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 169.

973 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 51.

974 According to Zühlke and others, 'Präimplantationsdiagnostik' (2016) 28(3) Medizinische Genetik p. 304, 306, the experience of the PGD Centre in Lübeck shows that only one or two out of ten interested couples actually apply to the PGD Commission, also due to financial or psychosocial constraints.

975 Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 51.

976 Zühlke and others, 'Präimplantationsdiagnostik' (2016) 28(3) Medizinische Genetik p. 304, 305.

977 As reported by Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 47; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) p. 51.

978 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 203.

The need to regulate the financing of expenses related to PGD was well known to the legislature, as the issue of reimbursement had already been addressed in one of the drafts submitted to Bundestag[979] and at the public hearing before the Committee on Health.[980] On those occasions the expected budgetary burden was estimated to be limited due to the small number of envisaged cases.[981] In the absence of Federal Joint Committee (G-BA) guidelines, the result of the legislature's failure to intervene is that PGD costs are currently not included in the statutory health insurance's benefit basket.

The current situation is considered particularly problematic[982] as it prevents patients from accessing a health treatment because of the high costs involved. Depending on the couple's financial status this can pose an insuperable obstacle.[983] Partially due to the costs involved in the procedure, the number of applications positively assessed by the ethics committees is significantly higher than the amount of PGDs actually carried out.[984]

As reported by the parliamentary Committee on Education, Research and Technology Assessment, the costs of the procedure in Germany range from €5,000 to €10,000 depending on the genetic condition, and in total can reach €15,000 or €20,000.[985] It must be borne in mind that couples who wish to resort to PGD also have to cover the high costs of the associated in vitro fertilisation. These costs would only be reimbursed by the statutory health insurance if there was a medical indication according to § 27a(1) no. 1 SGB V and even then only for half of the amount.[986] As clarified in the directive of the G-BA, which sets out the conditions for obtaining this

979 Deutscher Bundestag, 'BT-Drucks. 17/5452. Röspel, Hinz and others', 12.4.2011.
980 Deutscher Bundestag, 'Ausschuss für Gesundheit, Protokoll Nr. 17/42', Berlin 25.5.2011.
981 See Wostry, 'Fünf Jahre PID-Gesetz' (2016) 28(3) Medizinische Genetik p. 299, 302.
982 Hehr and others, 'Präimplantationsdiagnostik' (2014) 26(4) Medizinische Genetik p. 417, 425.
983 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 47.
984 As reported by the Federal Ministry of Health in its second report on PGD, Bundesministerium für Gesundheit, 'Zweiter Bericht über die Erfahrungen mit der Präimplantationsdiagnostik' (2020), p. 34.
985 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 47.
986 For details on this regulation see Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713; Tann, 'Die künstliche Befruchtung in der gesetzlichen Krankenversicherung' (2015) 68(26) NJW p. 1850.

benefit,[987] the medical indication for IVF presupposes a factual condition of infertility, which in most cases does not occur in couples applying for PGD.[988]

As mentioned above, the costs that couples have to face also include the fees of the procedure before the ethics commission. The German regulation of PGD thus imposes on patients additional expenses that mainly serve the purposes of protecting the life of a possible future embryo[989] and of ensuring that PGD ethics commissions set a certain ethical standard.

It has been argued that these substantial costs help to counter the risk of widespread use of PGD.[990] In other words, they would constitute a financial barrier capable of restricting access to an ethically undesirable healthcare service. While demonstrating the inherent illegitimacy of such an argument is one of the purposes of this dissertation, at this stage it is sufficient to highlight that using financial barriers to limit access means that more affluent patients may be able to buy their way out of alleged ethical limits to which less wealthy patients must adhere. The result of not publicly funding the costs of PGD is that patients with greater financial means may still be able to obtain access to the procedure after possibly bearing the costs of an appeal to the administrative courts against a negative decision by the ethics commission. At the same time less wealthy couples will be left with the option of relying on natural procreation and undergoing a series of abortions – reimbursed by the statutory health insurance according to § 24b SGB V – or miscarriages.[991] As has been rightly remarked by many authors, this outcome is unacceptable and creates an unjust differentiation in access to assisted reproduction techniques.[992]

987 Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über ärztliche Maßnahmen zur künstlichen Befruchtung („Richtlinien über künstliche Befruchtung"), 16.03.2017, BAnz AT 01.06.2017 B4.

988 As noted by Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 195.

989 Landwehr, 'Anmerkung zu BSG, Urt. V. 18.11.2014 – B 1 KR 19/13 R (LSG Bad.-Württ.)' (2017) 35(2) MedR p. 161.

990 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205; Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 77.

991 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205; Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 77.

992 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205; Nationale Akademie der Wissenschaften Leopoldina, 'Ad-hoc-Stellungnahme Präimplantationsdiagnostik (PID)', January 2011, p. 91; Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 77.

The issue of whether the statutory health insurance should cover the costs of PGD has also been raised before the social courts. As early as 2007, prior to the adoption of the PGD Act, a couple had applied to the Social Court in Berlin (*Sozialgericht, SG*) for the reimbursement of the costs of a PGD procedure carried out in Belgium. On that occasion the judges maintained that the reimbursement of the costs of health care received abroad could only be obtained in so far as the public healthcare system of the home Member State also guaranteed coverage.[993] As this was definitively ruled out at the time, the court then only added that any regulation of PGD financing by statutory health insurance funds would have to be provided for by the legislature and not by the G-BA because of the interference of preimplantation genetic diagnosis with the embryo's right to life.[994] The decision argued that legislative regulation would be necessary to ensure that PGD is widely debated in the public domain before it could be included in the benefit basket of the statutory health insurance.[995]

After the adoption of the PGD Act, two judgments of the Regional Social Court (*Landessozialgericht, LSG*) in Baden-Württemberg confirmed that a decision on the inclusion of PGD among the health services provided by the statutory healthcare insurance remains at the discretion of the legislature.[996] The court analysed all possible legal bases in the SGB V that could trigger an obligation to reimburse on the part of a statutory health insurance fund. However, none of the relevant provisions in the SBG V could be used to establish a right to reimbursement of PGD costs.[997]

In this respect the Regional Social Court inquired whether PGD could be regarded as a measure of early detection of a disease under §§ 25 and 26 SGB V. This was ruled out on the grounds that PGD is not performed on the body the applicants nor on an embryo that has already been conceived. Reimbursement through these provisions cannot therefore be guaranteed because the diagnosis does not take place on a living body.[998]

993 SG Berlin, 23.0.2007 - S 86 KR 660/04.
994 ibid.
995 ibid.
996 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12.
997 For a comment on the case law of the LSG, see Leonhard, 'Krankenkasse muss Kosten für PID nicht übernehmen' [2013](4) RdLh p. 214.
998 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12, para. 23; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12, para. 35.

Secondly, the court assessed whether PGD can be regarded as a medical treatment in the sense of § 27 SGB V, according to which insured persons are entitled to health treatment if it is necessary in order to recognise or cure a disease, to prevent its aggravation or to alleviate its symptoms. However, couples who seek access to a PGD do not suffer from any such disease, but only from a transmissible genetic condition that has no effect on their daily lives.[999] In any case, PGD would not be an adequate method of treating this genetic disorder, nor of preventing its aggravation or alleviating symptoms.[1000]

Neither could PGD be considered to be an in vitro fertilisation measure for which the public insurance funds would bear half the costs under §27a SGB V. As already mentioned, the prerequisites for access to this benefit are related to a condition of infertility, for reimbursement is only granted if the medical procedure is the only way to bring about a pregnancy.[1001]

Ultimately, the court maintained that the decision on this ethically and legally controversial issue, i.e. whether PGD should be covered by the statutory health insurance, requires a clear legislative decision.[1002] As PGD cannot be considered a medical treatment in the sense of the Fifth Book of the German Social Law Code, a regulation by the Federal Joint Committee assuming the costs for PGD is also excluded – at least in the absence of prior parliamentary intervention.[1003]

The case eventually reached the Federal Social Court, which confirmed that PGD cannot be deemed to be included in the benefit basket of the statutory health insurance.[1004] The court reiterated that PGD does not constitute medical treatment owed to the patient by the health insurance. For, although the patient was indeed suffering from a genetic condition, PGD was not a treatment capable of alleviating their suffering or curing

999 On this point, see Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 198.

1000 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12, para. 24; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12, para. 36. See also Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 203.

1001 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12, paras. 25-26; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12, para. 38-39.

1002 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12, para. 26; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12, para. 39.

1003 LSG Baden-Württemberg, 19.4.2013 - L 4 KR 5058/12, para. 27; LSG Baden-Württemberg, 19.7.2013 - L 4 KR 4624/12, para. 40.

1004 BSG, 18. 11. 2014 – B 1 KR 19/13 R.

their condition.[1005] The text of the decision also confirmed the findings of the lower courts regarding the non-applicability of §§ 25, 26 and 27a SGB V to PGD.[1006] As regards the alleged discrimination against infertile couples who have access to IVF with reimbursement of costs, the court held that this differentiation is in line with constitutional standards since Article 3 of the Basic Law does not require equal treatment of couples with fertility disorders and those with a high probability of procreating a genetically affected child.[1007] Ultimately, the judgment thus grants the legislature a very wide margin of discretion in determining the conditions for granting statutory health insurance benefits.[1008]

This result was confirmed by a further decision of the Federal Social Court[1009] in the case of a PGD performed with the special method of polar body biopsy.[1010] More recently, the issue was again raised before the Stuttgart Regional Social Court by two applicants who argued that they were entitled to PGD according to the principles established by the Federal Constitutional Court's '*Nikolaus*' decision.[1011] Based on their genetic condition, they claimed that their offspring were likely to suffer a severe clinical condition with high mortality rate. Yet this appeal also failed on the basis that PGD itself would not be a treatment capable of improving or remedying this condition. The court found that the hypothetical, albeit fatal, illness of the potential offspring could not be taken into account in this respect, since the embryo could not be considered an insured person nor a person entitled to social benefits before its implantation in the uterus.[1012]

As this overview shows, the social law courts have adhered to the letter of the provisions of the German Social Law Code, thus developing a rather

1005 BSG, 18. 11. 2014 – B 1 KR 19/13 R, para .15.
1006 For a detailed analysis of the decision, see Landwehr, 'Anmerkung zu BSG, Urt. V. 18.11.2014 – B 1 KR 19/13 R (LSG Bad.-Württ.)' (2017) 35(2) MedR p. 161.
1007 BSG, 18. 11. 2014 – B 1 KR 19/13 R, para. 19.
1008 BSG, 18. 11. 2014 – B 1 KR 19/13 R, para. 20.
1009 BSG, 12.9.2015 - B 1 KR 15/14 R. For a comment on this decision, see Mertens, 'Gendiagnostik nicht auf Kassenkosten' (2015) 18(12) G+G p. 44.
1010 For simplicity, this term indicates a diagnosis performed on an unfertilised egg cell. For more details see van der Ven, Montag and van der Ven, 'Polar Body Diagnosis – A Step in The Right Direction?' (2008) 105(11) Deutsches Ärzteblatt International p. 190.
1011 BVerfG, 6.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25). With this ruling, patients have acquired a constitutional right to healthcare services in the event of a life-threatening or typically fatal disease, see Introduction.
1012 SG Stuttgart, 3.4.2020 - S 28 KR 1051/19.

rigid and formalistic jurisprudence.[1013] As correctly remarked by commentators,[1014] the key point of the social courts' judgments lies in the fact that the future parents are not considered to be patients suffering from a disease that demands medical treatment and thus is to be covered by the statutory health insurance. However, this formal interpretation does not reflect the fact that PGD is indeed a treatment that, in the cases referred to in § 3a(2) ESchG, is medically indicated. The wish to procreate a child not affected by a serious genetic disease that could result in their early death cannot be regarded as a mere whim of the couple, comparable to cosmetic surgery or a tattoo.[1015]

By repeatedly emphasising that the decision on such an ethically sensitive issue rests solely with the legislature,[1016] which enjoys a wide margin of discretion, these judgments prove that the ethical conflicts arising in the debate on the permissibility of PGD are currently renewed with regard to the assumption of costs by the statutory health insurance.[1017] The resolution of this ethically controversial issue is thus left entirely to a legislature which to date remains inactive. The outcome of this case law thereby confirms that the ethical positioning of the majority – opposed to PGD on ethical grounds – may ultimately adversely affect the right of couples to have access to such medical treatment.

2. Reform Proposals

As the report of the parliamentary Committee on Education, Research and Technology Assessment points out, in the light of the strong stance taken by the social courts, the only way to ensure equal access to PGD would currently be through a legislative change including PGD in the statutory health insurance schemes.[1018]

1013 Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205.
1014 Landwehr, 'Anmerkung zu BSG, Urt. V. 18.11.2014 – B 1 KR 19/13 R (LSG Bad.-Württ.)' (2017) 35(2) MedR p. 161.
1015 ibid, p. 163. More comprehensively, Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 207.
1016 And, according to some authors, rightly so. See Wostry, 'Fünf Jahre PID-Gesetz' (2016) 28(3) Medizinische Genetik p. 299, 302; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205.
1017 Leonhard, 'Krankenkasse muss Kosten für PID nicht übernehmen' [2013](4) RdLh p. 214, 215.
1018 Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 13.

At the legislative level, the issue was first brought up at the end of November 2018, when the German Federal Council (*Bundesrat*) suggested that a measure providing for PGD reimbursement by statutory health insurance be included in the draft bill of the Schedule Services and Supplies Act (*Terminservice- und Versorgungsgesetzes,* TSVG).[1019] In its statement, the Bundesrat argued that the opportunity presented by the TSGV bill – introduced into Parliament by the Federal Government – should be used to fill the regulatory gap in the PGD reimbursement scheme. The text of the explanatory memorandum of this proposal reiterates that the additional costs for the public healthcare system would be limited, due to the small number of cases envisaged, and that the reimbursement of all costs incurred in a PGD would lead to equal treatment of fertile and infertile couples and remove the financial barrier to the use of a medically indicated diagnostic procedure.[1020]

The proposal initially received the support of the then Federal Minister of Health. The Minister accordingly prepared a draft amendment providing for the introduction of PGD into the benefit basket of the statutory health insurance.[1021] As reported by the media, the proposed amendment stipulated that reimbursement would only be offered to married couples and that only the gametes of the spouses could be used. Moreover, the statutory health insurance funds would only cover the costs of a total of three attempts to implant the selected embryos into the uterus of the future mother.[1022]

As expected, the Minister's proposal was harshly criticised by his own faction. The media reported that the amendment was withdrawn after the CDU/CSU parliamentary group on health unanimously voted against it.[1023] A letter from the Catholic and Protestant churches was sent to the leaders

1019 Bundesrat, 'BR-Drucks. 504/18. Stellungnahme des Bundesrates: Entwurf eines Gesetzes für schnellere Termine und bessere Versorgung (Terminservice- und Versorgungsgesetz - TSVG' (23.11.2018), p. 3.

1020 ibid, p. 4.

1021 'Krankenkassen sollen Präimplantationsdiagnostik bezahlen' (15.01.19) <https://www.aerzteblatt.de/nachrichten/100349/Krankenkassen-sollen-Praeimplantationsdiagnostik-bezahlen> accessed 8.9.2021.

1022 ibid.

1023 'Union stoppt Spahns Vorstoß zu Präimplantationsdiagnostik als Kassenleistung' (29.1.2019) <https://www.aerzteblatt.de/nachrichten/100748> accessed 8.9.2021; 'CDU stoppt Spahns Pläne für kostenlose Gentests' (29.1.2019) <https://www.spiegel.de/gesundheit/diagnose/jens-spahn-cdu-will-keine-kostenlosen-gentests-fuer-embryonen-a-1250600.html> accessed 8.9.2021.

of the of the CDU/CSU and SPD parliamentary groups. The churches criticised the Minister of Health for wanting to include such controversial regulations in a draft bill intended to regulate completely unrelated issues. The letter argued that the possible reimbursement of the costs of PGD by the statutory health insurance should be the subject of a broad and open public debate and not the result of a rushed legislative amendment.[1024]

After the withdrawal of the amendment proposal the Minister justified his apparently contradictory behaviour towards PGD. The introduction of the amendment, which sought to guarantee the reimbursement of PGD by the statutory health insurance, appeared to conflict with his previously expressed ethical and political views and his negative vote against the adoption of the PGD Act in 2011. He offered the justification that, after opting for the admissibility of PGD under certain conditions, the issue of public reimbursement should not be resolved on the basis of religious or ethical convictions, but rather according to considerations of social justice.[1025] The Minister of Health thus positioned himself against the use of social law as an instrument for imposing the ethical views of his political group. Additionally, after being asked whether the inclusion of PGD in the benefit baskets of the GKV implies its ethical acceptance, he maintained that the basis for public coverage of PGD costs would be merely its medical indication.[1026]

After the withdrawal of the draft amendment a similar proposal was nevertheless introduced to Parliament by the Free Democratic Party.[1027] Contrary to what the Minister of Health had planned to propose, the Free Democratic Party's amendment did not require couples to be married in order to qualify for the benefit.[1028]

The German Medical Council, the National Association of Statutory Health Insurance Funds and the AOK (one of the biggest health insurance

1024 'Widerstand der Kirchen gegen Spahn-Pläne zur Präimplantationsdiagnostik' (24.1.2019) <https://www.aerzteblatt.de/nachrichten/100628/Widerstand-der-Kirchen-gegen-Spahn-Plaene-zur-Praeimplantationsdiagnostik> accessed 8.9.2021.

1025 Becker, Grunert and Müller, '"Wir bauen Druck auf, aber wir sind es den Patienten schuldig": Jens Spahn im Gespräch' *Frankfurt Allgemeine Zeitung* (25.2.2019) accessed 8.9.2021.

1026 ibid.

1027 Deutscher Bundestag, 'BT-Drucks. 19/63371. Änderungsantrag 1 der Fraktion der FDP zum Entwurf eines Gesetzes für schnellere Termine und bessere Versorgung (Terminservice- und Versorgungsgesetz – TSVG)'.

1028 ibid.

funds in the country) touched on the matter in their opinions filed before the Committee on Health (*Ausschuss für Gesundheit*) of the Bundestag. The representatives of the statutory health insurance funds refrained from taking a clear position on the introduction of PGD as a benefit under the statutory health insurance because of its ethical and socio-political implications. But the German Medical Council welcomed the introduction of a reimbursement regulation that would guarantee access to PGD for all couples, regardless of their economic situation. Nonetheless, the proposal was ultimately discussed and rejected by the Committee on Health[1029] and therefore not included in the final version of the Schedule Services and Supplies Act approved by the Parliament.[1030]

A proposal to publicly cover the costs of preimplantation genetic diagnosis is now contained in the 2021 Coalition Agreement of the current government.[1031] At the time of writing, however, no steps have yet been taken in this direction.

B. Preimplantation Genetic Diagnosis in Italy

I. PGD in Law no. 40/2004

1. Ethical Approach

In approaching the case of preimplantation genetic diagnosis in Italy from the perspective of the principle of laicity, a brief introduction shall be given on Law no. 40/2004. For the first time this regulated medically assisted procreation within the Italian legal and healthcare system. The drafting and approval of this regulation was surrounded by heated public and religious debate, as well as by a sense of urgency, which resulted from a factual liberalisation of the use of these reproductive techniques given the delay

1029 Deutscher Bundestag, 'Beschlussempfehlung und Bericht des Ausschusses für Gesundheit (14. Ausschuss)' (13.3.2019), p. 159.

1030 Gesetz für schnellere Termine und bessere Versorgung (Terminservice- und Versorgungsgesetz – TSVG) BGBl I 2019, nr. 18, 10.05.2019); see also Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 77.

1031 Sozialdemokratische Partei Deutschlands (SPD) and BÜNDNIS 90/DIE GRÜNEN, Freie Demokratische Partei (FDP), 'Mehr Fortschritt Wagen. Bündnis für Freiheit, Gerechtigkeit und Nachhaltigkeit' , p. 92. <https://www.spd.de/fileadmin/Dokumente/Koalitionsvertrag/Koalitionsvertrag_2021-2025.pdf> accessed 6.4.2022

in regulation.[1032] As a result, the parliamentary discussion on the draft was largely based on hearings conducted for a previous legislative proposal in 1997.[1033]

It should be observed that Law no. 40/2004 was manifestly the outcome of the efforts of religious Catholic associations. These, with the support of the Italian Episcopal Conference, sought to reach an agreement between Catholics of various political affiliations and a number of non-religious Members of Parliament who had proven themselves sensitive to ethical issues and to the protection of the unborn child.[1034] The atmosphere in Parliament during the drafting of the law was accordingly clearly sympathetic to the ethical and religious views of the Catholic majority, resulting in a bill that largely disregarded scientific evidence on medically assisted procreation as well as constitutional values such as the right to health.[1035] As has been argued in the literature,[1036] the legislature seized on the difficulties in the constitutional balancing of relevant interests to pass a legislative text entirely based on ethical assumptions and ideological convictions. These actions were in direct contradiction with the constitutional principles of laicity[1037] and safeguard of ethical pluralism. [1038]

1032 Before 2004, artificially reproductive techniques had been regulated in Italy only by a circular letter from the Minister of Health (Circolare 28.5.1985, no. 23), so-called '*circolare Degan*'. This source was certainly not suitable for regulating the constitutional situations involved in the use of fertility treatments. Moreover, it had a very rigid approach based on ideological reasons and assumptions that had been overtaken by scientific development, see Casonato, *Introduzione al biodiritto* (3rd edn 2012) pp. 96-97. The author also notes how this delay in adopting legislation represents one of the instances of pathological inactivity of the Italian Parliament in the field of biolaw.

1033 As observed by Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 13.

1034 Milani, '«Veluti si Deus daretur»: la legge n. 40 del 2004 sulla procreazione medicalmente assistita dal dibattito parlamentare all'articolato' (2015) 23(1) Quad dir e pol eccl p. 117, 123-ff.

1035 Vallini, 'Il curioso (e doloroso) caso delle coppie fertili portatrici di malattie ereditarie, che potevano ricorrere all'aborto, ma non alla diagnosi e selezione preimpianto' (2015) 58(3) Riv it dir proc pen p. 1457, 1459.

1036 Mastropietro, 'Procreazione assistita: considerazioni critiche su una legge controversa' (2005) 34(4) Dir fam p. 1379, 1381.

1037 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 464; Rodotà, *Perché laico* (2010) pp. 75-80.

1038 See Carusi, 'La (imminente?) legge italiana sulla procreazione assistita: considerazioni nella propsettiva della "bioetica laica"' (2003) 34(2) Pol dir p. 287.

This clear ethical and religious background emerges from the original text of the Law, as approved by Parliament in 2004.

Already in Article 1 the legislature sets out certain fundamental statutory aims that reveal the ethical and religious premises of the entire piece of legislation. First and foremost, the use of medically assisted procreation techniques was only permitted in cases where it is necessary to provide a solution to problems of infertility. In this way, these reproductive technologies were characterised as being purely medical procedures reserved for couples with infertility problems. Although this provision may appear neutral at first glance, it carried a significant ideological component.[1039] It excluded the possibility of access to these medical treatments for other purposes, including the prevention of the transmission of genetic diseases to the embryo.[1040] Further, it imposed the condition that all other therapeutic methods aimed at removing the causes of infertility must be exhausted, even if more invasive, before such treatments could be accessed.[1041] Secondly, Article 1 showed clear a clear religious influence when adding that the rights of the unborn child must be guaranteed to the same extent as those of the other subjects involved.[1042] This provision, which runs counter to the case law of the Constitutional Court in this respect,[1043] openly endorsed a principle that is considered imperative according to certain ethical and religious views. Not least it constituted a condition for the support of the Catholic Church to the regulation of assisted procreation techniques.[1044]

1039 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 445; Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 42.

1040 In this regard, the relevance of this statement will become clear in the following paragraphs on the case study of preimplantation genetic diagnosis.

1041 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 444.

1042 Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 42.

1043 Italian Constitutional Court, judgment no. 27/1975, maintains that the right to life and health of the mother, who is already a person, trumps the protection of the embryo, which has yet to become a person.

1044 Milani, '«Veluti si Deus daretur»: la legge n. 40 del 2004 sulla procreazione medicalmente assistita dal dibattito parlamentare all'articolato' (2015) 23(1) Quad dir e pol eccl p. 117, 134.

Indeed, only by considering the rights of the unborn child on a level with those of other individuals can one find a justification for some of the law's subsequent provisions, which increase the risk to the woman's health that are inherent in these procedures. This includes, in particular, the provision in Article 14(2) according to which it was not allowed to generate more than three embryos, all to be implanted at the same time in the uterus of the future mother.[1045] Such a framing implied that all embryos created must be implanted without any selection of those most likely to become viable.[1046] Therefore, this provision both undermined the chances of a successful IVF and created a risk of multiple pregnancies that can be prejudicial to the health of the pregnant mother.

Outside of a framework of ideological and religious assumptions, whereby the rights of the unborn child must be accorded overriding relevance, these outcomes are hardly acceptable.[1047] Likewise, no strictly legal justification can be found for the absolute prohibition on the use gametes from donors outside of the couple (so-called heterologous fertilisation) that is laid down in Article 4(3).[1048] The prohibition can only be fully endorsed from the starting point of ethical and religious positions that view the splitting of parenthood, and the inclusion of a person from outside the couple in the reproductive process, negatively.[1049]

A confirmation of the legislature's negative perception of these technologies was provided by Article 16. This allows medical and healthcare personnel to raise conscientious objections and refuse to perform IVF procedures. This provision, which has been considered superfluous in light

1045 Mastropietro, 'Procreazione assistita: considerazioni critiche su una legge controversa' (2005) 34(4) Dir fam p. 1379, 1395.

1046 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 452.

1047 ibid, p. 456.

1048 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 448; Mastropietro, 'Procreazione assistita: considerazioni critiche su una legge controversa' (2005) 34(4) Dir fam p. 1379, 1410.

1049 Dolcini, 'Embrione, pre-embrione, ootide: nodi interpretativi nella disciplina della procreazione medicalmente assistita (L. 19 febbraio 2004 n. 40)' (2004) 47(2) Riv it dir proc pen p. 440, 448; Milani, '«Veluti si Deus daretur»: la legge n. 40 del 2004 sulla procreazione medicalmente assistita dal dibattito parlamentare all'articolato' (2015) 23(1) Quad dir e pol eccl p. 117, 133.

of the already restrictive regulation imposed by Law no. 40/2004,[1050] is only required if it is assumed that the use of medically assisted procreation technologies may fundamentally conflict with the moral convictions of the doctor.

A feeling of mistrust towards IVF procedures is also reflected in a provision specifying that, when obtaining informed consent, the doctor must inform the subjects in detail about the bioethical concerns of medically assisted reproduction and of the option of resorting to adoption or foster care procedures.[1051]

In conclusion, a reading of the regulation as it was originally enacted reveals not only the religious and moral foundations on which it was adopted, but also an attitude of exclusion towards any other possible ethical vision.[1052] Notwithstanding the law's proclaimed aim of facilitating the resolution of reproductive problems, legal scholars have noted that it has *de facto* hindered patients' ability to access treatment for reproductive disorders.[1053]

The existence of a clear ethical and religious background in support of this strict regulation and against the principle of laicity was also confirmed through developments following the adoption of the law. Three points are worth mentioning here. Firstly, the involvement of representatives of the Catholic religion in a referendum concerning the abrogation of a number of Law no. 40/2004's Articles, including the one banning heterologous fertilisation. The Catholic segment of the campaign called on all religious voters to refrain from participating in the referendum. The aim was to

1050 Carusi, 'La (imminente?) legge italiana sulla procreazione assistita: considerazioni nella propsettiva della "bioetica laica"' (2003) 34(2) Pol dir p. 287, 293; Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 60.

1051 For further details on this provision, laid down in Article 6 of Law no. 40/2004, see Chapter 1, sec. B.II.2.b.

1052 Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 62-ff; Turillazzi and Fineschi, 'Spunti di riflessione medico-legale sulle norme "etiche" in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 75, 76.

1053 Dolcini, 'La legge n. 40 del 2004: alla prova dei fatti, un efficace strumento di lotta contro la procreazione assistita' (2007) 3(12) Corr merito p. 1425; Sanfilippo, 'Dal 2004 al 2014: lo sgretolamento necessario della legge sulla procreazione medicalmente assistita' [2014](3-4) Diritto Penale Contemporaneo p. 376, 377.

prevent the referendum from reaching the necessary voter turnout. The religious lobby's appeal was successful: the proposal could not be approved due to the lack of quorum, despite the fact that the majority of voters who exercised their right to vote were in favour of the proposed amendments.[1054]

Secondly, it can be observed that, with regard to some particularly controversial points, the Italian Parliament was either unable to reach a clear formulation or unwilling to bear the additional ethical responsibility. The approved legislation consequently contains some ambivalent and vague provisions. Such provisions may be a sign that the issues are regarded as especially problematic from an ethical or religious point of view. [1055] This was particularly the case for the parts of the law dealing with preimplantation genetic diagnosis. As will be illustrated in the next paragraph, the question of the admissibility of this technology was left open for interpretation, thus requiring a concrete regulation by the following ministerial guidelines.

Last but most important, the Italian Constitutional Court in various rulings on Law no. 40/2004 has confirmed the illegitimacy of its underlying ethical and religious influences. As already mentioned,[1056] the Court has pointed out the irrationality of several provisions of the regulation on different occasions and has argued that there was no legal justification for the violation of the relevant subjects' fundamental rights.

2. Initial Uncertainty

a Ministerial Guidelines and First Case Law

As briefly noted above, the original wording of Law no. 40/2004 did not provide an unequivocal answer to the question of whether couples eligible for IVF techniques could have additionally resorted to PGD. Such diagnostic procedures, in the absence of a legislative ban, were performed freely

1054 As indicated by Milani, '«Veluti si Deus daretur»: la legge n. 40 del 2004 sulla procreazione medicalmente assistita dal dibattito parlamentare all'articolato' (2015) 23(1) Quad dir e pol eccl p. 117, 138, the proposed amendments were endorsed by more than 77% of the voters, but only 25.6% of the eligible voters took part in the referendum.

1055 Costantini, Chamayou and Guglielmino in D'Amico and Liberali, *La legge n. 40 del 2004 ancora a giudizio: La parola alla Corte costituzionale* (2012) p. 217.

1056 Chapter 1, sec. B.II.2.

until 2004.[1057] Those who believed that the embryo acquired the value of human life from fertilisation, however, already considered them ethically controversial, as the Italian Committee for Bioethics (*Comitato Nazionale per la Bioetica*, CNB) pointed out in its opinion on prenatal diagnoses in 1992.[1058] After the new regulation was approved in 2004, legal scholars were divided on the admissibility of PGD.[1059]

On the one hand, some of the new legal provisions seemed to imply a ban on the use of this diagnosis. Namely, Article 13(2) stated that clinical research on the embryo could only be permitted if it was aimed at the protection and development of that very embryo. The third paragraph of the same Article stated that the selection of embryos for eugenic purposes was prohibited. Moreover, the statutory requirement of a unique and simultaneous implantation of all produced embryos seemed to exclude any possibility of selection.[1060] In this sense, a systematic and combined reading of these provisions seemed to impose an implicit ban on PGD.[1061] On the other hand, it has been argued that a diagnosis with a view to avoiding the transmission of genetic diseases could not in itself be regarded as having eugenic purposes.[1062] Besides, Article 14(5) of Law no. 40/2004 provided that the future parents could be informed of the condition of the embryo's health. The law made no explicit reference either to PGD as such or to the imposition of a ban on it, resulting in an altogether ambiguous legal

1057 Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta: Nota a ord. Trib. Milano sez. I civ. 18 aprile 2017' [2017](6) Fam dir p. 541, 546.

1058 Comitato Nazionale per la Bioetica, 'Diagnosi prenatali' (18.7.1992), p. 33 <https://bioetica.governo.it/media/1920/p9_1992_diagnosi-prenatali_it.pdf> accessed 6.4.2022.

1059 La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 840-ff; Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 546.

1060 Liberali, 'La diagnosi genetica preimpianto fra interpretazioni costituzionalmente conformi, disapplicazione della legge n. 40 del 2004, diretta esecuzione delle decisioni della Corte Europea dei Diritti dell'Uomo e questioni di legittimità costituzionale' [2014](2) Rivista AIC, p. 5.

1061 La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 846.

1062 Scalera, 'Il problema della diagnosi pre-impianto: Nota a: Tribunale Cagliari, 09 novembre 2012' (2013) 45(5) Giurisprudenza di Merito p. 1020; Vallini, 'Ancora sulla selezione preimpianto: incostituzionale la fattispecie di selezione embrionale per finalità eugenetiche, ma non quella di embrionicidio: Corte costituzionale, 21 ottobre 2015, n. 229' [2015](Diritto Penale Contemporaneo).

framework.[1063] This lack of a clear normative stance has been strongly criticised by some legal scholars.[1064] They claimed that the legislature had refused to enshrine an open prohibition in the text of the law, while at the same time trying to create a hostile environment for the performance of such diagnostic techniques.

Ultimately, the task of resolving this normative ambiguity was left to the courts and to the ministerial guidelines that were to be adopted in the implementation of Article 7(1) of Law no. 40/2004. At first, a decision of the court of Catania of 3 May 2004 intervened and found that, in the spirit of the law, the possibility of selecting healthy embryos for the continuation of the procedure was prohibited.[1065] Such an interpretation was soon confirmed by ministerial guidelines that were approved by decree of the Minister of Health on 21 July 2004.[1066] This stated that investigations into the health of embryos could be no more than "merely observational"[1067], thus excluding the possibility of investigating possible genetic conditions and making the ban on PGD explicit.[1068]

On this very point, the ministerial guidelines were challenged by an association representing IVF centres and medical professionals, the World

1063 Liberali, 'La diagnosi genetica preimpianto fra interpretazioni costituzionalmente conformi, disapplicazione della legge n. 40 del 2004, diretta esecuzione delle decisioni della Corte Europea dei Diritti dell'Uomo e questioni di legittimità costituzionale' [2014](2) Rivista AIC, p. 4.

1064 Repetto, 'Non di sola Cedu … La fecondazione assistita e il diritto alla salute in Italia e in Europa' [2013](1) Dir pubbl p. 131, 135; Liberali, 'La diagnosi genetica preimpianto fra interpretazioni costituzionalmente conformi, disapplicazione della legge n. 40 del 2004, diretta esecuzione delle decisioni della Corte Europea dei Diritti dell'Uomo e questioni di legittimità costituzionale' [2014](2) Rivista AIC, p. 4.

1065 Liberali, *Problematiche costituzionali nelle scelte procreative: Riflessioni intorno alla fecondazione medicalmente assistita e all'interruzione volontaria di gravidanza* (2017) pp. 185-ff.

1066 Decreto Ministeriale 21.4.2004, Linee guida in materia di procreazione medicalmente assistita in Gazzetta Ufficiale of 16.8.2004, no. 191.

1067 Author's translation.

1068 See La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 841; Dolcini, 'Legge sulla procreazione assistita e laicità dello stato: da sempre, un rapporto difficile' (2013) p. 7 <https://archiviodpc.dirittopenaleuomo.org/d/2658-legge-sulla-procreazione-assistita-e-laicita-dello-stato-da-sempre-un-rapporto-difficile> accessed 14.4.2021; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 184; Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 547.

Association Reproductive Medicine, who claimed that they were manifestly unjustified and irrational and violated the common principles of the right to health.[1069] Initially, the guidelines passed judicial scrutiny. In its judgment no. 3452 of 9 May 2005, the Regional Administrative Court of Lazio endorsed the previous conclusions of the judges from Catania and held that the guidelines did not conflict with the spirit of Law no. 40/2004 and that there was no right of the couple to a healthy child.

The first signs of hesitation with regard to this restrictive position came from the Tribunal of Cagliari.[1070] This asked the Constitutional Court to rule on the constitutional legitimacy of Article 13 of Law no. 40/2004, insofar as it did not allow recourse to PGD in cases where its omission would entail a danger to the woman's health.[1071] On that occasion, however, the Constitutional Court rejected the question on grounds of inadmissibility.[1072]

In 2007 the same Tribunal of Cagliari set in motion a new development in the case law by concluding that access to PGD had to be granted on the basis of a constitutionally oriented interpretation of the provisions of Law no. 40/2004.[1073] In a judgment of 24 September 2007 the Tribunal held that, although access to PGD would be prohibited by a literal interpretation of the law in light of the criteria that inspired it and a literal reading of the ministerial guidelines, a constitutionally oriented interpretation leads to a different result. As the court pointed out, a constitutionally oriented interpretation, to which judges are bound, was possible due to the lack of

1069 De Francesco, 'La diagnosi genetica preimpianto nell'evoluzione giurisprudenziale: Rassegna Giurisprudenziale' [2016](8-9) Corr giur p. 1151; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 187.

1070 Tribunale di Cagliari, decision 16.7.2005 [2005] 128 Il Foro Italiano p. 2875; Tribunale di Firenze, judgment 17.12.2007 [2008](1) Giur Cost p. 537.

1071 Della Bella, 'La svolta: il Tribunale di Cagliari e il Tribunale di Firenze ammettono la diagnosi preimpianto: Nota a Trib. Cagliari 24 settembre 2007, ord. Trib. Firenze 17 dicembre 2007' [2008](5) Fam pers e succ p. 426.

1072 Della Bella, 'La svolta: il Tribunale di Cagliari e il Tribunale di Firenze ammettono la diagnosi preimpianto' [2008](5) Fam pers e succ p. 426, 431; La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 842.

1073 Casaburi, 'Procreazione assistita: il Tribunale di Cagliari dà luce verde alla diagnosi preimpianto: Nota a Trib. Cagliari 22 settembre 2007' [2008](3) Corr merito p. 313, 318; La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 842.

an express prohibition on the use of PGD in the statute.[1074] The interpretation of Law no. 40/2004 in light of Article 32 of the Constitution showed that PGD should be considered permissible when it is requested by future parents and when it is necessary to ensure their right to be informed about the state of the embryo's health.[1075] The court observed, in particular, that the implantation of an embryo in the uterus constitutes a health treatment and entails risks for the woman's health that might vary according to the state of the foetus' health.[1076] The decision was grounded partly on the protection of informed consent. This served as a means of safeguarding the right to health of individuals who resorted to reproductive technologies and who must be made fully aware of the chances of success and the risks of the procedures.[1077] The Tribunal also maintained that it would be unreasonable, and therefore contrary to Article 3(1) of the Constitution, to deny access to PGD in light of the possibility for the woman to seek invasive prenatal diagnosis or abortion procedures in the future.[1078]

A later ruling by the Tribunal of Florence[1079] confirmed this orientation. The Tribunal of Florence referred to the judgment delivered in Cagliari when it argued that there is no explicit prohibition of PGD in Law no. 40/2004 and that access to PGD is completely legitimate and necessary to ensure the parents' rights to be informed of the state of health of the conceived embryo.

Both rulings argued that, according to this constitutional framework, the ministerial guidelines should be overruled.[1080] The guidelines imposed a prohibition that could not be deduced merely from a reading of the parlia-

1074 Casaburi, 'Procreazione assistita: il Tribunale di Cagliari dà luce verde alla diagnosi preimpianto' [2008](3) Corr merito p. 313, 318; Liberali, 'La diagnosi genetica preimpianto fra interpretazioni costituzionalmente conformi, disapplicazione della legge n. 40 del 2004, diretta esecuzione delle decisioni della Corte Europea dei Diritti dell'Uomo e questioni di legittimità costituzionale' [2014](2) Rivista AIC, p. 9.

1075 Tribunale di Cagliari, judgment 24.11.2007 [2007] 130 Il Foro Italiano p. 3245, 3252-ff.

1076 Tribunale di Cagliari, judgment 24.11.2007 [2007] 130 Il Foro Italiano p. 3245, 3251.

1077 Meola in Fattibene, *La diagnosi genetica preimpianto tra normativa e giurisprudenza* (2017) p. 91.

1078 Tribunale di Cagliari, judgment 24.11.2007 [2007] 130 Il Foro Italiano p. 3245, 3254-ff. See also Gorgoni, 'Il diritto alla diagnosi preimpianto dell'embrione: Nota a Trib. Cagliari 24 settembre 2007' [2008](7) Fam pers e succ p. 605, 610.

1079 Tribunale di Firenze, decision 17.12.2007 [2008](1) Giur Cost p. 537.

1080 Tribunale di Cagliari, judgment 24.11.2007 [2007] 130 Il Foro Italiano p. 3245.

mentary text and they were therefore the result of an arbitrary restrictive interpretation by the government. Therefore, the guidelines were adopted in violation of the boundaries of the executive's powers and of the hierarchy of legal sources.[1081]

In contrast to the Tribunal of Cagliari, whose judgment was considered "free from any ideology"[1082], the judge in Florence seemed to include an openly ethical element in their decision. Regarding the principle of reasonableness, that is the need to interpret the law in conformity with the constitutional provisions of Article 3(1), the court argued that "it is not only irrational but also against a sense of morality" that access to PGD is denied and yet the woman is later allowed to have an abortion.[1083] This statement was a clear indication of the ethical implications of the issues at stake. It suggests, however, that, in this specific case, the Tribunal might have failed to limit the use of the principle of reasonableness to its constitutionally demanded form. The statement reveals that the judge's moral standpoint might have been applied as a yardstick for assessing the unreasonableness of the provision. In contrast with this approach, the principle of reasonableness should only be used to verify the correctness of the balance of interests within the constitutional system and thereby eliminates those ethical and religious considerations that must remain external to the legal system.

Ultimately, the ministerial guidelines containing the provision explicitly prohibiting PGD were rendered void in 2008 by a ruling of the Regional Administrative Tribunal in Lazio. Referring to the interpretation of the judges of Cagliari and Florence, the administrative court held that the

1081 See Della Bella, 'La svolta: il Tribunale di Cagliari e il Tribunale di Firenze ammettono la diagnosi preimpianto' [2008](5) Fam pers e succ p. 426, 437; La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 843.

1082 Casaburi, 'Procreazione assistita: il Tribunale di Cagliari dà luce verde alla diagnosi preimpianto' [2008](3) Corr merito p. 313, 318 (author's translation). However, some commentators argue that both courts have overstepped the bounds of a constitutional conform interpretation and have adopted their own views on the admissibility of the practices under scrutiny, thus encroaching on the competencies reserved to Parliament and the Constitutional Court, see Pellizzone, 'Fecondazione assistita e interpretazione costituzionalmente conforme. Quando il fine non giustifica i mezzi' [2008](1) Giur Cost p. 537, 562.

1083 Tribunale di Firenze, decision 17.12.2007 [2008](1) Giur Cost p. 537, 551 (author's translation).

ministerial authority only has the power to pass highly technical regulations and not to make choices that fall within the discretion of the legislature.[1084]

The new ministerial guidelines that were issued by the Ministerial Decree of 11 April 2008 implemented the judgment of the Regional Administrative Tribunal and merely included the prohibition to carry out diagnoses for eugenic purposes.

b PGD for Infertile Couples: Tacit Approval of the Constitutional Court

After the shift in the case law, the main remaining statutory obstacle to performing PGD was the provision in Article 14(2) of Law no. 40/2004. Under this it was mandatory to create a maximum of three embryos per cycle and to simultaneously implant them all in the uterus of the future mother. In 2009 a ruling of the Constitutional Court removed this legal obstacle. With its judgment no. 151/2009 the Court ruled that the requirement to create a maximum of three embryos and to implant them simultaneously violated not only Article 3 of the Italian Constitution, in its aspects of reasonableness and equality, but also Article 32, as it would imply an infringement of the woman's health.[1085] A margin of appreciation should have been left to the doctor for the medical evaluation of each individual case. A requirement of simultaneous implantation of all embryos, applicable to every woman regardless of her subjective circumstances, was considered by the Court to be unreasonable and contrary to scientific evidence.[1086]

As a result of the judgment, doctors were entitled to independently reach a decision on the number of embryos strictly necessary for the procedure in the specific case, possibly also taking into account the need to perform PGD.[1087] Although the text of the decision does not mention PGD, the substance of the ruling certainly influences the feasibility of this medical procedure.[1088] The cases from which the constitutional review was

1084 TAR Lazio, sez III quarter, judgment 21.1.2008, no. 398 [2008] 131 Il Foro Italiano, p. 207, 213-214. See also De Francesco, 'La diagnosi genetica preimpianto nell'evoluzione giurisprudenziale' [2016](8-9) Corr giur p. 1151.

1085 Italian Constitutional Court, judgment no. 151/2009, para. 6.

1086 Judgment no. 151/2009, para. 6.1.

1087 As sustained by Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 200.

1088 On the consequences of this ruling for PGD see D'Avack, 'L'ordinanza di Salerno: ambiguità giuridiche e divagazioni etiche' (2010) 39(4) Dir fam p. 1737; Baldini in

initiated involved precisely a number of couples with genetically transmissible diseases who wanted to have recourse to PGD but were unable to do so in practice because of the limits set out in Article 14(2) of Law no. 40/2004.[1089] Hence, had the constitutional judge not regarded this treatment as admissible within the existing legal framework, an additional constitutional question would have had to be raised on the legitimacy of PGD as a matter that was logically prior to the merits. The Court could not have ruled on issues arising from the applicants' request to carry out an unlawful practice.[1090] In this regard, the majority of the legal scholars regarded the Court's silence on the point as a tacit assent to PGD.[1091]

It has been argued, however, that the Court did not explicitly acknowledge the lawful nature of PGD and that legal scholars inferred this conclusion with a certain automatism.[1092] Some authors argued that, in light of the ethical and moral implications of PGD, it would have been more appropriate to interpret the silence of the constitutional judges as a form of respect for the margin of appreciation of the legislature.[1093] In this respect, the widespread uncertainty following the constitutional judgment can also be seen as a sign of a certain ideological disapproval of this reproductive technology.[1094]

These uncertainties were at least partially resolved by further decisions of the ordinary courts. Although no explicit statement on the lawfulness of PGD could be derived from the Constitutional Court's ruling, the tribunals of Bologna and Cagliari repeatedly[1095] maintained that the prohibition on preimplantation diagnosis had been lifted, expressly referring to judgment

D'Amico and Liberali, *La legge n. 40 del 2004 ancora a giudizio: La parola alla Corte costituzionale* (2012) pp. 205-ff.

1089 Baldini in D'Amico and Liberali, *La legge n. 40 del 2004 ancora a giudizio* (2012).

1090 ibid.

1091 ibid, p. 184. See also D'Amico in D'Amico and Pellizzone, *I diritti delle coppie infertili. Il limite dei tre embrioni e la sentenza della Corte costituzionale* (2010).

1092 Critically assessed by La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839, 845.

1093 La Rosa, 'La diagnosi genetica preimpianto: un problema aperto' [2011](8-9) Fam dir p. 839.

1094 Baldini in D'Amico and Liberali, *La legge n. 40 del 2004 ancora a giudizio* (2012) p. 181.

1095 For details on this case law, see Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 202.

no. 151/2009.[1096] The decision of the Tribunal of Cagliari clearly stated that the expenses related to PGD had to be covered by the National Health Service.[1097]

There must be an acknowledgement of the efforts of the judges to respond to the question of PGD's admissibility during a period of extreme uncertainty.[1098] The rulings of the civil and administrative courts overcame barriers on the ability to access a diagnostic procedure that had been imposed as a result of ethical and religious concerns. Indeed, a diagnostic procedure that the Constitutional Court would, only a few years later, recognise as essential to the protection of the fundamental right to health.

c PGD for Fertile Couples

It had seemed clear up to that point that couples could only apply for access to PGD if they also qualified for IVF under Article 1 of Law no. 40/2004 in the first place – i.e. if they also suffered from infertility.[1099] However, a later controversial decision of the Tribunal of Salerno, dated 9 January 2010, extended for the first time the right of access to IVF with PGD to fertile couples. This decision upheld the claim of a fertile couple who suffered from a severe genetic disease. Referring again to the Constitutional Court judgment of 2009, the ruling was based on two different arguments. Firstly, a regulation that prohibits access to PGD for a woman whose only other alternative is a natural pregnancy with subsequent abortion was deemed unreasonable. The second argument was based on the existence, in the opinion of the court, of a right of the woman to have a healthy child, which would fall within the fundamental rights set out in Article 2 of the Constitution. On this basis the Salerno ruling was strongly criticised by

1096 With regard to the decisions of the Tribunal in Bologna, see D'Avack, 'L'ordinanza di Salerno: ambiguità giuridiche e divagazioni etiche' (2010) 39(4) Dir fam p. 1737; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 202; for the decision of the Tribunal in Cagliari, see Scalera, 'Il problema della diagnosi pre-impianto' (2013) 45(5) Giurisprudenza di Merito p. 1020; Vallini, 'La diagnosi preimpianto è un diritto: Commento a Tribunale di Cagliari, 9 novembre 2012' [2013](4) Corriere del Merito p. 431.

1097 Tribunale di Cagliari, decision 9.11.2012 [2013](4) Corr merito p. 429.

1098 Iadicicco, 'La diagnosi genetica preimpianto nella giurisprudenza italiana ed europea: L'insufficienza del dialogo tra le Corti' [2015](2) Quaderni cost p. 325, 329-ff.

1099 As illustrated above, Law no. 40/2004 was indeed only aimed at addressing infertility issues.

many authors, who argued that the judge should have referred the matter to the Constitutional Court rather than deviating from a sound interpretation of the law.[1100]

Except for the isolated ruling of the Salerno court, barriers to accessing PGD remained in place in Italy for couples who were fertile but carried genetically transmissible diseases. Couples without fertility problems did not fall within the categories targeted by Law no. 40/2004. Against this background, a couple, who were both carriers of cystic fibrosis, decided to bring an application before the European Court of Human Rights after suffering a first abortion.[1101]

The applicants maintained that the ban that national law imposed on this technology infringed their right to private life and to non-discrimination according to Articles 8 and 14 of the ECHR.

In the assessment of the ECtHR, confirmed by the statements of the Italian government, the Italian legislation contained a general prohibition of PGD.[1102] The court held that this ban constituted an interference with the right to private and family life.[1103] Unlike the illusionary wish to a "healthy child",[1104] the "desire to conceive a child unaffected by the genetic disease of which they are healthy carriers" is protected under Article 8 of the Convention in the opinion of the court.[1105]

The subsequent analysis of the proportionality of the interference revealed the irrationality of the legislative choices underlying Law no. 40/2004. On the one hand, the court admitted that the regulation can

1100 D'Avack, 'L'ordinanza di Salerno: ambiguità giuridiche e divagazioni etiche' (2010) 39(4) Dir fam p. 1737, 1740; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 206.

1101 ECtHR, *Costa Pavan v Italy*, App. no. 54270/10 (28.8.2012).

1102 Thus allegedly including a ban on access to PGD for infertile couples. In this regard, the Court seems to have overlooked the developments in the case law illustrated in the previous paragraph. As pointed out by Penasa, 'The Italian regulation on Assisted Reproductive Technologies facing the European Court of Human Rights: the case of Costa and Pavan v. Italy' [2012](37) Revista de derecho y genoma humano p. 155, 172: this "represents further evidence of the condition of legal uncertainty provoked by a legislation which does not expressly take position on a relevant – ethically and socially sensitive – issue".

1103 ECtHR, *Costa Pavan v Italy*, App. no. 54270/10 (28.8.2012), para. 58.

1104 On this distinction made by the Court, see Penasa, 'The Italian regulation on Assisted Reproductive Technologies facing the European Court of Human Rights: the case of Costa and Pavan v. Italy' [2012](37) Revista de derecho y genoma humano p. 155, 171.

1105 ECtHR, *Costa Pavan v Italy*, App. no. 54270/10 (28.8.2012), para. 57.

be regarded as pursuing legitimate aims, such as the protection of morals and the rights and freedom of others.[1106] Nonetheless, the resulting legal framework was inconsistent.

The court pointed out that the legislation allowed the applicants to abort a genetically affected foetus while at the same time impeding access to a previous diagnosis.[1107] This revealed how the existing provisions upheld interests that were foreign to the protection of the constitutional rights of the involved subjects.[1108] Therefore, although the state's margin of appreciation is particularly wide when the case raises sensitive ethical issues, the court maintained that there was a disproportionate interference with the rights of the applicants. This was in light of the existence of a legislative framework in which abortion was authorised if prenatal diagnoses showed a genetically affected embryo.[1109]

From this brief overview of the judgment it becomes clear that the ethical and moral significance of the issues at stake was not sufficient to prevent a finding of an ECHR violation. In this respect, the ethical and religious stances promoted by Law no. 40/2004 could not justify an infringement of the couple's right to private and family life. This argument would also find traction in the later 2015 judgment of the Italian Constitutional Court.

3. Constitutional Court Intervention

Following the judgment of the European Court of Human Rights, a comparable matter was raised before the Italian Constitutional Court. Here again, the initial cases were filed by couples who, while not suffering from a diagnosed infertility condition, wanted to have access to PGD in order to avoid the risk of passing on genetically transmissible diseases to their offspring. The judicial review was submitted to the Constitutional Court by a judge in Rome, who claimed that Article 1 and 4(1) of Law no. 40/2004 – which only allowed couples with a certified infertility problem to access medically assisted reproduction techniques – could be in breach of Articles

1106 ECtHR, *Costa Pavan v Italy*, App. no. 54270/10 (28.8.2012), para. 59.

1107 On this point, see Iadicicco, 'La diagnosi genetica preimpianto nella giurisprudenza italiana ed europea' [2015](2) Quaderni cost p. 325, 331-ff.

1108 Repetto, 'Non di sola Cedu … La fecondazione assistita e il diritto alla salute in Italia e in Europa' [2013](1) Dir pubbl p. 131, 144.

1109 Penasa, 'The Italian regulation on Assisted Reproductive Technologies facing the European Court of Human Rights: the case of Costa and Pavan v. Italy' [2012](37) Revista de derecho y genoma humano p. 155, 177.

2 (inviolable rights of the person and self-determination in reproductive choices), 3 (reasonableness), 32 (right to health) and 117(1) (in combination with Articles 8 and 14 of the ECHR) of the Constitution.

The Constitutional Court investigated a possible violation of Articles 3 and 32, and found it unnecessary to address the other grounds of appeal. The judgment, no. 96/2015, was thus issued on the grounds of reasonableness and the right to health and held that the selective prohibition of access to PGD for couples not affected by infertility problems was unconstitutional.

The Court also referred to the above mentioned ECtHR decision of *Costa and Pavan v. Italy*.[1110] It noted that, within the current legal framework, couples carrying serious genetic conditions were left with no other option than to try with natural pregnancies and, if necessary, to have an abortion. The applicable legislation thus prevented future mothers from obtaining prior information that would prevent them from undergoing an abortion procedure later in their pregnancy, with possible adverse effects on their physical and mental health.[1111] For these reasons the judgment declared the measures contained in Law no. 40/2004 not only contrary to the right to health, but also unreasonable. The provisions resulted from an unreasonable balancing of the interests at stake, in breach of the principle of reasonableness of the legal system.[1112]

Following these considerations, the Constitutional Court used its powers to directly intervene and amend the statutory text. With a technique called 'additive ruling' (*sentenza additiva*) the Court can declare a statute unconstitutional insofar as it does not provide for a certain measure. The consequence of such rulings is that the Court is able to directly add a phrase to the legislative provision under review. In judgment no. 96/2015 the Court thus declared Articles 1 and 4 of Law no. 40/2004 unconstitutional insofar as they did not provide for fertile couples suffering from transmissible

1110 On this point, see Nardocci, 'Dalla Convenzione alla Costituzione: la tacita sintonia tra le Corti. A margine di Corte cost. sent. n. 96 del 2015.' [2016](1) BioLaw Journal – Rivista di BioDiritto p. 271, 273-ff.

1111 Italian Constitutional Court, judgment no. 96/2015, conclusions in point of law para. 9.

1112 Italian Constitutional Court, judgment no. 96/2015, conclusions in point of law para. 9. See also Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1742.

genetic diseases that met the seriousness criteria of the abortion legislation to have access to fertility treatment (including PGD).

The ruling also once again implicitly recognised the admissibility of PGD for couples who met the infertility requirements laid down by Law no. 40/2004.[1113] Furthermore, it endorsed the previous developments in the case law of the ordinary judges that already interpreted the provisions broadly and extended the possibilities of access to PGD.[1114]

The decision was partly criticised for having *de facto* distorted the original scope and purpose of the law on medically assisted procreation. The declared aim of Law no. 40/2004 had indeed been limited to addressing infertility problems.[1115] However, the judges could not shy away from their duty to rectify the manifest breach of reasonableness and the threat that this posed to the health of future mothers.[1116]

The Court's use of the standard of reasonableness shows how the Court wished to remove all those provisions from the legal system that, by responding to a normative framework external to the constitutional order, were lacking a legitimate basis of justification. If the ethical and religious perspectives are not taken into account, then the threat to the patient's health appears, as stated in the judgment, to be unreasonable. The only justification for such an infringement of the right to health could be derived from the consideration of ethical and religious aspects, which the Court definitively excluded as legitimate grounds in this ruling.[1117]

With two important clarifications the Court specified the scope of the judgment and showed a path for its implementation. Firstly, it stated that the medical conditions suffered by couples wishing to have access to PGD

1113 Pomiato, 'Diagnosi preimpianto e tutela dell'embrione: un equilibrio ancora precario' [2016](1) Europa e diritto privato p. 219, 232; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 220.

1114 Penasa, 'La sentenza n. 96 del 2015 della Corte costituzionale: l'insostenibile debolezza della legge 40' [2015](3) Quaderni cost p. 755.

1115 As reported by Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 223.

1116 Tripodina, 'Le parole non dette. In lode alla sentenza 96/2015 in materia di fecondazione assistita e diagnosi preimpianto per coppie fertili portatrici di malattia genetica' [2015](2) wwwcostituzionalismoit, p. 4-ff; Iannicelli, 'Diagnosi genetica preimpianto: battute finali della 'riscrittura costituzionale' della l. n. 40/2004' (2016) 33(2) Corr giur p. 188, 195.

1117 Cf. considerations by Vallini, 'Il curioso (e doloroso) caso delle coppie fertili portatrici di malattie ereditarie, che potevano ricorrere all'aborto, ma non alla diagnosi e selezione preimpianto' (2015) 58(3) Riv it dir proc pen p. 1457, 1472.

must be verified by specialised public structures. Secondly, the legislature was given the task of identifying the diseases that may justify access to this diagnostic procedure, as well as the ways in which the facilities carrying out this procedure will be authorised and monitored.[1118] More specifically, the Court maintained that these medical conditions must meet a certain severity threshold whereby, if transmitted to the foetus, they would negatively affect the physical and mental health of the pregnant mother. By doing so, the ruling explicitly echoed the legislation on abortion, thus correcting the system's irrationality and inconsistency.[1119]

Among the points left open by judgment no. 96/2015 there remained the question of whether the healthcare professional's actions when performing PGD were criminally relevant. Although the ruling had implicitly acknowledged the acceptability of these diagnostic procedures, it did not invalidate the provision of Law no. 40/2004 that determined embryonic selection of all kinds for eugenic purposes to be a criminal offence.[1120] This contradiction was addressed, once again, by the Constitutional Court in another judgment of the same year.[1121] The Court found the provision partially unconstitutional. It argued that the provision should explicitly exclude any conduct aimed at preventing the in-utero transfer of embryos which suffer from transmissible genetic disorders that meet the requirements of gravity and scrutiny set out in the previous decision.[1122] Although some authors have insisted that the applicability of Article 13 to such non-eugenic practices would have to be ruled out anyway, the ruling provided the

1118 Italian Constitutional Court, judgment no. 96/2015, conclusions in point of law para. 9.

1119 Pellizzone, 'L'accesso delle coppie fertili alla diagnosi genetica preimpianto dopo la sentenza 96 del 2015: le condizioni poste dalla Corte costituzionale' [2015] Forum di Quaderni Costituzionali, p. 5; Iannicelli, 'Diagnosi genetica preimpianto: battute finali della 'riscrittura costituzionale' della l. n. 40/2004' (2016) 33(2) Corr giur p. 188, 195; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) 228.

1120 For more details on the scope of application of this provision, see Iagnemma, 'Diagnosi genetica preimpianto: problemi aperti in rapporto alla sentenza della Corte costituzionale n. 229/2015' [2016](1) Riv ital med leg dirit campo sanit p. 317, 329.

1121 Italian Constitutional Court, judgment no. 229/2015.

1122 Italian Constitutional Court, judgment no. 229/2015, conclusions in point of law para. 2.2.

Court with the opportunity to explicitly endorse selective implantation of embryos following PGD.[1123]

II. PGD in the National Health Service

1. Lack of National Public Coverage

Since the initial approval of Law no. 40/2004 the performance of medically assisted procreation had been largely left to private facilities, rather than assigning responsibility for it to the National Health Service.[1124] It already appeared from the statutory text that the allocation of public funding to assisted reproduction techniques would be fairly modest.[1125] The provision of such a scarce allocation of public resources can be interpreted as a sign of the religious and moral foundations of this regulation and the compatibility of this measure with the constitutional right to health has been questioned.[1126]

The problem of a shortage of public funding has recurred repeatedly in the years following the adoption of the legislation. The most significant issues were in the field of medically assisted reproduction through the use of gametes external to the couple, so-called heterologous fertilisation, and preimplantation genetic diagnosis. In both these instances the delay in the National Health Service's coverage of costs has severely affected both the right to health of the individuals concerned and their right to equality. In the absence of an update of the Essential Levels of Care (LEA)[1127] at the national level, decisions on the reimbursement of these health technologies were left entirely to the discretion of the different Regions. This created

1123 Vallini, 'Ancora sulla selezione preimpianto: incostituzionale la fattispecie di selezione embrionale per finalità eugenetiche, ma non quella di embrionicidio' [2015](Diritto Penale Contemporaneo).

1124 See Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 62.

1125 For a comment on the limited fund for medically assisted procreation techniques provided for in Article 18 of Law no. 40/2004, see Gentilomo and Piga, 'La procreazione tra natura e cultura: alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita' (2004) 26(1) Riv it med leg p. 41, 62.

1126 ibid.

1127 Representing the health benefit basket of the National Health Service, see Chapter 1, sec. B.II.2.b.

differences in the protection of the right to health that were based on the place of residence of the patients.[1128]

For example, public coverage of the costs of heterologous fertilisation procedures was completely different from one Region to another[1129] for a significant period after the Constitutional Court judgment no. 162/2014.[1130] A draft decree-law aimed at including heterologous assisted reproduction among the LEA was presented to the Council of Ministers by the Minister of Health as early as August 2014. Yet this was discarded by the Prime Minister. Despite clear indications from the Constitutional Court that access to these techniques was relevant to fundamental rights and the right to health,[1131] the rejection was openly based on the ethical aspects of the matter. On account of this the decision allegedly fell within the responsibility of Parliament.[1132]

Subsequently, the Regions reached an agreement on the approach to be adopted in publicly funding heterologous fertilisation at the Conference

1128 Lugarà, 'L'abbandono dei LEA alle Regioni: il caso della procreazione medicalmente assistita' [2015](1) Rivista AIC p. 1, 8; Siciliano, 'Sull'apporto delle dinamiche del diritto amministrativo alla tutela della decisione di avere figli con la tecnica della PMA eterologa: dalla "relativizzazione" del vuoto normativo all'orizzonte delle generazioni future' [2020](2) BioLaw Journal – Rivista di BioDiritto p. 209, 215.

1129 For an overview on the different public coverage to heterologous fertilisation offered by the regional systems, see Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1745-ff.

1130 Which found heterologous fertilisation to be permitted within the constitutional order, thus declaring the prohibition in Article 4(3) of Law no. 40/2004 contrary to Articles 2, 3, 29, 31 and 32 of the Constitution. For the case of public funding of IVF using gametes from outside the couples, see further considerations in Chapter 1, sec. B.II.2.b.

1131 Italian Constitutional Court, judgment no. 162/2014, conclusions in point of law para. 7.

1132 As reported by Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1743; Veronesi, 'La legge sulla procreazione assistita perde un altro "pilastro": illegittimo il divieto assoluto di fecondazione eterologa' [2015](1) Istituzioni del federalismo p. 5, 29. A reference to ethical issues can be explicitly read in the Minister of Health's letter of 8 August 2014 to the group leaders of the Chamber of Deputies and the Senate, available online at: <https://www.salute.gov.it/portale/donna/dettaglioNotizieDonna.jsp?lingua=italiano&menu=notizie&p=dalministero&id=1701> accessed 10.8.2022.

of Regions and Autonomous Provinces.[1133] Nevertheless, given that the Regions are not obliged to ensure the financial coverage of services not included in the LEA, the failure to intervene at the national level has resulted in considerable discrimination across Regions with regard to the right to access these reproductive technologies.[1134]

A similar scenario with respect to PGD followed from the Constitutional Court judgment no. 96/2015.[1135] Due to 'precautionary needs' the Constitutional Court assigned the assessment of the medical conditions suffered by couples wishing to access PGD to public facilities.[1136] With this provision the judgment appears to have sought to avert the risk that a widespread use of preimplantation genetic diagnosis would be encouraged primarily by private facilities' prospects for financial gain.[1137] But more importantly, it seems that the Court also intended to ensure couples' effective access to these reproductive technologies.[1138] By assigning this activity to the National

1133 Conferenza delle Regioni e delle Province Autonome, 'Documento sulle problematiche relative alla fecondazione eterologa a seguito della sentenza della Corte Costituzionale nr. 162/2014' (04.9.2014). See Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1744; Veronesi, 'La legge sulla procreazione assistita perde un altro "pilastro": illegittimo il divieto assoluto di fecondazione eterologa' [2015](1) Istituzioni del federalismo p. 5, 32; Lugarà, 'L'abbandono dei LEA alle Regioni: il caso della procreazione medicalmente assistita' [2015](1) Rivista AIC p. 1, 3.

1134 Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1744; Lugarà, 'L'abbandono dei LEA alle Regioni: il caso della procreazione medicalmente assistita' [2015](1) Rivista AIC p. 1, 3; Siciliano, 'Sull'apporto delle dinamiche del diritto amministrativo alla tutela della decisione di avere figli con la tecnica della PMA eterologa: dalla "relativizzazione" del vuoto normativo all'orizzonte delle generazioni future' [2020](2) BioLaw Journal – Rivista di BioDiritto p. 209, 217-ff.

1135 Iadicicco, 'Finalmente una decisione del giudice delle leggi sulla diagnosi genetica preimpianto, in attesa del doveroso intervento del legislatore' [2015](3) Giur Cost p. 797, 803.

1136 Italian Constitutional Court, judgment no. 96/2015, conclusions in point of law para. 9.

1137 Pellizzone, 'L'accesso delle coppie fertili alla diagnosi genetica preimpianto dopo la sentenza 96 del 2015: le condizioni poste dalla Corte costituzionale' [2015] Forum di Quaderni Costituzionali, p. 6; Iadicicco, 'Finalmente una decisione del giudice delle leggi sulla diagnosi genetica preimpianto, in attesa del doveroso intervento del legislatore' [2015](3) Giur Cost p. 797, 803; Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 230.

1138 Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) pp. 230-ff.

Health Service's responsibilities the judgment ensures that it is provided within a neutral structure, devoid of any religious, ethical or political connotations. This will guarantee this service to all couples who have the right to access it. In this respect, the ruling of the Constitutional Court creates another implicit connection with the abortion regulation, [1139] which prescribes the involvement of public facilities in the abortion procedure.[1140]

This also results directly from the fact that the Court has, in this ruling, clearly placed access to PGD under the constitutional protection of Article 32.[1141] As previously illustrated this comprises not only a negative and individual component of the right to health but also a significant social and positive dimension. From this perspective the decision to base the right of access to PGD not on a right of self-determination in reproductive choices,[1142] but rather on the right to health,[1143] has consequences for the scope of the ruling as well as on the public healthcare system's responsibility for guaranteeing the service. This circumstance, together with the explicit mentioning of the public structures that are responsible for verifying the conditions, raises the question of the National Health Services' obligation to cover the costs of PGD.[1144]

In view of the explicit reference made in the ruling to the mandatory competence of public facilities for the verification of couples' genetically transmissible diseases, the subsequent update of the LEA was expected to specifically include PGD as one of the Essentials Levels of Care at the national level.

Nevertheless, already upon the publication of the judgment concerns were voiced that delays by the legislature and the health administration

1139 Pellizzone, 'L'accesso delle coppie fertili alla diagnosi genetica preimpianto dopo la sentenza 96 del 2015: le condizioni poste dalla Corte costituzionale' [2015] Forum di Quaderni Costituzionali, pp. 7-ff.

1140 See Chapter 1, sec. B.II.2.b.

1141 Liberali, *Problematiche costituzionali nelle scelte procreative* (2017) p. 231.

1142 As derived by Art. 2 of the Italian Constitution.

1143 Penasa, 'La sentenza n. 96 del 2015 della Corte costituzionale: l'insostenibile debolezza della legge 40' [2015](3) Quaderni cost p. 755, 756; Iadicicco, 'Finalmente una decisione del giudice delle leggi sulla diagnosi genetica preimpianto, in attesa del doveroso intervento del legislatore' [2015](3) Giur Cost p. 797, 801.

1144 As observed by Iadicicco, 'Finalmente una decisione del giudice delle leggi sulla diagnosi genetica preimpianto, in attesa del doveroso intervento del legislatore' [2015](3) Giur Cost p. 797, 803.

would ultimately undermine the Constitutional Court's decision and *de facto* prevent access to PGD.[1145]

This concern unfortunately proved to be well-founded. The update of the Essential Levels of Care occurred with the Prime Minister's Decree of 2 January 2017[1146] which added all health services necessary for homologous and heterologous medically assisted reproduction[1147] to the nomenclature of outpatient specialist care.[1148] This did not, however, include any reference to PGD.[1149]

In this instance too, pending a ministerial or legislative decision on National Health Service coverage, access to these diagnostic procedures depends entirely on the specific Region in which access to the service is being sought. Only a few Regions have included PGD services in their Regional Healthcare System's nomenclature. These include Tuscany. With its resolution no. 444 of 1 April 2019[1150] it established the reimbursement of PGD by the Regional Healthcare System for all eligible couples resident

---

1145 Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1760-ff; Iadicicco, 'Finalmente una decisione del giudice delle leggi sulla diagnosi genetica preimpianto, in attesa del doveroso intervento del legislatore' [2015](3) Giur Cost p. 797, 803.

1146 DPCM of 12.1.2017 'Definizione e aggiornamento dei livelli essenziali di assistenza, di cui all'articolo 1, comma 7, del decreto legislativo 30 dicembre 1992, n. 502' in Gazzetta Ufficiale Serie Generale no. 65 of 18.3.2017.

1147 As regards heterologous fertilisation, there are delays in the implementation of the LEA update. In fact, the new procedures included in the tariff nomenclature can only be offered to couples, upon payment of a small fee (the so-called "ticket"), once the relevant tariffs have been approved by the Ministry of Health. In the absence of approval of the tariffs, which has been delayed by more than three years, the schemes established at regional level continue to apply, see Aceti, 'Nuovi Lea. Che fine ha fatto il "Decreto Tariffe"? Approvarlo subito per rendere esigibili i nuovi diritti dei pazienti e ridurre le disuguaglianze' (29.9.2020) <https://www.quotidianosanita.it/lavoro-e-professioni/articolo.php?articolo_id=88333> accessed 14.7.2021; Siciliano, 'Sull'apporto delle dinamiche del diritto amministrativo alla tutela della decisione di avere figli con la tecnica della PMA eterologa: dalla "relativizzazione" del vuoto normativo all'orizzonte delle generazioni future' [2020](2) BioLaw Journal – Rivista di BioDiritto p. 209, 212.

1148 DPCM of 12.1.2017, attachment no. 4.

1149 Fattibene, 'La diagnosi genetica preimpianto dalla sentenza della Corte costituzionale all'ordinanza del giudice comune. Ed il legislatore?: Considerazioni, a prima lettura, sull'ord. Tr. Milano, sez. I civ. depositata il 18 aprile 2017.' [2017](2) BioLaw Journal – Rivista di BioDiritto p. 209, 225.

1150 Regione Toscana (Giunta Regionale), Deliberazione no. 444 of 1.4.2019 in Bollettino Ufficiale Della Regione Toscana, 10.4.2019 (15), pp. 109-111.

in the Region. It also provided for cost-sharing by patients and estimated a total expenditure for the Regional Healthcare System of € 120,000 in the coming years for PGD.

Currently the only possible solution for guaranteeing PGD services on an equal footing across the country would be to make a further revision of the Decree setting out the Essential Levels of Care. Nonetheless, such an update has not been implemented to date, despite the well-known discriminatory effects that follow from the current situation and the continuous letters sent by numerous associations operating at the national level to the Ministers of Health and to the members of the commission responsible for updating the LEA.[1151]

This issue and other unresolved problems of the regulation of medically assisted procreation have also been the subject of a recent draft law submitted by a group of Members of Parliament to the Chamber of Deputies on 11 June 2019.[1152] The proposal's introductory text argues that the regulation of medically assisted procreation and the shortcomings in its reimbursement policy are the irrational outcome of "ideological superstructures" and a veritable "ideological war".[1153]

2. Direct Application of Constitutional Principles in the Case Law

In the context of an ongoing failure to update the LEA, the decision on the reimbursement of preimplantation genetic diagnosis is left to the Regions and has been influenced by the case law of ordinary judges.

Even before the Constitutional Court's ruling of 2015, Tribunals had not only considered PGD admissible, but also in some instances ordered public hospitals to perform it. In 2012 the decision of the Tribunal of Cagliari had not only authorised the applicants to have access to preimplantation genetic diagnosis, but had also established that the costs should be borne

1151 See 'Pma. Luca Coscioni: "Inserire tra le tecniche di procreazione le indagini genetiche preimpianto"' (22.1.2018) <https://www.quotidianosanita.it/governo-e-parlamento/articolo.php?articolo_id=58200> accessed 14.7.2021 and the letter sent to the Minister of Health in 2020, available at <https://www.associazionelucacoscioni.it/wp-content/uploads/2020/07/Lettera-aperta-al-Ministro-della-Salute-Roberto-Speranza.pdf> accessed 8.8.2022.

1152 Mammì et al., Proposta di legge C. 1906 'Disposizioni in materia di procreazione medicalmente assistita e di prevenzione, diagnosi e cura dell'infertilità femminile e maschile' (11.6.2019).

1153 ibid (author's translation).

by the National Health Service.[1154] The judge found that the public facility was required to perform PGD and that, if unable to offer it directly to the patients, it would have to guarantee that patients receive the treatment in another facility and that the costs would be publicly covered.

Since the Constitutional Court's ruling which confirmed that preimplantation diagnosis must be guaranteed by public healthcare facilities[1155] and pending the update of the Essential Levels of Care, a number of couples have resorted to the ordinary courts to have their right of access to PGD in the public sector fulfilled.

A first decision was handed down in 2017 by the Tribunal of Milan, to which a couple had applied in order to be granted access to PGD techniques under emergency circumstances. The interim order, issued by a single judge on 18 April 2017, upheld the couple's right to access PGD.[1156]

In the first place the decision referred to the principles set out in judgment no. 96/2015 of the Constitutional Court. The judge argued that the constitutional ruling can be directly enforced by the ordinary courts, thanks to the indications and conditions established by the Constitutional Court.[1157] Following these criteria the judge examined the first requirement. Namely, the severity of the condition that is likely to be transmitted to the foetus in light of the serious damage that could be caused to the mother by the continuation of her pregnancy. Secondly, the question whether the facility is to be considered a public facility according to the precautionary principle (as laid down in the judgment no. 96/2015 of the Constitutional Court) was thoroughly assessed.[1158] Having found that both conditions prescribed by the Constitutional Court were fulfilled, the Tribunal had to rule on the alleged technical obstacles – related to the unavailability of the necessary equipment to perform PGD for the specific genetic condition of the couple – raised by the defendant. In this respect it was maintained that access to PGD falls within the essential core of the fundamental right to

1154 Tribunale di Cagliari, decision 9.11.2012 [2013](4) Corr merito p. 429.

1155 Bergo, 'Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di "regionalismo sanitario"' [2015](5) Giur Cost p. 1738, 1743-ff.

1156 Tribunale di Milano, decision 18.4.2017 [2017](6) Fam dir p. 535.

1157 Fattibene, 'La diagnosi genetica preimpianto dalla sentenza della Corte costituzionale all'ordinanza del giudice comune. Ed il legislatore?' [2017](2) BioLaw Journal – Rivista di BioDiritto p. 209, 211-ff.

1158 Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 556.

health and that it therefore cannot be jeopardised by technical or financial obstacles.[1159] Allowing women's access to PGD to be dependent on the technical availabilities of the healthcare facility would amount to a situation where this right is placed at the complete discretion of the healthcare facility.[1160]

In their argumentation the judge referred to the Council of State's ruling against the Region Lombardia.[1161] This had found the discrimination in the reimbursement regime for homologous and heterologous fertilisation to be unreasonable. In its ruling the highest administrative court had pointed out that the guarantee of the effectiveness of the right to health is entirely entrusted to the health administration. Accordingly, in a welfare state scarcity of means cannot allow the National Health Service to disregard patients' demands for healthcare treatments.[1162] Therefore, as reported by the Tribunal of Milan, whilst financial needs must be taken into account in the balancing of rights, they cannot entirely compromise the essential core of the right to health.[1163]

For these reasons the judge ordered the defendant to perform PGD and to only transfer the healthy embryos into the woman's uterus. The decision also provides that, should the public healthcare facility be unable to provide the healthcare service directly, PGD must be provided indirectly through the use of other healthcare facilities. The court thus demonstrates that, after the Constitutional Court's judgment no. 96/2015, access to PGD within

1159 Carlino, 'La selezione preimpianto tra autodeterminazione procreativa e tutela del diritto alla salute della donna: Nota a ord. Trib. Milano sez. I civ. 21 luglio 2017; ord. Trib. Milano sez. I civ. 18 aprile 2017' (2018) 83(1) Responsabilità civile e previdenza p. 229, 242-ff.

1160 Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 558; Fattibene, 'La diagnosi genetica preimpianto dalla sentenza della Corte costituzionale all'ordinanza del giudice comune. Ed il legislatore?' [2017](2) BioLaw Journal – Rivista di BioDiritto p. 209, 210.

1161 Consiglio di Stato, sez. III, judgment 20.7.2016, no. 3297 [2017] 2 Il Foro Italiano p. 74.

1162 Consiglio di Stato, sez. III, judgment 20.7.2016, no. 3297 [2017] 2 Il Foro Italiano p. 74, para 14.1.

1163 Tribunale di Milano, decision 18.4.2017 [2017](6) Fam dir p. 535. See Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 557.

the public healthcare system can no longer be left to the full discretion of individual healthcare facilities or Regions.[1164]

An appeal against the interim order was filed to a panel of judges of the same Tribunal by the Ministry of Health and the public healthcare facility. The appeal aimed, *inter alia*, to ask the tribunal to clarify which entity would have to bear the financial burden of providing the ordered healthcare treatment. The question was raised in light of the circumstance that PGD had not yet been included in the Essential Levels of Care nor provided for as a health benefit by the health administration of the Region Lombardia. Once again this factor was considered irrelevant by the court.[1165] Furthermore, with regard to the possible technical difficulties in the provision of the service, the judges reiterated that a patient residing in one Region can also receive health services in another Region.[1166] In order to avoid further delays in the couple's access to PGD the decision clarified that, if unable to overcome the technical difficulties, the public healthcare facility would have to refer the couple to another structure equipped to carry out PGD and that the financial burden would have to be borne by the Region Lombardia.[1167]

A similar case was later brought before the Tribunal of Vercelli.[1168] In this instance the couple applied for an interim measure aimed at granting them access to preimplantation genetic diagnosis in a healthcare facility of a different Region, for which the costs would be covered by their Region of residence. The Region Piemonte, where the couple resided, responded by arguing that PGD was not included among the services listed in the regional benefit baskets, nor in the Essential Levels of Care as updated by the Prime Ministerial Decree of 12 January 2017. It therefore could not be performed at a public facility. Moreover, the cost would have been unbearable considering that the couple would have travelled to another Region to

1164 Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta: Nota a ord. Trib. Milano sez. I civ. 18 aprile 2017' [2017](6) Fam dir p. 541, 558.

1165 Tribunale di Milano, sez. 1, decision 21.7.2018 [2018](1) Corr giur p. 50.

1166 ibid.

1167 On this point, Iannicelli, 'Diagnosi genetica preimpianto e coppie fertili portatrici di malattie genetiche trasmissibili: il giudice di merito applica la sentenza della Corte cost. n. 96/2015: Nota a ord. Trib. Milano sez. I civ. 18 aprile 2017; ord. Trib. Milano sez. I civ. 21 luglio 2017' [2018](1) Corr giur p. 52, 60-ff.

1168 Tribunale Vercelli, sez. lavoro, decision 15.10.2018 [2019](11) Giurisprudenza Italiana p. 2390.

receive the treatment. Nevertheless, the Tribunal of Vercelli maintained that the health administration did not have the discretion to exclude PGD from the services provided by its health system because, after the Constitutional Court ruling no. 96/2015, this would entail an infringement of the fundamental right to health of the woman and the unborn child.[1169] The regional administration would otherwise be allowed to *de facto* restrict patients' access to PGD, which would result in an administrative body's deliberations illegitimately trumping the Constitutional Court's directions.[1170] Once again reference is made to the aforementioned judgment of the Council of State of the exclusion of heterologous fertilisation from the healthcare services offered in Lombardia.

More recently, a case brought before the Tribunal of Rovigo was resolved by a settlement between the health administration and the appellant couple.[1171] In this case too the couple sought funding from the health service in their Region of residence to access PGD in another Region. At the first hearing the health administration of the Region Veneto agreed to provide reimbursement of the necessary costs and the proceedings were thus discontinued.

In conclusion, the illustrated case law demonstrates how ordinary judges have succeeded in granting couples access to PGD at the cost of the Regional Healthcare System. They were successful in spite of delays and opposition from the legislature and central government and from the individual regional administrations. The decisions analysed have thus succeeded in directly applying the Constitutional Court's judgment no. 96/2015 and in demonstrating how access to ethically controversial health technologies, such as PGD, can be essential for a full guarantee of the right to health.[1172]

However, it should be borne in mind that these are all isolated decisions, taken by judges of first instance that in fact only benefit the individual applicants. Moreover, criticism was expressed with regard to the way in which the ordinary courts resolved the issue of compensation for the parties' legal

1169 ibid.

1170 Falletti, 'Costi dell'accesso alla diagnosi preimpianto: alcune riflessioni giuridiche: Nota a ord. Trib. Vercelli sez. lav. 15 ottobre 2018; sent. Trib. Vercelli 20 dicembre 2018' [2019](11) Giurisprudenza Italiana p. 2393, 2398.

1171 Tribunale di Rovigo, sez. lavoro, decision 19.3.2019, available at: <http://schuster.pro/tribunale-rovigo-ordinanza-19-marzo-2019-in-materia-di-diagnosi-genetica-preimpianto/> accessed 10.8.2022.

1172 Carrato, 'Diagnosi preimpianto: l'applicazione giurisprudenziale della sentenza n. 96/2015 della Consulta' [2017](6) Fam dir p. 541, 558.

and procedural expenses.[1173] In both the proceedings before the Tribunal of Milan and the Tribunal of Vercelli the judges held that the absolute novelty of the matter or the change in the case law justified an equitable division of the litigation costs between the two parties to the case. They therefore refused to reimburse the legal expenses incurred by the couples. Especially in light of the fact that legal fees might be almost comparable to the cost of the requested healthcare treatment and that the issue could not be considered as absolutely new after the ruling of the Constitutional Court, these decisions were criticised as posing a further barrier to accessing PGD in the form of a procedural sanction.[1174]

In sum, the current circumstances do not ensure equal access to PGD for all eligible couples. This situation leads to an ongoing infringement of the right to health that, pending legislative intervention or the revision of the Essential Levels of Care, could only be remedied by resorting to judicial control, as happened in the case of heterologous fertilisation.[1175]

C. Preimplantation Genetic Diagnosis in England

I. PGD in the Human Fertilisation and Embryology Act 1990

1. Ethical Approach

The regulation of preimplantation genetic diagnosis falls within the scope of the Human Fertilisation and Embryology (HFE) Act. However, no mention of this technique was made in the original version of the Act passed in 1990. The reason for this omission is that PGD was not yet sufficiently developed at the time of the deliberations of the Warnock Committee,[1176]

1173 Falletti, 'Costi dell'accesso alla diagnosi preimpianto: alcune riflessioni giuridiche' [2019](11) Giurisprudenza Italiana p. 2393, 2402.

1174 Falletti, 'Costi dell'accesso alla diagnosi preimpianto: alcune riflessioni giuridiche' [2019](11) Giurisprudenza Italiana p. 2393, 2402.

1175 Fattibene, 'La diagnosi genetica preimpianto dalla sentenza della Corte costituzionale all'ordinanza del giudice comune. Ed il legislatore?' [2017](2) BioLaw Journal – Rivista di BioDiritto p. 209, 225.

1176 The Warnock Committee's report dedicates a paragraph on preimplantation genetic diagnosis but also admits that "given the present relatively low success rates for pregnancy following IVF, it is unlikely that embryonic biopsy will become a feasible method of detecting abnormal embryos for some considerable time", Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and

on whose report the legislation was based, nor at the time of the debate in Parliament.[1177] However, the development of a technique to select embryos carrying no genetic conditions for implantation was already looming on the horizon. Indeed, it appears that the prospect of the development of this technology served as an important driver for the approval of the Act itself.[1178] PGD's potential to fight severe genetic diseases was mentioned repeatedly by parliamentarians supporting the Bill in the debate[1179] and, as the case law would later confirm,[1180] the statutory text showed a tacit acceptance that, once developed, such diagnoses would fall within its regulatory framework.

The development of the ethical approach on which the legislation was to be based was entrusted to the Committee of Inquiry into Human Fertilisation and Embryology. This was known as the Warnock Committee as it was chaired by Baroness Warnock, then Professor of Moral Philosophy in Oxford.[1181]

In the absence of a written constitution, the English legal system lacked overriding and binding normative stances on the status of the embryo. Hence, the committee was entrusted with the task of considering the different ethical positions existing within society and to arrive at recommendations that represented the "embodiment of a common moral position"[1182] and could, therefore, provide a legitimate basis for legislation. As the committee noted in its report, it was called upon to reach a normative

---

Embryology', London 1984, p. 73 See also Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis: A Comparative and Theoretical Analysis* (2012) p. 71.

1177 Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 168; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 126; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 59.

1178 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 72; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 126; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 57.

1179 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 127.

1180 *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005).

1181 Other committee members were academics, lawyers, health professionals and social workers, see Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, pp. ii-iv.

1182 ibid, p. 3.

compromise that would be acceptable to society as a whole, even if different opinions would remain about the details of the regulation.[1183] The committee also pointed out that, after a legitimate common ethical baseline has been found, it is still possible for the individual to adhere to stricter moral standards.[1184] Specifically, the recommendations revolved around the common principle, endorsed by all members of the committee,[1185] that the embryo must be accorded a 'special status'.[1186] The language of rights and in particular the right to life could not be extended to the embryo under English law.[1187] The assumption that the embryo is not legally protected as a human person was reasserted by the committee and remained valid after the adoption of the Human Fertilisation and Embryology Act 1990, as later confirmed by the courts.[1188] However, the recognition of the embryo's special status required that some degree of legal protection be granted to it. This was indeed recommended by the committee.[1189]

1183 "In recommending legislation, then, we are recommending a kind of society that we can, all of us: praise and admire, even if, in detail, we may individually wish that it were different", see Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology' (London 1984), p. 3 <https://www.hfea.gov.uk/media/2608/warnock-report-of-the-committee-of-inquiry-into-human-fertilisation-and-embryology-1984.pdf> accessed 25.1.2022

1184 ibid.

1185 Warnock in Leist, *Um Leben und Tod* (1990) p. 227.

1186 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 63. See Scott, *Choosing Between Possible Lives: Law and Ethics of Prenatal and Preimplantation Genetic Diagnosis* (2007) p. 255; Hammond-Browning, 'Ethics, Embryos, and Evidence: A Look Back at Warnock' (2015) 23(4) Med Law Rev p. 588, 590; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 137.

1187 Warnock in Leist, *Um Leben und Tod* (1990) p. 220; McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 112. See also the considerations behind the abortion regulation: "The fact that we do not have a rights-based abortion law reflects the pragmatic development of the law in a country which, before the Human Rights Act 1998, did not deeply engage with rights language", Scott, 'The Uncertain Scope of Reproductive Autonomy in Preimplantation Genetic Diagnosis and Selective Abortion' (2005) 13(3) Med Law Rev p. 291, 314.

1188 *Evans v Amicus Healthcare Ltd & Ors* [2004] EWCA Civ 727 (25 June 2004), para 107. See Gomez, 'The Special Status of the Human Embryo in the Regulation of Assisted Conception and Research in the United Kingdom' (2011) 17(1) Medico-Legal Journal of Ireland p. 6, 16.

1189 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 63.

The scope of this protection has been specified in a compromise solution suggested by the committee. Hereby there is a threshold of 14 days after fertilisation beyond which the embryo cannot be kept alive, unless transferred to a woman, nor used for research purposes.[1190] Beyond that threshold the use of embryos in vitro was to be made a criminal offence.[1191]

The possibility of using the embryo only for the first fourteen days of its development was a pragmatic[1192] compromise inspired by utilitarian principles.[1193] This solution does not provide answers to the moral question of when human life begins, although it is considered informed by a gradualist approach.[1194] The committee's aim was not so much to provide a definitive answer to this moral question,[1195] but rather to find a core compromise that society would agree to and feel committed to.[1196] The members of the committee, who had very different moral opinions, felt they could endorse this compromise without necessarily having to find a solution to the moral question of the precise status of the embryo – on which disagreement in a pluralist society is inevitable.[1197] The committee also suggested establishing an independent authority to "regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions".[1198] This

1190 ibid, p. 66.
1191 ibid
1192 Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524, 528.
1193 As outlined in the report, Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 65 and later confirmed by Baroness Warnock, see Hammond-Browning, 'Ethics, Embryos, and Evidence' (2015) 23(4) Med Law Rev p. 588, 618; McMillan, *The Human Embryo In Vitro* (2021) p. 44.
1194 Hammond-Browning, 'Ethics, Embryos, and Evidence' (2015) 23(4) Med Law Rev p. 588, 605.
1195 Wilson, 'Creating the 'ethics industry': Mary Warnock, in vitro fertilization and the history of bioethics in Britain' (2011) 6(2) BioSocieties p. 121, 135; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 127.
1196 "Indeed, in the spirit of philosophical pluralism, the Committee viewed its role as 'discover[ing] the public good'", Conley, 'Who Gets to Be Born?: The Anticipatory Governance of Pre-implantation Genetic Diagnosis Technology in the United Kingdom from 1978–2001' (2020) 7(3) J Responsible Innov p. 507, 514.
1197 Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524.
1198 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 75.

authority would be in charge of regulating both human embryo research and fertility treatments.

Given the very different ethical and disciplinary backgrounds of its members, the committee understood itself as having public accountability in the formulation of recommendations.[1199] To ensure the legitimacy of the outcome it nevertheless proceeded to collect opinions and evidence from many stakeholders, such as health authorities, universities, medical and religious associations, charities and others.[1200] Due to the ethical concerns surrounding the issue the Department of Health and Social Security issued another consultation paper[1201] before presenting a proposal for legislation, which was largely based on the committee's recommendations, in a 1987 White Paper.[1202] In the meantime a less permissive proposal for legislation had been considered and rejected by Parliament.[1203] The ethically controversial nature of the in vitro use of human embryos was reflected in the extensive parliamentary debates on both bills and in the fact that MPs were given the freedom to vote according to their conscience.[1204] Altogether, the time span between the Warnock Committee's report and the adoption of the HFE Act in 1990 was quite long.[1205] Still, the committee's recommendations were a major influence on the legislation passed by Parliament.[1206]

1199 Wilson, 'Creating the 'ethics industry'' (2011) 6(2) BioSocieties p. 121, 130; Conley, 'Who Gets to Be Born?' (2020) 7(3) J Responsible Innov p. 507, 513.

1200 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, pp. 6 and 95-ff.

1201 Department of Health and Social Security, 'Legislation on human infertility services and embryo research: a consultation paper' (London 1986) Cm 46 <https://wellcomecollection.org/works/jvn4ek6a> accessed 18.2.2022, see Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524.

1202 Department of Health and Social Security, 'Human Fertilisation and Embryology: A Framework for Legislation' (1987) Cm 259, see Goodhart, 'Embryo experiments' (1988) 297(6651) BMJ p. 782; Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524.

1203 The Unborn Children (Protection) Bill, introduced into Parliament by the conservative MP Enoch Powell in 1985, see Wilson, 'Creating the 'ethics industry'' (2011) 6(2) BioSocieties p. 121, 134-135; Hammond-Browning, 'Ethics, Embryos, and Evidence' (2015) 23(4) Med Law Rev p. 588, 590.

1204 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 127.

1205 As noted by Hammond-Browning, 'Ethics, Embryos, and Evidence' (2015) 23(4) Med Law Rev p. 588, 591; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) pp. 56-57.

1206 And are still considered influential today, Hammond-Browning, 'Ethics, Embryos, and Evidence' (2015) 23(4) Med Law Rev p. 588, 589. For instance, the House

The HFE Act 1990 adopted the 14-day cut-off point for embryo research and use[1207] and established the Human Fertilisation and Embryology Authority (HFEA), an independent authority charged with the task of authorising the use of human embryos in vitro, including in the context of fertility treatments.[1208] According to Section 41 HFE Act, any use of the embryo in vitro outside the statutory boundaries of the Act or without prior authorisation of the HFEA would constitute a criminal offence. The option for the individual to remain bound by stricter moral standards than those set out in the legislation, which was supported by the Warnock Committee, is safeguarded by Section 38 of the HFE Act. This provides a conscience clause whereby no individual who has a conscientious objection shall be compelled to participate in any of the activities regulated by the Act.

The utilitarian and gradualist ethical perspective embraced by the Warnock Committee had thus been operationalised through parliamentary legislation.[1209]

2. Initial Uncertainty

a HFEA's Licensing of PGD

The HFE Act established the Human Fertilisation and Embryology Authority as an independent body consisting of members appointed by the Secretary of State. Schedule 1 to the HFE Act (as enacted) provided that between one third and one half of the members should be medical professionals or researchers with experience in the field of the use or storage of embryos in vitro.[1210] This membership has resulted in the licensing body deriving its legitimacy from its scientific expertise rather than from its democratic

of Commons Science and Technology Committee reaffirmed the validity of the Warnock approach when drafting a proposal to reform the HFE Act in 2005, see House of Commons Science and Technology Committee, 'Human Reproductive Technologies and the Law', London 14.3.2005, p. 22

1207 Human Fertilisation and Embryology Act 1990 (as enacted) sec. 3(4).

1208 Human Fertilisation and Embryology Act 1990 (as enacted) sec. 5 and sec. 11.

1209 McMillan, *The Human Embryo In Vitro* (2021) p. 68.

1210 Human Fertilisation and Embryology Act 1990 (as enacted) schedule 1 para. 4.

representativeness.[1211] As a form of public accountability, the Authority was required to submit annual reports for the Secretary of State to present to Parliament.[1212]

Aside from this, the Authority was given considerable autonomy in determining the scope of the practices to which a licence could be granted. The arrangement under the HFE Act enabled Parliament to establish the basic normative criteria, setting the general requirements and boundaries of permissible activities, whilst giving the Authority the discretion to determine the licensing of treatments within these legal boundaries. The Authority was required to issue and periodically update a code of practice, in order to provide guidance on the use of techniques involving fertility treatments.[1213] It was thus responsible for developing its own standards of acceptability for newly developed treatments.[1214]

This was also the case with PGD. As later confirmed by the case law,[1215] a presumption that PGD fell within the statutory limits of the HFE Act could be based on a reading of two of its elements. According to Schedule 2, which determines the activities for which licences may be granted, the HFEA could authorise all "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".[1216] Moreover, the Authority could explicitly authorise the licensing of embryo research for the purpose of "developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation".[1217] Considering that research to advance methods of preimplantation genetic diagnosis was promoted by the Act, it would be unreasonable to conclude that the techniques, once

1211 Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524, p. 528; Jones, 'The Department of Health Review of the Human Fertilisation and Embryology Act 1990' (2006) 1(4) Clinical Ethics p. 200, 203.

1212 Human Fertilisation and Embryology Act 1990 (as enacted) sec. 7.

1213 Human Fertilisation and Embryology Act 1990 (as enacted) sec. 7.

1214 Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524, 527.

1215 *Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 (16 May 2003).

1216 Human Fertilisation and Embryology Act 1990 (as enacted) schedule 2 para. 1(1)(d). See Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 59.

1217 Human Fertilisation and Embryology Act 1990 (as enacted) schedule 2 para. 3(2)(e).

fully developed, would be prohibited by the criminal law.[1218] Therefore, as soon as this technique developed enough for clinical practice, the HFEA began to license fertility centres to perform it.

In doing so, the Authority often made use of public consultations. In 1993 the HFEA held its first consultation exercise on the issue of sex selection using PGD.[1219] This resulted in a ban on selecting embryos on the basis of sex except for medical reasons, contained in the HFEA's Fifth Code of Practice.[1220] As PGD techniques became available to select for more complex characteristics, the granting of licences to fertility centres was initially carried out under an interim policy issued by the HFEA in 1999.[1221] In parallel, because of the ethical dilemmas raised by PGD, the Authority together with the Advisory Committee on Genetic Testing (ACGT) initiated a broad public consultation on the different uses of the technique with a view to updating and stabilising its guidance.[1222] The results of this extensive consultation were collected and processed by a working group involving the HFEA and the Human Genetic Commission (HGC). As a result, the HFEA was able to adapt its PGD guidelines in its Sixth Code of Practice in line with the outcome of the consultation as published in 2001.[1223]

In particular, the consultation suggested that the permissibility criteria for PGD should be aligned with those for prenatal diagnosis of the foetus in the mother's womb.[1224] The aim was to bring PGD under the same restric-

1218 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 72; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 73.

1219 Human Fertilisation and Embryology Authority, 'Sex Selection: Public Consultation Document. London' (London January 1993).

1220 Human Fertilisation and Embryology Authority, 'Code of Practice: 5th Edition' (London 2001), racc. 9.9, p. 41 <https://portal.hfea.gov.uk/media/1582/hfea-code-of-practice-5th-edition.pdf> accessed 18.2.2022.

1221 Conley, 'Who Gets to Be Born?' (2020) 7(3) J Responsible Innov p. 507, 517.

1222 Scott, *Choosing Between Possible Lives* (2007) p. 200; Fovargue and Bennett, 'What Role Should Public Opinion Play in Ethico-Legal Decision Making? The Example of Selecting Sex for Non-Medical Reasons Using Preimplantation Genetic Diagnosis' (2016) 24(1) Med Law Rev p. 34, 50; Conley, 'Who Gets to Be Born?' (2020) 7(3) J Responsible Innov p. 507, 518.

1223 Human Genetics Commission, Human Fertilisation & Embryology Authority, 'Outcome of the public consultation on preimplantation genetic diagnosis', London November 2001.

1224 Liddell, *Biolaw and Deliberative Democracy* (2003) p. 97.

tions applicable to lawful abortion.[1225] Just as the Abortion Act 1967 provided for the possibility of aborting a foetus where there was a substantial risk of "physical or mental abnormalities as to be seriously handicapped",[1226] the Sixth Code of Practice provided that PGD could only take place where there was a "significant risk of a serious genetic condition".[1227]

However, unlike in the case of abortion, both the outcome of the consultation and the provisions in the Sixth Code of Practice revealed that the assessment of the significant risk of a serious genetic condition shall be based not only on objective but also on subjective criteria.[1228] Indeed, the consultation document emphasised the importance of the views of the prospective parents in this regard. It was argued that patients seeking treatment should have a central role in assessing the significance and seriousness of a risk of a genetic condition, and that their opinions should be discussed and agreed upon with the health professional team providing the treatment.[1229] Accordingly, the Sixth Code of Practice provided a list of criteria to be considered in this evaluation. Among the circumstances to be taken into account in determining the appropriateness of PGD were "the view of the people seeking treatment of the condition to be avoided" as

1225 "The Consultation Document states that both 'raise the same general issues in relation to the seriousness of inherited conditions'" as reported by Scott, 'Choosing Between Possible Lives: Legal and Ethical Issues in Preimplantation Genetic Diagnosis' (2006) 26(1) Oxf J Leg Stud p. 153, 158–159. See also Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis' (2007) 15(3) Med Law Rev p. 320, 322; Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) 74.

1226 Abortion Act 1967 sec. 1(1)(d).

1227 Human Fertilisation and Embryology Authority, 'Code of Practice: 6th Edition' (London 2003), p. 124 <https://portal.hfea.gov.uk/media/1583/hfea-code-of-practice-6th-edition.pdf> accessed 18.2.2022 See Scott, 'Choosing Between Possible Lives' (2006) 26(1) Oxf J Leg Stud p. 153, 154-155; Scott, *Choosing Between Possible Lives* (2007) p. 200; Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 74.

1228 Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis' (2007) 15(3) Med Law Rev p. 320, 323; Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) pp. 75–76; Fovargue and Bennett, 'What Role Should Public Opinion Play in Ethico-Legal Decision Making? The Example of Selecting Sex for Non-Medical Reasons Using Preimplantation Genetic Diagnosis' (2016) 24(1) Med Law Rev p. 34, 39.

1229 Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis' (2007) 15(3) Med Law Rev p. 320, 323.

well as their previous reproductive experience and family circumstances.[1230] Other factors to be considered were the likely degree of suffering associated with the condition, the current or prospective availability of therapy, the speed of degeneration, the extent of any intellectual impairment and availability of social support.[1231] The rejection of a list of genetic conditions to be considered serious as such, together with the emphasis on the protection of the reproductive autonomy of couples seeking treatment was, according to the outcome of the consultation, appropriate to avoid discriminatory and stigmatising effects towards individuals affected by genetic disorders.[1232]

A constant adaptation to society's changing attitudes was regularly sought by bodies and authorities working in the field of reproductive technologies. Shortly after the publication of the Sixth Code of Practice, the Human Genetics Commission launched a further public consultation on the issues of prenatal diagnosis and preimplantation genetic diagnosis.[1233] Following the results of this consultation, the HGC changed its position on whether the criteria for preimplantation diagnosis of the embryo in vitro should be aligned with those for prenatal diagnosis of the foetus in utero.[1234] This was because, also according to the gradualist principle endorsed by the Warnock report, the moral status of the embryo in vitro would necessarily remain inferior to that of the foetus in an advanced pregnancy.[1235]

1230 Human Fertilisation and Embryology Authority, 'Code of Practice', London 2003, p. 124. See also Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis' (2007) 15(3) Med Law Rev p. 320, 323.

1231 Human Fertilisation and Embryology Authority, 'Code of Practice', London 2003, p. 124. See also Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis' (2007) 15(3) Med Law Rev p. 320, 329–330.

1232 Scott, 'The Uncertain Scope of Reproductive Autonomy in Preimplantation Genetic Diagnosis and Selective Abortion' (2005) 13(3) Med Law Rev p. 291, 318.

1233 The public consultation ran from July to October 2004. The results were published in 2005 in the document Human Genetics Commission, 'Choosing the Future: Genetics and Reproductive Decision-Making — Analysis of Responses to the Consultation' (2005). The conclusions and recommendations based on it were published in 2006, UK Human Genetics Commission, 'Making Babies: Reproductive Decisions and Genetic Technologies' (2006) 11(1) Jahrbuch für Wissenschaft und Ethik p. 485. See Kmietowicz, 'Commission Invites Discussion on the Future of Genetics in Reproduction' (2004) 329(7459) BMJ 192; Scott, 'Choosing Between Possible Lives' (2006) 26(1) Oxf J Leg Stud p. 153, 163 fn. 51.

1234 Scott, *Choosing Between Possible Lives* (2007) p. 294.

1235 ibid

The HFEA decided to follow the recommendations of the HGC on this point. As a result, the explicit equating of PGD admissibility criteria with those of prenatal diagnosis and abortion was abandoned in the Seventh Code of Practice.[1236] The HGC also concluded that the fear that PGD would initiate a slippery slope, which would lead to 'designer babies' with enhanced intelligence or beauty, was misplaced.[1237] Despite the expansion of the number of genetic conditions for which the HFEA guaranteed licences, a demarcation line had persistently been drawn that excluded diagnoses for purely non-medical conditions.[1238]

In conclusion, a continuous observation of public opinion has proven to have an influence on the adaptation of the criteria for the acceptability of PGD and on the decisions of the HFEA in the field.[1239] The possibility for the HFEA to monitor the technological developments and to adapt its guidance accordingly, as well as to the changing positions in society, is a successful feature of the normative framework established in 1990. It has endowed the original HFE Act with a great deal of flexibility and adaptability[1240] and allowed it to serve as a public forum for discussion.[1241] Within the limits of legal boundaries the regulation of reproductive techniques could be adjusted to the changing circumstances without having to go through Parliament. Simultaneously, the connection with public opinion was maintained through consultation mechanisms.[1242]

1236 See Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 75.

1237 UK Human Genetics Commission, 'Making Babies' (2006) 11(1) Jahrbuch für Wissenschaft und Ethik p. 485, 488.

1238 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 128.

1239 Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 177.

1240 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 125.

1241 Asscher, 'The Regulation of Preimplantation Genetic Diagnosis (PGD) in the Netherlands and the UK: A Comparative Study of the Regulatory Frameworks and Outcomes for PGD' (2008) 3(4) Clinical Ethics p. 176, 178; Moore, 'Public Bioethics and Deliberative Democracy' (2010) 58(4) Political Studies p. 715, 723.

1242 Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 60; Jasanoff and Metzler, 'Borderlands of Life: IVF Embryos and the Law in the United States, United Kingdom, and Germany' (2020) 45(6) Science, Technology, & Human Values p. 1001, p. 1028.

b Case law on PGD

Despite the ethical dilemmas raised by PGD techniques, their licensing by the HFEA was not initially challenged before the courts.[1243] This only came about as PGD began to be used in conjunction with the even more controversial technique of preimplantation tissue typing (PTT).[1244] PTT allowed for the selection of an embryo to serve as a tissue-matched donor for a living sibling already suffering from a disease which is curable by tissue transplant, thus creating a 'saviour sibling' for an existing child.

In 2002 the HFEA granted a licence to conduct preimplantation tissue typing in combination with PGD for the first time, albeit subject to several conditions. This decision was challenged through judicial review by Comment on Reproductive Ethics (CORE), a public interest group focusing on ethical concerns related to new reproductive technologies and proponent of absolute respect of the embryo in vitro.[1245] The judgments of the Court of Appeal[1246] and the House of Lords[1247] in the case, although focused on the admissibility of PTT, also touched on the issue of the lawfulness of the HFEA's practice of licensing PGD given that this competence was not explicitly conferred by the wording of the HFE Act (as enacted).[1248] The focus of CORE's appeal centred on the claim that Parliament had failed to transfer a power to issue licences for PGD and PTT to the HFEA. While at first instance the court overturned the HFEA's decision on this

1243 Indeed "[i]n the first ten years of the HFEA's existence, licensing PGD to enable couples to avoid passing on very serious genetic conditions to their offspring proved to be relatively uncontroversial", Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 72. The technique of PTT is not allowed in Germany nor in Italy.

1244 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis: A Comparative and Theoretical Analysis* (2012) p. 72.

1245 See Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 305.

1246 *Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 (16 May 2003).

1247 *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005).

1248 "CORE's challenge was by no means a hopeless cause for the question of whether the Authority has power to license the testing of embryos (whether by PGD, HLA, or both) is not straightforward. The framework legislation, the Human Fertilisation and Embryology Act, 1990, does not make specific and unequivocal provision for such testing", Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 305.

basis,[1249] both the Court of Appeal and the House of Lords rejected such an interpretation.

Through the consideration of background material, such as the report of the Warnock Committee and parliamentary proceedings and discussions, the Court of Appeal – later upheld by the House of Lords – maintained that the scope of the HFE Act encompassed an authorisation for the HFEA to grant licences for PGD. This was based on two considerations. Firstly, it was clear from the reading of the HFE Act that preimplantation genetic diagnosis should not be regarded as prohibited. Parliament could not have simultaneously declared PGD unacceptable while explicitly authorising embryo research to improve such techniques.[1250] Secondly, the Authority was empowered by the HFE Act to issue licences for all activities that were necessary or desirable for the purpose of providing treatment services.[1251] Paragraph 1 (1)(d) of Schedule 2 of the HFE Act (as enacted) provided that licences could be granted for any 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". According to the Court of Appeal this formulation left open the possibility for the HFEA to decide whether PGD was necessary or desirable for that purpose.[1252] This was based on the consideration that "[w]here the object of the treatment is to enable a woman to bear a child confident that it will not carry a hereditary defect, an embryo will only be suitable for the purpose of being placed within her if it is free of that defect".[1253] The Court of Appeal and the House of Lords thus endorsed the subjective approach towards the purpose of treatment that had also been enshrined in the HFEA codes of practice.

1249 *R (Quintavalle) v Human Fertilisation and Embryology Authority* [2002] EWHC 3000 (Admin) (20 December 2002).

1250 *Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 (16 May 2003), paras. 81-86 and 120. See Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 308.

1251 Human Fertilisation and Embryology Act (as amended), schedule 2 para. 1(3).

1252 Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority [2003] EWCA Civ 667 (16 May 2003), para. 90. See Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 175.

1253 Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority [2003] EWCA Civ 667 (16 May 2003), para. 44. See Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 308.

Both courts avoided the question of the ethical admissibility of PGD treatments. The reason for this did not lie in judicial restraint, but rather in the fact that the case only raised a question regarding the correct statutory interpretation of the scope of the powers entrusted to the HFEA by Parliament.[1254] In this respect, the judges argued that the Parliament had intended to confine itself to establishing a few fundamental prohibitions but had otherwise aimed at leaving the decision as to exactly what should be acceptable to the HFEA.[1255] It was thus confirmed that the ethical assessment of PGD was within the discretionary scope of the HFEA.[1256] Lord Phillips MR's judgment for the Court of Appeal stated that "[w]hether and for what purposes such a choice [as to the characteristics of the child to be born] should be permitted raises difficult ethical questions. My conclusion is that Parliament has placed that choice in the hands of the HFEA".[1257]

In sum, the case law confirmed that the HFEA had used its power correctly in issuing licences for PGD. However, this was not because PGD was considered ethically permissible, but rather because the decision on its ethical acceptability was entrusted to the HFEA in the first place.[1258]

1254 Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 307; Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 177; Veitch, *The Jurisdiction of Medical Law* (2017) p. 145.

1255 *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005), para. 22: "It could nevertheless be more sensible for Parliament to confine itself to a few prohibitions which could be clearly defined but otherwise to leave the authority to decide what should be acceptable".

1256 "[W]hilst there may be important ethical questions to be resolved where technology 'enables a choice to be made as to the characteristics of the child to be born', Parliament has handed this task to the Authority", Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 309.

1257 *Quintavalle, R (on the application of) v Human Fertilisation and Embryology Authority* [2003] EWCA Civ 667 (16 May 2003), para. 50. According to the House of Lords, "[t]he authority was specifically created to make ethical distinctions", *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005), para. 28.

1258 "[T]he Court remained true to its traditional role in dispensing its function of judicial review – that of upholding the rule of law. It decided that the HFEA had not exceeded its legal powers in permitting tissue typing because the 1990 Act allowed it to do so, and not because the Court was of the view that tissue typing was ethically permissible", Veitch, *The Jurisdiction of Medical Law* (2017) p. 145.

c Emergence of 'Regulatory Disconnections'

Although the House of Lords' confirmation of the HFEA's licensing powers gave legitimacy to its policies regarding PGD,[1259] a sense of "regulatory disconnection" [1260] soon became apparent.

First of all, the gap between what was explicitly allowed according to the statutory text as approved in 1990 and the range of reproductive techniques actually licensed by the HFEA became more and more pronounced.[1261] The wide margin of discretion left to the Authority, while allowing for a great deal of regulatory flexibility and adaptability, started to fall short in terms of public accountability.[1262] The HFEA is indeed a body legitimised by its expertise rather than by its representativeness. Therefore, the legitimacy of policies that concerned matters posing particular ethical problems or innovations, and which were not explicitly addressed by statutory provisions, could only be improved through the involvement of Parliament.[1263] Parliamentary intervention was increasingly considered desirable in order to avoid uncertainties arising from a complete reliance on discretionary case-by-case decisions by the HFEA.[1264] The uncertain legal framework also left open the possibility of further legal challenges to the HFEA's power

1259 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 76.

1260 Term used in this regard by Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 181 who argues that the development of PGD "generates a normative disconnection".

1261 ibid, p. 161.

1262 Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 319; Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 183.

1263 As was recognised by the HFEA, see Montgomery, Jones and Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Mod Law Rev p. 343, 354: "[t]he HFEA has recognised the legitimacy problems facing an unelected body making policy under the umbrella of its statutory powers and has had to fight a number of cases in the courts where its legal authority has been challenged. One of the strategies employed to address this concern, as with many of the regulatory bodies established to deal with matters of health care law, has been to legitimate decisions by preparing for them through public consultation". See also Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) pp. 201-202.

1264 Brownsword, 'Reproductive Opportunities and Regulatory Challenges' (2004) 67(2) Mod Law Rev p. 304, 320.

by those who were ethically opposed to new developments in reproductive technologies, as had happened in the case of PTT.[1265]

In addition, some inconsistencies had developed within the HFEA's own practices. Initially, licences to conduct PGD were given by the HFEA on a case-by-case basis. Preimplantation genetic diagnosis was not part of the general licence granted to centres offering fertility services. This implied that each individual licensed centre receiving a couple's request for PGD treatment had to submit an application to the HFEA in order to obtain authorisation to perform PGD for the particular condition suffered by that couple.[1266] In the case of a particularly ethically controversial case, the centre could seek support from an ethics committee in drafting the application.[1267] Following the application the HFEA's licensing committee would check whether both the objective and subjective requirements for PGD, as laid down in the Code of Practice, were met. If so, the HFEA would accordingly amend the centre's licence, including the authorisation to carry out preimplantation diagnosis for that specific condition from then on, and for all new couples turning to that centre.

The inconsistency in this procedure stemmed from the fact that subjective elements were only taken into account for the first couple. As mentioned above, the outcome of the HFEA and ACGT public consultation emphasised the need to consider the opinions of those seeking treatment and thus to focus on couples' reproductive autonomy.[1268] Reproductive autonomy was mitigated by requiring an agreement with the healthcare professionals on the significance and seriousness of the risk and by the possible intervention of the ethics committee.[1269] On the other hand, however, once a PGD licence was obtained for a certain genetic condition thanks to

1265 "[T]he mismatch between the law and the technology presents an opening for legal challenge to be taken up by those who (for dignitarian reasons) are ethically opposed to the use of human embryos for research", Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 161.

1266 Human Fertilisation and Embryology Authority, 'Code of Practice', London 2003, pp. 120-121, see Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) pp. 183-184.

1267 Scott, 'The Uncertain Scope of Reproductive Autonomy in Preimplantation Genetic Diagnosis and Selective Abortion' (2005) 13(3) Med Law Rev p. 291, 299.

1268 ibid, p. 306.

1269 Scott reports that this originated from the outcome of the public consultation: "[t]he JWP agreed the importance of placing greater emphasis on the role of those seeking treatment in reaching the decision about when treatment was appropriate, whilst at the same time maintaining that this should not imply that this treatment should be available on demand", Scott, 'The Uncertain Scope of Reproductive

the first couple, the centre would not have to apply for further licences with respect to future couples seeking a diagnosis for the same condition.

This inconsistency was exacerbated when, in 2005, the HFEA announced a streamlining of licensing procedures for PGD.[1270] Under the new policy, after one particular clinic had been licensed by the HFEA to conduct PGD for a certain condition, other fertility clinics would be authorised to conduct PGD for the same condition if performed using the same technique – upon informing the HFEA and demonstrating competence in performing embryo biopsies.[1271] This resulted in a situation where the clinic seeking to conduct PGD for the first time for a given condition had to go through the licensing procedure and prove the subjective conditions required in the Code of Practice. After the authorisation, however, other clinics and couples interested in performing PGD for that condition could undertake it without obtaining a licence. Thus, the only subjective conditions relevant to the procedure before the HFEA were those of the first couple.[1272] It should be mentioned, however, that the Codes of Practice set standards to be applied not only by the HFEA but primarily by the clinics.[1273] While it is true that the subjective condition of individual couples following the first was not considered by the HFEA, individual centres remained nonetheless responsible for assessing the appropriateness, including through subjective criteria, of the use of PGD in each individual couple.

This streamlining of the procedure resulted *de facto* in a list of conditions for which PGD was authorised in England.[1274] This was something that the 1999 public consultation had recommended avoiding.

Autonomy in Preimplantation Genetic Diagnosis and Selective Abortion' (2005) 13(3) Med Law Rev p. 291, 306.

1270 ibid, p. 299.

1271 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 80.

1272 Jackson refers to it as an "anomaly" in this approach, see Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis: A Comparative and Theoretical Analysis* (2012) pp. 80-81. See also Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 185.

1273 "[T]he criteria in the Code were, in practice, applied twice: first by the HFEA when deciding whether to vary a clinic's licence to include PGD for a particular condition, and then by the clinic, when determining whether PGD was appropriate for a particular couple", Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 76.

1274 House of Commons Science and Technology Committee, 'Human Reproductive Technologies and the Law', London 14.3.2005, p. 109.

3. Legislative Intervention

a Reform preparation

In light of the many regulatory disconnections and controversies surrounding the HFEA, the Science and Technology Committee of the House of Commons decided to undertake a revision of the 1990 HFE Act between 2003 and 2004 in order to "reconnect [it] with modern science".[1275] One of the aims of the revision was to address the challenges that arose for the existing legislation from the development of new technologies and their ethical implications, as well as from the recent changes in ethical attitudes.[1276] For this purpose the committee initiated a public consultation exercise both online and through meetings and evidence sessions with experts and stakeholders.[1277]

The results of the committee's considerations were published in a report in 2005, where PGD was mentioned as one of the most challenging aspects.[1278] The committee discussed some of the inconsistencies in the then current code of practice, including the alignment of prenatal diagnosis in the womb with preimplantation diagnosis in vitro. In this respect, acknowledging that in a multi-faith and secular society there can never be full consensus on the level of protection to be afforded to the embryo,[1279] it asserted the ongoing validity and acceptability of the Warnock Committee's gradualist approach.[1280] The inconsistencies created by the streamlining of licensing procedures were also addressed.[1281] In addition, the committee expressed its dissatisfaction with the regulatory activity of the HFEA, whose gatekeeper role had resulted in the imposition of several conditions on the licensing of PGD.[1282] The report argued that the risk of creating 'designer babies' was not realistic and that regulation could be liberalised. However, it stressed the need for "clinical decisions [to] operate within clear boundaries

1275 ibid, p. 3.
1276 ibid, p. 4.
1277 ibid.
1278 ibid, p. 52.
1279 ibid, p. 22.
1280 ibid, p. 56.
1281 ibid, p. 109.
1282 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 77.

set by Parliament and informed by ethical judgements".[1283] Parliament was thereby clearly called upon to establish its own ethical framework upon which to reform the regulation of PGD and the use of in vitro embryos more generally.

As a reaction to the report the government's Department of Health also decided to conduct a wider public consultation in 2005, addressing the review of the Human Fertilisation and Embryology Act 1990.[1284] The aim of the consultation was to identify a way to "pursue the common good through a system broadly acceptable to society".[1285] The government received input from about a hundred organisations, as well as feedback from individual health professionals, patients and members of the public.[1286] The resulting reform proposals were conceived as a basis for a draft government bill on a new HFE Act to be submitted to Parliament.

The government was also satisfied that the normative foundations of the 1990 Act, derived from the work of the Warnock Committee, remained valid. It was thus possible to prepare the reform through the public consultation exercises of government and Parliament without having to resort to the establishment of a further committee.[1287]

On the HFEA's regulatory activity, the government expressed a divergent opinion from the House of Commons Science and Technology Committee.[1288] It argued that the model of licensing activities within the prohibi-

1283 House of Commons Science and Technology Committee, 'Human Reproductive Technologies and the Law', London 14.3.2005, p. 201.

1284 See Scott, 'Choosing Between Possible Lives' (2006) 26(1) Oxf J Leg Stud p. 153, 175; Jones, 'The Department of Health Review of the Human Fertilisation and Embryology Act 1990' (2006) 1(4) Clinical Ethics p. 200; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 129

1285 Department of Health, 'Review of the Human Fertilisation and Embryology Act Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)' (London 2006) Cm 6989, foreword, p. v <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/272391/6989.pdf> accessed 18.2.2022.

1286 ibid, para. 1.10, p. 3.

1287 Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 389.

1288 Jones, 'The Department of Health Review of the Human Fertilisation and Embryology Act 1990' (2006) 1(4) Clinical Ethics p. 200, 201; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 129.

tions and parameters set by the legislature should be maintained.[1289] An "ongoing role" for the Authority was advocated especially in the field of preimplantation genetic diagnosis.[1290] In this respect the government observed that, although the creation of 'designer babies' was no imminent risk, there were still strong ethical concerns and a wide range of opinions on embryo selection and destruction.[1291] Hence, the Department of Health also advocated an explicit legislative intervention by Parliament on this point.[1292]

b The Human Fertilisation and Embryology Act (2008)

The statutory outcome of the findings of the government's Department of Health and the Science and Technology Committee of the House of Commons was the amended Human Fertilisation and Embryology Act as enacted in 2008. As the legislation passed by Parliament was substantially based on the recommendations of these two documents, it was argued that its content's fate had already been determined at the pre-parliamentary stage.[1293] This also meant that the normative framework of the new legislation was primarily shaped by the recommendations of scientists and experts in the field and not so much by parliamentary debate.[1294]

1289 Department of Health, 'Review of the Human Fertilisation and Embryology Act Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)', London 2006 Cm 6989, para. 2.4, p. 6. See also Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) pp. 77-78.

1290 Department of Health, 'Review of the Human Fertilisation and Embryology Act Proposals for revised legislation (including establishment of the Regulatory Authority for Tissue and Embryos)', London 2006 Cm 6989, para. 2.44, p. 15.

1291 ibid, para. 2.42, p. 14.

1292 ibid. The government was also moved by the concern of avoiding further legal challenges, see Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 78 who notes that "the government was keen to ensure that the HFEA did not have to spend more time and money defending the scope of its powers in the courts."

1293 Goodwin and Bates, 'The 'Powerless Parliament'?: Agenda-setting and the Role of the UK Parliament in the Human Fertilisation and Embryology Act 2008' (2016) 11(2) Br Polit p. 232, 241–243.

1294 "Through gaining (partial) control of the pre-legislative process, scientists and pro-research activists were able to determine the development of the legislation, while activist opponents of the Bill were unable to match or challenge the agenda set out in the pre-legislative phase, even with the advantages conferred by the

Nonetheless, parliamentary discussions were extensive and intense, reflecting the enduring ethical concerns surrounding the issue.[1295] The option of a conscience vote, initially denied, was eventually successfully invoked by MPs belonging to religious groups.[1296]

In the context of preimplantation genetic diagnosis, the approved legislation merely confirmed and sanctioned the previous status quo.[1297] The HFEA maintained its role in the regulation of fertility treatments. Schedule 2 paragraph 1ZA (2) of the HFE Act (as amended) provides that a licence for PGD can be granted if the Authority is satisfied that there is a significant risk that the embryo will develop a serious disability, illness or medical condition as a result of the genetic or chromosomal abnormality that is to be detected.[1298] Likewise, sex selection through PGD is explicitly

---

use of procedural devices associated with morality policy that ostensibly would grant them greater influence", Goodwin and Bates, 'The 'Powerless Parliament'?: Agenda-setting and the Role of the UK Parliament in the Human Fertilisation and Embryology Act 2008' (2016) 11(2) Br Polit p. 232, p. 249.

1295 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 130.

1296 On this point see Wicks, 'Religion, Law and Medicine' (2009) 17(3) Med Law Rev p. 410, 425; Warnock, *Dishonest to God* (2010) p. 103: "[i]t had been the intention of the Prime Minister, Gordon Brown, that, this being a Government Bill, all votes would be on party lines, and there should be no free or 'conscience' vote. But the representations of various Roman Catholic members of the Cabinet, and some junior ministers, forced him to remove the whip". However, the opposition of these parliamentarians was not sufficient to have a substantial influence on the Act as approved, see Goodwin and Bates, 'The 'Powerless Parliament'?' (2016) 11(2) Br Polit p. 232, 234: "The presence of free votes and the use of a Committee stage held in the whole House of Commons (conventional concessions to matters of conscience that enable greater parliamentary engagement) were relatively unimportant in shaping the content of the policy, as indeed they usually are on most matters of conscience subjected to free votes".

1297 Montgomery, Jones and Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Mod Law Rev p. 343, 354; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 141; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) pp. 83-85.

1298 Human Fertilisation and Embryology Act (as amended) schedule 2, para. 1ZA(2): A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied— (a)in relation to the abnormality of which there is a particular risk, and (b)in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

allowed when the Authority is satisfied that the embryo is at particular risk of having a serious disability, illness or medical condition that affects one sex significantly more than the other.[1299] The exact definition of the significance of the risk and the seriousness of the medical condition were left to the discretion of the HFEA.[1300] In doing so Parliament consolidated the authority of the HFEA and gave democratic legitimacy to its decisions, thereby effectively discouraging further challenges before the courts.[1301] By reaffirming the possibility to select embryos according to the risk of a serious genetic condition, the amended HFE Act enshrined the HFEA's previous policies in statutory form and confirmed the utilitarian inspiration derived from the deliberations of the Warnock Committee as its normative basis.[1302]

The inconsistency in the assessment of the subjective criteria for PGD eligibility was also resolved.[1303] The licensing requirements for PGD listed in Schedule 2 paragraph 1ZA of the HFE Act (as amended) are in fact intended to be criteria that can be objectively assessed and which will bind the HFEA. Binding criteria for individual clinics, on the other hand, continue to be set out in the HFEA's regularly updated Codes of Practice. The Eighth Code of Practice, which came into force at the same time as the new legislation, prescribed that "[w]hen deciding if it is appropriate to provide PGD in particular cases, the centre should consider the circumstances of those seeking treatment rather than the particular heritable condition".[1304]

1299 Human Fertilisation and Embryology Act (as amended) schedule 2, para. 1ZA(1)(c) and para. 1ZA(3).

1300 See Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 79; Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 134.

1301 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 87.

1302 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 132.

1303 See Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 81.

1304 Human Fertilisation and Embryology Authority, 'Code of Practice: 8th Edition' (London 2009) <https://www.hfea.gov.uk/media/2062/2017-10-02-code-of-practice-8th-edition-full-version-11th-revision-final-clean.pdf> accessed 18.2.2022; The same formulation is still contained in the Ninth Code of Practice, valid at the time of writing, Human Fertilisation and Embryology Authority, 'Code of Practice: 9th Edition' (London 2018), para. 10.5 <https://www.hfea.gov.uk/media/2565/hfea-draft-code-of-practice-9th-edition-consultation-version.pdf> accessed 18.2.2022.

There is thus a division of competences between the HFEA, which is responsible for assessing the objective seriousness of the medical condition, and the fertility clinics, which must decide whether PGD is desirable in the case of the concrete couple. The latter is done *inter alia* by assessing the couple's views, their previous reproductive experience and family circumstances, the degree of suffering associated with the condition and the social support available.[1305] As the HFEA did not have to take into account subjective conditions for the licensing, clinics could pre-emptively apply for a licence to conduct PGD without first receiving a request from a particular couple. This initially prompted clinics to apply for a range of potential conditions detectable with PGD.[1306] This consolidated the existence of a list of conditions for which PGD can be performed without going through the licensing committee process.[1307] The licence conditions indicate that each centre "must ensure that PGD is only being carried out for those genetic conditions, chromosomes or traits […] that are expressly authorised by the Authority".[1308] For any new conditions not included among those already approved, facilities would need to apply to the HFEA for an update of the list. The HFEA is responsible for keeping the list up to date by either adding, specifying or removing conditions.[1309] This latter option may arise if the objective seriousness of a condition decreases, for instance thanks to the development of a treatment.[1310]

1305 Human Fertilisation and Embryology Authority, 'Code of Practice', London 2018, para. 10.9.

1306 Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 81.

1307 The list, which currently includes more than 600 conditions, can be consulted at this link: <https://www.hfea.gov.uk/treatments/embryo-testing-and-treatments-for-disease/approved-pgt-m-and-ptt-conditions/> accessed 18.2.2022. See also Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 187.

1308 Human Fertilisation and Embryology Authority, 'Code of Practice', London 2009, p. 98.

1309 The list is seen as "a living document", Jackson in McLean and Elliston, *Regulating Pre-implantation Genetic Diagnosis* (2012) p. 82.

1310 Parliamentary Office of Science & Technology, 'Research Briefing: Pre-implantation Genetic Diagnosis' (September 2013) POSTNOTE Number 445, p. 3 <https://researchbriefings.files.parliament.uk/documents/POST-PN-445/POST-PN-445.pdf> accessed 18.2.2022.

II. PGD in the NHS

1. Initial Lack of National Public Coverage

In England, NHS funding of fertility treatments has always been particularly affected by the so-called 'postcode lottery' phenomenon. In general, due to the lack of a nation-wide benefit basket[1311] and because the commissioning of health services is entrusted to local health authorities, the financing of health technologies varies widely across the country.[1312] Despite the transition of local Clinical Commissioning Groups to Integrated Care Boards, patients in England still have access to a different range of NHS-funded services depending on the region in which they live.

This uneven geographical availability of NHS funded services is particularly significant in the case of fertility treatments, as local health authorities tend to afford a lower priority to them than the treatments for more severe illnesses.[1313]

That the 'postcode lottery' issue is especially acute in the case of fertility treatments has long been recognised by the government and the NHS,[1314] as well as by the HFEA.[1315] In 2004 the National Institute for Health and Care Excellence tried to remedy this situation by issuing a clinical guideline

1311 Except for those treatments recommended by NICE through technology appraisal, which effectively creates a subjective right to NHS funding for the patient, see Chapter 1, sec. B.3.2.a.

1312 On the postcode lottery phenomenon in general, see Palmer, 'Mechanisms of Health Care Accountability, Marketisation and the Elusive State' (2011) 11(1) Med Law Int p. 69, 70; Mason, 'Does the English NHS have a 'Health Benefit Basket'?' (2005) 6(S1) Eur J Health Econ p. 18.

1313 Aarden and others, 'Providing Preimplantation Genetic Diagnosis in the United Kingdom, The Netherlands and Germany: A Comparative In-depth Analysis of Health Care Access' (2009) 24(7) Human reproduction p. 1542, 1544; Johnson and Petersen in Sclater, Ebtehaj and Richards, *Regulating autonomy: Sex, reproduction and family* (2009) p. 186.

1314 Glennon in Sclater, Ebtehaj and Richards, *Regulating autonomy: Sex, reproduction and family* (2009) p. 160.

1315 This issue was also mentioned by the Human Genetics Commission, see UK Human Genetics Commission, 'Making Babies' (2006) 11(1) Jahrbuch für Wissenschaft und Ethik p. 485, 488. For considerations from the HFEA, see Human Fertilisation and Embryology Authority, 'Fertility treatment 2017: trends and figures' (2018) <https://www.hfea.gov.uk/media/2894/fertility-treatment-2017-trends-and-figures-may-2019.pdf> accessed 18.2.2022. See also Herring, *Medical Law and Ethics* (2020) p. 432.

on fertility treatments.[1316] In its guidance NICE advised local authorities to fund three cycles of treatment for all couples meeting certain requirements, including those relating to age and body mass index.[1317] However, since this type of recommendation is not binding on NHS bodies, a state of affairs that contrasts with technology appraisals, the number of local authorities adhering to the NICE guidelines has remained fairly small.[1318] In 2019 the HFEA also made an attempt to resolve geographical inequalities in the access to IVF by issuing its own recommendations, aimed at supporting local NHS bodies in their commissioning decisions.[1319] Unequal access to fertility treatments is currently still a major concern in spite of these efforts.[1320]

Initially, the issue of unequal geographical access to treatment was even more severe in the case of couples seeking preimplantation genetic diagnosis.[1321] This was because couples at risk of transmitting a serious genetic condition to their foetus were exposed to unequal funding policies not only for IVF, but also for the associated PGD.[1322] As with fertility treatments, the commissioning of PGD was in fact left to individual local authorities.[1323] In other words, couples seeking PGD had to be lucky enough to be located in a geographical area where the local NHS body had decided to fund not only IVF but also PGD.

The 'postcode lottery' for PGD was also exacerbated by the fact that this treatment was sought by a small number of couples[1324] and therefore did

1316 National Institute for Health and Care Excellence, 'Fertility: assessment and treatment for people with fertility problems: Clinical guideline [CG11]' (2004).

1317 NICE's clinical guidance on fertility treatments was updated in 2013 to include a recommendation that at least one cycle of treatment should also be offered to women over the age of 40, see National Institute for Health and Care Excellence, 'Fertility problems: assessment and treatment: Clinical guideline [CG156]' , p. 24 <https://www.nice.org.uk/guidance/cg156> accessed 18.2.2022.

1318 Herring, *Medical Law and Ethics* (2020) p. 433.

1319 Human Fertilisation and Embryology Authority, 'Commissioning guidance for fertility treatment' (London 2019) <https://www.hfea.gov.uk/media/2920/commissioning-guidance-may-2019-final-version.pdf> accessed 13.4.2022.

1320 Herring, *Medical Law and Ethics* (2020) p. 432.

1321 Aarden and others, 'Providing Preimplantation Genetic Diagnosis in the United Kingdom, The Netherlands and Germany' (2009) 24(7) Human reproduction p. 1542, 1546.

1322 Wu, Whiteford and Cameron, 'Preimplantation Genetic Diagnosis' (2014) 24(3) Obstetrics, Gynaecology & Reproductive Medicine p. 67, 71.

1323 NHS England, 'Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD)' (2014) Reference: E01/P/a, p. 7 <https://www.england.nhs.uk/wp-content/uploads/2014/04/e01-med-gen-0414.pdf> accessed 18.2.2022.

1324 ibid.

not feature in the prioritised community needs that were usually brought to the attention of local NHS bodies.[1325] Nor had local commissioning authorities received any direction from NICE, as PGD was not included in the clinical guidelines on fertility treatments.[1326]

The document analysing the public consultation conducted by the Human Genetics Commission in 2004-2005 called for public funding of PGD. However, according to the HGC, funding of PGD was to be confined to particularly serious conditions, at least until the technology was further developed.[1327]

2. Central Commissioning of PGD as Specialised Service

The Health and Social Care Act 2012 abolished the former local health authorities, called Primary Care Trusts.[1328] Their tasks and responsibilities were mainly entrusted to the new local NHS bodies, the Clinical Commissioning Groups (now Integrated Care Boards), and partly to NHS England. In this transition preimplantation genetic diagnosis became one of the health services centrally commissioned by NHS England as a specialised service.[1329] Central commissioning meant first and foremost that PGD would be funded equally across the country, thus eliminating substantial geographical inequalities.[1330]

The requirements for funding were laid down in 2013 when NHS England published its Clinical Commissioning Policy for PGD. A declared aim of the policy was to "ensure equity, consistency and clarity in the

1325 Aarden and others, 'Providing Preimplantation Genetic Diagnosis in the United Kingdom, The Netherlands and Germany' (2009) 24(7) Human reproduction p. 1542, 1544.

1326 Aarden and others, 'Learning from Co-evolution of Policy and Technology. Different PGDs in the Netherlands, Germany and Britain' (2008) 10(2) Journal of Comparative Policy Analysis: Research and Practice p. 191, 197.

1327 Human Genetics Commission, 'Choosing the Future: Genetics and Reproductive Decision-Making — Analysis of Responses to the Consultation', 2005, para. 4.5, as reported and discussed by Scott, 'Choosing Between Possible Lives' (2006) 26(1) Oxf J Leg Stud p. 153, 177.

1328 Health and Social Care Act 2012, sec. 34, see Herring, *Medical Law and Ethics* (2020) p. 56.

1329 Parliamentary Office of Science & Technology, 'Research Briefing: Pre-implantation Genetic Diagnosis', September 2013 POSTNOTE Number 445, p. 4.

1330 ibid.

commissioning of PGD services in England"[1331] for conditions on which there was acceptable evidence of clinical benefit and cost-effectiveness.

According to the policy a condition to be met by the couple is, in addition to those generally required for coverage of IVF, that their risk of passing on a serious genetic condition be at least 10%. Moreover, PGD is only funded for childless couples or couples whose living children are already affected by the genetic disorder.[1332] If all the requirements are met, the couple is entitled to three cycles of PGD.[1333] In addition, the NHS also covers the costs of the associated fertility treatment, thus relieving couples seeking PGD from the postcode lottery for IVF.[1334]

Although the NHS was aware that the number of PGDs performed in the country would obviously increase after the transition to central commissioning,[1335] such a decision was possible and sustainable in view of the expected limited number of couples requiring a PGD. Given the unique circumstances of couples seeking PGD, their number is significantly smaller than that of couples seeking just fertility treatment.[1336] As a result, access to fertility treatment for couples without a need for PGD represents a greater burden on the healthcare system and still remains subject to the problem of uneven commissioning in different regions.

The Clinical Commissioning Policy for PGD was most recently updated by NHS England in 2014 leaving the eligibility criteria and the scope of funding largely unchanged. This version is still in force at the time of writing, albeit pending the outcome of an ongoing review of the policy.[1337]

1331 NHS England, 'Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD)', 2014 Reference: E01/P/a, p. 4.
1332 ibid, pp. 8-9.
1333 ibid, p. 9.
1334 ibid.
1335 ibid, p. 13. See also Sharpe, Avery and Choudhary, 'Reproductive Outcome Following Pre-implantation Genetic Diagnosis (PGD) in the UK' (2018) 21(2) Human Fertility p. 120, 121.
1336 NHS England, 'Clinical Commissioning Policy: Pre-implantation Genetic Diagnosis (PGD)', 2014 Reference: E01/P/a, p. 7.
1337 Information received by the author after a request for clarification from NHS England, available at <https://www.whatdotheyknow.com/request/commissioning_of_pre_implantatio#incoming-1930935> accessed 18.2.2022.

D. Comparative Analysis

I. Development and Instruments of PGD Regulation

1. PGD within the Regulation of Fertility Treatments

In all three jurisdictions the regulation of PGD falls within the general framework governing fertility treatments and the handling of embryos in vitro. This is because PGD is a reproductive technology involving the use of embryos in vitro and is carried out as part of an in vitro fertilisation procedure. In Germany and the United Kingdom the legislature intervened to regulate the use of embryos in vitro as early as 1990, i.e. before PGD was fully developed.[1338] In Italy, on the other hand, the statutory regulation of fertility treatments was adopted only later, in 2004.[1339] This delay in adopting legislation on fertility treatment is a typical indicator of the pathological inactivity of the Italian legislature in the field of biolaw. Some legal scholars have labelled Italy's restricted and delayed intervention in reproductive matters an 'inactive' or 'abstentionist' model of legislation.[1340]

All three jurisdictions have set certain boundaries between permissible and unlawful behaviours in their legislation on fertility treatments. Accordingly, they have provided for criminal sanctions against uses of human embryos in fertility treatments which go beyond what is established as

1338 Embryo Protection Act 1990 (Embryonenschutzgesetz, ESchG) in Germany and Human Fertilisation and Embryology Act 1990 in the UK.

1339 With the approval of Law no. 40/2004.

1340 See Casonato, *Introduzione al biodiritto* (2012) p. 105; Busatta in Busatta and Casonato, *Axiological Pluralism* (2021) p. 19. This 'pathological' abstentionism of the Italian legislator is not limited to artificial reproductive technologies but has significantly affected the area of the 'end of life' in recent years. Emblematic in this respect is the case of the regulation of the refusal of medical treatment in the terminal phases of life (the lack of legislation was then remedied by the Corte di Cassazione in its judgment on the so-called 'Englaro case' (Corte di Cassazione, sez. I civ, judgment no. 21748/2007), or of assisted suicide, a matter in which the Constitutional Court has given multiple warnings to the legislator, see most recently its decision no. 207 of 2018. On the subject of legislative inaction in the field of assisted suicide, see *inter alia* Bucalo and Giaimo, 'Le sollecitazioni delle Corti e l'inerzia del legislatore in tema di suicidio assistito. Un confronto tra Italia e Inghilterra' [2019](2) p. 171; Zicchittu, 'Inerzia del legislatore e dialettica istituzionale nell'ordinanza della Corte costituzionale in tema di aiuto al suicidio' [2019](1) Dirittifondamentaliit p. 1; Morelli, 'La voce del silenzio. La decisione della Corte sull'aiuto al suicidio e il «perdurare dell'inerzia legislativa»' [2020](1) Dirittifondamentaliit p. 724.

acceptable under the ethical approach that has been translated into legislation.

The criminal law component was particularly prominent in the German regulation.[1341] Whereas the legislation in Italy and the UK aimed, respectively, at facilitating the resolution of fertility problems[1342] and at 'mak[ing] provision in connection with human embryos',[1343] the German law was introduced in Parliament by the Federal Government precisely in order to prevent the manipulation of human life, whereby human life was regarded as beginning with fertilisation.[1344]

However, in all three countries there was no explicit regulation of PGD in the first pieces of legislation on fertility treatments. In the UK and Germany this was due to the fact that PGD had not yet been fully developed – albeit enough to be mentioned in parliamentary discussions – whereas in Italy this was the result of a conscious omission on the part of the legislature. There PGD was already freely practised prior to 2004. Yet, after Law no. 40/2004 there was uncertainty as to whether it had become a criminal offence. The wording of the Law did not provide an unequivocal answer to the question of whether couples eligible for IVF techniques could have legally selected healthy embryos for implantation via means of preimplantation genetic diagnosis. While Article 13 stated that clinical research on the embryo could only be permitted if aimed at the protection and development of that very embryo and that the selection of embryos for eugenic purposes was prohibited, Article 14(5) provided that the future parents could be informed of the health condition of the embryo.[1345]

As a result, all three countries were initially confronted with the problem of regulatory uncertainty regarding PGD. Under these circumstances, in all jurisdictions a first step was required to solve the uncertainty before

1341 "Not surprisingly, the normative clarity of criminal law was deemed most appropriate to enforce Germany's moral position", Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1029.

1342 Art. 1 Law no. 40/2004.

1343 Human Fertilisation and Embryology Act 1990 (as enacted), Introductory Text.

1344 Deutscher Bundestag, 'BT-Drucks. 11/5460. Gesetzentwurf der Bundesregierung', 25.10.1989, p. 6.

1345 Moreover, many argued that a diagnosis with a view to avoiding the transmission of genetic diseases could not in itself be regarded as having eugenic purposes. See *inter alia* Scalera, 'Il problema della diagnosi pre-impianto' (2013) 45(5) Giurisprudenza di Merito p. 1020, 1029; Vallini, 'Ancora sulla selezione preimpianto: incostituzionale la fattispecie di selezione embrionale per finalità eugenetiche, ma non quella di embrionicidio' [2015](Diritto Penale Contemporaneo).

PGD could be considered for inclusion in the public health system. It was essential to establish whether these techniques should be allowed or criminalised, as their legality was a prerequisite for public funding.

2. Role of Case Law and Legislation in the Adoption of PGD Regulation

In all countries, the initial uncertainty surrounding the regulation of PGD has led to judicial interventions on the issue. While in Italy the pathological inactivity of the lawmaker resulted in the Constitutional Court taking the final decision on the regulation of PGD, in Germany and the UK the case law was followed by an adaptation of the statutory framework by the legislature.

In Germany a criminal investigation into a doctor performing PGD culminated in an acquittal by the Federal Court of Justice, which however explicitly called for legislative intervention in this area.[1346] By reconciling the legislature's evaluative choices into a coherent value system,[1347] the Court maintained that the performance of PGD was not punishable under the current Embryo Protection Act. This held at least in cases that, in light of a possible serious genetic damage to the foetus, would fall within the scope of the medical-social indication justifying an abortion at a later stage of fetal development.[1348]

In the UK, the Human Fertilisation and Embryology Act created the Human Fertilisation and Embryology Authority which was entrusted with the licensing of newly developed treatments within the legal boundaries set by Parliament. Accordingly, the Authority started licensing fertility centres to perform PGD under the assumption that this technique fell within the statutory limits of the HFE Act. This practice was brought before the courts and the case was finally decided by the House of Lords.[1349] This case law confirmed that the Authority had correctly used its power to issue licences for PGD.

1346 BGH, 6.7.2010 - 5 StR 386/09.

1347 Schroth, 'Anmerkung zu BGH, Urt. v. 6.7.2010 – 5 StR 386/09' (2010) 63(36) NJW p. 2676. On the insufficient consideration of constitutional law in the Federal Court of Justices' judgment, see Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) pp. 127-128.

1348 BGH, 6.7.2010 - 5 StR 386/09. See Schumann, 'Präimplantationsdiagnostik auf der Grundlage von Richterrecht?' (2010) 28(12) MedR p. 848.

1349 *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005).

In both of these countries judicial intervention has prompted a reform by the legislature. In Germany the decision of the Federal Court of Justice left a gap in the protection provided by the criminal law to the embryo, which the legislature rapidly sought to fill. In England the Authority succeeded in guaranteeing the adaptability of the HFE Act to the changing scientific landscape. However, a sense of 'regulatory disconnection'[1350] became apparent as the gap between what was explicitly allowed according to the statutory text and the range of reproductive techniques actually licensed by the Authority became more and more pronounced.[1351]

Against this background, the parliaments of both jurisdictions finally filled the legal vacuums and resolved the uncertainty by issuing amendments to the regulation of the uses of the embryo in vitro and fundamentally validating the outcome of the case law.[1352] In Germany PGD was found to be permissible at least in the case of serious hereditary diseases with the PGD Act of 2011, while in the UK the HFEA's licensing powers, as well as its current licensing practice, were upheld in legislation with the amendments to the Human Fertilisation and Embryology Act enacted in 2008.

In Italy, on the contrary, the reform of the normative framework for fertility treatments was carried out entirely by the courts. This was thanks to the combined actions of ordinary judges, administrative judges and the Italian Constitutional Court, as well as with the intervention of the European Court of Human Rights. Such strongly interventionist actions by the courts were necessary in the face of a pathological abstention on the part of the legislature. The persistent inactivity of the Italian lawmaker, despite scientific developments and calls for intervention by the courts, had perpetuated a situation where there was a violation of patients' fundamental rights.[1353] Against this background the Italian Constitutional Court, in its

1350 See Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 181.

1351 ibid, p. 161.

1352 Preimplantation Genetic Diagnosis Act (*Präimplantationsdiagnostikgesetz* – PräimpG*)* 2011 in Germany and Human Fertilisation and Embyology Authority (2008) as amended in the UK. See above in this Chapter, respectively at sec. A.I.3 and sec. C.I.3.

1353 As noted by Busatta in Busatta and Casonato, *Axiological Pluralism* (2021) p. 19, "[t]he inactive model is characterised by an abstentionist behaviour on the part of the lawmaker, who tends not to intervene in ethically sensitive decisions. In the face of normative silence, which might depend on different factors, jurisdiction is called upon to respond to individual requests, in order to re-establish a sustainable level of legal certainty and to ensure due protection of the fundamental rights

judgment no. 96/2015, used its power to intervene directly in the wording of the law and amended it so as to include fertile couples' right to access PGD.[1354] Thanks to the decisive intervention of the Constitutional Court the criteria for accessing PGD were made consistent with the provisions of abortion legislation. Couples with transmissible genetic diseases that, if passed on to the foetus, would justify an abortion were granted access to PGD.

De facto the initial statutory texts were amended in all three jurisdictions. Different actors have influenced this outcome. Whereas in the UK and Germany the reform was ultimately carried out by the legislature, in Italy changes to the regulation of PGD were progressively prepared by the case law and eventually formalised by an intervention of the Constitutional Court, which directly amended the text of the Law in 2015. Nonetheless, in the UK and Germany the legislature also largely confirmed the outcome of the case law. Thus, in all three jurisdictions, in the absence of prompt legislative intervention, the courts were forced to play a key role in the regulation of PGD, which has been considered detrimental to the principles of democracy and the separation of powers.[1355]

3. Substantial and Procedural Tools of PGD Regulation

The analysis of the different instruments used by the three jurisdictions to regulate PGD help to distinguish between a substantive and a procedural

---

at stake". See also Cortese and Penasa, 'Dalla bioetica al biodiritto: sulla giuridificazione di interessi scientificamente e tecnologicamente condizionati' [2015](4) Rivista AIC p. 1, 21, who note that the tendency of courts to replace legislation is proportional to the inability of the latter to adapt to the scientific context and to the principles set out in constitutional case law. A similar argument, for the German context, is made by Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 130.

1354 It is precisely because of the constant inaction of the legislature that the Italian constitutional court has started to experiment with new decision-making techniques. See, *inter alia,* Salazar in Ruggeri and Silvestri, *Corte costituzionale e parlamento: Profili problematici e ricostruttivi* (2000); Martire, 'Giurisprudenza costituzionale e rime obbligate: il fine giustifica i mezzi? Note a margine della sentenza n. 113 del 2020 della Corte costituzionale' [2020](6) Rivista AIC p. 244, 251–258.

1355 See the analysis, targeted to the German case but applicable to other jurisdictions, in Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) pp. 127-130.

approach to the regulation of ethically controversial reproductive technologies.[1356]

In Italy and Germany, the drafting of fertility treatment regulation proceeded mainly by reference to substantive principles and concepts derived from the constitution. In both jurisdictions the existence of an overarching constitutional text has consistently guided the case law and the legislation.[1357] In Germany constant reference was made to the substantive principle of the dignity of the embryo. This is due to the fact that protection of human dignity is enshrined in Article 1 of the Basic Law. Public, legal scholars' and parliamentary debates were focused on whether PGD would constitute an instrumentalisation of the embryo, which would be contrary to its dignity and to the right to life.[1358] This element was also relevant in the judicial decisions before legislation on PGD was enacted.[1359] Later, the 2011 PGD Act represented an agreement that, for certain cases, it would not be possible to argue that an instrumentalisation would occur. Namely, when there is a high risk of a serious hereditary disease for the offspring due to the genetic disposition of the future parents, or when the diagnosis is aimed at avoiding stillbirth or miscarriage. However, the legislature still felt that the substantive principles of human dignity and right to life had to be explicitly safeguarded through a strong normative commitment in the form of the criminal law. The use of criminal law was considered necessary to convey the normative protection of human dignity and life.

In Italy the case law had to use the standards of the right to health and reasonableness to mitigate the very restrictive framework provided by the legislation. The constitutional review of legislation by the Italian Constitutional Court was a very important tool in this regard. The substantive principles already applied in the abortion regulation were taken over by the Court to legitimise access to PGD.[1360]

1356 A similar classification is proposed by Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300.

1357 Although, as illustrated below, the values upheld in the Italian Law no. 40/2004 were partially derived from ethical and religious perspectives, resulting in an overall imbalance of the constitutional interests at stake.

1358 For the role of the argument of the instrumentalisation of the embryo in the German debate, see above in this Chapter sec. A.I.3.c.

1359 BGH, 6.7.2010 - 5 StR 386/09, see above in this Chapter, sec. A.I.2.b.

1360 Italian Constitutional Court, judgment no. 96/2015, see above in this Chapter, sec. B.I.3.

The UK legislation has also applied substantive principles. Although this jurisdiction lacks a written constitutional catalogue of general and binding rules, this was compensated somewhat by entrusting an interdisciplinary committee of experts, the Warnock Committtee, with the formulation of broadly acceptable principles on which legislation could be based.[1361] The principles endorsed by the Warnock Report, such as the gradualist and utilitarian approach with its 14-days cut-off, were successfully incorporated into legislation and are currently still applied and accepted. While the ethical approach of the Warnock Report remains readily modifiable by law and is in no way binding, it has assumed a normative force that survived moments of reform and contestation. In this regard, the Warnock Committee succeeded in establishing a durable consensus, to which Parliament and regulatory bodies have felt bound.[1362] The substantive principles previously adopted in abortion legislation were also important in the development of PGD regulation and licensing practices.[1363]

Compared to the other two jurisdictions, however, the English approach prominently displayed elements of procedural legitimacy. A first feature of this 'procedural' model is expert involvement, both at the decision-making and at the implementation stage.[1364] At the decision-making stage the substance of the regulation on the uses of the embryo in vitro drew largely upon the recommendations of the Warnock Committee.[1365] At the implementation stage the establishment of the Human Fertilisation and Embryology Authority, with responsibility for deciding on the licensing of innovations on a case-by-case basis, has made it possible for legislation to keep abreast of technological and scientific developments in the field. The Authority's task of authorising PGD in individual cases functioned as a

1361 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984.

1362 For considerations on the Warnock consensus as an element of the "bioconstitutional order" in the UK, see Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1015-ff.

1363 See above in this Chapter, sec. C.I.2.a.

1364 "Expertise's involvement guarantees that the decision makers' representative legitimacy is reinforced, by means of a technical and cognitive contribution that comes from outside the democratic system, but within the constitutional one. It can provide a new source of legitimacy for statutory decisions, on the grounds of the recognition of the pluralistic nature of those sources: constitutional, democratic but also scientific", Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 10–11.

1365 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984.

procedural safeguard to prevent the misuse of PGD treatments, for instance to detect non-serious or non-medical conditions. Thus, while the embryo is protected by a gradualist approach, research and treatments promising to tackle serious genetic conditions or diseases are also promoted. The composition of this regulatory Authority contributed to the legitimacy of its decisions, albeit based on expertise rather than representativeness.

A second element of procedural legitimacy is the existence of extra-parliamentary sites for deliberation and public consultation.[1366] The UK legislation was indeed strongly based on public consultation exercises, which were regularly conducted in the years following the development of PGD to maintain consistency with changing public attitudes. The Warnock consensus and the practices of the HFEA also proved so durable thanks to the mechanisms through which public opinions could be constantly kept in the loop.[1367]

Certain procedural elements have also been included in the German and Italian regulations, although they fulfilled a different function, for they only played a role at the implementation stage.

In the German case in particular, each individual couple must go through an ethics commission to receive authorisation to undergo PGD.[1368] The ethics commission is composed of four experts in the field of medicine, one expert each in the fields of ethics and law, and one representative each from the organisations responsible for representing the interests of patients and people with disabilities at the state level. The necessary approval by a PGD ethics commission is seen as a guarantee to avoid the use of PGD in cases where the condition to be diagnosed does not meet a certain degree of severity and, more generally, to prevent an undesirable expansion of the use of PGD.

1366 Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 309.

1367 Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1028. Sociologists have noticed that the durable success of the Warnock consensus is also due to a "social contract, or formula, of public consultation based on a high degree of trust that the general public will reach sensible conclusion when they are treated with respect and given time and information to think things through for themselves", Franklin, 'Developmental Landmarks and the Warnock Report: A Sociological Account of Biological Translation' (2019) 61(4) Comp Stud Soc Hist p. 743, 771.

1368 §3a(3)2 ESchG. For details on the functioning of the ethics commissions, see in this Chapter, sec. A.I.3.d.

In Italy, statutory law did not foresee any procedural mechanisms such as expert involvement or public consultations in the decision-making process.[1369] On the contrary, in fertility treatment legislation Italy subscribed to a full 'value-oriented' model, according to which a system of criminal sanctions is intended to be sufficient, without a need for bodies that are capable of ensuring adaptation to scientific developments.[1370] This led the law to place unreasonable obstacles in the way of accessing IVF and PGD, which hardly any medical expert would have approved. This included the compulsory and simultaneous implantation of all embryos created, which the Constitutional Court annulled as scientifically unreasonable.[1371]

In allowing access to PGD in its judgment no. 96/2015 the Constitutional Court ruled that the seriousness of the transmissible medical condition affecting the couple must be verified by National Health Service facilities. This was intended to avoid an undue promotion of PGD for financial gain and it could be considered a small procedural guarantee at the implementation stage.

In sum, while all countries applied both procedural mechanisms and substantive principles to the regulation of PGD, there is a substantial difference in their functions and scope. In England procedural principles have served the function of legitimising the regulation. The content of the entire regulation is procedurally legitimated through, for instance, stakeholder consultations and expert participation. The Warnock Committee and the HFEA provided durable, accepted principles of regulation and licensing mainly thanks to their procedural legitimacy and the successful maintenance of public assent and flexibility. On the other hand, in Italy and Germany, the legitimacy of the regulation was fundamentally grounded on the compliance with substantive principles and values. Any procedural mechanisms were only inserted at the implementation stage to avoid a misuse of the regulation. Their function is to make sure that the substantive values and criminal boundaries of the law are respected.

1369 Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 317.

1370 In Italy "the exclusion of expertise from both the decision-making and enforcement processes – combined with the lack of mechanisms for periodic evaluation of the performance of law – seems to produce an awkwardness effect, due to the lack of an essential cognitive source that is able to both orient and legitimise the legislature's choices", Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 14.

1371 Italian Constitutional Court, judgment no. 151/2009.

II. Ethical Concerns in PGD Regulation

1. Public Debates and Legislative Process

The three jurisdictions compared were all faced with the emergence of a reproductive technology that was considered by parts of their population to be ethically controversial. To other sections of their societies PGD was considered to be a health treatment essential to the full realisation of the reproductive health of couples suffering from serious transmissible genetic diseases.

Although in all three countries there were a number of voices calling for greater protection of the embryo in vitro, PGD met with less resistance in England compared to Italy and Germany.

Italy's aversion to PGD stemmed primarily from the country's Catholic background. Religious lobbies strongly supported the adoption of the restrictive regulation in Law no. 40/2004, as well as its preservation from attempted amendments. In Germany the undesirability of PGD was expressed with dignitarian reasoning and with the ethical argument of the 'slippery slope'.[1372]

In England the form that the most prevalent view took was a utilitarian and liberal approach, while the rest of the general public was prepared to accept a pragmatic compromise. The public agitation that characterised the debates in Germany and Italy was not quite as intense there.[1373] Rather the opposite, in England PGD was seen as a positive and promising development in the field of reproductive technologies. The promise of the advancement of PGD techniques weighed as a positive factor in parliamentary debates and was a driver towards the adoption of the HFE Act. Schedule 2 paragraph 3(2)(e) HFE Act considered research on human embryos desirable for detecting the presence of gene or chromosome abnormalities before implantation. This is not to say that the legislation was not controversial at all. It took many years to operationalise the Warnock consensus in the law.[1374] After that the compromise that had been reached proved valid and durable.

1372 For the meaning of the slippery slope argument in the German debate, see this Chapter, sec. A.I.3.c.

1373 Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1016.

1374 The Warnock Committee reported back in 1984, but the Human Fertilisation and Embryology Act was only enacted in 1990.

Statutory reforms on PGD were prepared with cautious attention to the public debate on the ethical acceptability of PGD in both Germany and the UK. Both in England and Germany a conscience vote was guaranteed in the parliamentary debate over reforms involving PGD, i.e. MPs were freed from party discipline.

In Germany the ethically controversial nature of the topic was reflected in parliamentary discussions and voting. After the first bill to regulate PGD was introduced in 2001 a study commission on law and ethics was set up by the German Parliament to discuss legislative proposals in the field of modern medicine. The commission highlighted the ethical concerns on PGD and the fear of a 'slippery slope'.[1375] Later, after the decision of the Federal Court of Justice, three draft bills were proposed in Parliament. The parliamentary discussion leading to the adoption of the PGD Act in 2011 contained several explicitly religious and ethical arguments. The German Ethics Council issued an opinion to be taken into account in the legislative process that also voiced the ethical concern of a 'slippery slope'.[1376] In both parliamentary and scholars' debates the broad scope of the constitutional concepts of dignity and the right to life led to a one-sided definition of these notions. Attempts have been made to fill these legal terms with meanings inspired by particular ethical perspectives, such as the claim that human life begins at the moment of fertilisation.[1377]

In the UK adaptation to society's ethical attitudes has been constantly sought through the widespread use of consultation exercises by different bodies. Thanks to the procedural elements of the model, outlined above, the regulatory framework has been made flexible to changes in the ethical and scientific landscape. Initially the decision on the ethical acceptability of PGD was entrusted to the Human Fertilisation and Embryology Authority. Later on the HFEA's assessment of PGD gained legitimacy through legislation.[1378] After a collection of opinions through public consultation it became apparent that the compromise reached by the HFEA was a widely acceptable one to English society. The reform proposal was then determined primarily at a pre-parliamentary stage on the basis of the consultation outcomes, thus resulting in parliamentary discussions having little

1375 See the final report of the 'Study Commission on Law and Ethics in Modern Medicine', Deutscher Bundestag, 'BT-Drucks. 14/9020', 14.5.2002.
1376 Deutscher Ethikrat, 'Präimplantationsdiagnostik' (2011).
1377 See above in this Chapter, sec. A.I.3.c.
1378 Human Fertilisation and Embyology Act, as amended in 2008.

to no influence on the final outcome.[1379] This is different to what happened in Germany, where the entire political and legislative process took place in Parliament.

2. Statutory Texts and Implementation

All three jurisdictions have, albeit on a different scale, incorporated in their legislative texts the acknowledgement of the ethical concerns raised by PGD.

A commitment to ethical pluralism is reflected insofar as all statutory texts provide conscience clauses for doctors.[1380] All pieces of legislation on the regulation of fertility treatments have acknowledged that the use of human embryos in vitro and embryo selection may be contrary to the moral standards of some members of society, and have therefore provided that healthcare personnel should not be obliged to participate in fertility treatments. Moreover, the use of criminal law in all three jurisdictions is appropriate to express the need for firm boundaries and the significance of the protected interests.

Nonetheless, compared to England, a more significant influence of religious and ethical concerns on the text of the legislation was evident in Germany and Italy.

In Italy ethical and religious concerns permeated the entire legislation as originally enacted. Law no. 40/2004 was openly the result of the advocacy efforts of religious associations. The law was based on strong ideological and value-based convictions, which were not sufficiently constitutionally anchored. It was entirely based on the ethical assumption that the human embryo should be absolutely protected. The mandate to protect the embryo to the same extent as the other individuals involved clashed with the Italian constitutional framework,[1381] not least because it conflicted with constitutional case law on abortion.[1382] This became evident at the latest when the

1379 Goodwin and Bates, 'The 'Powerless Parliament'?' (2016) 11(2) Br Polit p. 232, 241–243.

1380 § 3a(5) EschG in Germany, Art. 16 Law no. 40/2004 in Italy, Sec. 38 of the HFE Act 1990 in England.

1381 Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 317.

1382 As maintained in the Italian Constitutional Court judgment no. 27/1975. a woman's right to life and health prevails over the protection of the embryo, which has yet to become a person.

Constitutional Court began to intervene in the wording of the statute and eventually altered the core of its normative scope to make it compatible with the Constitution.[1383]

The statutory implementation of such a prominent ethical and religious standpoint was combined with a situation of great uncertainty about the possibilities for accessing PGD. Due to the ethical challenges posed by the technology the decision on its acceptability had not explicitly been taken. Whilst the regulation merely prohibited eugenic practices, PGD was not unanimously considered as such. This uncertainty has led to a delay in access to PGD. Couples with serious genetically transmissible diseases have had to file their cases before ordinary courts in order to be granted authorisation to access the treatment. The effect of the inclusion of ethical and religious considerations in the legislation was finally remedied by the Constitutional Court, which applied the constitutional principles of reasonableness and the right to health.[1384]

In Germany the regulation was influenced by a combination of ethical and constitutional concerns, which were often intertwined in the parliamentary and scholarly discussion. These considerations were reflected in the limitations imposed on access to PGD, both in terms of the material conditions under which the diagnosis could be performed in a non-illegal manner and in terms of procedure. The performance of PGD was only allowed in exceptional cases involving couples with a specific medical indication. In particular, PGD may only be carried out where there is a risk of a serious hereditary disease due to the genetic predisposition of the parents or where it is intended to detect damage to the embryo that could result in miscarriage or stillbirth. On the one hand, the narrow nature of these clinical requirements can be critiqued on the basis of the implications of ethical and religious convictions for the individual's freedom of reproduction and self-determination. On the other hand, the presence of a certain clinical condition as a requirement is acceptable insofar as it aims to ensure that PGD is only performed in medically indicated cases. The limitation of the performance of PGD to only medically indicated cases is necessary

1383 "Case law has probably moved a long way from the original legislative purpose, but it is due to a scientifically infeasible and constitutionally inconsistent regulatory regime, which has led to a substantial rewriting of the law by the judiciary", Penasa, 'Converging by Procedures: Assisted Reproductive Technology Regulation within the European Union' (2012) 12(3-4) Med Law Int p. 300, 320.

1384 Italian Constitutional Court, judgment no. 96/2015.

to respect the constitutional balance between the rights of the woman and the couple and the obligation of the State to protect the life and dignity of the unborn child.[1385] However, couples who actually meet the conditions laid down in § 3a of the Embryo Protection Act also encounter procedural restrictions. At the implementation stage access to PGD is only granted after going through an exhaustive assessment procedure. In particular, every PGD procedure to be performed in the country must be approved by one of the PGD ethics commissions existing in different *Länder*. The procedure before such commissions testifies to the fact that PGD is still regarded with suspicion, even if performed within the boundaries agreed upon by Parliament. Moreover, their mandatory approval has an influence on patient uptake of PGD.[1386]

Admittedly, ethical considerations have also been taken into account in the UK legislation. This remains largely rooted in the utilitarian perspective originally developed by the Warnock Committee. Even in such an ethically controversial area this approach has succeeded in finding a pragmatic compromise acceptable to all sides and aimed at maximising overall utility.[1387] The different ethical positions existing in society were an essential element that the Warnock Committee considered when drafting its recommendation. Unlike in Italy and Germany the framework that was approved as the basis for the legislation was not readily derived from one specific ethical approach. It was rather the result of an effort to find a common moral position capable of being an acceptable compromise between different ethical positions in society. Indeed, the entire work of the Warnock Committee was guided by the objective of finding a compromise that would be acceptable to virtually all reasonable members of society. At the implementation stage the HFEA's decisions on the acceptability of PGD have been influenced by its continuous observation of public opinion. Moreover, with the provision of subjective criteria in its Codes of Practices the HFEA also allowed for the individual couple's ethical stances to be taken into account in the licensing process.

1385 For arguments that the restriction of PGD to high-risk couples ensures the compatibility with the constitution and human dignity see, *inter alia*, Hufen, 'Präimplantationsdiagnostik aus verfassungsrechtlicher Sicht' (2001) 19(9) MedR p. 440, 446; Dreier in Dreier, *Grundgesetz* (2013) para 96; Herdegen in Dürig, Herzog and Scholz, *Grundgesetz* (2021) para. 113.

1386 See above in this Chapter, sec. A.I.3.d.iii.

1387 Snelling and Gavaghan in Horsey, *Revisiting the Regulation of Human Fertilisation and Embryology* (2015) p. 132.

3. Acceptance of PGD Regulation

There is a substantial difference in the way in which the multiplicity of ethical positions that exist within society have been considered. In England the potential ethical challenges of fertility treatments and uses of embryos in vitro were recognised from the outset and an effort was made to find acceptable compromises and a "common moral position".[1388] In Italy and Germany the initial effort was directed towards creating a legislative architecture that would primarily protect the embryo, resulting in very restrictive regulations that did not sufficiently take ethical pluralism into account. As a result, the acceptance of the initial normative frameworks varied in the three countries. An indicator of this is the case law on PGD during the period of uncertainty pending explicit legislative intervention.

In the UK the Warnock Committee's aim of a compromise through which a long-lasting consensus can be established – and one that can be constantly adapted to scientific developments – has been definitively achieved in the case of PGD. From a utilitarian perspective PGD has been judged desirable when it seeks to avoid a significant risk of a serious medical condition. The HFEA has succeeded in embracing this perspective and enshrining it in its Codes of Practice, thereby effectively regulating its use. The HFEA's procedural legitimacy, based on its expertise as well as on the constant adaptation to society's shifting ethical landscape through public consultations, also positively influenced the acceptance of its decisions. As a result of the application of the HFEA's guidelines, while PGD was still considered more problematic than simple fertility treatments, it was tolerated even by those who considered it contrary to their ethical views. The permissibility of PGD within the HFE Act only began to be challenged in court insofar as it was used in combination with another, more controversial technique, namely the creation of 'saviour siblings'.[1389] However, when subjected to parliamentary review, the HFEA's decisions were upheld and given democratic legitimacy.[1390]

In Germany the use of PGD, pending clearer rules from the legislature, escalated into a criminal trial following a doctor's self-reporting. Even after

1388 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 3.

1389 *Quintavalle v Human Fertilisation and Embryology Authority* [2005] UKHL 28 (28 April 2005).

1390 See above in this Chapter, sec. C.I.3.b.

the parliamentary approval of PGD the dissatisfaction with the resulting legislative framework is still being voiced with calls for reforms towards a comprehensive law on medically assisted reproduction.[1391]

In Italy too, the ministerial guidelines prohibiting PGD have been challenged before several different courts and eventually declared void.[1392] The build-up of case law along with the legislature's unwillingness to change the normative framework culminated in the intervention of the Italian Constitutional Court.

III. PGD in the Public Healthcare System

1. Public Funding

In all jurisdictions several years have passed (or are still passing) from the development of PGD for clinical practice and its full inclusion into the public healthcare system.[1393]

In all three countries the initial situation excluded public funding at the national level. In England and in Italy coverage was left to the discretion of, respectively, local and regional health authorities. In Germany reimbursement for PGD is still not provided by public health insurance funds because, according to the current social legislation, PGD does not treat an insured health condition and nor does it constitute the early detection of a disease in an insured subject.

In England a pragmatic and utilitarian view was later reflected in the funding of PGD by the NHS. Thanks to pragmatic considerations, related to the relatively small number of cases, PGD was finally classified as a specialized serviced to be commissioned at the national level in 2013. As

1391 As for instance the "Augsburg-Munich draft", a draft proposal for a comprehensive law on reproductive medicine written by legal scholars in Augsburg and Munich, Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013). See also Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013); Kersten, 'Regulierungsauftrag für den Staat im Bereich der Fortpflanzungsmedizin' (2018) 37(17) NVwZ p. 1248; Westermann and others, *Fortpflanzungsmedizin in Deutschland - für eine zeitgemäße Gesetzgebung* (2019).

1392 See in this Chapter, sec. B.I.2.a.

1393 The first successful case of a PGD that resulted in pregnancy was reported in April 1990, see Handyside and others, 'Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specific DNA Amplification' (1990) 344(6268) Nature p. 768.

a consequence, it is currently offered in NHS facilities and its funding is nationally provided. Hence PGD is not affected anymore by one of the most problematic aspects of public funding of reproductive services in England. Namely, the so-called 'postcode lottery' phenomenon.

In Italy, when deciding on the offer of PGD in public healthcare facilities, ordinary courts have been directly implementing the substantive principles dictated by the Italian Constitutional Court in its ruling no. 96/2015. This was primarily grounded on the relevance of access to PGD for the fundamental right to health, which is interpreted quite broadly in Italian law. Therefore, following the appeal of couples to whom the health authorities had denied funding, the courts guaranteed access to PGD within the National Health Service from 2017. Nevertheless, since this issue has so far only been resolved at the level of single cases, the decisions are merely valid between the parties to the proceedings and they involve considerable legal costs for the couples. Moreover, differences between regions persist which could only be overcome by an intervention at the national level.

In Germany the PGD regulation merely excluded criminalisation in exceptional cases, but did not lay down substantive principles for reimbursement. In the absence of any other general principle of health insurance applicable to PGD, social courts have not been able to expand the scope of the public health insurance without prior legislative intervention. They have thus denied that there is any obligation on statutory health insurance funds to reimburse PGD. Proposals to publicly fund PGD have been discussed since 2018 and a possible reform in this direction has been announced by the current government in its 2021 coalition agreement.[1394]

2. Influence of Ethical Concerns on Public Funding and Patient Uptake

The incorporation of ethical attitudes towards PGD into the legal framework also played a role in its public health coverage and patient uptake.

In Italy the initial moral disapproval of fertility treatments has resulted in poor coverage by the National Health Service. The lack of public support for the provision of artificial reproductive technologies was already evident from the scarce funds allocated by Law no. 40/2004. The funding of ethically controversial fertility treatments was initially left to the

1394 Sozialdemokratische Partei Deutschlands (SPD) and BÜNDNIS 90/DIE GRÜNEN, Freie Demokratische Partei (FDP), 'Mehr Fortschritt Wagen. Bündnis für Freiheit, Gerechtigkeit und Nachhaltigkeit', p. 92.

discretion of individual regions. A first opportunity to include heterologous fertilisation in the national Essential Levels of Care was openly delayed by the government because of the 'ethical relevance' of the issue. Regarding PGD in particular, a lack of public funding persists. Seven years after the Constitutional Court's ruling that declared access to PGD to be a part of the fundamental core of the right to health, this technology is still not introduced in the national Essential Levels of Care. As argued by proponents of a bill introduced into Parliament in 2019, the shortfall in coverage within the National Health Service is the result of an ideological war and of the ethical controversy that still surrounds PGD.

In Germany, as anticipated above, a first obstacle to patients' uptake of PGD comes from the mandatory procedure before ethics commissions. Although these ethics commissions should merely assess whether the medical and legal preconditions for access to PGD are met, their labelling as 'ethical' expresses the existence of a certain ethical reluctance towards PGD. This requirement places both a psychological and a financial burden on couples, given that the costs of the procedure before the ethics commission must be privately borne. Several other factors weigh on the chances and willingness of couples to (successfully) apply for PGD before these bodies.[1395] The composition of the commission includes experts in ethics and theology as well as representatives of disability associations. This, together with their possibility to summon the woman who submitted the application for an oral hearing, seems to encourage an ethical scrutiny of the couple's intentions. Second, the Federal Government's Ordinance on PGD has explicitly given commissions the task of considering psychological, social and ethical aspects. This general clause may be used to unlawfully widen their margin of discretion and thus limit access to PGD. Couples could secure a guarantee that this would not be the case through an appeal to the administrative courts.[1396] This is however expensive and should only be a last resort. Moreover, the application and the procedure create a delay in access to PGD, even though there is a three-month deadline for the commission's decision. In conclusion, compulsory examination by an ethics commission constitutes a financial, psychological and bureaucratic burden that is capable of limiting the uptake of PGD.

1395 For a better description of such circumstances, see above in this Chapter, sec. A.I.3.d.iii.

1396 See in this Chapter, sec. A.I.3.d.ii.

Ethical concerns were also voiced in Germany against the funding of PGD by the statutory health insurance. In 2002 the study commission on law and ethics in modern medicine suggested that reimbursement of PGD by the health insurance would expand its uptake and thus lead to an undesirable slippery slope. The minority opinion of the German Ethics Council in 2011 voiced the same concern. Social courts maintained that the decision on an ethically controversial topic, such as the public funding of PGD, had to be taken by Parliament. However, the 2018 reform proposal was blocked arguably due to the ethically controversial nature of PGD.[1397]

In England, the results of a public consultation by the Human Genetic Commission called for public funding of PGD already at a relatively early stage in the development of the technology.[1398] Ethical reservations against PGD do not seem to have played any role in the question of its public coverage. Sufficient evidence of clinical benefit and cost-effectiveness were the criteria used to decide in favour of the national commissioning of PGD.[1399]

IV. Coherence with the Normative Framework

1. PGD Regulation and Implementation

The analysis of this case study has shown that, when faced with an ethically controversial technology, parliaments naturally tend to mirror the ethical concerns existing in society in their legislation.

As was pointed out in this thesis' theoretical framework: the content of the laws in such cases reveal an overlap with morality. Legislators may unsurprisingly want to draw on the ethical views of their constituencies to support certain provisions in Parliament. The mirroring of ethical stances in the regulation of PGD happened in all three compared jurisdictions.

However, according to the thesis' theoretical framework, the ethical and the legal system remain completely separate; ethical stances that are mirrored in law assume a legal form and become part of the legal system.

1397 Becker, Grunert and Müller, '"Wir bauen Druck auf, aber wir sind es den Patienten schuldig"' *Frankfurt Allgemeine Zeitung*. 25.2.2019.

1398 Human Genetics Commission, 'Choosing the Future: Genetics and Reproductive Decision-Making — Analysis of Responses to the Consultation', 2005, para. 4.5.

1399 See above in this Chapter, sec. C.II.2.

The separation of those systems must be maintained given that law is a system that binds society as a whole, while the system of ethics is composed of a variety of moralities that exist in society and each of them can only bind those individuals who endorse them. In the case of PGD dignitarian, utilitarian and rights-based perspectives[1400] have proven to be conflicting.

In this sense, separation between ethics and law also has normative content, insofar as the law should respect individual autonomy and reasonable ethical pluralism. Thus, legal provisions must be justified in ways that can be reasonably acceptable to society as a whole. Ethical pluralism is a value protected, in different ways, in all the constitutional orders that form the subject of this investigation. In Germany the constitutional handling of ethical pluralism is governed by a principle of neutrality of justification. In Italy the constitutional framework is given by the principle of laicity. In the field of ethically controversial health technologies this principle works in combination with the right to health as well as with the reasonableness requirement laid down in Article 3 of the Italian Constitution. Finally, in England the protection of reasonable ethical pluralism happens within a framework of procedural principles.

Against this background, the mirroring of ethical concepts in the legal systems can only successfully happen if it is done in ways that are compatible with the legal system itself. Particular ethical perspectives, ones which are only shared by certain members of society, cannot be imposed in a one-sided manner as legitimately binding on society as a whole. Resulting norms run the risk of failing to be operationalised within the legal system. In particular, they risk being incompatible with the overarching constitutional framework of each jurisdiction.

In the German debate on PGD particular ethical perspectives have been used to define legal concepts such as the right to dignity and to life. The content of those constitutional principles, however, can only be determined by legal methods such as the balancing of constitutional interests through the assessment of the proportionality of interferences. Eventually the criteria under which PGD was considered admissible, those within the draft that was finally enacted by the German Parliament in 2011, were in compliance with a framework of ethical neutrality. The limitation of access to PGD only in medically indicated cases serves the purpose of striking a balance

1400 Following a classification of competing value perspectives devised by Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) pp. 35–41, see Chapter 1, sec. A.I.1.

between the constitutionally relevant positions of the embryo and the couple. Prior to this legislative intervention the Federal Court of Justice had warned that a complete ban on PGD, based on an assumption that human life starts from the moment of fertilisation, would have been incoherent with the current legal framework and the values enshrined in the abortion legislation. Yet this also would have violated the principle of neutrality of justification. For the interference in the future mother's right to physical integrity would have been grounded on an ethical assumption regarding the moment at which life begins. This assumption is not assimilated as such by the legal system, nor endorsed by society as a whole.

In Italy the separation between ethics and the law was openly violated in the regulation of PGD and of artificial reproductive technologies in general. The case study analysis has demonstrated how a regulation so loaded with ideological preconceptions could not be tolerated in the Italian constitutional system.[1401] Indeed, the fact that the legislation was so substantially conditioned by ethical concerns, and entirely premised on a religious stance, *de facto* determined its unconstitutionality. With several judgments the Italian Constitutional Court has reshaped the legislation in order to make it compatible with the right to health and with the reasonableness requirement.

Yet, indirectly and tacitly, the Constitutional Court has thus also enforced the principle of laicity. The principle of laicity always operates in conjunction with other constitutional principles. Among these the requirement of reasonableness and the right to health are the most relevant here. According to the principle of reasonableness any differential treatment in the access to health must serve a constitutionally relevant purpose. [1402] Therefore, if the aim pursued falls outside the constitutional framework, as moral and religious concerns do, it cannot be taken into account in the balancing of interests.[1403] Many of the provisions of Law no. 40/2004 indeed served the aim of enforcing certain ethical and religious standards. The Court did not consider such interests of constitutional relevance and could therefore not use them as a justification for the interference with constitutional rights.

1401 As also pointed out by Repetto, 'Non di sola Cedu … La fecondazione assistita e il diritto alla salute in Italia e in Europa' [2013](1) Dir pubbl p. 131, 157.

1402 Barberis, 'Eguaglianza, ragionevolezza e diritti' [2013](1) Rivista di filosofia del diritto p. 191, 197.

1403 Milani, '«Veluti si Deus daretur»: la legge n. 40 del 2004 sulla procreazione medicalmente assistita dal dibattito parlamentare all'articolato' (2015) 23(1) Quad dir e pol eccl p. 117, 139.

According to laicity the legal system is blind to ethical perspectives insofar as they do not reflect constitutional requirements. The Italian Constitutional Court was thus bound to regard the resulting legislation as unreasonable.

As regards England, it is also true that its legislative framework on PGD openly reflects a particular ethical viewpoint. Namely, the utilitarian and gradualist perspective adopted by the Warnock Committee. Nonetheless, the adoption and implementation of this ethical point of view has occurred in a manner compatible with the illustrated normative framework. The protection of reasonable ethical pluralism has been maintained through compliance with the procedural elements that guarantee the acceptability of regulation by virtually all parts of society. First of all, an expert committee worked on developing an acceptable ethical compromise on the uses of the embryo in vitro,[1404] which was then validated by Parliament.[1405] In this process citizens' ethical concerns were listened to through public consultations. Such consultations were also used to maintain the legislation's flexibility, an important factor for the purposes of securing room for the possible influence of different ethical opinions on amendments to the legislation. The legislature then entrusted an independent and experienced authority, the HFEA, with the task of assessing the ethical admissibility of new techniques. The authorisation of PGD techniques in individual cases was thus legitimised through the expertise of the members of the regulatory body. Moreover, in the initial period of uncertainty over PGD the Authority also based its decisions on the analysis of public consultation documents, thus taking into account reasonable ethical pluralism. In deciding on the authorisation of PGD, the HFEA applied an interpretation of the available legislative material. For instance, it accounted for the explicit promotion in the HFE Act of research aimed at improving techniques for detecting genetic malformations in the embryo. It has also considered the coherency with abortion legislation. The autonomy of the patients was protected by considering the subjective conditions of the couple. As a result, the ethical compromise reached by the Authority proved to be compatible with the legal system and was in fact promptly and successfully operationalised in legal terms by Parliament, finally resolving the legal uncertainty surrounding PGD.

1404 Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984.

1405 In the Human Fertilisation and Embryology Act 1990, as enacted.

In sum, the regulation of PGD within the HFE Act has met the requirements of procedural legitimacy in British constitutional law and appears to have achieved the goal of safeguarding ethical pluralism in society.

2. Access to PGD: The Case of the Ethics Commissions in Germany

In Germany the uncertainty of the initial legal framework was remedied by Parliament reaching a compromise grounded on a neutral justification. Only to this extent are the statutory limitations on PGD the result of a constitutional balance that is compatible with reasonable ethical pluralism.

The further restrictions encountered in Germany by couples who meet the legal requirements to access PGD – which negatively affect patients' chances of accessing PGD – remain questionable in light of the described normative framework. In particular, the mandatory procedure before the ethics committee and the exclusion of reimbursement could only be found legitimate in terms of the ethical and religious neutrality of the state as long as they can still be neutrally justified.

As for the mandatory approval of each individual case by an ethics commission, this requirement shows ethical scepticism and undesirability of widespread use of PGD. This is not only because of the designation of the commission as 'ethical' but also due to its composition and its competence to address psychological, social and ethical aspects. On the one hand, this control was justified with the need to avoid improper use and to individually verify the couple's fulfilment of the medical requirements established by the legislation. On the other hand, to be compatible with a framework of ethical neutrality, the decision about whether the individual couple meets the legal requirements should be free of any ethical or religious influence and should not, therefore, be made by an ethics commission.[1406] This is because interferences with the couple's right to access PGD must be legally and neutrally justifiable. However, the aim of ensuring that a couple meets the clinical requirements laid down in the PGD Act could be achieved by more adequate means. Means that are less invasive and less vulnerable to the infiltration of ethical considerations into a decision that is supposed to be based on purely legal and medical criteria. The very requirement of a

1406 Especially so considering that the commission is explicitly authorised to consider ethical issues and includes among its members an ethics expert and one who represents the interests of people with disabilities.

mandatory examination before an ethics commission seems disproportionate compared with the alternative of entrusting this task to a physician or a team of doctors.[1407] Indeed, the assessment could be conducted by physicians in a medical consultation with the woman or the couple with no involvement of an 'ethics' commission, whose very name might discourage the couple. One example is that access to regular prenatal diagnoses and abortion – which entail similar constitutional concerns – are carried out without the necessary consultation of an ethics committee.[1408] This alternative would better protect the interests of the couple by guaranteeing their informed consent. As indicated by the Federal Administrative Court, the requirements for access to PGD under § 3a of the Embryo Protection Act can be sufficiently defined using the legal methods of interpretation and with the support of medical experts. Thus, the assessment of whether the procedure is medically indicated is possible without there being a need to rely on an ethical normative system outside the law.[1409] By contrast, the presence of experts specialising in theology and ethics, for instance, does not seem adequate to achieve the commission's task of making a purely medical and legal assessment that is justifiable on neutral grounds. The same goes for the commission's consideration of ethical aspects in the decision.[1410] Interpreting the legal concepts of § 3a of the Embryo Protection Act with ethical tools would lead to an incompatibility with the legal system. In such a case couples may be able to resort to the administrative courts to ensure that the commissions are respecting the limits of their discretion as set out in the Embryo Protection Act. However, this implies that a remedy to the commission's use of illegitimate criteria could only be sought on a case-by-case basis and only for those couples who have the means to bring a claim before the administrative courts.

While the mandatory intervention of an ethics commission is unjustified from a legal point of view, it might seem justified for those who express the ethical concern of the slippery slope. This seems to be a case 'Trojan horse' for ethical considerations,[1411] as theorised by Tade Matthias Spranger.[1412] According to him, this term indicates cases where the division between

1407 As suggested in Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013).
1408 Kreß in Geis, Winkler and Bickenbach, *Von der Kultur der Verfassung* (2015) p. 49.
1409 BVerwG, 5.11.2020 - 3 C 12.19, para. 23.
1410 See Bögershausen, *Präimplantationsdiagnostik* (2016) p. 253.
1411 See Chapter 1, sec. B.I.1.
1412 Spranger, *Recht und Bioethik* (2010) pp. 38-39.

ethics and law is violated, as a norm, acting as a 'Trojan horse', brings ethical consideration into the legal system. Norms that function as 'Trojan horses' for ethics can be recognised by the fact that, from a legal point of view, the definition of the conflict of interests seems unbalanced and there is no compelling necessity for the creation of that norm. In other words, the resolution of a conflict between two interests is imbalanced due to the weight of ethical interests that should have not been brought into the balancing act.[1413] This does not always result in a proper breach of the fundamental rights of other individuals. However, it must be remedied since, on the one hand, only the legal system can impose generally binding standards and, on the other hand, it results in a violation of the standard of neutrality as developed in my theoretical framework. This is comparable to what transpired in the Italian Constitutional Court's judgment no. 96/2015. The unreasonableness of the prohibition of access to PGD for fertile couples stemmed from the fact that the legislature had primarily given importance to ethical considerations. Once transposed into the legal system these concerns did not have a constitutional weight that was comparable to the other constitutional rights at stake. Here too a clear constitutional imbalance resulted from the consideration of interests external to the legal system.

In sum, as currently designed, the mandatory approval by an ethics commission violates the requirement of ethical neutrality of justification. Although when it comes to PGD it is difficult to separate constitutional considerations from ethical and religious ones, the suspicion that in Germany there is a violation of ethical and religious neutrality is confirmed. The legal obstacles that the German legislature has consciously placed in the way of accessing medically indicated PGD have no clear constitutional justification and *de facto* steer the behaviour of individuals towards compliance with the particular ethical conception that has been adopted by the majority and not with what is legally acceptable.

3. Public Funding

The non-inclusion of PGD in the public healthcare system has proven, in both Italy and Germany, to be contrary to the normative framework of neutrality endorsed in this thesis. By contrast, the public coverage of PGD

1413 ibid.

by the English NHS was guaranteed regardless of ethical considerations on the procedure.

In Germany the main constitutional reasons justifying limitations on access to PGD have already been transposed by the provisions of the required medical indication under § 3a of the Embryo Protection Act. Against this background the exclusion of reimbursement can only be found legitimate in terms of the ethical and religious neutrality of the state as long as it can still be neutrally justified.[1414] It would run counter to the principle of ethical neutrality of the state if justified on purely ethical grounds. Indeed, the requirement of ethical and religious neutrality also applies to the social sphere of state action.[1415] Decisions on the funding of health services must therefore be based on legal considerations. With regard to the inclusion of PGD in the benefit basket of the statutory health insurance the social courts correctly considered that, for legal-technical reasons, this would require a positive decision by the legislature. The reimbursement of PGD under current circumstances is ruled out by the fundamental concepts of disease and of insured person adopted by the German public healthcare system, as well as by the concrete wording of the other relevant provisions in the Fifth Book of the German Social Law Code. Moreover, when it comes to determining public reimbursement of healthcare services, the legislature enjoys a wide margin of discretion.

Nevertheless, even in this field the legislature's discretion may not be exercised in a manner contrary to the principle of ethical and religious neutrality. Under the current conditions the inactivity of the legislator seems to be driven by the ethical and religious stance of the majority, especially in light of the reactions to reform proposals aimed at addressing the public reimbursement of PGD. As observed above, a justification for the continued exclusion from the benefit basket is intended to maintain limits on the spread of PGD.[1416] In other words, legislators anticipate that financial obstacles will dissuade couples from seeking PGD, even in cases where the democratic agreement has deemed it in line with the constitution. In this sense the justification stems from an ethical and religious normative system, according to which a widespread use of the technology, even when

1414 According to the theory of ethical and religious neutrality as neutrality of the justification, see Chapter 1, sec. A.II.2.

1415 As illustrated in Chapter 1, sec. B.I.

1416 See Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 205; Deutscher Bundestag, 'BT-Drucks. 19/8351', 4.11.2019, p. 77.

medically indicated, would be considered ethically undesirable in itself. There is therefore a clear violation of the separation between ethics and law and of the principle ethical and religious neutrality. Moreover, this occurs at the expense of couples who are in a more precarious social and economic situation. A counter-argument could be made that the exclusion of reimbursement could rather be based on financial and budgetary reasons. However, this justification is hardly plausible in light of the acknowledged[1417] limited impact of PGD costs on the public health insurance budget, which stems from the small number of couples who are eligible for PGD under § 3a of the Embryo Protection Act.

Lastly, the obstacles posed by the regulation to accessing PGD lead to a lack of coherence in the legal system. In this respect, the example of access to prenatal diagnosis and abortion is again emblematic, as both procedures are reimbursed by the statutory health insurance and accessible without the approval of an ethics committee. As a result, couples who cannot access PGD because of the above-mentioned obstacles will still be able to attempt a natural pregnancy and then possibly undergo an abortion after having diagnosed the presence of the genetic condition in the foetus through routine prenatal diagnosis. Although it seems evident that this second option is more prejudicial to the woman's right to physical integrity, [1418] it nevertheless seems to be the one that the German public healthcare system makes more accessible, at least to economically weaker groups.

In Italy the non-inclusion of PGD in the national Essential Levels of Care is an infringement of the right to health. It also goes against the principle of laicity insofar as it is mainly the result of an ethical bias against this procedure. Even after the clarifications made by the Constitutional Court, the coverage of PGD by the National Health Service has been jeopardised by delays on the part of the health administration. These were influenced in part by economic considerations and in part by a persistent commitment to an ethical view that negatively assesses the use of preimplantation diagnosis and the selective transfer of healthy embryos into the uterus of the future mother. The existence of alleged ethical concerns, for instance, led to the

1417 As noted by the cost assessment section of two of the draft bills introduced into Parliament in April 2011, Deutscher Bundestag, 'BT-Drucks. 17/5452. Röspel, Hinz and others', 12.4.2011 and Deutscher Bundestag, 'BT-Drucks. 17/5451. Flach, Hintze and others', 12.4.2011, as well as the explanatory memorandum of the reform proposal suggested by the Bundesrat in November 2018, Bundesrat, 'BR-Drucks. 504/18. Stellungnahme des Bundesrates', 23.11.2018.

1418 Dreier in Dreier, *Grundgesetz* (2013) para. 97.

delay of the decision on PGD reimbursement. After being brought before the government by the Minister of Health the matter was referred to the Parliament, which failed to address it.

These delays on the part of the health administration, both at central and regional level, have been overcome by the courts in individual cases. Starting from the consideration that all medical treatments that are fundamental to the protection of the right to health in its essential core must be guaranteed by the public healthcare system, ordinary judges ordered public facilities to perform PGD at the expense of the Regional Health Systems. Courts have thus applied principles of legal reasoning to determine the obligation of the National Health Service to provide PGD. In other words, the right to health has been directly applied, in its broad conception, to the activities of the health administration. All healthcare technologies falling within the scope of the essential core of the right to health lie within the duties of the public healthcare services, which can only impose a limited patient contribution to the expenses. This sort of automatism obviously leaves open the possibility of taking financial issues into account. The existence of limited finances, however, cannot be invoked in violation of the reasonableness requirement. This would occur, for instance, when the reasons for denying reimbursement of a certain healthcare treatment derive entirely from ethical assumptions foreign to the constitutional order, as defined by the Constitutional Court case law. In sum, it appears clear from reading the decisions of ordinary and administrative judges that ethical issues cannot be taken into consideration to justify the non-reimbursement of a service that the Constitutional Court has defined as essential to the protection of the minimum core of the right to health.

In England, once a reasonable ethical compromise had been reached and translated into legislation, the decision on NHS coverage of PGD was made according to criteria of clinical benefit and cost-effectiveness and on the basis of the need to address geographical inequality. Centralised commissioning of these services has been recognised as both feasible and affordable due to the fact that the number of couples seeking, or eligible for, them is expected to remain small. In contrast to IVF the resource allocation required to cover the demand for PGD treatments across the country is therefore confined and has only had a limited impact on the budget of the NHS. PGD is therefore, unlike IVF, financed for all couples across the country. NHS funding is provided in spite of the fact that PGD is regarded, from an ethical perspective, as much more problematic than

mere fertility treatments, with the latter being considered unproblematic and widely accepted in British society.[1419] This supports the conclusion that ethical concerns about PGD have not influenced its funding and that the primary concern of NHS bodies in this area remains the efficient allocation of resources. This decision is in line with the requirements of the 'accountability for reasonableness' model adopted by the NHS, according to which determinations on rationing healthcare resources must be reached without regard to irrelevant factors and are only legitimate if they are based on legal considerations that virtually all members of English society would admittedly hold to be relevant and acceptable. Ethical reasons for opposing a certain technology cannot be weighted as a relevant factor in the decision.

1419 McLean, 'De-Regulating Assisted Reproduction: Some Reflections' (2006) 7(3) Med Law Int p. 233, 238.