Studien aus dem Max-Planck-Institut
für Sozialrecht und Sozialpolitik

79

Irene Domenici

Between Ethical Oversight and State Neutrality

Introducing Controversial Technologies into the Public Healthcare Systems of Germany, Italy and England

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Preface

This book is the outcome of my work as a doctoral student at the Max Planck Institute for Social Law and Social Policy in Munich. The manuscript was submitted as a doctoral thesis at the Law Faculty of the Ludwig Maximilian University of Munich in August 2022.

It was while writing the last parts of my dissertation that I gained first-hand experience of what I was reflecting upon in my work. In the spring of 2022, I was told that my foetus was at risk of chromosomal conditions and that non-invasive prenatal testing (NIPT) would be recommended. I have faced how hard the choice is as to whether to take the test or not. The emotions involved are so strong that it seems impossible for anyone to mistake NIPT for a regular blood test. Eventually, I have felt relief knowing that, simply by taking a blood test and without invasively jeopardizing the little one in the womb, I could get a glimpse into her health conditions. Obviously, my personal experience is only anecdotal and does not aspire in any way at representing an empirically relevant result. However, I want to preface this thesis by saying that I am grateful that I had the choice of whether or not to take the test, that I had professional and personal help in making this conscious decision, and the financial means to do so. I wish that every future mother can have the opportunity to make this and other reproductive choices free of social or economic constraints.

I cannot disregard that the chance to scientifically reflect on these issues in the first place is a privilege in itself. This opportunity was given to me by my doctoral advisor, Prof. Dr. Ulrich Becker. To him I owe the greatest thanks. Without his support, encouragement and trust – but also challenges, rigorous standards and questions – I could have not written this book. I would also like to thank Prof. Dr. Jens Kersten, who in providing a second opinion to my thesis saw great potential in the work and suggested an additional reading angle.

Invaluable scholarly and personal support in the drafting of my dissertation also came to me from all the colleagues at the Max Planck Institute for Social Law and Social Policy. I would like to thank all my doctoral fellows (including Tim Rohmann, Christian Günther, Franciska Engeser, Lauren Tonti, Kristine Plank, Irene Carlet, Madeleine Beul, Teodora Petrova and Hung-Sheng Shan) and senior colleagues (including Anika Seemann, Simone von Hardenberg, Eva Hohnerlein, Julia Hagn, Tino Hruschka and Roman Grinblat), who were always ready for a spontaneous talk or coffee when I needed to recharge my batteries. I thank the library team and especially our head of library, Henning Frankenberger, for offering me all the help I needed, in the form of both academic literature and personal exchange. The Institute is also part of the Max Planck Law Network to which I am indebted for supporting me financially in my research visit to the Faculty of Law of the University of Cambridge.

I am also grateful for the support I received from outside the Institute. In particular, a huge thank you goes to the Biolaw group at the University of Trento. Especially to Prof. Carlo Casonato, for believing in me and sharing his contagious passions for biolaw, and to Dr. Lucia Busatta for accompanying me in my early steps in academic research and in my first teaching experience. I thank Prof. Dr. Stefan Huster whose work greatly inspired me. Prof. Kathleen Liddell from the University of Cambridge and Prof. Roger Brownsword from King's College London for finding the topic captivating and for the valuable exchange.

Finally, my thanks go to my family and friends for making me genuinely happy, even while writing a doctoral thesis. To my mother, father and sister, who have been my guiding light and safe haven. To my daughter, who was growing inside me when I submitted this thesis and was then smiling beside me at my *rigorosum* in May 2023. To the most important person in my private and academic life, my husband Tim, with whom I share and always will share all the good things in life, big and small.

Irene Domenici Munich, August 2023

Content Overview

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Zusammenfassung

Die Aufnahme neuer Gesundheitstechnologien in den Leistungskatalog des öffentlichen Gesundheitssystems ist das Ergebnis eines von Unsicherheit geprägten Bewertungsprozesses. Dies gilt umso mehr für ethisch umstrittene Gesundheitstechnologien, denn bevor Behörden Erstattungsentscheidungen treffen, müssen sie sich über die moralischen Implikationen und gesellschaftlichen Auswirkungen im Klaren sein. Die Entscheidung, ethisch umstrittene medizinische Verfahren in das öffentliche Gesundheitssystem aufzunehmen, hat zudem eine starke symbolische Bedeutung und damit Einfluss auf die Akzeptanz der Technologie in der Gesellschaft.

Trotz ihrer Relevanz kann die Berücksichtigung ethischer Aspekte während des Entscheidungsprozesses problematisch werden. Der weitreichende Ermessensspielraum, der den staatlichen Institutionen bei der Zusammenstellung der Leistungskataloge eingeräumt wird, birgt die Gefahr, dass Entscheidungen auf der Grundlage bestimmter ethischer, religiöser oder ideologischer Überzeugungen getroffen werden. Rechtsverbindliche Entscheidungen, die auf außerrechtlichen Erwägungen beruhen, bringen jedoch ein Legitimationsproblem mit sich. Moderne demokratisch verfasste Staaten sind durch einen breiten ethischen Pluralismus gekennzeichnet, was bedeutet, dass ihre Mitglieder unterschiedliche ethische Überzeugungen und Vorstellungen vom moralisch Guten haben. Vor diesem Hintergrund legt die Arbeit dar, dass die Wahrung ethischer Neutralität für den Staat zwingend erforderlich ist, um Pluralität überhaupt erst zu ermöglichen. Ethische Neutralität soll gewährleisten, dass die Rechtfertigung der Handlungen des Staates auf Gründen beruht, die von der Gesellschaft als Ganzes akzeptiert werden können und nicht lediglich ideologische oder religiöse Überzeugungen widerspiegelt, die von der politischen Mehrheit geteilt werden.

Vor diesem Hintergrund fragt die Dissertation, inwieweit ethische Bedenken bei Erstattungsentscheidungen der öffentlichen Gesundheitssysteme legitimerweise berücksichtigt werden können und welche Rolle das staatliche Neutralitätsgebot hierbei spielt. Die Untersuchung zeigt auf, dass auch Anlage und Ausgestaltung nationaler Gesundheitssysteme sowie die Beteiligung verschiedener Akteure und Institutionen den Entscheidungsprozess stark beeinflussen können, da so Spielräume für die Berück-

sichtigung ethischer Überlegungen beschränkt werden. Zu diesem Zweck wendet die Arbeit eine rechtsvergleichende Methode an und analysiert die Reaktion des Gesundheitssystems auf ethisch umstrittene Technologien in drei Ländern: Deutschland, Italien und England. Bei der Auswahl der Länder wurde berücksichtigt, dass es unterschiedliche Modelle von Gesundheitssystemen und verschiedene Vorstellungen von Gesundheit und Krankheit gibt. Außerdem wurden die Länder danach ausgewählt, wie ‚restriktiv' bzw. ‚liberal' ihre Gesetzgebung zu ethischen Fragen im Gesundheitswesen tendenziell ist.

Die Dissertation folgt einem "Fallstudien"-Ansatz. Die Fälle stammen aus den Bereichen Reproduktionsmedizin und Gentechnologie, die eine Vielzahl moralischer Implikationen mit sich bringen und daher als emblematisch für ethische Bedenken im Gesundheitswesen angesehen werden können.

Das erste Kapitel veranschaulicht den normativen Rahmen der Untersuchung. Dieser ergibt sich aus theoretischen Überlegungen zu der Frage nach der Trennung zwischen Ethik und Recht, und zwar sowohl von einem deskriptiven als auch von einem normativen Standpunkt aus. Die Wahl des Prinzips der ethischen Neutralität als normatives Kriterium für die Analyse wird dabei aus rechtstheoretischer und verfassungsrechtlicher Sicht erläutert und begründet. Insbesondere arbeitet die Dissertation die Idee der Begründungsneutralität heraus, der zufolge staatliche Maßnahmen nur dann legitim sind, wenn sie auf der Grundlage von Prämissen ausgeübt werden, von denen vernünftigerweise erwartet werden kann, dass sie von allen Bürgern unabhängig von ihrer Zugehörigkeit zu einer bestimmten ethischen oder religiösen Haltung gebilligt werden.

Die vergleichende verfassungsrechtliche Analyse ergab, dass alle drei betrachteten Rechtsordnungen den Wert der Trennung von Ethik und Recht anerkennen und dass es für den Staat zwingend erforderlich ist, sich für Maßnahmen zu entscheiden, die auf neutralen Begründungen beruhen. Zwar findet sich in keiner der Jurisdiktionen ein ausdrückliches Neutralitätsgebot im Verfassungstext, aber alle drei Länder verfügen über funktional gleichwertige Grundsätze, die den Zweck des Schutzes des ethischen Pluralismus erfüllen. Während das englische System einem prozeduralen Ansatz folgt, ist das italienische Verfassungsrecht an Laizität orientiert und dem deutschen Grundgesetz lässt sich ein Neutralitätsgebot entnehmen. Nachdem diese Grundsätze in den betreffenden verfassungsrechtlichen Ordnungen identifiziert wurden, wird dargestellt, dass sie auch für staatliche Aktivitäten im Rahmen des öffentlichen Gesundheitssystems und bei der Erbringung von Gesundheitsdienstleistungen gelten.

Kapitel 2 und 3 enthalten die Untersuchung der Einführungsprozesse der beiden Technologien, die als Fallstudien dienen, nämlich der genetischen Präimplantationsdiagnostik (PID) und der Nicht-Invasiven Pränataltests (NIPT), in die öffentlichen Gesundheitssysteme der ausgewählten Länder. Diese Kapitel bieten Einblicke in die Rolle, die ethische und religiöse Faktoren bei der Regulierung sowie bei den Entscheidungen über die Kostenerstattung für die ausgewählten Technologien gespielt haben. Darüber hinaus werden die für die Regulierung verwendeten Instrumente bewertet und in substanzielle und verfahrenstechnische Instrumente eingeteilt. Besonderes Augenmerk liegt insoweit auf der Beteiligung der verschiedenen Akteure.

In den Schlussfolgerungen vermittelt die Arbeit Erkenntnisse darüber, wie Staaten auf legitime Weise mit ethischen Belangen umgehen können. Erstens bezieht sich die Legitimität auf die Fähigkeit des Rechtssystems, die konzeptionelle Trennung zwischen Ethik und Recht aufrechtzuerhalten. Dies kann daran gemessen werden, ob das Rechtssystem in der Lage ist, eine bestimmte Norm ohne Bezugnahme auf außerrechtliche ethische Perspektiven zu operationalisieren. Dieses Erfordernis bedeutet, dass Normen keinen breiten und unbestimmten Bezug zur Ethik enthalten dürfen und dass Rechtsnormen nicht unter Bezugnahme auf bestimmte ethische oder religiöse Positionen ausgelegt werden dürfen. Außerdem müssen sie in Bezug auf den bestehenden verfassungsrechtlichen Rahmen kohärent und nachvollziehbar sein.

Zweitens erfordert Legitimität, dass Entscheidungen dem normativen Gebot der Begründungsneutralität gerecht werden. Sie müssen durch konsentierte Gründe gerechtfertigt werden können, deren Einbeziehung praktisch jedes Mitglied der Gesellschaft zustimmen kann. Mit anderen Worten: Der zweite Aspekt der Legitimität bewertet die Akzeptanz einer Vorschrift danach, ob alle Menschen, unabhängig von ihren unterschiedlichen ethischen Hintergründen und religiösen Überzeugungen, die Gründe als vernünftig und relevant anerkennen können. Insoweit kommt der Interaktion zwischen verschiedenen staatlichen Institutionen und anderen Akteuren für die Gewährleistung der Legitimität bei der Reaktion auf das Aufkommen neuer Technologien eine herausgehobene Bedeutung zu. Die vergleichende Analyse der institutionellen Interaktionen zeigt deren Einfluss auf die Legitimität der unterschiedlichen Lösungsansätze in den drei Rechtsordnungen auf. Die Dissertation bietet somit Einblicke in die optimale Gestaltung der Zusammenarbeit zwischen den verschiedenen Akteuren des Rechtssystems, um einen akzeptablen und legitimen Kompromiss in einer pluralistischen Gesellschaft zu erreichen. Dabei schlägt sie die Implementierung eines Verfahrensmodells vor, um ethische Bedenken im Bereich der reproduktiven Gesundheitstechnologien legitim zu behandeln.

Table of Abbreviations

ACGT	Advisory Committee on Genetic Testing
Acta Obstet Gynecol Scand	Acta Obstetricia et Gynecologica Scandinavica
Agenas	Agenzia Nazionale per i Servizi Sanitari Regionali
AIC	Associazione Italiana dei Costituzionalisti
Aifa	Agenzia Italiana del Farmaco
Annu Rev Genom Hum Genet	Annual Review of Genomics and Human Genetics
AOK	Allgemeine Ortskrankenkasse
AöR	Archiv des öffentlichen Rechts
Art.	Article
ASA	Advertising Standards Authority
Asian Bioeth Rev	Asian Bioethics Review
BÄK	Bundesärztekammer
Bay.VGH	Bayerische Verwaltungsgerichtshof
BGBl	Bundesgesetzblatt
BGH	Bundesgerichtshof
BMJ	British Medical Journal
Br Polit	British Politics
BSG	Bundessozialgericht
BVerfG	Bundesverfassungsgericht
BVerfGE	Entscheidungen des Bundesverfassungsgerichts
BVerfGK	Kammerentscheidungen des Bundesverfassungsgerichts
Camb Law J	Cambridge Law Journal
CCG	Clinical Commissioning Group
CDU	Christlich Demokratische Union Deutschlands
CE	Conformité européenne
Cff-DNA	Cell-free fetal DNA
CNB	Comitato Nazionale per la Bioetica

Colum L Rev	Columbia Law Review
Comp Stud Soc Hist	Comparative Studies in Society and History
CORE	Comment on Reproductive Ethics
Corr merito	Il Corriere del Merito
CSS	Consiglio Superiore di Sanità
CSU	Christlich-Soziale Union in Bayern
Curr leg probl	Current Legal Problems
d.lgs.	Decreto legislativo
Dir amm	Diritto Amministrativo
Dir eccl	Il diritto ecclesiastico
Dir eccl	Il Diritto Ecclesiastico
Dir pubbl	Diritto Pubblico
Dir pubbl comp eur	Diritto pubblico comparato ed europeo
DÖV	Die Öffentliche Verwaltung
DPCM	Decreto del Presidente del Consiglio dei Ministri
DVBl	Deutsches Verwaltungsblatt
Eccles Law J	Ecclesiastical Law Journal
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
Enc dir	Enciclopedia del Diritto
ESchG	Embryonenschutzgesetz
Ethik Med	Ethik in der Medizin
EU	European Union
Eu Const Law Rev	European Constitutional Law Review
Eur J Health Econ	The European Journal of Health Economics
Eur J Health Law	European Journal of Health Law
Eur J Hum Genet	European Journal of Human Genetics
Fam dir	Famiglia e Diritto
Fam pers e succ	Famiglia, Persone e Successioni
FDP	Freie Demokratische Partei
Fet Matern Med Rev	Fetal and Maternal Medicine Review
ff	and the following
fn.	footnote

G.U.	Gazzetta Ufficiale
G+G	Gesundheit und Gesellschaft
G-BA	Gemeinsamer Bundesausschuss
GEKO	Gendiagnostik-Kommission
GenDG	Gendiagnostikgesetz
Giur Cost	Giurisprudenza costituzionale
GKV	Gesetzliche Krankenversicherung
GuP	Gesundheit und Pflege
Harv L Rev	Harvard Law Review
Hastings Cent Rep	The Hastings Center Report
Health Care Anal	Health Care Analysis
Health Econ Policy Law	Health Economics, Policy and Law
HFE	Human Fertilisation and Embryology
HFEA	Human Fertilisation and Embryology Authority
HGC	Human Genetic Commission
HRA	Human Rights Act
HTA	Health Technology Assessment
i.e.	id est
Ibid	Ibidem
ICB	Integrated Care Board
IJGLS	Indiana Journal of Global Legal Studies
Int J Technol Assess Health Care	International Journal of Technology Assessment in Health Care
Int Urogynecol J	International urogynecology journal
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
IVD	In Vitro Diagnostics
IVF	In Vitro Fertilisation
J Appl Philos	Journal of Applied Philosophy
J Ethics	The Journal of Ethics
J Law Biosci	Journal of Law and the Biosciences
J Law Soc	Journal of Law and Society
J Med Ethics	Journal of Medical Ethics
J Med Pers	Journal of Medicine and the Person

J Med Philos	The Journal of Medicine and Philosophy
J Med Screen	Journal of Medical Screening
J of Inter Tech of Health Care	International Journal of Technology Assessment in Health Care
J Perinat Med	Journal of Perinatal Medicine
JIBL	Journal of International Biotechnology Law
JRE	Jahrbuch für Recht und Ethik
Jrnl App Lab Med	The Journal of Applied Laboratory Medicine
JZ	Juristen Zeitung
KG	Kammergericht
KJ	Kritische Justiz
Law Innov Technol	Law, Innovation and Technology
LEA	Livelli Essenziali di Assistenza
Legal stud	Legal Studies
LG	Landesgericht
LQR	Law Quarterly Review
LSG	Landessozialgericht,
Med Hist	Medical History
Med Law Int	Medical Law International
Med Law Rev	Medical Law Review
Med Sci Law	Medicine, Science and the Law
MedR	Medizinrecht
Milbank Q	The Milbank Quarterly
Minerva Obstet Gynecol	Minerva Obstetrics and Gynecology
Mod Law Rev	The Modern Law Review
MP	Member of Parliament
MPG	Medizinproduktegesetz
MPGD	Medizinprodukterecht-Durchführungsgesetz
MRT	Mitochondrial Replacement Therapy
Mu-RL	Richtlinien über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung
Nat Rev Genet	Nature Review Genetics
NCOB	Nuffield Council of Bioethics

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIPT	Non-Invasive Prenatal Testing
NJOZ	Neue Juristische Online-Zeitschrift
NJW	Neue Juristische Wochenschrift
no.	Number
NSC	National Screening Committee
NStZ	Neue Zeitschrift für Strafrecht
NVwZ	Neue Zeitschrift für Verwaltungsrecht
NVwZ	Neue Zeitschrift für Verwaltungsrecht
O.J.	Official Journal of the European Union
Oxf J Leg Stud	Oxford Journal of Legal Studies
para.	Paragraph
paras.	Paragraphs
PGD	Preimplantation Genetic Diagnosis
PIDV	Verordnung zur Regelung der Präimplantationsdiagnostik
Poiesis Prax	Poiesis & Praxis
Pol dir	Politica del Diritto
PräimpG	Präimplantationsdiagnostikgesetz
PTT	Preimplantation Tissue Typing
Quad dir e pol eccl	Quaderni di Diritto e Politica Ecclesiastica
Quaderni cost	Quaderni Costituzionali
RAPID	Reliable Accurate Prenatal Non-invasive Diagnosis
RCOG	Royal College of Obstetricians and Gynaecologists
RdLh	Rechtsdienst der Lebenshilfe
Rev med perinat	Revue de médecine périnatale
Riv it dir proc pen	Rivista italiana di diritto e procedura penale
Riv it med leg	Rivista Italiana di Medicina Legale
Riv ital med leg dirit campo sanit	Rivista italiana di medicina legale e del diritto in campo sanitario
SAcLJ	Singapore Academy of Law Journal
Sec.	Section
SG	Sozialgericht

SGB	Sozialgesetzbuch
Soc Phil Pol	Social Philosophy and Policy
SPD	Sozialdemokratische Partei Deutschlands
StGB	Strafgesetzbuch
TAR	Tribunale Amministrativo Regionale
UK	United Kingdom
UNESCO	United Nations Educational, Scientific and Cultural Organization
VG	Verwaltungsgericht
VVDStRL	Veröffentlichungen der Vereinigung der Deutschen Staatsrechtslehrer
VVG	Versicherungsvertragsgesetz
WHO	World Health Organisation
WRV	Weimarer Verfassung
Yale LJ	Yale Law Journal
ZaöRV	Zeitschrift für ausländisches öffentliches Recht und Völkerrecht
ZfL	Zeitschrift für Lebensrecht
ZFR	Zeitschrift Für Rechtspolitik
ZStW	Zeitschrift für die gesamte Strafrechtswissenschaft

Introduction

1. Problem Statement

Over the past fifty years, scientific and technological progress in the biomedical field has transformed many emerging possibilities into fully developed and clinically tested health technologies.[1] They are ready to be used safely for diagnostic or therapeutic purposes on human beings. Many of them are thus eligible to become embedded in the public healthcare system, as valuable resources in schemes of medical coverage that have the potential to be extremely innovative.

Among these innovations none has found such an ample space in legal scholars' debate as those developed thanks to the convergence of reproductive medicine and genetic technology.[2] This is mainly due to the implications of their use for other moral entities, such as embryos or future generations, and thus their considerable moral weight. With regard to reproductive medicine one need only think of the constant polarisation caused by the abortion issue[3] and, in more recent times, of the impressive legal, political and philosophical debates on medically assisted procreation that have been going on ever since the birth of the first in-vitro baby

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[1] The notion of health technology has been chosen for the thesis due to its comprehensive scope. According to the World Health Organisation (WHO), "[h]ealth technologies include medicines, medical devices, assistive technologies, techniques and procedures developed to solve health problems and improve the quality of life", <https://www.who.int/europe/news-room/fact-sheets/item/health-technologies> accessed 9.8.2022. Article 3(l) of the EU Directive 2011/24/EU on the Application of Patients' Rights in Cross-border Healthcare, O.J. L 88/45 defines *health technology* as "a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare".

[2] In his contribution on liberal eugenics of 2001, Habermas warned against the moral weight of questions surrounding technological developments brought about by this combination of fields and stressed the need to inquire about the normative evaluation of "one day theoretically possible genetic engineering developments", although they were at the time deemed to be "completely out of reach" (author's translation), see Habermas, *Die Zukunft der menschlichen Natur: Auf dem Weg zu einer liberalen Eugenik?* (2001) p. 39.

[3] Warren in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009).

back in 1978.[4] Both the removal of embryos form the mother's womb and their in-vitro creation and selection can cause ethical concerns related to, for instance, the right to life of the embryo and its dignity as a human being,[5] the respect for the laws of nature[6] and of the personal identity and self-determination of the child.[7]

As for genetic technology, the possibility of genetic modification raises, amongst others, the concern that researchers might be "playing God"[8] as well as questions of: selection, genetic enhancement and augmentation of inequalities,[9] safety of the procedures[10] and, in case of alteration in the germline, the right to self-determination of the future generations.[11]

Ultimately, the interaction of reproductive medicine and genetic technology could allow for the full realisation of parents' natural desire to have a healthy child[12] or, according to the slippery slope argument,[13] the "engineering of the perfect baby"[14]. Until now, the combined evolution of the two fields encouraged the development and refinement of, on the one hand, long-established mechanisms of embryo diagnosis and selection, such as

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[4] The news of the birth of Louise Brown was reported by the media in July 1978, see Dow, 'Looking into the Test Tube: The Birth of IVF on British Television' (2019) 63(2) Med Hist p. 189. Legal and ethical discussions on IVF are still carried out with reference to her name, see Bockenheimer-Lucius, Thorn and Wendehorst, *Umwege zum eigenen Kind; Ethische und rechtliche Herausforderungen an die Reproduktionsmedizin 30 Jahre nach Louise Brown* (2008).

[5] Nettesheim, 'Die Garantie der Menschenwürde zwischen metaphysischer Überhöhung und bloßem Abwägungstopos' (2005) 130(1) AöR p. 71; Habermas, *Die Zukunft der menschlichen Natur* (2001); Tooley in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009).

[6] Rostalski, *Das Natürlichkeitsargument bei biotechnologischen Maßnahmen* (2019).

[7] Turkmendag, 'The Donor-conceived Child's 'Right to Personal Identity': The Public Debate on Donor Anonymity in the United Kingdom' (2012) 39(1) J Law Soc p. 58.

[8] Peters, *Playing God?: Genetic Determinism and Human Freedom* (2nd edn 2003); Coady in Savulescu and Bostrom, *Human Enhancement* (2010).

[9] Gyngell, Douglas and Savulescu, 'The Ethics of Germline Gene Editing' (2017) 34(4) J Appl Philos p. 498, 509.

[10] ibid, p. 504.

[11] Kamm, 'Moral Status and Personal Identity: Clones, Embryos and Future Generations' (2005) 22(2) Soc Phil Pol p. 283; Agius and Busuttil, *Germ-Line Intervention and Our Responsibilities to Future Generations* (1998).

[12] For a reflection on the ethical issues and implications regarding the desire to conceive a healthy child, see Haker, *Hauptsache gesund?: Ethische Fragen der Pränatal- und Präimplantationsdiagnostik* (2011).

[13] See Chapter 1, sec. A.3.

[14] Regalado, 'Engineering the Perfect Baby' (3.5.2015) <https://www.technologyreview.com/s/535661/engineering-the-perfect-baby/> accessed 25.4.2022.

prenatal testing and preimplantation genetic diagnosis (PGD), and, on the other hand, very innovative therapeutic techniques involving genetic modifications of the embryo such as mitochondrial replacement therapy (MRT). However, both areas of technological advancement remain highly controversial and the same holds true for the decision regarding their possible inclusion in the publicly funded healthcare system.

While prenatal screening and diagnoses are currently offered within the publicly funded healthcare systems of most European countries, a "paradigm shift"[15] recently occurred with the development of innovative non-invasive prenatal testing (NIPT). This has led several states to reconsider the ethical and legal implications of wide-scale prenatal screening.[16] As for preimplantation genetic diagnosis, which offers an alternative to prenatal screening for couples that have a high risk of transmitting a genetic disease to the foetus, reimbursement through the healthcare system is not guaranteed in many countries.[17]

Mitochondrial replacement therapy, a procedure intended to prevent the transmission of serious mitochondrial diseases to the embryo, encounters the further obstacle of the international ban on germline genetic modification.[18] Only the English NHS, after Parliament passed a regulation permitting the use of MRT in 2015,[19] initially dedicated £8 million in funding over

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[15] Dines and others, 'A Paradigm Shift: Considerations in Prenatal Cell-Free DNA Screening' (2018) 2(5) Jrnl App Lab Med p. 784.

[16] See, for instance, the debates in Germany, Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625; Hufen, 'Verfassungsrechtliche Bedenken gegen frühe Pränataldiagnostik?' (2017) 35(4) MedR p. 277 and in Switzerland, Brauer and others, *Wissen können, dürfen, wollen?: Genetische Untersuchungen während der Schwangerschaft* (2016).

[17] In Germany, the exclusion of PGD from statutory health insurance has been confirmed by the Federal Social Court (*Bundessozialgericht*, BSG) in BSG, 18.11.2014 - B 1 KR 19/13 R.

[18] The ban appears in Art. 13 of the Convention on Human Rights and Biomedicine of the Council of Europe and is reiterated in the national legislation of several countries. The Swiss Constitution states, for instance, that « [t]oute intervention dans le patrimoine génétique de gamètes et d'embryons humains est interdite » (Art. 119, al. 2). Moreover, the UNESCO Universal Declaration of the Human Genome and Human Rights lists germline interventions as practices "contrary to human dignity" (Art. 24).

[19] The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

five years[20] for mitochondrial donation, thus allowing licenced clinics to ensure integrated NHS care for patients at high risk of transmitting serious mitochondrial disease.[21] The prohibition of germline genetic modification also affects the possible implementation of genome editing by CRISPR/Cas9 in human embryos, which would enable the correction of mutations responsible of serious genetic disease in future children. Although several ethical and safety concerns related to these procedures hinder any clinical implementation at the present time, the question of their possible funding by public healthcare systems in the foreseeable future has already been raised.[22]

Since the health technologies described above are of a deeply controversial nature, the issue of their coverage or reimbursement in the public healthcare system is often likely to fade into the background of legal debates. The use of health technologies developed from a combination of reproductive medicine and genetic technology presents deep ethical dilemmas, and the immediate legal response to their emergence is often to impose criminal law restrictions according to the precautionary principle.[23] In this sense the legal debate's focus is primarily on the constitutional acceptability of these prohibitions and on whether the use of such technologies is compatible with individual rights and constitutional principles. These discussions often fail to address fundamental questions concerning the possible implementation of those procedures in the healthcare system – particularly questions regarding the state's positive obligation to guarantee the social right to equal access to healthcare through a publicly funded system.

Nonetheless it is important to address this point. In fact, not only must states decide whether ethically controversial techniques shall be permitted,

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[20] NHS England, 'NHS England to fund ground-breaking new mitochondrial donation clinical trial' <https://www.england.nhs.uk/2016/12/mitochondrial-donation/> accessed 22.4.2022.

[21] Gorman and others, 'Mitochondrial Donation: From Test Tube to Clinic' (2018) 392(10154) Lancet p. 1191.

[22] See, for Germany, the speculations maybe by Bern, *Genome Editing in Zeiten von CRISPR/Cas* (2020) pp. 191-ff. and Deuring, *Rechtliche Herausforderungen moderner Verfahren der Intervention in die menschliche Keimbahn* (2019) pp. 413-ff. reaching opposite conclusions, on the possible reimbursement of human genome editing within the existing rules of the German Social Law Code (SGB) Book V.

[23] Andorno, 'The Precautionary Principle: A New Legal Standard for a Technological Age' (2004) 1(1) JIBL p. 11.

but also whether they should receive public funding, with funds being raised via taxation or contributions.

In light of the high costs of innovative health technologies it can be argued that a refusal of public coverage would effectively amount to a prevention of their use and distribution, especially amongst less affluent patients. As a matter of fact patients' access to innovative healthcare technologies is primarily determined by their inclusion in public healthcare coverage or insurance schemes.[24]

The choice of including ethically controversial health technologies in the public healthcare system not only has a substantive effect on a positive right to health, but also carries a certain symbolic value and has an impact on their acceptance by the community as a whole. This was also recognised by the German Constitutional Court in its second abortion decision.[25] The Court pointed out that the inclusion of certain medical procedures, such as abortion, in the statutory health insurance's benefit basket conveys an evaluation by the state that is liable to influence the population's perception towards them.[26] In fact, granting public funds through social benefits creates the impression that the state takes a positive stance towards the relevant health service. Conversely, withholding health insurance benefits conveys the idea that the procedure is not a standard one and is disapproved of or even condemned by the legal system.[27] According to the Court reimbursement decisions are thus capable of influencing public values. In addition the Court emphasised how an endorsement through the social insurance system is likely to "ease the conscience" of the people who are

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[24] Several studies investigate the diffusion of certain innovations after their introduction in the public health insurance or public coverage, see, for instance in the case of non-invasive prenatal testing, Vinante and others, 'Impact of Nationwide Health Insurance Coverage for Non-invasive Prenatal Testing' (2018) 141(2) Int J Gynaecol Obstet p. 189.

[25] BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92 (BVerfGE 88, 203 - *Schwangerschaftsabbruch II*). An English translation is available at https://www.bundesverfassungsgericht.de/SharedDocs/Entscheidungen/EN/1993/05/fs19930528_2bvf000290en.html> accessed 9.8.2022. More on this judgment at Chapter 1, sec. B.I.2.b.

[26] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

[27] Starck, 'Der verfassungsrechtliche Schutz des ungeborenen menschlichen Lebens. Zum zweiten Abtreibungsurteil des BVerfG' (1993) 48(17) JZ p. 816, 822. In the opinion of the court, however, the refusal to grant funding is "only limitedly" (*nur begrenzt*) suited to convey a negative view, see BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

close to the patient and share their responsibility in deciding to carry out the procedure.[28]

In other words, decisions regarding the public coverage or reimbursement of ethically controversial technologies tell us something about their acceptability and compatibility with a society's selection of values and contribute to a determination of "the kind of community we want to be".[29]

As a result, while the inclusion of a new health technology in the healthcare system's benefit basket is always the result of an assessment process characterised by uncertainty,[30] dealing with ethically disputed technologies adds another element of concern to the reimbursement decision. Further reflection is allegedly desired on possible moral harm resulting from their use or on the potential impact of their diffusion on the ethical values of a society.[31] Hence it could be argued that coverage decisions should be open to moral reflection and guarantee compliance with ethical standards and this applies particularly in the field of genetics and reproductive medicine.

The aim of incorporating ethical reflection into the decision-making process has been pursued on different levels. Ethical analysis has been recognised as a possible component of health technology assessment (HTA) procedures. These consist in systematic evaluations of properties, effects and impacts of health technologies[32] with a view to informing policy making in healthcare and, in particular, to supporting the healthcare system's reimbursement decisions.[33] Subject to the assessment is a broadly defined class of health technologies, including: drugs, medical devices, medical and

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[28] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (320), according to which those who are close to the pregnant woman may also feel relieved because they will perceive procedures for which social security benefits are granted as normal and lawful.

[29] An expression borrowed from Brownsword and Wale, 'Testing Times Ahead: Non-Invasive Prenatal Testing and the Kind of Community We Want to Be' (2018) 81(4) Mod Law Rev p. 646.

[30] Indeed, aspects of clinical effectiveness, quality, safety and cost-effectiveness are often unclear and need to be carefully evaluated in an assessment procedure.

[31] This twofold uncertainty is illustrated by Beyleveld and Brownsword, 'Emerging Technologies, Extreme Uncertainty, and the Principle of Rational Precautionary Reasoning' (2012) 4(1) Law Innov Technol p. 35.

[32] WHO Definition to be found in WHO Executive Board, 'Health Intervention and Technology Assessment in Support of Universal Health Coverage: Report by the Secretariat' (14.1.2014) EB 134/30 <https://apps.who.int/iris/handle/10665/172848> accessed 9.8.2022. See, also, Widrig, *Health Technology Assessment* (2015) pp. 48-ff.

[33] *Inter alia,* Luce and others, 'EBM, HTA, and CER: Clearing the confusion' (2010) 88(2) Milbank Q p. 256, 271; Drummond and others, 'Key Principles for the Improved Conduct of Health Technology Assessments for Resource Allocation Deci-

surgical procedures, diagnostic tests, biologics (e.g. blood products and gene therapies), equipment and support, and organisational and managerial systems.[34] Although HTA is traditionally aimed at evaluating clinical and economic aspects, the need to include ethical principles within its normative criteria has been widely argued for.[35] Allegedly this would inform decision makers of the ethical concerns linked to the use of a health technology and of the possible ways to implement it in a manner that is consistent with the prevailing societal ethical values.[36]

Moreover, many countries have already envisaged the involvement of ethics committees on different levels of decision making. Ethics committees established at the national level can be consulted by the government or legislature on any legislative or regulatory action that might entail ethical concerns.[37] Other *ad-hoc* committees may be foreseen by specific laws as safeguarding mechanisms that can issue concrete guidelines and advisory opinions. Alternatively, they can oversee the compliance with legal standards through a requirement that they must sanction the performance of specific procedures. In Germany, examples are provided by the local

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sions' (2008) 24(3) J of Inter Tech of Health Care p. 244, 247; Widrig, *Health Technology Assessment* (2015) p. 45.

[34] Available on the International HTA Glossary, at <http://htaglossary.net/technology> accessed 25.4.2022. See also Goodman, *HTA 101 Introduction to Health Technology Assessment* (2014) p. II-1.

[35] See, *inter alia,* Grunwald, 'The Normative Basis of (Health) Technology Assessment and the Role of Ethical Expertise' (2004) 2(2-3) Poiesis Prax p. 175; Reuzel and others, 'Ethics and HTA: Some Lessons and Challenges for the Future' (2004) 2(2-3) Poiesis Prax p. 247; Lucivero, *Ethical Assessments of Emerging Technologies: Appraising the Moral Plausibility of Technological Visions* (2016); Have, 'Ethical Perspectives on Health Technology Assessment' (2004) 20(1) Int J Technol Assess Health Care p. 71; Hofmann, 'Why Ethics Should Be Part of Health Technology Assessment' (2008) 24(4) Int J Technol Assess Health Care p. 423; Widrig, *Health Technology Assessment* (2015) pp. 248-ff.

[36] Giacomini, Miller and Browman, 'Confronting the Gray Zones of Technology Assessment: Evaluating Genetic Testing Services for Public Insurance Coverage in Canada' (2003) 19(2) Int J Technol Assess Health Care p. 301; Castro and others in Marsh and others, *Multi-criteria Decision Analysis to Support Healthcare Decisions* (2017).

[37] This is the case of the German Ethics Council (*Deutscher Ethikrat*), the Italian Committee for Bioethics (*Comitato Nazionale per la Bioetica,* CNB), the French National Consultative Ethics Committee for health and life sciences (*Comité consultatif national d'éthique*). The function of the UK-based Nuffield Council of Bioethics is slightly different, see later at Chapter 3, sec. C.II.3.a. On the roles of national ethics committees, see Vöneky, *Recht, Moral und Ethik: Grundlagen und Grenzen demokratischer Legitimation für Ethikgremien* (2010) pp. 233-ff.

Ethics Commissions for Preimplantation Diagnostics[38] and the Genetic Diagnostic Commission envisaged by § 23 of the Genetic Diagnosis Act (*Gendiagnostikgesetz*, GenDG).[39]

It is interesting to note that the EU Directive on the application of patients' rights in cross-border healthcare explicitly acknowledges that the public healthcare systems of the Member States may have made different ethical assessments of certain healthcare technologies.[40] Recital 7 of the Directive provides that "[n]o provision of this Directive should be interpreted in such a way as to undermine the fundamental *ethical* choices of Member States".[41] This clarification was introduced precisely to ensure that the directive would not oblige States to reimburse the costs of health services considered ethically controversial, such as in vitro fertilisation (IVF), if they are not funded in the Member State of origin.[42] The term 'ethical choices' is not defined by the Directive and remains relatively ambiguous.[43] In any case, it is assumed that the decision on whether or not to publicly fund a health technology also depends on an ethical, not just legal, assessment of it.

In sum, there is evidence that reimbursement decisions by the public healthcare system are not only the result of clinical and economic evaluations, but are also considered to depend on the ethical evaluations of relevant decision-makers.

Ethical concerns might enter the decision-making process even in an undisclosed or indirect way.[44] This has been the case with the Italian national and regional policies on heterologous IVF. After the Italian Constitutional Court had declared unconstitutional the prohibition of the use of

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[38] See Embryo Protection Act (*Embryonenschutzgesetz*, ESchG) § 3a(3) no. 1, as well as Chapter 2, sec. A.I.3.d.

[39] Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa: Festschrift für Edzard Schmidt-Jortzig* (2011) p. 829.

[40] Although the focus of this thesis is not directly on EU law, the latter still plays a fundamental role as part of the legal order of individual European states.

[41] 7th recital, Directive 2011/24/EU. Emphasis added by the author.

[42] van Hoof and Pennings, 'Extraterritorial Laws for Cross-border Reproductive Care: The Issue of Legal Diversity' (2012) 19(2) Eur J Health Law p. 187, 194; Frischhut, '"EU": Short for "Ethical" Union? The Role of Ethics in European Union Law' (2015) 75(3) ZaöRV p. 531, 548.

[43] Frischhut, '"EU": Short for "Ethical" Union? The Role of Ethics in European Union Law' (2015) 75(3) ZaöRV p. 531, 558.

[44] Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011) pp. 827-ff.

donor gametes in IVF (so-called heterologous IVF), laid down by Article 4(3) Law no. 40/2004,[45] some regional administrations attempted to limit the use of a technology that they still considered undesirable. They limited or altogether prevented its funding by the Regional Healthcare System.[46]

This case shows that the consideration of ethical concerns in the decision can become problematic if it is intended to ensure that the provision of healthcare follows the ethical agenda of a political majority. The rather broad margin of appreciation granted to state institutions in shaping the benefit baskets entails the risk that the decisions might be taken on the basis of particular ethical, religious or ideological convictions. This allows the ideological opposition of the majority towards a technology to manifest itself in the refusal to fund it. If so, reimbursement choices that are based on ethical considerations would carry a problem of legitimacy in modern democratic societies. These societies are characterised by broad ethical pluralism, meaning that their members have different axiological beliefs and conceptions of the moral good.[47] This holds true both in terms of different ethical assumptions – deriving from different moral intuitions proper to each individual – and in terms of their concrete significance on the desirability of certain technologies.[48]

Within this framework this dissertation endorses the view that the adoption of a position of ethical neutrality is imperative for the legitimacy of state action and is an essential element of a pluralistic society.[49] Ethical neutrality is intended to guarantee that state actions are justified on grounds that can be accepted by the society as whole, and not on ideological or religious convictions shared only by a political majority.[50] According to this

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[45] In its judgment no. 162/2014.

[46] Iadicicco, 'La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza' [2018](1) Rivista AIC p. 1, 29-ff. On this case, more information at Chapter 1, sec. II.2.b.

[47] John Rawls refers to this circumstance as "the fact of pluralism", see Rawls, 'The Idea of an Overlapping Consensus' (1987) 7(1) Oxf J Leg Stud p. 1, 4.

[48] See Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009) p. 4.

[49] Zotti in Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009) p. 104.

[50] Onida in Tedeschi, *Il principio di laicità nello stato democratico* (1996) p. 87; Valentini, 'La laicità dello Stato e le nuove interrelazioni tra etica e diritto' [2008](June) Stato, Chiese e pluralismo confessionale p. 1; Huster in Albers, *Bioethik, Biorecht, Biopolitik: Eine Kontextualisierung* (2016) p. 64.

principle it would be illegitimate for the majority to preserve and enforce its ethical or religious position by regulatory means.[51]

Although it is controversial in many respects,[52] the thesis will argue that the principle of the ethical neutrality of the state has an essential core element that can be widely agreed upon. Namely, that individuals in a constitutional state cannot suffer interferences with their fundamental rights, such as the right to health, if these can be only justified on the basis of particular ideological, ethical or religious considerations.[53]

2. State of Research

Much has been written about the emergence of innovations in healthcare and the legal and ethical concerns that arise from their implementation in the public healthcare system. More broadly, there is no lack of studies analysing the relationship and interplay between law and (bio)ethics with regard to the developments in modern biomedicine.[54] Many scholars advocate that law in the biomedical field should be open to ethical reflections.[55] Some of these scholars examine the role and legitimation of ethical committees in the public healthcare system.[56] Others have investigated the prin-

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[51] Korený, 'From a Tolerant to an Ethically Neutral State' (2016) 26(2) Human Affairs p. 409, 187; Huster, *Die ethische Neutralität des Staates* (2nd edn 2017) p. 106.

[52] Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) p. 67. Recently, a heated discussion about the validity of the neutrality requirement in German constitutional law arose at the conference of the *Vereinigung der Deutschen Staatsrechtslehrer*, which took place in Mannheim from 6 to 9 October 2021. The discussion is published in 'Aussprache und Schlussworte' [2022](81) VVDStRL p. 355.

[53] Huster, *Die ethische Neutralität des Staates* (2017) p. 117.

[54] See, *inter alia*, Piciocchi, 'Bioethics and Law: Between Values and Rules' (2005) 12(2) IJGLS p. 471; Casonato in Casonato and Piciocchi, *Biodiritto in dialogo* (2006); Vöneky and others, *Legitimation ethischer Entscheidungen im Recht* (2009); van der Burg in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009); Vöneky, *Recht, Moral und Ethik* (2010); Spranger, *Recht und Bioethik: Verweisungszusammenhänge bei der Normierung der Lebenswissenschaften* (2010); Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013); Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016).

[55] Vöneky, *Recht, Moral und Ethik* (2010); Casonato in Valdés and Lecaros, *Biolaw and Policy in the Twenty-First Century* (2019).

[56] Amongst others, Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen: Interdisziplinäre, internationale und interreligiöse Perspektiven* (2010); Videtta in Rodota, Zatti and Ferrara, *Trattato di biodiritto: Salute e sanità* (2011); Poscher in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013); Hermerén, 'Accountability, Democracy, and Ethics Committees'

ciple of the ethical neutrality of the State in the context of authorising new health technologies or in relation to the role of ethics in public health.[57]

Furthermore, several scholars have turned their attention to the health technology assessment process: since the beginning of this century researchers have investigated the inclusion of ethical values in the normative basis for the decision making process in health technology regulation and reimbursement decisions.[58] Although HTA is traditionally conducted with a view to safety, quality and cost-effectiveness criteria, many studies argue that these guiding principles are nowadays no longer sufficient for a full assessment of innovative products. A responsible implementation of novel medical products and procedures demands that ethical issues be addressed in the decision making process. Scholars acknowledged that, in order to be eligible for public coverage, an innovative healthcare technology must be judged to be consistent with the ethical standards or prevailing values in society. However, most of the relevant research in the field is not legal research. Rather it is conducted from a Science and Technology Studies (STS), bioethical or philosophical standpoint. As a result little or no attention centres on the legal significance of the inclusion of ethical evaluations within the public decision making procedure. In particular, one might wonder whether and to what extent the consideration of ethical aspects in the assessment process could – legally and legitimately – be relevant to the final decision.

Even if the assessment authorities were given a legal basis for the consideration of ethical aspects in their decision making process, it is uncertain whether public coverage could legitimately be denied on the basis of purely

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(2015) 1(2) Law Innov Technol p. 153; Faulkner and Poort, ‘Stretching and Challenging the Boundaries of Law: Varieties of Knowledge in Biotechnologies Regulation’ (2017) 55(2) Minerva p. 209.

[57] Huster in Kopetzki and others, *Körper-Codes: Moderne Medizin, individuelle Handlungsfreiheiten und die Grundrechte* (2010); Strech, Hirschberg and Marckmann, *Ethics in Public Health and Health Policy: Concepts, Methods, Case Studies* (2013).

[58] *Inter alia,* Grunwald, ‘The Normative Basis of (Health) Technology Assessment and the Role of Ethical Expertise’ (2004) 2(2-3) Poiesis Prax p. 175; Have, ‘Ethical Perspectives on Health Technology Assessment’ (2004) 20(1) Int J Technol Assess Health Care p. 71; Giacomini, ‘One of These Things is Not Like the Others: The Idea of Precedence in Health Technology Assessment and Coverage Decisions’ (2005) 83(2) Milbank Q p. 193; Hofmann, ‘Why Ethics Should Be Part of Health Technology Assessment’ (2008) 24(4) Int J Technol Assess Health Care p. 423; Lucivero, *Ethical Assessments of Emerging Technologies* (2016); Castro and others in Marsh and others, *Multi-criteria Decision Analysis to Support Healthcare Decisions* (2017).

ethical concerns. The perception of certain technologies as ethically controversial would give rise to more legal barriers for their publicly-funded implementation and therefore in hurdles to patients' prompt access to innovation. The legitimacy of this effect has not yet been investigated from a legal point of view. No study has assessed whether the decision-makers could legitimately operationalise an ethical position to limit patients' access to certain health services. As far as legal scholarship is concerned, research focuses primarily on the impact of innovations in healthcare on the fundamental rights of the individual and on human dignity, self-determination and privacy.[59] The emphasis remains mainly on whether it is constitutionally acceptable to prohibit the use or the provision of certain health services.

Undoubtedly the study of the compliance of health technologies with individual rights and constitutional principles is of particular interest and offers stimulating insights and reflections. Nevertheless, this approach leaves out fundamental questions concerning the coverage and reimbursement of these medical services in a publicly funded healthcare system.

The work of some German scholars must be mentioned separately. Although only in relation to specific instances, these have indeed inquired whether there is a legal basis for the consideration of ethical issues in the statutory health insurance's reimbursement decision.[60] The contributions on the subject mainly focus on medically assisted procreation.[61] However, these studies have not yet adopted a comparative approach. Being limited to a single country, they do not give insights into whether different normative frameworks may determine different outcomes in terms of the relevance of ethical considerations in reimbursement and coverage decisions.

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[59] See, for instance, Jasanoff, *Reframing rights: Bioconstitutionalism in the genetic age* (2011); Santosuosso, Goodenough and Tomasi, *The Challenge of Innovation inLlaw: The Impact of Technology and Science on Legal Studies and Practice* (2015); Lucchi, *The Impact of Science and Technology on the Rights of the Individual* (2016); Castaing, *Technologies médicales innovantes et protection des droits fondamentaux des patients* (2017).

[60] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282.

[61] Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713; Rauprich in Bockenheimer-Lucius, Thorn and Wendehorst, *Umwege zum eigenen Kind; Ethische und rechtliche Herausforderungen an die Reproduktionsmedizin 30 Jahre nach Louise Brown* (2008); Rauprich, *Die Kosten des Kinderwunsches: Interdisziplinäre Perspektiven zur Finanzierung reproduktionsmedizinischer Behandlungen* (2012).

On a more general note, the question of the relationship between law and morality or law and ethics has been subject to deep philosophical investigations and debates at least since Kant's reflection on the function of the legal system in relation to the moral autonomy of the citizens.[62] This literature, emerging also from the debate between positivists and natural law theorists,[63] offers a fruitful basis for concretising the principle of ethical neutrality and for embedding it in a more comprehensive theory of the state.[64]

3. Research Objectives and Methodology

As outlined above, public coverage and reimbursement decisions about ethically controversial technologies have to meet two contrasting demands. On the one hand, some commentators highlight the need to include ethical evaluations in the decision making process in order to address moral uncertainty. On the other hand, it cannot be denied that contemporary democratic societies require state authorities to reach a decision that is acceptable to individuals with different, and often opposite, moral stances and ethical principles. An examination of these conflicting positions is all the more needed in light of the innovation to be expected in this field in the near future.[65]

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[62] Kant, *Metaphysic of Morals: Divided into Metaphysical Elements of Law and of Ethics* (1799) pp. 11-ff and 26-ff.

[63] See Chapter 1, sec. A.II.2.a.

[64] Stefan Huster warns that the answer to the question of whether public health insurance should assume the costs of ethically controversial procedures cannot be simply answered by a mere reference to a principle of secularity or religious-ideological neutrality. The discussion must be accompanied by a more detailed concretization of this principle and its embedding in a comprehensive theory of the state, see Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) p. 69.

[65] See, as mentioned above, the developments in human gene editing promised by the CRISPR/CAS 9 technology. The announcement of the birth of the first children with edited genomic dates to the 25th of November of 2018 (for some consideration on this case, see Greely, 'CRISPR'd Babies: Human Germline Genome Editing in the 'He Jiankui Affair'' (2019) 6(1) J Law Biosci p. 111) and a possible future removal of the ban on germline editing has already been envisaged, *inter alia*, in Neri, 'Embryo editing: a proposito di una recente autorizzazione dell'HFEA' [2016](1) BioLaw Journal – Rivista di BioDiritto p. 261; Baertschi, 'CRISPR-Cas9: l'interdiction de la thérapie génique germinale est-elle devenue inappropriée?' (2017) 10(2) Bioethica Forum p. 41; Gregorowius, 'Human Genome Editing and the Need for Regulation and Deliberation' (2017) 10(2) Bioethica Forum p. 71; Sykora and Caplan, 'The Council of Europe

Against this background, the present dissertation inquires whether ethical concerns are and can legitimately be taken into account in reimbursement and coverage decisions of different public healthcare systems. The normative framework of the investigation follows from an analysis of the question of the separation between ethics and the law, both from a descriptive and a prescriptive point of view. From a legal-sociological angle, pluralism is a factual basis of modern societies. Starting from this assumption, a legal-ethical perspective demands that, in a pluralistic society, only values that are considered acceptable and relevant by virtually al members of society can be a legitimate basis for legal regulations. Accordingly, the main hypothesis that the state shall adopt a position of ethical neutrality will be justified by reference to the legal and constitutional background. Adopting a constitutional law approach, the state obligation of neutrality will be traced back to its constitutional embedding in the different jurisdictions.

By conducting two case studies an in-depth appreciation will be gained of the concrete mechanisms governing reimbursement decisions of ethically controversial technologies. This case study approach offers insights into the extent to which ethical concerns concretely played a role in relevant decision making processes, concerning both the regulation and the public funding of some of the most recently debated innovations in the field of reproductive medicine and genetic technology.

The analysis of the case studies will be conducted from a variety of angles. From an epistemological perspective, the aim will be to critically compare the ethical patterns of argumentation with the legal-constitutional background, and their influences on the regulation of controversial technologies in the public healthcare system. From the perspective of the separation of powers, the interaction between the legislative, executive, and judicial branches will be explored. This is complemented by a broader institutional perspective, through which the interaction of state powers with other entities including various stakeholders, civil society, ethics committees and other commissions will be observed. In doing so, the study will take into account the different regulatory frameworks of the various jurisdictions, such as the individual conceptions of constitution and state, as well as the different models of healthcare systems.

Should not Reaffirm the Ban on Germline Genome Editing in Humans' (2017) 18(11) EMBO reports p. 1871.

As mentioned above, progress in the fields of medicine and genetic technology can be considered emblematic of all ethical concerns in healthcare. Therefore the chosen cases consist of innovative technologies intended to prevent the birth of a child with specific genetic disorders or chromosomal anomalies. Namely: preimplantation genetic diagnosis (PGD) and non-invasive prenatal testing (NIPT).[66]

Unlike classic IVF procedures these technologies do not simply aim to satisfy the parents' desire to have a child, but rather involve the selection of embryos and foetuses that are not affected by severe health conditions. This makes them more ethically controversial than IVF, as they are linked to issues of eugenics and abortion. At the same time, as PGD is always performed in conjunction with IVF, issues relating to fertility treatments more generally will have to be addressed indirectly. The choice of conducting two case studies follows from the need to address two equally relevant aspects in the current investigation. The first is that ethical concerns may lead the state to prohibit a health technology through the criminal law. This has the effect that the technology will not be allowed into the public healthcare system either. The second aspect is the decision on public financing. While the first point is well illustrated by the PGD case, the second aspect is more prominent in the case of NIPT.

The dissertation adopts a comparative method. The choice of this method is partly motivated by the specific desire to learn how different states deal with ethically controversial health technologies. Comparative law serves to better grasp, understand and evaluate the law,[67] both in terms of its internal functional mechanisms and in terms of the role that the legal system plays in democratic societies. Moreover, the added value of a comparative study lies in the potential to reveal, through comparison with other countries, ethical and religious influences on the law that might otherwise remain concealed.

For the purposes of addressing the research question the comparative method is instrumental for understanding how the relationship between ethics and law is constructed from different constitutional premises. I hypothesise that the principles of the constitutional order of different jurisdictions will provide an indication as to how the spheres of ethics and

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[66] For more details on the functioning of the two technologies, see Chapter 1, sec. A.I.3.b.

[67] Zacher in Zacher and Schulte, *Methodische Probleme des Sozialrechtsvergleichs: Colloquium der Projektgruppe für internationales und vergleichendes Sozialrecht der Max-Planck-Gesellschaft* (1977) p. 22.

law should relate to each other. Constant progress in medical technology enables us to understand and potentially influence biological processes to an unprecedented extent, without social normative systems such as ethics, morality or the law necessarily being able to keep pace with these innovations. When deliberating on the use of and access to innovative health technologies different value systems collide with each other. Disagreements must ultimately be reconciled in a legally binding way to ensure the maintenance of a pluralist society. This resolution must balance patients' autonomy and access to innovative technologies, as well as the right to health and life respectively. The legal comparison will shed light on the ways in which different jurisdictions, with different constitutional and institutional settings, deal with the emergence of ethically controversial health technologies against the background of diverging and pluralist views.

It is the search for the functional equivalents that is at the core of comparative legal research.[68] Following the functional method, social law is particularly well suited for comparative research, since it is often based on specific social policies that address concrete social needs or objectives.[69] The case of health is even more striking, as all states will be faced with the emergence of the exact same technologies and will have to assess them according to their own normative background. The strong interdependency between the legal and political system within modern welfare states enables the identification of functional equivalents within different legal orders: while the objectives remain the same, the solutions to problems often differ. The comparative perspective allows identifying those functional equivalents, carving out the peculiarities of the respective social systems and, what is more, determining the extent to which the differences between the constitutional orders are effectively relevant in shaping positive law.[70] It is hypothesised that the way a public healthcare system is shaped and regulated, together with its constitutional setting and the involvement of different legal instruments and actors, can influence the space in which ethical considerations can play a role in decisions on the public funding of health technologies.

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[68] Zweigert and Kötz, *Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts* (3rd edn 1996) pp. 33-ff; Michaels in Reimann, Zimmermann and Michaels, *The Oxford Handbook of Comparative Law* (2006) pp. 340-ff.

[69] Becker in Becker, *Rechtsdogmatik und Rechtsvergleich im Sozialrecht I* (2010) p. 21.

[70] ibid, p. 22.

If these hypotheses are correct, then the comparative analysis, by following the perspectives mentioned above, should be able to identify which elements can legitimately contribute to deliberations dealing with ethical concerns in healthcare. The capability of legal systems to preserve pluralism by adopting a position of ethical neutrality, which will be developed in the theoretical chapter, is intended both as a measure of legitimacy and a standard of comparison.[71]

In addition the thesis will provide historical insights on how the current national rules came to being, bearing in mind that health law constantly develops against the background of emerging health technologies.[72]

Every comparison demands selecting jurisdictions with "wise restraint"[73] and with a view to addressing the research question. With these purposes in mind, the jurisdictions chosen for the comparison are Germany, Italy and England. Since health is a devolved matter and each country in the United Kingdom has an independent publicly funded national health service, the chosen jurisdiction is England and not the entire UK. However, some constitutional considerations apply to the United Kingdom as a whole. For this reason, the dissertation will refer to the UK where most appropriate while keeping in mind that the investigation of the case studies remains focused on the English National Health Service (NHS).

The country selection was based on several considerations. First of all, the pool of legal systems has been limited to European countries. This is, on the one hand, because of their common tradition of gradual emancipation of law from religion[74] which resulted in the development of a theory of separation of law and ethics that will form the theoretical background for this research. This thesis seeks to investigate both the differences and commonalities amongst constitutional orders that strive, to varying degrees, to ensure that legal and constitutional values are determined and pursued independently, without reference to particular religious beliefs. On the other hand, the existence of a publicly funded healthcare system covering

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[71] Michaels in Reimann, Zimmermann and Michaels, *The Oxford Handbook of Comparative Law* (2006) pp. 372-ff.

[72] On social law as a developing subject, see Zacher in Zacher and Schulte, *Methodische Probleme des Sozialrechtsvergleichs* (1977) pp. 66-ff.

[73] Zweigert and Kötz, *Einführung in die Rechtsvergleichung auf dem Gebiete des Privatrechts* (1996) p. 40 (author's translation). See also Constantinesco, *Rechtsvergleichung: Band 2: Die rechtsvergleichende Methode* (1972) p. 49.

[74] Böckenförde in Böckenförde, *Recht, Staat, Freiheit: Studien zur Rechtsphilosophie, Staatstheorie und Verfassungsgeschichte* (2006).

the majority of the population was considered a necessary requirement for establishing relevancy to the investigation. States based to a large extent on private health insurances were excluded on this account. The three selected jurisdictions all offer publicly funded universal healthcare. In Italy and England, the National Health Service offers universal healthcare free of charge to all residents.[75] In Germany, although the healthcare system is characterised by a coexistence of private and public insurance, around 90% of the population is covered by the public statutory health insurance.[76] Membership in the statutory health insurance is generally compulsory, with the exceptions listed in § 6 SGB V. Individuals who are not compulsorily insured in this system, however, have an obligation to stipulate an insurance with a private health insurance fund.[77] Civil servants fall under a particular regime and are therefore also listed in the category of subjects who are not mandatorily insured.

Secondly, jurisdictions have been selected according to their different legal and constitutional understanding of the right to health and of the concepts of illness and medical treatment. Here, the hypothesis is that the notions of illness or health might have an influence on the kind of health services that fall within the scope of the public healthcare system, and can thus be included in its benefit basket. The legal understanding of the right to health or physical integrity is supposed to be relevant in determining the individual's entitlement to health services.

Both Italy and Germany adopt a very substantial, albeit partially different, concept of the right to health. In Germany, Article 2(2) of the Basic Law protects the right to life and physical integrity. However, a fundamental right to claim access to healthcare benefits is not encompassed by this Article.[78] The Basic Law thus leaves a wide margin of appreciation to the

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[75] For England, see the National Health Service Act 2006 sec. 1. The Italian National Health Service was established in 1978 by Law no. 833/1978, which replaced the previously existing insurance-based system.

[76] Data for 2021 available at Bundesministerium für Gesundheit, 'Daten des Gesundheitswesens 2021' <https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Gesundheit/Broschueren/220125_BMG_DdGW_2021_bf.pdf> accessed 25.4.2022.

[77] § 193(3) German Insurance Contract Act (*Versicherungsvertragsgesetz*, VVG).

[78] Nonetheless, some obligations derive for the legislature by the principle of the social state enshrined in Article 20 of the Basic Law. See Steiner in Spickhoff, *Medizinrecht* (3rd edn 2018) para. 16; Di Fabio in Dürig, Herzog and Scholz, *Grundgesetz: Kommentar* (2021) para. 94.

legislature.[79] Very narrow exceptions to this have been developed by the case law of the Federal Constitutional Court for the medical treatment of life threatening diseases.[80] Legal scholars have also pointed out that the broad definition of health endorsed by the World Health Organisation (WHO)[81] does not fall within the scope of Article 2(2) of the Basic Law.[82]

In Italy, Article 32 of the Constitution provides the protection of health as a fundamental right of the individual. Unlike in Germany, this constitutional provision also covers the social aspect of the right to healthcare. The constitutional definition of health is repeated in Article 1 of Law no. 833/1978 establishing the National Health Service. Moreover, unlike Germany, Italy openly endorses the broad WHO definition of health.[83] As the case studies will show, due to influential interpretations in the legal scholarship and the jurisprudence of the Italian Constitutional Court, the protection of the right to health has proven of great importance in the Italian constitutional order.

In England, on the contrary, patients' rights to healthcare services are mainly procedural.[84] While patients do not usually have the right to claim a specific health service from the NHS, they are able to hold NHS bodies accountable for following certain procedural standards that can be checked via judicial review.

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[79] Steiner in Spickhoff, *Medizinrecht* (2018) para. 16.

[80] BVerfG, 6.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25) so-called '*Nikolaus*' decision. See, *inter alia*, Kingreen, 'Verfassungsrechtliche Grenzen der Rechtsetzungsbefugnis des Gemeinsamen Bundesausschusses im Gesundheitsrecht' (2006) 59(13) NJW p. 877; Huster, 'Anmerkung: BVerfG, Beschluss v. 6. 12. 2005 – 1 BvR 347/98' (2006) 61(9) JZ p. 466; Becker in Steiner and others, *Nach geltendem Verfassungsrecht: Festschrift für Udo Steiner zum 70. Geburtstag* (2009); Steiner in Spickhoff, *Medizinrecht* (2018) para. 17.

[81] According to which "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", see Preamble to the Constitution of WHO, as adopted by the International Health Conference, New York, 19 June - 22 July 1946, available at World Health Organization, 'Basic Documents' (2020), p. 1. <https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf> accessed 25.4.2022

[82] Rauschning, 'Staatsaufgabe Umweltschutz' [1979](38) VVDStRL p. 168, 179; Starck in Mangoldt, Klein and Starck, *Grundgesetz: Kommentar* (7th edn 2018) para. 193; Kämmerer and Kunig in Münch and Kunig, *Grundgesetz: Kommentar* (7th edn 2021) para. 116; Rixen in Sachs, *Grundgesetz: Kommentar* (9th edn 2021) para. 150.

[83] Formally transposed into the Italian legal system with the legislative decree no. 1086 of 4 March 1947. More on the Italian constitutional concept of health in Chapter 1, sec. B.II.2.a.

[84] See Newdick in Nagel and Lauerer, *Prioritization in Medicine: An International Dialogue* (2016) pp.124-ff; Lock and Gibbs, *NHS Law and Practice* (2018) p. 317.

Thirdly, countries have been selected according to how ‘restrictive’ or ‘permissive’ their legislation on ethically controversial healthcare services tends to be, especially in the field of reproductive technologies. This, admittedly approximate, distinction offers another indication for the ethical background of the countries and their attitude towards ethical concerns in healthcare. The hypotheses about the legislative tendencies in the three jurisdictions will be verified in the case studies. As a first assessment it can be noted that Germany has adopted legislation which is especially protective of the human embryo.[85] A precautionary attitude in the field of reproductive medicine likely results from the paramount importance of the inviolable right to human dignity in the Basic Law. Italy also tends to have a particularly restrictive regulation, given its broadly Catholic background and the influence this manages to exert on politics.[86] In contrast, England has proven to be a leading pioneer in fertility treatments and embryo research. Both the first IVF baby[87] and the first child conceived using IVF combined with PGD were born in England,[88] marking milestones in the field of reproductive medicine.

A shared touchstone that illustrates these distinctions is proved by the different attitudes shown by the three states in drafting and adopting the 1997 Oviedo Convention of the Council of Europe on Human Rights and Biomedicine.[89] In particular, Germany and the United Kingdom adopted diametrically opposed positions regarding ethical questions linked to the issues addressed by the Convention.[90] Both countries refused to sign the document, albeit based on opposite objections. While the Convention was

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[85] The regulation of fertility treatment is indeed contained in a Law titled “Embryo Protection Act” (*Embryonenschutzgesetz*). See Chapter 2, sec. A.I.1.

[86] See the influence of the Catholic Church on the approval of Law no. 40/2004 and following referendum. More on this in Chapter 2, sec. B.I.1.

[87] Louise Brown was born in Lancashire, see Dow, ‘Looking into the Test Tube’ (2019) 63(2) Med Hist p. 189, 192.

[88] The first PGD procedure resulted in healthy pregnancies were conducted in London in 1990, see Handyside and others, ‘Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specific DNA Amplification’ (1990) 344(6268) Nature p. 768.

[89] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164).

[90] Council of Europe, Steering Committee on Bioethics, ‘Preparatory Work on the Convention on Human Rights and Biomedicine’ (Strasbourg 28.6.2000) CDBI/INF (2000) 1 <https://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-INF%282000%291PrepConv.pdf> accessed 25.4.2022

considered too ‘permissive’ by the German representatives, the British delegation deemed it excessively restrictive on the freedom of research.[91] The analysis of the *travaux préparatoires* reveals that Germany was of the opinion that “in some areas [...] such as embryo protection [...] German law ensures a higher standard” than the Convention.[92] Italy, on the other hand, has signed and (almost) ratified the Convention.[93]

Finally, countries were chosen in which the legislative and societal debates on the technologies adopted as case studies here varied in scope and intensity. Public debates, or the absence of them, may offer insights into the perception of the community and the legislature towards coverage and reimbursement decisions of ethically controversial health technologies.

For these reasons, the three chosen jurisdictions offer a good variety of institutional and normative frameworks surrounding the protection of health and the regulation of access to reproductive technologies. At the same time comparability is ensured, both due to the common European context and through a shared understanding on the separation of ethics and law.

4. Overview of the Structure

In the first chapter, the relationship between ethics and the law is illustrated in both a descriptive and a normative way. Selecting the principle of the state’s ethical neutrality as a normative criterion is explained and justified through a legal theoretical and a constitutional reflection. In doing so

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[91] Wachter, ‘The European Convention on Bioethics’ (1997) 27(1) Hastings Cent Rep p. 13; Raposo and Osuna in Beran, *Legal and Forensic Medicine* (2013) pp. 1406-ff.

[92] Council of Europe, Steering Committee on Bioethics, ‘Preparatory Work on the Convention on Human Rights and Biomedicine’, Strasbourg 28.6.2000 CDBI/INF (2000) 1, p. 136. See also Schulze-Fielitz in Dreier, *Grundgesetz: Kommentar* (3rd edn 2013) para. 8.

[93] The Convention was indeed ratified with law no. 145/2001, but has not yet deposited the instrument of ratification. Therefore, it does not appear on the Council of Europe’s list of countries that have ratified the Convention, available at <https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=164>, accessed 24.4.2022. This omission has no apparent reason. On this point, see Penasa, ‘Alla ricerca dell'anello mancante: il deposito dello strumento di ratifica della Convenzione di Oviedo’ (2007) Forum di Quaderni Costituzionali <https://www.forumcostituzionale.it/wordpress/images/stories/pdf/documenti_forum/paper/0007_penasa.pdf> accessed 25.4.2022; Goffin and others, ‘Why eight EU Member States Signed, but Not Yet Ratified the Convention for Human Rights and Biomedicine’ (2008) 86(2-3) Health Policy p. 222, 225–226.

the chapter examines whether this principle has a more limited scope of application in an area of state action, such as the implementation of the positive dimension of the right to healthcare, which is characterised by a broad degree of discretion.

Chapter 2 and 3 contain the investigation of the processes that accompanied the implementation of PGD and NIPT in the public healthcare systems of the selected countries. These chapters offer insights into the role that the ethical and religious factors played in the regulation as well as in the reimbursement and coverage decisions on the chosen technologies. Moreover, the instruments used for regulation are assessed and categorised into substantial and procedural tools. The involvement of different actors is carefully evaluated.

The resulting reflections will converge in the concluding analysis, which combines the outcome of the case studies with the normative background and considers whether the current situation in the three countries is compatible with a state obligation of neutrality of justification. The conclusions look at the different factors that have amplified or limited the room for the consideration of ethical concerns in the different countries. A final assessment is made regarding the legitimacy of considering ethical concerns in public funding decisions on health technologies. The conclusions are accompanied by some observations on how to improve the ways of coping with ethically controversial technologies in an ethically neutral state.

Chapter 1: Theoretical and Constitutional Foundations

A. Theoretical Foundations

I. Ethically Controversial Health Technologies

1. Health Technologies and Ethical Pluralism

By using the term ‘ethics’ I refer to the philosophical reflection that subjects human behaviour to normative and evaluative assessments[94] and elaborates criteria for the evaluation of moral behaviour.[95] In other words, I shall consider ethics to be a discipline that conducts a methodical reflection of morality,[96] aiming at the development and justification of criteria to be adopted in order to pursue the moral good.[97]

As a subject of ethical reflection, morality can be understood as individual morality, formed by moral personal inner convictions that guide the individual’s behaviour, as well as a societal morality, consisting in non-legal and non-conventional moral rules of behaviour followed by a spatio-temporally defined community.[98] In both cases there are several moral options: on the one hand, different moral norms are valid in different communities and, on the other hand, every individual has a different conception of the moral good.[99] The same ethical problem may encounter different solutions depending on the ethical perspective that is assumed.

Hence, thinking in terms of moral philosophy, ethical concerns in the field of health technologies arise whenever the development of a new health technology implies uncertainty regarding the possibility of using it whilst

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[94] Düwell, Hübenthal and Werner, *Handbuch Ethik* (2011) p. 1.

[95] Vöneky, *Recht, Moral und Ethik* (2010) p. 26.

[96] Spranger, *Recht und Bioethik* (2010) p. 31.

[97] According to this definition, moral questions form the object of ethical reflection. No further clarification shall be given here on the difference between the concepts of ethics and morality, which will both appear in the thesis and be employed depending on the context.

[98] Vöneky, *Recht, Moral und Ethik* (2010) p. 25.

[99] Düwell, Hübenthal and Werner, *Handbuch Ethik* (2011) p. 1 refer to a “plurality of different, often contradictory concepts of the good” (author’s translation).

behaving according to moral standards.[100] In other words, ethical concerns stem from the fact that the existence of a given technology or a certain use of it might jeopardise the pursuit of the moral good.

In a pluralist society, however, there is hardly a widely shared definition of the moral good in the field of healthcare. Medical innovation and technological progress have contributed to increasingly widen the range of possible choices that each individual can make in relation to health issues. What once had to be accepted as fact, such as the birth of a genetically affected child, now becomes a choice thanks to the advancements in the field of medically assisted reproduction and prenatal diagnosis.[101]

Confronted with such possibilities, each individual tends to follow different personal moral and ethical criteria in making decisions pertaining to the particular relationship they have with their own body and health.[102] In this regard, a broader spectrum for individual choice brings about more opportunities for adopting divergent ethical criteria for moral behaviour.

The existence of different perspectives on morally correct behaviour stems from the assumption of different ideological or religious views,[103] resulting in the lack of consensus on even fundamental concepts, such as the concept of the person, the right to life or dignity.[104]

Against this background, societies become more pluralistic and accordingly face relevant challenges in the regulation of the field of healthcare. The achievement of a democratic consensus is particularly difficult in an area where the assessment of the correct behaviour depends primarily on the individual choice of ethical standards.[105]

The English legal scholar Roger Brownsword has exemplified this ethical pluralism in a model he refers to as the “bioethical triangle”.[106] According to this model the use of a certain health technology will be assessed differently by individuals endorsing a utilitarian, human rights or dignitarian perspective. Under the utilitarian approach the moral goal of behaviour is always

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[100] Here the definition of health technology is intended to be a rather comprehensive one, see fn. 1.

[101] Piciocchi, ‘Bioethics and Law: Between Values and Rules’ (2005) 12(2) IJGLS p. 471.

[102] Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) pp. 59-60.

[103] ibid, pp. 59-ff.

[104] Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011) p. 836.

[105] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 2.

[106] Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 32.

the "maximization of utility and the minimization of disutility".[107] By contrast, advocates of a human rights perspective will always refuse to sacrifice the human rights of a single individual for a greater utility.[108] As for the dignitarian approach, this refuses any health technology that is potentially compromising human dignity.[109] These different sets of behavioural moral norms are respectively grounded in a teleological, rights-driven or duty-driven ethical framework.[110]

Although this is only a model,[111] and the different ethical perspectives in society are much more varied and highly dependent on sets of standards adhered to by each individual,[112] it gives some insight into the various possible perspectives that can be adopted in response to the emergence of a new health technology. It helps one understand how, when confronted with the question on whether a new health technology can be used in a manner that is compatible with morality, different ethical perspectives will recommend following diverse criteria for correct moral behaviour.[113] They will lead to completely different results depending on the different basis on which their moral norms are grounded.[114]

Such pluralism is further accentuated by the existence of different religious approaches. In particular, the Catholic perspective has had a major influence on the development of bioethics[115] and still plays a relevant role in the bioethical discussion within the countries belonging to the Western legal tradition.

The Catholic view on moral decision-making perpetuates the idea that some principles are absolute. The fundamental value of Catholic bioethics in the field of reproductive technologies is the sanctity of human life, which

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[107] ibid, p. 37.

[108] ibid, pp. 37-38.

[109] ibid, p. 39.

[110] ibid, p. 35.

[111] Or a "matrix", Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 32.

[112] ibid.

[113] For an effective exemplification of the criteria of moral behaviour followed by the different ethical approaches, see Graf, *Ethik und Moral im Grundgesetz. Grenzen der Moralisierung des Verfassungsrechts* (2017) p. 53.

[114] Rostalski, *Das Natürlichkeitsargument bei biotechnologischen Maßnahmen* (2019) p. 25.

[115] See Harvey in Garrett, Jotterand and Ralston, *The Development of Bioethics in the United States* (2013) who highlights "the central place played by Roman Catholic institutions in the genesis of bioethics", p. 37.

is deemed to start at the moment of conception.[116] Moreover, respect for the person requires that the child be granted an own identity and personal development, achieved through the secure relationship established within a family founded on marriage.[117] In this sense the Catholic approach has its own interpretation of the moral good and one that is primarily based on inviolable dogmas.

As ethical dilemmas might stem both from following religious dogmas and from reflective ethical thinking,[118] religious concerns regarding a certain health technology also fall within the definition of 'ethical concerns' used in this thesis.

2. The Bioethical Approach

Some attempts have been made to draw up universally acceptable principles of ethics in the healthcare field, resulting in the recently developed discipline of bioethics.[119]

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[116] Magill in Have and Gordijn, *Handbook of Global Bioethics* (2014) p. 361.

[117] According to the Congregation for the Doctrine of the Faith's Instruction on Respect for Human Life in Its Origin and on The Dignity of Procreation, "[t]he fundamental values connected with the techniques of artificial human procreation are two: the life of the human being called into existence and the special nature of the transmission of human life in marriage", Ratzinger and Bovone, 'Congregation for the Doctrine of the Faith: Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation Replies to Certain Questions of the Day Vatican City 1987' (2018) 54(2) The Linacre Quarterly p. 24, 28.

[118] "Bioethical and philosophical thinking rests on assumptions, some of which are tacit, and thus also rely to some extent on a type of faith or faiths and are not fully objective or 'rational'. Similarly, religious reasoning has its own rationales based on its own differing assumptions about the nature of the world and of what it means to be human [...] There are other parallels in the way that religious and bioethical moral reasoning occur. They both try to organise and characterise consistent, coherent, and important values, and prescribe how to address situations when these values are in tension, they both refer to key texts/ scripts, wise authority figures, practice-based cases, reason, and established traditions of thought and doctrine", Liddell and Ravenscroft in Berg, Cholij and Ravenscroft, *Patents on Life* (2019) p. 29.

[119] The term 'bioethics' has been attributed to the oncologist Van Rensselaer Potter, who first used the word in an article published in 1970, Potter, 'Bioethics, the Science of Survival' (1970) 14(1) Perspectives in Biology and Medicine p. 127. With a view to the future of the human species and, in particular, to the prevention of ecological disasters, Potter proposed to build a new "science of survival" that would combine the science of living systems ("bio") and the knowledge of human value

The most influential approach in bioethics is the so-called principle-based approach. This became widespread with the publication of Beauchamp and Childress' *Principles of Biomedical Ethics* in 1979 and can be said to be the currently prevailing theory.[120] The normative framework developed by the two authors is based on the four principles of autonomy, beneficence, non-maleficence and justice.[121] The first principle means that the autonomous choices of individuals must be respected.[122] The moral obligations resulting from it include: empowering the decision making of the patient, providing full information and making sure that they have a full understanding of the situation.[123] The principle of beneficence involves the obligation to promote the welfare of – and provide benefits to – both individual patients and society in general. Some of the rules of beneficence consist in: protecting the rights of others, removing potential harms to others and helping people with disabilities.[124] Moreover, the obligation to act for the benefit of other individuals requires balancing the benefits of a treatment with its risks and harms. An obligation to do no harm is embodied by the principle of non-maleficence, according to which all actions that cause unnecessary and unjustifiable harm shall be avoided.[125] The

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systems ("ethics"). In his opinion, due to the recent developments in ecology, a study of behaviour according to moral standards could no longer go without an understanding of biological facts, see Potter, *Bioethics: Bridge to the Future* (1971). The term was proposed by André Hellegers, an obstetrician with a strong catholic background who, in October 1971, founded the Kennedy Institute for the Study of Human Reproduction and Bioethics, see Harvey in Garrett, Jotterand and Ralston, *The Development of Bioethics in the United States* (2013). According to Hellegers and his founding associates, bioethics should have involved the reasoning on the resolution of moral conflicts in the practice of medicine, see Rosenfeld and Sajó, *The Oxford Handbook of Comparative Constitutional Law* (2012); Harvey in Garrett, Jotterand and Ralston, *The Development of Bioethics in the United States* (2013). This last understanding of the concept has proved successful and is nowadays dominant.

[120] Nowadays the principle-based approach is most frequently used in bioethical discourses and education, and *Principles of Biomedical Ethics* has now reached its 8th edition, Beauchamp and Childress, *Principles of Biomedical Ethics* (8th edn 2019).

[121] Beauchamp and Childress, *Principles of Biomedical Ethics* (1979).

[122] ibid, p. 56: "Autonomy is a form of personal liberty of action where the individual determines his or her own course of action in accordance with a plan chosen by himself or herself".

[123] ibid, pp. 56-ff.

[124] ibid, pp. 135-ff.

[125] In the words of Childress and Beauchamp, the principle of non-maleficence requires "intentional avoidance of actions that cause harm", Beauchamp and Childress, *Principles of Biomedical Ethics* (1979) pp. 97-ff.

principle covers “both intentional harm and the risk of harm”.[126] Last but not least, the principle of justice requires: a fair distribution of benefits and costs in society, the avoidance of unfair discrimination and prejudice, equal treatment of people, and the provision of fair opportunities and fairness in biomedical research.[127]

The resolution of practical moral questions within this framework requires deriving concrete rules from it.[128] These rules of action for the concrete case stem from an interpretation, application, balancing and specification of the four major principles.[129]

The bioethical approach does not resolve pluralism precisely because the controversies lie in the way its principles are interpreted, applied and balanced. Each individual will give a different answer on how the conflicts between the various principles should be resolved. This is exacerbated by the fact that individuals subscribing to a religious ethic largely operate with principles that cannot be balanced. The same holds true for the dignitarian perspective, whereby the principle of human dignity cannot be balanced. As we shall see in the next section, it is also debatable to which entities these principles should be applied.

Therefore, even if a democratic society reaches an agreement on a set of widely shared moral principles, there will always be room for a ‘reasonable pluralism’.[130]

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[126] ibid, p. 99.

[127] ibid, p. 168-ff.

[128] Childress in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009) pp. 69-ff.

[129] Richardson, ‘Specifying, Balancing, and Interpreting Bioethical Principles’ (2000) 25(3) J Med Philos p. 285, 258–307. In this sense, the perspective of the principle-based approach structures the bioethical reasoning around categories that are comparable to those of legal theory. Within this approach, the notion of ethical concerns implies the emergence of fields of tension between the different bioethical principles at stake.

[130] Brownsword, ‘Regulating The Life Sciences, Pluralism And The Limits Of Deliberative Democracy’ [2010](22) SAcLJ p. 801, 819.

3. Ethical Concerns in the Field of Reproductive Technologies

a What is Special about Reproductive Technologies: The Question of Moral Status and Personhood

The field of reproductive technologies is emblematic of the ethical concerns in healthcare. A special feature of this area is that, even if agreement could be reached on a set of bioethical principles, there would still be fundamental disagreement surrounding the human entities that could be said to be under their protective umbrella.[131] In particular, there is no agreement on the moral personhood of the foetus, the embryo and future generations. It is discussed whether and to what extent an infringement of the moral good to the detriment of those entities would constitute an ethical concern.

A clear definition of the scope of the concept of moral personhood would be required to assess whether future individuals have a morally relevant status.[132] Nevertheless, the precise moment when personhood begins cannot be determined on the basis of clear scientific criteria.[133] First of all, the development of a person consists in a continuous process. Starting with a fertilised egg, this process involves the formation of a biological entity constituted by a group of cells, the embryo, which will grow into a foetus and then develop to become a baby. Within this framework, it could be said that personhood does not start at a given moment but, quite the opposite, is a matter of degree.[134]

Hence, defining the concept of personhood is a matter of choice rather than a biological classification and the criteria given by different scholars to establish the existence of a moral status are, indeed, based on moral

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[131] Warren, *Moral Status: Obligations to Persons and Other Living Things* (2000).

[132] Tooley in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 138.

[133] As shown by the “almost total absence of attempts to demonstrate a strictly scientific basis for determining when personhood begins”, Macklin, ‘Personhood in the Bioethics Literature’ (1983) 61(1) The Milbank Memorial Fund Quarterly Health and Society p. 35, 38.

[134] “[H]uman embryos before implantation (‘potential life’) are rudimentary in development and thus have a relatively low moral status and limited rights compared with a fetus at 12 weeks of gestation (‘developing life’). In the same way, the fetus does not assume the highest moral (and legal) status until delivery or at least viability (‘developed life’)”, El-Toukhy, Williams and Braude, ‘The Ethics of Preimplantation Genetic Diagnosis’ (2008) 10(1) The Obstetrician & Gynaecologist p. 49, 50.

decisions.[135] Some suggested criteria include neurological conditions, such as self-consciousness, self-awareness, minimum intelligence and communication, but also criteria linked to: fertilisation, the completion of the formation of the zygote, the implantation process, viability and birth.[136] In addition, the criterion of potentiality may be taken into consideration, meaning that an entity that cannot be called a person yet could still be considered as having equal moral status, and therefore fall under the protection offered by the principles of bioethics, on account of its potentiality to become one.[137]

Some of the ethical concerns associated with in vitro fertilisation techniques are derived from the assumption that the separation of sex and reproduction should be prohibited.[138] This is especially true from the perspective of Catholic bioethics, whereby the use of artificial reproductive techniques violates the dignity of marriage and human procreation.[139] Finally, when it comes to heterologous reproduction – involving a third gamete donor – the autonomy of the child might also be in jeopardy, given that the donor's claim to anonymity might compromise the child's ability to know his or her origin and therefore develop his or her personal identity.

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135 "In other words, the question "What is a person?" concerns not a scientific classification but rather a moral classification. The question turns out to be a moral question in disguise", Evans in Have and Gordijn, *Bioethics in a European Perspective* (2001) p. 152.

136 Macklin, 'Personhood in the Bioethics Literature' (1983) 61(1) The Milbank Memorial Fund Quarterly Health and Society p. 35; Tooley in Kuhse and Singer, *A Companion to Bioethics* (2009); Spagnolo, 'Personhood: Order and Border of Bioethics' (2012) 10(3) J Med Pers p. 99; Karbarz in Soniewicka, *The Ethics of Reproductive Genetics* (2018).

137 Tooley in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 135.

138 Purdy in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009) p. 179.

139 "[A]ttempts or hypotheses for obtaining a human being without any connection with sexuality [...] are to be considered contrary to the moral law, since they are in opposition to the dignity both of human procreation and of the conjugal union", Ratzinger and Bovone, 'Congregation for the Doctrine of the Faith' (2018) 54(2) The Linacre Quarterly p. 24, 34.

b Preimplantation Genetic Diagnosis and Non-invasive Prenatal Testing

i. Admissibility

Innovation in the field of prenatal and preimplantation diagnosis enables couples to make use of increasingly sophisticated methods to prevent the birth of a child affected by severe genetic or chromosomal conditions.

When carrying out an in vitro fertilisation procedure, preimplantation genetic diagnosis (PGD) can be conducted to detect embryos carrying specific severe genetic disorders, such as cystic fibrosis or Huntington's disease. This technique, developed in 1990,[140] is usually sought by fertile or infertile couples in which one or both members are carriers of a serious genetic condition and are at substantial risk of transmitting it to their offspring.[141] The embryos diagnosed as having the condition are then discarded for implantation in the uterus.

Non-invasive prenatal testing (NIPT) can be used in case of an already started pregnancy to test the foetus for common chromosome aneuploidies, such as trisomy 13, 18 and 21.[142] Until recently such tests could be performed either via non-invasive screening procedures, such as the combined test, or via invasive diagnostic techniques, namely amniocentesis or chorionic villus sampling. The latter options involve removing samples from the uterus or the placenta. They provide very accurate diagnostic results but can be uncomfortable for the patient and entail a risk of miscarriage.[143] Non-invasive screening is not risky but provides less accurate and non-diagnostic results. Against this background the development of non-invasive prenatal testing techniques analysing fetal DNA circulating in the maternal blood

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[140] Handyside and others, 'Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specific DNA Amplification' (1990) 344(6268) Nature p. 768.

[141] Braude and others, 'Preimplantation Genetic Diagnosis' (2002) 3(12) Nat Rev Genet p. 941.

[142] NIPT can also be for the detection of other conditions, such as single gene disorders, as well as for identifying a Rhesus-positive foetus, see Drury, Hill and Chitty, 'Recent Developments in Non-Invasive Prenatal Diagnosis and Testing' (2014) 25(3-4) Fet Matern Med Rev p. 295, 289–299. However, the thesis will focus on NIPT for the detection of chromosomal aneuploidies, in particular trisomy 13, 18 and 21.

[143] Although this risk is very limited – and calculated on average around 0.35%, see Beta and others, 'Risk of Miscarriage Following Amniocentesis and Chorionic Villus Sampling: A Systematic Review of the Literature' (2018) 70(2) Minerva Obstet Gynecol p. 215 – it remains a chance that no future parent takes lightly.

(so-called cff-DNA)[144] is a considerable improvement.[145] This procedure provides more accurate results than other non-invasive tests and, as it only requires a simple blood test of the mother, it does not carry any risk of miscarriage.[146]

However, the ethical desirability of both PGD and NIPT has been questioned. On the one hand, medical progress in this field strengthens the reproductive autonomy of the woman[147] and the couple, enabling them to decide on the pregnancy whilst having knowledge of the future child's state of health.[148] On the other hand, both procedures are likely to bring about the destruction of one or several entities, be it the discarded embryos or the genetically affected foetus. For this and other reasons the development and use of these testing procedures raises several ethical concerns.

Some preliminary observations should be borne in mind. First of all it is clear that, to a certain extent, the acceptability of those techniques depends primarily on how we assess the moral status of the two entities at stake: the embryo and the foetus. An alleged violation of the obligation to do no harm, for instance, can only be established if directed towards entities that fall under the protective umbrella of the principle of non-maleficence.

In both cases the assessment of the bioethical question might be influenced by the kind of condition being tested. Discarding an embryo or aborting a foetus because of the discovery of a serious medical condition or

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[144] The discovery of circulating fetal DNA in maternal blood dates back to 1997, Lo and others, 'Presence of fetal DNA in maternal plasma and serum' (1997) 350(9076) Lancet p. 485. Based on this, the first NIPTs were commercialised in Europe starting in 2011.

[145] See *inter alia* Rolfes in Jox, Marckmann and Rauprich, *Vom Konflikt zur Lösung* (2016) p. 316; Drury, Hill and Chitty, 'Recent Developments in Non-Invasive Prenatal Diagnosis and Testing' (2014) 25(3-4) Fet Matern Med Rev p. 295; Perrot and Horn, 'The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany: Findings from a Comparative Literature Review' (2022) 30 Eur J Hum Genet p. 676.

[146] Drury, Hill and Chitty, 'Recent Developments in Non-Invasive Prenatal Diagnosis and Testing' (2014) 25(3-4) Fet Matern Med Rev p. 295, 295.

[147] In the rest of the thesis, I will mainly refer to the person bearing a foetus in their womb as "woman" or "mother". The use of the term "woman" does not intend to exclude the possibility that transgender men or non-binary people might also be pregnant or wish to get pregnant. The definition of a woman or mother in this thesis, therefore, includes any person who is capable of bearing a child.

[148] For a general discussion on reproductive autonomy and conflicts between mother and foetus, see Steinbock in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009) and Warren, *Moral Status* (2000).

because of a mere susceptibility to a disease have a different relevance in the balancing of ethical principles.[149]

Even when only used for severe medical conditions, it is feared that the possibility to select healthy children will lead to attitudes of discrimination and stigmatisation against people with disability or parents who consciously decide to give birth to a disabled child.[150] This increasing selection of healthy individuals could allegedly bring about eugenic attitudes and infringe the principle of human dignity for embryos and foetuses.[151] In the case of the NIPT it is argued that this danger would be especially high, for the safety of the test could lead to an overall increase in screening requests, which would eventually result in a higher abortion rate.[152] A possible rise in the number of abortions is considered not only undesirable as such, but also because it diminishes the number of people with disabilities in the community, thus making it less sensitive and inclusive. The number of abortions is considered even more problematic as NIPT produces a limited number of false positive results, which means that there is a chance that a non-affected foetus is aborted on the basis of a wrong diagnosis.[153] However, scientific studies highlight the need to always confirm positive NIPT results with an invasive diagnostic procedure in order to avoid false positives.[154]

The risk of fostering a society with eugenic views is an argument that has especially been used in the case of PGD. In particular, the debate around PGD often employs the ethical argument of the ‘slippery slope’. This kind of argument is used, in general to deny the acceptability of a certain practice on the basis that allowing it will inevitably lead to harmful and morally intolerable consequences. More concretely, in the case of PGD, its implementation in the detection of certain serious genetic conditions is alleged to inevitably lead to a situation where babies are eugenically

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[149] El-Toukhy, Williams and Braude, ‘The Ethics of Preimplantation Genetic Diagnosis’ (2008) 10(1) The Obstetrician & Gynaecologist p. 49, 50.

[150] Purdy in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 187; Juth, *Encyclopedia of Life Sciences* (2012); Nuffield Council on Bioethics, ‘Non-invasive Prenatal Testing: Ethical Issues’ (London 2017), pp. 82-ff.

[151] Perrot and Horn, ‘The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany’ (2022) 30 Eur J Hum Genet p. 676, 679.

[152] Rolfes in Jox, Marckmann and Rauprich, *Vom Konflikt zur Lösung* (2016) p. 318.

[153] Nuffield Council on Bioethics, ‘Non-invasive Prenatal Testing: Ethical Issues’, London 2017, p. 8.

[154] Drury, Hill and Chitty, ‘Recent Developments in Non-Invasive Prenatal Diagnosis and Testing’ (2014) 25(3-4) Fet Matern Med Rev p. 295, 305.

designed to have specific aesthetic or intellectual characteristics.[155] In other words, PGD would predictably lead to a "eugenic mentality"[156] in society. An extreme version of this argument claims that allowing PGD for serious genetic conditions could, in the worst-case scenario, result into the killing of disabled people of all ages.[157]

Arguments based on the 'slippery slope' fear are often dismissed as fallacious and ill-founded.[158] On the one hand, they tend to overlook the fact that such developments are far from inevitable in a democratic society where the law can draw clear-cut boundaries which could then only be overcome by consensus.[159] On the other hand, they ignore the fact that PGD is a physically and psychologically burdensome procedure, sought by parents who wish to avoid the suffering of a severe genetic condition for their own child, without necessarily having a negative attitude towards people with disabilities per se.[160]

Lastly, both techniques might give rise to an issue of informed consent. In fact, their use only empowers the decision making of the prospective parents and truly enhances their autonomy if it is accompanied by genetic counselling and precise information on the consequences and the accuracy

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[155] Netzer, 'Führt uns die Primplantationsdiagnostik auf eine Schiefe Ebene?' (1998) 10(3) Ethik in der Medizin p. 138, 143. See also Choi, 'A Study of the Slippery Slope Argument in Bioethics, and its Application to the Case of Preimplantation Genetic Diagnosis' (2014) 7(2) Studia Bioethica p. 31, 34; Kemper, Gyngell and Savulescu, 'Subsidizing PGD: The Moral Case for Funding Genetic Selection' (2019) 16(3) Bioethical Inquiry p. 405, 410; Patzke, *Die gesetzliche Regelung der Präimplantationsdiagnostik auf dem Prüfstand - § 3a ESchG* (2020) pp. 85-ff.

[156] Choi, 'A Study of the Slippery Slope Argument in Bioethics, and its Application to the Case of Preimplantation Genetic Diagnosis' (2014) 7(2) Studia Bioethica p. 31, 35.

[157] Netzer, 'Führt uns die Primplantationsdiagnostik auf eine Schiefe Ebene?' (1998) 10(3) Ethik in der Medizin p. 138, 148.

[158] For a critical reconstruction, see Fumagalli, 'Slipping on Slippery Slope Arguments' (2020) 34(4) Bioethics p. 412, 412.

[159] "Furthermore, it should not be assumed that negative developments are as irreversible as the metaphors of the slippery slope and the dam breaking suggest. In a state governed by the rule of law, legal regulations can usually be withdrawn if there are increasing indications of an impending catastrophe", Netzer, 'Führt uns die Primplantationsdiagnostik auf eine Schiefe Ebene?' (1998) 10(3) Ethik in der Medizin p. 138, 140. See also Kemper, Gyngell and Savulescu, 'Subsidizing PGD' (2019) 16(3) Bioethical Inquiry p. 405, 411: "if society holds governments accountable for any changes to PGD laws, it is unlikely that PGD will be used in such a manner".

[160] Netzer, 'Führt uns die Primplantationsdiagnostik auf eine Schiefe Ebene?' (1998) 10(3) Ethik in der Medizin p. 138, 419.

of those diagnostic procedures.[161]. However, as NIPT is free of danger for patient and foetus, healthcare professionals might be tempted to skip accurate informed consent procedures.[162] The non-invasiveness of the test might thus mislead the woman, who could mistake it for a regular blood test, and eventually cause its routinisation.[163] Besides, it has been pointed out that the autonomy of the couple could be jeopardised by the social pressure to take the test, given the absence of risk for the foetus.[164]

ii. Public Funding

So far, the outlined ethical concerns were related to the admissibility of the use of these two technologies. However, heated ethical discussions have also emerged specifically in relation to the coverage or reimbursement of patients' access to these technologies in the public healthcare system.

While for PGD the mere use of the technique is generally seen to be the most problematic dimension, for NIPT it is precisely the aspect of its provision by the public healthcare system that seems to raise the greatest ethical concerns. This is possibly due to the special circumstances of couples seeking PGD. Namely, that they must be carriers of severe genetic disorders, which implies that its public reimbursement does not necessarily lead to an excessive expansion of its use.[165]

In the case of NIPT, on the contrary, its availability free of charge in the public sector could lead to an increase in the number of women participating in screening for chromosomal trisomies. As mentioned above,

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[161] Purdy in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 188; Juth, *Encyclopedia of Life Sciences* (2012); Munthe, 'A New Ethical Landscape of Prenatal Testing: Individualizing Choice to Serve Autonomy and Promote Public Health: A Radical Proposal' (2015) 29(1) Bioethics p. 36.

[162] Rolfes in Jox, Marckmann and Rauprich, *Vom Konflikt zur Lösung* (2016) p. 317; Perrot and Horn, 'The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany' (2022) 30 Eur J Hum Genet p. 676, 677.

[163] Deans and others, 'Non-invasive Prenatal Testing for Single Gene Disorders: Exploring the Ethics' (2013) 21(7) Eur J Hum Genet p. 713; Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 113-ff.

[164] Rolfes in Jox, Marckmann and Rauprich, *Vom Konflikt zur Lösung* (2016) p. 319; Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 113-ff.

[165] See, however, Kemper, Gyngell and Savulescu, 'Subsidizing PGD' (2019) 16(3) Bioethical Inquiry p. 405.

this would allegedly bring about a morally undesirable increase in the number of abortions of affected foetuses, with negative consequences for the inclusive character of society.[166] The empirical basis for this claim is disputed. Some commentators have noted that abortion is never an easy choice and that some couples may only want to take the test to be better prepared for the birth of a child with chromosomal trisomies.[167]

Another argument against the reimbursement of NIPT is that by providing public funding the state would send a negative signal towards people with disability.[168] Firstly, it would suggest that a life with a condition such as Down's syndrome is a life not worth living.[169] Secondly, it has been argued that offering the test within the public healthcare system would 'misleadingly' indicate that such screening has some medical utility. It is highlighted that, on the contrary, there is no preventive or therapeutic option for chromosomal aneuploidies.[170] Allegedly this indicates that there is no medical utility in conducting the test.[171] Conversely, advocates calling for the public funding of NIPT argue that the medical benefit lies in the fact that the test gives women the opportunity to consider reproductive

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[166] "One reason for charging pregnant women for NIPT is to prevent an increase in uptake of prenatal screening, and thus to prevent an increase in the number of abortions. Although commentators do not usually explicitly mention this rationale, it follows from the reverse concern that public funding of NIPT may encourage women to take part in prenatal screening", Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?: Implications for Reproductive Autonomy and Equal Access' (2020) 46(3) J Med Ethics p. 194, 195.

[167] Buyx, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 115(44) Deutsches Ärzteblatt A1988, A1988; Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194; Perrot and Horn, 'Preserving Women's Reproductive Autonomy While Promoting the Rights of People with Disabilities?: The Case of Heidi Crowter and Maire Lea-Wilson in the Light of NIPT Debates in England, France and Germany' [2022] (0) J Med Ethics p. 1, 2. See also results obtained in the RAPID study, Chapter 3, sec. C.II.2.a.

[168] This objection is referred to as the "expressivist" argument, see Bunnik and others, 'Why NIPT Should Be Publicly Funded' (2020) 46(11) J Med Ethics p. 783. Same concern could apply to public funding of PGD, as reported by Kemper, Gyngell and Savulescu, 'Subsidizing PGD' (2019) 16(3) Bioethical Inquiry p. 405, 411.

[169] Rüffer, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 114(44) Deutsches Ärzteblatt A1989.

[170] Schmitz, 'Why Public Funding for Non-invasive Prenatal Testing (NIPT) Might Still Be Wrong: A Response to Bunnik and Colleagues' (2020) 46(11) J Med Ethics p. 781.

[171] Rüffer, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 114(44) Deutsches Ärzteblatt A1989.

options or prepare for childbirth.[172] In addition, NIPT does not pose a risk of miscarriage and is therefore safer for both the foetus and the patient.[173]

Opponents of NIPT also question the claim that it protects the reproductive autonomy of the woman. It is feared that simply the decision of the public healthcare system to offer NIPT within its screening programmes may place excessive pressure on couples to take the test.[174] It is argued that women who are offered the test for free would have it performed without carefully reflecting on this choice and its consequences.[175] Against this it has been maintained that having to pay for the test would also not respect reproductive autonomy.[176] This is all the more so if one considers that safer and more accurate tests would then only be available to more affluent couples.[177]

Concerns have also been raised as regards as a possible shift of public resources from providing care for disabled people to investing in advanced

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[172] Buyx, ‘Kostenübernahme für pränatale Bluttests. Pro und Contra’ (2018) 115(44) Deutsches Ärzteblatt A1988; Bunnik and others, ‘Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?’ (2020) 46(3) J Med Ethics p. 194.

[173] Bunnik and others, ‘Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?’ (2020) 46(3) J Med Ethics p. 194.

[174] Clarke in Kuhse and Singer, *A Companion to Bioethics* (2nd edn 2009) p. 253.

[175] As reported by Bunnik and others, ‘Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?’ (2020) 46(3) J Med Ethics p. 194, 195.

[176] “When a prenatal screening offer is declined on the basis of financial constraints, in fact quite the opposite from the ideal of informed choice is being realised: women are not choosing for or against NIPT based on their values, but because of financial constraints.” ibid, p. 197. This argument has also been expressed in supporting public funding for PGD, especially considering that embryo selection is less invasive for the mother than a possible later abortion, see Kemper, Gyngell and Savulescu, ‘Subsidizing PGD’ (2019) 16(3) Bioethical Inquiry p. 405, 407.

[177] “Finally, by putting up a barrier that is higher for less affluent women than for more affluent women, the (co)payment requirement raises intractable justice concerns and hinders equity of access to first-trimester prenatal screening. Charging for NIPT affects disproportionally those who are least well off financially, which challenges the principle of equal access to first-trimester prenatal screening.” Bunnik and others, ‘Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?’ (2020) 46(3) J Med Ethics p. 194, 196. Again, this has also been argued in the case of PGD: “financial barriers mean that only the wealthy have access to it. Given the impact an unwell or disabled child can have on the financial status of a family, the argument for taxpayer funding of PGD is strengthened amongst low socioeconomic families. A lack of access to PGD could make people even less well-off and drop them below the minimum threshold for having a fair go”, Kemper, Gyngell and Savulescu, ‘Subsidizing PGD’ (2019) 16(3) Bioethical Inquiry p. 405, 408.

screening procedures.[178] A violation of the principle of justice might also arise if calculations related to the social cost of providing care for the disabled were included in the cost-effectiveness evaluation of innovative screening procedures.

Ethical objections to the public funding of NIPT have led many stakeholders to argue that it is necessary to include a more comprehensive consideration of ethical aspects in the decision on the reimbursement of new health technologies in the public healthcare system.[179] These voices join the long-standing calls for a greater inclusion of ethics in health technology appraisal processes. Such processes aim to inform public decision-makers about the appropriateness of public funding, not least in order to make the normative framework underlying the decision-making explicit.[180]

A clarification is needed at this point. Allocative considerations or issues of distributive justice are often addressed when discussing ethical considerations in the rationing of public health funding. These will not be included in the definition of 'ethical concerns' adopted in the course of this thesis. The aspect of interest for the current research consists in the objections raised specifically against the reimbursement of a certain health technology on the grounds that it is considered ethically problematic in itself.

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[178] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 115-ff.

[179] As will become apparent in the investigation of the case studies, in particular in Chapter 3 secs. A.II.2, A.II.3 and C.II.3. See, *inter alia*, Rüffer, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 114(44) Deutsches Ärzteblatt A1989, calling for a debate in the German Parliament to amend the criteria to be considered when deciding on the reimbursement of new technologies by the statutory health insurance.

[180] As anticipated in the Introduction. See, *inter alia*, Grunwald, 'The Normative Basis of (Health) Technology Assessment and the Role of Ethical Expertise' (2004) 2(2-3) Poiesis Prax p. 175; Have, 'Ethical Perspectives on Health Technology Assessment' (2004) 20(1) Int J Technol Assess Health Care p. 71; Reuzel and others, 'Ethics and HTA' (2004) 2(2-3) Poiesis Prax p. 247, 248; Hofmann, 'Why Ethics Should Be Part of Health Technology Assessment' (2008) 24(4) Int J Technol Assess Health Care p. 423; Lucivero, *Ethical Assessments of Emerging Technologies* (2016).

II. Between Ethical and Legal Concerns: Ethics and Law as Two Separate Systems

1. Descriptive Separation of Ethics and Law

a A Positivist Approach

As demonstrated in the previous section, morality and ethics are normative systems whose content depends on the value-based framework that is chosen to guide moral action. In a society featuring increasing pluralism, each individual has their own conception of the moral good and will develop their own ethical standards for pursuing morality.[181] The plurality of moral options results in the situation that the discipline of ethics itself does not speak in a unified way but consists of many possible conceptions of ethical action.[182]

Conversely, law constitutes – at least in the legal orders belonging to the Western legal tradition – a normative system that tends to have exclusive validity within a given community and territory.[183]

The relationship between these two normative systems has fascinated numerous legal theorists and has been the subject of extensive reflection and lively debates in jurisprudence.[184]

By far one of the most important debates in this field is that between the proponents of natural law theory and the advocates of legal positivism.

The Natural Law theory holds that a norm "can only be treated as legally valid if it is consistent with some moral requirements".[185] According to Robert Alexy, for instance, "there are conceptually necessary as well as normatively necessary connections between law and morality".[186] In other words, stated simply, natural law theorists claim that the legal validity of

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[181] Düwell, Hübenthal and Werner, *Handbuch Ethik* (2011) p. 1 refer to a "plurality of different, often contradictory concepts of the good".

[182] So that there is no such thing as 'ethics', but rather numerous types of ethics, Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011) pp. 835-836.

[183] Kelsen, *General Theory of Law and State* (2009) p. 212; Hart, *The Concept of Law* (3rd edn 2012) p. 24.

[184] Any list of contributions dealing with this subject would run the risk of being reductive. Besides the scholarship referred to throughout the following sections, a good overview of different theories of law's relation to morality is provided in Marmor, *The Routledge Companion to Philosophy of Law* (2012) pp. 3-ff.

[185] Beyleveld and Brownsword, *Law as a Moral Judgment* (1986) pp. 8-ff.

[186] Alexy, *The Argument from Injustice: A Reply to Legal Positivism* (2010) p. 23.

any norm must be assessed according to its conformity with moral considerations.

Legal positivism, on the other hand, – exemplified here with H. L. A. Hart's theory – supports the so-called 'separation thesis'. This thesis claims that there is neither a normative nor a conceptually necessary connection between law and morality.[187] It argues therefore that the incorporation of moral requirements is irrelevant for the definition of the law. The existence of the legal order is rather based on the fact that its rules of behaviour, "which are valid according to the system's ultimate criteria of validity", are obeyed and effectively accepted by society at one moment.[188] In sum, the existence and validity of the state's legal system does not depend on its congruence with moral requirements, but rather on the mere fact that a defined community has effectively accepted its criteria of legality. Therefore, to be recognised as valid, the law does not need to take into consideration values emanating from different normative systems.[189]

Niklas Luhmann's systems theory is also considered within the realm of legal positivism and argues along similar lines.[190] It understands validity as a purely intrinsic value of the legal system and thus excludes the relevance of compliance with moral or other external criteria.[191] Indeed, decoupling conflict resolution from individual moral positions is the main achievement of the functional differentiation of legal systems. The inclusion of extra-legal values would therefore risk the disintegration of the autonomous legal system.

It follows that the axiological dimensions of the different systems of law and ethics do not necessarily coincide, since the ethical principles that serve to achieve the moral good are not necessarily part of binding law.[192] In

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[187] Hart, *The Concept of Law* (2012) p. 268.

[188] ibid, p. 116.

[189] Legal positivism in this sense is, as a theory on the nature of law, first and foremost, a descriptive approach, according to which "determining what the law is does not necessarily, or conceptually, depend on moral or other evaluative considerations about what the law ought to be in the relevant circumstances", Marmor, 'Legal Positivism: Still Descriptive and Morally Neutral' (2006) 26(4) Oxf J Leg Stud p. 683, 686.

[190] Bolsinger, 'Autonomie des Rechts?: Niklas Luhmanns soziologischer Rechtspositivismus — Eine kritische Rekonstruktion' (2001) 42(1) Politische Vierteljahresschrift p. 3.

[191] Luhmann, *Das Recht der Gesellschaft* (1995) pp. 67-ff.

[192] Spranger, *Recht und Bioethik* (2010) p. 32.

Hart's words, there are no "necessary conceptual connections between the content of law and morality."[193]

The legal positivist approach is most persuasive, as it correctly portrays ethics and the law as two differentiated and separate normative systems. These have a different scope and pursue different aims.[194] Among the reasons to endorse the positivist theory is the observation that standards of moral behaviour are different for each individual and thus cannot necessarily be criteria for judging the validity of the law. Hart also seems to doubt that moral standards could be objective. One of the grounds for his separation thesis was that he considered the "purposes men have for living in society [as] too conflicting and varying"[195] to assume that legal rules must necessarily overlap with moral standards.

At this point it is important to clarify that the ethical normative perspective still exists outside the legal system. Even under positivist theories an external observation of the legal order can lead to an assessment of its moral correctness from an ethical point of view. Once again according to Luhmann, there must be a possibility of moral dissent in the evaluation of legal issues and the moral judgment of the law must be independent of the law itself.[196] However, this "moral scrutiny" of the system[197] remains an element in a differentiated normative system and is entirely determined by extra-legal considerations.

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[193] Hart, *The Concept of Law* (2012) p. 268.

[194] "Though ethics and law interact in various ways and may significantly overlap with one another, they remain as two different normative systems, for the simple reason that they pursue different goals: ethics reflects the effort of our reason in discovering whether something is right or wrong and aims at promoting the fulfillment of our tendencies toward the good [...]. The basic purpose of law is just to ensure that human relationships are governed by the principle of justice, or in other words, that the rights of each individual, as well as the common interests of society as a whole, are guaranteed. Whereas the fundamental question of ethics is 'What should I do to become a better person?,' the key question of law is 'What rules do we need to promote a peaceful and fair society?'", Andorno, 'Human Dignity and Human Rights as a Common Ground for a Global Bioethics' (2009) 34(3) J Med Philos p. 223, 224.

[195] Hart, 'Positivism and the Separation of Law and Morals' (1958) 71(4) Harv L Rev p. 593, 623.

[196] Luhmann, *Das Recht der Gesellschaft* (1995) p. 232.

[197] Hart, *The Concept of Law* (2012) p. 210.

b Ethical Concerns Turned Legal

Even when adopting a strictly positivist approach, there is no denying that some contingent connection between law and ethics might occur.

A certain 'influence' of ethical considerations on the legal sphere cannot be denied. As a matter of fact, law can and does open itself to values originating in different normative systems, in particular those of ethics or morality. Hart himself admitted that "[t]he law of every modern state shows at a thousand points the influence of both the accepted social morality and wider moral ideals".[198] Legal positivism does not deny that "by explicit legal provisions moral principles might at different points be brought into a legal system and form part of its rules".[199]

Hence, it must be recognised that the two systems of ethics and law can be mutually influenced.[200] Although it can be considered a "contingent matter",[201] it is quite frequent that the content of the law is at least indirectly determined by ethical and moral considerations existing in society and taken up by Parliament in mirroring the concerns of their constituency. Similarly, other disciplines, such as medical standards, naturally contribute in shaping the content of the law.[202] As is clearly illustrated by Luhmann's concept of structural coupling,[203] the law constantly interacts with other systems as it deals with issues that are generated outside of the legal system.[204] However, Luhmann would not entirely endorse the idea that

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[198] ibid, pp. 203–204.

[199] Hart, 'Positivism and the Separation of Law and Morals' (1958) 71(4) Harv L Rev p. 593, 599. See also Marmor, 'Legal Positivism' (2006) 26(4) Oxf J Leg Stud p. 683, 687: "legal positivism has no reason to deny that law's *content* necessarily overlaps with morality. It may well be the case that every legal system, immoral or wicked as it may be, would necessarily have some morally acceptable content, or that it would necessarily promote some moral goods".

[200] On the mutual influence of moral, ethics and the law see Vöneky, *Recht, Moral und Ethik* (2010) p. 99.

[201] "[M]oral and other evaluative considerations *may* determine, under certain circumstances, what the law is, but this is a contingent matter, depending on the particular social rules of recognition of particular legal systems, at particular times", Marmor, 'Legal Positivism' (2006) 26(4) Oxf J Leg Stud p. 683, 686.

[202] Taupitz in Schliesky, Ernst and Schulz, *Die Freiheit des Menschen in Kommune, Staat und Europa* (2011) pp. 835-ff.

[203] Luhmann, 'Operational Closure and Structural Coupling: The Differentiation of the Legal System' (1992) 13(5) Cardozo Law Review p. 1419.

[204] "[I]t is fundamental to take into account that the morally controversial issues that bioethics discusses and analyzes along with scientific questions are part of the social

law and ethics 'influence' each other. In his theory social systems are autonomous and can only observe each other, as part of the same societal environment, and adapt their structures accordingly.[205] Therefore, ethical and legal reasoning may converge because the legal system remains open to external information.[206]

It is my assumption, however, that in this case ethical or moral principles are 'juridified'. They are transformed and become part of the law through the normal procedure of law-making.[207] Thus they are subject to the legal system's rules of validity.[208] Some scholars have illustrated this concept with a comparison originally offered by Hans Kelsen. It is argued that "[j]ust as whatever Midas touched turned into gold, any concept taken up by the law turns into a legal concept, in the sense that a conception specific to the law has to be adopted".[209] According to this view, the meaning of extra-legal concepts, such as ethical concepts, is transformed after being incorporated into the law and no longer corresponds to what it used to be in the normative system of origin.[210]

The legal system must take extra-legal conflicts and transform them in a way that can be operationalised by it, so that they "can be both discussed in legally meaningful terms and resolved legally".[211] Hence, as soon as values

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phenomena that law must assimilate as a socially differentiated subsystem. And for this, law has to realistically consider that these disputes, fueled by needs, desires and very diverse social assessments, are born before and outside the legal world", Lecaros in Valdés and Lecaros, *Biolaw and Policy in the Twenty-First Century* (2019) p. 114.

[205] Luhmann, *Soziale Systeme: Grundriss einer allgemeinen Theorie* (1984) pp. 242-ff; Teubner, *Recht als autopoietisches System* (1989) pp. 102-ff.

[206] I refer here to the theory of autopoiesis of the legal system developed by Luhmann. See, Luhmann, *Das Recht der Gesellschaft* (1995) p. 77-ff.

[207] See Spranger, *Recht und Bioethik* (2010) p. 32, according to whom ethical assumptions can only be made binding on all citizens if they enter into law through the law-making procedure.

[208] Borrowing Luhmann's words, the closure of the system "does not prevent the legal system from incorporating moral constraints as legal constraints; but this has to be done within the system and has to be checked by the usual references to legal texts, precedents, or rulings that limit the realm of legal argument", Luhmann, 'Operational Closure and Structural Coupling' (1992) 13(5) Cardozo Law Review p. 1419, 1429.

[209] Poscher in Hage and Pfordten, *Concepts in Law* (2009) p. 103.

[210] Gruschke in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/Ethics and Law - The Ethicalization of Law* (2013) p. 45.

[211] Veitch, *The Jurisdiction of Medical Law* (2017) p. 135, who refers to Emilios Christodoulidis's 're-enactment' theory.

coming from other normative systems are taken up by the legal system, they cease to be considered ethical or moral values and become legal values. They are then subject to the hierarchy and evaluation of validity proper to the legal system. For instance, there is no denying that the protection of human rights embodies a certain ethical-moral ideal. Nevertheless, in my view, once the protection of human rights is enshrined in a given legal order, be it national or international, it undergoes a transformation from an ethical to a legal principle and thus becomes fully part of the closed legal system. In other words, from the legal system's internal perspective, the protection of rights constitutes a legal obligation and no longer a moral one and, therefore, the moral conviction behind it has no legal relevance.[212]

This clarification is essential to understand the concept of ethical concerns used in this dissertation. First, when I use the term 'ethical concerns' relating to a certain health technology, I am not referring to these concerns as they are transposed into legal principles. The aforementioned analytical distinction needs to be maintained. Secondly, those morality standards that can be established "in an empirical and uncontroversial way"[213] and are then 'juridified' through mechanisms of the legal systems are not relevant to the current analysis.

If we take the example of autonomy and informed consent, it is quite possible to see these interests as being among the moral goods pursued by an ethical system. However, as they are widely accepted by society as a whole and have undergone a process of transposition into the legal system, they also qualify as legal interests. It is precisely in such cases that, when making decisions that are binding on everyone, it is necessary to refer to such concepts as adopted by the legal system and not as interpreted by different ethical systems.

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[212] Luhmann, *Das Recht der Gesellschaft* (1995) p. 85 and Luhmann, 'Operational Closure and Structural Coupling' (1992) 13(5) Cardozo Law Review p. 1419, 1429: "Normative closure means, above all, that morality as such has no legal relevance- neither as code (good/bad, good/evil), nor in its specific evaluations".

[213] Campbell, 'The Point of Legal Positivism' [1998-1999](9) King's College Law Journal p. 63, 70.

2. Normative Separation of Ethics and Law

a Preservation of Ethical Autonomy and Pluralism

The descriptive account of the relationship between ethics and law – based on the observation that the law does not necessarily need to reflect morality in order to be recognised as valid – is only the first step toward addressing whether and to what extent ethical concerns can legitimately be taken into consideration by the law. The separation of ethics and law also has a normative component in democratic societies.[214] Not only is there a conceptual separation between the two normative systems, but it should also be considered desirable.[215]

This assessment is based on an understanding of the function that a legal system ought to fulfil in a pluralistic society composed of morally autonomous individuals.

As has been illustrated in the previous sections,[216] modern societies are inevitably characterised by autonomous individuals, with their own ethical standards of behaviour, and thus by growing ethical pluralism.

Against this background, and looking at the purpose of the legal system from a Kantian perspective, the very existence of the state is based on and justified by the necessity to guarantee the full realisation of the freedom of each individual.[217] Faced with the fundamental freedom of each individual to act according to their own choices, the function of law for Kant is to "reconcile these choices in such a way as to guarantee each individual a maximum sphere of external freedom".[218]

This conclusion is derived from Kant's conception of the moral autonomy of the person and culminates in a theory that separates ethics and law. Kant maintained that the state could not adopt a particular moral concep-

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[214] See Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) p. 37, who claim that a fairly democratic society would not be possible without a strict distinction between morality and law.

[215] In this sense, the dissertation falls within an approach of 'normative positivism', which may be described as the "thesis that it would be *a good thing* for the law to be as the descriptive positivist think it is", Waldron in Waldron, *Law and Disagreement* (1999) pp. 166-ff.

[216] See Chapter 1, sec. A.I.

[217] Fletcher, 'Law and Morality: A Kantian Perspective' (1987) 87(3) Colum L Rev p. 533, 535; Weinstock, 'Natural Law and Public Reason in Kant's Political Philosophy' (1996) 26(3) Canadian Journal of Philosophy p. 389, 392-ff.

[218] Fletcher, 'Law and Morality' (1987) 87(3) Colum L Rev p. 533, 534.

tion without infringing the autonomy of the individual citizen.[219] He drew a clear distinction between ethics and law based on the different reasons that drive the individual to comply with each of these two normative systems. Unlike legal obligations, whose respect comes from external coercion, ethical acts can only be defined as such when they are performed by a freely choosing individual who decides to pursue a certain action because of an idea of duty itself.[220] In other words, what makes an action ethical is that it is motivated by an internal duty. On the contrary, the law is something "with which noting ethical is mixed"[221] since it demands compliance to an external duty. Accordingly, the state cannot impose any moral obligation without the latter losing its characteristic of morality and, therefore, the law shall not prescribe moral behaviours.[222] As a result, the two systems are to stay mutually separated, insofar as "[t]he moral does not petition for inclusion in the legal and the legal cannot determine the moral".[223] This interpretation of Kant's theory has made him a "main proponent of state neutrality in ethical questions".[224]

Protection of the individual's autonomy goes hand in hand with the preservation of pluralism. Subsequent theorists have focused on this latter concept. According to John Rawls pluralism is an inherent condition of democratic societies. It results, necessarily, from such a society being composed of a plurality of individuals that stem from different cultural and social backgrounds and have different religious beliefs. These are inevitably reflected in a wide variety of moral principles. Rawls does not hesitate

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[219] Weinstock, 'Natural Law and Public Reason in Kant's Political Philosophy' (1996) 26(3) Canadian Journal of Philosophy p. 389, 401-ff.

[220] Kant, *Metaphysic of Morals* (1799) pp. 11–12: "All legislation then […] may relatively to the springs be distinguished. That, which makes an action duty, and this duty at the same time the spring is ethical. But that, which does not include the latter in the law, consequently permits another spring than the idea of duty itself, is juridical. […] The duties according to the juridical legislation can be but external ones, since this legislation requires not that the idea of this duty, which is internal, shall of itself be the determinative of the arbitrement of the actor, and, as it has however occasion for a spring fit for law, can conjoin external duties only with the law". See, also, Weinrib, 'Law as a Kantian Idea of Reason' (1987) 87(3) Colum L Rev p. 472, 501-ff.

[221] Kant, *Metaphysic of Morals* (1799) p. 26: "Thus, as law in general has for its object but that which is external in actions, strict law is that, with which nothing ethical is mixed, that which requires no other determinatives of the arbitrement; than merely the external; for it is then pure and not confounded with any precepts of virtue".

[222] As illustrated in Huster, *Die ethische Neutralität des Staates* (2017) pp. 71-ff.

[223] Fletcher, 'Law and Morality' (1987) 87(3) Colum L Rev p. 533, 534.

[224] Huster, *Die ethische Neutralität des Staates* (2017) p. 68, author's translation.

to designate the diversity of religious, philosophical and moral views as a first and permanent feature of a democratic society[225] and as an "inevitable outcome of free institutions".[226] He refers to this circumstance as "the fact of pluralism".[227] Similarly, the Italian legal philosopher Norberto Bobbio stresses that pluralism is an objective situation before being a theory.[228]

Pluralism can be characterised primarily as ethical pluralism since members of society disagree on the concept of the moral good.[229] In Luhmann's words: "[t]he legal system must account for the fact that even though the moral *code* applies to the whole society as binary scheme, the moral *programmes,* that is, the criteria for a distinction between good and bad or good and evil, are no longer consensual" .[230]

Pluralism, however, is not only a descriptive characteristic of modern societies. The moral autonomy of each individual and the plurality of moral options are recognised as normative values in modern democratic states. As the diversity of moral opinion is a factual condition that could only be eliminated by an oppressive state power, a democratic society cannot be based on a "comprehensive religious philosophical or moral doctrine".[231]

Against this background, the plurality of moral standpoints is recognised and valued[232] and the existence of disagreements on moral questions ought to be maintained.[233]

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[225] "[T]he diversity of reasonable comprehensive religious, philosophical, and moral doctrines found in modern democratic societies is not a mere historical condition that may soon pass away; it is a permanent feature of the public culture of democracy", Rawls, *Political Liberalism* (Expanded ed. 2005) p. 36.

[226] ibid, p. 4.

[227] Rawls, 'The Idea of an Overlapping Consensus' (1987) 7(1) Oxf J Leg Stud p. 1, 4.

[228] Bobbio, *Il futuro della democrazia* (1984) p. 49.

[229] Huster, *Die ethische Neutralität des Staates* (2017) pp. 5-ff.

[230] Luhmann, *Das Recht der Gesellschaft* (1995) p. 78. English translation from the English edition of the book, Luhmann, *Law as a Social System* (2004) p. 107.

[231] Rawls, *Political Liberalism* (2005) p. 37. See also Marmor, *Law in the Age of Pluralism* (2007) p. 67: "[t]he argument from value pluralism is based on the premise that there is something wrong in imposing an authoritative ruling on people who may *reasonably disagree* with it."

[232] «[I]n democratic and liberal societies, a normative commitment to pluralism means that we do not only observe that citizens disagree about many different issues, but also that we believe that such disagreement is not problematic in itself», Bardon and others in Stoeckl and others, *Religious Pluralism: A Resource Book* (2015) p. 2.

[233] "[T]here is considerable disagreement on moral questions. Claiming that one is in possession of the right answer, the moral truth, is a claim that is unacceptable in pluralistic societies", Friele in Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009) p. 343.

b Ethical Neutrality of the State

If the state's function is to guarantee the moral autonomy of the individual and to preserve ethical pluralism, then it is bound to assume a position of ethical neutrality. In order to fulfil its function and to guarantee the coexistence of different ethical convictions, the state must refrain from taking sides in favour of one definition of the moral good.[234] The same conclusion also follows from the consideration that the legitimacy of the democratic state is derived from consensus, which can only be achieved by avoiding placing reliance on ethical value systems that are not widely shared in society.[235]

Rawls asserted the idea of state neutrality primarily in the sense of a neutrality of justification.[236] He believed that in order to be legitimate in a pluralist society, political decisions had to be justifiable for reasons that could be widely agreed upon.[237] That is, broadly accepted as reasonable without having to endorse any particular conception of the moral good.[238]

Under this assumption, a legal system would only be legitimate if decisions on fundamental questions of justice[239] were taken in line with principles which "all reasonable citizens as free and equal might reasonably be expected to endorse".[240]

As an example Rawls asks whether same-sexual relationships should be considered criminal offences.[241] In his view the decision on how to regulate

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[234] Huster, *Die ethische Neutralität des Staates* (2017) p. 12.

[235] Rawls, *Political Liberalism* (2005) p. 134; Zotti in Vöneky and others, *Legitimation ethischer Entscheidungen im Recht* (2009) pp. 104-105.

[236] Mason, 'Autonomy, Liberalism and State Neutrality' (1990) 40(161) The Philosophical Quarterly p. 433, 434; Rawls, *Political Liberalism* (2005) p. 61.

[237] Rawls, *Political Liberalism* (2005) p. 224.

[238] As paraphrased by Marneffe in Mandle and Reidy, *The Cambridge Rawls Lexicon* (2014) p. 558: "On a justificatory interpretation, political decisions must be justifiable without presupposing that any particular conception of the good life or of what gives value to life is true". See also See also Huster, *Die ethische Neutralität des Staates* (2017) p. 85.

[239] Although Rawls did not explicitly cover healthcare in his theory, the thesis argues that amongst the matters of 'constitutional essentials and basic justice', matters of health and bodily integrity shall be included, as they are a basis for the full participation of the individual in the society.

[240] Rawls, *Political Liberalism* (2005) p. 393.

[241] The subject of same-sex relationships is recurrent in debates on the relationship between morality and law. It was precisely on the question of the permissibility of same-sex relations that the debate between Hart's legal positivism and Devlin's

such relationships could not be legitimately grounded on a philosophical or religious idea of the good, but only on "whether legislative statutes forbidding those relations infringe the civil rights of free and equal democratic citizens".[242]

This example illustrates that the only conceptions of the good that the state can legitimately use as justifications for its actions in 'constitutionally essential matters' are those referring to, what Rawls defines as, the 'political' good.[243] That is, conceptions that are shared by all constituents irrespective of possible different philosophical or religious ideas of the moral good.[244] In this sense the state must be neutral.[245]

This concept of neutrality fits into a positivist legal theory. For it requires that the legitimisation of the state be independent of a certain concept of the good.[246] And just as the legal positivist positions, the theory of state neutrality is also contested by scholars who either claim that the state is only legitimate insofar as it upholds moral principles or who consider the neutrality of the state to be unreachable.[247]

The outlined theory of ethical neutrality of justification can be applied to the field of healthcare. A decision on a health technology that "can be justified only on the assumption that a particular contested conception

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theory of natural law began. Lord Devlin had criticised the Wolfenden Committee's proposal that homosexual acts between consenting persons be decriminalised. He argued that a certain degree of moral conformity was necessary for the survival of society. Society may therefore use criminal law instruments to preserve a minimum moral standard. Otherwise, its survival would be threatened. One of Hart's criticisms of this view is that the enforcement of morality would not be legitimate since it would be intolerable that a particular moral concept held by some citizens at a certain moment in history be imposed by force. On this debate see Dworkin, 'Lord Devlin and the Enforcement of Morals' (1966) 75(6) Yale LJ p. 986; Feinberg, *The Moral Limits of the Criminal Law Volume 4: Harmless Wrongdoing* (1990); Cane, 'Taking Law Seriously: Starting Points of the Hart/Devlin Debate' (2006) 10(1-2) J Ethics p. 21; Bassham, 'Legislating Morality: Scoring the Hart-Devlin Debate after Fifty Years' (2012) 25(2) Ratio Juris p. 117.

[242] Rawls, *Political Liberalism* (2005) p. 458.

[243] Rudisill, 'The Neutrality of the State and Its Justification in Rawls and Mill' (2000) 23(2) Auslegung: a Journal of Philosophy p. 153, 161.

[244] Rawls, *Political Liberalism* (2005) p. 176.

[245] Jones in Goodin and Reeve, *Liberal Neutrality* (1989) p. 14.

[246] Huster, *Die ethische Neutralität des Staates* (2017) p. 12.

[247] See *inter alia* Dworkin, *Law's Empire* (1986); Marmor, *Law in the Age of Pluralism* (2007) pp. 48-ff and 215-ff; Sher, *Beyond Neutrality* (2009). On the latter point, an overview of the criticism to the liberal theory of neutrality is offered by Huster, *Die ethische Neutralität des Staates* (2017) pp. 98-ff.

of the good life (or set of such conceptions) is true"[248] would not be legitimate nor viable. On the one hand, this type of justification would be illegitimate because it would disregard the function of the legal system to protect individual moral autonomy and ethical pluralism. Moreover, such a decision would be adopting moral terms that would prevent it from being operationalised within the legal system and therefore prevent it from fulfilling its societal function, which is to create certainty while protecting autonomy and pluralism.

The legal system can therefore only base its measures on 'neutral' reasons. Reasons are neutral when they are based on ideas of the moral good that are generally accepted or not reasonably objectionable.[249] Accordingly, concerns that are based on such neutral reasons, such as freedom or equality, are not included in the notion of 'ethical concerns' which is employed throughout the rest of this thesis.

The neutral attitude of the state can be characterised as *religious* neutrality when this independence of the law from the concepts of the good only refers to religious doctrines, whereas it can be defined as *ethical* neutrality if it encompasses different ethical attitudes in a comprehensive sense.[250]

c The Separation of Ethics and Law from an Intra-Legal Perspective

My main hypothesis as outlined in the previous sections has both a descriptive and a prescriptive aspect. The former is based on a conceptualisation of law and ethics as two separate systems. The latter advocates that this separation is essential for the legitimacy of a democratic state – whose function is to protect moral autonomy and promote ethical pluralism – as well as for the functioning of the legal system as such. However, if we take the idea of law as a closed system seriously, it must be possible to assess the desirability of the separation of law and ethics using evaluative criteria from within the legal system itself.

The adoption of a perspective internal to the legal system is necessary to legally assess the validity of state provisions. According to Luhmann,

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[248] Marneffe in Mandle and Reidy, *The Cambridge Rawls Lexicon* (2014) p. 558.

[249] Martin, 'Liberal Neutrality and Charitable Purposes' (2012) 60(4) Political Studies p. 936, 948.

[250] Huster, *Die ethische Neutralität des Staates* (2017).

only the law can determine what is legally valid.[251] While sociology and philosophy can describe the law from an external perspective, a targeted analysis needs to adopt a point of view internal to the legal system.[252] For instance, according to the theory of the autopoiesis of the legal system, the right to equality[253] can only be implemented by using criteria that distinguish equal and unequal and are generated within the legal system – not within ethics or politics[254].

Also in Hart's view, one of the features of legal positivism is precisely that the "legal system is a 'closed logical system' in which correct legal decisions can be deduced by logical means from predetermined legal rules without reference to social aims, policies, moral standards".[255] The legitimacy of legal rules must therefore come from internal standards of evaluation within the system.

The use of intra-legal criteria is required for the purposes of the present analysis. It is crucial to point out, once again, that the aim of the thesis is not to provide an ethical evaluation of the legal system, but rather to evaluate the legitimacy of considering ethical concerns in legal decisions from a perspective internal to the legal system itself.[256]

Part of the investigation must therefore be dedicated to assess whether the separation of law and ethics is considered to be desirable from an intra-legal point of view in the jurisdictions that have been selected for comparison.

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[251] "As a closed system, the law is completely autonomous at the level of its own operations. Only the law can say what is lawful and what is unlawful, and in deciding this question it must always refer to the results of its own operations and to the consequences for the system's future operations", Luhmann, 'Law As a Social System' (1989) 83(1&2) Northwestern University Law Review p. 136, 139.

[252] Luhmann, *Das Recht der Gesellschaft* (1995) pp. 16 and 18.

[253] ibid, p. 115.

[254] ibid, pp. 115-ff, 216 and 232. This concept is clearly illustrated in the introduction to the English edition of "Das Recht der Gesellschaft": "Whatever politics or ethics have to say about the appropriate basis for equality, the basis of equality within law is an assessment of legal rights and duties, which is inevitably situated within, and compared with, other existing allocations of rights and duties. […] The application of the distinction equal/unequal within law will be unique to law. Ethics as a system would not select the same facts for the application of the distinction. This means both that equality within law is not the same thing as equality within politics and ethics", Nobles and Schiff in Luhmann, *Law as a Social System* (2004) p. 16 and 23-24.

[255] Hart, 'Positivism and the Separation of Law and Morals' (1958) 71(4) Harv L Rev p. 593, 602, fn. 25.

[256] Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen* (2010) p. 32.

A clarification is needed concerning the meaning and scope of this intralegal point of view. The standards I shall use to assess legitimacy are to be found solely within the law and, in particular, within the constitutional order of the selected jurisdictions. This means that these criteria stem from the rules on which the legitimacy of the legal systems themselves rests. I do not intend to join the debate about the existence of a rule of recognition or a basic rule here.[257] Rather, I will limit myself to assuming that the validity of the rules of a legal system is, in modern constitutional states, provided by the rules of the constitutional order.

Therefore, in the following sections I will investigate which constitutional tools each jurisdiction provides to guarantee the normative separation of ethics and the law within their legal system.

B. Constitutional Foundations of the Separation of Ethics and Law

I. Ethical Neutrality of the State in Germany

1. Constitutional Foundations

The principle of ideological (*weltanschauliche*), ethical and religious neutrality of the state is considered a structural criterion of the German constitutional order and has attracted the attention and scientific interest of several authors.[258] While its contents and scope remain highly contested

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[257] As it is well known, the views on that are extremely diverse. It is enough to say that even Hart's conception of the "ultimate rule of recognition providing authoritative criteria for the identification of valid rules in the system […] differs from Kelsen's in […] major respects", Hart, *The Concept of Law* (2012) p. 292.

[258] *Inter alia,* Schlaich, *Neutralität als verfassungsrechtliches Prinzip: Vornehmlich im Kulturverfassungs- und Staatskirchenrecht* (1972); Heinig, 'Verschärfung der oder Abschied von der Neutralität?: Zwei verfehlte Alternativen in der Debatte um den herkömmlichen Grundsatz religiös-weltanschaulicher Neutralität' (2009) 64(23) JZ p. 1136; Huster, *Die ethische Neutralität des Staates* (2017); Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts: Zur strafrechtlichen Beobachtung religiöser Pluralität* (2019); Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020); Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage: Fälle, Strukturen, Korrekturmöglichkeiten* (2021); Müller, 'Neutralität als Verfassungsgebot?: Der Staat und religiöse oder weltanschauliche Überzeugungen' [2022](81) VVDStRL p. 251.

among scholars,[259] its validity is broadly recognised as a major guarantee of value pluralism in society, which the state must always acknowledge and promote.[260]

Even the reference to God in the Preamble of the Basic Law could not undermine the affirmation of a constitutional requirement of religious neutrality of the state.[261] On the contrary, the existence of a constitutionally founded principle of neutrality offers a compelling argument for a neutral interpretation of this reference, whereby any attempt to found a Christian understanding of the state on this allusion to God shall fail.[262] When looking at the origins and the understanding of this allusion to God it becomes clear that it stands as a cultural reference to a spiritual dimension, including all forms of religious feelings.[263] This validates an interpretation of this reference as a fundamental support to the inner convictions and religious beliefs of the citizens, without denying the state's adherence to a principle of religious and *weltanschauliche* impartiality.[264]

In German constitutional law the requirement of religious and ethical neutrality is provided for by the combined provisions of Articles 4(1) (free-

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[259] As Stefan Huster points out, there is hardly a more controversial principle in constitutional law than that of the secularity or neutrality of the state, see Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) p. 67. See, for instance, the debate on Juristen Zeitung 23/2009 and 7/2010 between Huster and Hans Michael Heinig: Heinig, 'Verschärfung der oder Abschied von der Neutralität?' (2009) 64(23) JZ p. 1136; Huster, 'Erwiderung: Neutralität ohne Inhalt?' (2010) 65(7) JZ p. 354; Heinig, 'Schlusswort – Verschleierte Neutralität' (2010) 65(7) JZ p. 357, as well as the discussions at the Conference of the Association of German Professors of Constitutional Law following the contribution by Müller, 'Neutralität als Verfassungsgebot?' [2022] (81) VVDStRL p. 251.

[260] Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020) pp. 21 ff.

[261] The incipit of the Preamble of the Basic Law reads as follow: "Conscious of their responsibility before God and man, Inspired by the determination to promote world peace as an equal partner in a united Europe, the German people, in the exercise of their constituent power, have adopted this Basic Law". According to Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) p. 95, the majority of constitutional scholars do not grant a specific normative meaning to this reference to God, especially when interpreted in light of the general constitutional framework of the Basic Law.

[262] Czermak, '„Gott" im Grundgesetz?' (1999) 52(18) NJW p. 1300; Huster, *Die ethische Neutralität des Staates* (2017) p. 17; Dreier, *Staat ohne Gott: Religion in der säkularen Moderne* (2nd edn 2018) pp. 186-ff.

[263] Kreß, *Ethik der Rechtsordnung: Staat, Grundrechte und Religionen im Licht der Rechtsethik* (2012) pp. 34 ff.

[264] ibid, p. 48.

dom of faith and of conscience), 3(3) (right to equality), 33(3) (equal enjoyment of civil rights) of the Basic Law, as well as Articles 136(1) (enjoyment of civil and political rights independently of religious affiliation), 136(4) (negative right not to be required to perform religious acts) and 137(1) (prohibition of a state church) WRV (the Weimar Constitution) in connection with Article 140 of the Basic Law. This construction is upheld by several decisions of the German Federal Constitutional Court that have found that religious and *weltanschauliche* neutrality are a binding obligation on the constitutional state.[265] The role of the Federal Constitutional Court has been particularly pronounced in this field. It has built upon the efforts of legal scholarship to define the constitutional standard of neutrality and its concrete consequences for fundamental rights.[266] According to this case law, mainly developed in the context of state-church relations, the constitutional state is obliged to assume an impartial position in the face of citizens' ideological and religious convictions and not to identify with or promote any particular ethical view.

This stance is the outcome of a long evolution in the Court's jurisprudence, which has progressively reconstructed the principle of state neutrality from a combined reading of the above mentioned Articles. In the first judgment that dealt extensively with religious matters, dating back to 1957, the Court was still a long way from developing this concept. It considered it 'inevitable' that parents belonging to a religious minority might be forced to assign their children to a school that held a religious ideology different from their own.[267] In 1965 however, the constitutional case law explicitly, for the first time, derived a neutrality requirement from the Basic Law.[268] In a

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[265] At first, this reconstruction of the principle of neutrality was especially relevant in decisions concerning state-church relations; see the list in Huster, *Die ethische Neutralität des Staates* (2017) p. 13, fn. 31.

[266] Lepsius [2022](81) VVDStRL p. 372, 372 underlined how the development of the neutrality standard has been cultivated since the 1960s and has documented an innovative interpretative achievement of German constitutional law doctrine in collaboration with the Federal Constitutional Court. The comment was a reaction to the criticism in Müller, 'Neutralität als Verfassungsgebot?' [2022](81) VVDStRL p. 251, which accused the neutrality standard of not being sufficiently grounded in the constitutional text and only the product of constitutional case law and creative doctrine.

[267] BVerfG, 26.3.1957, 2 BvG 1/55, in BVerfGE 6, 309 (340) - *Reichskonkordat*.

[268] BVerfG, 14.12.1965, 1 BvR 413/60, 1 BvR 416/60 (BVerfGE 19, 206 - *Badische Kirchenbausteuer*). See Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 31-32.

ruling on church building taxes, the court emphasised that the Basic Law requires the state to be ideologically and religiously neutral as it shall be "the home of all citizens".[269] Privileges towards majority confessions were therefore to be excluded. Already in this first ruling, neutrality is established as an essential component of the German constitutional order.[270] In a 1968 judgment it was further specified that the State, being religiously neutral, must interpret constitutional concepts according to neutral, generally valid, non-confessional or ideological viewpoints.[271]

However, a real turning point in the case law is first seen in the 1995 judgment on the presence of crucifixes in Bavarian school classrooms.[272] This was declared incompatible with the respect of the students' freedom of faith under Article 4 of the Basic Law. With regard to the concept of neutrality, the court started from the premise of religious and ideological pluralism and argued that, under these circumstances, the state can only ensure peaceful coexistence if it guarantees to be neutral. It therefore concluded that the legislature has an obligation to refuse to identify with any religious denomination.[273] More notably, this landmark decision indicated that the principle of neutrality could assume practical significance for the fundamental rights of citizens. This sparked a debate on the legal consequences of this requirement and on its enforceability towards the legislature.[274] According to one interpretation of this judgment, the state's compliance with the neutrality requirement was not checked merely incidentally, as an objective requirement for the constitutional validity of the

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[269] BVerfG, 14.12.1965, 1 BvR 413/60, 1 BvR 416/60, in BVerfGE 19, 206 (216), which defines the state as "*Heimstatt aller Staatsbürger*" (author's translation). See also BVerfG, 14.1. 2020 - 2 BvR 1333/17 (BVerfGE 153, 1 - *Kopftuchverbot für Rechtsreferendarinnen*). An English translation of the judgment is available at https://www.bundesverfassungsgericht.de/SharedDocs/Entscheidungen/EN/2020/01/rs20200114_2bvr133317en.html accessed 9.8.2022. See Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) pp. 40-41.

[270] Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 122.

[271] BVerfG, 16.10.1968 - 1 BvR 241/66, in BVerfGE, 24, 236 (247, 248) - *(Aktion) Rumpelkammer*. For a sharp criticism of this judgment, however, see Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 37-39.

[272] BVerfG, 16.5.1995 - 1 BvR 1087/91 (BVerfGE 93, 1 – *Kruzifix*), see Czermak, 'Zur weltanschaulichen Schieflage des BVerfG in seiner 70-jährigen Geschichte' (2022) 22(3) NJOZ p. 33, 34.

[273] BVerfG, 16.5.1995 - 1 BvR 1087/91, in BVerfGE, 93,1 (16-17).

[274] Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020) pp. 50–53.

measure, but was part of the very core of the right to freedom of faith and conscience.[275]

While this conclusion is not widely shared, and it was not made explicit in the Court's judgment,[276] there is mainly agreement on the characterisation of the neutrality principle as an objective requirement for state action. This means that, even if no violation of the fundamental right of the applicants would have been found by the court in the crucifix case, there would have been no unequivocal consequences for the constitutional admissibility of the Christian cross in classrooms. Its presence could still conflict with the principle of neutrality as a structural standard.[277]

Furthermore, the relevance of the principle of neutrality in the German Federal Constitutional Court's jurisprudence is not limited to matters concerning state's relations with the Catholic Church. The standard of neutrality has also been applied more generally, scrutinising criteria that can be used by the state when regulating ethically controversial issues. In its second abortion decision of 28 May 1993,[278] the Federal Constitutional Court maintained that the state is not entitled to pass judgment on any particular religious or philosophical views "because it must remain religiously and ideologically neutral".[279] In the Court's reasoning, the foetus' right to life stems directly from its right to dignity and must therefore be protected by the legal system. If, on the contrary, a right to life could only be accorded to the unborn child on the basis of particular religious or philosophical convictions, then there would be neither a legal basis nor a justification for its protection by the state and thus for the subsequent violation of women's fundamental rights.[280]

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[275] As reported in Huster, *Die ethische Neutralität des Staates* (2017) at p. 134. According to Heinig, 'Verschärfung der oder Abschied von der Neutralität?' (2009) 64(23) JZ p. 1136, 1137, this conception is confirmed by the Federal Constitutional Court itself in its '*Osho*' judgment (BverfG, 26.6.2002 - 1 BvR 670/91, in BVerfGE 105, 279) on state 'sects warnings', which transforms the neutrality requirement into a constitutive element of religious freedom itself.

[276] Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 72-73.

[277] H Huster, *Die ethische Neutralität des Staates* (2017) p. 130.

[278] BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92 (BVerfGE 88, 203 - *Schwangerschaftsabbruch II*), author's translation.

[279] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (252).

[280] Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen* (2010) p. 45; Huster in Kopetzki and others, *Körper-Codes* (2010) p. 24. See, however, Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 68-71. The

In other words, the principle of neutrality stands as a requirement of non-identification, according to which the state cannot promote one specific ethical or religious belief nor, more generally, appear to identify with it.[281] In doing so the state guarantees its independent support to the numerous ethical and religious standpoints of the modern pluralist society.[282] These implications of the neutrality obligation have been reaffirmed by the Federal Constitutional Court more recently in its decision on the ban of headscarves for legal trainees. Here it held that the state duty to maintain ideological and religious neutrality, established by the Basic Law, encompasses an obligation that the state must be open to the diversity of ideological and religious beliefs and must not identify with a particular religious community.[283]

Under these circumstances, in a state that shall be a ‘home to all citizens’ and to all members of the pluralist society, the political majority is not authorised to affirm its own moral convictions by means of binding legal regulations. State measures cannot be grounded on justifications that are only comprehensible to those who share a certain religious or ideological belief.[284]

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author points out that this judgment mostly repeated the principles of the first abortion judgment of 1975 (BVerfG, 25.2.1975 - 1 BvF 1/74, 1 BvF 2/74, 1 BvF 3/74, 1 BvF 4/74, 1 BvF 5/74, 1 BvF 6/74, in BVerfGE 39, 1 - *Schwangerschaftsabbruch I*), insofar as the right to life of the embryo is guaranteed since the moment of nidation. Despite the explicit declaration of neutrality, the Court has thus, in fact, continued to endorse a morally charged conception of the embryo, which is not unambiguously inferred from Basic Law. However, the unambiguous statement concerning neutrality remains relevant to the purpose of the thesis.

[281] Dreier, *Staat ohne Gott* (2018) p. 98.

[282] An important element of this understanding of the principle of neutrality is that it poses an obligation of independence and impartiality on the part of the state, but not the rejection of any religious belief in a negative sense. On this concept of positive neutrality, see Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020) pp. 155 ff.

[283] BVerfG, 14.1. 2020 - 2 BvR 1333/17 (BVerfGE 153, 1 - *Kopftuchverbot für Rechtsreferendarinnen*). Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 135-ff considers this judgment a step towards a more consistent constitutional jurisprudence on the principle of neutrality. However, see remarks in Rudolph, ‘Neutralität – eine unverzichtbare Norm von begrenzter Tauglichkeit’ (2021) 54(4) KJ p. 435, according to whom the wearing of religious objects may not necessarily be an unequivocal sign of the partial attitude of the civil servant.

[284] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 18; Dreier, *Bioethik: Politik und Verfassung* (2013) pp. 16 ff.

From this concern for comprehensibility and acceptability stems the most widely embraced, albeit not uncriticised,[285] conception of neutrality. Namely, that of neutrality understood as a justification requirement. Thoroughly theorised by Stefan Huster,[286] the standard of neutrality of justification requires the state to always provide a religiously and ethically neutral justification for its regulatory actions.[287]

The concept of neutrality as a neutrality of justification is based on two constitutional foundations.[288] It would not be sufficient to ground the standard of neutrality on the principle of freedom of faith and religion alone. This only guarantees that the individual has freedom to decide on fundamental ethical issues.[289] To imply that the state must also remain fundamentally neutral with regard to different religious and ideological conceptions it is necessary to refer to the principle of equality as well.[290] Freedom of religion and belief is granted strengthened protection in the Basic Law through the prohibition of discrimination on the basis of faith and religious belief in Article 3(3) sentence 1.[291] This ensures that different concepts of freedom cannot be treated differently. The state is thus prohibited from taking a position on religious convictions and basing its measures on such evaluations.[292] Since the scope of protection for freedom of religion and belief must be interpreted in a neutral manner, any interference with fundamental rights can only be justified if it is based on neutral, non-religious views.[293] By contrast, admitting justifications merely based on one specific religious or moral judgment, not shared by all members of

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[285] See, for instance, Heinig, ‘Verschärfung der oder Abschied von der Neutralität?’ (2009) 64(23) JZ p. 1136 and Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020) pp. 219 ff.

[286] Mainly in Huster, *Die ethische Neutralität des Staates* (2017). See also Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) pp. 99–100.

[287] This theorisation also correlates with the concept of justification neutrality adopted as a theoretical foundation of this thesis, see in this Chapter, sec. A.II.2.

[288] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 18.

[289] In other words, “[f]reedom is not necessarily equal freedom” (author’s translation), Huster, *Die ethische Neutralität des Staates* (2017) pp. 89 and 652.

[290] ibid, pp. 652-653. An institutional level can be added to these two foundations of neutrality, according to which no state church exists in Germany, see Dreier [2022] (81) VVDStRL p. 367, 367–368. See also Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) pp. 33 and 89; Dreier, *Staat ohne Gott* (2018) p. 98.

[291] Huster, *Die ethische Neutralität des Staates* (2017) p. 220.

[292] ibid, p. 221.

[293] ibid, p. 653.

society, would imply a lack of equal respect for all citizens holding different convictions and beliefs.[294]

Therefore, within the framework of this theory, the reasons supporting a certain legal provision are of great relevance for its legitimacy. As a result, an ethically or religiously charged regulation might not only be inconsistent and implausible[295] but also unconstitutional.[296] With respect to possible interference in individuals' fundamental rights, the principle of neutrality operates at an even prior stage to that of proportionality.[297] As the principle of religious and ideological neutrality is a self-standing requirement of objective law, the very aims that the state can legitimately pursue are bound to meet this standard. Before the constitutional balancing of two interests can take place, it will be necessary to assess whether these interests are both legitimately placed on one side of the constitutional scale in the first place. The interest pursued by the legislature would be unconstitutional if it is not, on the one hand, driven by a legal necessity of protecting fundamental rights or other constitutional interests and, on the other hand, referable to a neutral justification. Thus, the neutrality check precedes the proportionality assessment and protects individuals from interferences in their fundamental rights "for the wrong reason".[298]

In the framework of neutrality of justification, respect for the neutrality requirement cannot be determined by assessing the effects of a given state provision, but only by evaluating the acceptability of the justification behind it. Whether this constitutes a satisfying yardstick is disputed. For, it would in fact always be possible to give some neutral reason for norms that in practice could have effects that favour one religion or belief over another. [299] This seems to be even more true when one considers that neutrality is not evaluated against the actual justification of the norm in

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[294] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 18.

[295] Especially with regard to the field of health law and bioethics, see Spranger, *Recht und Bioethik* (2010); Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt: Neue Demokratietheorie als Bedingung demokratischer Grundrechtskonkretisierung in der Biopolitik* (2015).

[296] Huster, *Die ethische Neutralität des Staates* (2017) p. LXII.

[297] ibid, p. 655.

[298] ibid, p. 112 (author's translation). However, the requirement of neutrality could also be conceived as part of the principle of proportionality in a broader sense, see Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) pp. 132-133.

[299] Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020) pp. 230-ff.

question,[300] but rather on the basis of finding any possible ethically and religiously neutral reason supporting it.[301]

As a consequence, even a very strong influence of religious or philosophical reasons in the political and parliamentary discussions concerning ethically controversial issues would not *per se* bring about a violation of the principle of neutrality. This would be respected if the final compromise reached in the political sphere leaves room for a neutral justification according to which the solution is considered as reasonably acceptable to virtually all individuals.

It is nonetheless true that the neutral justification found in this manner must also be reasonable and legitimate from a constitutional perspective.

To begin with, the neutral justification must be sufficient and necessary for the implemented measure. This means, firstly, that the norm must remain strictly proportionate to the realisation of the aim which constitutes the justification itself.[302] This requirement is not met, for instance, when the resolution of the conflict between two interests results imbalanced due to the weight of ethical interests that should have not been brought into the balancing act.[303] In such cases, as theorised by Tade Matthias Spranger, the norm acts as a “Trojan horse” [304] for ethical considerations in the law, and the division between ethics and law is violated.

Secondly, the justification must be plausible. Indeed, in many instances the only neutral explanation possible could appear clearly “speculative or unsubstantiated”.[305]Within the framework of this dissertation the possible existence of ethically neutral reasons for decisions to ration health resources must be acknowledged and is not seen as problematic. Ethically neutral justifications, such as the natural limitation of the public healthcare system’s means, shall certainly play a role in state decisions. Nonetheless, the possibility of providing neutral justifications remains conditioned on their plausibility.[306] The plausibility test requires a scrutiny of the empirical

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[300] Also considering that the legislature is not obliged to provide an official written justification for new laws, see Bornemann, *Die religiös-weltanschauliche Neutralität des Staates* (2020), fn. 377.

[301] As explicitly stated in Dreier, *Staat ohne Gott* (2018) p. 108.

[302] Huster, *Die ethische Neutralität des Staates* (2017) pp. 664 ff.

[303] Spranger, *Recht und Bioethik* (2010) pp. 38-39.

[304] ibid, p. 38.

[305] Huster, *Die ethische Neutralität des Staates* (2017) p. LXIII (author’s translation).

[306] Huster in Kopetzki and others, *Körper-Codes: Moderne Medizin, individuelle Handlungsfreiheiten und die Grundrechte* (2010) p. 30.

premises of the justification.[307] The refusal to reimburse a controversial technology based on financial constraints, for instance, will not be plausible if its inclusion in the public healthcare system makes it possible to waive a more expensive service or otherwise improves cost-effectiveness. In such case, room is left for the requirement of ethical and religious neutrality, as a neutrality of justification, to assume a substantial role.

2. Ethical Neutrality of the State in the Field of Health Technologies

a Neutrality of the State and the Fundamental Right to Personal Freedom and Physical Integrity

As acknowledged above,[308] recent scientific progress in the field of healthcare and reproductive technologies is not always uncontroversial. Ever since safe professional abortion services and new abortive drugs became more readily available it became clear that the assessment of the acceptability and desirability of certain medical technologies is liable to differ substantially amongst members of society. The existence of such diversity continues to be proven true by the strong ethical debates that regularly arise in the public sphere in Germany whenever an innovative technology for diagnosis or treatment is developed whose ethical implications are uncertain or contested amongst individuals holding different moral convictions. It is sufficient to consider the case-studies previously introduced[309] and, *inter alia,* the discussions on stem cells research and treatments,[310] genetic screening of new-borns and direct-to-consumer genetic testing,[311]

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[307] ibid. As examples of implausible arguments, Huster mentions the use of the promotion of human reproduction as a justification for the indivisibility of marriage (Huster, *Die ethische Neutralität des Staates* (2017) pp. 556-ff) as well as the use of slippery slope arguments (the assertion that acceptance of abortion would bring about a general weakening of the protection of life in a society and the claim that access to PGD would call into question the right to life of people with disabilities), see Huster in Kopetzki and others, *Körper-Codes* (2010) p. 30.

[308] See Chapter 1, sec. A.I.

[309] See Chapter 1, sec. A.I.3.b.

[310] See the opinion of the German Ethics Council, Nationaler Ethikrat, 'Zur Frage einer Änderung des Stammzellgesetzes: Stellungnahme' (2007) <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/Archiv/Stn_Stammzellgesetz.pdf> accessed 2.2.2021.

[311] Both addressed in the opinion of the German Ethics Council: Deutscher Ethikrat, 'The Future of Genetic Diagnosis: From Research to Clinical Practice' (2013)

genome editing in the human germline,[312] transgender and intersexuality treatments,[313] assisted suicide.[314] This anecdotal and not exhaustive list merely serves the purpose of demonstrating how frequently the German legislature is confronted with the emergence of ethically controversial technologies and has the difficult task of assessing the appropriateness of their prohibition or regulation. Against this background, as will be demonstrated throughout the thesis, criminal law was often instrumentalised by the lawmaker as their first reaction to the situation of ethical uncertainty or undesirability. This tool has often been used in a repressive manner, aimed at protecting societal and moral interests form an undifferentiated recourse to the new possibilities offered by scientific and technological progress in healthcare.[315]

Nonetheless, in the constitutional framework outlined above, such a response to newly developed health technologies must also fall within the limits imposed by the requirement of ethical and religious state neutrality.[316] In those instances the principle of neutrality operates on the level of objective law and furthermore affects the constitutional legitimacy of fundamental rights violation.

<https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-the-future-of-genetic-diagnosis.pdf> accessed 28.9.2021.

[312] Deutscher Ethikrat, 'Intervening in the Human Germline: Opinion: Executive Summary and Recommendations' (2019) <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-intervening-in-the-human-germline-summary.pdf> accessed 2.2.2021

[313] Deutscher Ethikrat, 'Intersexuality: Opinion' (2012) <https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-intersexuality.pdf> accessed 2.2.2021.

[314] Deutscher Ethikrat, 'The regulation of assisted suicide in an open society: German Ethics Council recommends the statutory reinforcement of suicide prevention: Ad Hoc Recommendation' (2014) <https://www.ethikrat.org/fileadmin/Publikationen/Ad-hoc-Empfehlungen/englisch/recommendation-assisted-suicide.pdf> accessed 2.2.2021.

[315] As will be illustrated when analysing the case of PGD, see Chapter 2, sec. A.I.

[316] See, however, the partially different opinion of Czermak and Hilgendorf, *Religions- und Weltanschauungsrecht* (2018) pp. 100-101. According to the authors, the legislature will necessarily have to take a stance in the field of health technologies. The lawmaker must justify its stance with considerations that are generally acceptable as reasonable by society as a whole, but some ideological positions will naturally be favoured over others. In the authors' view, the resulting legitimisation of the measures derives here from it being "an attempt to do the right thing" (author's translation) rather than from the neutrality of the justification.

According to an objective constitutional standard of neutrality, criminal law cannot be used to merely impose one particular ethical or religious standpoint.[317] All the more so in an area, such as that of controversial health and reproductive technologies, characterised by widespread moral disagreement amongst the members of a pluralist society. Under these circumstances, no criteria drawn from outside the legal system, such as form religious convictions or from a particular ethical or moral standpoint, can play a role in the enforcement of criminal law on all citizens.[318]

The imposition of criminal sanctions on the performance of certain medical treatments or on the use of a given health technology also triggers the protection of Article 2 of the Basic Law, since it constitutes a restriction of the individual's personal freedom (Art. 2(1) of the Basic Law) and right to life and physical integrity (Art. 2(2) of the Basic Law) in their negative dimension (as *Abwehrrechte*). State measures involving such restrictions are only legitimate if they can be constitutionally justified and if they respect a strict proportionality principle. As elucidated above, the requirement of ethical and religious neutrality of justification joins the proportionality criterion in the assessment of the constitutional legitimacy of the measure. The neutrality check must be conducted before the proportionality assessment since compliance with the neutrality standard does not involve a balancing test.[319] The constraints placed on state actions by the principle of religious and ideological neutrality are a self-standing requirement of objective law, whose cogency is not affected by the intensity of the infringement on the individual's fundamental rights.[320] Thus, the fundamental and negative dimension of individuals' rights protects them from both disproportionate interferences and arbitrary interventions that cannot be neutrally justified.[321]

Thereby the principle of ethical neutrality of the state also offers a protection against state paternalism in healthcare.[322] The state cannot ban certain health technologies on the simple grounds that they conflict with a

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[317] Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 93.

[318] Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen* (2010) pp. 43-ff.

[319] Huster, *Die ethische Neutralität des Staates* (2017) p. 655.

[320] ibid.

[321] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 26; Huster, *Die ethische Neutralität des Staates* (2017) p. 112.

[322] See, *inter alia,* Fateh-Moghadam in Voigt, *Religion in bioethischen Diskursen* (2010) p. 45; Huster, *Die ethische Neutralität des Staates* (2017) p. LXIII; Reitter, *Rechtspa-*

certain ethical conviction, not least because the right to physical integrity is relevant to the right of self-determination and to the very dignity of the individual. At the core of this dignity lies the possibility of living one's life according to one's personal moral and religious convictions.[323] In the same way, the right to personal freedom and free development of the personality are also protected from a majoritarian imposition of a morally or ethically correct use of one's personal freedom.[324]

The second decision on abortion of the Federal Constitutional Court can once again be quoted to exemplify the functioning of the neutrality principle in those instances. According to this decision the imposition of restrictions on access to abortion is legitimate and justified. The protection of the interests that it aims to safeguard is demanded by the constitutional framework and not by the adherence to a particular *Weltanschauung* or religious dogma. The protective scope of the right to life must be defined in an ethically and religiously neutral manner by deriving it from the right to dignity.[325] In balancing the foetus' right to life with the woman's rights to physical integrity the state can and must use only criteria internal to the legal system to define the scope of, and to balance, the various constitutional principles involved, thereby deciding on a proportionate regulation of access to abortion. This implies that, conversely, in circumstances where the protection offered by the constitutional framework is oriented towards the primacy of women's rights in the balancing act and thus towards the decriminalisation of abortion procedures, no ethical concern alone can be taken as sufficient justification for overcoming this outcome.[326]

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ternalismus und Biomedizinrecht: Schutz gegen den eigenen Willen im Transplantationsgesetz, Arzneimittelgesetz und Embryonenschutzgesetz (2020).

[323] Huster and Schramme in Huster and Schramme, *Normative Aspekte von Public Health* (2016) p. 53 ff; Kreßner, *Gesteuerte Gesundheit: Grund und Grenzen verhaltenswissenschaftlich informierter Gesundheitsförderung und Krankheitsprävention* (2019) pp. 241, 347 ff.

[324] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 23; Ammann, *Medizinethik und medizinethische Expertengremien im Licht des öffentlichen Rechts: Ein Beitrag zur Lösung von Unsicherheiten im gesellschaftlichen Umgang mit lebenswissenschaftlichen Fragestellungen aus rechtswissenschaftlicher Perspektive* (2012) p. 607; Huster, *Die ethische Neutralität des Staates* (2017) pp. 105-ff.

[325] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (252). For the literature, see *supra* at n. 280.

[326] This happens, for instance, when the life of the mother is at stake, see BVerfG, 25.2.1975 - 1 BvF 1/74, in BVerfGE 39, 1 (49).

Ultimately, a twofold effect of the principle of neutrality on the negative dimension of fundamental rights in the field of healthcare can be observed. Not only must the content and the scope of protection of each fundamental right be determined neutrally, but their violation by means of state regulations can also only be legitimate if justified by an ethically neutral purpose.[327] It must be possible to justify such regulations independently of adherence to a particular ethical or religious position.[328] Moreover, the assessment of neutrality comes before the evaluation of proportionality of the interference and thus does not depend on the intensity of the state's interference with the rights at stake.

b Neutrality of the State and the Statutory Health Insurance

The previous section dealt with the neutrality standard against which to assess state measures interfering with the rights to life, physical integrity and autonomy in their negative dimension protecting the individual against state interventions. For the purposes of this dissertation it is also essential to investigate the neutrality requirement for state measures taken in the framework of the implementation and development of a public healthcare system characterised by statutory health insurance (*Gesetzliche Krankenversicherung*, GKV). State action in this area is demanded by the positive aspect of the right to life and physical integrity, involving a state's positive obligation to protect and actively promote individuals' rights.

In contrast to the defence against state measures, this positive component of the right to life and physical integrity does not oblige the state to abstain from action, but rather to undertake measures and activities that promote and guarantee the conditions that enable individuals to fully enjoy their rights. A sufficient provision of healthcare is indeed an essential element for the exercise of the right to life and physical integrity and it must be guaranteed by the state, as confirmed by the Federal Constitutional Court.[329] According to this case law, fundamental rights do not only have a negative

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[327] Huster in Kopetzki and others, *Körper-Codes* (2010) pp. 22-ff.

[328] Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 91.

[329] See the first abortion decision of the Federal Constitutional Court, where a state obligation to protect is derived by the right to life of the foetus, BVerfG, 25.2.1975 - 1 BvF 1/74 (BVerfGE 39, 1).

dimension but also encompass an objective requirement for the state to act in a protective and supportive manner, which binds the legal order as a whole and affects all levels of state action.[330] This serves as a legal basis for the state's duty to protect.[331]

Although no mention is made in the Basic Law of a positive or social right to healthcare,[332] its existence becomes clear from a combined reading of Articles 2(2) and 20 of the Basic Law. The latter defines the Federal Republic of Germany as a social state, thus imposing a normative objective law requirement on state action, namely the respect of the principle of the welfare state.[333]

The public healthcare insurance system is implemented through the provisions of the Fifth Book of the Social Code (SGB V, *Sozialgesetzbuch*), in which it is maintained at § 27 that individuals who are insured are entitled to the necessary healthcare treatments. The guidelines of the Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) are of the utmost importance for the exact determination of the benefits to which each individual is entitled. Those guidelines address newly developed health technologies and allow their direct inclusion in the benefit basket of the GKV.[334] At the same time there is always room for direct and exceptional interventions by the legislature to provide for the inclusion of certain technologies in the catalogue of reimbursable services. This may be necessary in cases where the treatment would otherwise not fall within the scope of the necessary healthcare.[335]

Within this framework, the question to be answered concerns the validity of the neutrality principle for state measures taken to ensure the protection of a social right to healthcare. In other words, to address whether ethical concerns can legitimately be taken into account in reimbursement

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[330] Zwermann-Milstein, *Grund und Grenzen einer verfassungsrechtlich gebotenen gesundheitlichen Mindestversorgung* (2015) p. 101.

[331] Becker in Steiner and others, *Nach geltendem Verfassungsrecht* (2009) pp. 61-62.

[332] Although it must be noted that the omission of an explicit mention of social rights in the Basic Law stems from the circumstance that Germany already disposed of a well-established and functioning health system, see Becker in Steiner and others, *Nach geltendem Verfassungsrecht: Festschrift für Udo Steiner zum 70. Geburtstag* (2009) p. 59.

[333] ibid, pp. 63-64.

[334] According to §§ 135 and 137c SGB V.

[335] As, for instance, has happened in the cases of abortion and medically assisted procreation, where the lawmaker specially designed the provisions under § 24b and § 27a SGB V.

decisions, it is necessary to investigate whether this positive and promotional level of state action is equally subject to the neutrality requirement.

Although undoubtedly characterised by wider discretion and limited financial resources, state measures intervening to implement social rights are subject to constitutional limits and requirements. To investigate whether justification neutrality applies in this area of state action, considerations must be made concerning the role of social law in the German legal and constitutional order and the scope of the constitutional principle of ethical and religious neutrality.

The first aspect to consider is that objective requirements and structural demands of the rule of law, such as the neutrality requirement, bind the state in exercising its welfare action.[336] This is also based on the fact that the state, when acting as a welfare state, does not have the power to interpret the content of fundamental rights more restrictively than the state acting as a regulator of individuals' freedoms.[337] It is also a matter of normative coherence of the legal system. As a result, the requirement of justification neutrality shall be respected in all areas of the law. This has been referred to as an "expansive tendency of justification neutrality".[338] Huster argues this with relation to the funding and promotion of the arts. Accordingly, the state should not deny funding to a work of art on the ground that it conflicts with interests which would not justify an intervention in the negative freedom to practice arts in the first place.[339] When applied to the reimbursement of healthcare technologies, this means that the state cannot exclude the introduction in the statutory health insurance on the ground that a technology conflicts with interests, such as specific moral or religious convictions, that would not justify interfering with the negative right to physical integrity by prohibiting its use in the first place.[340]

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[336] Droege, *Staatsleistungen an Religionsgemeinschaften im säkularen Kultur- und Sozialstaat* (2004) p. 461.

[337] Huster, *Die ethische Neutralität des Staates* (2017) pp. 482-483.

[338] ibid, p. 572 (author's translation).

[339] ibid, pp. 482-483.

[340] ibid, p. 483. The parallel between reimbursement of controversial health technologies and the promotion and funding of the arts is suggested by Huster. When questioning precisely whether and to what extent the neutrality standard can be used to evaluate state measures in the case of healthcare insurance, the author quotes the example of in vitro fertilisation as a reproductive technology whose acceptance and ethical desirability are denied by several members of the insured community due to religious or moral convictions (Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) pp. 68-69). While not providing a direct solution to the

The Basic Law also foresees that the state must behave neutrally when performing specific support and financing tasks. Precisely for the promotion of the arts,[341] it appears that a neutrality requirement can be directly derived from Article 5(3) of the Basic Law. [342] In this field, therefore, state support and funding are subject to constitutional neutrality standards requiring the exclusion of assessment criteria considered to be drawn from normative fields outside of the law.[343]

Weltanschauliche neutrality is also mentioned as a characteristic of the welfare state in the wording of a Federal Constitutional Court decision on the employer's liability for the church income tax of its employees, where the social and cultural state is explicitly marked as ideologically neutral.[344]

A second aspect is that, from the individuals' perspective, the provision of state funding may be just as important as the absence of a norm prohibiting the use of certain health technologies.[345] Especially when these entail significant costs, the state's choice not to include them in the statutory healthcare insurance may have equally intrusive consequences for patients' possibility to access it. The application of the requirement of ethical and religious neutrality to the social sphere of the state action is especially relevant in matters where the individual is truly dependent on state support, as in the case of access to expensive health care innovation. Considerations that, in a pluralist state, shall be excluded from the pool of possible legitimate justifications for interferences in fundamental rights, such as those linked to a particular ethical and religious conviction, would be reintroduced into the legal order 'through the back door'. The state would also

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issue, he highlights that the matter is already known in the constitutional literature, mainly from discussions surrounding state support for the arts and sciences (Huster in Brockmöller, *Ethische und strukturelle Herausforderungen des Rechts, Referate der 2 Tagung der Initiative Junger Wissenschaftlerinnen und Wissenschaftler aus den Bereichen Rechtsphilosophie, Rechtstheorie und Rechtssoziologie* (1997) p. 21; Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) pp. 66-69.

[341] Mentioned in Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016) pp. 68-69 as a suitable comparison to the question of neutrality in the public healthcare system, as further discussed below.

[342] Palm, *Öffentliche Kunstförderung zwischen Kunstfreiheitsgarantie und Kulturstaat* (1998) p. 71.

[343] Höfling, 'Zur hoheitlichen Kunstförderung – Grundrechtliche Direktiven für den „neutralen. Kulturstaat"' [1985](10) DÖV p. 387, 389.

[344] BVerfG, 17.2.1977 - 1 BvR 33/76 (BVerfGE 44, 103), referring to "*der weltanschaulich neutrale Kultur- und Sozialstaat*".

[345] Droege, *Staatsleistungen an Religionsgemeinschaften im säkularen Kultur- und Sozialstaat* (2004) pp. 370 ff.

be failing in its obligation not only not to interfere with the negative side of the individual's freedom but also to support it and guarantee its full implementation by promoting its positive aspect.[346]

This holds especially true in the framework of the contemporary welfare state where the full enjoyment of fundamental rights is increasingly ensured by the promotion and support of the state.[347] As the Federal Constitutional Court notes in its judgment on the *numerus clausus*, concerning access to university studies, the more the modern state turns to social security, the more the task of ensuring freedom under fundamental rights is complemented by a demand for a guarantee of participation in state benefits.[348] In this sense the granting of social benefits is of great relevance for the protection of fundamental rights.

The acknowledgment of this positive or social aspect of fundamental rights implies that their scope is wide enough to protect against the state when it acts as a welfare state.[349] Therefore, even in carrying out its social policy, the state cannot pursue one particular ethical or religious perspective. Individuals receiving social benefits are not merely begging for state support, but also exercising their fundamental rights. Their ethical and religious freedom must be equally respected within the social benefits system.[350] The facilitation of the exercise of fundamental rights through the social state must be devoid of any finalisation to the pursuit of a particular idea of the good. The freedoms guaranteed by the Basic Law, including the right to physical integrity, must indeed be considered as "ideology-rejecting", [351] with the consequence that the social state must also tend towards ethical neutrality.[352]

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[346] Kreß, *Ethik der Rechtsordnung* (2012), pp. 166-167.

[347] Forsthoff, 'Begriff und Wesen des sozialen Rechtsstaates' [1953](12) VVDStRL p. 8, 32–33.

[348] BVerfG, 18.7.1972 – 1 BvL 32/70 und 25/71, in BVerfGE 33, 303 (330) - *numerus clausus I*. See, *inter alia*, Rixen, 'Das Grundrecht auf glaubenskonforme Gewährung von Sozialleistungen – Zugleich ein Beitrag zu den Leistungsgrundrechten des Grundgesetzes –' (2018) 133(14) DVBl p. 906, 911.

[349] Martens, 'Grundrechte im Leistungsstaat' [1972](30) VVDStRL p. 8, 10-ff; Häberle, 'Grundrechte im Leistungstaat' [1972](30) VVDStRL p. 43, 90-ff.

[350] Rixen, 'Das Grundrecht auf glaubenskonforme Gewährung von Sozialleistungen – Zugleich ein Beitrag zu den Leistungsgrundrechten des Grundgesetzes –' (2018) 133(14) DVBl p. 906, 913.

[351] Sommermann in Mangoldt, Klein and Starck, *Grundgesetz: Kommentar* (7th edn 2018) para. 114 (author's translation).

[352] ibid.

The determination of social benefits is especially significant for fundamental rights in those cases where the reliance on the state support is forced upon the individual. For instance if affiliation to the system is compulsory, as is the case with the GKV.[353] This perspective is adopted by the Federal Constitutional Court in its notorious so-called '*Nikolaus*' decision,[354] according to which the provision of a compulsory insurance affects the fundamental right of general freedom of the individual (Art. 2(1) of the Basic Law).[355] Although this circumstance alone cannot give rise to any claim to special medical treatment,[356] what is important to underline is that the court explicitly stated that the choice on the inclusion or exclusion of a certain benefit from the statutory health insurance must be justified and measured against the fundamental right of personal freedom under Article 2(1) of the Basic Law.[357] The right to personal freedom thus protects the individual, whose participation in the system is mandatory, from a possible disproportionality between contributions and benefits.[358]

Therefore, while it is certainly correct that the political sphere has a wide margin of appreciation in determining the benefit basket of the healthcare insurance,[359] the resulting decisions must be justified. And, as can be derived from the theory of ethical neutrality outlined above, the justification of state actions influencing the fundamental right of the individual can only be legitimate if based on an ethically and religiously neutral reasoning. Even if the influence on the fundamental right is limited and proportionate, the objective neutrality standard of justification must still be fulfilled because, as determined above, the assessment of compliance with the neutrality requirement comes prior to that concerning the proportionality of the interference.

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[353] Martens, 'Grundrechte im Leistungsstaat' [1972](30) VVDStRL p. 8, p. 12.

[354] BVerfG, 6.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25). The designation of this ruling as '*Nikolaus*' decision was diffused after appearing in Kingreen, 'Verfassungsrechtliche Grenzen der Rechtsetzungsbefugnis des Gemeinsamen Bundesausschusses im Gesundheitsrecht' (2006) 59(13) NJW p. 877, 880.

[355] See Huster, 'Anmerkung' (2006) 61(9) JZ p. 466; Becker in Steiner and others, *Nach geltendem Verfassungsrecht* (2009) pp. 64-66.

[356] BVerfG, 6.12.2005 - 1 BvR 347/98 in BVerfGE 115, 25 (43).

[357] BVerfG, 6.12.2005 - 1 BvR 347/98 in BVerfGE 115, 25 (42).

[358] BVerfG, 6.12.2005 - 1 BvR 347/98 in BVerfGE 115, 25 (43).

[359] Schuler-Harms in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt: Neue Demokratietheorie als Bedingung demokratischer Grundrechtskonkretisierung in der Biopolitik* (2015).

Moreover, mandatory affiliation implies that the pool of people who have to pay contributions to the system is unavoidably composed of individuals with several different religious and moral convictions and, therefore, characterised by a high degree of ethical pluralism. A demand for ethically and religiously neutral justification can also be derived from this circumstance. Since each individual has an obligation to contribute and, at the same time, has no possibility to influence the type and extent of the benefits that are owed to him by the insurance,[360] the decisions must be taken with criteria that are considered as reasonably acceptable to the community as a whole.[361]

Besides, the means to finance a public healthcare system with a mandatory affiliation must be publicly collected by force. The implementation of the healthcare system consequently falls to be considered as a coercive action of the state, which shall always be subject to neutrality standards.[362] When a public authority imposes binding measures on all members of society, these must be equally justifiable for all, irrespective of their inner moral convictions. Therefore the state's obligation of ethical and religious neutrality encompasses all spheres of the state's coercive power, including those in which the state acts as a welfare state, but also exercises its public authority by coercive means.[363]

Once again it must be emphasised that the constitutional pluralist state cannot be affiliated or identified with a particular religion or ethical conviction in any way. The fact that this principle covers all spheres of state action is intended to ensure that state power can be exercised over all members of the pluralist society and equally justified towards all.

With regard to the question of the statutory health insurance's benefit basket, compliance with the requirements of neutrality of justification or non-identification assumes particular importance; especially with regard

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[360] BVerfG, 6.12.2005 - 1 BvR 347/98 in BVerfGE 115, 25 (42).

[361] Huster, *Die ethische Neutralität des Staates* (2017) pp. 459 and 482. The Federal Constitutional Court was confronted precisely with the question of whether a person insured with statutory health insurance could demand that health insurance funds not be used for social benefits contrary to his ethical or religious convictions. In rejecting the claim, the court held in its decision BVerfG, 18.4.1984 - 1 BvL 43/81 (BVerfGE 67, 26) that a statutorily insured individual could not expect their ethical convictions to become the yardstick for determining general rules in this respect. This is because it is not possible to derive from fundamental rights an individual demand that social law norms not be applied in favour of third parties.

[362] ibid, p. 93.

[363] ibid, p. 94.

to those ethically controversial technologies that form the subject of this dissertation. When the state is confronted with a technology that is not equally ethically accepted by all, its choice of what to publicly reimburse or not becomes crucial and potentially constitutes a strong stance in favour of a specific ethical or religious viewpoint. If the need to comply with certain religious or moral requirements were taken into account, this decision would openly express the state's alignment with a corresponding religious or ethical belief. Moreover, this potential identification of the state with a particular faith or belief through the reimbursement decisions in the public healthcare system can have a major impact on society and even influence individuals' moral convictions. According to the Federal Constitutional Court's arguments in its second abortion decision, the state decision to provide reimbursement for a treatment within the public healthcare system sends society the message that said treatment is not seen as problematic. In a crucial passage of the decision – as far as the topic of the present dissertation is concerned – the federal constitutional judges admit that choices regarding the public healthcare system are, generally speaking, capable of shaping the beliefs of the population through the values expressed in them.[364] This is also deemed to be the case due to the large percentage of the population covered by the statutory health insurance.[365] The Court additionally states that the pregnant woman's conscience, as well as that of her relatives, would be eased by such an explicit acceptance of the abortive procedure by the state.[366] Conversely, the refusal to reimburse controversial technologies on grounds of ethical or religious reasons might signify the state's intention to morally distance itself from them[367] and is liable to

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[364] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319). See also comments in the Introduction.

[365] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

[366] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (320).

[367] Starck, 'Der verfassungsrechtliche Schutz des ungeborenen menschlichen Lebens. Zum zweiten Abtreibungsurteil des BVerfG' (1993) 48(17) JZ p. 816, 822; Stürner, *Der straffreie Schwangerschaftsabbruch in der Gesamtrechtsordnung: Rechtsgutachten für das Bundesverfassungsgericht mit seiner Vorgeschichte und einer Stellungnahme zur Entscheidung* (1994), p. 168. However, in the opinion of the Court, the refusal to reimburse a treatment only has limited implications for its acceptability, see BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

express a moral condemnation of the patients and doctors who decide to make use of them.[368]

According to the principle of ethical and religious neutrality, this distancing might legitimately happen only if it rests on constitutional obligations to protect other individuals' interests, rather than on moral convictions. This is deemed to be the situation in the abortion case, since the state's disapproval of the treatment is not required by an affiliation to a particular ethical or religious belief, but rather by the constitutional obligation to protect the right to life of the foetus.[369]

In sum, under the framework of the neutrality requirement, the welfare state cannot identify or promote a specific ethical viewpoint. When shaping the benefit basket of the healthcare insurance the welfare state fulfils the function of determining and protecting legitimate public interests,[370] which cannot coincide with those of one particular religious group.

II. Italian Laicity

1. The Principle of Laicity in the Constitution

In the Italian constitutional framework, the relationship between ethical or religious convictions and the law falls to be considered under the principle of laicity.

To avoid confusion, it is necessary to clarify that – due to a different historical and cultural background –[371] the Italian notion of laicity fun-

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[368] As demonstrated precisely by the Court's reference to the "unloading of a burden" for the patient's conscience, BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (320). See the comments already given in the Introduction.

[369] Once again, the obligation to protect the foetus's right to life is not based on specific moral convictions but rather directly derived from the Basic Law and, namely, by the right to dignity under Article 1. Nevertheless, if that is the case, the protection of the foetus' interests should not happen at the support and financing level of the state action but rather via direct interference in the conflicting fundamental rights of the woman and, therefore, through prohibition to perform the procedure in the first place. As mentioned above, the welfare state is not assigned a wider marge of appreciation than the regulatory state as far as the scope of the content of fundamental rights is concerned.

[370] Martens, 'Grundrechte im Leistungsstaat' [1972](30) VVDStRL p. 8, 16-ff.

[371] Cavana, *Interpretazioni della laicità: Esperienza francese ed esperienza italiana a confronto* (1998); Finocchiaro, 'Alle origini della laicità statale' (2002) 113(4) Dir eccl p. 1257, 1257-ff.

damentally differs from its best-known French analogue. Even after its constitutionalisation,[372] the traditional French principle of laicity remains strongly dependent on the strict separation between State and religion, on the religious neutrality of the public space, and on a protection of religious freedom that is limited to its expression in the private sphere.[373] As this section will illustrate, the Italian understanding of laicity is instead based on the active promotion of religious convictions and institutions as they are considered to be positive factors in the personal development of the individual.[374] This conception of laicity was agreed upon during the proceedings of the Italian Constituent Assembly. The Assembly established that religion could not be considered as a mere private matter and thus assigned the task of promoting religious institutions as social structures in which individuals can freely develop their personality to the newly formed Republic.[375] On these grounds, the constituent members drafted the current formulations of Articles 7 and 8 of the Constitution. Whereas the first declares that the State and the Catholic Church are independent and sovereign in their respective spheres and that their relations are regulated by pacts,[376] the second extends the possibility of signing similar agreements to other religious faiths. Additionally Article 19 was introduced to protect and promote religious beliefs and celebrations in public or in private.

The Italian legal theorist Luigi Ferrajoli reads an explicit constitutional embedding of the principle of the separation between law and morality in the combination of these provisions. They are taken to indicate a renuncia-

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[372] Which allowed a shift from laicity as a hostile struggle against confessional claims to laicity as a legal guarantee of freedom of conscience and societal pluralism, see Cavana, 'Laicità dello Stato: da concetto ideologico a principio giuridico' [2008] (September) Stato, Chiese e pluralismo confessionale p. 1, 7; D'Arienzo, 'La laicità francese: "aperta", "positiva" o "im-positiva"?' [2011](December) Stato, Chiese e pluralismo confessionale p. 1, 3; Alicino, 'Atheism and the Principle of Laïcité in France. A Shifting Process of Mutual Adaptation' [2018](32) Stato, Chiese e pluralismo confessionale p. 1, 9-ff.

[373] Cavana, 'Laicità dello Stato: da concetto ideologico a principio giuridico' [2008] (September) Stato, Chiese e pluralismo confessionale p. 1, 5-ff; Alicino, 'Atheism and the Principle of Laïcité in France. A Shifting Process of Mutual Adaptation' [2018](32) Stato, Chiese e pluralismo confessionale p. 1, 14-ff.

[374] Cavana, 'Laicità dello Stato: da concetto ideologico a principio giuridico' [2008] (September) Stato, Chiese e pluralismo confessionale p. 1, 10-ff.

[375] Cavana, 'Laicità dello Stato: da concetto ideologico a principio giuridico' [2008] (September) Stato, Chiese e pluralismo confessionale p. 1, 9.

[376] The Lateran Concordat of 1929, signed from the Italian Republic and the Holy See.

tion of the state as the promoter of a certain morality to the detriment of others.[377]

Other legal scholars have focused on the question of whether the Italian principle of laicity is equivalent to the notion of neutrality.[378] According to the interpretations of many authors, the concept of neutrality does not apply to the Italian approach of laicity. Neutrality allegedly implies that the law adopts a stance of complete indifference towards religious sentiments as such and that all religious convictions need to be confined to the private conscience of the single individual.[379]

An opposing group of scholars argue that this conception of neutrality is too narrow and that the adoption of a principle of neutrality does not necessarily imply indifference towards all ethical or religious feelings. On the contrary, the concept of neutrality should rather be interpreted as a requirement of impartiality, according to which the state may not align its legislation with a particular religious faith.[380] Following this understanding, the principle of laicity could not be fully respected within a legal system that fails to adopt a position of neutrality.[381]

The terms of this debate can be clarified by looking at the case law of the Italian Constitutional Court, which explicitly outlined the principle of laicity as one of the fundamental principles of the Italian constitutional order starting from its judgment no. 203 of 1989.[382]

The subject-matter of this first landmark case was the Law of 25 March 1985, no. 121 ratifying the 1984 amendment to the Lateran pacts. In particular, the Court was called upon to decide on the provision regarding

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[377] See Ferrajoli in Rodota, Zatti and Tallacchini, *Trattato di Biodiritto: Ambito e fonti del biodiritto* (2011) p. 245.

[378] For an overview of the different positions, see Pin, 'Il percorso della laicità "all'italiana". Dalla prima giurisprudenza costituzionale al Tar veneto: una sintesi ricostruttiva' [2006](1) Quad dir e pol eccl p. 203, 208-ff.

[379] *Inter alia*, Cavana, 'Laicità dello Stato: da concetto ideologico a principio giuridico' [2008](September) Stato, Chiese e pluralismo confessionale p. 1, 10 and Dalla Torre, *Il primato della conscienza: Laicità e libertà nell'esperienza giuridica contemporanea* (1992) as reported by Pin, 'Il percorso della laicità "all'italiana". Dalla prima giurisprudenza costituzionale al Tar veneto: una sintesi ricostruttiva' [2006](1) Quad dir e pol eccl p. 203, 208.

[380] Martinelli, 'La laicità come neutralità' [2007](April) Stato, Chiese e pluralismo confessionale p. 1, 2; Randazzo, 'La Corte «apre» al giudizio di uguaglianza tra confessioni religiose?' (1998) 43(3) Giur Cost p. 1843, 1864.

[381] Di Giovine, 'Stato liberale, Stato democratico e principio di laicità' [2019](Speciale) Dir pubbl comp eur p. 215, 217.

[382] Italian Constitutional Court, judgment no. 203/1989.

the teaching of the Catholic religion in public schools and during school hours. This norm had been interpreted by the administrative courts to require students who decided not to partake in lessons on religion to attend mandatory alternative courses, thus imposing an obligation on them allegedly amounting to an infringement of their freedom of equality and religion.

Starting from the assumption that the provisions of the Lateran pacts fall under a specific constitutional protection provided by Article 7(2) of the Constitution, the Court maintained that their constitutional review could only be based on their compliance with the 'supreme' principles of the constitutional order. As they are considered to be higher in value than any other single constitutional Article, those overriding principles cannot be trumped by other constitutional provisions. Consequently they constitute the only applicable criteria for the judicial review of the Lateran pacts.[383] Amongst the supreme norms of the constitutional order, the Court recognised the principle of laicity. This puts laicity in a position of primacy in relation to other constitutional norms.[384] The basis for the constitutional notion of laicity, as laid out in the reasoning of the judgment, is to be found in the constitutional Articles: regulating Church-State relationships (Art. 7 Const.) and ensuring equality of all religious faith before the law (Art. 8 Const.), as well as in the provisions guaranteeing the fundamental rights of individuals and the development of their personality in social structures (Art. 2 Const.), the right to equality (Art. 3 Const.), freedom of religion (Art. 19 Const.) and the non-discrimination of religious organisations (Art. 20 Const.).

Based on a combined reading of these constitutional provisions the Court defined the principle of laicity as an essential and irrevocable feature of the Italian constitutional order.[385] Moreover, the Court specified that

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[383] Italian Constitutional Court, judgment no. 203/1989, conclusions in point of law para. 3. It should be noted, however, that legal doctrine considers that the constitutional umbrella of Article 7 no longer protects the provisions of the 1984 Concordat since the new agreement revokes the original constitutionalised Lateran Pacts, thus currently having only the status of ordinary law, see Colaianni, 'Il principio supremo di laicità dello Stato e l' insegnamento della religione cattolica' (1989) 5(1) Il Foro Italiano p. 1333, 1335.

[384] Forni, *La laicità nel pensiero dei giuristi italiani: Tra tradizione e innovazione* (2010) p. 227.

[385] Italian Constitutional Court, judgment no. 203/1989, conclusions in point of law para. 4: Laicity is a "profile of the form of state as outlined in the constitutional charter of the Republic" (author's translation).

laicity does not imply an indifference of the State towards religions, but rather entails that the State shall safeguard religious freedom and religious and cultural pluralism[386] and shall remain at the service of the concrete religious needs of its citizens.[387]

The reasoning of the judgment shows that the constitutional judges intended to uphold a notion of laicity according to which religious convictions enjoy a protected status and deserve to be actively promoted.[388] Nonetheless, the promotion of religious beliefs does not necessarily entail a contrast between the Italian constitutional concept of laicity and the principle of neutrality. This holds true if the standard of neutrality is interpreted as requiring impartiality towards the individuals' choice of religious faiths and, therefore, equal support of all religious (as well as non-religious) convictions.[389] A neutrality requirement also results from the Court's emphasis on the need to safeguard the coexistence, within Italian democratic society, of different religious stances which shall all enjoy equal constitutional dignity.[390]

This view of laicity is confirmed by the subsequent jurisprudence of the Constitutional Court. In several judgments, regarding the provisions of the Criminal Law Code punishing crimes of blasphemy against God, members of religious faiths or religious objects and disturbances of religious ceremonies, the Court took the opportunity to uphold the right of all religious beliefs to be equal before the law.[391] The notion that laicity involves "equidistance and impartiality of the legislation with respect to all religious

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[386] Italian Constitutional Court, judgment no. 203/1989, conclusions in point of law para. 4.

[387] Italian Constitutional Court, judgment no. 203/1989, conclusions in point of law para. 7.

[388] Randazzo, 'La Corte «apre» al giudizio di uguaglianza tra confessioni religiose?' (1998) 43(3) Giur Cost p. 1843, 1865. In the court's perspective, laicity implies that the state should assist the citizen in fulfilling their religious needs, as noted by Montesano, 'Dalla laicità dello Stato alla laicità per lo Stato.: Il paradigma laico tra principio e valore' [2017](36) Stato, Chiese e pluralismo confessionale p. 1, 17.

[389] Del Bò, 'Il rapporto tra laicità e neutralità: una questione concettuale?' [2014](33) Stato, Chiese e pluralismo confessionale p. 1, 17-ff.

[390] Italian Constitutional Court, judgment no. 203/1989, para. 4.

[391] See Sicardi, 'Il principio di laicità nella giurisprudenza della Corte Costituzionale (e rispetto alle posizioni dei giudici comuni)' [2007](2) Dir pubbl p. 501, 530; Colaianni, 'La fine del confessionismo e la laicità dello Stato (il ruolo della Corte costituzionale e della dottrina)' [2009](1) Pol dir p. 45, 58.

denominations"[392] first appeared in judgment no. 329/1997[393] and was then reiterated in judgment no. 508/2000, in which the Court affirmed that "this position of equidistance and impartiality is a reflection of the principle of laicity […] characterising our State as a pluralist entity, within which different faiths, cultures and traditions have to coexist in equal freedom". [394]

In the Constitutional Court judgment no. 235/1997, deciding on a property tax exemption for Catholic clergy support institutions, this condition of impartiality is explicitly labelled as State "neutrality" towards all religious institutions.[395]

However, most relevant for the purpose of this Chapter is the reasoning of the Court in its judgment no. 334/1996 on the judicial oath in civil procedures. The judges argued that the distinction between religious systems and the legal system essentially characterises the fundamental constitutional principle of laicity and that religion, with its respective moral obligations, cannot be imposed by the State as a means to an end.[396] In other words, the State cannot rely on religious obligations to enforce legal norms.[397] As observed by different scholars,[398] the crucial point of this reasoning consists in the fact that the obligation to perform a morally charged act is as such considered to violate the freedom of conscience, regardless of whether it complies with the religious feelings of the individual under oath. In this judgment the Court tied the principle of laicity to a normative distinction

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[392] Author's translation.

[393] Dealing with crimes against religious objects, conclusions in point of law para. 2. The same principle will be confirmed in the following judgments on disturbances of religious ceremonies (judgment no. 327/2002) and offences against members of religious faiths (judgment no. 327/2002).

[394] Author's translation. On the public defamation of the Catholic religion, see conclusions in point of law para 3.

[395] See, also, Alicino, 'Esercizi di laicità: Ovvero de-finire (giuridicamente) lo Stato laico' [2008](January) Stato, Chiese e pluralismo confessionale p. 1, 28; Randazzo, 'La Corte «apre» al giudizio di uguaglianza tra confessioni religiose?' (1998) 43(3) Giur Cost p. 1843, 1864.

[396] Conclusions in point of law para 3.2.

[397] ibid.

[398] Pin, 'Il percorso della laicità "all'italiana". Dalla prima giurisprudenza costituzionale al Tar veneto: una sintesi ricostruttiva' [2006](1) Quad dir e pol eccl p. 203, 210-ff; Alicino, 'Esercizi di laicità' [2008](January) Stato, Chiese e pluralismo confessionale p. 1, 24; Colaianni, 'La fine del confessionismo e la laicità dello Stato (il ruolo della Corte costituzionale e della dottrina)' [2009](1) Pol dir p. 45, 72-ff.

between law and morals and maintained that legal provisions cannot be legitimately based on moral or religious norms.[399]

This distinction of normative orders is also invoked by the Supreme Court of Cassation (*Corte Suprema di Cassazione*) in its judgment no. 439 of 2000. It was the case of a polling station official who refused to perform his duties on the grounds that crucifixes were present in the electoral rooms.[400] The Court maintained that the public voting space must be neutral, insofar as it is intended to safeguard the confrontation between different value systems. In a situation of religious and cultural pluralism, in which different personal moral choices shall coexist with equal dignity, the laicity principle prevents the State from choosing and imposing one framework of values.[401] Further, the Court underlined the close link between the principle of laicity and the constitutional requirement of administrative impartiality (as laid down in Article 97 of the Constitution).[402]

It follows from this overview of the case law that the Italian principle of laicity, in the terms of the Constitution, requires the legal system to maintain equal distance from all religions convictions and, in this sense, to remain neutral.[403]

In these terms it could be argued that the standard of laicity appears rather undetermined and vague, hindering its direct applicability.[404] However, the literature has pointed out that, as a fundamental and transversal principle of the constitutional order, laicity always carries out its functions

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[399] Colaianni, 'La fine del confessionismo e la laicità dello Stato (il ruolo della Corte costituzionale e della dottrina)' [2009](1) Pol dir p. 45, 73.

[400] Court of Cassation, judgment no. 439 of 1.3.2000, para. 5.

[401] Court of Cassation, judgment no. 439/2000, para. 5. See also Pin, 'Il percorso della laicità "all'italiana". Dalla prima giurisprudenza costituzionale al Tar veneto: una sintesi ricostruttiva' [2006](1) Quad dir e pol eccl p. 203, 219-ff.

[402] Court of Cassation, judgment no. 439/2000, para. 5. See also Sicardi, 'Il principio di laicità nella giurisprudenza della Corte Costituzionale (e rispetto alle posizioni dei giudici comuni)' [2007](2) Dir pubbl p. 501, 540-ff.

[403] See, *inter alia*, Del Bò, 'Il rapporto tra laicità e neutralità: una questione concettuale?' [2014](33) Stato, Chiese e pluralismo confessionale p. 1, 15; Colaianni, 'Trent'anni di laicità: Rileggendo la sentenza n. 203 del 1989 e la successiva giurisprudenza costituzionale' [2020](21) Stato, Chiese e pluralismo confessionale p. 52, 63.

[404] As can be seen by reading the statements of the judgments, no law has been declared illegitimate solely on the grounds of conflict with the principle of laicity yet, as noted by Colaianni, 'Trent'anni di laicità' [2020](21) Stato, Chiese e pluralismo confessionale p. 52, 63.

in interaction with all the other constitutional principles[405] and must therefore always be appreciated within the framework of its constitutional context.[406] This interrelation with the constitutional framework also confirms that the scope of the principle of laicity is not reduced to governing the relationship between the legal order and purely religious convictions, but also encompasses other ethical and ideological beliefs. Considered in these terms, laicity goes so far as to entail that the legislature may not impose or favour particular values derived from any normative ethical or ideological system external to and separate from the law.[407]

One of the relevant constitutional principles to which the Constitutional Court frequently referred is the principle of pluralism, which has contributed significantly to the constitutional definition of laicity.[408] The notion of pluralism does not only cover religious diversity but also encompasses pluralism of cultures, traditions and other ethical convictions that, thanks to Articles 2 and 3 of the Constitution, shall receive equal constitutional protection. Therefore, guaranteeing ethical pluralism also means ensuring that the variety of moral positions that are found in society can unfold.[409] More broadly this results in a mandate for the State to refrain from giving

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[405] Folliero, ‘Multiculturalismo e aconfessionalità: Le forme odierne del pluralismo e della laicità’ [2007](March) Stato, Chiese e pluralismo confessionale p. 1, 5; Balestra, ‘Laicità e diritto civile’ (2008) 54(1) Rivista di Diritto Civile p. 13, 21–22; Stammati, ‘Riflessioni minime in tema di laicità (della comunità e dello stato).: Un colloquio con alcuni colleghi’ [2008](2) Dir pubbl p. 341, 402; Risicato, ‘Laicità e principi costituzionali’ [2008](June) Stato, Chiese e pluralismo confessionale p. 1, 18-ff.

[406] Balestra, ‘Laicità e diritto civile’ (2008) 54(1) Rivista di Diritto Civile p. 13, 21–22; Canestrari, ‘Biodiritto (diritto penale)’ (2015) Annali VIII, Enc dir p. 99, 104.

[407] Onida, ‘Il problema dei valori nello stato laico’ (1995) 3(1) Dir eccl p. 672, 675; D'Agostino, ‘Il Forum: Bioetica e Costituzione’ [1996](1) Rivista di Diritto Costituzionale p. 295, 298; Tripodina, ‘Dio o Cesare? Chiesa cattolica e Stato laico di fronte alla questione bioetica’ [2007](1) Costituzionalismoit p. 1, 10; Valentini, ‘La laicità dello Stato e le nuove interrelazioni tra etica e diritto’ [2008](June) Stato, Chiese e pluralismo confessionale p. 1, 19.

[408] Silvestri in Aqueci and Formigari, *Laicità e diritti: Studi offerti a Demetrio Neri* (2018) p. 36.

[409] Valentini, ‘La laicità dello Stato e le nuove interrelazioni tra etica e diritto’ [2008](June) Stato, Chiese e pluralismo confessionale p. 1, 32.

legal endorsement to ethical or religious norms[410] or to promote one particular ethical, ideological or religious belief.[411]

In this regard, the respect of the principle of laicity mandates the separation of law and morality and the full self-determination of the legal system in ethically controversial matters.[412] It entails an obligation to base all legal provisions on principles derived from within the constitutional order, without drawing upon external normative systems.[413]

This understanding of the requirement of the separation of law and morality can also be found in a ruling of the Constitutional Court that predates the first explicit declaration of the principle of laicity. Namely, the Constitutional Court judgment no. 9/1965, which dealt with the judicial review of the former Article 553 of the Criminal Code punishing incitement to practices against procreation, such as abortion and contraception. Originally intended to protect Catholic morals, the purpose of the Article was shifted by the Court's ruling, which, whilst not finding it unconstitutional, restored its legitimacy through a constitutionally oriented interpretation. The Court decided to dissociate the provision from its original ethical and Catholic assumptions.[414] On the one hand, it endorsed the view of the referring judge that Catholic morality cannot influence the determination of a legal concept. At the same time it argued that, on the other hand, the interest protected by the criminal provision is not an ethical one but rather a social dimension of morality, in the sense of decency in matters of sexuality.[415] The text of the judgment reads "a moral law lives in the individual

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[410] Randazzo, 'Le laicità' [2008](October) Stato, Chiese e pluralismo confessionale p. 1, 3.

[411] Ferrajoli in Rodota, Zatti and Tallacchini, *Trattato di Biodiritto* (2011) p. 235; Parisi, 'Ateismo, neutralità dell'istruzione pubblica e pluralismo delle opzioni formative' [2011](1) Quad dir e pol eccl p. 127, 129.

[412] Ferrajoli in Rodota, Zatti and Tallacchini, *Trattato di Biodiritto* (2011) p. 245; Di Giovine, 'Stato liberale, Stato democratico e principio di laicità' [2019](Speciale) Dir pubbl comp eur p. 215, 217.

[413] Alicino, 'Esercizi di laicità' [2008](January) Stato, Chiese e pluralismo confessionale p. 1, 8; Ferrajoli in Rodota, Zatti and Tallacchini, *Trattato di Biodiritto* (2011) p. 245.

[414] Fiore, 'Incitamento a pratiche contro la procreazione' (1971) XXI Enc dir p. 19, 26.

[415] See Fiore, 'Incitamento a pratiche contro la procreazione' (1971) XXI Enc dir p. 19; Perrone, *Buon costume e valori costituzionali condivisi: Una prospettiva della dignità umana* (2015) 40-ff.

conscience and as such cannot be the subject of legislative regulation",[416] thereby expressing a clear stance on the separation of ethics and law.[417]

Furthermore, the principle of laicity is supported and integrated by the so-called 'personalistic' orientation of the Italian Constitution, derived from the prioritisation of the individual over the state laid down in Article 2.[418] Likewise, the principle of equality is associated with the standard of laicity as it demands equal treatment of religious confessions and institutions (according to Articles 8 and 20 of the Constitution), as well as equal dignity of all citizens and of their different ethical convictions.[419]

2. Laicity in the Field of Health Technologies

a Laicity and the Fundamental Right to Health

The function of the principle of laicity in the regulation of the healthcare sphere must be assessed in conjunction with the other constitutional principles pertaining to the protection of the right to health of the individual. Indeed, depending on the specific matters involved, the concrete operability of the principle of laicity depends on its interplay with other constitutionally protected rights or interests. The relationship between the principle of laicity and the other constitutional principles is mutual. The principle of laicity complements the other constitutional principles, which must always be interpreted in the light of this overarching constitutional standard. On the other hand, the scope of laicity is shaped more concretely by its interaction with other fundamental principles relevant to each field of state action.[420] Thus, the separation of law and morality or religion in the field of healthcare stems not only from the fundamental principle

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[416] Italian Constitutional Court, judgment no. 9/1965, conclusions in point of law para. 5, author's translation.

[417] As observed by Patroni Griffi, 'Il bilanciamento nella fecondazione assistita tra decisioni politiche e controllo di ragionevolezza' [2015](3) Rivista AIC p. 1, 29.

[418] Stammati, 'Riflessioni minime in tema di laicità (della comunità e dello stato).' [2008](2) Dir pubbl p. 341; Rodotà, *Perché laico* (2010) p. 26.

[419] Stammati, 'Riflessioni minime in tema di laicità (della comunità e dello stato).' [2008](2) Dir pubbl p. 341; Di Cosimo, 'Quando il legislatore predilige un punto di vista etico/religioso: il caso del divieto di donazione dei gameti' [2013](21) Stato, Chiese e pluralismo confessionale p. 1, 5; Randazzo, 'La Corte «apre» al giudizio di uguaglianza tra confessioni religiose?' (1998) 43(3) Giur Cost p. 1843.

[420] Balestra, 'Laicità e diritto civile' (2008) 54(1) Rivista di Diritto Civile p. 13, 21-22.

of laicity but also from the many other constitutional provisions which operate in conjunction with it.[421] The case of ethically controversial health technologies in the public healthcare system is covered, first and foremost, by the protection provided by the fundamental right to health as laid down by Article 32 of the Constitution. The relevance of the right to health is symbolically expressed by the wording of this Article, which refers to health as a "fundamental right of the individual".[422] Within the text of the Italian Constitution, this is the only instance in which a single right is explicitly defined as fundamental.[423]

As the proceedings of the Constituent Assembly show, the constitutional conception of the right to health was meant to derive from a strongly liberal approach. According to this all paternalistic views shall be rejected and the focus shall be on the protection of the individual's autonomy.[424] This emphasis on the patient, in conjunction with the general 'personalistic' approach adopted by the Constitution according to Article 2, allows each individual to have full disposal of their body. Moreover, it implies that the content of the notion of health can only be determined by reference to what the patient perceives as health.

Thanks to this underlying constitutional approach, the scope of the concept of health has gradually been broadened.[425] Initially regarded only as a safeguard against physical and mental illness, the state's task of protecting

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[421] Vettori, 'Laicità e servizi pubblici. Il caso della sanità' [2020](3) BioLaw Journal – Rivista di BioDiritto p. 239, 241-ff.

[422] On the possible relevance of this constitutional definition, see Morana, *La salute come diritto costituzionale: Lezioni* (3rd edn 2018) pp. 64 ff., who argues that the explicit emphasis put on the fundamental nature of this right cannot be overlooked. However, she points out that the Constitutional Court has stated that this wording does not necessarily give precedence to the right to health over other conflicting rights (in Italian Constitutional Court, judgment no. 85/2013).

[423] Scaccia in Clementi and others, *La Costituzione italiana: Commento articolo per articolo* (2017) p. 214.

[424] Chieffi, 'Una bioetica attenta ai valori costituzionali' [2019](4) Riv ital med leg dirit campo sanit p. 1247, 1249-ff.

[425] The WHO definition of health as a state of complete physical, mental and social well-being, World Health Organization, 'Basic Documents', 2020, was formally transposed into the Italian legal system as early as 4 March 1947, with legislative decree no. 1086. However, the full transition from a legal concept of health as mere protection of the clinical picture to a broader legal vision of health as psychophysical well-being took place mainly from the mid-1970s, thanks to the influence of the case law, and was completed at the beginning of the 2000s, see Durante in Canestrari and others, *Trattato di biodiritto: Il governo del corpo* (2011) pp. 583-592.

individual health has come to encompass the social dimension of health.[426] From this perspective personal well-being is seen as a means to guarantee the full development of one's personality, including through social and emotional relationships.[427] Additionally, the legislature clearly accepted a comprehensive notion of well-being when defining health as a "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [428] under Article 2, letter o) of legislative decree no. 81/2008.[429]

The expansion of the scope of Article 32 has been confirmed by the case law of the highest courts. For instance, in a notorious case concerning the refusal of life-supporting treatment, the Court of Cassation held that a modern understanding of health could no longer be linked to the mere absence of disease. It required the attainment of a state of complete physical and mental well-being, also involving the inner aspects of life as perceived and experienced by the individual subject.[430] The case concerned a girl, Eluana Englaro, who had fallen into a permanent vegetative state after a car accident and whose father, as her legal guardian, had requested the interruption of artificial hydration and nutrition. According to her father and on the basis of various previous statements of the girl, such treatments were not compatible with her religious and philosophical, ethical convictions and wishes. Starting from a broad understanding of the right to health the Court of Cassation decided that, if the patient's vegetative state were irreversible and her will and convictions were unequivocally ascertained, then the judge could order the interruption of the treatment.

The case law of the Constitutional Court also embraces a wide interpretation of the concept of health. In its judgment on the ban on heterologous

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[426] Morana, *La salute come diritto costituzionale* (2018) pp. 69-ff.

[427] Rivera, 'La comparazione giuridica nel concetto di 'salute': possibili scenari evolutivi alla luce della giurisprudenza costituzionale e sovranazionale' (2017) 39(1) Riv it med leg p. 117, 118-ff.

[428] Author's translation. This statutory definition also coincides with the one found in the WHO Constitution, see Morana, *La salute come diritto costituzionale* (2018) p. 28.

[429] Containing provisions relating to health and safety on the workplace.

[430] Court of Cassation, I sec. civ., judgment no. 21748 of 16.10.2007, para. 6.1. See Scaccia in Clementi and others, *La Costituzione italiana* (2017), who points out that this definition's wording matches with precisely the definition of health endorsed by the WHO.

IVF,[431] i.e. insemination using gametes from a donor outside the couple, the Court held that the inability to have children could have a major negative impact on the right to health of a couple.[432]

As anticipated in the selected examples, some of the leading cases in which the constitutional definition of the fundamental right to health was investigated have involved ethically sensitive issues that have been widely debated in the Italian legal, political and social spheres.[433]

The uncertainty over the exact definition of the right to health in the face of medical progress in ethically controversial fields must be resolved following constitutional principles – namely by combining a patient-centred notion of the right to health and the primacy of the principle of laicity.

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[431] Italian Constitutional Court, judgment no. 162 of 10.4.2014, declaring the ban on heterologous fertilization, as laid down by Article 4(3) of Law no. 40/2004, unconstitutional.

[432] Italian Constitutional Court, judgment no. 162/2014, conclusions in point of law para. 7. For a comment of the judgment, see Vallini, 'Sistema e metodo di un biodiritto costituzionale: l'illegittimità del divieto di fecondazione "eterologa"' [2014] (7) Diritto Penale e Processo p. 825, 825-ff.

[433] The story of Eluana Englaro, for instance, was brought to the attention of the population by the massive media coverage, see Striano, Bifulco and Servillo, 'The Saga of Eluana Englaro: Another Tragedy Feeding the Media' (2009) 35(6) Intensive Care Med p. 1129; Latronico and others, 'Quality of Reporting on the Vegetative State in Italian Newspapers: The case of Eluana Englaro' (2011) 6(4) PloS one e18706; Rambotti, 'Narratives of a Dying Woman: Contentious Meaning at the End of Life' (2017) 3(3) Socius: Sociological Research for a Dynamic World p. 1. Legal scholars extensively discussed the matter, due to its several legal implications on the level of civil law, fundamental and social rights, as well as on the division of powers of the state, *inter alia* Casonato, 'Il caso Englaro: fine vita, il diritto che c'è' [2009] (1) Quaderni cost p. 99; D'Aloia, 'Il diritto di rifiutare le cure e la fine della vita. Un punto di vista costituzionale sul caso Englaro' [2009](2) Diritti umani e diritto internazionale p. 370; Santosuosso, 'Sulla conclusione del caso Englaro' (2009) 3(2) La Nuova Giurisprudenza Civile Commentata p. 127; Molaschi, 'Withdrawal of Artificial Hydration and Nutrition from a Patient in a Permanent Vegetative State in Italy.: Some Considerations on the 'Englaro' Case' [2012](1) Italian Journal of Public Law p. 122; Ferrara, 'Il caso Englaro innanzi al Consiglio di Stato' (2015) 2(1) La Nuova Giurisprudenza Civile Commentata p. 9; Chianca, 'La responsabilità della p.a. per provvedimento illegittimo e risarcimento del danno non patrimoniale: la conclusione della vicenda Englaro' [2017](2) Riv ital med leg dirit campo sanit p. 816. The case has been brought to the attention of several courts and was the subject of four decisions by the country's highest courts (Court of Cassation, judgment no. 21748/2007; Council of State, III sec., judgment of 2.9.2014 no. 4460; Italian Constitutional Court, Decision of the 8.10.2008, no. 334; Council of State III sec., judgment of the 21.6.2017, no. 3058). Moreover, the events were adapted into a film directed by Marco Bellocchio (Dormant Beauty).

Under the principle of laicity, it will be necessary to define the scope of the right to health by, firstly, respecting the ethical and religious views of the individual patient and secondly, drawing on reasons acceptable in a pluralistic society by virtually all individuals.[434]

However, in practice, this constitutional premise has been confronted with the fact that not only the public debates but also the legislation on those ethically controversial matters have been constantly characterised by a certain confusion between moral and legal choices. [435] In some cases the ethical or religious viewpoint of the political majority has been implemented by providing criminal or administrative sanctions on the performance of health treatments that were considered immoral.[436]

This has also occurred due to the strong influence of Catholic values on Italian political decision-making. It has been noted that, when dealing with choices pertaining to ethically sensitive matters, the Italian political and societal debate is often characterised by the opposition between Catholic and secular approaches[437] and tends to become polarised. Frequently this leads to the political majority aligning themselves with the prevailing Catholic ethical views in society.[438] Moreover, the Catholic Church has often been accused of persuading its believers to comply with Catholic values when faced with political choices,[439] thus illegitimately encroaching on the sphere of state law[440] and violating the separation of orders referred to in Article

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[434] Neri, 'Può la bioetica non essere laica?' (1996) XXII(41-42) Notizie di Politeia p. 33; Canestrari, 'Biodiritto (diritto penale)' (2015) Annali VIII, Enc dir p. 99, 106; Colaianni, 'Trent'anni di laicità' [2020](21) Stato, Chiese e pluralismo confessionale p. 52, 66.

[435] D'Avack, 'La legge sulla procreazione medicalmente assistita: Un'occasione mancata per bilanciare valori ed interessi contrapposti in uno Stato laico' (2004) 33(3-4) Diritto di famiglia e delle persone p. 793, 812.

[436] Article 12(1) of the Law on medically assisted procreation (Law no. 40/2004) prescribed an administrative sanction for the use of gametes external to the couple, while criminal sanctions are foreseen by Article 13(3) letter b) for embryo selection and by Article 12(6) for the commercialisation of gametes or embryos.

[437] Di Marzio, 'Bioetica cattolica e laica: una contrapposizione da superare' (2002) 1(2) Dir fam p. 101, 101-ff; Vettori, *Diritti della persona e amministrazione pubblica: La tutela della salute al tempo delle biotecnologie* (2017) p. 11.

[438] Rodotà, *Perché laico* (2010) pp. 127-ff.

[439] As, for instance, happened during the campaign preceding the referendum on the Law on medically assisted reproduction, see D'Amico, 'I diritti "contesi" fra laicità e fondamentalismi' [2014](January) Stato, Chiese e pluralismo confessionale p. 1, 3.

[440] Rodotà, *Perché laico* (2010) pp. 19-ff; D'Amico, 'I diritti "contesi" fra laicità e fondamentalismi' [2014](January) Stato, Chiese e pluralismo confessionale p. 1, 3-ff.

7 of the Constitution and accepted by the Church through the Lateran pacts.[441]

Both the undue influence of the Catholic Church in the legislative process and the imposition of ethical and religious views through legislation bring about a clear violation of the principle of laicity.[442] First, laicity in its meaning of equal distance of the state from all religious confessions is violated whenever the lawmaker openly embraces Catholic positions.[443] Furthermore, the legislative ban on access to certain healthcare treatments, based on an ethical or religious position external to the constitutional system is illegitimate. On the one hand it is in violation of the principle requiring the separation between ethics and the law and, on the other, it imposes on the individual an ethically laden notion of health. In other words, the legal enforcement of ethical or religious norms in the field of healthcare amounts to an infringement of the laicity requirement in conjunction with the fundamental right to health. What's more, when the implementation of ethical or religious views happens by means of criminal law, the violation of the principle of laicity is particularly severe due to the grave invasion of the individual's personal sphere and the lack of any 'social harm' justifying it.[444]

As a result, the courts have been regularly called upon to perform constitutional reviews of legislation dealing with ethically charged issues. They have assumed this task in order to ensure respect for the individuals and their inner ethical convictions, as required in a state governed by the principle of laicity.[445]

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[441] Casuscelli, 'Le laicità e le democrazie: la laicità della "Repubblica democratica" secondo la Costituzione italiana' [2007](1) Quad dir e pol eccl p. 169, 179-180.

[442] D'Avack, 'La legge sulla procreazione medicalmente assistita' (2004) 33(3-4) Diritto di famiglia e delle persone p. 793, 812; Tripodina, 'Dio o Cesare? Chiesa cattolica e Stato laico di fronte alla questione bioetica' [2007](1) Costituzionalismoit p. 1, 10; Rodotà, *Perché laico* (2010) p. 24; Di Cosimo, 'Quando il legislatore predilige un punto di vista etico/religioso: il caso del divieto di donazione dei gameti' [2013](21) Stato, Chiese e pluralismo confessionale p. 1, 2; D'Amico, 'I diritti "contesi" fra laicità e fondamentalismi' [2014](January) Stato, Chiese e pluralismo confessionale p. 1, 2.

[443] Di Cosimo, 'Quando il legislatore predilige un punto di vista etico/religioso: il caso del divieto di donazione dei gameti' [2013](21) Stato, Chiese e pluralismo confessionale p. 1, 6.

[444] See Dolcini, 'Il punto sulla procreazione assistita: in particolare il problema della fecondazione eterologa' (2013) 9(1) Corr merito p. 5, 7-ff.

[445] Rimoli, 'Laicità, postsecolarismo, integrazione dell'estraneo: una sfida per la democrazia pluralista' [2006](2) Dir pubbl p. 335, 358; Chieffi, 'Una bioetica attenta ai valori costituzionali' [2019](4) Riv ital med leg dirit campo sanit p. 1247, 1248.

Although the wording of Constitutional Court's decisions seldom expressly refers to the concept of laicity,[446] its jurisprudence has been striving to remove ethical and religious dogma from the legal norms affecting the individual's fundamental right to health. The Court has shown in several rulings that all elements whose normative force is derived from ethical or religious frameworks outside the law shall be considered irrelevant.[447] Thereby it has confirmed the assumption that the legislature can only endorse one particular ethical conception insofar as it has already become part of the overarching normative constitutional framework.[448]

A clear example can be found when looking at the case law on Law no. 40/2004 on medically assisted reproduction. Ever since the parliamentary discussions, this piece of legislation has been heavily influenced by Catholic ethics.[449] This led to a one-sided weighing of interests by the legislature in favour of the embryo and the Catholic conception of a "natural family",[450] resulting in a regulation whose provisions were in clear contradiction with the principle of laicity and the overall constitutional framework.

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[446] It is often the case that applications of the principle of laicity in the Italian constitutional case law are implicit and can only be found in the legal-cultural background of the motivation, as noted by Colaianni, 'Trent'anni di laicità' [2020](21) Stato, Chiese e pluralismo confessionale p. 52, 65.

[447] The Constitutional Court tends to dismiss all "moralistic inferences" (author's translation), see Vallini, 'Sistema e metodo di un biodiritto costituzionale: l'illegittimità del divieto di fecondazione "eterologa"' [2014](7) Diritto Penale e Processo p. 825, 844. On the contrary, critical remarks were made in cases where ethically controversial issues were left outside the scope of its judgment, see Casonato, 'Sensibilità etica e orientamento costituzionale. Note critiche alla sentenza della Corte costituzionale n. 84 del 2016' [2016](2) BioLaw Journal – Rivista di BioDiritto p. 157; Sorrenti, 'Note minime sul rapporto tra ius, ethos e scientia' [2017](2) Osservatorio Costituzionale p. 1, 6-ff.

[448] 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, 462 ff.

[449] See Rodotà, *Perché laico* (2010) pp. 78-80. The Catholic influences on the legislative procedure before the approval of the Law will be described in Chapter 2, sec. B.I.1.

[450] Author's translation. See Cicero and Peluffo, 'L'incredibile vita di Timothy Green e il giudice legislatore alla ricerca dei confini tra etica e diritto: Ovverosia, quando diventare genitori non sembra (apparire) più un dono divino' [2014](4) Diritto di famiglia e delle persone p. 1290, 1315; Fattori, 'Il rovesciamento giurisprudenziale delle norme in materia di procreazione medicalmente assistita. Interpretazione evolutiva e dilemma contromaggioritario' [2015](1) Quad dir e pol eccl p. 143, 165; Sanfilippo, 'La riscrittura giurisprudenziale della legge n. 40/2004: una caso singolare di eterogenesi dei fini' (2015) 58(2) Riv it dir proc pen p. 851, 864.

As a result, the Constitutional Court has been called upon repeatedly to carry out a constitutional review of the most problematic aspects of the Law. A long collection of rulings has accumulated on this controversial statute in a continuous effort to reshape it and to ensure its conformity with the Constitution. Several provisions have been declared unconstitutional in a process that has been described as a dismantling of the original regulation.[451]

The Constitutional Court's opinion on the relevant interests to be taken into account when dealing with ethically controversial topics is illustrated by judgment no. 162/2004 on heterologous fertilisation (i.e. IVF using gametes from a donor outside the couple).

Firstly, the Court notes that decisions on ethically controversial questions to a large extent fall within the legislature's margin of appreciation. Nonetheless, it is the task of the Constitutional Court to assess the balancing of interests carried out by the lawmaker and to verify whether the outcome is unreasonable.[452] In other words, the decisions on ethically controversial topics are subject to a judicial review of legislation according to the reasonableness requirement.

The reasonableness standard originally derives its constitutional force from Article 3(1) of the Constitution.[453] This prescribes the principle of formal equality and contains the basic assumption that equal situations must be treated equally and different situations differently. In this sense the principle of equality is abstractly translated into a principle of reasonableness: the different treatment of two equal situations is only justified if it is based on reasonable grounds.[454] At first the principle of reasonableness was used primarily to ensure internal coherence within the legal system, in the

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[451] Salanitro, 'A strange loop. La procreazione assistita nel canone della corte costituzionale' [2020](1) Nuove leg civ comm p. 206. For an overview of the main case law that has affected the text of the Law since its approval, see Tomasi, 'Come è cambiata la legge 40 (2004-2017)' <https://www.biodiritto.org/Dossier/Come-e-cambiata-la-legge-40-2004-2017> accessed 26.5.2021.

[452] Italian Constitutional Court, judgment no. 162/2014, conclusions in point of law para. 5.

[453] For a comprehensive reflection on the principle of reasonableness, see Paladin, 'Ragionevolezza (principio di)' (1997) Aggiornamento I, Enc dir p. 899, 899–911.

[454] Barberis, 'Eguaglianza, ragionevolezza e diritti' [2013](1) Rivista di filosofia del diritto p. 191, 196; Romboli, 'Il giudizio di ragionevolezza: la nozione e le diverse stagioni della stessa attraverso la giurisprudenza costituzionale' [2019](1) Revista de la Sala Constitucional p. 20, 23.

classical mathematical sense of non-contradiction.[455] It then evolved in the Constitutional Court's case law and came to encompass the safeguarding of a certain 'justice' within the constitutional system.[456] As such, legal scholars consider that it is currently entirely emancipated from its original textual reference in Article 3(1) of the Constitution.[457] The reasonableness standard is now regarded as enabling a general check on the correct balancing of constitutional values, thereby responding to the needs of a system characterised by a high degree of pluralism.[458]

Being potentially subject to rather arbitrary uses, this standard is usually applied very cautiously by the Court.[459] A regulation would consequently be declared unconstitutional only in cases where it is manifestly unreasonable.[460]

In its judgment on heterologous fertilisation the Court has shown that a piece of legislation that takes an ideologically predetermined stance and seeks to impose a specific ethical value can be considered unconstitutional on the ground of its unreasonableness within the legal order.[461] Indeed, the Court could not find any constitutional basis justifying the prohibition of

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[455] Scaccia in Cerri, *La ragionevolezza nella ricerca scientifica ed il suo ruolo specifico nel sapere giuridico: Atti del convegno di studi 2-4 ottobre 2006, Aula Betti, Facoltà di giurisprudenza, Università degli studi di Roma La Sapienza* (2007) p. 294.

[456] Scaccia in Cerri, *La ragionevolezza nella ricerca scientifica ed il suo ruolo specifico nel sapere giuridico* (2007) 296-ff; Barberis, 'Eguaglianza, ragionevolezza e diritti' [2013](1) Rivista di filosofia del diritto p. 191, 197.

[457] Scaccia in Cerri, *La ragionevolezza nella ricerca scientifica ed il suo ruolo specifico nel sapere giuridico* (2007) p. 300; Romboli, 'Il giudizio di ragionevolezza: la nozione e le diverse stagioni della stessa attraverso la giurisprudenza costituzionale' [2019](1) Revista de la Sala Constitucional p. 20, 24.

[458] Scaccia in Cerri, *La ragionevolezza nella ricerca scientifica ed il suo ruolo specifico nel sapere giuridico* (2007) p. 302.

[459] Patroni Griffi, 'Il bilanciamento nella fecondazione assistita tra decisioni politiche e controllo di ragionevolezza' [2015](3) Rivista AIC p. 1, 4.

[460] Scaccia in Cerri, *La ragionevolezza nella ricerca scientifica ed il suo ruolo specifico nel sapere giuridico* (2007) p. 297; Cartabia, 'I principi di ragionevolezza e proporzionalità nella giurisprudenza costituzionale italiana.: Intervento presentato a: Incontro trilaterale tra la Corte costituzionale italiana, la Corte costituzionale spagnola e il Tribunale costituzionale portoghese, Roma.' (2013) p. 4. <https://www.cortecostituzionale.it/documenti/convegni_seminari/RI_Cartabia_Roma2013.pdf> accessed 14.7.2021

[461] Patroni Griffi, 'Il bilanciamento nella fecondazione assistita tra decisioni politiche e controllo di ragionevolezza' [2015](3) Rivista AIC p. 1, 19-ff.

heterologous fertilisation.[462] The reason for this was that the prohibition stemmed entirely from a religious and ethical framework outside of the Constitution. Therefore the reviewed provisions, involving a violation of individuals' right to health, could not find any reasonable justification within the constitutional system and had to be declared unconstitutional. The Constitutional Court made use of the reasonableness standard (based on Article 3 of the Constitution) to strike down those statutory provisions that contradicted the principle requiring the separation of law and morality, thus completely rewriting the regulation in accordance with the constitutional requirement of laicity.[463]

b The Principle of Laicity in the National Health Service

A broad understanding of the concept of health is not only applied to the right to health in its negative aspect but also to the right to healthcare as a social right. The relevance of this social dimension of the right to health is demonstrated by the Constituent Assembly's choice to place the relevant constitutional provision within the title of the Constitution dedicated to "ethical and social rights and duties".[464] This categorisation reinforces the conviction that no distinction can really be made between the two facets of the right to health and that its positive or social aspect is necessary to fully guarantee its negative character as well.[465] In order to be able to fully exercise the right of self-determination in matters of health, the individual must be offered practical access to health services, guaranteed by a public healthcare system.

As already illustrated, the scope of the individual's right to health can be better appraised when considered in its interaction with the whole constitutional framework. Both as a positive social right and as a negative

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[462] Italian Constitutional Court, judgment no. 162/2014, conclusions in point of law para. 6.

[463] Patroni Griffi, 'Il bilanciamento nella fecondazione assistita tra decisioni politiche e controllo di ragionevolezza' [2015](3) Rivista AIC p. 1, 5, reporting from D'Amico and Puccio, *Laicità per tutti* (2009) p. 20.

[464] See Morana, *La salute come diritto costituzionale* (2018) p. 9; Busatta, *La salute sostenibile: La complessa determinazione del diritto ad accedere alle prestazioni sanitarie* (2018) p. 36.

[465] Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 249; Busatta, *La salute sostenibile* (2018) p. 39.

fundamental right, health is conceived as the means by which the individual can develop his personality.[466] Accordingly, Article 32 of the Constitution read in conjunction with the principles of equality and of the inviolability of human rights compels the public health administration to take action to guarantee the satisfaction of any claim arising from the right to health, in its broadest conception.[467]

Naturally the right to health as a social right is conditioned by financial constraints. According to the Italian Constitutional Court, however, these cannot have such a predominant weight in the legislature's balancing of interests as to compress the 'inviolable' core of the right.[468] Therefore health services that are essential to ensure the minimum core of the right to health cannot be entirely withheld, even if this decision is motivated by financial constraints on health expenditure.[469]

Guaranteeing the core of the fundamental right to health is within the competence of the national legislature. Although the Regions have the power to intervene with concurrent legislation in the field of health protection,[470] the national legislature retains exclusive competence to determine the 'essential levels of services' concerning the social rights that must be guaranteed throughout the national territory.[471] In the field of healthcare those levels are called 'Essential Levels of Care' (*Livelli Essenziali di Assistenza*, LEA) and they represent the health benefit basket of the National Health Service. At the same time, Regions have the discretion to offer additional, non-essential health services to their residents by adding them to their regional catalogues.[472] So it is important to observe that not only those services that are included in the national benefit basket can and must

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[466] Rivera, 'La comparazione giuridica nel concetto di 'salute': possibili scenari evolutivi alla luce della giurisprudenza costituzionale e sovranazionale' (2017) 39(1) Riv it med leg p. 117, 119-ff.

[467] Ferrara in Rodota, Zatti and Ferrara, *Trattato di biodiritto: Salute e sanità* (2011) p. 51; Vettori, *Diritti della persona e amministrazione pubblica* (2017) pp. 54-ff; Busatta, *La salute sostenibile* (2018) p. 41.

[468] As, for instance, declared in the Italian Constitutional Court judgments nos. 267/1998, 416/1995, 304/1994, 247/1992, 455/1990 and 309/1999. On this topic see, *inter alia*, Busatta, *La salute sostenibile* (2018) pp. 83-136.

[469] Leaving open the possibility of requiring a patient co-payment where necessary, see Article 1(3) d.lgs. 502/1992.

[470] According to Art. 117(3) Italian Constitution.

[471] As provided by Art. 117(2) letter m) of the Italian Constitution.

[472] See *inter alia* Balboni, 'I livelli essenziali e i procedimenti per la loro determinazione: Nota a Sentenza n. 88/2003' [2003](6) Le Regioni p. 1183, 1191.

be publicly reimbursed. The Regional Healthcare Systems also have as their primary task the protection of patients' right to health.

The interpretation of the constitutional framework thus defined is a complex task and has attracted the interest of several legal scholars.[473] It is true that there is a lot of room for the legislature to exercise political discretion in establishing the Essential Levels of Care. However, the Constitution requires that all the healthcare services that are needed to protect the 'inviolable' core of the right to health must be included in the LEA and thus guaranteed uniformly throughout the country.[474]

For the purpose of this dissertation it suffices to point out that an essential and minimum content of the right to health is constitutionally protected against delays or omissions that are caused by the national legislature and which are due to political considerations.[475] It follows that, even if ethical or religious objections are raised against the inclusion of a particular health technology in the LEA, the legislature could not act on such reservations if that service is necessary to guarantee the essential core of the right to health.

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[473] See, *inter alia,* Pinelli, 'Sui "livelli essenziali delle prestazioni concernenti i diritti civili e sociali" (art. 117, co. 2, lett. m, Cost.)' [2002](3) Dir pubbl p. 881; Balboni, 'I livelli essenziali e i procedimenti per la loro determinazione' [2003](6) Le Regioni p. 1183; Belletti, 'I "livelli essenziali delle prestazioni concernenti i diritti civili e sociali..." alla prova della giurisprudenza costituzionale. Alla ricerca del parametro plausibile' [2003](3-4) Istituzioni del federalismo: rivista di studi giuridici e politici p. 613; D'Aloia, 'Diritti e stato autonomistico. Il modello dei livelli essenziali delle prestazioni' [2003](6) Le Regioni p. 1063; Balduzzi, *La sanità italiana tra livelli essenziali di assistenza, tutela della salute e progetto di devolution: Atti del convegno, Genova, 24 febbraio 2003* (2004); Atripaldi, 'Diritto alla salute e livelli essenziali di assistenza (LEA)' [2017] Federalismi p. 1.

[474] See for instance Italian Constitutional Court, judgment no. 88/2003. On this topic, see Balboni, 'I livelli essenziali e i procedimenti per la loro determinazione' [2003](6) Le Regioni p. 1183, 1188-1189; Pesaresi, 'La "determinazione dei livelli essenziali delle prestazioni" e la materia " tutela della salute": la proiezione indivisible di un concetto unitario di cittadinanza nell'era del decentramento instituzionale' (2006) 51(2) Giur Cost p. 1733, 1742; Aperio Bella, 'Tecnologie innovative nel settore salute tra scarsità delle risorse e differenziazione: alla ricerca di un equilibrio difficile' [2020](2) Federalismi p. 245, 257.

[475] Pesaresi, 'La "determinazione dei livelli essenziali delle prestazioni" e la materia " tutela della salute": la proiezione indivisible di un concetto unitario di cittadinanza nell'era del decentramento instituzionale' (2006) 51(2) Giur Cost p. 1733, 1746; Atripaldi, 'Diritto alla salute e livelli essenziali di assistenza (LEA)' [2017] Federalismi p. 1, 9; Busatta, *La salute sostenibile* (2018) pp. 97-98.

Moreover, the consideration of the right to health in relation to other constitutional provisions uncovers a mutual relationship between the positive right to healthcare and the principle of laicity. For instance, Article 1 of the Law establishing the Italian National Health Service (Law no. 833/1978) incorporates a principle of equality according to which the National Health Services shall operate "without distinction as to individual and social conditions and in such a way as to ensure the equality of citizens with regard to the service".[476] In line with the principle of laicity it follows from this provision that any religious or ideological convictions that are held by individuals who seek treatment in the public healthcare system must be considered irrelevant.

Likewise, the interpretation of Article 32 in accordance with the 'personalistic' approach of the Italian Constitution reaffirms the individual's fundamental right to self-determination in health matters. This ensures that the patient is not bound to conceive of health in such a way that it corresponds with specific ethical or religious beliefs. Hence the public healthcare system and the healthcare providers must respect the individual's conception of health when providing healthcare.[477] A similar conclusion follows from the principle of laicity[478] and from the constitutional acceptance and promotion of the ethical and religious pluralism inherent in society.[479] In light of this the state must guarantee that the healthcare administration does not exercise its powers by seeking to impose its own ethical views on patients.[480]

From these premises conclusions can also be drawn about the scope of the information that the public health administration is required to provide to the patient. The information that medical professionals give to their

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[476] Article 1(3) Law no. 833/1978 (author's translation).

[477] According to Rodotà, *Perché laico* (2010) p. 27, the welfare state should not be used as a means of dissuasion but as a sign of public willingness to build an environment favourable to effective freedom of decision-making; see also Serra, 'Religione e Sanità. Per una realizzazione laica del diritto alla salute' (2017) 24(2) Diritto e Religioni p. 483.

[478] For laicity also entails refraining from putting resource constraints or economic barriers between individuals and their freedom to pursue their conception of health. See Rodotà, *Perché laico* (2010) p. 28.

[479] Busatta, *La salute sostenibile* (2018) p. 192.

[480] Ferrando, 'Autonomia delle persone e intervento pubblico nella riproduzione assistita. Illegittimo il divieto di fecondazione eterologa' (2014) 30(9) La Nuova Giurisprudenza Civile Commentata p. 393, 396; Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 263.

patients in order to receive their informed consent must be instrumental in ensuring that the patient is fully aware, not only of the medical implications of the procedure, but also that the treatment will be in accordance with their personal ethical convictions.[481] Patient information within the public healthcare system can therefore never become a form of persuasion or deterrence for a particular treatment on ethical or religious grounds.[482]

Against this background, Article 6(1) of Law 20/2004 regulating informed consent in medically assisted reproduction has been strongly criticised. This norm not only obliges doctors to give patients detailed information on the bioethical issues surrounding their treatment at every stage of the procedure, but also requires them to give them advice on the availability of procedures for adoption and fostering. Framed in this manner, the informed consent procedure is likely to dissuade the patient from undertaking medically assisted reproduction treatments, thus constituting a misuse of the powers conferred to the health administration.[483]

Given these factors, based on the constitutional protections afforded to the fundamental rights of the individual, consideration must be given to the institutional element that calls on all public administrations to respect the principle of laicity. Just as the state cannot base its provisions on ethical and religious premises that are external to the constitutional value system, so too the National Health Service must comply with the laicity requirement as developed by the Constitutional Court in its judgment no. 203/1989.[484]

Further, the laicity standard is accompanied by the principle requiring the impartiality of the public administration laid down in Article 97 of the Constitution.[485] This constitutional requirement aims to ensure that the decision-making processes of the public administrations, including those

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[481] Pioggia, ‘Questioni di bioetica nell'organizzazione delle strutture sanitarie’ [2008](2) Dir pubbl p. 407, 431.

[482] Vettori, *Diritti della persona e amministrazione pubblica* (2017) pp. 147 ff.

[483] Pioggia, ‘Questioni di bioetica nell'organizzazione delle strutture sanitarie’ [2008](2) Dir pubbl p. 407, 431; Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 145.

[484] Pioggia, ‘Questioni di bioetica nell'organizzazione delle strutture sanitarie’ [2008](2) Dir pubbl p. 407, 439; Vettori, ‘Laicità e servizi pubblici. Il caso della sanità’ [2020] (3) BioLaw Journal – Rivista di BioDiritto p. 239, 259.

[485] It should be noted, however, that the Constitutional Court has been criticised for not openly linking the principle of impartiality of the public administration with the requirement of laicity, see for instance Guazzarotti, ‘Laicità e Giurisprudenza’ (2012) p. 5. <http://www.europeanrights.eu/public/commenti/Commento_Guazzarotti.pdf> accessed 26.5.2021

of the health administration, are compatible with the principles of a democratic constitutional state,[486] including the fundamental principle of laicity. Hence, the principle of impartiality obliges the public healthcare system to guarantee neutrality in the provision of healthcare services and to ensure its distance from all ideological and religious beliefs.[487]

The concept of laicity currently embraced by the National Health Service corresponds to the open and positive understanding of laicity outlined above. This requires that patients' religious beliefs and their manifestations are supported and promoted also within the context of their healthcare. Article 38 of Law no. 833/1978, for instance, provides that religious assistance must be guaranteed in National Health Service facilities for patients of all religious confessions.[488] However, this concept of laicity also mandates equal treatment, not only of all religious denominations, but also of all ideological and ethical convictions.

Another fundamental consideration concerning the role of the public healthcare system emerges from this constitutional background. Namely, that the availability of publicly provided health services and therefore the very existence of a public healthcare system is indispensable in order to guarantee that the constitutional principle of laicity is respected. If the delivery of health services were left entirely to private entities, then the state could not guarantee the provision of ethically neutral healthcare, except by encroaching on the freedom of thought and religion of private healthcare providers.[489]

Conversely, the availability of public health services can ensure ethical, religious and ideological neutrality in the services provided. As result, room is left for private providers to characterise their health services religiously if they wish[490] and yet there is also a guarantee that no patient is forced to adhere to ethical views that they do not share in order to cover their health needs.[491]

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[486] Cortese, 'Costituzione e nuovi principi del diritto amministrativo' (2020) 28(2) Dir Amm p. 329, 352.

[487] Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 59.

[488] Vettori, 'Laicità e servizi pubblici. Il caso della sanità' [2020](3) BioLaw Journal – Rivista di BioDiritto p. 239, 246.

[489] Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 60.

[490] ibid.

[491] Pioggia, *Diritto sanitario e dei servizi sociali* (2014) p. 171.

It is for the same reason that Law no. 194/1978 guarantees that abortions can be performed at the expense of the National Health Service[492] and in public facilities.[493] Article 2 of Law no. 194/1978 also provides for the involvement of the so-called ‘family counselling services’. The provision of this network of public facilities seeks to guarantee the neutral and pluralist character of healthcare facilities that support women’s decisions to have an abortion.[494]

Confirmation of the assumption that public health facilities are bound to be neutral is also found in the case law of the administrative courts. Acting as the highest administrative court, the Council of State has stated on several occasions that the principle of impartiality binds the public administration when defining the treatments to be offered in the benefit basket of the healthcare system.

The Council of State intervened, for instance, in the aforementioned case of Eluana Englaro when, following the civil judge’s authorisation to stop artificial nutrition and hydration, the Regional Health System of Lombardia refused to provide a facility where the treatment could be interrupted.

One of the reasons given by the regional administration to justify its refusal was that the suspension of artificial nutrition and hydration was not envisaged by the Prime Ministerial Decree establishing the LEA.[495] However, in the opinion of the administrative judges this aspect could not be considered decisive in justifying a refusal to provide the service. This is because the obligations of the health administration do not depend exclusively on the catalogue of health services, but may also derive from a direct application of Article 32 of the Constitution. The obligation to provide the relevant services also derives from the principle of solidarity according to which the state, and hence the regional health administration, must fulfil its duty to remove all obstacles to the full development of the individual’s personality.[496] Moreover, the Council of State observed how the Region had only at a later stage of the procedure raised the question that the treatment was not included in the LEA. The Region’s refusal to provide treatment was not solely based on the exclusion from the health benefit basket but on

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[492] Article 10 Law no. 194/1978.

[493] Article 8 Law no. 194/1978.

[494] Brunelli in Brunelli, Pugiotto and Veronesi, *Scritti in onore di Lorenza Carlassare. Il diritto costituzionale come regola e limite al potere* (2009) p. 866.

[495] Council of State, judgment no. 4460/2014, paras. 40.8 and 41, author’s translation.

[496] The Council of State takes up the formulation of Article 3(2) of the Constitution at para. 57.9 of judgment no. 4460/2014.

ethical and religious reasons and amounted to a “conscientious objection” on the part of the health administration.[497]

As the wording of the judgment emphasised, no concept of disease or health, no matter how morally elevated, could legitimately be imposed on the patient by the State or the health administration.[498] Therefore, the Council of State called on the administration to adopt a neutral vision of healthcare[499] and to offer its services in an ethically neutral manner.[500] It was argued that the imposition of an ethically charged concept of health would violate the patient's right to self-determination in matters of health.[501] Additionally, the court sustained that the Region Lombardia violated the impartiality requirement of public administration as laid down in Article 97 of the Constitution. Access to health services was *de facto* denied by the administration on account of the patient’s ethical convictions and concept of health.[502]

A later judgment on the reimbursement of costs for heterologous fertilisation services also confirms this approach. The Council of State was called upon to rule on another case against Lombardia, based on the fact that this regional administration, along with those of other Italian Regions, had refused to cover the costs of reproductive treatments using gametes from outside the couple, without providing adequate justification.[503] The Region argued once again that, since these treatments were not yet included

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[497] Amitrano Zingale, ‘L'obiezione di coscienza nell'esercizio della funzione pubblica sanitaria’ [2015](3) Giur Cost p. 1099, 1098; Grandi, ‘Questioni di coscienza del pubblico potere: risvolti costituzionali dell'infedeltà/inosservanza dell'amministrazione’ [2016](3) Giur Cost p. 1289, 1294.

[498] Council of State, judgment no. 4460/2014, para. 44.4.

[499] Attollino, ‘La laicità della cura (a margine della sentenza del Consiglio di Stato n. 4460 del 2014 sulle direttive anticipate di trattamento)’ [2015](21) Stato, Chiese e pluralismo confessionale p. 1, 9.

[500] Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 148.

[501] Council of State, judgment no. 4460/2014, paras. 42.5, 46.2 and 55.1.

[502] Council of State, judgment no. 4460/2014, para. 48.

[503] Bergo, ‘Il riconoscimento del diritto alla fecondazione eterologa e alla diagnosi preimpianto nel sistema italiano di “regionalismo sanitario”’ [2015](5) Giur Cost p. 1738, 1738-ff; Lugarà, ‘L'abbandono dei LEA alle Regioni: il caso della procreazione medicalmente assistita’ [2015](1) Rivista AIC p. 1, 1-ff; Iadicicco, ‘La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza’ [2018](1) Rivista AIC p. 1, p. 27; 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, 218.

in the LEA catalogue, there was no obligation to offer them to patients at no charge.[504] By contrast, medically assisted procreation using gametes from within the couple was included in the national benefit basket, being offered so long as a very low contribution (a so-called 'ticket') was paid.

An administrative appeal against the differentiation in the reimbursement regime of the two medical procedures was raised before the Regional Administrative Court (TAR) of Lombardia[505] and eventually reached the Council of State.[506] The highest administrative court confirmed that the non-specification of the service as a nationally essential level of care did not automatically negate the regional administration's obligation to publicly fund the treatment.[507]

Furthermore, the Council checked the administrative decision against the standard of reasonableness. It should be noted, however, that the principle of reasonableness employed by administrative courts differs from the one applied under a constitutional review. This check on the actions of the administrative authorities aims to investigate possible abuses of power, something that is not applicable to legislative activities.[508] Moreover, in the context of administrative justice, the reasonableness requirement is deemed to be based on the constitutional principle of impartiality of the public administration (Article 97 of the Constitution).[509] In this sense, the principle of reasonableness in administrative law also serves as a safeguard for pluralism and ensures a reasonable balancing of the interests at stake.

In the case of heterologous fertilisation, the Council of State held that its funding could not be differentiated from the classic homologous fertilisation without stating the underlying reasons, as required by the principle

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[504] Council of State, III section, judgment of 23.6.2016, no. 3297, para 9.6. See also Giubilei in Colapietro and others, *I modelli di welfare sanitario tra qualità e sostenibilità: Esperienze a confronto* (2018) pp. 396-ff.

[505] TAR Lombardia, judgment of 24.9.2015, no. 2271.

[506] Council of State, judgment no. 3297/2016.

[507] Council of State, judgment no. 3297/2016, para 19.2.

[508] Paladin, 'Ragionevolezza (principio di)' (1997) Aggiornamento I, Enc dir p. 899, 900; Trimarchi Banfi, 'Ragionevolezza e razionalità delle decisioni amministrative' [2019](2) Diritto Processuale Amministrativo p. 313.

[509] Paladin, 'Ragionevolezza (principio di)' (1997) Aggiornamento I, Enc dir p. 899, 900; Morrone, 'Verso un'amministrazione democratica. Sui principi di imparzialità, buon andamento e pareggio di bilancio' [2019](2) Dir Amm p. 381, 390; Cortese, 'Costituzione e nuovi principi del diritto amministrativo' (2020) 28(2) Dir Amm p. 329, 344.

of impartiality.[510] The Region Lombardia, however, could not provide any justification that would be reasonable within the legal system, since the differentiation was based solely on the intention to discourage the use of what the Region considered an ethically controversial treatment.[511] Therefore, according to both the Regional Administrative Court of Lombardia and the Council of State, the provision of different reimbursement regimes for the two medically assisted procreation techniques appeared unreasonable and infringed not only the right to health but also the principle of impartiality of the administration.[512]

III. Procedural Principles and Accountability for Reasonableness in England

1. Constitutional Framework

a Procedural Principles and Political Constitutionalism

In the constitutional system of the United Kingdom there is no equivalent to a substantive and legally binding principle of neutrality for the justification of state action. The primacy of the principle of parliamentary sovereignty under its constitution prevents the formulation of substantive limits on the justification of statutory measures.[513] According to the orthodox position the UK Parliament could, in theory, lawfully enact the most unjust of laws.[514]

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[510] Council of State, judgment no. 3297/2016, para. 16.3.

[511] Iadicicco, 'La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza' [2018](1) Rivista AIC p. 1, 34

[512] Council of State, judgment no. 3297/2016, para 22.c). On the unreasonableness of the differences in the offer of heterologous versus homologous PMA, see also the recent Council of State judgment, no. 7343/2020.

[513] On the principle of parliamentary sovereignty, see Elliott and Thomas, *Public Law* (2020) pp. 245-269.

[514] As demonstrated by the famous example of a law imposing the killing of all blue-eyed babies: "Stephen famously pointed out that '[i]f a [sovereign] legislature decided that all blue-eyed babies should be murdered, the preservation of blue-eyed babies would be illegal'", see Elliott and Thomas, *Public Law* (2020) p. 246. Summed up in very straightforward terms, "Parliament has the legal authority to enact, amend or repeal any law, and no one has the legal authority to stop it from doing so. But this notion is as extravagant as it is simple: it means, as Stephen famously put it, that a law directing the killing of all blue-eyed babies would be valid", Elliott, '1000

Admittedly, especially after the adoption of the Human Rights Act (HRA) 1998[515] and the implications brought about by the former membership of the European Union,[516] this prominent tradition has been partially questioned.[517] However, it is still widely accepted that there are few legal constraints on the content of a democratic decision of the legislature.[518] From this point of view, Parliament would be free to enact a law implementing or enforcing a particular and controversial ethical or religious stance. There is no legal guarantee that prevents the political majority from unilaterally imposing its ethical stances, thereby disrespecting ethical pluralism.

The constitutional framework, however, adopts mechanisms to ensure that this will not be the case. These guarantees differ fundamentally from those analysed in the Italian and German legal systems since they are based on respect for procedural and political principles rather than substantive and legal ones. In the United Kingdom's constitutional culture a renunciation of substantive limitations on the contents of state action is considered necessary so that the existence of pluralism is not disregarded and so that

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words/Parliamentary sovereignty' (2014) <https://publiclawforeveryone.com/2014/10/15/1000-words-parliamentary-sovereignty/> accessed 17.1.2022. This example has been most notoriously used by Dicey, *Introduction to the Study of the Law of the Constitution* (1979) p. 81. However, while it is true that Dicey claims that there are no legal boundaries to parliamentary sovereignty, the anecdote of the 'blue-eyed babies' is rather mentioned as an instance of a Law that Parliament, as a product of its social environment, would not enact. For this perspective, see Walters, *A.V. Dicey and the Common Law Constitutional Tradition* (2021) p. 203.

[515] Which gave effect to the rights and freedoms guaranteed under the European Convention on Human Rights, see Human Rights Act 1998, Introductory Text, and is considered the "new British bill of rights", see Allan, *Constitutional Justice* (2003) p. 226.

[516] The EU supremacy principle has proven "in tension with the UK Parliament's claim to legislative supremacy" and this has brought about the "spectacle of a British court 'disapplying' an Act of Parliament on the ground of its incompatibility with EU law", Elliott in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) p. 75. The author refers to the judgment in the landmark case *Factortame Ltd, R (On the Application Of) v Secretary of State for Transport* [1990] UKHL 13 (11.10.1990). See also Craig, 'Sovereignty of the United Kingdom Parliament after Factortame' (1991) 11(1) Yearbook of European Law p. 221; Young, *Democratic Dialogue and the Constitution* (2017) pp. 194-196.

[517] See Allan, *Constitutional Justice* (2003) pp. 225-ff.

[518] Gordon, *Parliamentary Sovereignty in the UK Constitution: Process, Politics and Democracy* (2015) pp. 42-43.

respect for the views of others is maintained.[519] In the face of pluralism, primacy is given to the outcomes of a democratic decision-making process which truly respects the diversity of opinions existing in society.[520]

Within this constitutional framework, the guarantee that state decisions on ethically controversial issues are acceptable to all – and not solely based on unshared moral or religious reasons – is mainly given by political mechanisms. The importance of public opinion for the legislators cannot be overstated. Legislators will strive to ensure the acceptability of legislative measures to society as a whole, not only in order to maintain public order and obedience, but also with a view to the following political elections where their performance will be judged.[521] Moreover, several other accountability devices, such as public inquiries, ensure continuous public scrutiny of state action throughout the government's and legislature's term of office.[522] The established constitutional order in the United Kingdom is therefore referred to as political constitutionalism.

Political constitutionalism implies that the legitimacy of state measures derives primarily from the guarantee that the legislature will respect democratic procedures and strive for consensus, and not from a substantive restriction on the permissible contents of legislation. There is a reciprocal trust between the legislature and the citizens. On the one hand, there is faith in politics to do what is right because this is what public opinion demands.[523] For this reason the legislature will take all relevant interests into

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[519] ibid, p. 35: "Consequently, Waldron argues 'if we resolve to treat each other's views with respect, if we do not seek to hide the fact of our differences or to suppress dissent, then we have no choice but to adopt procedures for settling political disagreements which do not themselves specify what the outcome is to be'", See also Elliott and Thomas, *Public Law* (2020) p. 85: "Judges have generally recognised that formal and procedural principles have what Laws has called 'a settled, overarching quality'".

[520] Gordon, *Parliamentary Sovereignty in the UK Constitution* (2015) p. 35.

[521] Elliott and Thomas, *Public Law* (2020) p. 245: "Any politician who voted in favour of such a law would be almost certain to lose his or her parliamentary seat at the following election, and it is highly likely that, in such an extreme case, there would be widespread civil and official disobedience, with individuals refusing to obey, and organisations such as the police refusing to enforce such a law".

[522] Wright in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) p. 104; Elliott and Thomas, *Public Law* (2020) p. 52. An example of this continuous public scrutiny is the so-called 'surgeries', whereby MPs give people in their constituency a weekly opportunity to meet them and express their concerns, see <https://www.parliament.uk/site-information/glossary/surgeries/> accessed 18.4.2022.

[523] Elliott and Thomas, *Public Law* (2020) p. 245.

consideration and try to reach, by way of compromise, measures acceptable to the whole of society. When necessary parliamentary committees will also resort to public consultations.[524] On the other hand, the citizens will have to regard legislation that is enacted democratically in this manner as legitimate in its own right.[525] It goes without saying that many citizens may disagree with the substantial outcome. The legislature might even decide to ground a statute, which concerns ethically controversial topics, on one particular moral view held by a majority in Parliament. However, a law that is contrary to the morality of one section of the citizens will still be accepted and respected by them as the result of a process that has reflected the collective judgment of society.[526] The acceptability of the outcome is thus safeguarded by the adherence to a neutral democratic procedure that has equally considered the concerns of all parties and then produced a compromise. Moreover, under a stable system of political constiutionalism, citizens will be able to use the same democratic instruments to advocate for the need to revise legislation in the name of Parliament's political obligation to respect pluralism.[527]

Therefore, even when assuming the prominent orthodox position on the principle of parliamentary sovereignty, it is hardly possible to claim that Parliament is free to enact any legislation and one-sidedly implement one ethical stance. This is also guaranteed by the separation of powers. While the executive branch exercises an enormous influence over the activities of Parliament,[528] oversight by the courts guarantees that actions of both the legislature and the government are not unchecked, albeit this is subject to the principle of parliamentary sovereignty. The constitutional framework thus outlined ensures that state measures remain within the bounds of democratic procedures and acceptability. Indeed, it should not be forgotten that, in the absence of a written and legally binding constitution, the

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[524] For instance, the parliamentary committee that prepared the reform of the Human Fertilisation and Embryology Authority made use of public consultation mechanisms, see House of Commons Science and Technology Committee, 'Human Reproductive Technologies and the Law: Fifth Report of Session 2004–05' (London 14.3.2005), p. 4. <https://publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/7i.pdf> accessed 17.1.2022

[525] Wright in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) p. 102.

[526] Elliott and Thomas, *Public Law* (2020) p. 70.

[527] Gordon, *Parliamentary Sovereignty in the UK Constitution* (2015) p. 47.

[528] Elliott and Thomas, *Public Law* (2020) pp. 229-ff.

constitutional balance in the United Kingdom is maintained by all powers of the state respecting certain limitations, including substantive ones. The very primacy of parliamentary sovereignty is arguably only ensured by the courts' adherence to it as a common law principle. Courts might only feel bound to accept all parliamentary provisions as valid if the legislature continues to abide by the fundamental principles of democracy. Under this approach, if the legislature were to show a lack of respect for political constitutionalism, courts might refuse to accord primacy to parliamentary sovereignty.[529] This has been discussed particularly with reference to the possibility of Parliament abolishing fundamental procedural guarantees of the constitutional order, such as judicial review.[530] Such a scenario would represent an extreme case, signifying a constitutional crisis.[531]

There are more nuanced means that the courts have devised in order to ensure that the activities of the legislature fall within a number of principles that are considered fundamental to the democratic system. Firstly, courts will seek to read all acts of legislation in a way that respects common law constitutional principles derived from a substantive conception of the rule of law.[532] For instance, statutes will be interpreted compatibly with the rights to equality, to freedom of expression and to a fair hearing.[533] Moreover, with the adoption of the HRA in 1998 the provisions of the European Convention on Human Rights have become part of UK law. Section 3(1) of the HRA requires courts to read legislation in a manner that is compatible with Convention rights, insofar as it is possible to do so. Under section 4

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[529] Young, *Democratic Dialogue and the Constitution* (2017) p. 184; Elliott and Thomas, *Public Law* (2020) p. 259.

[530] Elliott and Thomas, *Public Law* (2020) p. 265. See the *obiter dicta* in the case *Jackson & Ors v. Her Majesty's Attorney General* [2005] UKHL 56 (13.10.2005). At para. 102, Lord Steyn notices that "[i]n exceptional circumstances involving an attempt to abolish judicial review or the ordinary role of the courts, the Appellate Committee of the House of Lords or a new Supreme Court may have to consider whether this is a constitutional fundamental which even a sovereign Parliament acting at the behest of a complaisant House of Commons cannot abolish". On this point, see Lakin, 'Debunking the Idea of Parliamentary Sovereignty: The Controlling Factor of Legality in the British Constitution' (2008) 28(4) Oxf J Leg Stud p. 709, 720-ff.

[531] "[J]ust as courts are not eager to provoke a constitutional crisis, so Parliament is not anxious to do so. As a result, both sides, for the most part, exercise a degree of self-restraint born of healthy concern as to how the other might react in the event of an excessive use of legislative or judicial power", Elliott, '1000 words/Parliamentary sovereignty' (2014).

[532] Elliott and Thomas, *Public Law* (2020) pp. 88-89.

[533] See ibid, p. 88.

of the HRA, courts are entrusted with the task of issuing a declaration of incompatibility when acts of Parliament violate Convention rights and their wording excludes any reading that is compatible with them.[534] Although the declaration of incompatibility does not directly invalidate legislation, and it is up to Parliament to voluntarily remedy the relevant violation, it demonstrates that the rights of the Convention are considered to be a catalogue of protected principles that legislators must abide by, irrespective of their ethical or moral view.[535]

These mechanisms reinforce the principle of accountability embodied in political constitutionalism. It is thus ensured that the legislature will be free, if it wishes, to enact legislation that violates a right guaranteed by the ECHR or another fundamental principle of the common law. Yet, if it wishes to do so, this intention will have to be expressed unequivocally.[536] In this way, the violation of a fundamental right would not escape the attentive scrutiny of public opinion.[537]

As a result, the political and procedural principles characteristic of the UK constitutional order ultimately also guarantee the acceptability of the substantive outcome.

More specifically, with regard to the concern for ethical and religious neutrality in ethically controversial matters, the legislature may be expected to strive for it in spite of the fact that it is not translated into a legally binding principle. Legislation might in practice follow a principle of neutrality, not because it is legally bound to do so, but because of the need to issue decisions that are acceptable to all, in order to preserve ethical pluralism and the democratic order.[538] The principle of political accountability also requires the legislature to promote the general interests of the population as

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[534] ibid, p. 90.

[535] McLean in Ashcroft and others, *Principles of Health Care Ethics* (2007) pp. 196-197.

[536] Young, *Democratic Dialogue and the Constitution* (2017) p. 192.

[537] See Lord Hoffmann’s statement in *R v Secretary of State for the Home Department, ex parte Simms* [1999] UKHL 33 (8.7.1999) “[b]ut the principle of legality means that Parliament must squarely confront what it is doing and accept the political cost. Fundamental rights cannot be overridden by general or ambiguous words. This is because there is too great a risk that the full implications of their unqualified meaning may have passed unnoticed in the democratic process”, as reported by Young in Elliott and Hughes, *Common Law Constitutional Rights* (2020) p. 227.

[538] O'Halloran, *State Neutrality* (2021) p. 37.

a whole.[539] Rather than pursuing the interests of a single ethical grouping, it requires it to reach an acceptable compromise in a pluralist society.[540]

The right to equality provides a particular incentive to strive for neutrality. Recognised as one of the fundamental principles of the UK constitutional order,[541] the right to equality was codified under the Equality Act 2010 and includes a right not to be discriminated on grounds of religion or beliefs.[542] Therefore, public authorities have a positive duty to promote equality amongst citizens holding different ethical beliefs.[543] This obligation also derives from the observance of the procedural principles of the democratic order. The equal respect due to all citizens in a democracy mandates that the equality of their beliefs must be upheld and promoted by all public authorities.[544]

b A Secular and Neutral State

One of the greatest threats to state neutrality comes from the privileged constitutional status enjoyed by the Church of England. The latter is in fact regarded as an established church.[545] It enjoys a preferential position in the constitutional order because of the formal ties binding it to the state. There is therefore a very close relationship between church and state.

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[539] Elliott and Thomas, *Public Law* (2020) pp. 96-97.

[540] This is demonstrated by the compromises made to enact the controversial regulation of the use of human embryos for research or fertility treatment, see Chapter 2, sec. C.1.

[541] Elliott and Thomas, *Public Law* (2020) p. 15; O'Cinneide in Elliott and Hughes, *Common Law Constitutional Rights* (2020) p. 173.

[542] Rivers in Durham and others, *Law, Religion, Constitution: Freedom of religion, equal treatment, and the law* (2013) p. 299; O'Halloran, *State Neutrality* (2021) p. 255.

[543] Rivers in Durham and others, *Law, Religion, Constitution* (2013) p. 299.

[544] "Laws LJ, in McFarlane […] advised thus: We do not live in a society where all the people share uniform religious beliefs. The precepts of any one religion – any belief system – cannot, by force of their religious origins, sound any louder in the general law than the precepts of any other. If they did, those out in the cold would be less than citizens; and our constitution would be on the way to a theocracy", see O'Halloran, *State Neutrality* (2021) p. 251. See also Wicks, 'Religion, Law and Medicine: Legislating on birth and death in a Christian state' (2009) 17(3) Med Law Rev p. 410, 418.

[545] Ahdar and Leigh, *Religious Freedom in the Liberal State* (2005) p. 100; Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, 375; O'Halloran, *State Neutrality* (2021) p. 251.

The establishment of the Church of England exerts a twofold influence on state action. First, the Church exercises some functions that are mostly symbolic and rather innocuous,[546] such as organising formal state ceremonies and providing chaplains to state prisons and hospitals.[547] This residual aspect of its establishment is not considered a major challenge to state neutrality. Second, certain elements of this institution allow the Church of England to directly contribute to decisions on government policy and legislation.[548] Despite reform proposals on this point,[549] twenty-six Church of England bishops, traditionally called Lord Spirituals, still sit in the House of Lords today. The Church of England is thus currently the only religion to enjoy such representation in Parliament.[550] This adds to the religious influence already exerted on individual politicians by the Church of England or the Catholic Church,[551] thus compromising the separation of state and religion and the principle of state neutrality.[552]

However, the outcome of parliamentary debates on ethically controversial legislation shows that the presence of Lord Spirituals in the House of Lord has exerted a fairly limited influence.[553] While their contribution

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[546] Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, p. 375; Rivers in Durham and others, *Law, Religion, Constitution* (2013) p. 294; O'Halloran, *State Neutrality* (2021) p. 260.

[547] O'Halloran, *State Neutrality* (2021) p. 251.

[548] Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, p. 375; Bonney, *Monarchy, religion and the state: Civil religion in the United Kingdom, Canada, Australia and the Commonwealth* (2013) p. 5.

[549] First, a reform proposal in this sense came in January 2000 from the report of a Commission on the reform of the House of Lord, see Royal Commission on the Reform of the House of Lords, 'A House for the Future' (January 2020) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/266061/prelims.pdf> accessed 27.1.2022, as reported by Lynch in Radan, Meyerson and Croucher, *Law and Religion: God, the State and the Common Law* (2005) p. 172. More recently, in 2021, a similar proposal was brought forward by the House of Lords, Reform Bill (HC Bill 52) 2012-13, part 1 sec. 1, available at <https://bills.parliament.uk/bills/1067> accessed 9.8.2022.

[550] O'Halloran, *State Neutrality* (2021) p. 251.

[551] Wicks, 'Religion, Law and Medicine' (2009) 17(3) Med Law Rev p. 410.

[552] Wicks, 'Religion, Law and Medicine' (2009) 17(3) Med Law Rev p. 410, 418; Soper, *The Challenge of Pluralism: Church and State in Six Democracies* (3rd edn, 2017) p. 248; Bradney in Nelis, Sägesser and Schreiber, *Religion and Secularism in the European Union: State of Affairs and Current Debates* (2017) p. 187; O'Halloran, *State Neutrality* (2021) p. 499.

[553] Suffice it to say that legislation in ethically controversial areas such as embryo research and reproductive technologies has proved to be relatively liberal, see considerations in Introduction.

to parliamentary debates offers members of the Church of England the opportunity to raise their voices as legislators in ethically controversial matters, liberal measures can easily be enacted despite religious opposition. This is due to the secularisation and pluralism of English society, reflected in the overall composition of the legislative body.[554]

In fact, surveys demonstrate that the UK population is retreating from religion and that attendance at church services, religious marriages and baptisms is diminishing.[555] As English society has thus proven to be increasingly secular and pluralist, the neutrality of state action can be guaranteed alongside the established church.[556] The increasing plurality of moral and religious views is an aspect that the government and the legislature will strive to respect in order to maintain the acceptability and legitimacy of their action. Effectively, religious arguments cannot be used to justify state measures, for they would only sound convincing to a limited section of the population.[557] Public reasoning is therefore *de facto* bound to avoid religious arguments.[558]

The judiciary has also repeatedly declared that courts and other state actors shall be neutral in matters of religion.[559] This reflects the view that a liberal democracy must remain neutral and secular in order to guarantee equal respect for all citizens.[560] These claims are usually also based on Article 9 of the ECHR which requires courts to respect the individual's right

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[554] Soper, *The Challenge of Pluralism* (2017) p. 255 gives the example of the debate over the government's 2013 Marriage Act, which extended marriage to same-sex couples. Despite strong and united opposition among the Lords Spiritual, the proposal was passed by a wide margin.

[555] Bradney, *Law and Faith in a Sceptical Age* (2009) p. 7; Bradney in Nelis, Sägesser and Schreiber, *Religion and Secularism in the European Union* (2017) p. 188; O'Halloran, *State Neutrality* (2021) p. 252.

[556] O'Halloran, *State Neutrality* (2021) p. 251.

[557] Bradney in Nelis, Sägesser and Schreiber, *Religion and Secularism in the European Union* (2017) p. 188.

[558] Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, 397–398.

[559] As Munby J pointed out in *Sulaiman v Juffali* [2001] EWHC 556 (Fam) (09.11.2001), para. 47: "[a]lthough historically this country is part of the Christian west, and although it has an established church which is Christian, I sit as a secular judge serving a multi-cultural community of many faiths". See O'Halloran, *State Neutrality* (2021) p. 265. See also Bradney in Martínez-Torrón, Durham and Thayer, *Religion and the Secular State* (2015) p. 738.

[560] Bradney, *Law and Faith in a Sceptical Age* (2009) p. 29; O'Halloran, *State Neutrality* (2021) p. 265.

to behave freely in matters of religion and belief. The entry into force of the Human Rights Act consequently marked a definitive departure from the principle of established religion and mere tolerance for other religions.[561]

All these guarantees result in a form of neutrality for the justification of state action. This is invoked by Laws LJ in the case of *McFarlane v Relate Avon Ltd*. According to him, while it is true that the legislature may embrace a position that coincides with a Christian standpoint, it will not do so because of moral adherence to that religion but because it believes in the merits of the argument and is thus pursuing the general good on objective grounds.[562]

A strong indication of the shift of legislation towards a principle of neutrality was the amendment of the law regulating charitable organisations through the Charities Act 2006. This regulation is particularly relevant because the economic privileges and financial state support of religious groups derive precisely from their designation as charitable organisations.[563] The status of a charitable organisation is therefore often mentioned as the main source of state support for religious organisations and influences their activities as providers of social welfare services.[564] Traditionally, the advancement of religion was considered a purpose for which organisations would automatically be granted charitable status.[565] After the Charities Act 2006, however, all organisations must demonstrate that they are serving the public benefit. In other words, whereas previously the advancement of religion was presumed to be of public benefit in itself, religious groups must now be assessed to determine the public utility of

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[561] Lynch in Radan, Meyerson and Croucher, *Law and Religion* (2005) p. 174.

[562] *McFarlane v Relate Avon Ltd* [2010] EWCA Civ 880 (29.4.2010), para. 21.

[563] Rivers in Durham and others, *Law, Religion, Constitution* (2013) p. 294; Bradney in Martínez-Torrón, Durham and Thayer, *Religion and the Secular State* (2015) p. 745.

[564] Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, p. 395 notices that the 2008 statutory guidance of the Charity Commission gave "the impression that religions are morally suspect, and only allowed to be 'discriminatory' if they are open and clear to others about the fact. Social welfare should be limited to activities required by 'specific obligations' of the religion and should be disconnected from proselytism".

[565] Martin, 'Liberal Neutrality and Charitable Purposes' (2012) 60(4) Political Studies p. 936, 938; Bradney in Nelis, Sägesser and Schreiber, *Religion and Secularism in the European Union* (2017) p. 189.

their purpose.[566] The abolition of the presumption that religion is for the public benefit leads to the idea that the definition of public good should be derived from non-religious criteria.[567]

This commitment to a principle of neutrality can also be seen in other areas of the regulation of religious organisations. With the strengthening of legal safeguards for the principle of equality the ability of religious organisations to offer public services in line with their religious ethics has diminished. One such instance is the case of a Catholic charity offering adoption services. This was prevented from discriminating against same-sex couples in its activities, as required by the Equality Act (Sexual Orientation) Regulations 2007. The court found that the charity's policy of refusing adoption to same-sex couples was not proportionate to a legitimate aim and therefore not objectively justified under the criteria of Article 14 ECHR and Section 193 of the Equality Act 2010.[568] These developments are in line with the commitment of a pluralist and secular state towards ensuring that all publicly funded welfare services comply with a concept of the common good characterised by religious neutrality and inclusiveness.[569]

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[566] Martin, 'Liberal Neutrality and Charitable Purposes' (2012) 60(4) Political Studies p. 936, 938; Bradney in Martínez-Torrón, Durham and Thayer, *Religion and the Secular State* (2015) p. 743.

[567] Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, 395.

[568] *Catholic Care (Diocese of Leeds) v Charity Commission for England & Wales* [2012] UKUT 395 (TCC) (2.11.2012); see Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, 396; Soper, *The Challenge of Pluralism* (2017) p. 245.

[569] "If the aim is re-characterized as one of ensuring that all publicly-funded welfare service provision is carried out in an ethos of religious neutrality or inclusivity, then of course contracting with distinctively faith-based providers becomes problematic", Rivers, *The Law of Organized Religions: Between Establishment and Secularism* (2010) p. 282. See, also Rivers, 'The Secularisation of the British Constitution' (2012) 14(3) Eccles Law J p. 371, 396.

2. Procedural Legitimacy and Accountability for Reasonableness in the Field of Healthcare Technologies

a Building Consensus

i. Ethics and Law in Courts' Decisions

In the absence of a written constitution containing a legally binding commitment to fundamental substantive rights, more room is left for direct reference to ethical criteria as a basis for decisions on ethically controversial matters, especially in the field of health. The legislature and the government, as well as the judiciary, have been more inclined to openly refer to ethical and moral standards when dealing with ethically controversial medical procedures than their counterparts in Germany and Italy. Since no direct reference can be made to overarching constitutional rights and interests, legislation on ethically controversial issues often finds an explicit basis for legitimacy in compliance with carefully balanced ethical principles.[570] However, rather than trying to impose its own morality, the legislature tries to reconstruct the different ethical stances that are present in its pluralistic society and, to the extent possible, strives to reach a broadly acceptable compromise.[571]

Similarly, the literature has noted that common law courts in particular are prompted to think in ethical or moral terms when confronted with novel controversial cases in medical law.[572] Principles of the common law often require interpretation by the courts and judges might refer to moral standards to settle a legal dispute.[573] It has been noted, for instance, how in the case of *Airedale NHS Trust v Bland* – concerning the withholding of medical treatment from a patient in a persistent vegetative state – [574] "the

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[570] McLean in Ashcroft and others, *Principles of Health Care Ethics* (2007) p. 193.

[571] On the legislature's pursuit of ethical compromise, see later in this section, at para. 2.a.ii.

[572] Brownsword in Murphy, *New technologies and human rights* (2009) pp. 71–72; Brassington, 'On the Relationship between Medical Ethics and the Law' (2018) 26(2) Med Law Rev p. 225.

[573] Brassington, 'On the Relationship between Medical Ethics and the Law' (2018) 26(2) Med Law Rev p. 225, 241.

[574] *Airedale NHS Trust v Bland* [1993] UKHL 17 (4.2.1993).

bench spent a great deal of time establishing the proper meaning and place of the principle of the sanctity of life".[575]

Yet, although the legal solution of a case before the judiciary might be informed by ethical criteria, this does not always imply that a particular moral stance endorsed by the judges in the case is enforced.[576] The reference to ethical criteria is generally used to assist in the interpretation and adaptation of the law to the concrete circumstances of cases where there is no clear legal solution.[577] Analysing the connection between ethical and legal arguments in some medical and health law decisions may help to unravel this apparent contradiction.

As a matter of principle judges are very keen to remark that they sit in "a court of law, not of morals".[578] In the recent case of *Crowter and Others v Secretary of State for Health And Social Care,*[579] concerning the criteria to access abortion according to the Abortion Act 1967, the judges maintained that "[t]he issues which have given rise to this claim [...] generate strong feelings, on all sides of the debate, including sincere differences of view about ethical and religious matters. This court cannot enter into those controversies; it must decide the case only in accordance with the law".[580] This distinction between law and morality in the resolution of ethically challenging cases is also vividly illustrated in the tragic case of the conjoined twins: *Re A (Children)*. This dealt with the case of two twins who were born conjoined and thus destined to die prematurely. One of the twins could have been saved by a surgical operation to split them, but this would have resulted in the death of the other one. The parents, who were devout

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[575] Brassington, 'On the Relationship between Medical Ethics and the Law' (2018) 26(2) Med Law Rev p. 225, 240.

[576] As expressed by Lord Browne-Wilkinson precisely in the case mentioned above of *Airedale NHS Trust v Bland* [1993] UKHL 17: "The judges' function in this area of the law should be to apply the principles which society, through the democratic process, adopts, not to impose their standards on society". On this decision see Montgomery, Jones and Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Mod Law Rev p. 343, 360–361.

[577] Although Brassington, 'On the Relationship between Medical Ethics and the Law' (2018) 26(2) Med Law Rev p. 225, 241 argues that in those cases judges would simply "take a moral position and attach the law's imprimatur to it".

[578] *A (Children), Re* [2000] EWCA Civ 254 (22.9.2000).

[579] *Crowter & Ors, R (On the Application Of) v Secretary of State for Health And Social Care* [2021] EWHC 2536 (Admin) (23.9.2021)

[580] *Crowter & Ors, R (On the Application Of) v Secretary of State for Health And Social Care* [2021] EWHC 2536 (Admin), para 5.

Catholics, refused to consent to the performance of the operation. On appeal by the doctors, the Court of Appeal ordered the operation to be carried out. In reaching this controversial decision the judges pointed out that the decision on the case could only be grounded on legal criteria.[581] The court could not have made its decision by referencing religious values,[582] nor did it have the competence to assess the validity of "competing philosophies"[583] such as the sanctity of human life and utilitarianism.[584]

Especially in cases concerning patient autonomy and informed consent, courts have more and more frequently been declaring that their approach should be legal and rights-based.[585] In the case of Ms. Pretty, a patient suffering from a degenerative illness and wishing to end her own life, the appellate committee of the House of Lord admitted to be neither "entitled [n]or fitted to act as a moral or ethical arbiter".[586] In a similar case, *Ms B v An NHS Hospital Trust*,[587] the High Court dismissed the ethical argumentations of the doctors and applied the established legal principles on informed consent.[588]

An apparent disavowal of the assumption that courts are 'courts of law and not of morality' has occurred in a number of tort law cases in the field of healthcare, where judges have used the consideration of public policy or legal policy at various stages of the assessment process to decide whether or not to award recovery for damages suffered as a result of medical negli-

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[581] Cranmer, ''A Court of Law, Not of Morals?'' (2008) 160(1) Law & Justice - The Christian Law Review p. 13, 16; Veitch, *The Jurisdiction of Medical Law* (2017) p. 136.

[582] Wicks, 'Religion, Law and Medicine' (2009) 17(3) Med Law Rev p. 410, 422.

[583] *A (Children), Re* [2000] EWCA Civ 254.

[584] "The court is not equipped to choose between these competing philosophies', noted Brooke LJ (at 98F), essentially referring to the conflicting answers to the question 'to separate or not?' that would be offered by a deontological, sanctity of human life, ethic and a consequentialist, quality of life, ethic", Huxtable, 'Logical Separation?: Conjoined Twins, Slippery Slopes and Resource Allocation' (2010) 23(4) Journal of Social Welfare and Family Law p. 459, 461–462.

[585] Foster and Miola, 'Who's in Charge?: The Relationship Between Medical Law, Medical Ethics, and Medical Morality' (2015) 23(4) Med Law Rev p. 505, 508-ff.

[586] *Pretty v Director of Public Prosecutions and Secretary of State for the Home Department* [2001] UKHL 61 (29.11.2001), see McLean in Ashcroft and others, *Principles of Health Care Ethics* (2007) p. 194.

[587] *Ms B v An NHS Hospital Trust* [2002] EWHC 429 (Fam) (22.3.2002).

[588] "[T]he law took control of a matter with ethical content and defined it as legal", Foster and Miola, 'Who's in Charge?' (2015) 23(4) Med Law Rev p. 505, 508–509.

gence. [589] This is because the determination of what is considered to be contrary to public or legal policy openly includes moral considerations.

It is undeniable that the relevance of the use of moral arguments in tort law cases is necessarily constrained by, and limited to, the peculiar structure of the law of torts.[590] However, courts' considerations in tort law cases have the potential to influence areas of law beyond the law of torts, and are thus relevant to mention within this thesis. This is due to the expansive character of tort law. On the one hand, it can constantly embrace new categories of damages and concepts of 'harm'.[591] On the other hand, it applies to (almost) all agents in society,[592] including medical doctors and hospitals, thereby also shaping public healthcare.[593] Indeed, as illustrated by the examples briefly discussed below, rulings on medical negligence by NHS providers often grant heads of damages that result in a *de facto* shift in the allocation of NHS resources.

In tort law cases dealing with negligence, legal or public policy considerations have, *inter alia*, played a role in determining the existence and extent of a duty of care,[594] the breach of that duty and the damage thus caused. This has happened especially in cases involving damage that went beyond a straightforward physical injury, where a certain margin of uncertainty was left by the absence of unambiguous legal coordinates.[595] Therefore, policy considerations are especially relevant in cases related to the advances in reproductive health, which cannot be easily solved by

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[589] While a discussion of the structure of the law of torts is beyond the scope of this thesis, an account of the debate is available in Nolan and Davies in Burrows, *English Private Law* (2013) pp. 927-ff. On the "Nature and Functions of the law of tort" see Rogers, *Winfield and Jolowicz on Tort* (18th edn 2010) pp. 1-57.

[590] Robertson in Robertson and Tang, *The Goals of Private Law* (2009) pp. 268-ff.

[591] For instance, "the action for wrongful conception can be viewed as a product of 'medical progress'. While relatively new to the UK courts, this action clearly demonstrates the law of tort's ability to embrace a widening ambit of harms under its cloak. Bringing fresh promises for claimants whose reproductive decisions are destroyed through negligent treatment, it has also required the courts to address difficult ethical and legal questions", Priaulx, 'Joy to the World! A (Healthy) Child is Born! Reconceptualizing 'Harm' in Wrongful Conception' (2004) 13(1) Soc Leg Stud p. 5, 6.

[592] This is consistent with Dicey's model of the rule of law, according to which public bodies and officials should be subject to the same law as private individuals, see Dicey, *Introduction to the Study of the Law of the Constitution* (1979) pp. 193-195.

[593] Koyuncu in Kirch, *Encyclopedia of Public Health* (2008) p. 1398.

[594] Rogers, *Winfield and Jolowicz on Tort* (2010) pp. 182-183.

[595] Nolan and Davies in Burrows, *English Private Law* (2013) pp. 939-940.

reference to traditional case law. Insofar as "[h]eightened expectations in the promises of [reproductive medicine] have not only led to an expansion of the ethical obligations of medicine, but also legal duties under the law of negligence",[596] courts have found themselves in the position to assess whether new claims of damages can or should be afforded protection under tort law. In doing so, policy considerations have come into play and have taken the shape of moral considerations or theories. Policy considerations based on reasonableness and justice have for instance influenced the outcome of actions for 'wrongful life'[597]: first "because to allow the action would be inconsistent with the sanctity of life and, secondly, because it was beyond the power of reason to conceive of a duty owed to a person to terminate that person's existence".[598] Here, the argument of the sanctity of life is used to support the view that awarding damages for the event of being born is wrong in itself.[599] Such policy consideration entails a moral argument and is classified as "deontological".[600]

In the resolution of such difficult and controversial cases, however, the considerations of morality should not reflect "the subjective view of the judge but what he reasonably believes that the ordinary citizen would regard as right", as pointed out by Lord Steyn in the landmark case of *Macfarlane and Another v Tayside Health Board*.[601] The decision concerned a claim for damages for the maintenance of a child born after a failed sterilisation. While courts had traditionally recognised this claim,[602] the House of Lords rejected it by invoking various policy considerations, such as principles of distributive justice, fairness and reasonableness. Lord Steyn, while openly stating that his judgment was based on the "moral theory" of distributive justice, qualified it as a pursuit of what would be morally

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[596] Priaulx, 'Joy to the World! A (Healthy) Child is Born! Reconceptualizing 'Harm' in Wrongful Conception' (2004) 13(1) Soc Leg Stud p. 5, 6.

[597] In an action for 'wrongful life', a child would claim for damage to them arising from their birth. The English case law and legislation does not allow children to bring action for failure to terminate the pregnancy, see *McKay v Essex Area Health Authority* [1982] QB 1166 (19.2.1982).

[598] Nolan and Davies in Burrows, *English Private Law* (2013) p. 940.

[599] Robertson in Robertson and Tang, *The Goals of Private Law* (2009) p. 263.

[600] ibid.

[601] *Macfarlane and Another v Tayside Health Board (Scotland)* [1999] UKHL 50 (25.11.1999).

[602] Priaulx, 'Joy to the World! A (Healthy) Child is Born! Reconceptualizing 'Harm' in Wrongful Conception' (2004) 13(1) Soc Leg Stud p. 5, 7.

acceptable to the ordinary person.[603] He openly denied that such policy considerations would derive from "the subjective view of the judge" and claimed that they would rather result from "what he reasonably believes that the ordinary citizen would regard as right".[604] Lord Steyn reiterated this point when he elsewhere sustained that "[m]orality is a vital force in judicial decision making. It is however, not the judge's personal values that are relevant but his perception of prevailing community standards. In this sense law and morality are inextricably interwoven".[605] Yet, it has been pointed out how policy considerations in the *Macfarlane and Another v Tayside Health Board* case might have masked the moral preconception of individual judges.[606] This is reflected in Lord Clyde's judgement, who argued that ethical and moral considerations could not inform the decision in the case in light of the contrasting ethical views in society, ranging from the sanctity of human life to the recognition of the value of reproductive autonomy.[607] In the following case of *Rees v Darlington Memorial Hospital*

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[603] "Should the parents of an unwanted but healthy child be able to sue the doctor or hospital for compensation equivalent to the cost of bringing up the child for the years of his or her minority, i.e. until about 18 years? My Lords, I am firmly of the view that an overwhelming number of ordinary men and women would answer the question with an emphatic 'No.' And the reason for such a response would be an inarticulate premise as to what is morally acceptable and what is not", *Macfarlane and Another v Tayside Health Board (Scotland)* [1999] UKHL 50.

[604] *Macfarlane and Another v Tayside Health Board (Scotland)* [1999] UKHL 50.

[605] Lord Steyn, 'Perspectives Of Corrective And Distributive Justice In Tort Law' [2002] (37) Irish Jurist p. 1, 12.

[606] "The suspicion is that their Lordship's appeal to the supposed opinion of ordinary people was merely a means by which they might objectify their own moral persuasions by presenting them as those of the majority of society", Chico, 'Wrongful Conception: Policy, Inconsistency and the Conventional Award' (2007) 8(2) Med Law Int p. 139, 144. See also Priaulx, 'That's One Heck of an "Unruly Horse": Riding Roughshod over Autonomy in Wrongful Conception' (2004) 12(3) Feminist Legal Stud p. 317, 322-323.

[607] "To take but one example, the 'sanctity of human life' can be put forward as a ground for justifying the law's refusal of a remedy for a wrongful conception. On the other hand the general recognition of the importance of family planning in society and of the propriety of adopting methods of contraception including those involving a treatment designed to achieve a permanent solution, reflects the recognition that unlimited child-bearing is not necessarily a blessing and the propriety of imposing a liability on those who negligently provide such a treatment. Particularly where consideration of public policy can be invoked by both sides to the dispute, it seems to me that to proceed upon such a ground is unlikely to lead to any confident solution", *Macfarlane and Another v Tayside Health Board (Scotland)* [1999] UKHL 50.

NHS Trust,[608] the Lord Steyn indeed recognised that the issue was profoundly controversial due to the existence of such conflicting positions.[609] Nonetheless, it is important to note that judges are aware of the fact that moral considerations can only play a role in decision-making to the extent that they reflect policy considerations that the ordinary citizen would agree with and regard as right.[610]

Similarly, in the case of a woman having lost the ability to bear children due to an undiagnosed cancer (*Whittington Hospital NHS Trust v XX),* the Supreme Court sought to appraise the public moral attitude towards surrogacy in order to decide whether or not a right to have a child through surrogacy could be recognised as a head of damages according to the common law.[611] In the minority opinion, Lord Carnwath maintained that the claim should be denied based on an assessment of what would be morally acceptable to the ordinary citizen.[612] Lady Hale, writing the majority judgment, drew on recent developments in the law and in social attitudes to argue that the attitude towards surrogacy in society had changed, thus making the award of damages for the costs of a foreign commercial surrogacy no longer contrary to public policy.[613] In the interpretation of the common law standards, while partially resorting to morality, both minority and majority opinions in *Whittington Hospital NHS Trust v XX* placed particular emphasis on the legislative background. Lord Carnwath argued that there is a need for legal coherence and that, in highly controversial

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[608] *Rees v Darlington Memorial Hospital NHS Trust* [2003] UKHL 52 (16.10.2003).

[609] See also Chico, 'Wrongful Conception' (2007) 8(2) Med Law Int p. 139, 144.

[610] See also the arguments in the case of *Rees v Darlington Memorial Hospital NHS Trust* [2003] UKHL 52, where the judges tried to clarify and legitimise the reasoning behind *Macfarlane and Another*. In particular, Lord Steyn once again stated that in *Macfarlane and Another* "the Law Lords relied on legal policy. In considering this question the House was bound, in the circumstances of the case, to consider what in their view the ordinary citizen would regard as morally acceptable". For criticism on this point, see Priaulx, 'That's One Heck of an "Unruly Horse"' (2004) 12(3) Feminist Legal Stud p. 317, 328.

[611] For a summary of the facts and a commentary see Domenici and Günther, 'Judging Commercial Surrogacy and Public Policy: An Analysis of Whittington Hospital NHS Trust v XX (UK Supreme Court)' [2020](2) BioLaw Journal – Rivista di BioDiritto p. 373; Alghrani and Purshouse, 'Damages for reproductive negligence: commercial surrogacy on the NHS?' [2019](135) LQR p. 405.

[612] Domenici and Günther, 'Judging Commercial Surrogacy and Public Policy' [2020] (2) BioLaw Journal – Rivista di BioDiritto p. 373, 383.

[613] Domenici and Günther, 'Judging Commercial Surrogacy and Public Policy' [2020] (2) BioLaw Journal – Rivista di BioDiritto p. 373, 376–379.

areas, the rules should be dictated by Parliament.[614] Lady Hale focused on the changes in the legal framework for surrogacy – including reform proposals – and in the law's conception of family.[615] This demonstrates that, in cases dealing with issues for which Parliament has provided a general statutory framework, an acceptable consensus on the principles that guide public morality can be achieved by respecting the legitimacy of the parliamentary process. Insofar as Parliament has expressed a view on these matters through legislation the role of the judiciary is to apply these standards, which are reached by consensus in the democratic process, and to combine them with the principles of the common law.[616]

The described case law reveals that courts would not openly seek to justify their decisions based on their own moral views. Rather, they strive to capture the accepted morality in society, or the morality of the ordinary citizen, in order to interpret existing law and to develop a widely acceptable legal criterion for their decision.[617] In this sense, ethics can be used to interpret the law as a 'living instrument' and to adapt it to the evolution of society's morals.[618] In conclusion, there is an understanding that a legitimate and acceptable decision can only be reached by respecting the moral attitudes of society as a whole.

ii. Acceptability of Legislation through Procedural Legitimacy

The reconstruction of a moral consensus on which legislation on highly controversial ethical issues can be rooted lies primarily in the responsibility of the democratic legislature. Although a shared public morality is almost unattainable in a pluralistic state, the idea that the democratic process can still achieve acceptable solutions for society as a whole is part of

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[614] *Whittington Hospital NHS Trust v XX* [2020] UKSC 14 (1.4.2020), para. 63.

[615] *Whittington Hospital NHS Trust v XX* [2020] UKSC 14, paras. 29-39; see Domenici and Günther, 'Judging Commercial Surrogacy and Public Policy' [2020](2) BioLaw Journal – Rivista di BioDiritto p. 373, 378; Bhatia, 'Whittington Hospital NHS Trust v XX [2020] UKSC 14' (2020) 17(4) Bioethical Inquiry p. 455, 458.

[616] On the difficult interaction between legislation and tort law, see Steele and Arvind in Steele and Arvind, *Tort Law and the Legislature: Common Law, Statute and the Dynamics of Legal Change* (2013) pp. 1-ff.

[617] Lord Steyn, 'Perspectives Of Corrective And Distributive Justice In Tort Law' [2002] (37) Irish Jurist p. 1, 12.

[618] Moss and Hughes, 'Hart–Devlin Revisited: Law, Morality and Consent in Parenthood' (2011) 51(2) Med Sci Law p. 68, 74.

the approach of political constitutionalism outlined above. Adherence to a democratic procedure in which the opinions of all members of society are equally relevant guarantees legitimacy and acceptance.

On highly divisive issues of medical and health law, the achievement of a consensus via procedural legitimacy is facilitated by the circumstance that English society has a relatively unified and pragmatic position.[619] Because of their fundamental acceptance of the primacy of democratic procedure,[620] the members of the community agree to fully respect the decision taken by the sovereign Parliament.[621] A certain spirit of pragmatism contributes to the awareness that the democratic decision is welcome, at least in so far as it provides legal certainty, and that the possibilities of calling for further public debate and for amendments to legislation remain open.[622]

Especially when deciding on ethically controversial issues in the field of health technologies, procedural legitimacy can be preserved by adhering to a set of standards in the decision-making process. Those standards are not, however, enshrined in statutory form. They have rather been inferred from observations of the continuous development of the political processes.

One such political development is represented by the emblematic case of legislation regulating the use of human embryos outside the body. Initially passed in 1990 and then thoroughly revised in 2008, the Human Fertilisation and Embryology (HFE) Act came into being as the result of a procedure aimed at reaching a compromise and increasing public acceptance.[623] Moreover, the procedural mechanisms foreseen in the Act preserve the legitimacy and acceptability of the regulation of embryos.

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[619] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 264; Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 144.

[620] Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 144.

[621] "[M]embers will be disposed to accept a procedural justification on a contested question, not as a confirmation of the correctness of the standard set but as a reason for respecting the regulatory position that, for the time being at least, has been adopted", Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 126.

[622] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 264; Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 144: "the British public tend to be fairly pragmatic about their ethical differences, accepting that life goes on and that there will be opportunities in future to renew debates and review decisions".

[623] "[The Human Fertilisation and Embryology 1990 Act is] significant as a model for establishing a workable compromise between incompatible ethical positions. The issues underlying the provisions of the Act are not ones on which a consensus exists

The preparation for the drafting of what was already anticipated to be an ethically controversial piece of legislation began with the establishment of the Warnock Committee in 1982.[624] The task of the Warnock Committee was to examine the social, ethical and legal implications of recent and future developments in human assisted reproduction in order to make recommendations on the principles that should guide legislation and policies in the field.[625] The committee, acknowledging the existence of many different ethical approaches in society, engaged in an attempt to discover a compromise on which to base an acceptable common moral position.[626] The committee was able to reach a pragmatic[627] compromise that is still valid today,[628] based on the recognition of the embryo as an entity having a "special status".[629] The committee's activity also had the merit of being able

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within our society", Montgomery, 'Rights, Restraints and Pragmatism: The Human Fertilisation and Embryology Act 1990' (1991) 54(4) Mod Law Rev p. 524.

[624] Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology' (London 1984), p. 4. <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

[625] ibid, pp. 2-ff.

[626] "Our modest hope was that we could come up with something practical, regretted no doubt by some as too lax, by others as too strict, but something to which, whatever their mental reservations, everyone would be prepared to consent", Warnock, 'Moral Thinking and Government Policy: The Warnock Committee on Human Embryology' (1985) 63(3) The Milbank Memorial Fund Quarterly Health and Society p. 504, 521. See also Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, pp. 2-5.

[627] "[A]ll the deliberations of the Committee were restricted, though not always explicitly, by a kind of pragmatic framework", Warnock, 'Moral Thinking and Government Policy' (1985) 63(3) The Milbank Memorial Fund Quarterly Health and Society p. 504, 505.

[628] In revisiting the law in 2005 in preparation for the amendments that would be passed in 2008, the House of Commons Science and Technology Committee in its report Human Reproductive Technologies and the Law 2005 recognised the enduring validity of the Warnock approach: "[g]iven the rate of scientific change and the ethical dilemmas involved, we conclude, therefore, that we should adopt an approach consistent with the gradualist approach, of which the Warnock Committee is one important example", House of Commons Science and Technology Committee, 'Human Reproductive Technologies and the Law', London 14.3.2005, p. 22. See also Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 313.

[629] See Warnock in Leist, *Um Leben und Tod: Moralische Probleme bei Abtreibung, Künstlicher Befruchtung, Euthanasie und Selbstmord* (2nd edn 1990) p. 227; McMillan, *The Human Embryo In Vitro*: *Breaking the Legal Stalemate* (2021) pp. 41-47.

to involve the population, thus increasing acceptance of the decision.[630] The establishment of the committee led to debates at various levels and the committee itself encouraged and took into account comments from the public.[631]

Based on the committee's report Parliament passed the Human Fertilisation and Embryology Act 1990 and established a new regulation and monitoring authority called the Human Fertilisation and Embryology Authority (HFEA).[632] Due to the ethical relevance of the issues at stake, MPs were given the freedom to vote according to their conscience. The delegation of the more specific regulation and monitoring of embryo research and infertility treatment to the Authority was recommended by the Warnock Committee in order to ensure an ongoing consideration of medical and scientific evidence.[633]

The activity of the HFEA contributes in many respects to the procedural legitimacy and acceptability of the resulting regulation. The involvement of experts ensures that decisions are clear, consistent and informed by scientific evidence.[634] The Authority is able to guarantee the flexibility of the regulatory framework,[635] which can be continuously adapted not only to medical and scientific developments but also to changes in public attitudes. In addition, the HFEA is independent of political influence[636] and yet ultimately subject to parliamentary accountability mechanisms.[637] This helps to preserve public oversight and transparency, and thus the legitimacy, of the Authority's decisions. Moreover, the HFEA regularly engages in public

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[630] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 390.

[631] Warnock, 'Moral Thinking and Government Policy' (1985) 63(3) The Milbank Memorial Fund Quarterly Health and Society p. 504, 505.

[632] The ethical and normative framework of the HFE Act, as well as the specific tasks of the Authority will be addressed in Chapter 2, sec. C.I.

[633] Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, pp. 75-ff.

[634] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 201.

[635] Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524, 533.

[636] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 118.

[637] Montgomery, 'Rights, Restraints and Pragmatism' (1991) 54(4) Mod Law Rev p. 524, 527; Montgomery, Jones and Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Mod Law Rev p. 343, 347.

consultations.[638] Besides these elements, the basic democratic legitimacy of the Authority is guaranteed by the fact that its powers derive directly from a mandate given by Parliament and that the normative and ethical framework to be followed has been clearly defined by the legislature.[639]

Based on the observation of this political process, which took place at the end of the last century, some assumptions can be made on the set of principles of procedural legitimacy that are desirable in the regulation of reproductive technologies.[640]

Firstly, the decision-making process begins by assuming a position of fundamental openness to all opinions that are potentially present in the debate. All parties must be equally encouraged to advocate their positions.[641] When voting on a proposal, legislators have the freedom to vote according to their conscience without being bound by party discipline.[642] Elements of participatory and deliberative democracy, such as transparency and public consultation, should be incorporated into the process in order to increase acceptance and legitimacy of the decisions taken.[643] The majority shall be

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[638] Moore, 'Public Bioethics and Deliberative Democracy' (2010) 58(4) Political Studies p. 715, 723; Montgomery, Jones and Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence' (2014) 77(3) Mod Law Rev p. 343, 356. See, for instance, the public consultation on PGD conducted in 1999 by the HFEA and the Advisory Committee on Genetic Testing (ACGT), which resulted in the outcome document: Human Genetics Commission, Human Fertilisation & Embryology Authority, 'Outcome of the public consultation on preimplantation genetic diagnosis' (London November 2001), as illustrated by Scott and others, 'The Appropriate Extent of Pre-implantation Genetic Diagnosis: Health Professionals' and Scientists' Views on the Requirement for a 'Significant Risk of a Serious Genetic Condition'' (2007) 15(3) Med Law Rev p. 320, 321–326.

[639] Montgomery, 'Law and the Demoralisation of Medicine' (2006) 26(2) Legal stud p. 185, 192.

[640] The continuous validity, in more recent times, of the so inferred set of procedural standards will be checked in the case studies, see Chapter 2 sec. C and Chapter 3 sec. C.

[641] An approach based on the procedural aspects of public reasoning has been embraced by the Nuffield Council of Bioethics, which "committed itself to a different legitimation narrative based on the procedural aspects of public reasoning rather than its conceptual content. In response to the fact of pluralism, it has committed to a principle of 'inclusiveness […] On this basis legitimacy can be drawn partly from the fact that no one has been excluded from the debate", Montgomery, 'Bioethics as a Governance Practice' (2016) 24(1) Health Care Anal p. 3, 19–20.

[642] This practice is discussed, *inter alia,* in Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 131.

[643] Moore, 'Public Bioethics and Deliberative Democracy' (2010) 58(4) Political Studies p. 715, 727; Penasa, 'Converging by Procedures: Assisted Reproductive Technology

prepared to have regard to the ethical views of different minorities and shall endeavour to reach a decision that represents a compromise acceptable to the parties. For instance, although pro-choice positions were overwhelmingly favoured in the debate on abortion regulation, the legislative outcome nevertheless took into account the concerns of the pro-life group by establishing that doctors must act as gatekeepers.[644]

Furthermore, the arguments put forward by all parties should meet the standard of reasonableness necessary for the purposes of public reasoning.[645] They should be consistent, supported by evidence and theoretically acceptable as valid by the rest of the participants in the public discussion.[646]

The involvement of experts in the decision-making process is also an important element of procedural legitimacy. Collecting and communicating scientific information on the risks and benefits of new health technologies improves the public's understanding of the issue and contributes to the legitimacy and acceptability of the decision.[647]

Finally, the compromise reached by the democratic decision must be flexible. Indeed, it shall always remain open to being re-examined through the same procedure in the light of new evidence or arguments, or simply as a result of a shift in public opinion.[648]

In sum, reaching a compromise as widely shared as possible – together with guaranteeing that flexibility, ethical debate and respect for scientific

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Regulation within the European Union' (2012) 12(3-4) Med Law Int p. 300, p. 309; Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 121.

[644] Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 132.

[645] In this sense, public debate in England tends to follow the elements of public reasoning in a liberal society developed by Rawls, see Liddell, *Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society* (2003) pp. 50-51. See also Montgomery, 'Bioethics as a Governance Practice' (2016) 24(1) Health Care Anal p. 3, 20; Syrett, 'Deconstructing Deliberation in the Appraisal of Medical Technologies: NICEly Does it?' (2006) 69(6) Mod Law Rev p. 869, 873.

[646] Liddell, *Biolaw and Deliberative Democracy* (2003) pp. 55-ff; Montgomery, 'Bioethics as a Governance Practice' (2016) 24(1) Health Care Anal p. 3, 20.

[647] Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 308; Brownsword and Goodwin in Brownsword and Goodwin, *Law and the Technologies of the Twenty-First Century* (2012) p. 253; Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 118.

[648] McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 116; Brownsword, 'Regulating The Life Sciences, Pluralism And The Limits Of Deliberative Democracy' [2010](22) SAcLJ p. 801, 822.

evidence are maintained – ensures that there is, if not consensus on every single detail of a piece of legislation, at least a commitment to respect the reached decision as a legitimate one.[649]

b Judicial Review and Accountability for Reasonableness

i. Procedural Duties and Rights in the NHS

The procedural element legitimising state regulation in controversial fields in England also plays a fundamental role in allocation decisions in the healthcare system. With regard to ethically controversial technologies, the implementation of procedural principles is suited to ensuring that decisions by NHS public bodies cannot legitimately be based on a particular moral or religious position – unless this reflects the consensus position existent in society or democratically achieved by the legislature.

When it comes to decisions on financing given health services, reliance on procedural principles is essential. Under English law there is no enforceable individual right to health in the sense of a substantive right of patients to claim specific treatments.[650] The wording of the National Health Service Act 2006 is that the Secretary of State has a duty to "continue the promotion of comprehensive health care in England".[651] This formulation, however, does not imply a legal obligation to provide a specific level of healthcare,[652] also considering that an obligation of such a scale could not possibly be achieved with limited human and financial resources.[653]

Amongst the other duties of the Secretary of State the National Health Service Act 2006 mentions the duty to secure continuous improvement in the quality of services[654] and a duty to reduce inequalities. Accordingly

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[649] Brownsword, 'Regulating The Life Sciences, Pluralism And The Limits Of Deliberative Democracy' [2010](22) SAcLJ p. 801, 829.

[650] McHale and Fox, *Health Care Law: Text and Materials* (2nd edn 2007) p. 1; Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) pp. 112-113; Herring, *Medical Law and Ethics* (2020) p. 66.

[651] See National Health Service Act (NHS Act) 2006 sec. 1.

[652] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 112; Lock and Gibbs, *NHS Law and Practice* (2018) p. 8.

[653] Foster, 'Simple Rationality?: The Law of Healthcare Resource Allocation in England' (2007) 33(7) J Med Ethics p. 404; Lock and Gibbs, *NHS Law and Practice* (2018) p. 8.

[654] National Health Service Act (NHS Act) 2006 sec. 1A.

the Secretary of State "must have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service".[655]

However, the listed duties are better understood as 'target duties' that confer procedural rights rather than substantial ones.[656] The Secretary of State, as well as the other public bodies to whom the implementation of these duties is delegated, have wide discretion in identifying the scope of NHS services.[657]

The majority of NHS services commissioning is carried out by the 42 Integrated Care Boards, which in 2022 took on the commissioning functions of the local Clinical Commissioning Groups (CCGs) following the reform introduced by the Health and Care Act 2022. Each ICB is entrusted with developing its own normative framework to make commissioning decisions in light of the limited resources available.[658] In doing so an ICB is not required to commission specific services, but rather to "arrange for the provision of [certain health services] to such extent as it considers necessary to meet the reasonable requirements of the people for whom it has responsibility".[659] In exercising their function, CCGs used to have a duty to conduct a fair procedure, take into account specific considerations and fulfil other procedural duties listed in the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.[660] After the abolishing of CCGs, ICBs were given several procedural duties as incorporated in the National Service Act 2006, such as the duty to publish constitution (sec. 14Z29), to follow principles of effectiveness and efficiency, to reduce inequalities between persons with respect to their ability to access health services, and others (secs. 14Z32-14Z44). In other words, the relevant legal obligations that are imposed on NHS public bodies mostly concern elements of the process through which they reach decisions. To increase acceptability, local CCGs

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[655] National Health Service Act (NHS Act) 2006 sec. 1C.

[656] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 113.

[657] McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 16; Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 112.

[658] As it used to be the case for the local CCGs, see Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) pp. 48-49.

[659] See National Health Service Act (NHS Act) 2006 sec. 3(1).

[660] Lock and Gibbs, *NHS Law and Practice* (2018) pp. 143-146.

tended to include public consultation techniques in their procedures.[661] A duty of public engagement was assigned to CCGs by the National Health Service Act of 2006 and is not transferred to ICBs. Section 14Z required the CCG to "secure that individuals to whom the services are being or may be provided are involved (whether by being consulted or provided with information or in other ways)" in the planning of the commissioning arrangements.[662] Section 14Z36 now sets a duty for each ICB to promote the involvement of patients, and their carers and representatives. These provisions are part of a more comprehensive recent emphasis on public involvement in NHS decision-making.[663]

Against this background, the sense in which patients' rights vis-à-vis the NHS are mainly procedural becomes clear. The only exceptions are the substantive rights that are derived from a certain type of decision made by the National Institute for Health and Care Excellence (NICE). Namely those made via Technology Appraisal Guidance.[664] Through this instrument, NICE – a public body created precisely with the aim of ensuring more consistency in healthcare commissioning across the country – can issue recommendations that are binding on the NHS.[665]

The rights to NHS treatments as procedural rights have been acknowledged and reaffirmed with the NHS Constitution in 2010. This confers on individuals the right to "expect local decisions on funding of […] drugs and treatments to be made rationally following a proper consideration of the evidence" and states that "[i]f the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain

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[661] "More recently, the Labour Government has proclaimed its commitment to the use of such participatory mechanisms to assist in making policy and reaching decisions locally within the NHS […]. Decisions which are reached by a process which can be viewed as inclusive, rational and procedurally fair will command public acceptance, given commitment to some form of reciprocity among citizens", Syrett, 'Deconstructing Deliberation in the Appraisal of Medical Technologies' (2006) 69(6) Mod Law Rev p. 869, 871–873.

[662] See Syrett in Laing and others, *Principles of Medical Law* (4th edn 2017) p. 40.

[663] ibid, p. 39.

[664] See Newdick in Nagel and Lauerer, *Prioritization in Medicine* (2016) pp.124-ff; Lock and Gibbs, *NHS Law and Practice* (2018) p. 317.

[665] NHS bodies are therefore legally obliged to fund technologies recommended via this procedure, as provided by sec. 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

that decision to you".[666] Public and patient involvement also features in the document, which states that patients have the right to "be involved, directly or through representatives, in the planning of healthcare services commissioned by NHS bodies".[667]

The NHS Constitution has been defined as a "bill of rights for patients".[668] Although it is a declaratory document that is not legally binding as such,[669] it received statutory recognition when the Health and Social Care Act 2012 included a duty on the Secretary of State to "have regard to the NHS Constitution"[670] when exercising their functions. A duty to promote awareness of the NHS Constitution and to provide health services in a way that promotes the NHS Constitution also applies to the ICBs[671] and to NHS England.[672] Therefore, the procedural rights set out in the NHS constitution must always be taken into account by health authorities and can only be legitimately derogated from for justifiable reasons.[673]

While procedural rights do not guarantee the patient's entitlement to a given health treatment, they nonetheless ensure that the decision-making procedure followed by the authority is fair and transparent and that the resulting decision is justifiable and based on reasonable grounds.[674]

Patients' procedural rights to health services can be effectively enforced by challenging NHS decisions through the judicial review of administrative

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[666] Department of Health and Social Care, 'The NHS Constitution for England' (1.1.2021) <https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england> accessed 23.3.2022. See Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 114; Newdick in Nagel and Lauerer, *Prioritization in Medicine* (2016) p. 125.

[667] Department of Health and Social Care, 'The NHS Constitution for England', 1.1.2021.

[668] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 114.

[669] Lock and Gibbs, *NHS Law and Practice* (2018) pp. 25-26.

[670] National Health Service Act (NHS Act) 2006 sec. 1B. See also Palmer, 'Mechanisms of Health Care Accountability, Marketisation and the Elusive State' (2011) 11(1) Med Law Int p. 69, 70.

[671] National Health Service Act (NHS Act) 2006 sec. 14Z32.

[672] National Health Service Act (NHS Act) 2006 sec. 13C.

[673] Lock and Gibbs, *NHS Law and Practice* (2018) p. 35; Newdick in Nagel and Lauerer, *Prioritization in Medicine* (2016) pp. 124-ff; Herring, *Medical Law and Ethics* (2020) pp. 52-53.

[674] Newdick in Nagel and Lauerer, *Prioritization in Medicine* (2016) p. 125; Newdick in McLean, *First Do No Harm* (2016) p. 580.

actions.[675] According to the common law standards developed in this area, the patient may argue that the decision to refuse funding of a given technology was either contrary to the principle of legality, irrational or otherwise procedurally improper.[676]

While detailed specification of the merits of each ground for judicial review will be provided in the next paragraph, it is important to underline here that the remedy is always a procedural one.[677] Once the court has determined that the decision is illegal, unreasonable or procedurally improper, it will not replace it with one it considers legitimate by ordering the provision of the treatment.[678] Rather, courts normally overturn the decision and invite the authority to deliberate again following the criteria indicated in the ruling.[679] The patient is not granted a right to a particular substantive outcome, but only to a legal, reasonable and procedurally fair decision, and thus a right to have the authority reconsider the case following the guidelines provided by the court.[680] Provided it follows the legality requirement and all procedural safeguards as indicated by the court, the decision-maker has the right to reach a decision with the same substantive outcome.[681] In practice, this is seldom the case as health authorities usually tend to accommodate the patient's request after a successful judicial review.[682]

Judicial review of administrative action benefits the legitimacy of decision-making in the NHS[683] in two ways. First, control by the judiciary

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[675] McHale and Fox, *Health Care Law* (2007) p. 45; Syrett, 'Health Technology Appraisal and the Courts: Accountability for Reasonableness and the Judicial Model of Procedural Justice' (2011) 6(4) Health Econ Policy Law p. 469, 470.

[676] Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 94; McHale and Fox, *Health Care Law* (2007) p. 45.

[677] Newdick, 'Solidarity, Rights and Social Welfare in the NHS – Resisting the Tide of Bioethics?' (2008) 27(3) Medicine and Law p. 547, 559.

[678] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 114; Newdick in McLean, *First Do No Harm* (2016) p. 583; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 191.

[679] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 113; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 189.

[680] Allan, *Constitutional Justice* (2003) p. 191.

[681] Newdick, 'Solidarity, Rights and Social Welfare in the NHS – Resisting the Tide of Bioethics?' (2008) 27(3) Medicine and Law p. 547, 559.

[682] Newdick, 'Health Care Rights and NHS Rationing: Turning Theory into Practice' (2014) 32(2) Revista Portuguesa de Saúde Pública p. 151.

[683] Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) p. 135.

increases legitimacy by ensuring that NHS public bodies follow those principles of procedural justice that allow acceptable decision-making in an ethically controversial field where there can be no substantive agreement on the outcome.[684] The executive is held to standards of legality, consistency and accountability[685] that ensure that its decisions fall within the democratically agreed normative framework.[686] Second, the purely procedural nature of the remedy is in line with the recognition that health authorities are in a better position to reach allocative choices, for they have the necessary expertise and resources, as well as an overview of the overall needs of the community.[687] This guarantees that the final decision remains with a democratically legitimised decision-maker and that the court will not be accused of overstepping its boundaries and acting as a legislator.[688] The axiological position taken by the democratic legislature is thus guaranteed against both executive and judiciary action.[689] This is especially important in the field of ethically controversial technologies, where it is essential to ensure that health authorities cannot use commissioning decisions to enforce their hostility towards a certain health technology.

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[684] "[A]ttention should be given to the possibilities which law opens up for enhancing the public acceptability of decision-making which has the consequence of denying or restricting access to healthcare as a good of special moral importance, given the existence of incommensurable moral positions in a state of ethical pluralism", Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) p. 135.

[685] Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 125; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 189; Elliott and Thomas, *Public Law* (2020) p. 494.

[686] Palmer, 'Resource Allocation, Welfare Rights—Mapping the Boundaries of Judicial Control in Public Administrative Law' (2000) 20(1) Oxf J Leg Stud p. 63, 70-71; Syrett, 'Health Technology Appraisal and the Courts' (2011) 6(4) Health Econ Policy Law p. 469, 470.

[687] Elliott and Thomas, *Public Law* (2020) p. 560.

[688] ibid, p. 491.

[689] "Unless the courts have been clearly mandated to adjust the legislative position, their responsibility is to uphold the legislative position not to rewrite it and engage with axiological pluralism in their own way", Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 141.

ii. Reasonableness and Relevancy in Judicial Review

Courts have traditionally maintained a rather deferential attitude towards public authorities in the judicial review of health resources allocation. Especially when it comes to politically sensitive choices, courts consider themselves neither equipped nor authorised to interfere in the decisions of the responsible political body.[690]

This is especially true when choices of distributive justice are involved. If one considers ethics in terms of distributive justice, each local health authority has its own 'ethical framework' based on which allocation decisions are made.[691] Allocating funds on the basis of utilitarian ethics, or due to budgetary restrictions, to prioritise treatments for life-threatening diseases over milder conditions will be considered legitimate.[692] In the case of *R v North Lancashire Health Authority, ex p A, D & G*, for instance, the Court of Appeal recognised that "it is an unhappy but unavoidable feature of state funded health care that Regional Health Authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others obviously less demanding of medical intervention".[693] It is indeed acknowledged that the ambition of a comprehensive free health service can never be fully achieved.[694] Hence, administrative courts respect the necessity for

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[690] Newdick in McLean, *First Do No Harm* (2016) p. 580; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 188.

[691] Newdick, 'Solidarity, Rights and Social Welfare in the NHS – Resisting the Tide of Bioethics?' (2008) 27(3) Medicine and Law p. 547, 558–559. See also Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 49.

[692] In *R v North Lancashire Health Authority, ex p A, D & G* [1999] EWCA Civ 2022 (29.7.1999), LJ Auld found that "it makes sense too that, in settling on such a policy, an Authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure". A critical stance towards such deference is taken by Foster and Miola, 'Who's in Charge?' (2015) 23(4) Med Law Rev p. 505, 523: "NHS bodies will (effectively non-reviewably) take into account not only data justified by the objective utilitarian tools of Quality Adjusted Life Years per Pound, but also views which can only bear the name of ethical or moral".

[693] *R v North Lancashire Health Authority, ex p A, D & G* [1999] EWCA Civ 2022.

[694] "The truth is that, while he has the duty to continue to promote a comprehensive free health service and he must never, in making a decision under section 3, disregard that duty, a comprehensive health service may never, for human, financial and

public authorities to make pragmatic and efficient rationing decisions due to the limited resources available to the NHS.[695]

The fact that public authorities tend to make their decisions on the basis of pragmatic criteria and explicitly on the basis of budgetary restrictions is one reason why there is no case in which an NHS body explicitly refuses to fund a treatment on the basis of its ethical desirability.[696] For instance, the many constraints on fertility treatments, including age restrictions or the limit of one child per couple, are generally justified by the very limited availability of NHS resources or by a lack of clinical effectiveness.[697]

Nonetheless, a reading of the case law and an analysis of the grounds for judicial review indicates that an NHS local authority's refusal to commission a certain treatment based solely on the moral or religious views of its members could potentially be quashed by the administrative courts.

As mentioned in the last paragraph, the fact that patients' rights and remedies against the decisions of NHS bodies are only procedural does not imply that authorities are free to determine the funding of health technologies as they please. Such an argument gains added force given that the courts have recently adopted the so-called 'hard look' strategy. While traditionally administrative courts had been "wholly deferential and

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other resource reasons, be achievable", *Coughlan & Ors, R v North & East Devon Health Authority [1999] EWCA Civ 1871* (16.7.1999) para. 25. See Lock and Gibbs, *NHS Law and Practice* (2018) p. 8.

[695] See, *inter alia*, the cases of *AC, R (on the application of) v Berkshire West Primary Care Trust & Anor* [2011] EWCA Civ 247 (11.3.2011): "But the court is not appropriately placed to make either clinical or budgetary judgments about publicly funded healthcare: its role is in general limited to keeping decision-making within the law" and *R. v Cambridge Health Authority, ex parte B* [1995] EWCA Civ 49 (10.3.1995): "Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make".

[696] On the tendency of English public authorities to reach pragmatic – rather than value-driven – decisions, see Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 256.

[697] In *R v Sheffield Health Authority, ex p Seale* (1994) 25 BMLR 1 (17.10.1994), for instance, the court sanctioned a decision of the health authority to set an age cut-off of 35 years for women wanting to undergo in vitro fertilisation, taking into account the smaller likelihood of achieving a pregnancy in older age, see Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 106; McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 21; Wang, 'From Wednesbury Unreasonableness to Accountability for Reasonableness' (2017) 76(3) Camb Law J p. 642, 645–646. See also Brazier, 'Regulating the reproduction business?' (1999) 7(2) Med Law Rev p. 166, 176.

uncritical"[698] of allocative decisions in the health system, a series of cases in the mid-1990s initiated a new stage of judicial review. English courts have started to use a strong interpretation of procedural rights to allow for stricter control of NHS bodies' decisions. Since then, local health authorities' activities have been subjected to more rigorous scrutiny.

The reasons for this shift in the courts' jurisprudence can be found in a number of developments during this period. One change was that the rationing of health services became more explicit. This happened first with the reform of the health system by the National Health Service and Community Care Act 1990, which created an internal market for health services and made commissioning decisions in the NHS publicly visible, and then with the establishment of NICE. [699] However, the major factor in the shift to a 'hard look' judicial review was undoubtedly the introduction of the language of human rights into the English legal system.[700] Admittedly, the primarily procedural nature of patients' rights in the healthcare system has not changed since the adoption of the Human Rights Act 1998. As confirmed by the case law of both English courts[701] and the ECtHR,[702] Convention rights do not confer a positive right to obtain a specific health

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[698] Newdick in McLean, *First Do No Harm* (2016) p. 573.

[699] See Syrett, 'Impotence or Importance?: Judicial Review in an Era of Explicit NHS Rationing' (2004) 67(2) Mod Law Rev p. 289, 295–298. Up to that stage, the efficient use of healthcare resources was largely left to the doctors themselves, who had to decide in each individual case whether the treatment of a particular patient met the criteria of efficiency and cost-effectiveness of the healthcare system, see Syrett, 'Impotence or Importance?' (2004) 67(2) Mod Law Rev p. 289, 293; Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) pp. 18-19.

[700] "English public law was already 'feeling its way' towards a 'culture of justification' and the HRA accelerated the pace of this process", Wang, *Can Litigation Promote Fairness in Healthcare?: The Judicial Review of Rationing Decisions in Brazil and England* (2013) p. 169.

[701] See, *inter alia,* the decisions in the cases *North West Lancashire Health Authority v A, D & G* [1999] EWCA Civ 2022: "In any event, Article 8 imposes no positive obligations to provide treatment", and *Condliff, R v North Staffordshire Primary Care Trust* [2011] EWCA Civ 910 (27.7.2011). See Newdick, 'Judicial Review: Low-priority treatment and exceptional case review' (2007) 15(2) Med Law Rev p. 236, 244; Herring, *Medical Law and Ethics* (2020) p. 72.

[702] See, *inter alia,* ECtHR cases *Wiater v Poland*, app no. 42290/08 (15.5.2012) and *McDonald v The United Kingdom*, app. no. 4241/12 (20.5. 2014) para. 54, according to which the state enjoys an extensive margin of appreciation in assessing priorities in the context of the allocation of limited State resources.

treatment.[703] However, the HRA and the subsequent introduction of the proportionality standard have contributed to a ‘cultural shift’ in the case law on judicial review.[704] In other words, although Convention rights do not encompass a right of access to specific health treatments, the idea that an interference with the right to health must be adequately justified by the health authorities increasingly became part of the courts’ approach.[705]

One of the first cases featuring this novel approach is the above-mentioned *R v North West Lancashire Health Authority ex p A, D and G*, in which the court quashed the decision of a health authority refusing to fund gender reassignment surgery for three patients suffering from gender dysphoria.[706] While the specialist consultant had identified a clinical need for surgery, the local Authority had refused funding. Its adopted policy classified gender reassignment surgery amongst the procedures allocated a low priority due to their lack of beneficial health gain or proven benefit.[707] These treatments could only exceptionally be funded in case of overriding clinical need or other exceptional circumstances. In deciding on the case the Court of Appeal announced this new stage of judicial review by assert-

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[703] Foster, ‘Simple Rationality?’ (2007) 33(7) J Med Ethics p. 404, 405–406; Wang, *Can Litigation Promote Fairness in Healthcare?* (2013) p. 170; Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 123.

[704] This is clearly demonstrated by the debates in jurisprudence on the opportunity that courts might replace the judicial review criteria of unreasonableness with proportionality. In fact, “the possibility of the Wednesbury unreasonableness test being replaced by proportionality has been canvassed. It has been argued that proportionality, as a more structured test, is preferable to Wednesbury and that any concerns there might be about proportionality being unduly intrusive can be assuaged by recourse to the notion of deference”, Elliott and Thomas, *Public Law* (2020) p. 561. See *inter alia* Sales, ‘Rationality, proportionality and the development of the law’ (2013) 129(2) LQR p. 223; Craig, ‘Proportionality, Rationality and Review’ [2010](2) New Zealand Law Review p. 265.

[705] This has led to higher standards for judging the reasonableness of NHS bodies’ decisions, Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 119; Wang, ‘From Wednesbury Unreasonableness to Accountability for Reasonableness’ (2017) 76(3) Camb Law J p. 642, 648.

[706] “Especially since 1999 and the case of ex p A, D & G, a very different approach has developed in which the courts have adopted a proactive role by subjecting public authority discretion to close scrutiny under a ‘hard look’ approach”, Newdick in Flood and Gross, *The Right to Health at the Public/Private Divide* (2014) p. 125. See also McHale and Fox, *Health Care Law* (2007) pp. 57-ff; McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 22.

[707] As pointed out by the court, this list included gender reassignment, tattoo removals, cosmetic plastic surgery, sterilisation reversal, and hair transplantation.

ing that "the more important the interests of the citizen that the decision effects, the greater will be the degree of consideration that is required of the decision-maker".[708] The court argued that the Health Authority had failed to evaluate the condition as an illness worthy of treatment. While the authority had claimed to recognise gender dysphoria as a disease before the court, the wording of the policy strongly indicated that it did not believe in its treatment. Therefore, the policy failed to reflect medical evidence in its priority scale,[709] relegating gender dysphoria to an "attitude or state of mind which does not warrant medical treatment".[710] The fact that an exception was provided for in cases of overriding clinical need was effectively rendered meaningless by the reluctance to accept gender reassignment as an effective treatment, amounting to a 'blanket policy' against its funding.

Two considerations played a major role in the court's conclusions. First, health authorities' policies are to be found unreasonable when they are not grounded on proper and rational medical grounds.[711] Second, blanket bans are not acceptable, as individuals must be given the chance to demonstrate their clinical need for treatment.[712] Although the authority had not explicitly included ethical considerations in its decision not to fund sex reassignment surgery, its policy was quashed on the grounds that there was clearly a fundamental reluctance to consider this treatment worthy of funding. This hesitancy was not based on a rational consideration of clinical need, but rather on a bias against the treatment stemming from non-medical considerations.

This decision, together with a subsequent stream of 'hard look' judicial review cases, applied the standard of reasonableness in a stricter manner

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[708] LJ Buxton in *R v North Lancashire Health Authority, ex p A, D & G* [1999] EWCA Civ 2022, see Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) p. 174.

[709] Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) pp. 101-102.

[710] *North West Lancashire Health Authority v A, D & G* [1999] EWCA Civ 2022.

[711] Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) pp. 173-174; McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 22.

[712] The illegality of 'blanket bans' on treatments was confirmed in the decision in the case of *Rogers, R v Swindon NHS Primary Care Trust & Anor* [2006] EWCA Civ 392 (12.4.2006), see Newdick, 'Judicial Review' (2007) 15(2) Med Law Rev p. 236, 238. On the unlawfulness of blanket bans, see Newdick, 'Solidarity, Rights and Social Welfare in the NHS – Resisting the Tide of Bioethics?' (2008) 27(3) Medicine and Law p. 547, 559; McLean and Mason in McLean and Mason, *Legal and Ethical Aspects of Healthcare* (2009) p. 22.

than had traditionally been the case. Whereas previously courts had declared that they would only find decisions unreasonable if they were affected by 'Wednesbury unreasonableness'[713], and thus "so outrageous in its defiance of logic or accepted moral standards[714] that no sensible person [...] could have arrived at it",[715] they are currently inclined to invalidate all decisions based on flawed logic.[716]

However, the exact interpretation that courts will give to the reasonableness requirement in each individual case remains rather difficult to predict.[717] Even with heightened scrutiny, the standard of reasonableness leaves considerable room for discretion to public authorities.

For the purposes of this dissertation, it is a consideration of the reasonableness criterion alongside another ground for judicial review, relevancy, which confirms that a decision of a local health authority could be overturned if it is based on a moral or ethical bias against a certain health technology. Indeed, these two remedies tend to overlap considerably in the reasoning of the courts.

Judicial review on the grounds of relevancy assesses whether public bodies' decisions have been based on relevant considerations and serve the purpose set by the legislature.[718] According to the relevancy doctrine, public

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[713] On the criterion of 'Wednesbury unreasonableness' and its use by the administrative courts, see *inter alia*, Daly, 'Wednesbury's Reason and Structure' [2011](2) Public Law p. 238; Craig, 'The Nature of Reasonableness Review' (2013) 66(1) Curr Leg Probl p. 131; Leyland and Anthony, *Textbook on Administrative Law* (8th edn 2016) pp. 325-ff; Dindjer, 'What Makes an Administrative Decision Unreasonable?' (2021) 84(2) Mod Law Rev p. 265.

[714] Moral standards thus feature in the jurisprudence concerning the reasonableness standard. Similar to what has been observed in tort law cases, these represent the ethical standards accepted by society as a whole and not the moral views of the court or public authority making the decision.

[715] Lord Diplock in *Council of Civil Service Unions v Minister for the Civil Service* [1984] UKHL 9 (22.11.1984), see Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 97.

[716] Lord Woolf MR in *Coughlan & Ors, R v North & East Devon Health Authority* [1999] EWCA Civ 1871, see Newdick, *Who Should We Treat? Rights, Rationing, and Resources in the NHS* (2005) p. 97. On the shift in the interpretation of the unreasonableness criterion see also, Wang, *Can Litigation Promote Fairness in Healthcare?* (2013) p. 129.

[717] Elliott and Thomas, *Public Law* (2020) pp. 552-553; O'Cinneide in Elliott and Hughes, *Common Law Constitutional Rights* (2020) p. 185.

[718] Herling, 'Weight in Discretionary Decision-Making' (1999) 19(4) Oxf J Leg Stud p. 583, 585; Craig, 'The Nature of Reasonableness Review' (2013) 66(1) Curr Leg Probl p. 131, 135.

bodies may only use their discretion in pursuance of the goals determined by the legislature.[719] A decision grounded on a consideration of factors that are legally irrelevant or inconsistent with the statutory purpose will be judged unlawful.[720]

While logically it would seem appropriate to check the decision for relevancy before reasonableness,[721] the two grounds of judicial review are often considered together. This was also the case in the landmark case *Associated Provincial Picture Houses v Wednesbury Corporation*,[722] where the court argued that a reasonable decision is also one that excludes irrelevant factors from consideration.[723] Taking irrelevant matters into account might lead to unreasonable outcomes.[724] It thus appears that the grounds for judicial review need not be considered separately, but may arise simultaneously and influence each other in the process.[725]

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[719] As "Parliament must have conferred the discretion with the intention that it should be used to promote the policy and objects of the Act", *R v Minister of Agriculture and Fisheries ex p. Padfield* [1968] UKHL 1 (14.2.1968), as reported by Herling, 'Weight in Discretionary Decision-Making' (1999) 19(4) Oxf J Leg Stud p. 583, 590.

[720] The relevancy doctrine "requires decision-makers to take into account all legally relevant matters and to ignore legally irrelevant matters", Elliott and Thomas, *Public Law* (2020) p. 549.

[721] "If the public body pursues a purpose that is outside its statutory remit, or bases its determination on an irrelevant consideration, then its decision is struck down on that ground. The fact that the contested decision was reasonable is no defence in this respect. Thus the assumption is that the contested action has or can survive review in terms of purpose and relevance, and is then subject to reasonableness review. It follows that when the court is dealing with reasonableness review the factors taken into account by the primary decision-maker have been or can be adjudged relevant, since otherwise the case would be decided within the confines of the relevancy head of review", Craig, 'The Nature of Reasonableness Review' (2013) 66(1) Curr Leg Probl p. 131, 136.

[722] *Associated Provincial Picture Houses Ltd v Wednesbury Corporation* [1947] EWCA Civ 1 (10.11.1947).

[723] As reported by Leyland and Anthony, *Textbook on Administrative Law* (2016) p. 327.

[724] "[T]aking irrelevant considerations into account, or ignoring relevant considerations . . . may lead to an irrational result", Boddington v British Transport Police , as observed by Ip, 'Taking a 'Hard Look' at 'Irrationality': Substantive Review of Administrative Discretion in the US and UK Supreme Courts' (2014) 34(3) Oxf J Leg Stud p. 481, 503.

[725] Leyland and Anthony, *Textbook on Administrative Law* (2016) p. 327. See also, Craig, 'The Nature of Reasonableness Review' (2013) 66(1) Curr Leg Probl p. 131, 140; Newdick, 'Health Care Rights and NHS Rationing' (2014) 32(2) Revista Portuguesa de Saúde Pública p. 151, 154; Dindjer, 'What Makes an Administrative Decision Unreasonable?' (2021) 84(2) Mod Law Rev p. 265, 293.

The relevance standard seems to prohibit health authorities from basing a decision to fund a technology on their ethical or moral views on it. The ethical perspective of the members of commissioning bodies is not legally relevant to the NHS objective of promoting comprehensive health, nor does it serve the statutory mandate of, *inter alia,* improving the quality of care, ensuring a sound allocation of financial resources and reducing inequalities.[726]

This assessment is confirmed by the reasoning of the High Court of Justice[727] and of the Court of Appeal[728] in *R v Somerset County Council, ex parte Fewings.* The case concerned a County Council decision to ban deer hunting with hounds on a piece of land it owned. As illustrated by the High Court, it was clear from the background that "the resolution was passed because the majority of those voting for it were and are deeply opposed to the practice of deer hunting on ethical grounds".[729] Justice Laws, deciding the case, argued that the subjective views of the majority, which regarded deer hunting as morally undesirable, were an irrelevant consideration, thus rendering the resolution unlawful. According to his reasoning, a public body has no legal rights of its own and is only given discretion in order to carry out its duties of public responsibility.[730] While the court accepted that there may be some statutory purposes whose fulfilment requires ethical views to be considered relevant, the legal framework applicable in this case left no room for moral views and "confers no entitlement on a local authority to impose its opinions about the morals of hunting on the neighbourhood".[731] On appeal by the County Council, the Court of Appeal slightly modified this assessment, but reached the same conclusion.[732] It conceded that the ethical argument could have been relevant if used as a tool to serve the

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[726] See the general duties of ICBs listed in the NHS Act 2006 at sections 14Z32 - 14Z44.

[727] *Regina v Somerset County Council ex parte Fewings and Others* [1995] 1 All ER 513 (10.2.1994).

[728] *Regina v Somerset County Council ex parte Fewings and Others* [1995] EWCA Civ 24 (17.3.1995).

[729] *Regina v Somerset County Council ex parte Fewings and Others* [1995] 1 All ER 513.

[730] "A public body has no heritage of legal rights which it enjoys for its own sake; at every turn, all of its dealings constitute the fulfilment of duties which it owes to others. The public responsibility defines its purpose and justifies its existence". On this point, see Thomas, 'Stag Hunting, Irrelevant Considerations and Judicial Review' [1996](3) Web Journal of Current Legal Issues.

[731] *Regina v Somerset County Council ex parte Fewings and Others* [1995] 1 All ER 513.

[732] Thomas, 'Stag Hunting, Irrelevant Considerations and Judicial Review' [1996](3) Web Journal of Current Legal Issues.

statutory purpose of benefiting or improving the area. However, the court found that the County Council had not acted with the benefit of the area in mind, but only to protect the moral views of its member.[733] The quashing of the decision was thus upheld on grounds of relevancy.[734]

If we transfer this reasoning to the allocation of healthcare resources, it can be assumed that the only ethical standards that could be legally relevant in the health administration's assessment are those of distributive justice or utilitarianism. A religiously connoted objection to the implementation of a certain technology would likely fail to meet the standard of relevancy.

iii. Accountability for Reasonableness in the NHS

Both the criteria applied by courts under judicial review and the standards of decision-making that NHS bodies tend to follow come remarkably close to what is required by the 'accountability for reasonableness' model developed by Norman Daniels and Charles Sabin.

Starting from the assumption that rationing health care inevitably raises moral controversies, their theory advocates a model of procedural, rather than substantive, justice.[735] Because of the inevitability of ethical pluralism, decisions must be the result of deliberation carried out on terms that are justifiable and reasonable for all.[736] To achieve this, the decision-making process must fulfil four conditions, namely publicity, relevance, challenge and enforcement.

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[733] *Regina v Somerset County Council ex parte Fewings and Others* [1995] EWCA Civ 24: "For example, the Council could impose such a ban if hunting deer ran the risk that the herd would become extinct, and they concluded that the retention of deer on the land was for the benefit of their area. However the decision was not reached on any such basis but on the basis that hunting was morally repulsive". See Herling, 'Weight in Discretionary Decision-Making' (1999) 19(4) Oxf J Leg Stud p. 583, 595: "such opinions were not necessarily irrelevant to the councillors' exercise of their power to ban, but might only be applied as modified by the realisation that [the Act] dictated an overriding and impersonal objective, the 'benefit, improvement or development of the council's area'".

[734] "The debate ranged over many emotive ethical issues and in doing so lost sight of what was of benefit to the area as required by the statute", Leyland and Anthony, *Textbook on Administrative Law* (2016) pp. 279-280.

[735] Daniels and Sabin, *Setting Limits Fairly: Learning to Share Resources for Health* (2nd edn 2008) pp. 34-ff; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 191.

[736] Daniels and Sabin, *Setting Limits Fairly* (2008) p. 36.

Following the first condition, the reasoning behind decisions on coverage of health technologies must be made publicly accessible.[737]

The relevance condition demands that the reasons on which the decision is grounded are ones that everyone can regard as relevant and acceptable.[738] This requirement is justified by the fact that, when a fundamental interest of the individual such as healthcare is at stake, people are expected to consider a decision acceptable only if it is based on reasons that they can consider relevant and appropriate.[739] As an example of unshared and unacceptable grounds for decision, Norman and Sabin mention reasons resting on religious faith. Religious reasoning has no relevance for those who do not share the same faith perspectives[740] and therefore religious members of the society cannot claim to impose their beliefs on all other patients.[741]

The third condition requires that a mechanism for challenging and reviewing decisions is put in place, while the fourth and final criterion stipulates that measures must be put in place to ensure that the previous conditions are enforced.[742]

The theory of 'accountability for reasonableness' offers one of the most influential models of procedural justice in health care,[743] to which several health authorities in England have explicitly proclaimed their adherence.[744] Most notably, the National Institute for Health and Care Excellence has endorsed this model. The former chairman of NICE, Michael Rawlins,

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[737] ibid, p. 46. See, also, Daniels and Sabin, 'Limits to Health Care: Fair Procedures, Democratic Deliberation, and the Legitimacy Problem for Insurers' (1997) 26(4) Philosophy & Public Affairs p. 303, 307.

[738] Daniels and Sabin, *Setting Limits Fairly* (2008) p. 4.

[739] "[P]eople should not be expected to accept binding terms of cooperation that rest on reasons they cannot view as acceptable types of reasons", ibid, p. 36.

[740] "[C]riteria that a religious patient or clinician might offer to justify a claim that a treatment be covered [have] no relevance at all for those who lack the appropriate faith. The patient advancing it must recognize that she cannot expect those who do not share her faith to give weight to this type of reason", ibid, p. 53.

[741] "People whose religious beliefs preclude pursuit of standard medical treatments would not be involved in offering or seeking justification about the inclusion of treatments within the benefit package", Daniels and Sabin, 'Limits to Health Care' (1997) 26(4) Philosophy & Public Affairs p. 303, 331.

[742] ibid, p. 323.

[743] "[A]rguably the dominant paradigm in the field of health policy" as reported by Syrett, 'Health Technology Appraisal and the Courts' (2011) 6(4) Health Econ Policy Law p. 469, 472.

[744] For instance, nine commissioners of the South Central region of the English NHS have adopted 'accountability for reasonableness' as ethical framework, as reported by Newdick in Nagel and Lauerer, *Prioritization in Medicine* (2016) p. 126 fn. 15.

declared that their method of procedural justice was inspired by accountability for reasonableness[745] and explicit mention of this model has been made in the normative framework for the development of NICE's guidance.[746] Moreover, local health authorities in England are committed to a model of procedural justice that ensures that commissioning decisions are made following a procedural framework that can be considered acceptable to virtually all. NHS bodies are pragmatically inclined to make decisions that are widely recognised as a fair compromise by the community.

Even the mechanism of judicial review by administrative courts seems to validate the hypothesis that decision-making in the NHS should follow the procedural framework of accountability for reasonableness. Especially in the second stage of 'hard look' judicial review, administrative courts have effectively checked and enforced the requirements of accountability for reasonableness, albeit without explicitly referring to it.[747] Indeed, a decision which takes into account irrelevant factors[748] or imposes blanket bans will most likely be quashed via judicial review.[749]

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[745] Daniels and Sabin, *Setting Limits Fairly* (2008) p. 180; Wang, 'From Wednesbury Unreasonableness to Accountability for Reasonableness' (2017) 76(3) Camb Law J p. 642, 665.

[746] National Institute for Health and Care Excellence, 'Social value judgements: Principles for the development of NICE guidance' (31.7.2008). See Syrett, 'Nice Work?: Rationing, Review and the 'Legitimacy Problem' in the New NHS' (2002) 10(1) Med Law Rev p. 1, 14-ff; Syrett, 'Deconstructing Deliberation in the Appraisal of Medical Technologies' (2006) 69(6) Mod Law Rev p. 869, 884; Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) p. 107; Wang, *Can Litigation Promote Fairness in Healthcare?* (2013) p. 221; Charlton, 'NICE and Fair?: Health Technology Assessment Policy Under the UK's National Institute for Health and Care Excellence, 1999–2018' (2020) 28(3) Health Care Analysis p. 193, 194.

[747] Wang, *Can Litigation Promote Fairness in Healthcare?* (2013) p. 116.

[748] It remains clear, however, that compliance with the relevancy condition applied by the administrative courts is entirely dependent on the statutory purpose of the discretion conferred on the public authorities. As discussed in the previous paragraph, a factor will be considered irrelevant to the decision if it is not suitable for achieving the purpose set by the legislator. In the case of judicial review, therefore, relevancy has a narrower scope than the broad requirement to use "terms of fair cooperation that rest on justifications acceptable to all" set out by Norman and Daniels. The latter is so far-reaching that it comes close to placing a substantive condition on decision-making, a condition that the English courts could not check through their judicial review based on procedural justice, see Syrett, 'Health Technology Appraisal and the Courts' (2011) 6(4) Health Econ Policy Law p. 469, 481; Wang and Rumbold in Phillips, Campos and Herring, *Philosophical Foundations of Medical Law* (2019) p. 193.

This is not surprising if one considers that the English tradition of judicial review is based on the same procedural justice principles that have also inspired Norman and Daniel.[750] In fact, the English model of health care rationing was already – before and independently of Norman and Daniels' work – based on the elements of procedural justice outlined in the theory of accountability for reasonableness.[751] As has been illustrated, the statutory framework governing the NHS and the NHS Constitution already require local health authorities to respect procedural duties.

However, the concept of accountability for reasonableness can serve as an emblematic umbrella term referring, more broadly, to the English attitude towards decisions on the coverage of new health technologies. For the purposes of this thesis, reference to this theory allows for a conceptualisation of the English model and for its comparability to the other analysed jurisdictions.

IV. Comparative Findings

1. Constitutional Framework

The previous sections have shown that in all three jurisdictions there are fundamental principles of the constitutional order, be it substantive or

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[749] "These changes in the administrative decision-making reflect the fact that the denial of funding for a health intervention will hardly ever be upheld by courts if the decision and the grounds for it are not made public ('publicity'), based on sound evidence and reasonable policy considerations ('relevance') and if the opportunity for adequately challenging the policy or presenting a case for an exception is not given ('challenge'). Accordingly, the courts are guaranteeing that health care rationing decisions in the NHS will comply with the first three conditions for 'accountability for reasonableness' and are thus materialising the last condition ('regulation/enforceability')", Wang, 'From Wednesbury Unreasonableness to Accountability for Reasonableness' (2017) 76(3) Camb Law J p. 642, 668. See, also, Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) p. 143.

[750] Syrett, 'Health Technology Appraisal and the Courts' (2011) 6(4) Health Econ Policy Law p. 469, p. 473.

[751] As Norman and Daniels also acknowledge in Daniels and Sabin, *Setting Limits Fairly* (2008) p. 180: "All of the core components in our conceptualisation have been articulated forcefully in UK policy discussion quite independently of our work. Accountability for reasonableness offered an additional tool for conceptualising and advancing a process that was well underway in the UK prior to the founding of NICE in 1999. It appears that the theory has helped policy leaders in the UK articulate the rationale for what they are doing".

procedural, which guarantee a certain degree of ethical neutrality of the state in decisions regarding ethically controversial health technologies.

In both Italy and Germany, the requirement for a separation of ethics and the law is not explicitly enshrined in the wording of their Constitutions. However, it can be derived from the combined reading of different Articles of the Constitution. These Articles operate on different levels. First, they include an institutional separation of state and church.[752] Second, they recognise each individual's freedom of faith and religion.[753] Third, they both reinforce this freedom by declaring adherence to a principle of equality and non-discrimination on the grounds of religion.[754]

In both countries the action of the courts and the legal scholarship has been fundamental in developing and cultivating this constitutional requirement. In Germany this principle has been explicitly theorised as a constitutional requirement of neutrality of justification, in line with the concept of neutrality endorsed in this dissertation.[755] In Italy this principle is referred to as the principle of laicity and its relation to the concept of neutrality is disputed.[756] Here, the case law of the Constitutional Court has established this principle as being paramount to other constitutional interests.

The constitutional framework for the separation of ethics and law is different in the UK. This jurisdiction lacks a written binding and overarching constitutional text from which supreme principles can be deduced. Additionally the institutional level in England, unlike Germany and Italy, is clearly characterised by an established Church.

However, procedural principles of political constitutionalism still guarantee that the state will try to reach compromises based on reasons that are acceptable to society as a whole. Moreover, freedom of religion and faith as well as the right to equality are upheld in this jurisdiction thanks to the Human Rights Act 1998 and the Equality Act 2010. As a result, the procedural principles applied in England fulfil the function of a neutrality standard. They guarantee that the moral autonomy of the individuals is respected and that decisions will be taken in line with principles that can

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[752] For Germany, see Article 137(1) in combination with Article 140 of the Basic Law. For Italy, Articles 7 and 8 of the Italian Constitution.

[753] Art. 4 Basic Law and Art. 19 Italian Constitution.

[754] Art. 3(3) of the Basic Law, as well as Art. 3(1) of the Italian Constitution.

[755] See Chapter 1, sec. A.II.2.

[756] See Chapter 1, sec. B.II.1.

be considered acceptable and reasonable by virtually all members of the pluralist society.

2. Coverage and Reimbursement of Ethically Controversial Health Technologies

For the purpose of this dissertation, this constitutional framework is particularly relevant when applied to the decision-making process of the public healthcare systems of the three countries.

In Germany, the principle of neutrality is concretised and conceived as a justification requirement. The pluralist constitutional state can and must guarantee the application of religiously and ethically neutral criteria to the choices made since it commits itself to grounding its decisions on reasons derived from within the legal and constitutional order. At the same time the state cannot ensure neutrality of effects. The principle of ethical and religious neutrality also applies to the choices made by the welfare state in its action to implement the public healthcare system. Namely, neutrality of justification must be respected with regard to decisions on whether or not to include new health technologies in the benefit basket of the healthcare insurance.

However, a series of legitimate considerations are within the state's wide margin of appreciation that, while being neutrally justified, may have the effect of excluding certain categories of health technologies from the benefit basket of the publicly funded system. The second abortion decision of the Federal Constitutional Court exemplifies this difference. It states that abortion cannot be "categorized as a normal insurance risk".[757] Under these circumstances the refusal to reimburse abortion procedures within the public healthcare insurance is not based on a particular moral or religious conviction according to which abortions are unethical. Rather, it is based on the fact that such risk is not covered by the public health insurance.

In a theoretical framework in which the neutrality requirement consists mainly in a neutrality of justification, there will be no violation of the principle of ethical neutrality as long as the justification for a refusal to fund a certain technology can be based on other legitimate reasons. Namely on criteria that can be endorsed as reasonable independently from the assumption of a particular ethical stance. Such criteria include: the non-qualification of the treatment as part of necessary healthcare, its lack of

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[757] BVerfG, 28.5.1993 - 2 BvF 2/90, in BVerfGE 88, 203 (319).

clinical efficacy and safety, or more simply the scarcity of financial means. Those decisions would thus be made based on a normativity level which is internal to the legal system, rather than on criteria derived from a different and separate normative system such as ethics or religion. If, on the other hand, it can be established that the lack of funding is based on the fact that the treatment is regarded as ethically undesirable by part of the population, this would constitute a blatant violation of the ethical neutrality of the state and the normative separation of ethics and law.

Likewise, the very scope of fundamental rights must be defined in a religiously and ethically neutral manner. For these reasons, the very concepts of health and disease, as well as that of necessary healthcare, must be defined or definable – for the purposes of the public healthcare insurance – according to ethically and religiously neutral parameters, since they delimit the scope within which treatment is offered by the public healthcare system, according to § 27(1) SGB V.[758] These concepts are in fact also inherently loaded with normative value,[759] which implies that they allow interpretations based on specific ethical approaches, with the danger that specific moral positions could find themselves to be privileged simply thanks to a reference to the definition of disease in the healthcare insurance.[760]

The position is similar in Italy. Here, the constitutional requirement of laicity applies to all activities of the public administration. This principle shapes the interpretation of other fundamental rights in the Constitution. Therefore, the right to health must be interpreted according to laicity both in its negative aspect and in its positive and social component.

Firstly, laicity and the right to health ensure that the patient is not bound to conceive of health in such a way that it corresponds with specific ethical or religious beliefs. The Constitutional Court has promptly intervened in cases where the ethical or religious views of the political majority have determined a ban on the performance of health treatments considered immoral. In its constitutional review of Law no. 40/2004, the Court has been striving to tacitly implement the principle of laicity by considering irrelevant all justifications whose normative force is derived from a particular ethical or religious framework.

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[758] Huster in Beck, *Krankheit und Recht* (2017) pp. 42 ff.

[759] On the (lack of a) possible objective assessment of the concept of disease, see Kreßner, *Gesteuerte Gesundheit* (2019) pp. 40–41 and 52.

[760] ibid, p. 54.

Secondly, the public healthcare system and the healthcare providers must respect the individual's conception of health when providing health services. Combined with the principles of impartiality of the administration and reasonableness, laicity obliges the public healthcare system to respectively guarantee neutrality in the provision of healthcare services and to provide a justification for their decision-making that is considered reasonable within the legal system.[761] This ensures that health administrations cannot legitimately deny or discourage access to health treatments on the basis of ethical or religious grounds.

Despite a wide conception of the concept of health, the right to health as a social right is necessarily conditioned by financial constraints. However, the case law of the Italian Constitutional Court has confirmed that financial consideration cannot have such a predominant weight in the legislature's balancing of interests as to compress the 'inviolable' core of the right to health.

In sum, ethical or religious objections against the inclusion of a particular health technology in the health benefit basket cannot be legitimately raised according to the principle of laicity. Moreover, a health service must be offered by the National Health Service, with a possibility of co-payment, if it is instrumental in guaranteeing the essential core of the right to health.

In England a respect for the criteria of procedural legitimacy, when adapted to the healthcare system, results in a decision-making system that resembles the model of 'accountability for reasonableness'.[762] Decisions on the coverage of health technologies in the English NHS are made through a decision-making process which tends to be based on reasoning that is acceptable and justifiable to all. Considerations about the ethical or religious desirability of a certain technology by public bodies or their members would not qualify as factors relevant to the decision. This stems both from the voluntary approach of public authorities wishing to issue decisions that are widely regarded as legitimate, and from the legal constraints on their actions. Administrative courts, for instance, will ensure that resolutions on the coverage of new health technologies are made in accordance with the criteria of relevance and reasonableness that are necessary for them to qualify as lawful. These requirements likely lead to a situation where the personal opinions of members of NHS bodies are excluded from the scope

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[761] See Chapter 1, sec. B.II.2.b.

[762] See this Chapter, sec. B.III.2.b.

of decision-making and where the criteria adopted in decisions are accepted as justifiable by society. This 'culture of justification' has been especially present since administrative courts have intensified their scrutiny and moved into a phase of 'hard look' judicial review.[763] This strong conception of patients' procedural rights guarantees that the grounds for rationing health care spending are reasonable and justifiable for all, even though they by no means secure a right of access to a given health treatment.[764]

In addition, public bodies may legally use the discretion conferred on them by the legislature only if they pursue 'statutory purposes'.[765] As considered in the case of *R v Somerset County Council, ex parte Fewings*, public authorities do not have a right per se to assert their own ethical considerations. On the contrary, these will have to be set aside in the pursuit of the public benefit.[766] The range of instruments of judicial review is designed to ensure that public authorities respect the boundaries set by the legislature. Parliament, as a democratically legitimised body, has primacy in shaping an ethics that is widely shared in society and which can guide decisions in the healthcare system. The courts, sometimes even when dealing with common law cases, can use the legislature's determinations to reconstruct this public morality.[767]

In conclusion, the role of the courts and the framework of procedural legitimacy limit the space for a consideration of ethics and religion in decisions on the funding of ethically controversial technologies. A decision-maker seeking to introduce their own moral standards into the decision-making process and thus to impose them on patients would face the risk of having their resolution overturned on grounds of relevancy or reasonableness.

By contrast, ethical considerations concerning allocative justice can and must legitimately influence decisions on the funding of health care, as they are considered relevant to the exercise of the tasks of NHS bodies and, in particular, to the effective allocation of health care resources. They are, however, beyond the scope of this thesis.

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[763] The culture of justification and the shift from a very limited judicial review to more heightened scrutiny was also facilitated by the inclusion of the language of fundamental rights in the English legal culture, see Chapter 1, sec. B.III.2.b.

[764] Newdick in McLean, *First Do No Harm* (2016) p. 582.

[765] Regina v Somerset County Council ex parte Fewings and Others [1995] 1 All ER 513.

[766] Aronson in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) pp. 143-144.

[767] And especially in *Whittington Hospital NHS Trust v XX* [2020] UKSC 14.

Given this background of neutrality in their public healthcare systems, the following sections will analyse how the three different jurisdictions can legitimately deal with the emergence of ethically controversial technologies. Through the analysis of two case studies the thesis will first investigate the actors and instruments involved in the decision-making process, determining the regulation of emerging technologies whose implementation poses ethical concerns. Second, the analysis will focus on the public coverage of the reimbursement of ethically controversial technologies. In both these fields the thesis will assess whether there has been compliance with the theoretical and constitutional foundation of the ethical neutrality of the state and whether it is possible to argue that ethical neutrality shall always be respected when deciding on the public funding of controversial health technologies.

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

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[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-

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[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

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(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

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[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

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[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 Prĩmplantationsdiagnostik* (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

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[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

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[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

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[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

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[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

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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-

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[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-

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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

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[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

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[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

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[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-

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[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

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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.

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[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

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[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

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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]

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[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]

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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

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[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]

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[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

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[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-

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[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

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[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]

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[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

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[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

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[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

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[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-

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[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

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[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

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[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]

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[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

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[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]

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[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]

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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-

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[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

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[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

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[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

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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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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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

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[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

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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

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[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-

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[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

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[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

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[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

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[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

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[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

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[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-

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[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

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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

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[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

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[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

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[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

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[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

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[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

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[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

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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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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.

Chapter 3: Non-Invasive Prenatal Testing

A. Non-Invasive Prenatal Testing in Germany

I. NIPT in the Private Sector

The first non-invasive prenatal test (NIPT) available in Germany was marketed in 2012 under the trade name PraenaTest by the company LifeCodexx. Under § 3(1)(b) of the former Medical Devices Act (*Medizinproduktegesetz*, MPG)[1420] the test qualified as a medical device for the detection of disability and therefore only required a CE mark to be placed on the market in Germany.[1421] Its placing on the market immediately sparked considerable controversy and public debate. After a series of articles denouncing the market entry of the test in national newspapers[1422] a legal expert opinion commissioned by the Federal Government Commissioner for Matters relating to Persons with Disabilities was released.[1423]

The opinion, drafted by Klaus Ferdinand Gärditz, argued that the test could not lawfully be placed on the market.[1424] According to § 4(1) of the old MPG it was prohibited to place a medical device on the market when there were reasonable grounds for suspecting that they directly or indirectly endangered the safety and health of patients or third parties. In the legal expert's view the medical device legislation would lead to a ban on the marketing of NIPT and an obligation on the competent authorities to prevent it from being placed on the market[1425] because the foetus was

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[1420] The Medical Devices Act was replaced in May 2021 by the Medical Devices Implementation Act (*Medizinprodukterecht-Durchführungsgesetz*, MPDG).

[1421] According to the then current § 6(1) MPG, as pointed out by Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 283.

[1422] As reported by Braun and Könninger, 'Realizing Responsibility.: Institutional Routines, Critical Intervention, and the "Big" Questions in the Controversy over Non-invasive Prenatal Testing in Germany' (2017) 37(3) New Genetics and Society p. 248, 256.

[1423] Gärditz, 'Gutachtliche Stellungnahme zur Zulässigkeit des Diagnostikprodukts "PraenaTest"' (2012), pp. 10-11. <https://cdl-online.net/uploads/pdf/praenatest.pdf> accessed 28.9.2021

[1424] ibid, p. 11.

[1425] ibid.

argued to be a third party under the MPG. Its health and safety would then be endangered because there was a 90% chance of it being aborted as a result of the information revealed by the test.[1426]

The competent authorities did not act in accordance with this opinion.[1427] Moreover, the expert's assessment was contradicted by a subsequent opinion of another legal expert appointed by the manufacturer[1428] and by contributions from other legal scholars.[1429] The second legal expert's opinion found that the foetus could not be regarded as a third party within the meaning and the spirit of the Medical Devices Act.[1430] Furthermore, the opinion argued that the decisive factor in this respect is the fact that the mere use of the test poses no danger to the health and safety of the foetus.[1431] The test discloses information that, in itself, could also be beneficial in protecting the health of the unborn child, for example by choosing appropriate delivery methods for a genetically affected foetus.[1432] By contrast, the possibility that the foetus might suffer harm to its health as a result of the information provided by the test would depend entirely on the mother's decision to have an abortion.[1433]

The legal and ethical controversies that followed the introduction of NIPT tests onto the market also prompted the Federal Government to seek the opinion of the German Ethics Council.[1434] The Council assumed that,

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[1426] ibid, p. 5.

[1427] As notices Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 283.

[1428] Hufen, 'Zur verfassungsrechtlichen Beurteilung frühzeitiger pränataler Diagnostik: Dargestellt am Beispiel des Diagnoseprodukts PraenaTest®' (4.1.2013) <https://lifecodexx.com/wp-content/uploads/2015/03/Jan-2013_PraenaTest_Zur_verfassungsrechtlichen_Beurteilung_fruehzeitiger_praenataler_Diagnostik_Friedhelm_Hufen.pdf> accessed 21.9.2021.

[1429] *Inter alia,* Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 283; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin: Ethische, juristische und gesellschaftliche Aspekte* (2018) pp. 148-ff.

[1430] Hufen, 'Zur verfassungsrechtlichen Beurteilung frühzeitiger pränataler Diagnostik', 4.1.2013, p. 9.

[1431] ibid, p. 10, in contrast to the previously used invasive procedures, which, as indicated above in Chapter 1, sec. A.I.3.b pose a small risk of miscarriage.

[1432] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 283 mentions, for instance, the possibility of choosing a caesarean section rather than natural birth.

[1433] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 283; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) p. 149.

[1434] Deutscher Ethikrat, 'The Future of Genetic Diagnosis' (2013) p. 7.

since the authority responsible for reviewing the test did not object to its marketability under the Medical Devices Act, the test was legally placed on the market.[1435] On the basis of this premise the majority of the Council's members focused on envisaging a legal framework for an ethically acceptable use of NIPT. This would for instance include appropriate and comprehensive information and counselling[1436] and limiting the possibilities for performing NIPT to cases of pregnancy with an increased risk of genetic conditions in the foetus.[1437]

II. NIPT in the Statutory Health Insurance

1. Access to Prenatal Testing

a Prenatal Diagnoses in the Statutory Health Insurance

The reimbursement of prenatal diagnoses by the statutory health insurance is regulated in § 24d SGB V according to which the insured subject is entitled to medical care and midwifery assistance during pregnancy, including prenatal care. The medical services to be offered during pregnancy are specified in the guidelines on medical care during pregnancy and after delivery (*Richtlinien über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung*, Mu-RL), or Maternity Guidelines, issued and updated by the Federal Joint Committee.[1438]

According to the maternity guidelines a primary objective of prenatal care is the early detection of high-risk pregnancies and births.[1439] For this purpose the pregnant woman is entitled to a number of examinations, including early detection and investigation of risk pregnancies. Not included in the statutory health insurance offer is the so-called first-trimester screening, which is a combined blood test and ultrasound examination procedure

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[1435] ibid, p. 80.

[1436] ibid, pp. 157-158.

[1437] ibid, p. 165.

[1438] Pursuant to § 92(1) sentence 2 no. 4 of the SGB V, see Welti in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 1.

[1439] Gemeinsamer Bundesausschuss (G-BA), Mutterschafts-Richtlinien, Richtlinien über die ärztliche Betreuung während der Schwangerschaft und nach der Entbindung 10.12.1985, p. 2.

that can estimate the probability of a chromosomal trisomy being present. The first-trimester screening can be conducted between the 11th and 14th week, but the cost must be borne out-of-pocket.[1440]

If this initial screening gives indications that there may be a trisomy, the pregnancy is classified as at risk. In such instances the statutory health insurance covers the costs of an invasive diagnosis such as amniocentesis or chorionic villus sampling.[1441] A pregnancy is automatically considered to be at risk – and non-invasive diagnoses are therefore reimbursed even without a previous first trimester screening – when the woman is a first-time mother and over 35.[1442]

The prenatal invasive diagnoses thus offered by the statutory health insurance are seen as controversial by some legal scholars[1443] who argue that the aim of medical care during pregnancy is to avoid dangers to the life and health of the child and not the early detection of disabilities that might lead to an abortion. This is considered to be an explanation for the lack of reimbursement for the first trimester screening.[1444] However, it does not explain the statutory health insurance's coverage of possible abortion procedures.[1445]

Against the background of this existing discussion, the emergence of NIPT has sparked debates among legal and ethics scholars on its possible reimbursement by health insurance funds.[1446]

[1440] Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) p. 145; Kießling in Rolfs and others, *BeckOK Sozialrecht* (61st edn 2021) para. 8.

[1441] Gemeinsamer Bundesausschuss (G-BA), Mutterschafts-Richtlinien 10.12.1985, p. 10; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 8.

[1442] Gemeinsamer Bundesausschuss (G-BA), Mutterschafts-Richtlinien 10.12.1985, pp. 9-ff; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 10.

[1443] Welti in Becker and Kingreen, *SGB V* (2020) para. 4.

[1444] Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) p. 145; Welti in Becker and Kingreen, *SGB V* (2020) para. 4; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 9.

[1445] Found in compliance with the Basic Law by the BVerfG in its second abortion decision (BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92, BVerfGE 88, 203), see Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 10.

[1446] See, *inter alia*, Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282; Buyx, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 115(44) Deutsches Ärzteblatt A1988; Rüffer, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 114(44) Deutsches Ärzteblatt A1989; Freiherr von Ulmenstein, 'Tagungsbericht: Nicht-invasive Pränataldiagnostik als GKV-Leistung? – Medizinische, ethische und rechtliche Fragen' (2018) 36(9) MedR p. 680.

Considering the criteria that guide the inclusion of a new technology in the statutory health insurance,[1447] NIPT seems to be an excellent candidate to be included in the medical care that is offered during pregnancy.[1448] Compared to invasive prenatal diagnoses NIPT is not only cheaper[1449] but also safer. Amniocentesis and chorionic villus sampling, being invasive procedures, are deemed to be dangerous due to their – albeit low – potential to cause miscarriages. Some legal scholars therefore welcome the reimbursement of these tests by the health insurance,[1450] not least because it is a measure aimed at protecting the foetus from the risk of miscarriage.[1451]

By contrast, the expert opinion commissioned by the Federal Government Commissioner for Matters relating to Persons with Disabilities had claimed that reimbursement by the GKV would constitute a violation of the constitutional obligations of the state.[1452] The author had started from the assumption that Article 3(3) sentence 2 of the Basic Law requires that no one shall be discriminated against or disadvantaged because of their disability. Against this background the emergence of NIPT would trigger the state's responsibility to actively intervene to counteract the possible discrimination against people with disabilities. He argued that the early detection of a chromosomic trisomy would be likely to result in the woman's decision to undergo an abortion procedure which, depriving the foetus of the opportunity to become part of society in the first place, would

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[1447] According to § 135(1) SGB V, new diagnostic and treatment methods may only be provided at the expense of public health insurance funds if their diagnostic and therapeutic benefit, as well as their medical necessity and economic efficiency, are recognised and evaluated in comparison to services already included in the benefit basket, see below at sec. II.2.d.

[1448] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 284; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) pp. 145-146. For the clinical benefits of NIPT compared to other procedures, see Chapter 1, sec. A.I.3.b.

[1449] Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 11.

[1450] Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625, 627; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) pp. 146-ff; Rolfes in Steger, Orzechowski and Schochow, *Pränatalmedizin: Ethische, juristische und gesellschaftliche Aspekte* (2018) pp. 66-67.

[1451] Tolmein, 'Selbstbestimmungsrecht der Frau, Pränataldiagnostik und die UN-Behindertenrechtskonvention' (2012) 45(4) KJ p. 420, 428; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 11.

[1452] Gärditz, 'Gutachtliche Stellungnahme zur Zulässigkeit des Diagnostikprodukts "PraenaTest"', 2012, p. 10.

allegedly be the "most intense" form of discrimination.[1453] The outcome of these arguments is that the provision of financial support by the state for the performance of this test, such as the inclusion in the catalogue of the statutory health insurance, would constitute a breach of Article 3(3) sentence 2 of the Basic Law.[1454]

However, the opinion was silent on the invasive and more dangerous prenatal diagnostic procedures that are already offered by the statutory health insurance. As other commentators have noted from a legal perspective, the non-invasiveness of the test does not imply a qualitative leap in its potential to lead to constitutional violations.[1455] NIPT itself does not detect more disabilities, but only detects them in a less invasive way and thus with greater respect for the health and safety of the foetus.[1456] Therefore, the non-invasiveness of the test has no consequences for its legal assessment compared to the other diagnoses that are already publicly funded.[1457] From this point of view NIPT is indeed more compatible with, what part of the legal literature considers to be, the main purpose of prenatal care offered by the statutory health insurance. Namely, to avoid danger to the health and life of the mother and child.[1458]

Moreover, the expert's opinion disregarded the legal consequences of the fact that a possible abortion following NIPT is caused by the mother's decision and not by the performance of the diagnosis.[1459] Any disadvantage to the foetus would derive from the need to avoid a future risk to the health of the pregnant woman and would therefore be justified by the protection of her life and physical integrity.[1460] Rather, from the point of view of protecting the woman's physical integrity – and that of the foetus – the non-reimbursement of the least invasive test, while reimbursing more dangerous

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[1453] ibid, p. 4 (author's translation).

[1454] ibid, p. 10.

[1455] Tolmein, 'Selbstbestimmungsrecht der Frau, Pränataldiagnostik und die UN-Behindertenrechtskonvention' (2012) 45(4) KJ p. 420, 430; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 11.

[1456] Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 11.

[1457] Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625, 629; Tolmein, 'Selbstbestimmungsrecht der Frau, Pränataldiagnostik und die UN-Behindertenrechtskonvention' (2012) 45(4) KJ p. 420, 430.

[1458] Welti in Becker and Kingreen, *SGB V* (2020) para. 4.

[1459] Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) p. 149.

[1460] Hufen, 'Verfassungsrechtliche Bedenken gegen frühe Pränataldiagnostik?' (2017) 35(4) MedR p. 277, 281.

diagnostic methods, is problematic. Women with limited financial means would be *de facto* excluded from access to the less invasive procedure and therefore, as a consequence of their economic condition, would have to bear the risk of a miscarriage.[1461]

b Right to Know and Right Not to Know

A mother's right to know the health status of the foetus derives directly from her fundamental right to physical integrity, as set out in Article 2(1) sentence 1 of the Basic Law, which the state is obliged to protect. The right to physical integrity also includes the right to know about one's own health condition according to the current state of medical knowledge. In the case of a pregnant woman this extends to all the physical and psychological hazards that may arise from the pregnancy.[1462] The right to be informed of all conditions relevant to one's health is also supported by the fundamental right to informational self-determination that is guaranteed by Article 2(1) in conjunction with Article 1 of the Basic Law.[1463]

On the other hand, the right to physical integrity and informational self-determination equally encompass a 'right not to know',[1464] given that merely obtaining genetic information can seriously affect some patients.[1465]

[1461] Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625, 628; Rolfes in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) pp. 63-ff.

[1462] Hufen, 'Zur verfassungsrechtlichen Beurteilung frühzeitiger pränataler Diagnostik', 4.1.2013, p. 22; Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) pp. 174-176.

[1463] Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) pp. 149-165.

[1464] See Joschko, *Das Recht auf Nichtwissen in der Gesundheitsversorgung* (2022) pp. 53-61. Particularly with regard to NIPT, criticism that it may undermine the right not to know was reported by Gärditz, 'Gutachtliche Stellungnahme zur Zulässigkeit des Diagnostikprodukts "PraenaTest"', 2012, p. 15; Hufen, 'Verfassungsrechtliche Bedenken gegen frühe Pränataldiagnostik?' (2017) 35(4) MedR p. 277, 281; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) pp. 151-152.

[1465] Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) p. 178; Laufs and Rehborn in Laufs, Kern and Rehborn, *Handbuch des Arztrechts* (5th edn 2019) para. 85; Kämmerer and Kunig in Münch and Kunig, *Grundgesetz* (2021) para. 80.

The 'right to know' and the 'right not to know' must equally receive sufficient protection when the patient is presented with the option to undergo prenatal screening. Adequate safeguard of both rights appears to be accomplished by the provisions of the Genetic Diagnosis Act (*Gendiagnostikgesetz,* GenDG) on informed consent and counselling.[1466] § 15 of the GenDG deals specifically with prenatal diagnosis and provides that testing may only be carried out if the pregnant woman has been duly informed, has given her consent and has received appropriate genetic counselling.[1467]

Moreover, before asking for consent, the medical practitioner responsible must inform the patient of the nature, significance and scope of the test, including the characteristics of the condition being tested for and their right not to know.[1468] Following this information the patient must be given an appropriate period of time before giving their consent.[1469] The latter must be in writing and may be revoked at any time.[1470]

Genetic counselling should be offered both before and after a prenatal genetic test.[1471] Counselling takes place at a separate time from the provision of information and the taking of informed consent and forms part of the treatment itself.[1472] Counselling must be 'non-directive', meaning that it must be impartial and should aim at assisting the patient in forming their own opinion.[1473]

[1466] Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) p. 313.

[1467] On this point see Joerden and Uhlig in Steger, Ehm and Tchirikov, *Pränatale Diagnostik und Therapie in Ethik, Medizin und Recht* (2014) pp. 105-107.

[1468] § 9(2) no. 5 GenDG, see Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) p. 312.

[1469] § 9 GenDG.

[1470] § 8 GenDG.

[1471] § 15 GenDG. On the differences between counselling before and after the testing, see Joerden and Uhlig in Steger, Ehm and Tchirikov, *Pränatale Diagnostik und Therapie in Ethik, Medizin und Recht* (2014) p. 107.

[1472] Fündling, *Recht auf Wissen vs. Recht auf Nichtwissen in der Gendiagnostik* (2017) p. 225.

[1473] Fenger in Spickhoff, *Medizinrecht* (3rd edn 2018) para. 3; Laufs and Rehborn in Laufs, Kern and Rehborn, *Handbuch des Arztrechts* (2019) para. 84.

2. The G-BA's Assessment of NIPT

a Reactions to the Initiation of the Procedure

Right after it was placed on the market the price of NIPT was very significant and represented a major financial obstacle for most patients.[1474] In 2013 the manufacturer submitted an application to the G-BA to initiate a medical device evaluation procedure under § 137e SGB V. According to this provision the Federal Joint Committee can evaluate new medical devices through a 'coverage with evidence development' procedure, which could also be initiated upon application of the manufacturer.[1475] This procedure allows for the temporary reimbursement,[1476] in a trial stage,[1477] of a medical device or medical treatment whose benefits have not yet been sufficiently proven.[1478]

The G-BA's announcement that a consultative procedure was launched, leading to a 'coverage with evidence development' procedure for NIPT,[1479] revived the heated ethical debate.[1480]

In particular, an article published in January 2015 by the weekly *Zeit* denounced the prospective reimbursement of NIPT by the statutory health insurance as the first step towards a society that wants to get rid of people with congenital disabilities.[1481] The G-BA was forced to respond to these allegations by publishing an official position stating its awareness of the

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[1474] Schmitz, 'Ethische Herausforderungen der neuen nichtinvasiven Pränataltestung' (2016) 49(6) Gynäkologe p. 442, 443; Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 251.

[1475] According to § 137e (7) SGB V.

[1476] According to § 137e(1) sentence 2 SGB V.

[1477] The trial period is meant to collect additional data that will be used to reach the final decision on the reimbursement of the device or procedure by the statutory health insurance. On the data collection, see Becker in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 9.

[1478] Becker in Becker and Kingreen, *SGB V* (2020) para. 3; Propp in Rolfs and others, *BeckOK Sozialrecht* (61st edn 2021) para. 5–6.

[1479] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 20/2014: Methodenbewertung: Erprobung von neuen Untersuchungs- und Behandlungsmethoden: Weiterer Meilenstein erreicht' (8.5.2014) <https://www.g-ba.de/downloads/34-215-534/20-2014-05-08_Erprobungsrichtlinien.pdf> accessed 15.12.2019.

[1480] As reported by Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 260; Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, p. 284.

[1481] Bahnsen, 'Pränataldiagnostik: Der Test' *Die Zeit* (22.1.2015) <https://www.zeit.de/2015/04/praenataldiagnostik-down-syndrom-krankenkasse> accessed 28.9.2021.

ethical concerns surrounding NIPT.[1482] On this occasion the chairman of the Federal Joint Committee clarified that the trial procedure and reimbursement of costs for study participants had not yet begun and reassured the public that the committee would treat ethical issues with great sensitivity.

A similar statement was issued the following year, on the occasion of the G-BA's decision to discontinue the trial procedure in order to start a regular assessment of the medical device as per § 135(1) SGB V.[1483] As the collection of further data to assess the benefits of NIPT was not found to be necessary for its evaluation,[1484] a regular assessment procedure, aimed at obtaining a definitive inclusion of NIPT in the statutory health insurance, had been initiated on 4 July 2016 by an application of the National Association of Statutory Health Insurance Funds, the National Association of Statutory Health Insurance Physicians as well as the chairman and impartial members of the G-BA.[1485]

The announcement of the application to start the regular procedure triggered a reaction from a group of MPs who, in a letter to the G-BA, claimed that the test did not offer any medical benefit.[1486] The letter urged the G-BA

[1482] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 02/2015: Methodenbewertung: Klarstellung des Sachstandes zu Pränatests für Schwangere' (22.1.2015) <https://www.g-ba.de/downloads/34-215-566/02-2015-01-22_Erprobung.pdf> accessed 10.8.2022.

[1483] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 32/ 2016: Methodenbewertung: Nicht-invasive Pränataldiagnostik bei Risiko-schwangerschaften - G-BA beginnt Verfahren zur Methodenbewertung - Beratungen zur Erprobung ruhend gestellt' (18.8.2016) <https://www.g-ba.de/downloads/34-215-635/32_2016-08-18_Methodenbewertung%20NIPD.pdf> accessed 28.9.2021.

[1484] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 284; Richter-Kuhlmann, 'Nicht invasive Pränataldiagnostik: Es geht um mehr als nur Geld' (2019) 116(16) Deutsches Ärzteblatt A774-A778, A778.

[1485] Gemeinsamer Bundesausschuss (G-BA), 'Antrag auf Bewertung der Methode der nicht-invasiven Pränataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekular-genetischen Tests für die Anwendung bei Risikoschwangerschaften im Rahmen der Mutterschafts-Richtlinien nach § 135 Absatz 1 SGB V' (4.7.2016) <https://www.g-ba.de/downloads/40-268-3933/2016-08-18_Einleitung-Beratungsverf_nicht-invasive-Praenataldiagnostik_Antrag.pdf> accessed 28.9.2021.

[1486] Hüppe and others, 'TOP 8.2.1 der 91. Öffentlichen G-BA Sitzung am 18. August 2016' (17.8.2016) <https://www.netzwerk-praenataldiagnostik.de/data/praenatal-diagnostik/pdf/Brief_MdBs_zur_91_G-BA-Sitzung.pdf> accessed 28.9.2021. See Deutscher Bundestag, 'BT-Drucks. 19/9059: Bericht des Ausschusses für Bildung, Forschung und Technikfolgenabschätzung (18. Ausschuss) gemäß § 56a der to consider ethical and social consequences in the medical evaluation of the test and to involve associations of people with disabilities in the procedure.[1487] A further letter, coming from a network against selection through prenatal diagnosis and other stakeholders, expressed similar concerns.[1488]

In response, in the statement accompanying the press release that was issued upon the launch of the procedure, the chairman of the committee reiterated that the ethical concerns raised by NIPT would be taken into account and that the German Ethics Council and other social or scientific organisations would be consulted during the procedure.[1489]

b Health Technology Assessment

The authority responsible for health technology assessment in Germany,[1490] namely the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*, IQWiG), performs a preparatory function for the G-BA's issuing of guidelines.[1491] The Institute's tasks include the research, presentation and evaluation of the current state of medical knowledge on diagnostic and therapeutic procedures, as laid down in § 139a(3) no. 1 of the SGB V.

As a first step in the evaluation procedure of NIPT the G-BA decided to commission an assessment by the IQWiG of the current state of medical knowledge on NIPT, with a view to its possible use in high-risk pregnancies within the framework of the maternity guidelines.[1492] Furthermore, the HTA authority was instructed to prepare an informative brochure for

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Geschäftsordnung' (4.4.2019), p. 68. <https://dserver.bundestag.de/btd/19/090/1909059.pdf> accessed 28.9.2021.

[1487] Hüppe and others, 'TOP 8.2.1 der 91. Öffentlichen G-BA Sitzung am 18. August 2016', 17.8.2016; Andorno, 'The Precautionary Principle' (2004) 1(1) JIBL p. 11.

[1488] See Deutscher Bundestag, 'BT-Drucks. 19/9059', 4.4.2019, p. 67.

[1489] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 32/ 2016', 18.8.2016.

[1490] On the IQWiG as the German authority for HTA, see Widrig, *Health Technology Assessment* (2015) pp. 348-ff.

[1491] Wallrabenstein in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 1.

[1492] Gemeinsamer Bundesausschuss (G-BA), 'Konkretisierung des Auftrags des Gemeinsamen Bundesausschusses an das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen: Evidenzbewertung der nicht-invasiven Pränataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests für die Anwendung bei Risikoschwangerschaften im Rahmen der Mutterschafts-Richtlinien (Mu-RL)' insured persons on the existing options for prenatal diagnosis under the Maternity Guidelines.[1493]

In a preliminary report the IQWiG declared that an assessment of the scientific studies indicated that NIPT was very accurate and reliable for trisomy 21.[1494] While for trisomies 13 and 18 the results were less conclusive, NIPT showed potential to significantly reduce the number of possible miscarriages due to invasive diagnoses.[1495] Based on these considerations the IQWiG evaluated several scenarios for the possible integration of NIPT into the prenatal care pathway offered by the Maternity Guidelines.[1496] Its assessment was published in a preliminary draft and open to comments from all interested individuals, institutions and organisations.[1497]

After the public consultation phase, the final assessment was published in June 2018.[1498] In response to comments criticising the lack of consideration of ethical issues, a paragraph on ethical dimensions was added to the final report. However, the section only stated that the ethical dimension of NIPT was known to the G-BA as a final decision-making body and should therefore not be addressed in the health technology assessment.[1499]

(26.1.2017) <https://www.g-ba.de/downloads/40-268-4204/2017-01-26_Mu-RL_Auftragskonkretisierung_Evidenzbewertung.pdf> accessed 28.9.2021.

[1493] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss über eine Beauftragung des Instituts für Qualität und Wirtschaftlichkeit im Gesundheitswesen: Erstellung einer Versicherteninformation über die bestehenden Möglichkeiten der Pränataldiagnostik gemäß Mutterschafts-Richtlinien (Mu-RL) sowie der Einbindung von Eckpunkten, die sich gegebenenfalls aus einer zukünftigen Änderung der Mu-RL ergeben' (16.2.2017) <https://www.g-ba.de/downloads/39-261-2857/2017-02-16_Mu-RL_IQWiG-Beauftragung-Versicherteninformation-PD-NIPD.pdf> accessed 28.9.2021.

[1494] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 'Nicht invasive Pränataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 bei Risikoschwangerschaften (Vorbericht)' (11.12.2017), p. 21 <https://www.iqwig.de/download/s16-06_nicht-invasive-praenataldiagnostik-nipd_vorbericht_v1-0.pdf?rev=187029> accessed 28.9.2021.

[1495] ibid.

[1496] ibid, p. 71.

[1497] ibid, p. III.

[1498] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 'Nicht invasive Pränataldiagnostik kann Trisomie 21 zuverlässig bestimmen' (27.6.2018) <https://www.iqwig.de/presse/pressemitteilungen/pressemitteilungen-detailseite_10172.html> accessed 28.9.2021.

[1499] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 'IQWiG-Berichte - Nr. 623: Nicht invasive Pränataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 bei Risikoschwangerschaften (Ab-

The IQWiG's refusal to address possible ethical problems has been criticised as a failure to reflect on the qualification of fetal disability as a problem to be diagnosed[1500] and consequently on the existence of a medical benefit in the use of the test.[1501]

c Consultation and Parliamentary Debate

Based on the health technology assessment report the G-BA published a draft decision in March 2019. The key points of the draft were that NIPT should only be reimbursed by the statutory health insurance with a view to the individual circumstances of the pregnant woman and after the 12th week of pregnancy.[1502] A purely statistical risk due to the mother's age would therefore not be sufficient to qualify for reimbursement. The aim of including NIPT in prenatal care would be to enable the pregnant woman to face the possible presence of a trisomy while avoiding invasive diagnoses that could lead to miscarriages. To achieve this the draft envisaged that the mother would be provided with comprehensive counselling and information.[1503]

Upon publication of the draft the G-BA initiated a formal consultation procedure. In accordance with §§ 91(5) and 91(5a), §§ 92(1b) and 92(7d) of the SGB V written comments were solicited from the German Medical Association, the Federal Commissioner for Data Protection and Freedom

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schlussbericht)' (30.4.2018), p. 85 <https://www.iqwig.de/download/s16-06_nicht-invasive-praenataldiagnostik-nipd_abschlussbericht_v1-0.pdf> accessed 28.9.2021.

[1500] Deutscher Bundestag, 'BT-Drucks. 19/9059', 4.4.2019, p. 67.

[1501] Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 260; BioSkop, GeN and Netzwerk gegen Selektion durch Pränataldiagnostik, 'Gemeinsame Stellungnahme zum Bericht der IQWiG: "Nicht invasive Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 bei Risikoschwangerschaften": Moratorium für den Bluttest!' (4.7.2018) <https://gen-ethisches-netzwerk.de/sites/default/files/dokumente/2018-07/2018_07_04-stellungnahme-gen_iqwig.pdf> accessed 28.9.2021.

[1502] Gemeinsamer Bundesausschuss (G-BA), 'Tragende Gründe zum Beschlussentwurf über eine Änderung der Mutterschafts-Richtlinien (Mu-RL): Nicht-invasive Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT) für die Anwendung bei Risikoschwangerschaften' (22.3.2019), pp. 3-ff <https://www.g-ba.de/downloads/40-268-5640/2019-03-22_Einleitung-SN_NiPT_Beschlussentwurf_TrG_WZ.pdf> accessed 29.9.2021.

[1503] ibid, p. 4.

of Information, midwives associations, professional societies, organisations of medical device manufacturers and NIPT manufacturers. [1504] At the same time, as part of a wider public debate, the G-BA also called on the German Ethics Council and the Genetic Diagnostics Commission (*Gendiagnostik-Kommission*, GEKO) to comment on the draft,[1505] and on the Bundestag to initiate a parliamentary debate on the political and normative aspects.[1506]

The German Ethics Council declined to intervene, but referred back to the statement it had already issued in 2013 on the future of genetic diagnostics.[1507] On that occasion the Council had stated that NIPT serves medical purposes and could therefore be offered by the statutory health insurance in the case of pregnancies at increased risk. A dissenting opinion signed by four members had on the contrary argued that NIPT should not be supported by public funding and should not be part of the services offered by the statutory health insurance.[1508]

As for the Bundestag, a parliamentary 'orientation debate' on the issue of NIPT reimbursement by the GKV was conducted in April 2019.[1509]

Whereas no MPs were in favour of a routine screening of trisomies that would be provided indiscriminately to all pregnant women, most agreed that NIPT should be offered by statutory the health insurance instead of the riskier invasive diagnoses already carried out.[1510] In addition, some speakers pointed out that integrating NIPT into the Maternity Guidelines

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[1504] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss des Gemeinsamen Bundesausschusses über die Einleitung des Stellungnahmeverfahrens gemäß § 91 Absatz 5, § 91 Absatz 5a sowie § 92 Absatz 1b und § 92 Absatz 7d des Fünften Buches Sozialgesetzbuch (SGB V) vor einer abschließenden Entscheidung über eine Änderung der Mutterschafts-Richtlinien: Nicht-invasive Pränataldiagnostik (NIPD) autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT) für die Anwendung bei Risikoschwangerschaften im Rahmen der Mutterschafts-Richtlinien (Mu-RL)' (22.3.2019).

[1505] Gemeinsamer Bundesausschuss (G-BA), 'Nicht-invasive Tests bei Risikoschwangerschaften: G-BA fordert zur Stellungnahme auf' (22.3.2019) <https://www.g-ba.de/presse/pressemitteilungen-meldungen/789/> accessed 28.9.2021.

[1506] Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 262.

[1507] As reported by Deutscher Bundestag, 'BT-Drucks. 19/9059', 4.4.2019, p. 67.

[1508] Deutscher Ethikrat, 'The Future of Genetic Diagnosis' (2013) p. 167.

[1509] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), pp. 11315-ff.

[1510] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), see *inter alia*, the speeches of Karl Lauterbach; Cornelia Möhring, Volker Münz, Katja Dörner, Katrin Helling-Plahr, Stephan Pilsinger.

would guarantee adequate information counselling for pregnant women, which could otherwise not be ensured in the private sector.[1511] Moreover, the fact that the tests would still be available out-of-pocket to those women who have sufficient financial resources was considered by many MPs to be discriminatory. Women with fewer financial means would be forced to accept a certain risk of miscarriage in order to obtain information on the health of the foetus.[1512] As one speaker put it: the reimbursement of costs by statutory health insurance can be seen as not an ethical but rather a social issue.[1513]

In opposition to this, a consistent minority of MPs argued against the public funding of NIPT. Some claimed that it would be incompatible with the purpose of the public healthcare system to treat individuals[1514] and that the state should not actively bring about the conditions for the abortion of foetuses with chromosomal trisomies, as such a value choice would be ethically and politically wrong.[1515] Others emphasised that the possibility for a woman to decide free of pressure and her right not to know, as well as the importance of an inclusive society, were essential values that were at stake.[1516]

However, this parliamentary debate has not been followed up upon to date. As the scheduled date for the G-BA's final decision on the amendments to the Maternity Guidelines approached, a group of MPs decided to address the G-BA members directly. They sent a letter asking them to consider suspending the procedure and the decision in order not to prevent further parliamentary discussions.[1517]

[1511] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), see the interventions of Claudia Schmidtke and Thomas Rachel.

[1512] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), *inter alia,* Karl Lauterbach, Christine Aschenberg-Dugnus, Petra Sitte, Katrin Helling-Plahr, Marja-Liisa Völlers.

[1513] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), p. 11337, intervention by Erwin Rüddel.

[1514] Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), p. 11319, Corinna Rüffer.

[1515] Matthias Bartke in Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019)

[1516] Dagmar Schmidt and Christine Aschenberg-Dugnus in Deutscher Bundestag, 'Plenarprotokoll 19/95: 95. Sitzung' (Berlin 11.4.2019), pp. 11318-11321.

[1517] As explained in the G-BA chairman's reply to the letter of the MPs, Gemeinsamer Bundesausschuss (G-BA), 'Schreiben von Prof. Josef Hecken, unparteiischer Vorsitzender des G-BA, an Mitglieder des Deutschen Bundestages zur Nichtvertagung der Beschlussfassung zu NIPT' (19.9.2019) <https://www.g-ba.de/

The response letter from the chairman of the G-BA stated that the committee had unanimously decided to continue the procedure. The inclusion of NIPT in the maternity guidelines would serve primarily to avoid high-risk invasive diagnoses. The chairman acknowledged that the committee was aware of the fundamental ethical issues at stake but argued that these require a legislative response. For these purposes the letter pointed out that the committee had left room for discussion and possible parliamentary decision on the issue during the three years of the assessment procedure. Moreover, the decision on the amendments to the maternity guidelines would not, in any case, preclude other initiatives by Parliament, which remained free to intervene with a legislative act to revise the G-BA decision. Lastly, the chairman mentioned that the G-BA decision would not yet warrant any claim for reimbursement. An assumption of costs by the GKV could not take place until the information brochure for insured persons was adopted.[1518]

Beside the feedback from the Bundestag, the G-BA had received a total of 30 comments from the other associations called upon to intervene. These were taken into account when reformulating the final decision.[1519]

d Inclusion of NIPT in the Maternity Guidelines

In its final decision of 19 September 2019 the G-BA amended the Maternity Guidelines to include NIPT in the prenatal care pathway. In order to avoid invasive diagnostic measures reimbursement of NIPT by the statutory health insurance was foreseen in those cases where “it is necessary to enable a pregnant woman to discuss her individual situation with regard to the presence of a trisomy within the framework of medical support”.[1520] It was

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downloads/17-98-4847/2019-09-19-PA-JHecken_an-BT-Abgesordnete_NIPT.pdf> accessed 28.9.2021.

[1518] ibid.

[1519] Gemeinsamer Bundesausschuss (G-BA), ‘Pressemitteilung Nr. 26/2019: Nicht-invasiver Test zum Vorliegen von Trisomien als mögliche Alternative zu invasivem Eingriff’ (19.9.2019) <https://www.g-ba.de/downloads/34-215-810/26_2019-09-19_Mu-RL_NIPT.pdf> accessed 28.9.2021.

[1520] Gemeinsamer Bundesausschuss (G-BA), ‘Beschluss über eine Änderung der Mutterschafts-Richtlinien (Mu-RL): Nicht-invasive Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT) für die Anwendung bei Schwangerschaften mit besonderen Risiken’ (19.9.2019) BAnz AT 20.12.2019 B6, p. 3 <https://www.g-ba

again pointed out that a statistically increased risk of trisomy would not be sufficient to access this test.[1521]

In explaining the reasons for the decision the Committee addressed the three criteria regulating the inclusion of new diagnostic or therapeutic services in the benefit basket of the GKV according to § 135(1) no. 1 SGB V. Namely, diagnostic or therapeutic benefit, medical necessity and economic efficiency. The provision also states that these aspects must be evaluated in comparison with other services already included in the benefit basket.

The diagnostic benefit and medical necessity of NIPT were determined, on the one hand, on the basis of the possibility it offered to replace invasive diagnoses and lower the risk of miscarriages and, on the other hand, on the grounds of its high specificity and sensitivity, which reduces the amount of false positives and false negatives.[1522] More generally, the medical necessity of prenatal diagnosis was grounded on the need to enable pregnant women to confront the possibility of fetal trisomies and to assess, within a medical framework, whether the pregnancy could result in a serious impairment of the physical or psychical health of the patient.[1523]

As regards the criterion of economic efficiency, the G-BA acknowledged that the reimbursement of NIPT would lead to additional costs for the public healthcare system. However, economic efficiency would be ensured by decreasing costs for the avoidable invasive diagnoses and related complications.[1524]

As part of the measures to ensure quality of care the final decision included comprehensive counselling and information for the pregnant woman. The requirements that such information must fulfil were based on the provisions contained in the Genetic Diagnosis Act. Counselling must therefore include a thorough discussion of possible medical, psychological and social issues related to the test and the consequences of the results.

.de/downloads/39-261-3955/2019-09-19_Mu-RL_NIPT_BAnz_WZ.pdf> accessed 28.9.2021 (author's translation).

[1521] ibid.

[1522] Gemeinsamer Bundesausschuss (G-BA), 'Tragende Gründe zum Beschluss über eine Änderung der Mutterschafts-Richtlinien (Mu-RL): Nicht-invasive Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT) für die Anwendung bei Schwangerschaften mit besonderen Risiken' (19.9.2019), p. 3 <https://www.g-ba.de/downloads/40-268-6007/2019-09-19_Mu-RL_NIPT_TrG.pdf> accessed 28.9.2021.

[1523] ibid, p. 4.

[1524] ibid, p. 7.

After counselling, the woman must be given a reasonable period of time to reflect before the test.[1525] The right not to know must also be guaranteed at all stages of the procedure in accordance with the Genetic Diagnosis Act.[1526] It is prescribed that the information shall be given on the basis of an informative brochure for insured persons. As stated in the Press Release accompanying the decision, the amendments to the Maternity Guidelines concerning the use of NIPT would only come into force with the approval of this informative brochure. Until then, G-BA decision did not ground any right to claim a reimbursement of NIPT by the GKV.[1527]

After another consultation procedure in which comments were again solicited from the German Ethics Council and the GEKO – among other organisations –[1528] the information for insured subjects was approved as an annex to the maternity guidelines in August 2021.[1529] The information

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[1525] ibid, p. 5.

[1526] ibid. On the counselling and informed consent requirement provided for by the Genetic Diagnosis Act, see above in this section at para. II.1.b. Initially, there was some doubt as to whether the provisions of the Genetic Diagnosis Act could also be applied to NIPT, see *inter alia* Lindner, 'Fällt der "PraenaTest" in den Anwendungsbereich des §15 GenDG?' (2013) 31(5) MedR p. 288. However, doubts were soon removed thanks to a statement by the Commission on Genetic Testing (*Gendiagnostik-Kommission, GEKO*), '8. Mitteilung der GEKO zur Einordnung der nicht-invasiven Pränataldiagnostik (NIPD) und der diesbezüglichen Beratungsqualifikation' (12.3.2014) <https://www.rki.de/DE/Content/Kommissionen/GendiagnostikKommission/Mitteilungen/GEKO_Mitteilungen_08.html> accessed 13.4.2022, see Hübner and Pühler in Katzenmeier and Ratzel, *Festschrift für Franz-Josef Dahm* (2017) pp. 257-258.

[1527] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 26/2019', 19.9.2019.

[1528] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss zur Einleitung des Stellungnahmeverfahrens gemäß § 91 Absatz 5, § 92 Absatz 1b und § 92 Absatz 7d des Fünften Buches Sozialgesetzbuch (SGB V) sowie gemäß 1. Kapitel § 8 Absatz 2 Satz 1 lit. a) VerfO vor einer abschließenden Entscheidung über eine Änderung der Mutterschafts-Richtlinien: Aufnahme einer Versicherteninformation zur Nicht-invasiven Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekular-genetischen Tests (NIPT-Trisomie 13,18,21) für die Anwendung bei Schwangerschaften mit besonderen Risiken' (22.4.2021) <https://www.g-ba.de/downloads/39-261-4803/2021-04-22_Mu-RL_Einleitung-SN-Versicherteninfo-NIPT.pdf> accessed 28.9.2021.

[1529] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss über eine Änderung der Mutterschafts-Richtlinien (Mu-RL): Aufnahme einer Versicherteninformation zur Durchführung der Nicht-invasiven Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT-Trisomie 13,18,21) für die Anwendung bei Schwangerschaften mit besonderen Risiken' (19.8.2021) <https://www.g-ba.de/downloads/39-261-4987/2021-08-19_Mu-RL_NIPT_Versicherteninformation.pdf> accessed 29.9.2021.

leaflet specifies that NIPT is not a generally recommended screening test and that it can only be reimbursed by statutory health insurance in exceptional cases on the basis of the specific situation of the individual patient.[1530] It is made clear that NIPT for chromosomal trisomies is not a form of routine screening and that the costs can only be covered when a woman and her doctor conclude that the test is necessary in view of the woman's personal situation, for instance in cases where uncertainty about the presence of a chromosomal trisomy in the foetus affects the woman intolerably.[1531] Alternatively, NIPT is also covered if a previous screening has already shown an increased risk of trisomies.[1532]

However, some further steps were necessary after the approval of the information brochure in order to allow patients' use of NIPT at the expenses of statutory health insurance funds. Firstly, as required by § 94 SGB V, the Federal Ministry of Health was given two months to submit a possible objection to the inclusion of the informative brochure in the maternity guidelines.[1533] Following this, the guidelines containing the annex could be published in the Federal Gazette (*Bundesanzeiger*).[1534] Finally, the health insurance funds and the doctors' representatives were to negotiate the details regarding the invoicing of the test and the counselling service within six months.[1535] On the 18 May 2022 the evaluation committee (*Bewertungsausschuss*) in charge of this decision agreed on the details of the reimbursement of NIPT for the determination of the risk of trisomies 13, 18 and 21, including the medical consultation prior to the test.[1536] Based on

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[1530] Gemeinsamer Bundesausschuss (G-BA), Mutterschafts-Richtlinien 10.12.1985, p. 44.

[1531] ibid p. 48.

[1532] ibid.

[1533] The approval of the Federal Ministry of Health was also required for the adoption of the previous changes to the maternity guidelines, on that occasion it promptly arrived at the end of November 2019, see document available at <https://www.g-ba.de/downloads/40-268-6166/2019-09-19_Mu-RL_NIPT_BMG.pdf> accessed 28.9.2021.

[1534] According to § 94(2) SGB V.

[1535] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 28/2021: Versicherteninformation zum vorgeburtlichen Bluttest auf Trisomien liegt nun vor' (19.8.2021) <https://www.g-ba.de/presse/pressemitteilungen-meldungen/974/> accessed 29.8.2021.

[1536] Kassenärztliche Bundesvereinigung, 'Beschluss des Bewertungsausschusses nach § 87 Abs. 1 Satz 1 SGB V in seiner 594. Sitzung am 18. Mai 2022 zur Änderung des Einheitlichen Bewertungsmaßstabes (EBM)' (2022) 119(24) Deutsches Ärzteblatt A1108-A1111.

this decision NIPT has been reimbursed by the statutory health insurance funds – in the individual cases provided for by the maternity guidelines – starting from the 1 July 2022, i.e. six years after the start of the regular assessment procedure.

The final decision of the G-BA did not put an end to the public debate. In February 2022 the German Ethics Council held an online public discussion in view of the upcoming reimbursement of NIPT by statutory health insurance funds.[1537] Among the topics addressed were: the arguments for and against the use of NIPT, the design of appropriate counselling and the possible social consequences of NIPT routinisation.[1538] The audience was given the opportunity to participate in the panel discussion by asking questions online.

In July 2022 a group of parliamentarians again called for legislative intervention on NIPT. They expressed fear of routinisation of the test and argued that the ethically controversial decision on whether or not to reimburse NIPT under the statutory health insurance should be made by the legislature rather than the health administration.[1539]

3. *Room for Ethical Considerations in the G-BA's Assessment*

The description of the assessment procedure for NIPT shows how the G-BA decided to concentrate exclusively on the medical and scientific appraisal of the innovative prenatal diagnostic technique, while shifting responsibility for the ethical and normative aspects to other bodies such as the Bundestag and the German Ethics Council, which were called upon to intervene.[1540]

The decision to provide for the reimbursement of NIPT only after a careful assessment of the woman's personal circumstances was welcomed

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[1537] Deutscher Ethikrat, 'Pressemitteilung 01/2022: Ethikrat lädt ein zum Thema „Wissens-Wert? Zum verantwortlichen Umgang mit nichtinvasiven Pränataltests (NIPT)"' <https://www.ethikrat.org/mitteilungen/mitteilungen/2022/ethikrat-laedt-ein-zum-thema-wissens-wert-zum-verantwortlichen-umgang-mit-nichtinvasiven-praenataltests-nipt/?cookieLevel=not-set> accessed 6.4.2022.

[1538] ibid.

[1539] 'Pränatale Diagnostik:"Wir stehen erst am Beginn einer besorgniserregenden Entwicklung"' *Süddeutsche Zeitung* (28.7.2022) <https://www.sueddeutsche.de/politik/praenatale-diagnostik-bundestag-trisomie-1.5629581> accessed 3.8.2022.

[1540] See Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 262-ff.

as a pragmatic solution suited to the German context and debate.[1541] The emphasis on the individual case was said to have a legitimising effect on the G-BA's solution, which succeeded in both ensuring that NIPT does not become a routinely performed test and at the same time provides all women who deem it necessary with affordable access to the test.[1542]

However, some authors have argued that the G-BA did take an ethical stance in deciding to consider NIPT to be medically necessary.[1543] Criticism of the G-BA's decision has brought into question the very concept of fetal trisomies as medical problems requiring a diagnosis.[1544] These arguments appear unconvincing, however, when one considers that other prenatal diagnoses for detecting trisomies are reimbursed by statutory health insurance, even if they are more dangerous to the health of the foetus.[1545] Against this background, the decision to consider NIPT to be medically necessary cannot be considered an ethical choice.

On the other hand, many have argued that the G-BA should have taken into account the ethical aspects of NIPT and, based on them, decided to either suspend the assessment procedure or exclude reimbursement by the GKV.[1546]

However, these options are not compatible with the legal framework regulating the G-BA and its competences. Firstly, the G-BA cannot legitimately suspend the procedure because of ethical issues. As regards the

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[1541] Rehmann-Sutter and Schües, 'Die NIPT-Entscheidung des G-BA. Eine ethische Analyse' (2020) 32(4) Ethik Med p. 385, 399-400.

[1542] ibid, p. 399.

[1543] Braun and Könninger, 'Realizing Responsibility.' (2017) 37(3) New Genetics and Society p. 248, 262.

[1544] As reported by the Bundestag report on prenatal diagnosis, Deutscher Bundestag, 'BT-Drucks. 19/9059', 4.4.2019, p. 67: The 'technicist tunnel vision of the study design' which 'unreflectively presupposes the disability of the foetus as a problem to be diagnosed' met with public criticism (author's translation). See also Freiherr von Ulmenstein, 'Tagungsbericht' (2018) 36(9) MedR p. 680, 680–681.

[1545] And as Huster notes (in Huster, 'Non-invasive Prenatal Diagnostics (NIPD) in the System of Medical Care: Ethical and Legal issues' (2021) 49(8) J Perinat Med p. 1, 5), no one in the discussion suggested removing them from the benefit basket of the statutory health insurance.

[1546] As was demanded of the G-BA in a letter from ten MPs, see Gemeinsamer Bundesausschuss (G-BA), 'Schreiben von Prof. Josef Hecken, unparteiischer Vorsitzender des G-BA, an Mitglieder des Deutschen Bundestages zur Nichtvertagung der Beschlussfassung zu NIPT', 19.9.2019.

coverage with evidence development procedure,[1547] the G-BA is given a deadline of three months to decide on the application of the producer.[1548] The suspension or stalling of a regular evaluation procedure could lead to a so-called 'system failure' according to § 13 SGB V if it occurs due to arbitrary reasons.[1549] Thus, in the case of a product that meets all the requirements for inclusion in the statutory health insurance, a suspension of the assessment on purely ethical grounds could have entitled patients to obtain reimbursement of NIPT directly from the public health insurance funds.[1550]

Once the evaluation procedure has started the list of aspects that have to be taken into account by the G-BA under § 135(1) of the SGB V is exhaustive.[1551] There is no legal basis that would allow the G-BA to bring ethical aspects into consideration when deciding on reimbursement by the statutory health insurance. For this reason objections had already been raised in response to the G-BA's press release that sought to reassure stakeholders and the public that the German Ethics Council would be involved in the procedure.[1552] The adoption of further evaluation criteria by the G-BA could only be made legitimate by a legal provision that integrated them into the exhaustive list in § 135(1) of the SGB V.[1553] Such a legal basis would be necessary also considering the relevance of the G-BA's guidelines for the fundamental rights of the individual.[1554]

[1547] As implemented by the Act on the Improvement of Care Structures in Statutory Health Insurance (Gesetz zur Verbesserung der Versorgungsstrukturen in der gesetzlichen Krankenversicherung, GKV-VStG) which introduced § 137e in the SGB V.

[1548] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 284. See also the position of the G-BA's chairman in an interview in Deckers and Mihm, '"Das wäre Zwei-Klassen-Medizin" Im Gespräch: Josef Hecken, Vorsitzender des Gemeinsamen Bundesausschusses' *Frankfurter Allgemeine Zeitung* (14.12.2016), p. 4.

[1549] As pointed out by Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 284.

[1550] ibid. For details on the functioning of the reimbursement claim based on the so-called 'system failure', see Kingreen in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 16-ff.

[1551] Hufen, 'Zur verfassungsrechtlichen Beurteilung frühzeitiger pränataler Diagnostik', 4.1.2013, p. 17; Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 285.

[1552] Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 284-ff.

[1553] See ibid, p. 284.

[1554] ibid.

Admittedly, there is indeed an abstract possibility for the legislature to provide a legal basis authorising or encouraging the use of ethical criteria in the G-BA decisions or in the health technology assessment conducted by the Institute for Quality and Efficiency in Health Care.[1555] Nonetheless, it must be considered that a series of constraints and precautions would be needed in order to guarantee that respect for constitutional standards is maintained.

In this respect, the G-BA's lack of democratic legitimacy[1556] already constitutes a disincentive to granting it the competence to decide which of the ethical and religious convictions, which are represented in the pluralist society, should prevail and contribute to the shaping of the publicly funded healthcare system.[1557] The inclusion of ethical concerns in health technology assessments would pave the way to taking into consideration extra-legal norms and standards that have neither undergone public discussion nor any democratic legitimation process. [1558] This would also result in the introduction of an element of arbitrariness into the decisions regarding the scope of the statutory health insurance.[1559]

Introducing ethicists amongst the members of the G-BA would not eliminate the problem either. While it is correct that ethicists can be considered experts in ethical argumentation and can show the flaws or strengths of certain arguments, it is also true that they cannot be legitimised to democratically represent the various moral and religious convictions that exist in a highly pluralistic society.[1560]

[1555] As advocated, for instance, in Rüffer, 'Kostenübernahme für pränatale Bluttests. Pro und Contra' (2018) 114(44) Deutsches Ärzteblatt A1989, A1989.

[1556] According to the Federal Constitutional Court, the doubts on the democratic legitimacy of the Federal Joint Committee shall be considered "quite weighty" (BVerfG, 10.11.2015 - 1 BvR 2056/12, author's translation), as highlighted by Kingreen, 'Der Gemeinsame Bundesausschuss vor dem BVerfG: Das Tor liegt in der Luft!' (2017) 35(1) MedR p. 8, 9.

[1557] See Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 285, who argues that a legal basis for the consideration of ethical concerns in the procedure would not be a viable option, given the already controversial legitimacy of the G-BA that would not benefit from such 'ethicalisation'.

[1558] Gruschke in Vöneky and others, *Ethik und Recht - Die Ethisierung des Rechts/ Ethics and Law - The Ethicalization of Law* (2013) p. 42.

[1559] ibid.

[1560] Vöneky in Vöneky and others, *Legitimation ethischer Entscheidungen im Recht: Interdisziplinäre Untersuchungen* (2009).

But more fundamentally, the principle of the ethical neutrality of the state as a neutrality of justification comes into play. According to this standard, access to a health service could not be legitimately denied on the basis of purely ethical considerations.[1561]

As already mentioned, the legal assessment of NIPT does not differ compared to any other test for the prenatal diagnosis of fetal trisomies already available in the public healthcare system. From a social law perspective NIPT must be considered a valid innovation for the statutory health insurance. It meets the legal criteria set out in § 135(1) of the SGB V and fulfils the same function as invasive diagnosis, albeit without carrying any risk of miscarriage.

Also from the point of view of constitutional law NIPT raises no more concerns than existing invasive diagnoses. The balance between a woman's reproductive self-determination and the rights of the foetus does not change just because the diagnosis is less risky and therefore more widely used. [1562] In other words, the quantitative dimension of the use of prenatal diagnoses to detect fetal trisomies does not change their legal assessment.[1563]

Against this background, the only objection to the inclusion of NIPT in the statutory health insurance is an ethical one. Indeed, it can be argued that NIPT could contribute to increasing the use of prenatal screening. Indeed, with NIPT being reimbursed by health insurance funds, more women may potentially decide to take up the screening option, as this less invasive test presents no danger to the health of the foetus. A wider distribution of the diagnosis is considered by part of the society as ethically problematic, although it does not affect the legal and constitutional evaluation of the screening itself. Hence, any justification for refusing to reimburse NIPT through the statutory health insurance would only be grounded in ethical concerns related to the increased use of prenatal diagnoses. However, according to the principle of the ethical neutrality of the state, such concerns could not legitimately provide a basis of justification for measures taken

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[1561] See considerations on the ethical neutrality of the state in the German public healthcare system, in Chapter 1, sec. B.I.2.b.

[1562] Heinrichs, Spranger and Tambornino, 'Ethische und rechtliche Aspekte der Pränataldiagnostik' (2012) 30(10) MedR p. 625, 629; Huber in Steger, Orzechowski and Schochow, *Pränatalmedizin* (2018) p. 155.

[1563] Tolmein, 'Selbstbestimmungsrecht der Frau, Pränataldiagnostik und die UN-Behindertenrechtskonvention' (2012) 45(4) KJ p. 420, 430; Kießling in Rolfs and others, *BeckOK Sozialrecht* (2021) para. 11.

by the ethically neutral welfare state. In sum, the constitutional standard of neutrality of justification prevents the use of arguments drawn from specific ethical or religious convictions as legitimate criteria for the decisions of the G-BA.

B. Non-Invasive Prenatal Testing in Italy

I. NIPT in the Private Sector

Non-invasive prenatal testing entered the Italian private market through its CE marking in 2012.[1564]

Before being implemented in some Regional Healthcare Systems NIPT was only offered at several private clinics and laboratories with costs borne by the patients.[1565] Despite its initially high price, a study has found that uptake of NIPT in Italy was higher than the European average and its use occurred mainly through private clinics.[1566]

The rapid spread of NIPT in the private sector has caused some concerns. The Italian National Health Council (*Consiglio Superiore di Sanità*, CSS), the technical and scientific consulting body to the Ministry of Health, has been warning that some private facilities do not provide appropriate counselling before and after the test and has noted that patients have reported inadequate communication and informed consent.[1567] The CSS and other organisations have expressed their concern that the use of non-invasive screening for chromosomal trisomies predominantly in a deregulated private context would lead to biased reporting of scientific data and access to testing without the necessary quality assurance.[1568]

[1564] At the time, entry into market of in vitro diagnostics with CE marking was regulated by d. lgs. n. 322/2000, as amended by d. lgs. 37/2010.

[1565] Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)' (05.2015), p. 14 <https://www.salute.gov.it/imgs/C_17_pubblicazioni_2381_allegato.pdf> accessed 6.4.2022.

[1566] Gadsbøll and others, 'Current Use of Noninvasive Prenatal Testing in Europe, Australia and the USA: A Graphical Presentation' (2020) 99(6) Acta Obstet Gynecol Scand p. 722, 724–725.

[1567] Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015, p. 14.

[1568] Fondazione ONDA, 'Atti tavolo tecnico interregionale Test Prenatali Non Invasivi (NIPT)' (Milano 13.12.2019), p. 5 <https://ondaosservatorio.it/ondauploads/20

Moreover, access to NIPT through the private market in the absence of homogeneous state funding has been noted to create inequalities both between different Regions across the national territory and between wealthy and less wealthy patients.[1569]

II. NIPT in the National Health Service

1. Access to Prenatal Screening and Diagnoses

a Prenatal Screening and Diagnoses in the Essential Levels of Care

In Italy screening and prenatal diagnosis procedures for chromosomal trisomies have long been part of the maternity protection measures contained in Essential Levels of Care.[1570] These represent the benefit basket of the National Health Service. As illustrated above,[1571] health services must be included in the LEA when they are necessary to guarantee the essential core of the fundamental right to health.[1572] As such they fall within the exclusive competence of the national legislature[1573] and must be equally provided to all national residents.[1574]

The inclusion of prenatal screening in the LEA thus indicates that they are considered part of a minimum standard of health protection that the state must ensure, as they are essential to the protection of the right to

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20/10/NIPT-ONDA_atti-tavolo-tecnico_DEF.pdf> accessed 6.4.2022; Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015, p. 14.

[1569] Fondazione ONDA, 'Atti tavolo tecnico interregionale Test Prenatali Non Invasivi (NIPT)', Milano 13.12.2019, p. 4; Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica' (9.3.2021), p. 3 <https://www.salute.gov.it/imgs/C_17_pubblicazioni_3097_allegato.pdf> accessed 6.4.2022.

[1570] See Decree of the Minister of Health of 10 September 1998 in Gazzetta Ufficiale no. 245 of 20.10.1998 also known as '*Decreto Bindi*'.

[1571] See Chapter 1, sec. B.II.2.b.

[1572] Pesaresi, 'La "determinazione dei livelli essenziali delle prestazioni" e la materia " tutela della salute": la proiezione indivisible di un concetto unitario di cittadinanza nell'era del decentramento instituzionale' (2006) 51(2) Giur Cost p. 1733, 1742.

[1573] Art.117(2) letter m) Italian Constitution.

[1574] Italian Constitutional Court, judgment no. 88/2003. See Balboni, 'I livelli essenziali e i procedimenti per la loro determinazione' [2003](6) Le Regioni p. 1183, 1187; Bergo, 'I nuovi Livelli Essenziali di Assistenza. Al crocevia fra la tutela della salute e l'equilibrio di bilancio' [2017](2) Rivista AIC p. 1, 5.

health of pregnant women. Prenatal diagnosis was already foreseen in the Decree of the Minister of Health of 10 September 1998 as an Essential Level of Care that was free of co-payment for certain categories of patients at risk.[1575]

In December 2015 an annex to the Decree of the Minister of Health containing the eligibility conditions for outpatient care services included an entry for the reimbursement of invasive tests, performed to confirm the finding of chromosomal trisomies detected by NIPT, by the National Health Service.[1576] However, NIPT itself was not covered, presumably because its clinical implementation was still at an early stage.

In 2017 the Prime Ministerial Decree of January 12th updated the catalogue of nationally provided health services. In its Article 59 the decree confirmed that prenatal diagnoses are nationally provided as part of the Essential Levels of Care.[1577] Moreover, the list of specialised outpatient services for pregnant women was updated by offering, for the first time, prenatal screening through combined testing free of charge to all patients.[1578] In the case of a high risk pregnancy, detected by the combined test or due to family conditions, invasive diagnoses would be offered regardless of the woman's age.[1579]

The DPCM of 12 January 2017 specified that the 2015 Decree of the Minister of Health on outpatient care services would stays in force until the approval of a new 'tariff decree', which at the time of writing has not yet been issued.[1580] Therefore, invasive tests confirming the result of NIPT remain nationally reimbursed.

[1575] Decree of the Minister of Health of 10 September 1998 in Gazzetta Ufficiale no. 245 of 20.10.1998.

[1576] Decree of the Minister of Health 9 December 2015 in Gazzetta Ufficiale no. 15 of 20.1.2016, attachment 2, p. 37. See Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021, p. 4.

[1577] DPCM 12 January 2017 in Gazzetta Ufficiale no. 65 of 18.3.2017, Suppl. n. 15. On the much awaited updating of the LEA, see, *inter alia,* Bergo, 'I nuovi Livelli Essenziali di Assistenza. Al crocevia fra la tutela della salute e l'equilibrio di bilancio' [2017](2) Rivista AIC p. 1; Vicarelli, 'I nuovi LEA: Passaggio storico o illusione collettiva?' [2017](3) Politiche Sociali p. 517.

[1578] DPCM 12 January 2017 in Gazzetta Ufficiale no. 65 of 18.3.2017, Suppl. n. 15, attachment 10B.

[1579] ibid attachment 10C.

[1580] This decree is still applicable pending the decree defining the maximum tariffs for ambulatory services, see Art. 64(2) DPCM 12 January 2017 in Gazzetta Ufficiale no. 65 of 18.3.2017, Suppl. n. 15. Concrete steps towards the adoption of this decree were only taken at the end of January 2022, see Martini and Marchetti, 'Decreto

However, there is still no mention of NIPT in the updated regulation containing the new Essential Levels of Care. Yet this omission does not seem to stem from an ideological opposition against NIPT. The Italian public debate on NIPT was in fact nowhere near as extensive as in Germany and the UK. As will be illustrated in detail below,[1581] government and parliamentary bodies have rather unanimously insisted on the benefits of non-invasive diagnoses.

From the perspective of legal scholars, the few contributions published on this question have primarily called for a careful consideration of informed consent issues in the possible implementation of NIPT in clinical practice.[1582] It is considered that the increased availability of these non-invasive testing methods will add significantly to the patients' need for accurate and unbiased information.[1583] It is considered essential, *inter alia*, that women have a realistic option of deciding not to undergo any kind of prenatal screening and that they are made aware of alternatives to abortion.[1584] Particular concerns are only voiced in view of the possible use of NIPT to detect non-pathological features in the foetus, such as aesthetic traits or other non-medical conditions.[1585]

Doubts were also expressed about the possible routinisation of NIPT use and a perceived stigmatisation of the community of people with disability

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sulle tariffe e aggiornamento dei LEA: una neverending story?' *Quotidiano Sanità* (8.2.2022) <https://www.quotidianosanita.it/lettere-al-direttore/articolo.php?articolo_id=102142> accessed 6.4.2022. This problematic delay prevents the new services from being offered at the expense of the National Health System, and creates inequalities especially against Regions subject to recovery plans, which cannot implement the new LEAs on their own.

[1581] See below in this section at para. II.3.

[1582] Palazzani, *Dalla bio-etica alla tecno-etica: Nuove sfide al diritto* (2017) pp. 138–144; Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225.

[1583] Palazzani, *Dalla bio-etica alla tecno-etica* (2017) p. 142; Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225, 229.

[1584] Palazzani, *Dalla bio-etica alla tecno-etica* (2017) p. 144; Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225, 229.

[1585] Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225, 232–234.

and women deciding to avoid testing.[1586] In this regard, the question of whether NIPT should be provided to patients through public funding was raised, although it was concluded that adequate information and communication with patients before and after the test would overcome possible doubts.[1587]

In short, it seems that most of the contributors to the Italian debate maintain that the new moral issues emerging with NIPT can be resolved by means of adequate counselling, provided that this is realised in practice. Except for calls for the consideration of possible informed consent issues,[1588] there has not been much debate in the wider public sphere about the desirability of NIPT in general. NIPT seems to be tacitly accepted as an improvement in the safety and accuracy of previous diagnostic techniques.

b Informed Consent

The understanding of prenatal diagnoses as part of a minimum standard of health that the state must protect is in line with the principles endorsed by the Italian Constitution. This places a very high value on the right to health and the right to self-determination in matters of health, according to the combination of Articles 2, 13 and 32. In particular, information on the health condition of the foetus is considered, both by legislation and the case law, to be closely connected with the physical and psychological health of pregnant women.[1589] The Court of Cassation pointed out that prenatal diagnosis is relevant to a woman's health not only insofar as it enables her to make an abortion decision but also because, if abortion is ruled out, it

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[1586] Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225, 234.

[1587] Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225, 239.

[1588] Fondazione ONDA, 'Atti tavolo tecnico interregionale Test Prenatali Non Invasivi (NIPT)', Milano 13.12.2019, p. 14.

[1589] Article 6 Law no. 194/1978 and Corte di Cassazione, judgments nos. 16754/2012, 25767/2015 and 5004/2017. See Conte, '"And makes us rather bear those ills we have?" L'inizio della vita e i confini della sofferenza risarcibile (Nota a Corte di Cassazione, Sezioni Unite, n. 25767/2015)' [2016](2) BioLaw Journal – Rivista di BioDiritto p. 433, 436.

equips her psychologically and materially for the birth of a child with a particular genetic condition.[1590]

The right to self-determination and the right to health are brought together under the umbrella principle of informed consent, according to which each patient has the right to receive information on their health status and on the available medical possibilities in order to be able to make a free and informed choice.[1591] The right to informed consent received dedicated statutory protection with Law no. 219/2017, which placed a special focus on doctor-patient dialogue by establishing that the time spent in communication effectively constitutes treatment time.[1592]

In the case of prenatal screening, the right to informed consent must be read in conjunction with the constitutional requirement of laicity of the State.[1593] In adopting a laicity-driven approach the ethical perception of the woman and the foetus occupying essentially conflicting positions must be abandoned and the woman's right to prenatal diagnoses must be seen as the result of a balancing of rights in compliance with the relevant constitutional principles.[1594]

[1590] Corte di Cassazione, judgment no. 5004/2017. See Salvatore, 'La recente legge sul consenso informato. Un passo in avanti in tema di responsabilità medica per violazione degli obblighi informativi?' [2018](3) Riv ital med leg dirit campo sanit p. 993, 1007.

[1591] The concept of informed consent as grounded in Articles 2, 13 and 32 of the Constitution was elaborated for the first time in the Italian Constitutional Court judgment no. 438/2008. This was recently confirmed in the Italian Constitutional Court judgment no. 144/2019, see Balduzzi and Paris, 'Corte costituzionale e consenso informato tra diritti fondamentali e ripartizione delle competenze legislative' (2008) 53(6) Giur Cost p. 4953; Casonato, 'Il principio della volontarietà dei trattamenti sanitari fra livello statale e livello regionale: Nota a Sentenza n. 438/2008' (2009) 37(3-4) Le Regioni p. 627, 627–628.

[1592] Russa and others, 'Consenso informato e dat (disposizioni anticipate di trattamento): Momento legislativo innovativo nella storia del biodiritto in italia' (2018) 83(1) Responsabilità civile e previdenza p. 353, 359; Salvatore, 'La recente legge sul consenso informato. Un passo in avanti in tema di responsabilità medica per violazione degli obblighi informativi?' [2018](3) Riv ital med leg dirit campo sanit p. 993, 996–997.

[1593] D'Amico, 'Il concepito e il diritto a nascere sani: Profili costituzionali alla luce della decisione della Corte di Cassazione (n. 16754 del 2012)' [2014](2) Rivista AIC p. 1, 2.

[1594] As envisaged in the abortion decision of the Italian Constitutional Court, judgment no. 27/1975; see D'Amico, 'Il concepito e il diritto a nascere sani: Profili costituzionali alla luce della decisione della Corte di Cassazione (n. 16754 del 2012)' [2014](2) Rivista AIC p. 1, 5; Conte, '"And makes us rather bear those ills we have?" L'inizio della vita e i confini della sofferenza risarcibile (Nota a Corte

In the light of these principles, prenatal screening for chromosomal trisomies has traditionally been seen as relatively uncontroversial in Italy, provided that the patient's fully informed consent is maintained. As early as 1992 the Italian Committee for Bioethics (*Comitato Nazionale per la Bioetica*, CNB) issued an "overall positive"[1595] assessment of the different prenatal screening procedures and argued that the right to know the health status of the foetus was undisputed.[1596] However, the document stressed that couples should be provided with a 'non-directive' medical consultation, i.e. the information given by the doctor should not exert any pressure to undergo the diagnosis and the doctor should refrain from encouraging or discouraging abortion.[1597] The members of the Committee noted that the permissibility of prenatal diagnoses could be challenged only if they were associated with selection and eugenic purposes.[1598] In this regard, it was emphasised that prenatal screening should be kept conceptually distinct from any possible abortion choice. The CNB recommended that the essential distinction between the two moments must be guaranteed in practice and borne in mind during the consultation.[1599]

2. Coverage of NIPT in Different Regional Healthcare Systems

As it is not currently included in the Essential Level of Care, public funding of NIPT is still left to the discretion of individual Regional Healthcare Systems.

Regions have, first of all, the task of implementing the Essential Level of Care in their Regional Healthcare Systems. As regards prenatal screening, annex 10C of the Prime Minister's Decree of 12 January 2017 calls on the Regions to adopt methods for calculating the risk of chromosomal trisomies in pregnancy that have greater sensitivity and fewer false positives, taking into account the developments in scientific research.

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di Cassazione, Sezioni Unite, n. 25767/2015)' [2016](2) BioLaw Journal – Rivista di BioDiritto p. 433, 436.

[1595] Comitato Nazionale per la Bioetica, 'Diagnosi prenatali', 18.7.1992, p. 28 (author's translation).

[1596] ibid, pp. 36-37.

[1597] ibid, pp. 30-31.

[1598] ibid, p. 42.

[1599] ibid, p. 43.

Moreover, individual Regions have the possibility to include additional so-called 'extra-LEA' services in their Regional Healthcare System's services.[1600] While the essential levels of protection must be guaranteed throughout the national territory,[1601] the Regions have concurrent legislative competence in the sphere of health protection according to Article 117(3) of the Italian Constitution.[1602] This increase in benefits may be offered in line with the political orientation of each Region and by allocating funds from the regional budget.[1603]

On the basis of their concurrent competence, and in light of the persistent delay of the national government, many Regions have decided to independently undertake action to publicly fund and provide NIPT to their residents. This development was also prompted by the 2015 guidelines of the Italian National Health Council, which recommended the introduction of NIPT in all public facilities.[1604]

Emilia Romagna has decided to offer free NIPT to all pregnant women regardless of risk factors. Already in March 2015 this Region commissioned a scientific evaluation on the possibility of including NIPT in the Region's antenatal pathway.[1605] The assessment team also included members with

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[1600] See Pellegrini in Balduzzi, *La sanità italiana tra livelli essenziali di assistenza, tutela della salute e progetto di devolution: Atti del convegno, Genova, 24 febbraio 2003* (2004). The possibility for Regions to offer additional health services to their residents is an entirely physiological feature of the Italian public healthcare system. However, the concentration of therapeutic and diagnostic innovations in only a few Regions leaves room for potentially unsustainable inequalities, see Aperio Bella, 'Tecnologie innovative nel settore salute tra scarsità delle risorse e differenziazione: alla ricerca di un equilibrio difficile' [2020](2) Federalismi p. 245, 260–261.

[1601] Art. 117(2) letter m) Italian Constitution.

[1602] Regions have legislative powers in all matters of concurrent legislation, except for the determination of fundamental principles, which is reserved for State legislation, see Art. 117(3) Italian Constitution.

[1603] Balboni, 'I livelli essenziali e i procedimenti per la loro determinazione' [2003](6) Le Regioni p. 1183, 1191.

[1604] Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015. See, for instance, references to the CSS guidelines in Regione Emilia-Romagna (Giunta Regionale), Delibera no. 1894, 4.11.2019; Regione Umbria (Assemblea Legislativa), Deliberazione no. 279, 23.10.2018.

[1605] Gruppo di Lavoro Regionale Test Prenatali Non Invasivi (NIPT), 'Resoconto delle attività: marzo - giugno 2015' (28.12.2015), p. 5 <https://assr.regione.emilia-romagna.it/pubblicazioni/rapporti-documenti/test-prenatali-2015/@@download/publicationFile/Gruppo%20RER%20NIPT.pdf> accessed 6.4.2022; Fondazione ethical and legal expertise and citizen representatives and thus assessed not only the clinical and organisational implications but also the ethical and legal consequences of offering NIPT in the Regional Healthcare System.[1606] This group found a unanimous consensus in recommending the offer of NIPT as a replacement for the combined test.[1607] Accordingly, in 2019 the Region's governing body gave its approval to the Regional Healthcare System offering NIPT to all pregnant women for the detection of the presence of trisomy 12, 18 and 21.[1608] This was initially launched as a 9-month trial project at the end of which an evaluation and subsequent confirmation of the new screening pathway would be carried out.[1609]

In the self-governing province of Bolzano the provincial government decided to offer NIPT at the expense of the provincial health service at the end of 2018, albeit only to patients who, following the assessment of the combined test, were found to be at intermediate risk of having an affected foetus.[1610] The provincial deliberation stipulated that women who meet the requirements to be eligible for the test should be given an informational consultation aimed at guiding the patient to an informed choice and at collecting informed consent. This counselling is granted an independent tariff and reimbursement code.[1611]

In late 2018 Tuscany also decided to integrate NIPT into the catalogue of specialised outpatient services provided by the Regional Healthcare System.[1612] Here this test is available to pregnant women who have been found to be at risk of between 1/301 and 1/1000 after the combined test. [1613] Unlike Emilia Romagna and Bolzano, however, Tuscany asks for a patient

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ONDA, 'Atti tavolo tecnico interregionale Test Prenatali Non Invasivi (NIPT)', Milano 13.12.2019, p. 10.

[1606] Gruppo di Lavoro Regionale Test Prenatali Non Invasivi (NIPT), 'Resoconto delle attività: marzo - giugno 2015', 28.12.2015, p. 29.

[1607] Fondazione ONDA, 'Atti tavolo tecnico interregionale Test Prenatali Non Invasivi (NIPT)', Milano 13.12.2019, p. 10.

[1608] Regione Emilia-Romagna (Giunta Regionale), Delibera no. 1894, 4.11.2019, Art. 1.

[1609] ibid Art. 2.

[1610] Provincia Autonoma di Bolzano - Alto Adige (Giunta Provinciale), Deliberazione no. 1413, 18.12.2018, p. 31.

[1611] ibid p. 32.

[1612] Regione Toscana (Giunta Regionale), Delibera no. 1371, 10.12.2018. See also 'Percorso nascita. In Toscana test combinato gratuito a tutte le gestanti e test Nipt a tariffa ridotta. Saccardi: "Facciamo da apripista a livello nazionale"' *Quotidiano Sanità* (5.3.2019) <https://www.quotidianosanita.it/regioni-e-asl/articolo.php?articolo_id=71605> accessed 6.4.2022.

[1613] Regione Toscana (Giunta Regionale), Delibera no. 1371, 10.12.2018.

co-payment amounting to half the price. Full reimbursement of costs is only granted to pregnant women who fall into certain high risk or low income categories.[1614]

In 2021, the parliamentary body of the Region Puglia unanimously approved a bill to provide NIPT as prenatal screening for the detection of chromosomal trisomies to pregnant women over the age of forty or those who are found to be at a high or intermediate risk after combined testing.[1615] The main aim of the bill was to improve the quality of pregnancy in both medical and psychological terms and to limit the risks of invasive diagnosis.[1616]

The enactment of this regional law was challenged by the Italian government before the Constitutional Court.[1617] The central government argued that the introduction of NIPT into the Regional Healthcare System in Puglia is in breach of the financial deficit recovery plan to which the Region is subject.[1618] The appeal before the Constitutional Court on the regional law on public funding of NIPT is currently pending.

[1614] ibid.

[1615] Art. 3 Legge Regionale Puglia no. 31/2021, “Implementazione del Test prenatale non invasivo (NIPT)” 6.8.2021

[1616] Articles 1 and 3 Legge Regionale Puglia no. 31/2021, “Implementazione del Test prenatale non invasivo (NIPT)” 6.8.2021.

[1617] Ricorso per legittimità costituzionale 6.10.2021, in Gazzetta Ufficiale 1° Serie Speciale (Corte Costituzionale) no. 43 of 27.10.2021, N. 55, p. 62 < https://www.gazzettaufficiale.it/atto/corte_costituzionale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2021-10-27&atto.codiceRedazionale=21C00246> accessed 10.8.2022.

[1618] Ricorso per legittimità costituzionale 6.10.2021, in Gazzetta Ufficiale 1° Serie Speciale (Corte Costituzionale) no. 43 of 27.10.2021, N. 55, p 62. Recovery plans are an instrument through which the national legislature ensures that Regions in a financial deficit maintain the provision of the Essential Levels of Care and contain public health expenditure. The introduction of a recovery plan is admittedly a fairly significant level of State interference in the sphere of regional autonomy. However, it is justified by the exclusive competence of the State in relation to the coordination of public finance and the determination of the essential levels of services that must be guaranteed to all residents across the national territory, see Carpani in Balduzzi, *La sanità italiana alla prova del federalismo fiscale* (2012) pp. 36-37; Cerioni, ‘Stato e Regioni di fronte alla gestione dei Piani di rientro nei sistemi sanitari regionali in deficit’ [2017](1) Politiche Sociali p. 175, 176. As confirmed also recently by a ruling of the Constitutional Court against Puglia, the Regions subject to the recovery plans cannot foresee additional expenses to those necessary to guarantee the LEA, see Italian Constitutional Court, judgment no. 142/2021, considerations in point of law para. 2.

In Basilicata too, a project was approved in 2019 to include NIPT in the prenatal screening pathway in order to reduce the number of invasive diagnoses performed. Also in this Region the test will be offered to pregnant women at intermediate risk after the combined test.[1619]

In November 2021, Lombardia started a 6-month phase of provisional reimbursement in which NIPT is offered in one regional health facility before being opened up for all pregnant women in the Region.[1620]

A few more Regions, although they have not yet included NIPT in their regional health benefit catalogues, have at least initiated its assessment or expressed political will in this direction.

In Umbria this occurred as early as 2018 when the legislative assembly unanimously passed a resolution committing the regional governing body to consider introducing NIPT for chromosomal trisomies for all women over the age of 35.[1621] The main aim was stated to be the reduction of potential, albeit rare, harm resulting from the use of invasive diagnosis among women over 35.

The regional legislative assembly of Piemonte followed in 2021, when it issued an agenda committing the regional government to consider the introduction of NIPT for all women regardless of their age and risk factors.[1622] This political motion was approved almost unanimously by the governmental majority and the opposition[1623] and was at least on one occasion criticised in the local press out of concern that the inclusion of non-invasive tests for chromosomal trisomies in the Regional Healthcare System would create a slippery slope towards stigmatisation of people with disabilities.[1624]

Also in 2021, Liguria's parliamentary body unanimously issued an agenda calling on the regional government to consider including NIPT free of

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[1619] Regione Basilicata (Giunta Regionale), Delibera no. 456, 12.7.2019.

[1620] 'Lombardia. Approvati nuovi test fetali non invasivi per le donne in gravidanza' *Quotidiano Sanità* (16.11.2021) <http://www.quotidianosanita.it/regioni-e-asl/articolo.php?articolo_id=100054> accessed 6.4.2022.

[1621] Regione Umbria (Assemblea Legislativa), Deliberazione no. 279, 23.10.2018.

[1622] Regione Piemonte (Consiglio Regionale), Ordine del giorno no. 170, 3.2.2021.

[1623] Giacosa, 'Sinistra e Lega, la "strana coppia" che in Piemonte ha ottenuto il test del dna per le donne incinte' *La Repubblica* (4.2.2021) <https://torino.repubblica.it/cronaca/2021/02/04/news/strana_coppia_sinistra_lega_test_dna_gravidanza_gratuito-285999290/> accessed 6.4.2022.

[1624] Dovico, 'Il Piemonte, il Nipt e la china scivolosa sui bimbi Down' *La Nuova Bussola Quotidiana* <https://lanuovabq.it/it/il-piemonte-il-nipt-e-la-china-scivolosa-sui-bimbi-down> accessed 6.4.2022.

charge in the regional antenatal diagnosis pathway. [1625] The government accepted this invitation and set up a technical panel in August 2021 to evaluate the test.[1626]

3. Prospective Coverage of NIPT at the National Level

a Guidelines of the Italian National Health Council

While several Regions have already taken action, parliamentary and governmental bodies at the national level have correctly pointed out that NIPT must be implemented by the National Health Service, claiming that it belongs to the minimum services that the state must provide to all residents in order to protect the essential core of the right to health.

In May 2015, the Italian National Health Council issued its first guidelines on NIPT. The document was drafted by the first section of the Council, which is responsible, *inter alia*, for consulting the Ministry of Health on the Essential Levels of Care and on HTA for the evaluation of innovative technologies in the National Health Service.[1627] The multidisciplinary team working on the NIPT recommendations included three members of the CNB.[1628]

The guidelines maintained that NIPT would not provide an incentive for inappropriate use of prenatal screening compared to current clinical practice. If only used for trisomies 21, 18 and 13 it would not expand the range of conditions for which many women already wish to be informed.[1629] In this respect, one benefit of NIPT would be that it provides more accurate

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[1625] 'Nipt test. Regione valuta utilizzo gratuito dopo Odg approvato all'unanimità in Consiglio' *Quotidiano Sanità* (7.4.2021) <https://www.quotidianosanita.it/liguria/articolo.php?articolo_id=94373> accessed 6.4.2022.

[1626] Azienda Ligure Sanitaria della Regione Liguria, Deliberazione no. 308, 11.8.2021.

[1627] Art. 7 Decree of the Minister of Health, 6 August 3002, n. 342 Gazzetta Ufficiale no. 287 of 11.12.2003. The functions of the CSS are laid down in Article 4 of d.lgs. no. 266/1993, according to which the *Consiglio Superiore di Sanità* may, among other things, propose the study of problems relating to hygiene and health and propose to the health administration the formulation of draft rules and measures for the protection of public health.

[1628] The list of the members of the working group is available in Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015, p. 3.

[1629] ibid, p. 13.

information without putting the pregnancy at risk.[1630] To this end, however, the Council argued that it is essential to make counselling an integral part of the screening offer and to thoroughly prepare prospective parents for the information that will result from the test and the possible decisions to be taken as a consequence.[1631] In addition, the guidelines acknowledged that new ethical issues may arise if the number of detectable genetic conditions would increase.[1632]

In conclusion, the CSS supported the need for NIPT to be offered by the healthcare systems at central and regional level.[1633] Centralisation of testing laboratories was also recommended to maintain cost-effectiveness.[1634]

In a follow-up paper in 2016 another working group of the National Health Council assessed the socio-economic impact of incorporating NIPT into public healthcare. This argued that establishing criteria and modalities for testing at a national level would be necessary to overcome some critical issues related to its unregulated use in the private sector.[1635] The sensitive nature of the issue was pointed out in relation to the ethical, emotional and social implications of NIPT and its connection with abortion. [1636] The working group concluded by recommending that the National Health Service should reimburse NIPT as a contingent addition to the combined test, whereby the service must be subject to adequate standards of quality and proper informed consent mechanisms.[1637]

Building on the Council's guidelines, an agreement between the Regions and the State in October 2017 recommended promoting country-wide implementation of NIPT as one of the priorities for the innovation of the National Health Service.[1638]

[1630] ibid.

[1631] ibid.

[1632] ibid.

[1633] ibid, p. 19.

[1634] ibid, p. 15.

[1635] Consiglio Superiore di Sanità, Sez. I, 'Gruppo di Lavoro "NIPT 2". Impatto socio-economico del test del cfDNA/NIPT in Sanità pubblica' (07.2016), p. 12 <http://www.plurigentest.it/NIPT2%20%20doc%20%20finale%2012%20LUGLIO%202016.pdf> accessed 6.4.2022.

[1636] ibid, p. 13.

[1637] ibid, passim.

[1638] Conferenza Stato-Regioni, 'Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n. 131, tra il Governo, le Regioni e le Province autonome di Trento e Bolzano sul documento recante "Piano per l'innovazione del sistema sanitario basata sulle scienze omiche"' (26.10.2017).

The CSS last confirmed and updated its recommendations regarding NIPT in March 2021. In this document the Council noted with concern the inequalities created by devolving the implementation of NIPT to individual Regions.[1639] The main purpose of the new guidelines was therefore to recommend national implementation of NIPT. It was suggested that NIPT should be included in the Essential Levels of Care as contingent screening for trisomies 13, 18 and 21 after combined testing.[1640]

More space was devoted in these revised guidelines to the ethical considerations involved in the implementation of the test. For instance, the conflict between liberalist theories, utilitarian approaches and dignitarian perspectives is mentioned.[1641] The ethical problems of prenatal screening appear to be accentuated by the availability of extensive information about the foetus through a simple blood sample.[1642] The ease with which the test can be carried out could lead to the risk that pregnant women undergo screening without previous adequate critical reflection.[1643] To overcome such ethical concerns, the Council once again emphasised the importance of counselling and the provision of information on alternatives and consequences of the test as an integral part of screening. It reiterated that counselling should be 'non-directive' and that the couple should be able to freely choose whether to undergo screening or not.[1644]

The document also indicated as ethically problematic the possibility that the widespread use of the test would lead to increased discrimination or social exclusion against people with disabilities.[1645] As a response to this issue it is argued that the inclusion of NIPT in the offer of the National Health Service must be accompanied by policies of social justice and support for people with disabilities.[1646]

[1639] Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021, p. 3.

[1640] ibid, p. 5.

[1641] ibid, p. 19.

[1642] ibid, p. 20.

[1643] ibid.

[1644] ibid, p. 21.

[1645] ibid.

[1646] ibid, p. 22.

b NIPT before the National Commission for the Updating of the Essential Levels of Care

At the end of 2019, on the occasion of the budget bill for the financial year 2020, the Health Commission of the Senate presented an order of the day (*ordine del giorno*) committing the government[1647] to "assess the possibility of taking initiatives to include NIPT in the Essential Levels of Care".[1648] The Commission considered it necessary to ensure equal access throughout the country to safer and more accurate prenatal screening procedures.[1649] The government accepted this order of the day, thereby making a political commitment to explore the possibility of national public funding for NIPT.

In the same year the Ministry of Health received a parliamentary question from a member of the Senate urging it to undertake initiatives to include NIPT in the Essential Levels of Care, also in the light of the guidelines of the National Health Council.[1650]

In response to these political solicitations the Ministry for Health confirmed that the proposal to include NIPT in the outpatient specialised services of the National Health Service would be submitted to the National Commission for the Updating of Essential Levels of Care.[1651] The Ministry announced that the decision on the inclusion of NIPT in the LEA would

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[1647] In Italian parliamentary law, an order of the day is an instrument with which Parliament exercises its political steering function vis-à-vis the government. The submission of orders of the day in connection with the draft budget law is governed by a special procedure in the parliamentary regulations for the Senate see Art. 127(1). An order of the day that 'commits' the government to a certain action is more binding than one that merely 'invites' it, although it is still only politically and by no means legally binding. The degree of the binding political force of the order of the day increases if the government fully accepts it. On the orders of the day in Italian parliamentary law, see Ciaurro, 'Ordine del giorno' (1980) XXX Enc dir p. 1018, 1035–1037; Mannino and Curreri, *Diritto parlamentare* (2019) p. 316-ff.

[1648] Senato della Repubblica, 'Ordine del Giorno n. G/1586 sez I/18/12 (testo 2) al DDL n. 1586' <https://www.senato.it/japp/bgt/showdoc/frame.jsp?tipodoc=Emendc&leg=18&id=1126780&idoggetto=1134832> accessed 6.4.2022, author's translation.

[1649] ibid.

[1650] Senato della Repubblica, 'M. Rizzotti. Legislatura 18 Atto di Sindacato Ispettivo n° 3-01021' <https://www.senato.it/japp/bgt/showdoc/18/Sindisp/0/1118781/index.html> accessed 6.4.2022.

[1651] 'Test prenatali. Sileri: "All'esame della Commissione Lea inserimento dei test non invasivi"' *Quotidiano Sanità* (9.1.2020).

be taken in cooperation with the Regions and with the involvement of technical and scientific bodies, including the CSS.[1652]

c Criteria for Updating the Essential Levels of Care and Room for Ethical Concerns

A first Commission with the task of updating the Essential Levels of Care was already founded by Decree-Law no. 63 of 15 April 2002.[1653] Later on this function was taken over by the Technical Committee for Health operating at the Ministry of Health.[1654] Currently the updating of the LEA catalogue is entrusted to the National Commission for the Updating of Essential Levels of Care, established by Article 1(556) of Law 208/2015. The Commission has the task of systematically evaluating the health care services included in the LEA in order to decide on the maintenance of already existing measures and on proposals for the inclusion of new benefits in the catalogue.[1655] It is envisaged that on this basis the commission should formulate an annual proposal for the updating of the Essential Levels of Care, which would then be implemented by a decree either of the Minister of Health, if no additional costs arise for the public budget, or of the President of the Council of Ministers.[1656]

The legal framework governing the updating of the LEA lays down precise rules on the criteria to be used when assessing new health technologies. As provided for in Article 1(2) of Legislative Decree no. 502 of 30 December 1992, the Essential Levels of Care must be designed in accordance with the principles of human dignity, healthcare needs, equal access, quality of care, appropriateness and economical use of resources.[1657] In order for a new health service to be included in the benefit basket it must comply with

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[1652] ibid.

[1653] Article 4-bis(10) Decree-law 63/2002, see Bergo, 'I nuovi Livelli Essenziali di Assistenza. Al crocevia fra la tutela della salute e l'equilibrio di bilancio' [2017](2) Rivista AIC p. 1, 8–9.

[1654] Decree of the President of the Republic, 28 March 2013, n. 44 Gazzetta Ufficiale no. 98 of 27.4.2013.

[1655] Art. 1(557) Law no. 208/2015.

[1656] Respectively Art. 1(559) and Art. 1(554) of Law no. 208/2015. On how the commission operates in general see Bergo, 'I nuovi Livelli Essenziali di Assistenza. Al crocevia fra la tutela della salute e l'equilibrio di bilancio' [2017](2) Rivista AIC p. 1, 8-9; Vicarelli, 'I nuovi LEA' [2017](3) Politiche Sociali p. 517, 519.

[1657] As amended by Article 1 d. lgs. no. 229/1999.

these guiding principles and meet requirements of appropriateness.[1658] The statutory text affirms that, in order to meet the appropriateness criterion, the effectiveness of the health service must be proven on the basis of scientific evidence.[1659]

The appropriateness criterion is a cornerstone principle in this framework.[1660] On the one hand, clinical appropriateness implies quality and safety of health services[1661] and in particular that the benefits for the patient should outweigh the risks.[1662] On the other hand, appropriateness also means that the catalogue of services must be constantly updated, taking into account innovative scientific developments.[1663] The wording of the legislation states that the purpose of the Commission is to ensure the effectiveness and clinical appropriateness of the services provided by the National Health Service, also in relation to scientific and technological developments.[1664] In other words, the appropriateness of a health technology is measured by its compliance with constantly developing scientific and technical rules in response to which the Essential Level of Care must also be adjusted.[1665]

Given the principles guiding the definition and updating of the Essential Levels of Care it would not seem that the Commission is entitled to consider possible ethical issues regarding individual technologies in the updating

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[1658] Art. 1(7) d. lgs. no. 502/1992, as amended by Article 1 d.lgs. no. 229/1999.

[1659] Art. 1(7) letter b) d.lgs. no. 502/1992, as amended by Article 1 d.lgs. no. 229/1999; see Antonelli, 'La garanzia dei livelli essenziali di assistenza nei primi 40 anni del Servizio sanitario nazionale: dall'uniformità all'appropriatezza: efficacia non è dimostrabile in base alle evidenze scientifiche' [2018](7) Federalismi p. 1, 19.

[1660] Molaschi, 'Sulla determinazione dei livelli essenziali delle prestazioni: riflessioni sulla vis expansiva di una 'materia'.' [2003](5) Sanità Pubblica e Privata p. 525, 538; Antonelli, 'La garanzia dei livelli essenziali di assistenza nei primi 40 anni del Servizio sanitario nazionale: dall'uniformità all'appropriatezza: efficacia non è dimostrabile in base alle evidenze scientifiche' [2018](7) Federalismi p. 1, 19.

[1661] Antonelli, 'La garanzia dei livelli essenziali di assistenza nei primi 40 anni del Servizio sanitario nazionale: dall'uniformità all'appropriatezza: efficacia non è dimostrabile in base alle evidenze scientifiche' [2018](7) Federalismi p. 1, 21–22.

[1662] Materia, 'Appropriatezza: Origini, implicazioni, valutazione' [2003](4-5) Tendenze nuove p. 343, 344.

[1663] Pesaresi, 'La "determinazione dei livelli essenziali delle prestazioni" e la materia " tutela della salute": la proiezione indivisible di un concetto unitario di cittadinanza nell'era del decentramento instituzionale' (2006) 51(2) Giur Cost p. 1733, 1760.

[1664] Art. 1(556) Law no. 208/2015.

[1665] Pesaresi, 'La "determinazione dei livelli essenziali delle prestazioni" e la materia " tutela della salute": la proiezione indivisible di un concetto unitario di cittadinanza nell'era del decentramento instituzionale' (2006) 51(2) Giur Cost p. 1733, 1757.

process.[1666] The Commission should not refuse to include an innovation in the benefit basket if this was, first, proven to be necessary to protect the minimum core of the right to health and, second, in line with the criterion of appropriateness.[1667] The constitutional framework governing the LEA is intended precisely to protect the essential content of the right to health against political determinations or ethical and religious influences on the legislature or government.[1668]

Nevertheless, the former Commission for the updating of the LEA, established in 2002, had explicitly included the consideration of ethical aspects in its methodology for the assessment of new health technologies. The strategy designed by the Commission consisted of a series of questions aimed at ascertaining whether a new health technology could be included in the Essential Levels of Care.[1669] The questions were largely drafted on the basis of the normative criteria of appropriateness and efficient use of resources, but also took into account further aspects. Among these additional factors, one of the questions that the Commission identified for its assessment concerned the 'ethical desirability' of the service. The question read: "Is this a service that is manifestly at odds with the fundamental ethical principles of our society?".[1670]

[1666] This is also reflected in the purely 'technical' composition of this commission, which is chaired by the Minister of Health and composed of the Director of the Directorate-General for Health Planning of the Ministry of Health, fifteen qualified experts and the same number of substitutes, four of whom are designated by the Minister of Health, one by the Italian National Institute of Health, one by the Agenas, one by Aifa, one by the Ministry of the Economy and Finance and seven by the Conference of Regions and Autonomous Provinces, see Article 1(556) Law no. 208/2015.

[1667] NIPT appears to comply with this description fully. First of all, as a method of prenatal diagnosis, it falls within the essential scope of the right to health that the state must guarantee. Secondly, NIPT improves the accuracy, safety and quality of prenatal diagnosis, thus constituting an innovation fulfilling the standard of appropriateness.

[1668] For the illustration of the conception of the Essential Levels of Care as a guarantee of the minimum core of the right to health against possible political determinations of the state, see Chapter 1, sec. B.II.2.b.

[1669] Commissione nazionale per la definizione e l'aggiornamento dei Livelli essenziali di assistenza in Falcitelli and Langiano, *La remunerazione delle attività sanitarie: Caratteristiche attuali e ipotesi evolutive* (2007) pp. 232-ff; Arcà and Cislaghi, 'Percorsi metodologici per l'inserimento o l'esclusione di una prestazione dai Livelli essenziali di assistenza' [2006](2) Tendenze nuove p. 97, 98-ff.

[1670] (Autor's translation). Ordered according to their power of exclusion, the question of the ethical nature of the service was already the second of twelve, see the table in

However, the Commission specified that this standard could only exclude health services that conflicted with widely accepted fundamental principles.[1671] In the view of the Commission the only ethical standards that could influence the inclusion of a health technology in the LEA are those that are defined as fundamental principles in legislative acts or, alternatively, on which there is almost unanimous consensus.[1672] Reference to principles laid down in legislative acts was thus considered to be the only reasonable criterion and also one that was capable of ensuring coherence in the legal system.[1673] It thus seems that the Commission had set out to assess the compliance of new health technologies with the normative framework established by the democratic legislature, rather than their ethical desirability. Hence, despite the terminological ambiguity, the methodological procedure adopted by the 2002 Commission seems in line with the framework of separation of ethics and law adopted in this dissertation.[1674]

As for the most recently established Commission for the Updating of LEA, the legislation only requires it to use health technology assessment procedures in order to assess the inclusion of new technologies in the benefit basket.[1675] This commitment is confirmed by the "Pact for Health 2019-2021" of 27 May 2019, according to which HTA methodologies should be used to assess the impact of new technologies on the healthcare system when annually updating the Essential Levels of Care.[1676]

Commissione nazionale per la definizione e l'aggiornamento dei Livelli essenziali di assistenza in Falcitelli and Langiano, *La remunerazione delle attività sanitarie* (2007) p. 260.

[1671] Commissione nazionale per la definizione e l'aggiornamento dei Livelli essenziali di assistenza in Falcitelli and Langiano, *La remunerazione delle attività sanitarie* (2007) p. 254; Arcà and Cislaghi, 'Percorsi metodologici per l'inserimento o l'esclusione di una prestazione dai Livelli essenziali di assistenza' [2006](2) Tendenze nuove p. 97, 102.

[1672] Arcà and Cislaghi, 'Percorsi metodologici per l'inserimento o l'esclusione di una prestazione dai Livelli essenziali di assistenza' [2006](2) Tendenze nuove p. 97, 102.

[1673] ibid.

[1674] Although a legal representation in the commission might be necessary to verify this compliance with the legal framework.

[1675] Art. 1(557) Law no. 208/2015, see Antonelli, 'La garanzia dei livelli essenziali di assistenza nei primi 40 anni del Servizio sanitario nazionale: dall'uniformità all'appropriatezza: efficacia non è dimostrabile in base alle evidenze scientifiche' [2018] (7) Federalismi p. 1, 20.

[1676] Conferenza Stato-Regioni, 'Intesa, ai sensi dell'articolo 8, comma 6, della legge 5 giugno 2003, n. 131 , tra il Governo, le Regioni e le Province autonome di Trento e di Bolzano concernente il Patto per la salute per gli anni 2019-2021' (18.12.2019); see Aperio Bella, 'Tecnologie innovative nel settore salute tra scarsità delle risorse e

This normative benchmark leaves room for the Commission to flesh out its assessment methodology with the criteria it deems necessary. These must, however, be consistent with the legislative framework establishing the requirements of appropriateness, effectiveness and quality of care.

Such standards appear to be fully met in the case of NIPT. Invasive prenatal diagnoses are already considered part of the LEA and compared to them NIPT can be considered to be a more appropriate healthcare technology. The CSS guidelines have also observed that the inclusion of non-invasive diagnoses in the Essential Levels of Care is necessary to ensure compliance with the criterion of appropriateness and in order to prevent the carrying out of risky diagnoses.[1677] It can be anticipated that the Commission will largely draw upon these guidelines when assessing NIPT for inclusion in the benefit basket.

The consideration of 'ethical' issues could only legitimately take place within the scope defined by the former Commission, whereby the crucial factor in assessing the ethics of a health technology is its compliance with normative principles that have been established by the legislature. Therefore the Commission is expected to take into account, for instance, the need for adequate informed consent and counselling, as enshrined in the Constitution under the combination of Articles 2, 13 and 32, as well as in the recent Law no. 219/2017 on informed consent.

C. Non-Invasive Prenatal Testing in England

I. NIPT in the Private Sector

Non-invasive prenatal testing for trisomies 13, 18 and 21 has been available in the United Kingdom since 2012. Its entry onto the UK market was governed by the, then current, Medical Devices Regulations 2002. This legislation gave effect to the European Directives on medical devices and on in vitro diagnostic medical devices[1678] in UK law and regulated the assessment

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differenziazione: alla ricerca di un equilibrio difficile' [2020](2) Federalismi p. 245, 260.

[1677] Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021, p. 4.

[1678] EU Directive 93/42/EEC on medical devices and EU Directive 98/79/EC on in vitro diagnostic medical devices.

procedure for in vitro diagnostic medical devices before notified bodies.[1679] Under these regulations, the market availability of in vitro diagnostic medical devices, such as NIPT, was conditional only on the control of certain essential requirements of quality and safety by the notified bodies.[1680]

Under this regime NIPT has been widely available for purchase in the private sector since 2012, accessible to those patients who could afford to pay for it. Private NIPT providers do not just provide tests to detect trisomies, but also offer to disclose the sex of the foetus.[1681] The tests are either performed through private clinics or obtainable in a 'direct-to-consumer' format, whereby the patient can order the test online and have it performed by a medical practitioner.[1682]

This wide offer of NIPT, accessible through the private sector, raised a number of concerns, especially given the initial lack of its availability in the public sector. Obvious concerns were voiced about potential inequalities arising from the initial high cost of testing in the private sector. This meant that only wealthy patients could afford access to a less invasive test, while less well-off women had to settle for the more invasive and risky tests offered by the public sector.[1683] The main cause for concern, however, was the lack of guarantees on the quality of information offered to pregnant women in the private sector.[1684] Poor information by private providers, often accompanied by misleading statements, affected women's ability to

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[1679] The Medical Devices Regulations 2002, Reg. 42. The competent authority for implementing medical device legislation and designating notified bodies was and remains the Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care. For more information, see <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency> accessed 28.3.2022.

[1680] The Medical Devices Regulations 2002, Reg. 34.

[1681] Wale, 'Don't Forget the Legal Framework: The Public Provision of Non-invasive Prenatal Testing in England and Wales' (2016) 15(4) Med Law Int p. 203, 205.

[1682] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 91.

[1683] "This means that there is potential for health inequalities to be created or worsened by the fact that the goods of NIPT are, at the moment, inaccessible to those with less financial means. It might be thought unfair that those who are already better off financially may benefit exclusively from the enhanced choice that NIPT can provide", Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues' (London 2017), p. 33.

[1684] ibid, pp. 93-ff.

fully understand the procedure and to give their informed consent.[1685] In addition, it was perceived that the private sector would fail to offer the necessary support to women after a positive result, especially when in the form of direct-to-consumer testing.[1686] The lack of adequate follow-up support and counselling was confirmed by the fact that many patients had to seek advice and clarification from NHS medical staff regarding the outcome of privately performed NIPT.[1687]

Evidence that these worries were well founded came when, in 2019, the UK Advertising Standards Authority – an independent organisation regulating advertising practices – issued three rulings declaring the advertisement and information practices of some NIPT providers to be misleading and contrary to the standards developed by the Committee of Advertising Practice. In particular, the marketing material available online exaggerated the accuracy of the test.[1688]

As has been suggested, concerns about health inequalities, misleading information and lack of counselling can, at least partially, be tackled by introducing NIPT into the NHS. Publicly offering these tests free of charge is likely to limit the reach of the private sector.[1689]

[1685] "[T]he information and support provided by the private sector may in some cases be affecting the ability of women and couples to make informed choices about NIPT, Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues' (London 2017), p. 98.

[1686] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 96; Joynson, 'Our concerns about non-invasive prenatal testing (NIPT) in the private healthcare sector' (8.2.2019) <https://www.nuffieldbioethics.org/blog/nipt-private> accessed 23.3.2022.

[1687] Jackson, 'Regulating Non-Invasive Prenatal Testing: the view from the UK' [2014] (50) Japanese Journal of Law and Political Science p. 9, 17; Joynson, 'Our concerns about non-invasive prenatal testing (NIPT) in the private healthcare sector', 8.2.2019.

[1688] ASA, 'Ruling on The Birth Company: Complaint Ref: A19-564688' (20.11.2019) <https://www.asa.org.uk/rulings/the-birth-company-A19-564688.html> accessed 23.3.2022; ASA, 'Ruling on My Baby Enterprises Ltd: Complaint Ref: A19-564685' (20.11.2019) <https://www.asa.org.uk/rulings/my-baby-enterprises-ltd-A19-564685.html> accessed 23.3.2022; ASA, 'Ruling on Ultrasound Direct Ltd: Complaint Ref: A19-564681' (20.11.2019) <https://www.asa.org.uk/rulings/ultrasound-direct-ltd-A19-564681.html> accessed 23.3.2023.

[1689] Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 661.

II. NIPT in the NHS

1. Access to Prenatal Screening and Diagnoses

a Prenatal Screening and Diagnoses in the NHS

Before the introduction of non-invasive prenatal testing for the screening of chromosomal trisomies, the antenatal screening programme offered by the NHS was already quite comprehensive and far-reaching.[1690] All women in the first trimester of pregnancy are offered screening for Down's, Edwards' and Patau's syndrome by means of a 'combined test'. This test takes into account maternal age in combination with the result of ultrasound measurements and the analysis of biochemical markers in the maternal blood.[1691] A 20-week screening scan is also offered that, in addition to chromosomal trisomies, can identify eleven physical malformations including neural tube defects and abdominal wall defects.[1692] In some cases women may have access to a quadruple test in the second trimester of pregnancy to assess the chances of Down's syndrome.[1693]

The provision of this screening programme is in line with NICE's recommendation in its guidance for antenatal care, which advises that all women should be offered screening for chromosomal trisomies in the first trimester.[1694]

[1690] Wale, 'Don't Forget the Legal Framework' (2016) 15(4) Med Law Int p. 203, 204–205.

[1691] Public Health England, 'Guidance. Down's syndrome, Edwards' syndrome and Patau's syndrome screening pathway requirements specification' (21.6.2021) <https://www.gov.uk/government/publications/downs-syndrome-edwards-syndrome-and-pataus-syndrome-screening-pathway-requirements-specification/downs-syndrome-edwards-syndrome-and-pataus-syndrome-screening-pathway-requirements-specification> accessed 23.3.2022. See Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 7-8.

[1692] Public Health England, 'Guidance. 20-week screening scan pathway requirements specification' (21.6.2021) <https://www.gov.uk/government/publications/20-week-screening-scan-pathway-requirements-specification/20-week-screening-scan-pathway-requirements-specification> accessed 23.3.2022.

[1693] Details on the difference between these tests can be found in Public Health England, 'Guidance. Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome' (10.12.2021) <https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook/screening-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome--3#quadruple-test> accessed 23.3.2022.

[1694] National Institute for Health and Care Excellence, 'Antenatal care: Guideline NG201' (19.8.2021), recommendations no. 1.2.14 and 1.2.15 <https://

If the test result reveals a high possibility that the foetus has a chromosomal trisomy - calculated as a 1 in 150 chance of having an affected foetus - the patient is offered the possibility of confirming this result by invasive diagnosis, i.e. chorionic villus sampling and amniocentesis.[1695] With regard to the uptake of the screening, estimates prior to the introduction of NIPT calculated it at 74 per cent of all women benefiting from NHS services. It was also calculated that, despite the increasing uptake of screenings, the proportion of children born with Down's syndrome had remained fairly constant over the past 25 years.[1696]

In order to receive NHS funding, screening tests must be of a certain medical relevance. That is, they should provide information that may be relevant either to possible prenatal treatment, though this is not available in the case of chromosomal trisomies, or to enable the woman to consider terminating the pregnancy. The last option only comes into question in cases covered by the provisions of the Abortion Act 1967 and in particular section 1(1)(d), according to which the patient may request an abortion if two registered medical practitioners are of the opinion that there is a substantial risk the child would suffer from serious physical or mental conditions.[1697] In this respect, the aim of including these screening tests within NHS

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www.nice.org.uk/guidance/ng201/chapter/Recommendations> accessed 23.3.2022 This guidance updates and replaces previous NICE guidance CG62 that recommended that the ‘combined test’ to screen for Down’s syndrome should be offered to all pregnant women should be offered screening for Down’s syndrome and that women should understand that it is their choice to embark on this procedure, National Institute for Health and Care Excellence, ‘Antenatal care for uncomplicated pregnancies: Clinical guideline CG62’ (4.2.2019) <https://www.nice.org.uk/guidance/cg62> accessed 23.3.2022. On this policy decision, see Scott, *Choosing Between Possible Lives* (2007) p. 177.

[1695] Nuffield Council on Bioethics, ‘Non-invasive Prenatal Testing: Ethical Issues’, London 2017, p. 8; Public Health England, ‘Guidance. Prenatal diagnosis’ (10.12.2021) <https://www.gov.uk/government/publications/fetal-anomaly-screening-programme-handbook/prenatal-diagnosis> accessed 23.3.2022.

[1696] “The proportion of women having a termination after a diagnosis has remained steady, ranging from 89 to 95 per cent between 1989 and 2012, meaning that the actual number of terminations has increased. However, the number of live births of babies with Down’s syndrome has remained fairly constant. This is likely to be due to an increased incidence of Down’s syndrome in fetuses caused by an increase in the average age of women at delivery”, Nuffield Council on Bioethics, ‘Non-invasive Prenatal Testing: Ethical Issues’, London 2017, p. 9.

[1697] “For any new screening or testing to become part of the standard of care in England, this must ultimately have some connection with the terms of the disability ground of the Abortion Act”, Scott, *Choosing Between Possible Lives* (2007) p. 193.

care is to contribute to women's reproductive autonomy, enabling them to make informed choices about their pregnancies. This is both in terms of continuing the pregnancy with the benefit of additional information about the special needs of the developing foetus and also in terms of opting for an abortion procedure.

b Autonomy and Informed Consent

To achieve the overarching goal of facilitating women's reproductive autonomy it is essential for the NHS to guarantee that screening procedures are offered in a way that is compatible with the patients' fully informed consent. In order to achieve an improvement in reproductive autonomy the information provided to the patient about screening for chromosomal trisomies must meet certain requirements. First of all, it must be clear that screening is in all its stages entirely voluntary.[1698] Healthcare professionals must refrain from creating any pressure that would make the woman feel obliged to accept the offer of screening.[1699] In addition, the given information should include details about the conditions for which screening is performed and about the quality of life of children born with chromosomal trisomies.[1700]

The provision of comprehensive and detailed information about a pregnant woman's diagnostic and treatment options is also a common law requirement, the violation of which can amount to clinical negligence. Obligations to obtain the patient's informed consent have indeed become more stringent following the 2015 landmark decision of the UK Supreme Court in the case of *Montgomery v Lanarkshire Health Board*.[1701] The case

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See also Wale, 'Don't Forget the Legal Framework' (2016) 15(4) Med Law Int p. 203, 211.

[1698] Scott, *Choosing Between Possible Lives* (2007) p. 146.

[1699] UK Human Genetics Commission, 'Making Babies' (2006) 11(1) Jahrbuch für Wissenschaft und Ethik p. 485, para. 20; Scott, *Choosing Between Possible Lives* (2007) p. 146.

[1700] „To give valid consent, a woman must also be informed about the nature of any screening or testing. Arguably 'nature' includes purpose (rather than just the physical nature of a test, eg, the mechanisms of an ultrasound scan or the taking of blood) and in this context 'purpose' should include information about the condition that is the subject of screening.", Scott, *Choosing Between Possible Lives* (2007) p. 149.

[1701] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015).

concerned a diabetic woman with a high-risk pregnancy whom the doctor had failed to inform about the possible negative consequences of a vaginal delivery for a patient in her condition and about the possibility of alternatively requiring a caesarean section. As a result of the attempt to perform a natural birth, the baby was born with severe disabilities. Whereas, according to previous case law, the support of a responsible body of medical opinion that withstood logical scrutiny was capable of excluding negligence,[1702] the Supreme Court in *Montgomery* overturned this professional standard by according a greater significance to the need to respect the patient's autonomy. As Lady Hale maintained: patient autonomy is an important feature of a person's physical and psychiatric integrity.[1703] The judgment recognised that patients have a right to be given more comprehensive information, for they are "now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession".[1704] This decision thus clearly marks the final realisation of the paradigm shift from medical paternalism to patient rights.[1705] As Lady Hale pointed out, this is particularly true when the doctor's judgment goes beyond a purely medical one and takes on an ethical connotation.[1706] In the *Montgomery* case, for example, it was the idea that vaginal delivery is in some way morally preferable to a caesarean section. [1707] In these circumstances patients are all the more entitled to decide according to their own values.[1708]

[1702] According to the so-called *Bolam* test, as developed in the case of *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (26 February 1957).

[1703] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para. 108.

[1704] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para 75.

[1705] "Without doubt, the headline story in Montgomery is that the doctor / patient relationship is now predicated on the rights paradigm rather than ethical paradigms that prioritise professional duties or paternalistic responsibilities or that centre on maximising utility or minimising distress", Brownsword and Wale, 'The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions' [2016] (24) JRE p. 31, 41.

[1706] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para 114. See Sutherland Qc, 'The Right of Patients to Make Autonomous Choices: Montgomery v Lanarkshire Health Board: A Landmark Decision on Information Disclosure to Patients in the UK' (2021) 32(7) Int Urogynecol J p. 2005, 2007.

[1707] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para. 114.

[1708] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para. 115.

The court indicated that the scope of the information to be given to the patient can be inferred by means of a 'materiality test'. The doctor must thereby disclose all diagnostic and therapeutic possibilities that a 'reasonable person' or that particular patient (where the doctor should reasonably have been aware of the relevant particularities) might consider relevant.[1709]

The implication for prenatal screening and diagnosis is, on the one hand, that the doctor must inform the woman of any tests that may disclose a risk to which she "would be likely to attach significance".[1710] On the other hand, respect for the value judgements of the particular patient must be maintained and this implies not only that the woman also has a right not to know, but also that she must be made aware of all the circumstances necessary to make an informed choice.[1711] Sometimes in clinical practice the extent of the information provided is insufficient when it comes to non-invasive methods of screening, such as ultrasound.[1712] This stems from the fact that there is no risk to the foetus or the patient in performing the test. However, based on *Montgomery*, the information to be given to the patient goes beyond the possible risks involved in the testing and encompasses the consequences of screening, the accuracy of the results and clarifications on the conditions that can be detected.

As argued by the Nuffield Council of Bioethics (NCOB) in 2017, a possible consequence of *Montgomery v Lanarkshire Health Board* was that, before NIPT was finally offered by the NHS, doctors were required to inform women of its availability in the private sector as an alternative.[1713]

[1709] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015), para. 87.

[1710] Montgomery v Lanarkshire Health Board [2015] UKSC 11 (11 March 2015), On the 'materiality test' in prenatal screening, see Scott, *Choosing Between Possible Lives* (2007) pp. 173- 174.

[1711] Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 651.

[1712] See Ravitsky, 'The Shifting Landscape of Prenatal Testing: Between Reproductive Autonomy and Public Health' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S35, who claims that "[t]he informed-consent process for ultrasound has been completely abandoned".

[1713] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 41. The obligation to inform the patients is all the more valid in case of inclusion of NIPT in the NHS care, see Brownsword and Wale, 'The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions' [2016](24) JRE p. 31, 42: "after *Montgomery*, we suggest that it is reasonable to assume that, at all stages of a pregnancy, whether in the ante-natal screening clinic or in the delivery room, a woman has a right to be informed about the options that are available to her. It follows that, once NIPT is embedded in the screening

2. Evaluation Procedure before the UK National Screening Committee

a The UK National Screening Committee's Recommendation

Following its introduction into the private sector, an evaluation of NIPT for Down's, Edward's and Patau's syndrome was undertaken by the UK National Screening Committee (UK NSC). This is an independent advisory body responsible for assessing all aspects of screening programmes and making recommendations to health ministers and to the NHS across the UK.[1714]

In England the Secretary of State is responsible for defining screening programmes based on the recommendations of the UK NSC, while NHS England[1715] provides the commissioning and delivery of the service in exercise of the public health functions delegated to it according to Section 7A of the National Health Service Act 2006.[1716]

The value of the decisions of the UK National Screening Committee is recognised by the NHS Constitution for England, which states that the NHS is committed to providing the population with the screening

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pathway, pregnant women will have a right to know about the availability of the test, and to be informed about the risks and consequences of having the test".

[1714] For information on the UK NSC, see <https://www.gov.uk/government/organisations/uk-national-screening-committee/about> accessed 23.3.2022. See also Mauthoor, 'Five things you should know about the UK NSC' (7.6.2021) <https://nationalscreening.blog.gov.uk/2021/06/07/five-things-you-should-know-about-the-uk-nsc/> accessed 23.3.2022.

[1715] Since end of 2021, previously this task was entrusted to Public Health England. The passing of delegated functions with regard to screening to NHS England occurred in October 2021 through a letter of the Department of Health and Social Care to NHS England, see Department of Health and Social Care, 'NHS public health functions (section 7A) agreement 2021 to 2022: letter from DHSC to NHSE' (18.11.2021) <https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2021-to-2022/nhs-public-health-functions-section-7a-agreement-2021-to-2022-letter-from-dhsc-to-nhse> accessed 23.3.2022

[1716] National Health Service Act 2006 sec. 7A. The NHS fetal anomaly screening programme is included in the public health functions delegated by the Secretary of State to NHS England according to this section, see Department of Health and Social Care, 'Annex: public health functions (section 7A) agreement 2020 to 2021 – services to be provided' (26.10.2020) <https://www.gov.uk/government/publications/public-health-commissioning-in-the-nhs-2020-to-2021/annex-public-health-functions-section-7a-agreement-2020-to-2021-services-to-be-provided> accessed 23.3.2022 programmes recommended by the Committee.[1717] Once approved by the health ministers, screening programmes that have been recommended by the UK NSC are publicly funded and offered free of charge to patients.[1718]

In order to best inform its recommendation on NIPT the UK NSC first gathered scientific evidence by analysing the medical literature and the results of clinical trials. Moreover, in order to gain an insight into the impact of the introduction of NIPT into clinical practice in an NHS setting, the Committee supported the initiation of the RAPID study, funded by the National Institute for Health Research, evaluating the use of NIPT for Down's syndrome in several NHS maternity units.[1719] This study implemented a sort of 'coverage with evidence development' scheme in that it allowed the UK NSC to obtain more information about the accuracy, cost and effectiveness of screening for Down's syndrome with NIPT, while the costs of the test could be publicly covered for all patients recruited as study participants. The key aim of the RAPID study was to obtain data necessary to evaluate, *inter alia*, the accuracy of NIPT in low-risk pregnancies, its cost-effectiveness and uptake, as well as the possibility of maintaining informed choice in accepting or declining testing.[1720]

The study concluded that implementing NIPT in the NHS screening programme for Down's syndrome could "improve quality of care, choices for women, and overall performance within the current budget".[1721] This outcome can be reached by offering NIPT as a contingent test, depending on the results of the first screening. It was calculated that the accuracy of the test would only be guaranteed if it was conducted within a population for which the initial screening had revealed a chance of at least 1 in 150 of having a foetus with Down's syndrome.[1722]

[1717] Department of Health and Social Care, 'The NHS Constitution for England', 1.1.2021

[1718] See Ravitsky and others, 'The Emergence and Global Spread of Noninvasive Prenatal Testing' (2021) 22(1) Annu Rev Genom Hum Genet p. 309, 324.

[1719] Hill and others, 'Evaluation of Non-invasive Prenatal Testing (NIPT) for Aneuploidy in an NHS Setting: A Reliable Accurate Prenatal Non-invasive Diagnosis (RAPID) Protocol' (2014) 14(229) BMC Pregnancy Childbirth p. 1, 11.

[1720] ibid, p. 3.

[1721] Chitty and others, 'Uptake, Outcomes, and Costs of Implementing Non-invasive Prenatal Testing for Down's Syndrome into NHS Maternity Care: Prospective Cohort Study in Eight Diverse Maternity Units' (2016) 354(i3426) BMJ p. 1

[1722] ibid, p. 9.

The study also revealed that about one third of women with a positive NIPT result decided to continue with the pregnancy.[1723] The non-invasive nature of the test also allows it to be used by those women who would like to have more information in order to prepare for giving birth to a child with a chromosomal aneuploidy. The findings of the study thus suggested that the number of children born with Down's syndrome may not vary significantly with the introduction of NIPT in the public sector.[1724] Moreover, it was argued that guaranteeing a high level of informed consent is both necessary and achievable.[1725]

In terms of costs it was estimated that the introduction of NIPT into NHS maternal care would be cost-neutral or even result in a slight reduction in expenses due to the fact that many invasive procedures would be avoided.[1726]

In mid-2015 the RAPID study team reported the evidence and its positive assessment of NIPT to the UK NSC.[1727] On this basis, and aware of the different opinions on the implementation of the test in the NHS, the UK NSC decided to launch a three-month public consultation at its June

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[1723] ibid, p. 10. In another study, termination of pregnancy was chosen by 74% of the patients, see Gil and others, 'Clinical Implementation of Routine Screening for Fetal Trisomies in the UK NHS: Cell-free DNA Test Contingent on Results from First-trimester Combined Test' (2016) 47(1) Ultrasound Obstet Gynecol p. 45, 51.

[1724] Chitty and others, 'Uptake, Outcomes, and Costs of Implementing Non-invasive Prenatal Testing for Down's Syndrome into NHS Maternity Care' (2016) 354(i3426) BMJ p. 1, 10. While "[t]he overall proportion of terminations of pregnancy following a diagnosis of Down's syndrome is likely to fall, […] the number of terminations is likely to increase", Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, 51.

[1725] On this point see Ravitsky and others, 'The Emergence and Global Spread of Noninvasive Prenatal Testing' (2021) 22(1) Annu Rev Genom Hum Genet p. 309, p. 324.

[1726] Chitty and others, 'Uptake, Outcomes, and Costs of Implementing Non-invasive Prenatal Testing for Down's Syndrome into NHS Maternity Care' (2016) 354(i3426) BMJ p. 1, 11; Mackie, 'Addition of non-invasive test to screening for Down's syndrome, Edward's syndrome, Patau's syndrome' (3.11.2016) <https://nationalscreening.blog.gov.uk/2016/11/03/addition-of-non-invasive-test-to-improve-screening-for-pregnant-women/> accessed 23.3.2022; Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 39.

[1727] Chitty and others, 'Uptake, Outcomes, and Costs of Implementing Non-invasive Prenatal Testing for Down's Syndrome into NHS Maternity Care' (2016) 354(i3426) BMJ p. 1, 11; Wale, 'Don't Forget the Legal Framework' (2016) 15(4) Med Law Int p. 203, 206.

2015 meeting, before issuing its final recommendation.[1728] The consultation sought reactions to the proposal to publicly fund NIPT only for women who were found to be at a higher risk after the combined test.[1729]

The 30 stakeholders who responded to the consultation offered the committee a variety of voices and perspectives. [1730] However, the majority of them reacted positively to the proposal and some argued that the risk threshold for accessing the test should be reduced.[1731] Respondents opposed to the inclusion of NIPT in the public service were mainly those who were fundamentally against all prenatal screening for chromosomal aneuploidies that could lead to abortion.[1732]

Based on the research and evidence gathered in the evaluation process, the UK NSC decided in January 2016 to recommend an evaluative implementation of NIPT within the existing NHS Fetal Anomaly Screening Programme.[1733] The recommendation to include NIPT in an initially cautious and controlled manner showed a pragmatic approach while at the same time taking into account ethical issues and the relatively new nature of the test.[1734] The UK NSC hoped that the evaluative roll out in the NHS would provide a better understanding of the impact of publicly funded

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[1728] UK National Screening Committee, 'Note of the meeting held on the 18 June 2015' <https://www.gov.uk/government/publications/uk-nsc-meeting-june-2015> accessed 23.3.2022

[1729] ibid.

[1730] Marshall, 'Evidence update: consultation on non-invasive prenatal testing and latest UK NSC recommendations' (13.8.2022) <https://nationalscreening.blog.gov.uk/2015/08/13/evidence-update-new-consultation-on-non-invasive-prenatal-testing-and-latest-uk-nsc-recommendations/>.

[1731] UK National Screening Committee, 'Note of the meeting held on the 19 November 2015' <https://www.gov.uk/government/publications/uk-nsc-meeting-november-2015> accessed 23.3.2022; Ravitsky and others, 'The Emergence and Global Spread of Noninvasive Prenatal Testing' (2021) 22(1) Annu Rev Genom Hum Genet p. 309, 325.

[1732] UK National Screening Committee, 'Note of the meeting held on the 19 November 2015'; Ravitsky and others, 'The Emergence and Global Spread of Noninvasive Prenatal Testing' (2021) 22(1) Annu Rev Genom Hum Genet p. 309, 325.

[1733] UK National Screening Committee, 'UK NSC non-invasive prenatal testing (NIPT) recommendation' (01.2016) <https://legacyscreening.phe.org.uk/policydb_download.php?doc=602> accessed 23.3.2022.

[1734] UK National Screening Committee, 'Note of the meeting held on the 19 November 2015'.

NIPT on the reproductive autonomy of pregnant women before its full and permanent implementation.[1735]

The UK NSC recommendation confirmed the option for contingent use of NIPT, i.e. dependent on the results of initial screening. It was recommended that women should be offered the usual combined ultrasound and blood test or other non-invasive screening in the first trimester and that NIPT for trisomy 21, 13 and 18 should only be offered to women who exceed the risk threshold of 1 in 150.[1736] Among these, women who received a positive NIPT result would be advised to seek amniocentesis or chorionic villus sampling, whereas there would be no need for an invasive test in the case of a negative NIPT finding.[1737] Accordingly, NIPT is not offered as a standard test to all women, but still helps to avoid the majority of invasive procedures with a risk of miscarriage.[1738]

b Reactions to the UK NSC's Assessment

Following the UK NSC's recommendation extensive media coverage addressed the effects of offering NIPT in the public sector on people with disabilities. Public debate was especially prompted by a highly successful BBC documentary, presented in October 2016 by actor Sally Phillips,

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[1735] Mackie, 'Addition of non-invasive test to screening for Down's syndrome, Edward's syndrome, Patau's syndrome', 3.11.2016; Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 37. According to Brownsword and Wale "the 'piloting' of NIPT within the NHS Fetal Anomaly Screening Programme, leaves its status somewhere between 'research' and 'implementation", Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 672.

[1736] "Covering NIPT for all pregnancies was not deemed cost effective in terms of anticipated savings to the health care system (compared with the current program) with respect to a reduction in the number of invasive tests and the anticipated number of Down syndrome diagnoses during pregnancy", Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37. See also Ravitsky and others, 'The Emergence and Global Spread of Noninvasive Prenatal Testing' (2021) 22(1) Annu Rev Genom Hum Genet p. 309, 324.

[1737] See Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 647–648.

[1738] Wale, 'Regulating Disruptive Technology and Informational Interests in the Arena of Reproductive Tests' (2019) 3(1) Journal of Information Rights, Policy and Practice p. 1, 3.

who has a child with Down's syndrome.[1739] The documentary argued that women who are offered screening are often given misleading and biased information on the condition.[1740] Hence, the provision of cost-free NHS testing would lead to an increase in abortions of foetuses with chromosomal aneuploidies and an overall decrease in the births of children with Down's syndrome.[1741] In the same year a Down's syndrome advocacy group launched a petition and awareness campaign under the slogan 'Don't Screen Us Out'.[1742] The campaign argued that the introduction of NIPT into the NHS setting would give pregnant women the impression that screening for trisomy 21 is encouraged and hard to turn down.[1743] It was alleged that, eventually, the public funding of NIPT would result in a greater routinisation of screening, poor information for pregnant women and in the stigmatisation of people with disabilities.[1744]

These concerns were expressed in a letter to the Department of Health in which the government was accused of failing to properly consult the community of people with Down's syndrome.[1745] A parliamentary motion signed by thirty-four MPs of different political parties joined in support of the campaign and asked the government to postpone the implementation

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[1739] Phillips and Richards, 'A World Without Down's Syndrome' (First Broadcast 5.10.2016) BBC <https://www.bbc.co.uk/programmes/b07ycbj5> accessed 6.4.2022; Burch, 'A world without Down's syndrome?: Online resistance on Twitter: #worldwithoutdowns and #justaboutcoping' (2017) 32(7) Disability & Society p. 1085. See Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 14-15.

[1740] Perrot and Horn, 'The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany' (2022) 30 Eur J Hum Genet p. 676, 678.

[1741] Although the RAPID study had suggested that "Down's syndrome live birth rates may not change significantly", see Chitty and others, 'Uptake, Outcomes, and Costs of Implementing Non-invasive Prenatal Testing for Down's Syndrome into NHS Maternity Care' (2016) 354(i3426) BMJ p. 1, 11.

[1742] Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37; Perrot and Horn, 'The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany' (2022) 30 Eur J Hum Genet p. 676, 678.

[1743] Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37.

[1744] Brownsword and Wale, 'The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions' [2016](24) JRE p. 31, 32.

[1745] As reported by Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37; Iacobucci, 'Non-invasive Prenatal Testing: Public and Doctors Should be Consulted, says BMA' (2018) 362(k2916) BMJ p. 1.

of NIPT in the NHS until possible discriminatory effects on people with Down's syndrome and their families had been investigated and prevented.[1746] The British Medical Association also advocated wider consultation on the views of the public and medical profession.[1747]

Fears of increased discrimination against people with Down's syndrome have been intensified by a controversy involving the United Kingdom's Royal College of Obstetricians and Gynaecologists (RCOG). The RCOG was accused of suggesting, in its response to the public consultation conducted by the UK NSC, that the lifetime costs of caring for a child with Down's syndrome should have been included in the economic cost-effectiveness analysis.[1748] However, on the one hand, the RCOG argued that this was a misunderstanding of their statement[1749] and, on the other hand, this perspective had not been embraced by the UK NSC in its recommendation.

Although the voices of advocacy groups were prominent in the public debate, the inclusion of NIPT in the existing NHS Fetal Anomaly Screening Programme enjoyed widespread public support.[1750] Most members of society, including some belonging to the Down's syndrome community,[1751] supported women's reproductive autonomy and their right to obtain comprehensive information about the health of the foetus.[1752] It was emphasised that NIPT had the advantage of reducing the invasiveness and risks of miscarriage associated with the existing screening programme. This was

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[1746] UK Parliament, 'Early Day Motion 44: Down's Syndrome, Don't Screen Us Out Campaign' (19.5.2016) <https://edm.parliament.uk/early-day-motion/49295/downs-syndrome-dont-screen-us-out-campaign> accessed 23.3.2022. See Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37.

[1747] Iacobucci, 'Non-invasive Prenatal Testing' (2018) 362(k2916) BMJ p. 1.

[1748] Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37-S38.

[1749] Wise, 'The End of Down's Syndrome?' (2016) 355(i5344) BMJ p. 1, 2.

[1750] Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37.

[1751] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 54; Perrot and Horn, 'Preserving Women's Reproductive Autonomy While Promoting the Rights of People with Disabilities?' [2022](0) J Med Ethics p. 1, 2.

[1752] Perrot and Horn, 'The Ethical Landscape(s) of Non-invasive Prenatal Testing in England, France and Germany' (2022) 30 Eur J Hum Genet p. 676, 678.

seen as a positive development and an “if not entirely unproblematic, at least relatively uncontroversial”[1753] innovation.

Also the report on the ethical issues of NIPT, issued by the Nuffield Council of Bioethics after extensive public consultation, was critical but ultimately supportive of the UK NSC recommendations.[1754]

Some legal scholars have even described the approach of the UK NSC and the Nuffield Council of Bioethics as relatively conservative[1755] and have pointed out the desirable aspects of including non-invasive screening technologies in NHS care.[1756] Indeed, emphasis has been placed on the fact that publicly funded NIPT increases the quality of the health service. Firstly, it reduces the inequality between wealthy couples, who can afford safer tests in the private sector, and those who lack financial means.[1757] In addition, NIPT limits the overall amount of invasive procedures required. Finally, it improves women’s reproductive health and physical and psychological well-being, both by enabling them to decide for an abortion and in terms of preparedness for the birth of a child with chromosomal aneuploidies.[1758]

The effective improvement of the quality of the health service obviously presupposes high standards of information and counselling, as well as the guarantee of fully informed consent. It is important to ensure that women do not feel obliged to participate in the screening programme and that they are not misled as to the implications of having a child with a chromosomal trisomy. Adequate NHS screening programmes therefore also include education and training for health professionals.[1759]

In this respect, offering NIPT within the public sector has the advantage of allowing control over the quantity and quality of information given to

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[1753] Brownsword and Wale, ‘The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions’ [2016](24) JRE p. 31.

[1754] Details of this report are outlined below.

[1755] Brownsword and Wale, ‘Testing Times Ahead’ (2018) 81(4) Mod Law Rev p. 646, 672.

[1756] Scott, *Choosing Between Possible Lives* (2007) p. 176.

[1757] Wale, ‘Don’t Forget the Legal Framework’ (2016) 15(4) Med Law Int p. 203, 208.

[1758] Scott, *Choosing Between Possible Lives* (2007) 176; Wale, ‘Don’t Forget the Legal Framework’ (2016) 15(4) Med Law Int p. 203, 208; Brownsword and Wale, ‘The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions’ [2016](24) JRE p. 31, 35.

[1759] Ravitsky and others, ‘The Emergence and Global Spread of Noninvasive Prenatal Testing’ (2021) 22(1) Annu Rev Genom Hum Genet p. 309, 324.

patients.[1760] While the private sector has an interest in offering as much testing as possible and persuading women into believing that the tests are entirely accurate, implementation in the public sector has the potential to ensure that information is neutral and aimed at the full realisation of women's reproductive autonomy.

c Evaluative Implementation of NIPT in the NHS

In November 2016, the government announced that it would follow the recommendations of the UK NSC and offer NIPT for trisomies 21, 18 and 13 under an evaluative roll out for all women found to be at high risk after initial screening.[1761] The inclusion of NIPT in the NHS fetal anomaly screening programme was due to begin in late 2018. The implementation of the screening programme was entrusted to Public Health England, a former executive agency of the Department of Health. The evaluation period was planned to last three years during which the effects of publicly offering NIPT could be monitored and the screening programme modified as necessary.[1762]

During the preparation of the evaluative roll out the possibility of a further consultation of advocacy groups and stakeholders was raised. In a parliamentary question the Secretary of State for Health and Social Care was asked if the government would "consider conducting a consultation on

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[1760] Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 648 and 660.

[1761] Department of Health and Social Care, 'News story. Safer screening test for pregnant women: New non-invasive prenatal test for Down's, Edwards' and Patau's syndromes, which is safer for women and their babies.' (02.11.2016) <https://www.gov.uk/government/news/safer-screening-test-for-pregnant-women> accessed 23.3.2022; Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues. Review of Activities Since Publication' (November 2018), p. 5 <https://www.nuffieldbioethics.org/assets/pdfs/Nuffield-Council-NIPT-review-of-activites.pdf> accessed 23.3.2022.

[1762] "NIPT will be introduced as an 'evaluative roll out'. This means we will be able to monitor how the introduction of NIPT is working at each stage of the roll out and make any changes to the pathway and screening processes quickly and effectively", McHugh, 'NIPT procurement and launch update' (28.1.2021) <https://phescreening.blog.gov.uk/2021/01/28/nipt-procurement-and-launch-update/> accessed 22.3.2023.

the ethical implications of non-invasive prenatal testing".[1763] However, the government considered that the extensive work that the UK NSC and the Nuffield Council of Bioethics had already done, in terms of consultation and in terms of assessing the ethical issues, was sufficient. It was rather necessary to review and assess the test in practice.[1764]

While the evaluative introduction of NIPT was promptly implemented in Wales in April 2018,[1765] in Scotland and England there were some delays due to procurement issues.[1766] NIPT was finally implemented in the NHS fetal anomaly screening programme[1767] from 1 June 2021 in most parts of England[1768] and then extended to all maternity care units in July 2021.[1769]

The information booklet 'Screening tests for you and your baby' to be distributed to pregnant women in NHS care has also been updated by the UK NSC to include NIPT. The leaflet contains detailed information on the testing procedure, on each condition screened for and on the voluntariness

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[1763] Parliamentary question posed by Lavery, 'Pregnancy: Screening. Question for Department of Health and Social Care: UIN 285277 (Answer: Caroline Dinenage)' (2.9.2019) <https://questions-statements.parliament.uk/written-questions/detail/2019-09-02/285277#> accessed 23.3.2022.

[1764] ibid.

[1765] Public Health Wales, 'New screening for pregnant women to be offered in Wales' <http://www.wales.nhs.uk/news/48260> accessed 23.3.2022.

[1766] See parliamentary question posed by Morris, 'Pregnancy: Screening. Question for Department of Health and Social Care: UIN 251394 (Answer: Selma Kennedy)' (7.5.2019) <https://questions-statements.parliament.uk/written-questions/detail/2019-05-07/251394> accessed 23.3.2022. See also McHugh, 'NIPT procurement and launch update', 28.1.2021.

[1767] Public Health England, 'Guidance. Screening for Down's syndrome, Edwards' syndrome and Patau's syndrome: NIPT' (23.9.2021) <https://www.gov.uk/government/publications/screening-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome-non-invasive-prenatal-testing-nipt/screening-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome-nipt> accessed 23.3.2022

[1768] Mackie, 'NIPT to be evaluated as a new part of NHS screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome' (1.6.2021) <https://phescreening.blog.gov.uk/2021/06/01/nipt-to-be-evaluated-as-a-new-part-of-nhs-screening-pathway-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome/> accessed 23.3.2022.

[1769] Permalloo, 'NIPT rolls out to all areas of England as part of the existing NHS screening pathway for Down's syndrome, Edwards' syndrome and Patau's syndrome' (1.7.2021) <https://phescreening.blog.gov.uk/2021/07/01/nipt-rolls-out-to-all-areas-of-england-as-part-of-the-existing-nhs-screening-pathway-for-downs-syndrome-edwards-syndrome-and-pataus-syndrome/> accessed 23.3.2022.

of the participation in the screening programme. [1770] This information has been updated also with the involvement of stakeholders such as associations representing people with disabilities.[1771]

3. Ethical Considerations in the Assessment Procedure of NIPT

a The Nuffield Council of Bioethics' Report on NIPT

Following the recommendations of the UK NSC the Nuffield Council of Bioethics contributed to the debate with the publication of a report on the ethical issues surrounding NIPT. The document sought to consider the ethical and legal implications of NIPT's use in both the private sector and the NHS and to share insights with decision-makers and stakeholders.[1772] The aim was not primarily to provide advice for the government but rather to investigate and illustrate the various ethical viewpoints voiced across society in order to better prepare the ground for informed public participation in the debate.

In this respect the Council's fundamental approach differs, at least in part, from that of bioethics committees in other European countries. Firstly, the NCOB is a non-governmental organisation, which was established independently by a charitable foundation.[1773] Although it has no democratic legitimacy[1774] it has established itself as a *de facto* national ethics committee.

[1770] Public Health England, 'Guidance. Screening tests for you and your baby' (3.5.2019) <https://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby> accessed 23.3.2022.

[1771] As outlined in the intervention by Dr Elizabeth Corcoran, Chair of the Down's Syndrome Research Foundation at the Conference Prenatal Testing, Disability, and the Ethical Society, 'Reflections Following Crowter' (4.3.2022) <https://www.law.ox.ac.uk/events/prenatal-testing-disability-and-ethical-society-reflections-following-crowter> accessed 23.3.2022.

[1772] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. x: "[t]he terms of reference of the Working Group on non-invasive prenatal testing (NIPT) were: 1 to consider the ethical, legal and regulatory implications of recent and potential future scientific developments in NIPT, with regard to its use in both NHS and commercial services, including for whole genome/exome sequencing; 2 to engage a range of people and organisations in the consideration of these questions; 3 to report and disseminate findings and recommendations amongst key decision-makers and other stakeholders".

[1773] Montgomery in Palazzani, *Role and Functions of Bioethics Committees* (2014).

[1774] Montgomery, 'Bioethics after Brexit: An Opportunity to Rationalize Bioethics Governance in the United Kingdom' (2018) 18(2-3) Med Law Int p. 135, 150–151.

The reputation it has acquired guarantees a "tacit acceptance" of its authority, which is "consistent with traditional British political pragmatism".[1775] Secondly, although its reports usually include some recommendations for the decision-makers, these are never their main purpose.[1776] The aim of the Nuffield Council of Bioethics is rather to prepare a basis for adequately informed public discussion on new developments in science and healthcare.[1777] For this purpose the Council sets up a working group for each medical innovation with the task of gathering and systematising different ethical approaches and scientific evidence. The focus is on maintaining broad inclusiveness by ensuring that all opinions can initially be given a voice and only then be put to a test of rigorousness and reasonableness.[1778] Hence, the Council does not strive to establish a definite and consistent ethical paradigm across its various reports.[1779] The legitimacy of the Council's documents is not based on the adoption of certain substantive principles, but rather on compliance with criteria of procedural legitimacy, including gathering evidence, bringing together members with expertise in different areas, conducting public consultations, listening to all sides and applying reasonableness standards.[1780]

These procedural principles were also applied in drafting the report on the ethical issues of NIPT. The working group in charge of NIPT started from the collection of evidence and opinions. Between April and December 2016 it met with various stakeholders, including health professionals, organisations representing people with disabilities, as well as regulatory and

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[1775] ibid, p. 150. See also Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 668.

[1776] Montgomery in Palazzani, *Role and Functions of Bioethics Committees* (2014).

[1777] Hagedorn, *Legitime Strategien der Dissensbewältigung in demokratischen Staaten* (2013) p. 327; Montgomery in Palazzani, *Role and Functions of Bioethics Committees* (2014); Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 668

[1778] Montgomery in Palazzani, *Role and Functions of Bioethics Committees* (2014). See also Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 669.

[1779] Montgomery in Palazzani, *Role and Functions of Bioethics Committees* (2014); Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 649.

[1780] "[T]he approach of the Nuffield Council on Bioethics [...] has avoided a principle-based approach in favour of a procedural sense of legitimacy based on the inclusiveness of its listening processes, and the rigorous quality of the tests of rationality it applies to the arguments", Montgomery, 'Bioethics after Brexit' (2018) 18(2-3) Med Law Int p. 135, 153.

governmental bodies.[1781] An anonymous online survey was launched. In particular this sought to gather the opinions of individuals with personal and professional experience with NIPT. More than 700 people responded to the survey.[1782] In addition, the Council conducted an open public consultation between May and August 2016, asking for open answers to twenty questions. After spreading the consultation through social media and mailing lists, the Council received 28 responses from religious organisations, associations of people with Down's syndrome, medical societies, universities and others.[1783]

The outcome of the working group's activities was published in March 2017 in the report 'Non-invasive Prenatal Testing: Ethical Issues'. The document outlined an ethical framework based on the values of autonomy and consent, avoidance of harm, equality and inclusion.[1784] Having established the necessity to respect these principles, the Council clearly positioned itself in favour of the option endorsed by the UK National Screening Committee.[1785] The decision to offer NIPT to all women at high risk after initial screening was recognised by the Council as "a proportionate and ethical approach at the current time".[1786] This represents a compromise solution between protection of the woman's reproductive autonomy, avoidance of

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[1781] In June and July 2016, the Working Group met with healthcare professionals involved in delivering NIPT, charities representing people with genetic conditions and people with family members with genetic conditions, government, regulatory and professional bodies. Interviews were carried on with scientists working in areas relevant to NIPT, manufacturers of NIPT, women who had recently undergone NIPT, and people with genetic conditions; see Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 145–147.

[1782] ibid, p. 141.

[1783] ibid, p. 143. The responses can be read in the document Nuffield Council on Bioethics, 'Non-invasive prenatal testing. Summary of consultation responses' (June 2017) <https://www.nuffieldbioethics.org/assets/pdfs/Analysis-of-NIPT-consultation-responses.pdf> accessed 24.3.2022.

[1784] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017. On the ethical starting points, see Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 649.

[1785] „The Working Group supports the introduction of NIPT for Down's, Edwards' and Patau's syndromes in the NHS for women who have been found to have at least a 1 in 150 chance of having a fetus with one of these conditions", Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 134. See also Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, p. 656.

[1786] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 134.

harm, and inclusiveness.[1787] On the one hand, offering the test guarantees the patient's right to information pertaining to her reproductive health. The Council acknowledged that the diagnosis enables the woman to make informed choices during pregnancy or, alternatively, to psychologically prepare and make practical arrangements for the birth of a child with a chromosome anomaly.[1788] In addition, the supply of NIPT is in line with the state's commitment to provide high-quality and safe health care.[1789] On the other hand, the highest accuracy of results must be ensured and NIPT must not be misused or used to diagnose non-significant or non-medical conditions.[1790]

The Council placed particular emphasis on the need to ensure women's informed consent, also mentioning the UK Supreme Court decision in *Montgomery v Lanarkshire Health Board*. High-quality information and support, including the communication that screening remains entirely voluntary, is considered essential for the ethical implementation of NIPT in the NHS.[1791]

Furthermore, the NCOB was concerned to ensure that the availability of the test did not lead to worse conditions for people with Down syndrome. The report pointed out that the impact of supporting children with disabilities on state resources cannot be included in the calculation of the cost-effectiveness of the test.[1792] In sum, the state must ensure that the

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[1787] Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 653.

[1788] "The anxiety and uncertainty generated by a postnatal diagnosis relating to a lack of understanding about the condition and its implications, compounded by the physical aspects of childbirth and potential health threats to the baby, can make the assimilation of new information at this time extremely challenging. A prenatal diagnosis, on the other hand, can mean having time to understand and accept the diagnosis, to seek information and advice from support groups and other parents and to put any practical arrangements in place for after the birth, such as sourcing any special equipment or arranging additional childcare support. [...] A prenatal diagnosis also allows medical interventions to be offered that can potentially improve the outcomes for the baby", Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 52-53.

[1789] ibid, p. 30.

[1790] The prohibition of the use of NIPT to diagnose non-medical or less significant conditions represents an approach that some scholars have called paternalistic, albeit justifiable, see Brownsword and Wale, 'The Right to Know and the Right Not to Know Revisited' (2017) 9(1) Asian Bioeth Rev p. 3, 15.

[1791] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 128.

[1792] ibid, p. 70.

implementation of the test remains in line with social equality and with the public support of people with disabilities.[1793]

b Considerations of Ethical Aspects by the UK National Screening Committee

In June 2017 the Nuffield Council of Bioethics' report on the ethical issue of NIPT was presented to the UK National Screening Committee.[1794] While supporting the decision to offer NIPT to women with a greater than 1 in 150 chance of having an affected foetus, the NCOB accused the UK NSC to have fallen short in considering the ethical aspects related to NIPT. The Council accordingly recommended that the UK NSC more fully consider the psychological, ethical and social consequences of prenatal screening programmes that could possibly lead to termination of pregnancy.[1795] In particular, the Nuffield report argued that attention should be paid to the possibility of passing unintended offensive messages towards people with disabilities. More generally, it was suggested that the UK NSC should develop ethical criteria for assessing screening programmes where abortion is an option and strengthen their public engagement activities as well as the representation of ethics experts on the committee.[1796] Associations representing people with disabilities have also denounced how an 'ethical vacuum' around the evaluation of prenatal screening has been made particularly visible through the case of NIPT.[1797] Feedback from a previous consultation conducted in 2015 by the UK NSC had already found insufficiencies in this regard and had suggested that the committee could benefit from the inclusion of additional members with expertise on ethical issues.[1798]

[1793] ibid, p. 120.

[1794] UK National Screening Committee, 'Note of the meeting held on the 23 June 2017' <https://www.gov.uk/government/publications/uk-nsc-meeting-june-2017> accessed 23.3.2022.

[1795] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 136.

[1796] ibid.

[1797] Intervention by Dr Elizabeth Corcoran at the Conference Prenatal Testing, Disability, and the Ethical Society, 'Reflections Following Crowter', 4.3.2022.

[1798] UK National Screening Committee, 'Review of the UK National Screening Committee (UK NSC): Recommendations' (June 2015), p. 13 <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/443953/20150602_-_Final_Recommendations.pdf> accessed 23.3.2022: "Responses to the consultation

The UK NSC Guidance Criteria for appraising the viability, effectiveness and appropriateness of a screening programme had been updated in October 2015. This already stated the need to collect evidence that each screening programme would be socially and ethically acceptable to health professionals and the public in all its phases.[1799] Moreover, the Committee has always applied principles of deliberative democracy, by conducting public consultations and remaining fundamentally open to reviewing any decision should new evidence or any other arguments emerge.[1800]

However, as a result of the NCOB's recommendations on NIPT, the UK NSC has further intensified its focus on the ethical issues of prenatal screenings.[1801] For this purpose it has relied on the temporary transfer of a member of the Nuffield Council of Bioethics[1802] and on the recruitment of another permanent member with ethical expertise.[1803] The two new members assisted other committee members in setting up a new ethics task group within the UK NSC that was chaired by law professor Roger Brownsword.[1804]

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are clear that the UK NSC would benefit from additional ethical expertise, in particular there is support for drawing expert advice from a reference group of experts. Responses vary on whether this should be a standing organisation, a more ad hoc group or referring to external established ethical groups. The review group […] acknowledges that sometimes particular expertise or a more focused consideration may be required".

[1799] UK National Screening Committee, 'Criteria for appraising the viability, effectiveness and appropriateness of a screening programme' (23.10.2015), para. 4.12. <https://www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes/criteria-for-appraising-the-viability-effectiveness-and-appropriateness-of-a-screening-programme> accessed 23.3.2022

[1800] Brownsword, 'Regulating The Life Sciences, Pluralism And The Limits Of Deliberative Democracy' [2010](22) SAcLJ p. 801, 822.

[1801] As gladly noted by the Nuffield Council of Bioethics in Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues. Review of Activities Since Publication', November 2018, p. 15.

[1802] Joynson, 'Embedding ethics at the UK National Screening Committee' (23.3.2021) <https://phescreening.blog.gov.uk/2021/03/23/embedding-ethics-at-the-uk-national-screening-committee/> accessed 23.3.2022.

[1803] UK National Screening Committee, 'Note of the meeting held on the 29 June 2018' <https://www.gov.uk/government/publications/uk-nsc-meeting-june-2018> accessed 23.3.2022. See also Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues. Review of Activities Since Publication', November 2018, p. 15.

[1804] Who was already a permanent member of the Committee. See UK National Screening Committee, 'Screening in the UK: making effective recommendations: 1 April 2017 to 31 March 2018' Ref: PHE gateway number 2018283, pp. 4–5 <https:/

An opportunity for the ethics task group to engage with NIPT presented itself in 2018, as the UK NSC received a proposal to include NIPT 'reflex testing' for chromosomal trisomies as part of the NHS Fetal Anomaly Screening Programme.[1805] This would imply that the future mother's blood sample to be used for NIPT would be collected already upon collection of the sample for the preliminary combined screening. Only if the result of the combined screening would reveal a probability of having an affected foetus of 1 in 800 would the second sample actually be used for NIPT. Such a procedure would in practice both reduce the eligibility threshold for NIPT and eliminate the need to recall the woman for a further consultation appointment and second blood sample collection after the combined test.[1806]

The responsibility for assessing this proposal was given to the newly established task group on ethics.[1807] Reporting back in October 2018 the task group advised the committee not to recommend the 'reflex' strategy for NIPT.[1808] They argued that such an approach raises several broad concerns regarding, *inter alia*, its suitability to support reproductive autonomy and its benefits in terms of resources savings. Moreover, the lower threshold for access to the test would lead to an expansion of its uptake, the ethical acceptability of which is, according to the task group, uncertain.[1809] The committee endorsed the group's assessment and agreed to waiting for the results of the evaluative roll out before making any adjustments to the NIPT screening pathway.[1810]

More generally, the work of the ethics task group has continued in the form of consultations with the public and stakeholders. The views gathered

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/assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733226/Screening_in_the_UK_making_effective_recommendations_2017_to_2018.pdf> accessed 23.3.2022 See also Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues. Review of Activities Since Publication', November 2018, p. 15.

[1805] UK National Screening Committee, 'Note of the meeting held on the 29 June 2018'.

[1806] ibid, paras. 3.8–3.10 for a description of the proposed procedure.

[1807] ibid.

[1808] UK National Screening Committee, 'Note of the meeting held on the 31 October 2018' <https://www.gov.uk/government/publications/uk-nsc-meeting-october-2018> accessed 23.3.2022.

[1809] ibid, para. 3.13: "[T]here is uncertainty on whether expansion of the use of NIPT which would be a consequence of the strategy as currently proposed is ethically acceptable".

[1810] UK National Screening Committee, 'Note of the meeting held on the 8 November 2019' <https://www.gov.uk/government/publications/uk-nsc-meeting-november-2019> accessed 23.3.2022.

have been used to develop ideas on how to improve procedures to more effectively include ethical considerations in the UK NSC's assessments.[1811] Most recently the ethics group worked to design an ethical framework for the analysis of screening programmes that was adopted[1812] and published[1813] by the UK NSC in 2021. This ethical framework is composed of four principles. They are aimed at: improving health and wellbeing, treating people with respect, promoting equality and inclusion and using public resources fairly and proportionately.[1814] For the improvement of health and wellbeing, benefits should be measured in terms of the individual to whom the screening is offered and should always prevail over potential harms. However, after ascertaining the potential benefits to the individual, the harms to others and to society can be considered. The principle of respect is specified in two ways. First, it implies that individual patients should be able to make fully informed screening choices aligned with their personal values. Second, it is argued that screening programmes "should take into account the views of those affected".[1815] According to the principle of equality and inclusion "any potential wider consequences of screening for society in the initiation and implementation of screening, both in the short and long term, should be considered".[1816] The ethical framework also calls for access to screening to be equitable and inclusive and for public resources to be used equitably and cost-effectively.

[1811] "The ethics group would soon be engaging with external stakeholders and members of the public in order to gather views and experiences which would provide options on where, how and what is needed to engage, manage and allow for ethical considerations to be better incorporated into the UK NSC's processes", UK National Screening Committee, 'Note of the meeting held on the 28 October 2020' , para. 5.2 <https://www.gov.uk/government/publications/uk-nsc-meeting-october-2020> accessed 23.3.2022.

[1812] UK National Screening Committee, 'Minutes 25 June 2021' <https://www.gov.uk/government/publications/uk-nsc-meeting-june-2021/uk-nsc-minutes-june-2021-draft> accessed 23.3.2022.

[1813] UK National Screening Committee, 'UK NSC ethical framework for screening' (10.8.2021) <https://www.gov.uk/government/publications/uk-nsc-ethical-framework-for-screening/uk-nsc-ethical-framework-for-screening> accessed 23.3.2022.

[1814] ibid.

[1815] ibid.

[1816] ibid.

c Room for Ethical Considerations in the Evaluation of Screening Programmes

The work that the ethics group has devoted to the publication of the UK National Screening Committee's ethical framework is to be welcomed insofar as it promotes the transparency of decisions that may be taken in the case of ethically controversial screening programmes. However, any normative framework influencing decision-making in the delivery of health services in England must be assessed in relation to the previously outlined procedural principles and in relation to the notion of accountability for reasonableness.[1817]

It must be borne in mind that the UK NSC is tasked with making recommendations to bodies, such as the Secretary of State and NHS England, that are bound by a legal and procedural framework. For example, the National Health Service Act 2006 in section 1A requires the Secretary of State to secure "continuous improvement in the quality of services". In particular, the provision of the services must ensure the outcomes of: service effectiveness, service safety and quality of patient experience. An equivalent duty to improve the quality of services is imposed on NHS England under section 13E of the NHS Act 2006, together with a duty to promote innovation in the provision of health services[1818] and a duty to enable patient choice.[1819] Both NHS England and the Secretary of State are also under an obligation to, respectively, promote the NHS Constitution[1820] and to have regard to it in exercising their functions.[1821] The NHS Constitution requires, *inter alia*, that the most effective use be made of scarce NHS resources. NHS patients have rights, albeit only procedural ones, that correspond to these obligations. Decisions concerning the design of screening programmes, as well as their public provision and commissioning, must be made with due regard to these obligations and procedural rights. NHS patients therefore have a procedural right to expect the authorities to strive to achieve this quality improvement. In the case of NIPT scientific evidence shows that its public funding would serve to improve the effectiveness and the safety of screening, as well as the quality of the patient experience.

[1817] See Chapter 1, sec. B.III.2.b.

[1818] National Health Service Act 2006 sec. 13K.

[1819] National Health Service Act 2006 sec. 13I.

[1820] National Health Service Act 2006 sec. 13C.

[1821] National Health Service Act 2006 sec. 1B.

Furthermore, it was illustrated in the Chapter 1 how the commissioning of health services in England is subject to a procedural framework of accountability for reasonableness. Hereby decisions on the public funding of health services should be made by taking into consideration only relevant factors for the decision and avoiding grounds on which reasonable people might disagree.[1822] Thus, it is questionable whether ethical considerations that are only endorsed by a certain section of society and not widely accepted could legitimately play a role within this framework. Decisions that are binding on society as a whole primarily need to be taken in a manner that is coherent with a legal framework that all reasonable subjects can agree on.

Admittedly, as the Nuffield Council of Bioethics also noticed in its report on the ethical issues of NIPT, full consensus on all aspects of prenatal screening programmes is virtually unachievable.[1823] What is needed in order to comply with the English normative framework is to bring together the various ethical perspectives present in society and to try to reach a lowest common moral denominator on which to base the rules of the public healthcare system. In this context it is necessary to keep the public well informed about ethical aspects of new health services so that the constituency can express their informed opinion and so that the procedural legitimacy of the choices made by public authorities can be upheld. According to the UK constitutional framework legal measures are acceptable insofar as they respect procedural principles and, *inter alia*, remain flexible for challenges and amendments advocated by societal groups with diverging ethical views. This goal is facilitated, in the absence of an official national ethics council, by the work of the Nuffield Council of Bioethics.

The task of the UK NSC, however, seems to be a rather different one; namely to advise health ministers and the NHS on their decisions regarding, respectively, the design and implementation of screening. In fulfilling these functions it appears essential that all bodies involved be committed primarily to ensuring compliance with a framework of accountability for reasonableness.

This implies, first, that the principles and duties imposed on public bodies in designing the provision of health services must be adhered to. Such duties include those of quality improvement and respect for the NHS Constitution, as well as the standards of reasonableness and relevancy.

[1822] See Chapter 1, sec. B.III.2.b.

[1823] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, pp. 69-70.

Although it might be unlikely that a court in judicial review would overrule an ethically charged decision of a public body, such standards nevertheless politically constrain public authorities.

Second, compliance with the more general legal framework must also be respected, for example compliance with the rules on abortion and on patients' informed consent. This legal environment amounts to fundamental value decisions that are procedurally legitimate and generally binding and thus dictate substantive conditions, which are 'the embodiment of a common moral position', for the acceptability of screening programmes.

As far as NIPT is concerned this point has been elucidated clearly by Jeffrey Wale who rightly argues that "the purposes or aims of any prenatal testing regime need to be consistent with, and correlate to, the wider regulatory/legal framework in which that regime operates".[1824] In this sense, screening through NIPT should not be offered publicly for "purposes that would be or are likely to be incompatible with any framework for lawful abortion".[1825] The legal system must maintain its coherence.[1826] Conversely it follows that where NIPT meets all the criteria of quality, safety and effective use of public resources, with which the NHS and the Secretary of State are obliged to comply, its public funding could not reasonably be refused[1827] on the grounds of, for example, the ethical undesirability of abortion.[1828] The common moral position is represented by the Abortion Act 1967 and this remains open to amendments according to possible shifts in society's views.[1829]

[1824] Wale, 'Don't Forget the Legal Framework' (2016) 15(4) Med Law Int p. 203, 209.

[1825] ibid, p. 214.

[1826] See also Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 662.

[1827] This point is not shared by J. Wale, who claims that "even if a State provides lawful options to terminate pregnancy, it does not follow that those options should be encouraged via prenatal testing or otherwise through unlimited public funding", Wale, 'Don't Forget the Legal Framework' (2016) 15(4) Med Law Int p. 203, p. 210. This thesis concurs with the author only to the extent that unlimited public funding is certainly not mandatory. However, the possible rejection of inclusion within publicly funded medical care must come from allocation reasons and not from ethical considerations external to the legal system.

[1828] This is because the common moral position is embodied in the Abortion Act 1967, which remains, admittedly, open to being amended in the event of changing views in society.

[1829] This was ultimately recognised also by the opponents of NIPT. After losing the battle against public funding of NIPT, advocates tried to challenge sec. 1(1)(d) of the Abortion Act 1967 in front of the High Court of Justice for its alleged

In the same way the autonomy of the patient and their ability to make individual ethical choices is a legal value that must be maintained. This has two implications. On the one hand, patient autonomy is a legal constraint which requires that the inclusion of NIPT in the screening pathway is done with due regard to women's informed consent. It must be avoided, for instance, that the test is offered routinely without patients actually understanding which new information the test will provide and its consequences. On the other hand, however, the value of autonomy seems to conflict with a position of ethical paternalism in which the public provision of NIPT is rejected for fear that it may be contrary to the morality of a part of society.[1830] The refusal to include NIPT in NHS services would establish an economic barrier to accessing a more effective and safer screening that would otherwise facilitate equal access for all patients to an informed choice about their pregnancy.[1831]

In sum, the consideration of ethical aspects in the evaluation of screening programmes by the UK NSC can only be undertaken with the understanding that consistency with the regulatory framework must be maintained. Substantive concerns about NIPT should be resolved not by appeals to morality but by compliance with an approach that aims at protecting the interests of the various parties involved through a compromise widely acceptable to society as a whole.

If a number of ethical concerns remain inadequately protected by the statutory framework, then the latter might become the target of campaigns to promote amendments. Ethical and religious concerns, on the other hand, cannot significantly affect the arrangements for public coverage of health technologies, as this has to follow procedural principles whereby patients

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incompatibility with several provisions of the HRA Act, see *Crowter & Others, R v Secretary of State for Health And Social Care* [2021] EWHC 2536 (Admin) (23 September 2021). The challenge was, however, unsuccessful.

[1830] The same view is endorsed by Nicholas Wald – albeit without employing legal reasoning – according to whom "[i]t is arguable that ethical review by a public agency [...] in respect of a screening programme deemed to be worthwhile [...] replaces individual choice with institutional decision making in areas where individual choice should prevail. [...]. Provided that a screening programme is lawful and is also justified on scientific and medical grounds, the individual is sovereign in determining the ethical position", Wald, 'Are Screening Practice Ethics Committees Needed?' (2021) 28(4) J Med Screen p. 377.

[1831] On this point see Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194, 196; Bunnik and others, 'Why NIPT Should Be Publicly Funded' (2020) 46(11) J Med Ethics p. 783, 784.

cannot be denied access to health services on the basis of unreasonable or irrelevant factors.

As demonstrated in the case study on preimplantation genetic diagnosis, the legal criteria featured in the statutory framework already tend to accommodate the constituency's ethical concerns. Regarding the method of 'reflex testing' in the use of NIPT for example, this would not be compatible with the legal framework. This is not so much because it is 'ethically wrong' but rather because it does not seem to successfully respect women's informed consent and because the gathered scientific evidence suggests that offering the test to women with a chance of having an affected foetus of 1 in 800 would make screening less accurate and reduce the quality of the offer.[1832] Certainly, however, the reconstruction of the different ethical aspects is useful for informing the population and keeping the public debate open, thereby helping to maintain the legitimacy of public decisions, as the Nuffield Council of Bioethics has suggested.[1833]

These findings are relevant to the assessment of the ethical framework adopted by the UK National Screening Committee. The decisions of this committee are particularly influential for the shaping of screening programmes by the Secretary of State and their provision by NHS England. This influence is not only political but also legal since, according to the NHS Constitution to which the Secretary of State and the NHS must have regard, the NHS "commits to provide screening programmes as recommended by the UK National Screening Committee".[1834] In this way the consideration of ethical aspects in the decisions of the UK NSC is likely to be directly transposed into the choices of the public authorities following its recommendations. It is therefore desirable for the ethical framework adopted by the UK NSC to maintain consistency with the legal framework and accountability for reasonableness.

Depending on how the framework published in 2021 will be implemented in practice, the only problematic points in this respect are the reference to harms to others and to society and the consideration of "any potential

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[1832] Concerns about the allocative efficiency of public resources can admittedly also be described as 'ethical', but these fall beyond the scope of this dissertation.

[1833] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017, p. 70.

[1834] Department of Health and Social Care, 'The NHS Constitution for England', 1.1.2021.

wider consequences of screening for society".[1835] As these statements are broadly open to interpretation they have the potential to be entry points for ethical considerations that are not compatible with the currently existing normative framework and thus function as 'Trojan horses'[1836] for ethical or religious considerations in the law.[1837]

D. Comparative Analysis

I. NIPT in the Private Sector

NIPT entered the European market as an IVD device in 2012. Not in all the three countries, however, has its mere entry onto the market triggered a large-scale public debate. Germany is the country where the discussions have been most heated ever since the introduction of this screening technology.[1838] An opinion of the German Ethics Council was requested as early as one year after NIPT was launched on the market, at a time when the G-BA had not yet expressed a position on whether or not an evaluation procedure for introducing this new technology into the statutory health insurance could be initiated.[1839] Germany is also the only one of the investigated countries where it was even disputed whether the test could be legally marketed. Reservations in this regard resulted from a legal expert opinion requested by the Federal Government Commissioner for Matters relating to Persons with Disabilities. The opinion stated that NIPT would endanger the health and safety of the foetus as a third party and that therefore its marketing should be prohibited.[1840]

In Italy and England too the rapid spread of NIPT on the private market has generated some apprehension. In contrast to Germany, however, such concerns were raised by specialised technical and scientific bodies. In Italy, for example, concerns have been expressed by the Italian National

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[1835] UK National Screening Committee, 'UK NSC ethical framework for screening', 10.8.2021.

[1836] Using the term introduced by Spranger, *Recht und Bioethik* (2010) p. 38. See Chapter 1, sec. B.I.1.

[1837] See Chapter 2, sec.D.IV.2.

[1838] See above in this Chapter, sec. A.

[1839] Deutscher Ethikrat, 'The Future of Genetic Diagnosis' (2013).

[1840] Gärditz, 'Gutachtliche Stellungnahme zur Zulässigkeit des Diagnostikprodukts "PraenaTest"', 2012.

Health Council, which is responsible, among other things, for consulting the Ministry of Health on new health technologies.[1841] Moreover, in both countries worries about the use NIPT on the private market have focused on the possibly of poor quality information and counselling being given to patients by private facilities and not on the negative consequences for screened foetuses.[1842]

In sum, for as long as NIPT has been on the private market concerns about its uptake in England and Italy did not come close to reaching the broad scope of public discussion observed in Germany.

II. Public Coverage of Traditional Prenatal Testing

Having an overview of the traditional prenatal testing methods that are already included in the public coverage of the three jurisdictions provides insights into their general attitude towards public funding of screening for chromosomal aneuploidies.

A certain reluctance towards prenatal testing as part of the offer of the public healthcare system can be observed in Germany. Unlike in Italy and England the so called first-trimester screening or combined test is not included in the benefit basket of the statutory health insurance. This non-invasive screening technique can be performed at the patient's request, but the cost must be borne out-of-pocket. In England, on the contrary, combined screening is offered to all women in the first trimester of pregnancy, independently of their risk group. This is in line with NICE's recommendation that all women should be offered screening for chromosomal trisomies in the first trimester.[1843] In Italy as well, prenatal screening through combined testing has been offered free of charge to all patients starting from 2017.

With regard to invasive diagnoses, i.e. amniocentesis and chorionic villus sampling, these are offered to all patients found to be at high risk after combined testing in all three countries. In Germany a woman who is a first-time mother and over 35 is automatically considered to be at high

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[1841] Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015.

[1842] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017.

[1843] National Institute for Health and Care Excellence, 'Antenatal care', 19.8.2021 risk. Among the analysed countries it is only in Germany that the public healthcare system's offer of these invasive diagnoses is seen as controversial by some legal scholars. They argue, in particular, that the detection of disability is not part of the statutory purpose of the health insurance.[1844] In Italy the National Bioethics Committee made an assessment of prenatal screening procedures in 2012 that was positive overall and argued that the right to know the health status of the foetus is undisputed, provided that couples are accompanied by a 'non-directive' medical consultation.[1845]

The different legal cultures of the three countries with respect to traditional prenatal screening or diagnosis are arguably reflected in their reaction to the emergence of more innovative testing tools. Indeed, Germany's skepticism towards classic prenatal testing methods resulted in a more heated public debate about NIPT.

III. Autonomy and Informed Consent

Legal principles protecting a woman's right to information on the health condition of her foetus are found in all three jurisdictions. These stem mainly from the protection of a patient's right to health, physical integrity and self-determination.

In Germany the state has an obligation to protect the right to physical integrity which includes, in the case of the pregnant woman, possible factors arising from the pregnancy that may affect her health. In Italy the right to health and the right to self-determination in matters of health receive special constitutional protection through a traditional patient-centred approach. It is assumed that knowledge of the foetus' health status strongly influences the pregnant woman's overall state of health. In England the value of patient autonomy has been given special consideration not least thanks to the intervention of the Supreme Court in 2015 in the landmark case of *Montgomery v Lanarkshire Health Board*.[1846] The improvement in reproductive autonomy is thus considered the main aim of prenatal testing.

Since its purpose is also the safeguarding of the woman's self-determination, prenatal testing should, according to the approach of all the analysed

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[1844] Welti in Becker and Kingreen, *SGB V* (2020) p. 254; Gärditz, 'Gutachtliche Stellungnahme zur Zulässigkeit des Diagnostikprodukts "PraenaTest"', 2012.

[1845] Comitato Nazionale per la Bioetica, 'Diagnosi prenatali', 18.7.1992, pp. 28–31.

[1846] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015).

countries, only be offered if accompanied by adequate information and counselling. Its uptake is conditional on the informed consent of the patient, who must have fully understood the consequences and scope of the test about to be performed. It is clear in all jurisdictions that the information and counselling offered by the doctor should be of a non-directive nature, i.e. it should not aim to influence the woman and make her lean towards one choice over another. In the UK, for instance, it is emphasised that the value-based choices of individual patients must be protected and that healthcare professionals should not try to impose their ethical convictions on the patients.[1847]

This element was particularly relevant in Italy, where effectively implementing these informed consent principles was considered necessary and sufficient to overcome potential ethical concerns raised by NIPT. In contrast, a certain reluctance towards NIPT stems from the German approach placing particular emphasis on a woman's right not to know. This is not seen as a merely negative dimension of the right to know, but is considered an autonomous aspect of the right to self-determination in matters of health.[1848] This right is protected by the Genetic Diagnosis Act according to which the woman must be actively informed of her right not to know.

IV. NIPT in the Public Healthcare System

1. Criteria for Access to NIPT

The case study shows that there are several possibilities for designing prenatal screening programmes involving NIPT in a public setting. NIPT could be offered to all pregnant women or only to those in a certain risk category. In the second case, risk could be defined either by biological criteria, such as age, or by a previous screening test such as the combined test.

In Germany and England the public coverage of NIPT is now provided nationwide according to access requirements respectively established by the G-BA or suggested to the Secretary of State by the UK National Screening Committee.

[1847] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 (11 March 2015).

[1848] See, in this Chapter, sec. A.II.1.b.

In Germany a solution was found that requires an individual risk assessment for the specific patient. A statistically increased risk of trisomy would not be sufficient to access the test. Reimbursement is only granted when it is necessary to allow that particular woman to confront the possible presence of a chromosomal trisomy in the foetus within the framework of medical support.[1849] In other words, in order to obtain reimbursement from public health insurance funds the doctor and the patient must agree that in the individual case the uncertainty about the condition of the foetus is a disproportionate burden. Alternatively, the test can be accessed after a positive result from previous screening.[1850] This can be considered an acceptable compromise in that, on the one hand, it prevents the routinisation of the test but, on the other hand, it guarantees access to all women who consider NIPT necessary for the protection of their health.

In a similar fashion, the English UK NSC recommended NIPT for contingent use, i.e. dependent on the results of the combined test. Under its recommendations NIPT for trisomy 21, 13 and 18 should only be offered to women who exceed the risk threshold of 1 in 150 after the first screening.[1851] Accordingly, NIPT is not offered as standard testing to all women.

In Italy the access criteria for NIPT currently depend on the Region where the patient is resident. NIPT is still undergoing assessment by the Commission for the Updating of the LEA for its inclusion in the national Essential Levels of Care. However, the National Health Council has already issued guidelines, to which this commission can be expected to refer, which suggest that NIPT be offered for trisomies 13, 18 and 21 as a contingent screening after the combined test.[1852] As for the individual Regions, there is still some variety. Emilia Romagna has decided to offer free NIPT to all

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[1849] Gemeinsamer Bundesausschuss (G-BA), ‘Beschluss über eine Änderung der Mutterschafts-Richtlinien (Mu-RL): Aufnahme einer Versicherteninformation zur Durchführung der Nicht-invasiven Pränataldiagnostik zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT-Trisomie 13,18,21) für die Anwendung bei Schwangerschaften mit besonderen Risiken’, 19.8.2021.

[1850] ibid.

[1851] UK National Screening Committee, ‘UK NSC non-invasive prenatal testing (NIPT) recommendation’, 01.2016.

[1852] Consiglio Superiore di Sanità, Sez. I, ‘Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)’, 05.2015; Consiglio Superiore di Sanità, Sez. I, ‘Screening del DNA fetale non invasivo (NIPT) in sanità pubblica’, 9.3.2021.

pregnant women regardless of risk factors.[1853] The self-governing province of Bolzano decided to provide NIPT only to patients who are found to be at intermediate risk after the combined test.[1854] In Tuscany as well, the test is only available to pregnant women who have been found to be at risk between 1/301 and 1/1000 after the combined test.[1855] Moreover, a small patient co-payment is applied to most patients here. Puglia statutorily introduced reimbursement of NIPT to all pregnant women who are either over the age of forty or found at high or intermediate risk after combined testing.[1856]

2. Ethical Concerns to Public Funding of NIPT

a Public Debates

In both England and Germany, the announcement that NIPT was being considered for introduction into the public healthcare system reinvigorated the public debate. Concerns about the possible effects of the use of NIPT were expressed in leading national media. In Germany an article in the newspaper *Zeit* denounced the introduction of NIPT into the GKV as the first step towards a society without people with disabilities.[1857] Similarly, in England a BBC documentary called out a possible drastic decrease in the number of children born with Down's syndrome.[1858]

In both jurisdictions these considerations also came to the attention of Parliament. In England the 'Don't screen us out' campaign was supported by a parliamentary motion.[1859] In Germany a parliamentary orientation debate on the issue of NIPT reimbursement by statutory health insurance was conducted in April 2019. On this occasion some MPs expressed the view that the state should not actively support any methods of screening people

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[1853] Regione Emilia-Romagna (Giunta Regionale), Delibera no. 1894, 4.11.2019.

[1854] Provincia Autonoma di Bolzano - Alto Adige (Giunta Provinciale), Deliberazione no. 1413, 18.12.2018.

[1855] Regione Toscana (Giunta Regionale), Delibera no. 1371, 10.12.2018.

[1856] Legge Regionale Puglia no. 31/2021, "Implementazione del Test prenatale non invasivo (NIPT)" 6.8.2021.

[1857] Bahnsen, 'Pränataldiagnostik: Der Test' *Die Zeit.* 22.1.2015.

[1858] Phillips and Richards, 'A World Without Down's Syndrome', First Broadcast 5.10.2016 BBC.

[1859] UK Parliament, 'Early Day Motion 44', 19.5.2016.

with chromosomal trisomies.[1860] They also noted that women must be guaranteed a right not to know and that discriminating messages towards people with disability must be avoided.

Groups advocating the ethically problematic nature of NIPT in both countries sought to influence the process of evaluating this technology for inclusion in the public healthcare system. In Germany the body responsible for deciding on the inclusion of NIPT in the statutory health insurance received letters from MPs twice. In the first one it was urged simply to consider the ethical and social consequences of NIPT in its assessment.[1861] In the second, more directly, the G-BA was asked to consider suspending the evaluation procedure because of ethical concerns.[1862] This and solicitations from other advocacy groups forced the authority to issue several statements on its awareness of the ethical issues of NIPT and to promise that the German Ethics Council would be involved in the decision.[1863] Even the technical body responsible for HTA in Germany was criticised for refusing to address possible ethical problems and devolving the consideration of such issues to the G-BA.[1864]

In England the parliamentary motion supporting the Down's syndrome community asked the government to postpone the introduction of NIPT in the NHS antenatal screening programme to allow further consultations.[1865] Responses to the public consultations have demonstrated, however, that the introduction of NIPT into NHS care, albeit with due caution, is ultimately relatively uncontroversial in the country. This view was also expressed by those legal scholars who intervened in the debate.[1866] It was observed that, in general, those members of society who are most critical of NIPT are also more generally opposed to any screening for chromosomal aneuploidies

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[1860] Deutscher Bundestag, 'Plenarprotokoll 19/95', Berlin 11.4.2019. See above, in this Chapter, sec. A.II.2.c.

[1861] Hüppe and others, 'TOP 8.2.1 der 91. Öffentlichen G-BA Sitzung am 18. August 2016', 17.8.2016.

[1862] As reported in the answer by the chairman of the G-BA, Gemeinsamer Bundesausschuss (G-BA), 'Schreiben von Prof. Josef Hecken, unparteiischer Vorsitzender des G-BA, an Mitglieder des Deutschen Bundestages zur Nichtvertagung der Beschlussfassung zu NIPT', 19.9.2019.

[1863] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 02/2015', 22.1.2015.

[1864] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 'IQWiG-Berichte - Nr. 623', 30.4.2018.

[1865] UK Parliament, 'Early Day Motion 44', 19.5.2016.

[1866] Brownsword and Wale, 'The Development of Non-Invasive Prenatal Testing: Some Legal and Ethical Questions' [2016](24) JRE p. 31.

that could lead to abortion. They believe that the public funding of such screenings sends an undesirable message by creating feelings of stigmatisation and discrimination in people with disabilities. The consensus of the general population, by contrast, seems to be that NIPT represents a fairly uncontroversial and beneficial innovation insofar as it limits the risks associated with invasive diagnoses that are already practised. This admittedly remains true only under certain conditions. First, NIPT should only be used for medical conditions that are already detectable by other screening techniques, such as chromosomal trisomies, and it should not be extended to purely aesthetic or non-medical conditions of the foetus.[1867] Moreover, respect of women's autonomy must be fully guaranteed.[1868]

Similarly, in Italy it is considered that the use of NIPT would not expand the uptake of prenatal screening to an unacceptable extent if it is limited to the detection of chromosomal trisomies.[1869] Here, in contrast to Germany and England, there has been no large-scale public debate on NIPT. The topic has only been addressed by bodies responsible for consulting the Ministry of Health or updating the Essential Levels of Care, a foundation dealing with women's health, and a few legal scholars.[1870] In Regions where NIPT has become part of the Regional Health System's benefit basket or where its evaluation for this purpose is ongoing, decisions on NIPT have generally been taken unanimously or almost unanimously. Those contributing to the Italian debate have agreed that the new moral issues emerging with NIPT can be effectively addressed by an adequate implementation of informed consent and counselling procedures in clinical practice.[1871]

[1867] Brownsword and Wale, 'The Right to Know and the Right Not to Know Revisited' (2017) 9(1) Asian Bioeth Rev p. 3, 15.

[1868] See above, in this Chapter, sec. C.II.1.b.

[1869] Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015.

[1870] See, *inter alia*, Consiglio Superiore di Sanità, Sez. I, 'Linee-Guida. Screening prenatale non invasivo basato sul DNA (Non Invasive Prenatal Testing – NIPT)', 05.2015; Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021; Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225; Palazzani, *Dalla bio-etica alla tecno-etica* (2017).

[1871] Palazzani, *Dalla bio-etica alla tecno-etica* (2017); Rizzo, 'Il consenso informato come strumento per l'implementazione etica dei test genetici non invasivi per la diagnosi prenatale' [2018](3) BioLaw Journal – Rivista di BioDiritto p. 225;

This comparatively uncontroversial approach to public funding of NIPT can be explained, firstly, by a relatively positive attitude to traditional prenatal diagnoses. Compared to them, NIPT is regarded as merely an improvement in the interests of both the future mother and the foetus. This attitude is in line with the Italian constitutional approach to the right to health as a fundamental right of every individual which is connected to their most intimate sphere. The fact that a potential public funding of NIPT does not lead to ethical conflicts could be linked to the idea that the National Health Service aims at protecting the core of the right to health, combined with a traditionally very broad conception of the notion of health.[1872] It follows that all health services pertaining to this essential core, which include prenatal diagnoses because of their importance for the psycho-physical well-being of the mother, are worthy of being equally guaranteed to all residents. This conception of the benefits provided by the National Health Service differs from the traditional conception of the German healthcare system, which is seen as an insurance scheme covering specific health risks.

b Consideration of Ethical Concerns in the Evaluation Procedure

i. Procedural Aspects

Although to varying degrees, ethical considerations were accounted for in the process that led (or is leading) to the inclusion of NIPT in the coverage of the public healthcare system in all three jurisdictions.

With regard to procedural elements used in dealing with ethical concerns in the three jurisdictions, it is not surprising that the element of public and stakeholder consultations played a particularly essential role in England. The UK National Screening Committee, the body in charge of evaluating screening programmes, decided to launch a three-month public consultation before issuing its final recommendation on NIPT.[1873] Thirty stakeholders with very different backgrounds and perspectives responded

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Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021.

[1872] On the broad definition of health endorsed by Italian Constitutional Law, see Introduction and Chapter 1, sec. B.II.2.

[1873] UK National Screening Committee, 'Note of the meeting held on the 18 June 2015'.

to this consultation. In the aftermath of the approval of NIPT for inclusion in NHS care, and as a response to the call to strengthen the consideration of ethical aspects, an ethics task group was set up within the UK NSC and this also worked through consultations with the public and stakeholders. In addition, the government has twice been called upon to consult more appropriately with the community of people with Down's syndrome before providing for public reimbursement of NIPT.[1874] This demonstrates the importance of consultation as an essential element of the legitimacy and acceptability of decision-making in England.

Also the Nuffield Council of Bioethics, when dealing with the ethical issues of public funding of NIPT, first of all engaged in public consultations and collection of stakeholders' opinions. The Council also launched an anonymous online survey to reach the opinions of individuals who had dealt with the test through personal or work experience.[1875] When drafting its NIPT report the Council followed its traditional method of applying criteria of procedural legitimacy and standards of reasonableness.

Public consultations did not have the same relevance in Germany and Italy. However, the German G-BA did use its formal consultation procedure to get the opinion of various stakeholders. It also sought to widen the debate by asking for comments from the German Ethics Council and the Genetic Diagnostics Commission.[1876] Moreover, the authority encouraged Parliament to initiate a discussion on the political and normative aspects of NIPT and directly interacted with stakeholders and the general public through its press releases. The IQWiG also conducted a public consulta-

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[1874] UK Parliament, 'Early Day Motion 44', 19.5.2016; Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S37.

[1875] Nuffield Council on Bioethics, 'Non-invasive Prenatal Testing: Ethical Issues', London 2017.

[1876] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss des Gemeinsamen Bundesausschusses über die Einleitung des Stellungnahmeverfahrens gemäß § 91 Absatz 5, § 91 Absatz 5a sowie § 92 Absatz 1b und § 92 Absatz 7d des Fünften Buches Sozialgesetzbuch (SGB V) vor einer abschließenden Entscheidung über eine Änderung der Mutterschafts-Richtlinien: Nicht-invasive Pränataldiagnostik (NIPD) autosomaler Trisomien 13, 18 und 21 mittels eines molekulargenetischen Tests (NIPT) für die Anwendung bei Risikoschwangerschaften im Rahmen der Mutterschafts-Richtlinien (Mu-RL)', 22.3.2019; Gemeinsamer Bundesausschuss (G-BA), 'Nicht-invasive Tests bei Risikoschwangerschaften: G-BA fordert zur Stellungnahme auf', 22.3.2019.

tion open to all interested individuals, institutions and organisations.[1877] Furthermore, in February 2022 – on the occasion of the approaching implementation of NIPT reimbursement by health insurance funds – the German Ethics Council revived the debate by holding an online public discussion on NIPT with public participation via online questions.[1878] It can thus be observed how elements of the procedural model were incorporated into the decision-making procedure for NIPT in Germany and contributed to the achievement of an acceptable compromise regarding its reimbursement scheme.

ii. Substantive Elements

In terms of substantive considerations, in all three countries the bodies responsible for evaluating NIPT for public funding focused primarily on ensuring that women are not pressured into taking the test or into making any particular choice after a positive result. Reproductive autonomy and informed consent were the main theme throughout this case study and guaranteed acceptability of public funding for NIPT. Partially related to this, the need to avoid routinisation of NIPT was also addressed.

The element of reproductive autonomy and informed choice was of decisive significance especially in Italy. As demonstrated above,[1879] the Italian debate indicated that respect for the woman's informed consent, accompanied by adequate counselling, could be a necessary and sufficient condition to overcome any doubts about the desirability of publicly funding NIPT. Along the same lines the National Health Council also argued that the way to settle the ethical concerns raised by NIPT would be through non-directive counselling, offered as part of the diagnostic treatment.[1880] The focus of public decision-makers has thus been on maximising respect for women's reproductive autonomy. The overarching consensus on informed consent has here prevented the emergence of ethical controversies over NIPT.

[1877] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, 'Nicht invasive Pränataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 bei Risikoschwangerschaften (Vorbericht)', 11.12.2017, p. III.

[1878] Deutscher Ethikrat, 'Pressemitteilung 01/2022'.

[1879] See above, in this Chapter, at sec. B.3.

[1880] Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021, p. 21.

In England too the decision-making process has taken into account the need to avoid misleading information and the application of inappropriate pressure to patients. The RAPID study, initiated with input from the UK NSC, aimed not only at considering the scientific accuracy of the test, but also to assess the possibility of maintaining high levels of informed choice.[1881] NIPT was then recommended for introduction into NHS care on an evaluative rather than a permanent basis in order to better understand the impact of public funding on patients' reproductive autonomy. The UK NSC then used the argument of reproductive autonomy to reject the proposal received in 2018 to include the 'reflex testing' method for NIPT in the prenatal care pathway. It is to be noted, however, that the uncertain ethical assessment of a possible expansion in the uptake of NIPT, given the lower risk threshold for access, also played a role in this appraisal.[1882] Here too, the inclusion of an evaluation period and the emphasis on informed consent ensured the acceptability of the final compromise.

In Germany, the G-BA effectively addressed concerns about the right to know and not to know. The authority confirmed that NIPT can only be performed after giving the patient comprehensive counselling and information as well as sufficient time for reflection.[1883] Moreover, the possible routinisation of NIPT was prevented when setting the requirements for access to the test. Statutory health insurance coverage is provided only after an individual assessment of the woman's situation and her personal need to obtain information on the health status of the foetus.[1884]

As regards the other ethical concerns raised, they were not explicitly targeted by the relevant decision-making authorities. The G-BA in Germany emphasised that they had followed the legally prescribed procedure of evaluating the test and stressed that any remaining ethical issues at stake would require a legislative response.[1885] In England the issue of a possible increase in abortion rates was tackled by the RAPID study. With regard to the negative signals allegedly sent to the disabled community by the provision of public funding for NIPT, the UK NSC responded by including certain

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[1881] Hill and others, 'Evaluation of Non-invasive Prenatal Testing (NIPT) for Aneuploidy in an NHS Setting' (2014) 14(229) BMC Pregnancy Childbirth p. 1.

[1882] UK National Screening Committee, 'Note of the meeting held on the 31 October 2018'.

[1883] Gemeinsamer Bundesausschuss (G-BA), 'Beschluss über eine Änderung der Mutterschafts-Richtlinien (Mu-RL)', 19.9.2019 BAnz AT 20.12.2019 B6.

[1884] ibid.

[1885] Gemeinsamer Bundesausschuss (G-BA), 'Pressemitteilung Nr. 26/2019', 19.9.2019.

principles in its ethical framework for the assessment of new screening methods. These include: the possibility to consider harms to others and to society, as well as any potential wider consequences of the implementation of the screening for society.[1886]

c Assessment

i. Compliance with the Normative Framework

When considering the high accuracy, safety and cost-effectiveness of NIPT it seems that any refusal to include it in the public healthcare system could only be based on ethical or religious considerations. From a legal point of view these non-invasive technologies are no different from other existing prenatal screening methods. They simply better protect the rights of the foetus and increase the quality and safety of health services. The mere possibility of the test being used more often does not create any discrimination against people with disabilities. Discrimination would be caused, if anything, by the woman's subsequent choice to have an abortion. This choice, however, can legitimately be made if it remains within the statutory agreement and constitutional balance reached in each jurisdiction. The argument that an increase in the use of prenatal diagnostics would be undesirable is based on purely ethical and not legal grounds.

Thus, for each country an assessment can be made to determine whether purely ethical concerns could legitimately result in a decision not to publicly fund NIPT.

First, it results from the considerations made within the case study, that in all three jurisdictions the evaluation of NIPT for inclusion in the public healthcare system should primarily be carried out in accordance with the legal framework.[1887] In Italy and Germany substantive legal principles that govern the updating of the health benefit basket remove any room for the consideration of purely ethical concerns in the decision-making process.

In Germany the decision must be made on the basis of the aspects defined in § 135(1) of the SGB V. Namely, diagnostic or therapeutic benefit, medical necessity and economic efficiency. The list of criteria contained in

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[1886] UK National Screening Committee, 'UK NSC ethical framework for screening', 10.8.2021.

[1887] See in this Chapter, for Germany sec. A.II.3, for Italy sec. B.II.3.c, and for England sec. C.II.3.c.

this paragraph is exhaustive and there is no legal basis that would allow the G-BA to bring ethical aspects into consideration. Neither could the G-BA legitimately block the procedure or postpone the decision on ethical grounds.

In Italy, a health service falls under the Essential Levels of Care when it is necessary to uphold the ‘inviolable’ core of the fundamental right to health throughout the national territory. Inclusion of a new health technology in the benefit basket follows the criteria set out in Article 1(2) of Legislative Decree no. 502 of 30 December 1992, and in particular those of quality of care, appropriateness and economical use of resources.

In England too there is rather limited space for the influence of purely ethical concerns, although this stems mainly from the particular pragmatic and procedural approach surrounding the public funding of new technologies in the NHS. English health authorities tend to take pragmatic decisions and to comply with a procedural model of ‘accountability for reasonableness’. Moreover, the Secretary of State and NHS England are bound to respect procedural rights of the patients, as enshrined in the National Health Service Act 2006 and the NHS Constitution. These require, *inter alia*, that the state continuously pursues the improvement of quality of health care.

Beyond the legal criteria specifically drafted for the updating of the services provided by each healthcare system, each analysed jurisdiction is embedded into an overarching constitutional framework which would still preclude purely ethical considerations from negatively influencing the public funding decision for new health technologies.[1888]

In the case of NIPT, all three jurisdictions have proven their commitment to their legal and constitutional frameworks in deciding on the public coverage of NIPT.

In Germany, there has been no violation of the principle of ethical neutrality of the state in the G-BA’s decision to introduce NIPT into the maternity guidelines. The instruments used to ensure the acceptability of the decision in this ethically controversial issue were mainly substantive and legal, although procedural mechanisms and dialogue with the public were implemented by the G-BA and the German Ethics Council. In explaining the reasons for its decision the G-BA focused mainly on the legal criteria regulating the inclusion of new products in the benefit basket of the GKV according to § 135(1) no. 1 SGB V. The provision of appropriate

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[1888] ibid.

counselling and information is a legal requirement that derives its validity from constitutional norms on self-determination and bodily integrity. This is reflected in the rights to know and not to know. Also the decision to only grant reimbursement of NIPT after individual assessment of each patient's case can be considered justified on the basis of these two constitutional interests. In sum, ethical considerations did not ultimately influence the reimbursement decision, which was lawfully made by the G-BA following the procedure set out in § 135 of the SGB V. The only factor that might have been negatively affected by the ethical weight of this topic is the timing of the decision. Given the demands from society and from members of Parliament the G-BA felt compelled to leave enough time for the legislature to intervene independently on the matter.[1889] This might have resulted in a lengthening of the timeframe needed for the decision.[1890]

The principle of laicity has been respected in the Italian case. The regional and national public authorities involved to date have upheld the constitutional principle of informed consent, as enshrined in the Constitution under the combination of Articles 2, 13 and 32. Any ethical issues relating to NIPT were held to be resolvable by protecting patients' ability to give informed consent, thus demonstrating a laicity-driven approach to the balancing of interests between the woman and the foetus. The final decision of the Commission for the updating of the Essential Levels of Care has not yet been reached, but it can be expected that it will rely on the guidelines of the National Health Council. These have stressed that the inclusion of NIPT in the Essential Levels of Care is necessary to ensure compliance with the criterion of appropriateness and to prevent carrying out riskier diagnoses.[1891]

In sum, both Italy and Germany based the neutrality and legitimacy of their decisions on NIPT primarily on substantial legal considerations.

[1889] As sustained by the chairman of the G-BA in his letter to the MPs, the G-BA "has initiated a formal method evaluation procedure and conducted an extended (public) comment procedure in order to create time and space for parliamentary decision-making and, if necessary, also a parliamentary decision", see Gemeinsamer Bundesausschuss (G-BA), 'Schreiben von Prof. Josef Hecken, unparteiischer Vorsitzender des G-BA, an Mitglieder des Deutschen Bundestages zur Nichtvertagung der Beschlussfassung zu NIPT', 19.9.2019.

[1890] While the procedure was first initiated in 2014, the final decision arrived in 2019 and the reimbursement from the health insurance funds will only be granted starting from spring 2022.

[1891] Consiglio Superiore di Sanità, Sez. I, 'Screening del DNA fetale non invasivo (NIPT) in sanità pubblica', 9.3.2021.

Unsurprisingly, mainly procedural means were used in England to ensure that the decision remained legitimate and widely acceptable despite dealing with a highly ethically controversial question. This is consistent with the principles of procedural legitimacy underlying the English constitutional system. For example, the public was able to participate in the debate on the ethical aspects of the inclusion of NIPT in NHS care through consultation exercises from the UK NSC and the Nuffield Council of Bioethics. The opinions thus collected were put to a test of reasonableness. As far as the substantive considerations weighing on the decision are concerned, they were in line with the principles of accountability for reasonableness and other statutory requirements. All factors that weighed on the final decision could be broadly regarded as relevant and reasonable. Indeed, reasonable criteria of quality and accuracy were used and reference to factors on which reasonable people might disagree was avoided. The adherence to legal criteria ensured that the decision was in line with factors widely accepted as relevant, such as the "continuous improvement in the quality of services" established by the National Health Service Act 2006.[1892] Inclusion of NIPT in NHS antenatal care for patients at high risk after combined testing, in order to avoid invasive and harmful diagnoses, upholds the procedural rights of patients to the improvement of both the effectiveness and the safety of screening. Patients' procedural rights under the NHS constitution were also respected. This requires the government to provide screening programmes as recommended by the UK National Screening Committee. The government fulfilled this obligation by refusing to further delay the implementation of NIPT in the NHS.[1893]

ii. Calls for More Consideration of Ethics in the Decision-Making

In England and Germany the public funding of NIPT has triggered calls for a better inclusion of ethics in the assessment procedure leading to the public coverage of health technologies.[1894] However, if the normative framework of neutrality of justification is to be maintained, then it is not

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[1892] National Health Service Act 2006 sec. 1A.

[1893] Lavery, 'Pregnancy: Screening. Question for Department of Health and Social Care', 2.9.2019.

[1894] See criticism of G-BA and IQWiG in Germany (in this Chapter, sec. A.II.2.b) as well as the proposals for better inclusions of ethics in the UK NSC assessment of screening programmes (in this Chapter, sec. C.II.3.b).

possible to authorise public decision-makers to refuse the reimbursement of health technologies on purely ethical grounds. This consideration is valid for all three examined jurisdictions.

The German G-BA could only have blocked or delayed the evaluation procedure on the grounds that the increased use of prenatal diagnosis was concerning if the legislature had given it the competence to assess ethical or religious aspects. However, the suggestion that the legislature in future might allow the G-BA to consider ethical aspects in its evaluation procedure[1895] creates fertile ground for an infringement of the principle of neutrality of justification. Granting competence in ethical matters to the self-administration authority of the statutory health insurance could serve as a 'Trojan horse' for considerations linked to one specific ethical or religious belief in reimbursement decisions. Such justifications are not acceptable under a constitutional framework where the principle of ethical and religious neutrality also applies to the choices made by the welfare state in its action to implement the public healthcare system. In sum, any justification for refusing public funding purely based on ethical or religious views must be considered purely arbitrary and as contrary to the principle of ethical neutrality of justification.

In England too the ethical framework recently adopted by the UK NSC has a potential to function as 'Trojan horse' for ethical or religious considerations in the law.[1896] This would happen if one or more of the principles of this framework were interpreted according to a perspective that was not widely shared and if this were used to impose a particular belief without it being subject to the procedural principles that determine its legitimacy and acceptability by society as a whole. This could also lead to irrelevant factors or unreasonable considerations being taken into account in the decision-making of this public body. A consideration of non-widely shared ethical principles in the decisions of health authorities would thus run against the procedural principles of English constitutional law and the requirements of the model of accountability for reasonableness. Admittedly, however, the pragmatic and utilitarian positioning of the UK NSC seems to exclude this possibility, at least for the time being.

[1895] Huster, 'Non-invasive Prenatal Diagnostics (NIPD) in the System of Medical Care' (2021) 49(8) J Perinat Med p. 1; Gemeinsamer Bundesausschuss (G-BA), 'Schreiben von Prof. Josef Hecken, unparteiischer Vorsitzender des G-BA, an Mitglieder des Deutschen Bundestages zur Nichtvertagung der Beschlussfassung zu NIPT', 19.9.2019.

[1896] See, in this Chapter, sec. C.II.3.c.

Such calls for a greater consideration of ethical aspects in the health technology assessment process did not occur in Italy in the case of NIPT, given the relatively uncontroversial nature of this new prenatal screening. Also in this jurisdiction, however, a consideration of the 'ethical desirability' of new technologies could only be legitimately influential on decision-making if this ensured the compliance of new health services with widely accepted fundamental principles laid down in legislative acts that were themselves in line with the Constitution. This was the definition of ethical desirability endorsed by the previous Commission for the updating of the LEA.[1897] This strictly secular definition of 'ethical concerns' would be compatible with the Italian normative and constitutional framework of laicity.

[1897] Arcà and Cislaghi, 'Percorsi metodologici per l'inserimento o l'esclusione di una prestazione dai Livelli essenziali di assistenza' [2006](2) Tendenze nuove p. 97, 102; Commissione nazionale per la definizione e l'aggiornamento dei Livelli essenziali di assistenza in Falcitelli and Langiano, *La remunerazione delle attività sanitarie* (2007) p. 254.

Conclusions

I. Summary of Argumentation

1. Theoretical and Constitutional Foundations

The aim of this thesis has been to assess how pluralistic democracies can legitimately address ethical concerns surrounding health technologies. In particular, it has sought to investigate whether ethical considerations are – and can legitimately be – taken into account when evaluating the introduction of a new ethically controversial health technology into the public healthcare system.

This question emerges against the background of two core hypotheses. The first is that ethical neutrality is a key element of pluralist democracies belonging to the liberal tradition and that this will be reflected in their constitutional frameworks. The second is that some health services – such as reproductive health technologies – are likely to pose ethical problems that state regulation will try to address.

At first glance, there would appear to be a fundamental contradiction between these two statements. This dissertation has argued, however, that it is imperative to find a viable way of coping with ethical concerns whilst at the same time preserving the separation of ethics and law. This thesis therefore conducted a comparative study to understand the instruments through which ethically neutral states legitimately regulate and publicly fund ethically controversial health technologies. It did so by comparing Germany, Italy and England and focusing on the different legal, cultural and constitutional backgrounds of these jurisdictions.

The first hypothesis is explored in the theoretical and constitutional foundations of the thesis. Here the normative framework adopted to examine the research question was that of the separation of ethics from law and the need for contemporary democracies to adopt a position of ‘neutrality of justification’. Exploring this principle from a normative perspective, focusing on each of the legal-constitutional orders under investigation, was a central step in validating the hypothesis that one of the core characteristics of liberal democracies is that they are, in principle, ethically neutral.

The conceptual separation between ethics and law stems from the adoption of a positivist position according to which the validity of the law is not derived from moral norms.[1898] This thesis assumes that, as law and ethics are two separate normative systems, ethical concepts must be transposed into the legal system and 'juridified' before they can be operationalised by it.[1899]

The argument that states must guarantee the separation of ethics and law and adopt a position of ethical neutrality stems from a legal-sociological and a legal-ethical premise. The first is that there is a growing ethical pluralism. In the field of healthcare this is fuelled by the constant introduction of new health technologies that extend each individual's sphere of choice and their possibilities for self-determination in matters of health.[1900]

The second premise is that the "fact of pluralism"[1901] is a value to be protected. This follows from the consideration that contemporary democracies primarily have the function of protecting the autonomy of the individual, as is maintained by Kant's theory of law.[1902] Indeed, according to Kant, the function of law is to guarantee the maximum freedom of each individual to act in line with their own decisions and, therefore, also to guarantee the coexistence of these different individual freedoms.[1903]

This thesis argues that, to fulfil this function, the state needs to remain neutral. In particular, the dissertation supports the idea of neutrality of justification that is central to Rawls' model of political liberalism. According to this model state measures touching on 'constitutional essentials' are only legitimate when exercised based on premises that "all citizens as free and equal may reasonably be expected to endorse in the light of principles and ideals acceptable to their common human reason".[1904] Government policies must therefore be justified by neutral 'public reasons'. Namely, by concepts

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[1898] Marmor, 'Legal Positivism' (2006) 26(4) Oxf J Leg Stud p. 683, 686; Hart, *The Concept of Law* (2012) p. 268. See Chapter 1, sec. A.II.1.a.

[1899] Luhmann, 'Operational Closure and Structural Coupling' (1992) 13(5) Cardozo Law Review p. 1419, 1429; Poscher in Hage and Pfordten, *Concepts in Law* (2009) p. 103. See Chapter 1, sec. A.II.1.b.

[1900] See Chapter 1, sec. A.I.1.

[1901] Rawls, 'The Idea of an Overlapping Consensus' (1987) 7(1) Oxf J Leg Stud p. 1, 4.

[1902] See Chapter 1, sec. A.II.2.a.

[1903] Fletcher, 'Law and Morality' (1987) 87(3) Colum L Rev p. 533, 535.

[1904] Rawls, *Political Liberalism* (2005) p. 137.

whose validity does not depend upon the endorsement of any particular moral doctrine.[1905]

It was particularly relevant for the legal analysis conducted in the thesis to determine whether these theoretical assumptions are actually reflected in the constitutional order of the chosen jurisdictions. For this purpose the section on constitutional foundations investigated, firstly, whether the three jurisdictions have adopted a normative idea that law and ethics must be separated and, secondly, whether a requirement of neutrality of justification equivalent to that assumed in the theoretical framework derives from this. The constitutional law analysis confirmed the hypothesis that these legal systems acknowledge the value of separating ethics and law. Especially that it is imperative to opt for measures based on justifications that can be regarded as acceptable to all reasonable individuals; at least in the sense that such justifications must not derive their validity from particular ethical or religious considerations.

All three jurisdictions under investigation found unique solutions to address this that were contingent on their respective legal culture and constitutional background.

In Germany a combined reading of several Articles of the Basic Law, within the framework of the principles of equality and freedom of belief, reveals precisely that the state is obliged to follow a standard of neutrality. Although this requirement does not appear explicitly in the Basic Law[1906] it has been *de facto* embedded in the legal order thanks to a creative constitutional jurisprudence that has joined forces with the interpretative efforts of the constitutional scholarship. As a result, neutrality has been conceptualised as 'neutrality of justification' by constitutional doctrine.[1907] In Italy the role of guaranteeing neutrality is performed by the principle of laicity.[1908] Here too the requirement of the laicity of the state derives from the interpretation of scholarship and the Constitutional Court based on a set of different constitutional principles.

[1905] Marneffe in Mandle and Reidy, *The Cambridge Rawls Lexicon* (2014) p. 560.

[1906] Based on this consideration, the validity of such a standard has been questioned by a minority of authors. For a very recent opinion, see Müller, 'Neutralität als Verfassungsgebot?' [2022](81) VVDStRL p. 251. Most of the comments received by the author in the following discussion were, however, in favour of the validity of the constitutional requirement of neutrality, see the contributions in the section 'Aussprache und Schlussworte' [2022](81) VVDStRL p. 355.

[1907] See Chapter 1, sec. A.II.2.b.

[1908] See Chapter 1, sec. B.II.

In England neutrality is fulfilled by a model of procedural justice that has been adopted in political processes and in the rationing of health resources.[1909] In contrast with the two other jurisdictions there is no superior and binding written constitution and, despite recent developments in the national codification of human rights[1910] and the consequences of European Union membership,[1911] the orthodox position that accepts the primacy of parliamentary sovereignty remains influential.[1912] However, the principles of procedural legitimacy under political constitutionalism ensure that state decisions are based on justifications that can be accepted as reasonable by society as a whole.

Therefore, while there is no explicit neutrality requirement to be found in the constitutional text of any of the three jurisdictions, all of them feature functionally equivalent principles fulfilling the purpose of protecting ethical pluralism.

Having established the existence of such principles in the constitutional frameworks concerned, the thesis investigated whether they also apply to state activities in the context of the public healthcare system and in the provision of health services.

In Germany and Italy the constitutional principles of neutrality and laicity respectively apply to all spheres of state action and thus also to the measures adopted within the public healthcare system. In Germany the welfare state may not exercise its function with a view to implementing particular ethical perspectives.[1913] In Italy the very existence of a National Health Service that is run by the state is seen as a guarantee of the ethically neutral protection of every individual's right to health.[1914] In England the NHS public bodies' adherence to a model of procedural justice based

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[1909] See Chapter 1, sec. B.III.

[1910] With the Human Rights Act 1998, which implemented the rights and freedoms guaranteed under the European Convention on Human Rights.

[1911] Craig, 'Sovereignty of the United Kingdom Parliament after Factortame' (1991) 11(1) Yearbook of European Law p. 221; Elliott in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) p. 75; Young, *Democratic Dialogue and the Constitution* (2017) pp. 194-196.

[1912] Famously theorised by Dicey, *Introduction to the Study of the Law of the Constitution* (1979). See Walters, *A.V. Dicey and the Common Law Constitutional Tradition* (2021) pp. 162-225.

[1913] See Sommermann in Mangoldt, Klein and Starck, *Grundgesetz* (2018) para. 114.

[1914] Pioggia, *Diritto sanitario e dei servizi sociali* (2014) p. 171; Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 59. See Chapter 1, sec. B.II.2.b.

on “accountability for reasonableness”[1915] – which is also mirrored in the common law standards of judicial review – ensures that decisions in the allocation of healthcare resources must follow a reasonableness standard and be based on factors that can be considered relevant by virtually all.[1916]

2. Case Studies

The second hypothesis of the dissertation, which was that new reproductive health technologies inevitably raise ethical concerns that state regulation will try to address, has been confirmed through the cases studies. Evaluating how the jurisdictions addressed the emergence of two reproductive technologies was carried out with a view to discovering the instruments that were used in considering ethical issues and to assessing their legitimacy according to the normative framework outlined above. In doing so, the study investigated both the separation of powers and institutional dynamics, remaining aware of the broader context in which the regulation of novel health technologies occurs in different jurisdictions.

The first case study, preimplantation genetic diagnosis, primarily provided insights into how states approach the regulation of ethically controversial health technologies and how they decide on their *admissibility*. The second, non-invasive prenatal testing, focused on the problems that arise when it comes to deciding on *public funding* for a technology that is considered to be ethically undesirable by many.

In Germany and Italy the regulation of PGD was finalised only after the intervention of the courts. In Germany the ethical controversy surrounding this technology resulted in delayed action by the legislature, which shied away from regulating it explicitly until the Federal High Court practically forced it to pass new legislation.[1917] In a similar fashion the Italian legislature refrained from establishing specific rules and left it to the case law of the ordinary and constitutional courts to regulate the use of PGD.[1918] While the original 1990 legislation in the UK also did not contain an

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[1915] According to the proponents of this health resources allocation model, “Reasonable people differ in their religious philosophical and moral views and yet we must seek terms of fair cooperation that rest on justifications acceptable to all”, Daniels and Sabin, *Setting Limits Fairly* (2008) p. 36.

[1916] See Chapter 1, sec. B.III.2.b.

[1917] BGH Urteil vom 6.7.2010 - 5 StR 386/09. See Chapter 2, sec. A.I.2.b.

[1918] See Chapter 2, sec. B.I.2.

express regulation of PGD, the establishment of the Human Fertilisation and Embryology Authority ensured that, in practice, the regulation would be continuously kept up-to-date.[1919]

This thesis went on to illustrate how the ethical concerns about new reproductive technologies do not only extend to deciding on their admissibility, but also to considering whether or not they do and should receive public funding.

The case studies found that public coverage of the two technologies varied in the three jurisdictions. With regard to PGD access to the treatment is publicly funded in England, while reimbursement – respectively by the statutory health insurance and by the National Health Service – is not yet provided for in Germany or Italy.

As far as NIPT is concerned the desirability of its public funding was particularly discussed in Germany and England, whereas it remained relatively uncontroversial in Italy. Here the rights to health and to patient self-determination outweighed possible ethical or religious objections. They ensure that the test will eventually be included in the coverage of all Regional Health Systems or in the benefit basket of the National Health Service. In Germany and England the public bodies in charge of deciding on the public funding of NIPT assessed its accuracy and safety and eventually decided positively. However, some voices have called for a broader consideration of ethical aspects in the evaluation procedure of new health technologies or screening programmes.[1920] The fundamental importance of the autonomy of the individual was a theme throughout this case study. Indeed, it seems that respect for the patient's informed consent, including their right to know or not to know, was an important element in implementing NIPT in the public healthcare systems of all three jurisdictions in a manner that was widely acceptable.[1921]

II. Legitimately Dealing with Ethical Concerns

1. Operationalisation and Neutrality

To assess the legitimacy of the inclusion of ethical concerns in the regulation and reimbursement of ethically controversial technologies this thesis

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[1919] See Chapter 2, sec. C.I.2.a.

[1920] See Chapter 3, secs. A.II.3 and C.II.3.

[1921] See Chapter 3, sec. D.III.

has, first, elaborated a notion of legitimacy and, second, analysed the reactions of the selected jurisdictions to the emergence of reproductive health technologies. Comparing the instruments and strategies used in the three countries offers key insights into how the incorporation of ethical concerns into regulation negatively influences its legitimacy. Starting from these premises and thanks to the different perspectives adopted, the study built a comprehensive tool to assess the legitimacy of decisions on the introduction of novel technologies into the public healthcare system.

The notion of legitimacy underlying this thesis has been developed in line with the theoretical and constitutional framework that calls for the separation of ethics and the law and which was set out in Chapter 1. It has been elaborated by combining a legal-social and ethical-legal perspective with an analysis of constitutional law. The function of this concept is to help distinguish between regulations that protect a legitimate legal interest and those that implement an illegitimate transposition of particular ethical considerations into the legal system.

As clarified in the theoretical framework,[1922] concerns that could be defined as ethical, but are also considered relevant and reasonable by society as a whole, can be brought into the legal system through law-making procedures and become legal concerns. They can thus be regarded as legitimate bases of justification for other legal norms. For instance, the case study on NIPT has illustrated how concerns about informed consent and the future mother's autonomy have been transposed into legal and constitutional interests.

However, ethical concerns do not always legitimately enter the legal system, despite compliance with the appropriate law-making procedure. To be legitimate the transposition of ethical concerns into law must respect two normative standards.

Firstly, legitimacy refers to the capability of the legal system to maintain the conceptual separation between ethics and law. This can be measured by analysing whether the legal system is capable of operationalising a given norm without reference to extra-legal ethical perspectives. This requirement implies that norms cannot include a broad and undefined reference to ethics and that legal standards cannot be interpreted by reference to particular ethical or religious positions. Moreover, they must be consistent and reasonable in relation to the existing constitutional framework.

[1922] See Chapter 1, sec. A.II.1.b.

Secondly, legitimacy requires that norms must comply with a normative framework of neutrality of justification. It must be possible for them to be justified by reference to shared reasons that virtually everyone can agree are relevant.[1923] In other words, the second aspect of legitimacy assesses the acceptability of a regulation by reference to whether all individuals, irrespective of their different ethical backgrounds and religious convictions, can recognise its grounds are reasonable and relevant.

When these legitimacy criteria are disregarded the boundaries between ethics and law may become blurred. The analysis of the case studies revealed instances of non-compliance with the legitimacy criteria.

A striking violation of the conceptual separation between ethics and law, resulting in the insertion of an illegitimate element of inconsistency into the autonomous legal system, was found in the case of the regulation of fertility treatments and PGD in Italy. This case has proven that the legal system tends to reject extra-legal ethical factors that are introduced into it without being consistent with the constitutional framework. These ethical perspectives cannot be operationalised in the legal system. The legislators of the Italian Law no. 40/2004 on medically assisted reproduction adopted one particular ethical and religious stance and the original provisions of the law were clearly shaped according to it.[1924] This had two implications for the constitutional review of the law. Firstly, the resulting regulations were not compatible with the constitutional case law on the status of the embryo and with the constitutional principle of informed consent and the right to health.[1925] Secondly, the provisions appeared unreasonable, as they were not adequate to pursue a constitutionally protected aim. With regard to this second element this thesis has argued that the standard of unreasonableness has been used by the Italian Constitutional Court to expunge

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[1923] "A claim to legitimacy is, therefore, a normative claim to acceptability or validity [...]. The discourse of legitimacy is thus one in which an action, decision, rule or political order is explained and justified – by reference to beliefs shared by dominant and subordinate actors – such that those affected can understand and accept why the exercise of authority is valid [...]. If, as argued, legitimacy is concerned with justification of the exercise of authority by reference to shared beliefs, then a claim to legitimacy by a rationing body is, as Daniels and Sabin contend, likely to hinge upon its capacity to provide reasons for its choices which rest upon evidence, arguments and principles which fair minded people can agree are relevant (even though, if placed in charge, they might make different choices)", Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) pp. 137-138.

[1924] See Chapter 2, sec. B.I.1.

[1925] See Chapter, secs. B.I.2.b and B.I.3.

ethical considerations from the legal system that were incompatible with it. Its judgments no. 151/2009 and no. 96/2015 are exemplary in this regard.[1926] In judgment no. 151/2009 the Court declared that the requirement to simultaneously implant all of the embryos created in fertility treatment into the uterus – which effectively constituted a legal obstacle to the performance of PGD – was unreasonable. In its later judgment no. 96/2015 the Court again applied the criterion of reasonableness to the provisions of Law no. 40/2004. In particular, the Court considered the ban on access to fertility treatment by fertile couples seeking PGD unreasonable. Had the ethical interest of the absolute protection of the life of the embryo – assumed by the legislators in drafting Law no. 40/2004 – been a constitutionally protected value, then the Constitutional Court could not have declared these provisions unreasonable. They would have been justified by the need to pursue the ultimate aim of protecting the embryo. This indicates how the Court purged the law on fertility treatment from religious influences external to the legal system which could not be properly operationalised by it. The cases also show that the legislature had failed to meet the requirements of neutrality of justification.

The legitimacy of PGD regulation was challenged in Germany too. Here a compromise was reached through Parliament that made access to PGD conditional on strict medical criteria. However, some factors in this process contributed to undermining both the first and the second element of legitimacy.

Firstly, the analysis of parliamentary and academic discussion has shown that the interpretation of some fundamental constitutional principles, namely the right to life and dignity, has often been determined by ethical coordinates concerning the status of the embryo in vitro. These have not been transposed into law and are not widely agreed upon. The interpretation of legal norms on the basis of unshared ethical principles has also been considered problematic insofar as it could lead to an outcome that is incompatible with the legal system.[1927] The ethical concerns regarding PGD have converged in the provision that each procedure must be approved by an ethics commission. However, this scrutiny creates an excessive burden on couples given that the ethics commission's function could be performed by a physician who is in a personal dialogue with the patients.[1928] As indi-

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[1926] See Chapter 2, secs. B.I.2.b and B.3.

[1927] Spranger, *Recht und Bioethik* (2010) p. 41.

[1928] See Chapter 2, sec. A.I.3.d.iii.

cated by the Federal Administrative Court, the interpretation of the legislative criteria for access to PGD can be conducted following the established rules of legal interpretation and with the assistance of medical expertise.[1929] The acceptability of the approval requirement by an ethics commission has been rightly questioned in the literature.[1930] Moreover, the requirement that the commission should take 'ethical aspects' into account when deciding what constitutes a serious illness does not guarantee that the individual decision is based on reasons that can be considered relevant and acceptable to all. The thesis found that the inclusion of ethics commissions as gatekeepers to PGD fails to meet the requirement of neutrality of justification.

2. Between Ethical Concerns and Legitimate Legal Interests

Despite these legitimacy criteria, a closer investigation of the case studies through an epistemological perspective has shown that tracing a clear line between particular ethical concerns and legitimate legal interests is not always straightforward. The boundaries between reasons that are generally acceptable as relevant and those that are only comprehensible when adopting a particular ethical stance are not easily drawn.[1931]

One obstacle to a clear definition of what constitutes a neutral norm is the fact that ethical views in society are far from static. The definition of 'neutral' is continuously evolving, as the reasons that can be recognised as acceptable by virtually all members of society change over time. This dynamism in the field of health technology is fuelled not only by cultural and social changes but also by continuous scientific developments and the emergence of new technologies. Consequently, the scope of the neutrality

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[1929] From this point of view, should this task be deemed too 'normative' to be left to the medical profession, an alternative solution could be to entrust the control of the requirement to access PGD to a judge. The application to a judge is the instrument used in Italy by Law no. 194/1978 to authorise minors to have an abortion in cases where it is either not advisable to consult the persons exercising parental authority or said persons have refused to consent.

[1930] See Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013) p. 52; 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.

[1931] Huster, *Die ethische Neutralität des Staates* (2017) pp. LX-LXI.

standard evolves in parallel to changes in the ethical beliefs shared by members of society.[1932] The legal assessment of controversial health technologies will thus need to accommodate these changes to maintain legitimacy and acceptability.

Another factor challenging this distinction between legal and ethical concerns is the variety of interests that the legal system is required to protect. This potentially allows for any ethical stance to be translated into a legally protected interest. Such a possibility is all the more relevant where the interests protected by the constitutional framework are vaguely formulated and open to interpretation. As a result, it might be possible to bend legal or constitutional arguments in support of any rule so that the requirement of neutrality would lose practical relevance.[1933]

Illustrations of this can be found in the German constitutional framework. Dignity and the right to life are supreme constitutional principles in this system. In analysing the scholars' discussions on PGD it was found that these tend to be invoked as a vehicle for particular ethical views.[1934] Another striking example is the Federal Constitutional Court's second ruling on abortion.[1935] Here the Court stated that the state has a duty to protect the unborn child's right to life from conception. At the same time, however, it defined this position as a neutral one. Indeed, this judgment is often cited[1936] as demonstrating that the Court upholds the neutrality requirement. However, it is questionable whether the statement that life begins at conception is neutral. It appears, instead, that this can only be

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[1932] The case of the ban on homosexuality, reported by Huster, is exemplary in this regard. The ban was justified on the grounds of the immorality of the behaviour. This, however, with the evolution of ethics in society, lost its neutrality. It could no longer be justified without referring to ideological convictions that were not widely shared, see Huster, *Die ethische Neutralität des Staates* (2nd edn 2017) pp. 569-570.

[1933] Huster notes that this already frequently happens as there is widespread agreement that legislators should try and give reasons that translate religious arguments into secular terms and thus make them generally acceptable, see Huster in Kopetzki and others, *Körper-Codes* (2010) p. 11.

[1934] See Chapter 2, sec. A.I.3.c.

[1935] BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92 (BVerfGE 88, 203 - *Schwangerschaftsabbruch II*).

[1936] Even in this very thesis, see Chapter 1, sec. B.I.1. See also, *inter alia* Huster, *Die ethische Neutralität des Staates* (2017) p. 15; Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 126.

considered acceptable by those who adhere to particular ethical or religious principles.[1937]

In response to the observation that neutral justifications for a given norm are often conceivable Huster counters that these will have to be subjected to a plausibility test.[1938] This entails, *inter alia*, an analysis of the empirical assumptions on which the justification rests. Among the arguments that fail this plausibility test,[1939] and which have limited legal relevance,[1940] are the slippery slope arguments against the admissibility and financing of PGD and NIPT.

Even if a plausible neutral justification was virtually always available, the theoretical framework and case studies have shown that it is valuable in itself to ensure that measures in the field of healthcare are always to be justified neutrally. Ultimately, ethical neutrality is not so much about the content of a norm as it is about its possibility of being recognised as valid and justified independently form the adherence to a certain ethical or religious faith.[1941] The neutrality standard aims, if only that, to hold legal actors accountable for issuing or implementing legal measures solely based on a specific religious or ethical stance. The legal and constitutional obligation of neutrality aims to push state institutions towards measures that are more widely acceptable and best protect both autonomy and ethical pluralism.

It remains unavoidable that a neutrally justified solution may still be disputed in its content or details and that those with a more permissive or restrictive ethical approach may find it inconsistent with their own standards. However, the purpose of neutrality is for everyone to be able to recognise the reasons behind state decisions as generally acceptable without having to subscribe to an ethical position they do not share. Members of society do not need to compromise on their moral convictions, which they must be able to maintain, but only on what they can expect the state to impose as binding for all in a pluralistic society.[1942]

[1937] See also Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 68-71.

[1938] Huster, *Die ethische Neutralität des Staates* (2017) p. LXIII. See Chapter 1, sec. B.I.1.

[1939] Huster in Kopetzki and others, *Körper-Codes* (2010) p. 30.

[1940] See Chapter 2 secs. A.I.3.c and D.IV.2.

[1941] Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 86.

[1942] On the fundamental difference between compromising one's own moral standards and making compromises by recognising as valid a solution widely accepted by

3. Relevance of the Institutional Interplay

This thesis has been mainly focused on the question of the legitimacy of the consideration of ethical concerns in regulating and funding health technologies. In answering this research question, the case studies have also adopted a separation-of-powers and an institutional perspective to show the relevance of the interaction between different state institutions and other actors in the reaction to the emergence of novel technologies. Not only the constitutional framework of the individual jurisdiction but also each actor in the system with their respective (non-)interventions influenced the legitimacy and acceptability of state regulation in this ethically controversial field. In this respect the case of PGD is particularly telling. Here a wide variety of actors, including legislators, courts, medical associations, ethics councils, and expert bodies, were involved in the reaction to the emergence of this technology in all three jurisdictions. In shaping PGD regulation the interaction between institutions has proved necessary to guarantee legitimacy in several ways.

First, the comparative analysis shows how the cooperation of different institutions was necessary to issue legislation responding to the emergence of new technologies and to the current ethical and scientific landscape.[1943] Adaptation of the legal framework in this sense is not only necessary to keep the law abreast of technological developments but it also has a normative component. An "outdated law" is nothing short of a legislative failure and likely problematic in a constitutional democracy.[1944] This is undoubtedly because it affects the democratic principle[1945] and the principle of legal certainty, but also because ethical and scientific developments result in a constantly changing scope of the standard of neutrality. Thus, following the requirement of neutrality of justification, a constant revision and updating of state regulations is essential to ensure the maintenance of a legitimate regulation and practice.

When a new controversial technology is developed, a reaction might be expected from the legislature. Its intervention is especially essential in cases where the existing legal framework does not give precise provisions on the

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other members of society, see Zanetti, *Spielarten des Kompromisses* (2022) pp. 106-113.

[1943] Rodotà, *Perché laico* (2010) p. 26.

[1944] Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 113 (author's translation).

[1945] ibid, p. 116.

restrictions placed on the implementation of the technology, thus leaving room for uncertainty.

An initial scenario of regulatory uncertainty was experienced in both Germany and Italy in relation to PGD. The German Embryo Protection Act of 1990 originally did not contain any provision to regulate PGD. Although the German Medical Association and the 'Benda Commission' had expressed an opinion favourable to PGD, a statutory regulation was still considered premature at the time by the legislature as the technique had not yet been fully developed.[1946] As a result of this failure to pursue the outcome of the exchange between institutions with regard to PGD, the Embryo Protection Act was unequipped to accommodate this new technology's emergence. This was also a consequence of the underlying intention of the law, which was precisely to ensure that the human embryo would be protected against the emergence of new controversial technologies.[1947] Parliamentary oversight was considered a necessary instrument to guarantee this constitutional protection.

When PGD was ready for clinical practice a situation of uncertainty arose in which legislative intervention would be required. The scientific community once again argued in favour of legislation that would allow its use in limited cases. The German Parliament established a study commission for this purpose. Yet, it seems that the role of this expert consultation was once again to ensure that sufficient legislative barriers could be put in place to protect the embryo against developments in modern medicine.[1948] The majority of the commission supported a blanket ban on PGD because of the fear of a 'slippery slope'.[1949]

This flawed institutional interplay and the resulting restrictive approach failed to take into account the developments that had occurred in the ethical perception of society.

In Italy Law no. 40/2004, regulating medically assisted reproduction, also failed to provide a clear legal framework for PGD. Unlike in Germany, however, this was not because the technique was not sufficiently developed at the time. On the contrary, PGD was already performed in the country. Rather, this was the result of the Catholic Church's extensive influence

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[1946] See Chapter 2, sec. A.I.1.

[1947] Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1020.

[1948] Jasanoff, *Designs on Nature* (2005) p. 184.

[1949] See Chapter 2, sec. A.I.2.a.

on the legislative process and the fact that parliamentary discussions were primarily based on hearings and opinions obtained in 1997.[1950] Parliament failed to establish cooperation with other actors in order to seek more evidence from expert committees or to secure a broader societal consensus. As a result Law no. 40/2004 appeared already obsolete at the time of its enactment.

The situation in the UK was markedly different. Here too the Fertilisation and Embryology Act of 1990 did not provide explicit regulation of PGD. However, unlike in Germany and Italy, the legislature had integrated mechanisms into the HFE Act that were intended to ensure the continuous adaptability of the legislation through the involvement of experts.[1951] The Human Fertilisation and Embryology Authority was entrusted with the power to authorise new treatments, which it used to regulate access to PGD.

This leads to the consideration of a further way in which the interaction between institutions may be relevant. Namely, where the legislature fails to maintain the legislative framework ethically neutral and up-to-date, the intervention of other actors can compensate for this. This happened in the UK because the legislature consciously decided to assign the authority to regulate future technological developments to the HFEA. By contrast, a remedy was brought about by other institutions in Germany and Italy as they responded to pathological legislative inactivity. In these two jurisdictions, in the absence of legislative intervention, claims from the scientific community and individuals had to be addressed by the judiciary.

In Germany an update of the legislation was finally initiated thanks to the intervention of a member of the medical profession who self-reported the use of PGD.[1952] This forced the courts to confront the question of the legal admissibility of the technique. The BGH was thus required to act as

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[1950] Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 13.

[1951] See Franklin, 'Developmental Landmarks and the Warnock Report' (2019) 61(4) Comp Stud Soc Hist p. 743, 771; Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1016.

[1952] As put by Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1021, "[i]t took an individual act of conscience by a member of Germany's respected medical profession".

a substitute for the democratic legislature at a time of uncertainty over the regulation of PGD.[1953]

The Italian legislature also failed to provide a mechanism for adapting to the changing scientific landscape. While the law left room for uncertainty, ministerial guidelines intervened to confirm the ban on PGD.[1954] Ultimately it was only possible to update the legal framework for PGD thanks to citizens and to representatives of medical associations who had recourse to the courts. After the intervention of the ordinary courts and the European Court of Human Rights, the Italian Constitutional Court finally managed to recognise the developments in ethical convictions and to implement corresponding norms. By depriving the law of its ideological and religious perspective and by declaring that access to PGD was a part of the essential core of the right to health the Court ensured that the regulation was acceptable, reasonable and that it respected the principle of laicity.[1955]

The crucial role of the Italian Constitutional Court in this case resulted from the confluence of two trends. First, the Constitutional Court had recently embarked on its journey to achieve a "stronger, more active and central role" in the Italian legal system.[1956] This required the Court to be able to grasp the changes in the ethical and societal landscape and translate them into its judgments.[1957] Second, the Italian legislature had exhibited the first indications of a pathological inactivity in ethically controversial matters.[1958] The case of PGD offered a perfect opportunity for the Court to exercise its stronger role given the inability of the legislature to keep the legislation up-to-date and the resulting lack of legitimacy and acceptability.

These two cases demonstrate that where state actors fall short of their legal obligation of neutrality, by either actively promoting particular ethical views or passively omitting to adapt regulation, respect for the standard of neutrality depends on the separation of powers enabling other actors, such as the judiciary, to compensate. In concrete cases the courts could directly

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[1953] Arguably, an update of the legal framework finally came about, but at the expense of the principle of democracy, see Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 130.

[1954] See Chapter 2, sec. B.I.2.a.

[1955] See Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 20.

[1956] Tega, 'The Italian Constitutional Court in its Context: A Narrative' (2021) 17(3) Eu Const Law Rev p. 369, 375.

[1957] Rodotà, *Perché laico* (2010) p. 26; Tega, *La corte nel contesto: Percorsi di ri-accentramento della giustizia costituzionale in Italia* (2020) p. 91.

[1958] See Chapter 2, sec. D.I.1.

adapt legislation to new ethical and scientific requirements within the margin of interpretation left open by the legislature. If necessary, constitutional courts have the power to verify whether obsolete legislation complies with scientific reasonableness and ethical neutrality. In this sense the principle of neutrality activates the rule of law's system of checks and balances.

Institutional interaction through dialogue also strives to ensure the acceptability of the regulation. Acceptability can be a suitable measure for assessing the validity of the compromise reached in a pluralist society on ethically controversial issues. It ensures that decisions have been made on grounds that are accepted as reasonable by virtually all members of society.[1959] Dialogue between the involved stakeholders is thus also an instrument of compliance with the requirement of neutrality.

In the Italian legislation on medically assisted reproduction the highly ideological approach and a total disregard for scientific evidence also derived from a parliamentary failure to enter into a dialogue with the scientific community and society.[1960] The aim of the legislation was, similarly to the German Embryo Protection Act, to assert ideological and religious values by protecting the embryo from being used in fertility treatments. Differing views were deliberately excluded from the parliamentary process. This jeopardised the acceptability of the legislation, as demonstrated by the several claims brought to ordinary and constitutional courts by citizens and representatives of medical associations.

The soon obsolete German legal framework also increasingly lost acceptability. Here the courts and scientific associations addressed the demands of civil society and the scientific community before the legislature. After the BGH's ruling the German Medical Association and the German Academy of Sciences Leopoldina again argued in favour of authorising PGD in limited cases. The German Ethics Council also reflected the changes in scientific and ethical developments when intervening in the parliamentary debates following the ruling.[1961] The minority of the Council supported a legislative ban on PGD out of a concern that a slippery slope would emerge. Its majority, however, supported the most permissive of the three drafts introduced into Parliament to regulate PGD and was influential in bringing about its adoption.

[1959] Rodotà, *Perché laico* (2010) p. 82.

[1960] Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1. See also Chapter 2, sec. B.I.

[1961] Deutscher Ethikrat, 'Präimplantationsdiagnostik' (2011). See Chapter 2, sec. A.I.3.a.ii.

In the UK the HFE Act's ability to respond to scientific and ethical developments in a way that was acceptable to society as a whole was based squarely on two premises. First, the involvement of a committee of experts before drafting the legislation guaranteed the acceptability of the initial compromise. The very aim of the work of the Warnock Committee was to find a compromise that everyone could accept as grounded on reasonable premises.[1962] Second, the HFEA went about the licensing of new technologies by taking into account the existing legal framework and conducting several public consultations with other public bodies.[1963] This ensured consideration of possible changes in the ethical landscape. Moreover, institutional dialogue was kept open after the emergence of particularly ethically controversial techniques, such as preimplantation tissue typing combined with PGD. In this case courts were called upon to contribute to the adaptation of the legal framework. They were able to do this by sanctioning the results of the HFEA's assessments rather than by imposing their rulings as substitutes for an inactive legislature. The legislature also promptly intervened to ensure that the ethical implications of new technologies would be taken into account by a democratically elected body.[1964] The most challenging aspects of the regulation were reconsidered and submitted to public consultation. The legislative intervention confirmed the legitimacy of previous developments and the appropriateness of maintaining the HFEA as the licensing body for human fertilisation techniques.[1965]

This overview shows how many different actors in the legal system are well placed to guarantee the acceptability of the legislation by interacting and liaising with society or by providing scientific expertise. The involvement of expert commissions in drafting legislation contributes to legitimacy if it is not merely aimed at representing a particular ethical perspective but genuinely seeks to garner societal consensus. Upon legislative mandate expert committees and public consultation bodies can play a role in responding to ethical and scientific developments. The role of ethics committees is essential to inform the public and interpret the changing ethical landscape.[1966]Together with acceptability, a well-functioning institutional

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[1962] The "embodiment of a common moral position", as described in Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 3.

[1963] See Chapter 2, sec. C.I.2.a.

[1964] See Chapter 2, sec. C.I.3.

[1965] See Chapter 2, sec. C.I.3.b.

[1966] Rodotà, *Perché laico* (2010) pp. 28-30.

interplay promotes the scientific reasonableness and ethical neutrality of the legislation.

In the various ways illustrated here – be it institutional dialogue, compensation for the inaction of other actors, or consultation with the scientific community and society – institutional interaction has proved essential to the legal system's ability to legitimately address ethical issues in the field of health technologies.

4. Ethical Considerations in the Public Funding of Health Technologies

a Neutrality in Coverage Decisions

Access to health technologies not only depends on the lack of a state ban on them, but also on their public funding. As the case studies have shown the hesitancy surrounding the ethical desirability of a certain technology also affects its reimbursement in the public healthcare system. For this reason it is also imperative to develop a legitimate way of dealing with ethical concerns at this stage of decision-making.

The fact that the state generally has broad discretion in deciding which treatments to publicly fund in the healthcare system does not mean that ethical concerns can be used to justify withholding funding for a certain technology. On the contrary, in this area of state action the scope for legitimately considering ethical concerns is particularly limited. This thesis has demonstrated that the decision on public funding must be made in accordance with strictly neutral coordinates. This conclusion derives from a number of observations.

First of all, this field of state action is also subject to the requirement of ethical neutrality. Indeed, such a guarantee becomes even more essential in the context of welfare state action, given the traditionally wide discretion enjoyed by the legislature in this area. As some commentators have pointed out, fundamental rights will not necessarily have a strong "steering capacity" in the sphere of the entitlement to healthcare benefits.[1967] This can be observed in all three jurisdictions. An entitlement to health care benefits derived directly from the German Basic Law, first identified in the so-called

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[1967] As observed by Schuler-Harms in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 153 (author's translation).

'*Nikolaus*' decision, only exists in exceptional cases.[1968] With this ruling the constitutional right to life and bodily integrity was given an essential core, insofar as patients acquired a constitutional right to healthcare services in the event of a life-threatening or typically fatal disease.[1969] In Italy there is no obligation to list a benefit that is not included in the minimum essential core of the right to health in the Essential Levels of Care. It can therefore be left to the discretion of the individual Regional Healthcare Systems.[1970] Article 32 of the Italian Constitution states that free medical care is only guaranteed to the most deprived and that the possibility of patient co-payment always remains open.[1971] The determination of which health services are to be provided by the English NHS is left to public bodies whose decisions can only be quashed by the courts in very exceptional cases. In general the courts maintain a certain deference to public decision-makers.[1972]

This means that it is relatively difficult for patients to successfully argue that they have a right to access health care services within the public healthcare system when they have not been included in the benefit basket. Given the narrow scope of the protection offered by the positive dimension of the right to health it is all the more imperative that there is a guarantee for the individual that the state will adopt a position of neutrality of justification when deciding on the public funding of health treatments. Only then can the state's function of protecting the fundamental autonomy of the individual, particularly in the field of health, be fulfilled.

This does not mean altogether disregarding the fact that there are certain paramount interests to be preserved when making a public funding

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[1968] BVerfG, 06.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25); see Kingreen, 'Verfassungsrechtliche Grenzen der Rechtsetzungsbefugnis des Gemeinsamen Bundesausschusses im Gesundheitsrecht' (2006) 59(13) NJW p. 877.

[1969] Huster, 'Anmerkung' (2006) 61(9) JZ p. 466; Becker in Steiner and others, *Nach geltendem Verfassungsrecht* (2009) pp. 66-67; Schuler-Harms in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 154; Huster in Brune, Lang and Werner, *Konzepte normativer Minimalstandards* (2016) pp. 130–131; Ströttchen, *Verfassungsrechtliche Ansprüche auf konkrete medizinische Leistungen* (2019) pp. 260-ff.

[1970] However, it has also been observed that the content of the right to health is interpreted rather broadly. This point will be touched on below.

[1971] D'Arrigo, 'Salute (diritto alla)' (2001) V Enc dir p. 1009, 1010-1011; Zagrebelsky in Rossi and Bottari, *Sanità e diritti fondamentali in ambito europeo e italiano* (2013) p. 12; Iadicicco, 'La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza' [2018](1) Rivista AIC p. 1, 19.

[1972] See Chapter 1, sec. B.III.2.b.

decision. The NIPT case study has shown that ethical concerns can be effectively addressed through the principles which have already been widely agreed upon and are protected in the legal system. Indeed, ethical concerns regarding the possible routinisation of the screening or the social pressure potentially exerted on women to undergo testing also exist as a legal concern. The corresponding values have been transposed into the legal system in a form in which all reasonable subjects in the legal system can be expected to agree with. These include legal principles such as women's reproductive autonomy, their informed consent and right to know or not to know. For this reason, for instance, the emergence of NIPT has not been considered ethically problematic in Italy insofar as it is possible to ensure that full informed consent can be maintained when accessing screening.[1973] The detailed design of the screening programme must be made consistent with the principle of informed consent, on the one hand, and with the more general statutory framework of abortion regulation on the other. This implies that a woman's right to know – but also to refuse the information – must be guaranteed and that screening must not be aimed at providing knowledge which cannot be relevant to reproductive choices, such as aesthetic or non-medical features of the future child.[1974] To maintain full informed consent the design of the screening programme must aim to "increase the offer, not the uptake, of the test".[1975] As regards

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[1973] "To the extent that policy recommendations by bodies such as NICE or professional bodies such as the ACOG serve the purpose of facilitating individual choice, such policies do not have the negative connotations of state-led eugenic programmes of the last century. What is crucial, however, is that women are well informed about a condition that is the subject of screening and testing, such as Down's syndrome, and do not feel pressured to accept screening in the first instance", Scott, *Choosing Between Possible Lives* (2007) p. 177.

[1974] "For instance, in deciding what information to disclose to prospective parents as the result of a range of tests, in England health professionals will inevitably be mindful of the scope of the Abortion Act and its requirement of a 'serious handicap'", Scott, *Choosing Between Possible Lives: Law and Ethics of Prenatal and Preimplantation Genetic Diagnosis* (2007) p. 176.

[1975] According to Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S38-S39 it is imperative to "[e]nsure that the objective and performance measure of any government-run prenatal screening program is to *increase the offer, not the uptake*, of the test. Increasing the offer of screening is a measure that aligns perfectly with the promotion of reproductive autonomy, since it allows more women to have a choice regarding testing. In contrast, increasing the uptake of testing is a measure that reflects a public health rationale and that represents a direct threat to reproductive autonomy. It puts the question of a potential increase in abortion cases, this is not legally relevant as long as the balancing of fundamental interests carried out by the legislature in regulating abortion is respected. Provided that abortion regulation is still considered as being accepted by society as a whole, or its terms are constitutionally fixed, the increase in the number of women who benefit from this statutory framework is not legally relevant. If the problem lies in the legitimacy and acceptability of abortion as such then this cannot be solved by restricting women's access to prenatal care. Rather it requires an argument that, given the change of opinion in society, the agreement on abortion legislation should be amended.[1976]

Refusing public funding for health technologies would also go against the principle of autonomy, as it would introduce an economic barrier to accessing them.[1977] Pursuing the objective of quantitatively limiting the use of the test by excluding it from statutory health insurance is especially detrimental to people on lower incomes. In the case of NIPT this would result in the use of the least risky technology being guaranteed only to those who can afford to bear the cost out of their own pocket.[1978] While it could be argued that it is natural that the exclusion of any benefit from public healthcare is to the detriment of less affluent patients,[1979] in the case of ethically controversial technologies such as NIPT this effect is unjustified. The barrier to accessing the service would not be based on neutral justifications, such as lack of efficacy, safety or cost-effectiveness, but rather on reasons with ethical connotations that the state, according to the standard of neutrality of justification, cannot legitimately adopt. In sum, healthcare rationing can only be legitimately justified if it is based on neutral reasons.

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explicit pressure on clinicians to push women toward testing so that they can meet the expectations set by the screening program", emphasis added by the author.

[1976] Admittedly, attempts to review the compromise on abortion have been made but without success. For the UK, for instance, see the legal challenge to the Abortion Act 1967 brought in the case of *Crowter & Others, R v Secretary of State for Health And Social Care* [2021] EWHC 2536 (Admin) (23 September 2021).

[1977] Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194, 197.

[1978] This approach was strongly criticised by the chairman of the G-BA, who warned that it would lead to a "Two-tier healthcare", Deckers and Mihm, '"Das wäre Zwei-Klassen-Medizin" Im Gespräch: Josef Hecken, Vorsitzender des Gemeinsamen Bundesausschusses' *Frankfurter Allgemeine Zeitung.* 14.12.2016. See Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194, 196-197.

[1979] Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1715.

b Legal and Institutional Settings

As shown in the previous paragraph, the decision on public funding of ethically controversial health technologies must be made in compliance with a broader legal and statutory framework.[1980] This ensures that they are justified by criteria that are considered relevant and acceptable to society as a whole.

However, the possibility of legitimately dealing with ethical concerns also depends on the instruments that jurisdictions can use to define the benefit basket of the public healthcare system. Here again the adoption of a separation-of powers and institutional perspective is crucial. The different ways in which institutions collaborate to define the basket of health services influence the extent to which ethical concerns might inform public funding decisions in violation of the standard of neutrality. Additionally, the different regulatory contexts, such as different models of healthcare systems and varying conceptions of health and illness, must be considered.

First, institutional considerations prevent ethical concerns from being legitimately included in the funding decision. Indeed, the public authorities of the healthcare system will have to comply with the normative construction enacted by Parliament as the democratically legitimised body. Other public bodies would thus not be legitimised to include new ethical considerations in the decision-making process and reach a divergent normative assessment.[1981]

In Germany ethical interference was excluded from the decision on the reimbursement of NIPT through the scrupulously statutorily regulated process before the G-BA. Indeed, the authority is bound by clear statutory criteria under § 135 of the Fifth Book of the Social Law Code. The reference to this legal framework enabled the G-BA to settle the ethically controversial question of whether NIPT should be included in the Maternity Guidelines of the statutory health insurance.

However, the German model of statutory health insurance is not always capable of adapting to the changing scientific and ethical landscape. It is indeed affected by a certain degree of rigidity in that, in order to qualify for GKV benefits, it is necessary to incur an ‘insured risk’. Therefore only

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[1980] Brownsword and Wale, ‘Testing Times Ahead’ (2018) 81(4) Mod Law Rev p. 646, 662.

[1981] See Huster, ‘Der Gemeinsame Bundesausschuss als Ethikbehörde?’ (2017) 35(4) MedR p. 282, 285.

those services falling under the notion of the medical treatment of an illness (*Krankheit*) under statutory health insurance law are covered by statutory health insurance funds. Although German scholarship maintains that the lack of a definition of illness in the Fifth Book of the Social Law Code is adequate to leave room for possible shifts in the societal conception of health,[1982] this notion has remained the same since the beginning of the last century.[1983] Moreover, the definition of medical treatment for the purposes of health insurance remains rather limited in scope, as it has been used by the courts to justify limitations on entitlements to healthcare services, particularly in the field of reproductive technologies.[1984] The Federal Constitutional Court, for instance, denied an application for the constitutional review of the provision limiting the reimbursement of IVF to only 50% of the costs by arguing with the notion of a 'medical treatment for a disease'.[1985] The reasoning of the decision argued that IVF does not aim at curing a state of disease but rather circumvents it.[1986]

Similar reasons were given in the case law that denied public funding for PGD. As it does not fall under any of the relevant definitions of the SGB V, this procedure was not considered a health treatment for the purposes of the statutory health insurance.[1987] German social courts, including the Federal Social Court, also confirmed that PGD does not constitute a medical treatment that is owed to the patient by the GKV. This resulted especially from the definition of 'medical treatment of an illness', as PGD was not considered a treatment capable of alleviating suffering or curing a

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[1982] Lang in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 3; Nolte in Körner and others, *Kasseler Kommentar: Sozialversicherungsrecht* (2021) para. 9.

[1983] Bieback, 'Zur Neubestimmung des Krankheitsbegriffs in der GKV' (1978) 27(12) Sozialer Fortschritt p. 265. For the current definition of the prevailing literature and case law, see Lang in Becker and Kingreen, *SGB V* (2020) para. 6; Nolte in Körner and others, *Kasseler Kommentar* (2021) paras. 9a and 9b.

[1984] For a criticism of the (mis-)use of the concept of illness in the rulings on the reimbursement fertility treatments (BVerfG, 28.2.2007 - 1 BvL 5/03, in BVerfGE 117, 316 and BVerfG, 27.2.2009 - 1 BvR 2982/07, in BVerfGK 15, 152), see Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1715.

[1985] BVerfG, 27.2.2009 - 1 BvR 2982/07 (BVerfGK 15, 152).

[1986] See Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1714–1715.

[1987] It is not a measure of early detection of a disease under §§ 25 and 26 SGB V, nor a health treatment necessary to recognise or cure a disease, to prevent its aggravation or to alleviate its symptoms, according to § 27 SGB V, see Chapter 2 sec. A.II.1.

condition. The inclusion of PGD in the GKV would thus require explicit intervention by the legislature. Given the ethical problematic nature of the issue such an intervention is long overdue.

This exemplifies a certain conundrum. While the G-BA could use the ethically neutral statutory framework as a stable point of reference to legitimately decide on NIPT, the legal structure for decision-making in the statutory health insurance has prevented actors from living up to their obligation to recognise shifts in the ethical and scientific landscape in the case of PGD. In particular, the courts have so far succeeded in using the concept of 'medical treatment of a disease' to limit the scope of treatments that must be reimbursed by the GKV. However, this has resulted in implausible and unacceptable reasoning.[1988] In this regard these legal definitions of illness and treatment seem hardly adequate to deal with the emergence of new health services and new forms of medicine, especially in the field of genetic and reproductive healthcare.[1989] It will thus no longer be possible for courts to persuasively apply the stringent notion of medical treatment currently relevant to statutory health insurance.[1990] For the purpose of this thesis it is worth noting that a strict interpretation of this notion prevents courts from intervening to ensure compliance with the constitutional standards of neutrality in the reimbursement of new ethically controversial health technologies.

By contrast, the constitutional concept of illness and health adopted in Italy can be used by the Constitutional Court to adapt to new developments in the ethical and scientific landscape and to implement laicity. The wide scope of the notion of the right to health as well as its distinctive patient-centeredness, for instance, helped the Court to overcome the decidedly Catholic background of Law no. 40/2004. The right to health is of primary importance in the Italian constitutional framework and is the only one expressly defined as fundamental in the constitutional text.[1991] Combined with the individual's right to self-determination and the 'personalistic' approach of the Italian constitution, this notion of the right to health guarantees its adaptability to reproductive health needs. Article 32 of the Italian

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[1988] Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, p. 1715-1716.

[1989] ibid, p. 1716.

[1990] ibid.

[1991] See Ferrara in Rodota, Zatti and Ferrara, *Trattato di biodiritto* (2011) pp. 53-55; Busatta, *La salute sostenibile* (2018) p. 41; Morana, *La salute come diritto costituzionale* (2018) pp. 64-65.

Constitution has proven to have a particularly far-reaching scope when used by the courts to expand the right to access health treatments that, due to ethical considerations, have either been prohibited by the legislature or not yet covered by the National Health Service. Thanks to this constitutional provision the regulation of PGD has been *de facto* dictated by the Constitutional Court, whereas access to NIPT remains uncontroversial in view of its undeniable benefits for the right to health and self-determination.[1992]

In Italy, however, the devolution of a residual part of funding decisions to the healthcare systems of the individual Regions undoubtedly risks leaving a gap in the national protection when it comes to ethically controversial health technologies. In the absence of national regulation individual Regions have tended to use their margin of discretion to refuse funding to services that they consider ethically problematic. In the Region of Lombardia this has happened, for instance, with regard to heterologous IVF and in the case of the interruption of life-sustaining treatments. [1993] In this regard it is imperative for this jurisdiction to find mechanisms to ensure the quicker adaptation of the national Essential Levels of Care, especially when the jurisprudence of the Constitutional Court demands it. In the absence of an intervention that updates the benefit basket at the national level, individual ordinary and administrative courts are once again called upon to act as a substitute for the responsible state bodies.[1994]

In England, unlike Italy, there is no general recognition of a right to health and healthcare.[1995] The definition of the health services that need to be granted by the NHS is mainly left to the discretion of NHS bodies and what they consider appropriate. The National Health Service Act, for instance, states that ICBs must arrange health services to the extent they consider necessary to meet reasonable requirements.[1996]

While this discretion is coupled with a model that requires such bodies to be accountable for the reasonableness of their decisions, which ensures legitimacy, the English approach requires a certain amount of trust in the observance of procedural principles by NHS bodies. In this regard, judicial review allows for the striking down of decisions that are based on irrelevant or unreasonable ethical or religious considerations and the courts have re-

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[1992] See Chapter 3, sec. B.II.

[1993] See Chapter 1, sec. B.II.2.b.

[1994] See Chapter 2, sec. B.II.2.

[1995] McHale and Fox, *Health Care Law* (2007) p. 7. See Chapter 1, sec. B.III.2.b.i.

[1996] National Health Service Act 2006, sec. 3 (1).

cently tightened their scrutiny of health authorities' decisions.[1997] Admittedly, however, the likelihood of a court overturning an ethically or religiously motivated decision not to publicly fund a health service remains difficult to assess. As a result, unlike the other two investigated jurisdictions, English courts are only limitedly suitable to act as substitutes for the health authorities in this field. Religious and ethical neutrality of the decision-making can thus not be legally enforced and it is only guaranteed by the adherence to a procedural model of accountability for reasonableness.

5. Towards a Procedural Approach to Neutrality

The comparative analysis of the institutional interactions has shown how successful the different solutions adopted in the three jurisdictions have been in guaranteeing legitimacy when dealing with ethical concerns in the constantly developing field of new health technologies. By answering the main research question, this thesis adds to a body of research that has already touched on the issue[1998] and contributes to addressing some of the challenging questions that arise next.

Guided by the different perspectives mentioned in the Introduction, the study provides insights into the optimal design of collaboration between the legal system's different actors to reach an acceptable and legitimate compromise in a pluralistic society. In doing so, it offers a tool for assessing the legitimacy of decisions concerning the introduction of novel technologies into the public healthcare system.

Ethical concerns about new reproductive health technologies were raised and considered in all three countries. However, from a constitutional law angle, while Italy and Germany adopted a primarily substantial value-driven approach, England grounded its regulation on principles of procedural legitimacy. Unlike in Italy and Germany, the ethical point of view adopted by the English regulation resulted from an effort to find a widely accept-

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[1997] See Chapter 1, sec. B.III.2.b.

[1998] See, *inter alia,* Spranger, *Recht und Bioethik* (2010); Werner in Rothhaar and Frewer, *Das Gesunde, das Kranke und die Medizinethik: Moralische Implikationen des Krankheitsbegriffs* (2012); Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300; Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1; Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015); Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016); Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001.

able solution, which was validated by scientific evidence and continuously adapted to it. As the institutional perspective has shown, expert and public involvement were two prominent features of this model and they have positively influenced the extent to which the normative approach of the legislation could be operationalised and integrated into the legal system.[1999]

The thesis demonstrates that the adoption of a model of procedural legitimacy for the institutional interaction helps to find a reasonable compromise that can be widely agreed upon in a pluralist society.[2000] In turn, the neglect of procedural elements in the relations between the actors involved has negatively influenced the legitimacy and acceptability of the regulation.

This can be observed when analysing the two case studies in Germany. Here public acceptance of the Embryo Protection Act is especially fragile. It suffers both from the fact that the legislation has sought to adopt a standpoint that offers absolute protection to the embryo, a position which is not widely shared by society, and from its lack of mechanisms for adapting to new scientific and ethical coordinates. In other words: acceptance is undermined by the lack of instruments of procedural legitimacy both at the time of its adoption and in its continuous implementation. As evidence of this there is a growing criticism in the legal scholarship and there are calls for the reform of the Embryo Protection Act that are increasingly being voiced.[2001]

In the case of NIPT some elements of a procedural model were included in the decision-making. The G-BA, an expert body, was the leading player in the procedure. Recognising the ethical issues behind the new test, it directly confronted the public through press releases and gave Parliament

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[1999] Penasa, ‘Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU’ (2012) 12(1) Global Jurist p. 1, 2.

[2000] The consensus achieved with such a model is fundamentally different from the one established by a large parliamentary majority, as noted by Rodotà, *Perché laico* (2010) p. 82.

[2001] *Inter alia*, Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013); Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013); Hübner and Pühler, ‘Systematische Rechtsentwicklung für die Reproduktionsmedizin’ (2017) 35(12) MedR p. 929, 933; Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda* (2018); Kersten, ‘Regulierungsauftrag für den Staat im Bereich der Fortpflanzungsmedizin’ (2018) 37(17) NVwZ p. 1248; Lindner, ‘Ein zeitgemäßes Fortpflanzungsmedizinrecht für Deutschland’ (2019) 52(6) ZFR p. 171; Taupitz, ‘Zur Notwendigkeit eines Fortpflanzungsmedizingesetzes’ (2022) 50(1) Pro Familia Magazin Frankfurt p. 6 .

room for a consultative debate. The opinions of several scientific organisations and the German Ethics Council were gathered through a formal consultation procedure. This positively influenced the chances for the G-BA to reach a broadly acceptable compromise, avoiding the routinisation of the test but still guaranteeing access and respecting patients' autonomy.

In Italy the complete failure to provide procedural instruments capable of ensuring adaptability has negatively affected the legitimacy of the legislation on fertility treatments. Notably, the refusal to involve medical experts in the decision-making process has resulted in the scientific unreasonableness of the adopted measures.[2002] The adoption of one particular religious stance in the Italian legislation on fertility treatment also ran against the principle of laicity and undermined its acceptance. The regulation was not widely agreed upon, as is shown by the comments of legal scholars[2003] and the frequent recourse to ordinary, administrative and constitutional courts.[2004] NIPT in this country has so far not generated extensive public debate. The main actors in its regulation are the Regional Health Systems, while at the national level scientific expertise is ensured by the regularly updated guidelines of the Italian National Health Council. Public funding of NIPT has been justified on the basis of constitutional provisions concerning the right to health and self-determination in health and it thus respects the standard of neutrality.

In England the set of procedural principles outlined in Chapter 1 have been respected throughout the whole regulatory development. First, the procedural model facilitates adaptability to scientific developments thanks to the openness to scientific expertise as a component of procedural legitimacy. This guarantees the flexibility of the regulation and its scientific

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[2002] A striking example of this is the provision requiring simultaneous implantation of all embryos in the uterus, which was deemed unreasonable by the Constitutional Court in its judgment no. 151/2009. See Casonato, *Introduzione al biodiritto* (2012) pp. 96-97; Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 317.

[2003] *Inter alia*, Manetti, 'Profili di illegittimità costituzionale della legge sulla procreazone medicalmente assistita' [2004](3) Pol dir p. 453; Tripodina, 'Il "diritto" a procreare artificialmente in Italia: una storia emblematica, tra legislatore, giudici e Corti' [2014](2) BioLaw Journal – Rivista di BioDiritto p. 67; Casonato in Camassa and Casonato, *La Procreazione medicalmente assistita: Ombre e luci* (2005); Dolcini, 'Legge sulla procreazione assistita e laicità dello stato: da sempre, un rapporto difficile' (2013); Penasa, 'La sentenza n. 96 del 2015 della Corte costituzionale: l'insostenibile debolezza della legge 40' [2015](3) Quaderni cost p. 755.

[2004] See Chapter 2, sec. D.II.3.

reasonableness. Moreover, ongoing public consultations and the search for a compromise that is acceptable as reasonable to virtually everyone have imbued the choices on the ethical admissibility of new reproductive treatments with a lasting legitimacy. While it is true that it may not be possible to find a consensus in these ethically controversial areas,[2005] the principles of procedural legitimacy provide a reasonably acceptable justification for the measures taken.[2006] Not everyone might agree with the outcome. However, this is the acceptable result of a political process that remains open to changes according to societal shifts.[2007] Admittedly, the fairly unified utilitarian approach of English society might have played a relevant role here. Nonetheless, the involvement of the Warnock Committee and the described procedural safeguards surely helped to ensure the continued acceptability of the regulation.[2008]

This model of procedural legitimacy was also applied in the case of NIPT where the UK NSC took into account public consultations and the stance of advocacy groups, while the public's opinion was informed and gathered through the work of the Nuffield Council of Bioethics.

In both cases an interaction based on procedural mechanisms took place between the legislature, NHS bodies and society. This was mediated through the work of experts in ethics and science, including in particular the HFEA and the Nuffield Council of Bioethics. The role of the courts in this interplay has been to monitor compliance with procedural legitimacy mechanisms.

The success of the English regulatory model confirms the hypothesis that, while finding complete agreement on substantive principles – or on their interpretation in the case of a written constitution – might be unattainable in a pluralist society, it is possible to find a frame of reference

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[2005] 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, 54–56.

[2006] “The long-standing British approach, exemplified by the Warnock Committee’s proposal of the 14-day limit on embryo research, has tended to assume that public policy should be driven by acceptability as much as principle”, Montgomery, ‘Bioethics after Brexit’ (2018) 18(2-3) Med Law Int p. 135, 153.

[2007] See Chapter 1, sec. B.III.2.a.ii.

[2008] See Franklin, ‘Developmental Landmarks and the Warnock Report’ (2019) 61(4) Comp Stud Soc Hist p. 743, 771; Jasanoff and Metzler, ‘Borderlands of Life’ (2020) 45(6) Science, Technology, & Human Values p. 1001, 1016.

in procedural principles that can give legitimacy and acceptability to the grounds on which legislation is adopted.[2009]

Adopting a procedural approach may also be a suitable response to the shortcomings mentioned above with regard to the concept of medical treatment in the German statutory health insurance. Indeed, the procedural model could positively contribute to a definition of the concept of illness and medical treatment that remains appropriate for purposes of defining and restricting health insurance benefits while also meeting the requirements of justification neutrality. A similar solution has been advocated by Huster, who argues that it has become necessary to allow some decisions on the scope of statutory health insurance coverage to be left to deliberative decision-making and the political process.[2010] In this regard, including elements of the procedural justice method adopted in England, as shown in this thesis, seems well suited to accommodating changes in society's attitudes towards notions of disease and health. In emphasising the need to establish ethically neutral criteria for the definition of health Micha H. Werner also pointed to the strategy of 'proceduralising' existing institutional mechanisms as a possible way forward.[2011] This dissertation joins these proposals by indicating that, in order to comply with ethical neutrality, it is necessary to interpret the concept of health according to coordinates that are acceptable as reasonable to virtually all individuals participating in the public healthcare system. The autonomy of the individual patient can play an essential role in this determination, as seen in the case of NIPT.

In consequence it is argued that Italy and Germany[2012] should also consider including more principles of procedural legitimacy in their substantial

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[2009] Indeed, in pluralistic societies where reaching an ethical consensus on the content of the regulation appears difficult or impossible, agreement might be more easily found in terms of procedural requirements. See van der Burg in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 62. On the importance of the guarantees provided by the procedural approach, see Casonato in Casonato and Piciocchi, *Biodiritto in dialogo* (2006).

[2010] Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713.

[2011] Werner in Rothhaar and Frewer, *Das Gesunde, das Kranke und die Medizinethik* (2012) pp. 221-223.

[2012] In the course of the thesis, however, it became apparent that Germany already tends to include more procedural elements than Italy in its decision-making. Apart from the already mentioned consultations conducted in the case of NIPT (Chapter 3, sec. A.II.2.), on the structures existing in Germany for expert consultations in the democratic process, see for all Münkler, *Expertokratie* (2020) pp. 540-ff.

and value-driven approach. The adoption of procedural principles can assist in the interpretation of constitutional standards, in continuously adapting to shifts in the ethical attitudes of society and in ensuring the constant inclusion of experts in decision-making procedures. This could obviate the need for court intervention to rectify the coordinates of legislation that is uncertain, incompatible with the rest of the legal system or inconsistent with scientific evidence. Clearly this would only be legitimate insofar as the principles of democracy and of the separation of powers are preserved in entrusting different institutions with the task of guaranteeing the ethical neutrality of legislation.[2013]

Concurrently, the English model is based on an equilibrium of political constitutionalism that, at least on paper, could be considered precarious. For instance, there is no constitutional guarantee that the principle of neutrality of justification will always be respected in decisions on health technologies. Judicial review is not very powerful against decisions of NHS bodies when it comes to defining the health benefit basket. Moreover, the state's neutrality remains threatened, at least on a formal level, by the connections with the Church of England and the presence of the Lords Spiritual in Parliament.[2014] In other words, the English model of procedural legitimacy requires a certain trust in the ability and willingness of institutions to follow it.

In light of these circumstances hardly any element of the procedural model could be legally included in Italy and Germany unless the prevalence of a fundamental value-based approach is maintained. This follows from several considerations. A first reason is the fundamental difference between the constitutional model in Germany and Italy compared to England. That the constitutional traditions in the investigated jurisdictions are essentially different can be seen from the comparative analysis of the constitutional frameworks in Chapter 1. The constitutional principles of the two jurisdictions must under no circumstances be violated when introducing procedural elements into the decision-making on ethically controversial health technologies.

Second, the ethical background of the three countries is very different and might influence societal acceptance of a procedural model. Whereas in

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[2013] Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 131.

[2014] See Chapter 1, sec. B.III.1.b.

England diffuse pragmatism and utilitarianism[2015] lend themselves particularly well to this, the dignitarian and human rights-based[2016] perspectives, respectively found in Germany and Italy, might call for more strictly regulated legal frameworks. The confidence placed on statutory regulation precludes placing the updating of the legislative framework in the hands of expert committees. When a technology emerges that is particularly ethically controversial the legislature may promptly be called upon to intervene. Looking at the fear of the slippery slope for instance, this concern is deeply rooted in the German ethical discussion, but it is hardly relevant in the English one.[2017] As a reaction to the concern for slippery slopes, a resolute intervention of the legislature might be advocated. Once again the case of NIPT in Germany proves this. Despite the inclusion of elements of procedural legitimacy in the G-BA decision and the eventual achievement of a broadly acceptable compromise, certain groups still advocate for intervention by the legislature.[2018] They argue that the ethically controversial decision to include NIPT in statutory health insurance should be made by the legislature and not by the health administration.[2019] While there is an evolution towards accepting a more procedural approach, it hardly seems that a sufficient trust in the procedural model has developed in Germany at this point.

Third, several tools for guaranteeing neutrality are also effective in these two jurisdictions and mitigate the need to introduce more procedural elements. Although the value-based approach struggles to guarantee increasing ethical pluralism, the steering potential of the written and binding constitution in these two jurisdictions is relevant in this regard. In Italy ordinary and constitutional courts can always rely on the fundamental right to health combined with the principle of laicity to redress ethical and religious biases of other state institutions. In Germany the respect of the principle of neutrality is checked by the Federal Constitutional Court. Furthermore, the inclusion of services within the statutory health insurance is carried out under a highly regulated system which, to a large extent,

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[2015] Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 144.

[2016] Referring here again to the 'bioethical triangle' theorised in Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 32. More on this in Chapter 1, sec. A.I.1.

[2017] Jasanoff, *Designs on Nature* (2005) p. 279.

[2018] 'Pränatale Diagnostik:"Wir stehen erst am Beginn einer besorgniserregenden Entwicklung"' *Süddeutsche Zeitung*. 28.7.2022.

[2019] ibid.

ensures that legal criteria are followed and excludes the relevance of ethical criteria.

In conclusion, while not intending to offer simple solutions, this thesis supports the argument that more elements from the procedural model should be adopted in order to legitimately address ethical concerns in the field of reproductive health technologies. However, the legal culture in different jurisdictions and the preparedness of society to embrace a procedural turn cannot be overlooked.

III. Closing Remarks

In a recent editorial of the *Journal of Medical Screening* Nicholas Wald[2020] made the provocative statement that “it may be unethical” to have ethical oversight on the public funding of screening programmes.[2021]

Although the criteria applied in this thesis are legal and not ethical, I endorse this view. This thesis has shown that the state cannot legitimately impose certain ethical standpoints through a refusal to publicly fund ethically controversial health technologies. In other words, decisions on the coverage and reimbursement of health technologies cannot depend on their ethical desirability. The function of the legal system in modern pluralistic democracies is to enhance the moral choice of the individual rather than

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[2020] Wald was a pioneer in the field of prenatal screening. He introduced the idea of screening pregnant women for congenital disorders and discovered that neural tube defects in the foetus could be prevented by increasing folic acid intake. See, *inter alia*, Wald and Bower, ‘Folic Acid and the Prevention of Neural Tube Defects’ (1995) 310(6986) BMJ p. 1019; Wald and others, ‘Maternal Serum Screening for Down's Syndrome in Early Pregnancy’ (1988) 297(6653) BMJ p. 883; Wald, Cuckle and Royston, ‘Antenatal Screening For Down Syndrome’ (1988) 332(8624) Lancet p. 1362; Wald, Gilbertson and Doyle, ‘Folic Acid in Prevention of Neural Tube Defects’ (1995) 345(8946) Lancet p. 389.

[2021] “To even suggest that it may be unethical to have ethical committee oversight may seem strange, but such a requirement replaces individual choice with institutional decision making in areas where individual choice should prevail. It denies autonomy because one cannot choose to have a screening test that is not available. Provided that a screening programme is lawful and is also justified on scientific and medical grounds, the individual is sovereign in determining the ethical position. The decisions of such a committee could not only deny public access to useful medical advances but also could offend some people by giving ethical endorsements that conflict with their own views”, Wald, ‘Are Screening Practice Ethics Committees Needed?’ (2021) 28(4) J Med Screen p. 377.

to impose external ethical views. The public healthcare system must also strive in this direction. Those who argue for the need to include more ethical evaluations in decision-making processes on the public funding of new health technologies[2022] overlook this key premise.

This argument also derives strength from the circumstance that agreement on acceptable values is reached during the democratic process. To legitimately operationalise this agreement the bodies that decide on the inclusion of new technologies in the public healthcare system should include more legal expertise rather than ethical evaluations. This would be in line with the findings of this study, which has shown how important it is for the public funding of health services to comply with the fundamental legal and constitutional framework. It would also help to ensure that there is a coherent normative approach within the legal system that is and must remain separate from ethics.

[2022] See Introduction, as well as Chapter 3 secs. A.3 and C.3.

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