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

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

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

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]

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

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]

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

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.

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

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

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

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

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,

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

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

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.

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

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

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.

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

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.

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-

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

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

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,

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 intra-legal 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

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-

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

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

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

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

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

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]

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

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

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

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]

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

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]

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.

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

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

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-

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-

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

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

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

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

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

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

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

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

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

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

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.

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

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]

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.

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

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

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

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

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.

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

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

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]

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

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

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

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

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

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

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

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

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.I.

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

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

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

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]

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

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

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-

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

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

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*

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

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

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.

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

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

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

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

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

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

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

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

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.

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

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

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

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-

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

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

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]

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

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.

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,

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]

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

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

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

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.

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

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.

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.