Conclusions

I. Summary of Argumentation

1. Theoretical and Constitutional Foundations

The aim of this thesis has been to assess how pluralistic democracies can legitimately address ethical concerns surrounding health technologies. In particular, it has sought to investigate whether ethical considerations are – and can legitimately be – taken into account when evaluating the introduction of a new ethically controversial health technology into the public healthcare system.

This question emerges against the background of two core hypotheses. The first is that ethical neutrality is a key element of pluralist democracies belonging to the liberal tradition and that this will be reflected in their constitutional frameworks. The second is that some health services – such as reproductive health technologies – are likely to pose ethical problems that state regulation will try to address.

At first glance, there would appear to be a fundamental contradiction between these two statements. This dissertation has argued, however, that it is imperative to find a viable way of coping with ethical concerns whilst at the same time preserving the separation of ethics and law. This thesis therefore conducted a comparative study to understand the instruments through which ethically neutral states legitimately regulate and publicly fund ethically controversial health technologies. It did so by comparing Germany, Italy and England and focusing on the different legal, cultural and constitutional backgrounds of these jurisdictions.

The first hypothesis is explored in the theoretical and constitutional foundations of the thesis. Here the normative framework adopted to examine the research question was that of the separation of ethics from law and the need for contemporary democracies to adopt a position of 'neutrality of justification'. Exploring this principle from a normative perspective, focusing on each of the legal-constitutional orders under investigation, was a central step in validating the hypothesis that one of the core characteristics of liberal democracies is that they are, in principle, ethically neutral.

The conceptual separation between ethics and law stems from the adoption of a positivist position according to which the validity of the law is not derived from moral norms.[1898] This thesis assumes that, as law and ethics are two separate normative systems, ethical concepts must be transposed into the legal system and 'juridified' before they can be operationalised by it.[1899]

The argument that states must guarantee the separation of ethics and law and adopt a position of ethical neutrality stems from a legal-sociological and a legal-ethical premise. The first is that there is a growing ethical pluralism. In the field of healthcare this is fuelled by the constant introduction of new health technologies that extend each individual's sphere of choice and their possibilities for self-determination in matters of health.[1900]

The second premise is that the "fact of pluralism"[1901] is a value to be protected. This follows from the consideration that contemporary democracies primarily have the function of protecting the autonomy of the individual, as is maintained by Kant's theory of law.[1902] Indeed, according to Kant, the function of law is to guarantee the maximum freedom of each individual to act in line with their own decisions and, therefore, also to guarantee the coexistence of these different individual freedoms.[1903]

This thesis argues that, to fulfil this function, the state needs to remain neutral. In particular, the dissertation supports the idea of neutrality of justification that is central to Rawls' model of political liberalism. According to this model state measures touching on 'constitutional essentials' are only legitimate when exercised based on premises that "all citizens as free and equal may reasonably be expected to endorse in the light of principles and ideals acceptable to their common human reason".[1904] Government policies must therefore be justified by neutral 'public reasons'. Namely, by concepts

1898 Marmor, 'Legal Positivism' (2006) 26(4) Oxf J Leg Stud p. 683, 686; Hart, *The Concept of Law* (2012) p. 268. See Chapter 1, sec. A.II.1.a.

1899 Luhmann, 'Operational Closure and Structural Coupling' (1992) 13(5) Cardozo Law Review p. 1419, 1429; Poscher in Hage and Pfordten, *Concepts in Law* (2009) p. 103. See Chapter 1, sec. A.II.1.b.

1900 See Chapter 1, sec. A.I.1.

1901 Rawls, 'The Idea of an Overlapping Consensus' (1987) 7(1) Oxf J Leg Stud p. 1, 4.

1902 See Chapter 1, sec. A.II.2.a.

1903 Fletcher, 'Law and Morality' (1987) 87(3) Colum L Rev p. 533, 535.

1904 Rawls, *Political Liberalism* (2005) p. 137.

whose validity does not depend upon the endorsement of any particular moral doctrine.[1905]

It was particularly relevant for the legal analysis conducted in the thesis to determine whether these theoretical assumptions are actually reflected in the constitutional order of the chosen jurisdictions. For this purpose the section on constitutional foundations investigated, firstly, whether the three jurisdictions have adopted a normative idea that law and ethics must be separated and, secondly, whether a requirement of neutrality of justification equivalent to that assumed in the theoretical framework derives from this. The constitutional law analysis confirmed the hypothesis that these legal systems acknowledge the value of separating ethics and law. Especially that it is imperative to opt for measures based on justifications that can be regarded as acceptable to all reasonable individuals; at least in the sense that such justifications must not derive their validity from particular ethical or religious considerations.

All three jurisdictions under investigation found unique solutions to address this that were contingent on their respective legal culture and constitutional background.

In Germany a combined reading of several Articles of the Basic Law, within the framework of the principles of equality and freedom of belief, reveals precisely that the state is obliged to follow a standard of neutrality. Although this requirement does not appear explicitly in the Basic Law[1906] it has been *de facto* embedded in the legal order thanks to a creative constitutional jurisprudence that has joined forces with the interpretative efforts of the constitutional scholarship. As a result, neutrality has been conceptualised as 'neutrality of justification' by constitutional doctrine.[1907] In Italy the role of guaranteeing neutrality is performed by the principle of laicity.[1908] Here too the requirement of the laicity of the state derives from the interpretation of scholarship and the Constitutional Court based on a set of different constitutional principles.

1905 Marneffe in Mandle and Reidy, *The Cambridge Rawls Lexicon* (2014) p. 560.

1906 Based on this consideration, the validity of such a standard has been questioned by a minority of authors. For a very recent opinion, see Müller, 'Neutralität als Verfassungsgebot?' [2022](81) VVDStRL p. 251. Most of the comments received by the author in the following discussion were, however, in favour of the validity of the constitutional requirement of neutrality, see the contributions in the section 'Aussprache und Schlussworte' [2022](81) VVDStRL p. 355.

1907 See Chapter 1, sec. A.II.2.b.

1908 See Chapter 1, sec. B.II.

In England neutrality is fulfilled by a model of procedural justice that has been adopted in political processes and in the rationing of health resources.[1909] In contrast with the two other jurisdictions there is no superior and binding written constitution and, despite recent developments in the national codification of human rights[1910] and the consequences of European Union membership,[1911] the orthodox position that accepts the primacy of parliamentary sovereignty remains influential.[1912] However, the principles of procedural legitimacy under political constitutionalism ensure that state decisions are based on justifications that can be accepted as reasonable by society as a whole.

Therefore, while there is no explicit neutrality requirement to be found in the constitutional text of any of the three jurisdictions, all of them feature functionally equivalent principles fulfilling the purpose of protecting ethical pluralism.

Having established the existence of such principles in the constitutional frameworks concerned, the thesis investigated whether they also apply to state activities in the context of the public healthcare system and in the provision of health services.

In Germany and Italy the constitutional principles of neutrality and laicity respectively apply to all spheres of state action and thus also to the measures adopted within the public healthcare system. In Germany the welfare state may not exercise its function with a view to implementing particular ethical perspectives.[1913] In Italy the very existence of a National Health Service that is run by the state is seen as a guarantee of the ethically neutral protection of every individual's right to health.[1914] In England the NHS public bodies' adherence to a model of procedural justice based

1909 See Chapter 1, sec. B.III.

1910 With the Human Rights Act 1998, which implemented the rights and freedoms guaranteed under the European Convention on Human Rights.

1911 Craig, 'Sovereignty of the United Kingdom Parliament after Factortame' (1991) 11(1) Yearbook of European Law p. 221; Elliott in Elliott and Feldman, *The Cambridge Companion to Public Law* (2015) p. 75; Young, *Democratic Dialogue and the Constitution* (2017) pp. 194-196.

1912 Famously theorised by Dicey, *Introduction to the Study of the Law of the Constitution* (1979). See Walters, *A.V. Dicey and the Common Law Constitutional Tradition* (2021) pp. 162-225.

1913 See Sommermann in Mangoldt, Klein and Starck, *Grundgesetz* (2018) para. 114.

1914 Pioggia, *Diritto sanitario e dei servizi sociali* (2014) p. 171; Vettori, *Diritti della persona e amministrazione pubblica* (2017) p. 59. See Chapter 1, sec. B.II.2.b.

on "accountability for reasonableness"[1915] – which is also mirrored in the common law standards of judicial review – ensures that decisions in the allocation of healthcare resources must follow a reasonableness standard and be based on factors that can be considered relevant by virtually all.[1916]

2. Case Studies

The second hypothesis of the dissertation, which was that new reproductive health technologies inevitably raise ethical concerns that state regulation will try to address, has been confirmed through the cases studies. Evaluating how the jurisdictions addressed the emergence of two reproductive technologies was carried out with a view to discovering the instruments that were used in considering ethical issues and to assessing their legitimacy according to the normative framework outlined above. In doing so, the study investigated both the separation of powers and institutional dynamics, remaining aware of the broader context in which the regulation of novel health technologies occurs in different jurisdictions.

The first case study, preimplantation genetic diagnosis, primarily provided insights into how states approach the regulation of ethically controversial health technologies and how they decide on their *admissibility*. The second, non-invasive prenatal testing, focused on the problems that arise when it comes to deciding on *public funding* for a technology that is considered to be ethically undesirable by many.

In Germany and Italy the regulation of PGD was finalised only after the intervention of the courts. In Germany the ethical controversy surrounding this technology resulted in delayed action by the legislature, which shied away from regulating it explicitly until the Federal High Court practically forced it to pass new legislation.[1917] In a similar fashion the Italian legislature refrained from establishing specific rules and left it to the case law of the ordinary and constitutional courts to regulate the use of PGD.[1918] While the original 1990 legislation in the UK also did not contain an

1915 According to the proponents of this health resources allocation model, "Reasonable people differ in their religious philosophical and moral views and yet we must seek terms of fair cooperation that rest on justifications acceptable to all", Daniels and Sabin, *Setting Limits Fairly* (2008) p. 36.

1916 See Chapter 1, sec. B.III.2.b.

1917 BGH Urteil vom 6.7.2010 - 5 StR 386/09. See Chapter 2, sec. A.I.2.b.

1918 See Chapter 2, sec. B.I.2.

express regulation of PGD, the establishment of the Human Fertilisation and Embryology Authority ensured that, in practice, the regulation would be continuously kept up-to-date.[1919]

This thesis went on to illustrate how the ethical concerns about new reproductive technologies do not only extend to deciding on their admissibility, but also to considering whether or not they do and should receive public funding.

The case studies found that public coverage of the two technologies varied in the three jurisdictions. With regard to PGD access to the treatment is publicly funded in England, while reimbursement – respectively by the statutory health insurance and by the National Health Service – is not yet provided for in Germany or Italy.

As far as NIPT is concerned the desirability of its public funding was particularly discussed in Germany and England, whereas it remained relatively uncontroversial in Italy. Here the rights to health and to patient self-determination outweighed possible ethical or religious objections. They ensure that the test will eventually be included in the coverage of all Regional Health Systems or in the benefit basket of the National Health Service. In Germany and England the public bodies in charge of deciding on the public funding of NIPT assessed its accuracy and safety and eventually decided positively. However, some voices have called for a broader consideration of ethical aspects in the evaluation procedure of new health technologies or screening programmes.[1920] The fundamental importance of the autonomy of the individual was a theme throughout this case study. Indeed, it seems that respect for the patient's informed consent, including their right to know or not to know, was an important element in implementing NIPT in the public healthcare systems of all three jurisdictions in a manner that was widely acceptable.[1921]

II. Legitimately Dealing with Ethical Concerns

1. Operationalisation and Neutrality

To assess the legitimacy of the inclusion of ethical concerns in the regulation and reimbursement of ethically controversial technologies this thesis

1919 See Chapter 2, sec. C.I.2.a.
1920 See Chapter 3, secs. A.II.3 and C.II.3.
1921 See Chapter 3, sec. D.III.

has, first, elaborated a notion of legitimacy and, second, analysed the reactions of the selected jurisdictions to the emergence of reproductive health technologies. Comparing the instruments and strategies used in the three countries offers key insights into how the incorporation of ethical concerns into regulation negatively influences its legitimacy. Starting from these premises and thanks to the different perspectives adopted, the study built a comprehensive tool to assess the legitimacy of decisions on the introduction of novel technologies into the public healthcare system.

The notion of legitimacy underlying this thesis has been developed in line with the theoretical and constitutional framework that calls for the separation of ethics and the law and which was set out in Chapter 1. It has been elaborated by combining a legal-social and ethical-legal perspective with an analysis of constitutional law. The function of this concept is to help distinguish between regulations that protect a legitimate legal interest and those that implement an illegitimate transposition of particular ethical considerations into the legal system.

As clarified in the theoretical framework,[1922] concerns that could be defined as ethical, but are also considered relevant and reasonable by society as a whole, can be brought into the legal system through law-making procedures and become legal concerns. They can thus be regarded as legitimate bases of justification for other legal norms. For instance, the case study on NIPT has illustrated how concerns about informed consent and the future mother's autonomy have been transposed into legal and constitutional interests.

However, ethical concerns do not always legitimately enter the legal system, despite compliance with the appropriate law-making procedure. To be legitimate the transposition of ethical concerns into law must respect two normative standards.

Firstly, legitimacy refers to the capability of the legal system to maintain the conceptual separation between ethics and law. This can be measured by analysing whether the legal system is capable of operationalising a given norm without reference to extra-legal ethical perspectives. This requirement implies that norms cannot include a broad and undefined reference to ethics and that legal standards cannot be interpreted by reference to particular ethical or religious positions. Moreover, they must be consistent and reasonable in relation to the existing constitutional framework.

1922 See Chapter 1, sec. A.II.1.b.

Secondly, legitimacy requires that norms must comply with a normative framework of neutrality of justification. It must be possible for them to be justified by reference to shared reasons that virtually everyone can agree are relevant.[1923] In other words, the second aspect of legitimacy assesses the acceptability of a regulation by reference to whether all individuals, irrespective of their different ethical backgrounds and religious convictions, can recognise its grounds are reasonable and relevant.

When these legitimacy criteria are disregarded the boundaries between ethics and law may become blurred. The analysis of the case studies revealed instances of non-compliance with the legitimacy criteria.

A striking violation of the conceptual separation between ethics and law, resulting in the insertion of an illegitimate element of inconsistency into the autonomous legal system, was found in the case of the regulation of fertility treatments and PGD in Italy. This case has proven that the legal system tends to reject extra-legal ethical factors that are introduced into it without being consistent with the constitutional framework. These ethical perspectives cannot be operationalised in the legal system. The legislators of the Italian Law no. 40/2004 on medically assisted reproduction adopted one particular ethical and religious stance and the original provisions of the law were clearly shaped according to it.[1924] This had two implications for the constitutional review of the law. Firstly, the resulting regulations were not compatible with the constitutional case law on the status of the embryo and with the constitutional principle of informed consent and the right to health.[1925] Secondly, the provisions appeared unreasonable, as they were not adequate to pursue a constitutionally protected aim. With regard to this second element this thesis has argued that the standard of unreasonableness has been used by the Italian Constitutional Court to expunge

1923 "A claim to legitimacy is, therefore, a normative claim to acceptability or validity [...]. The discourse of legitimacy is thus one in which an action, decision, rule or political order is explained and justified – by reference to beliefs shared by dominant and subordinate actors – such that those affected can understand and accept why the exercise of authority is valid [...]. If, as argued, legitimacy is concerned with justification of the exercise of authority by reference to shared beliefs, then a claim to legitimacy by a rationing body is, as Daniels and Sabin contend, likely to hinge upon its capacity to provide reasons for its choices which rest upon evidence, arguments and principles which fair minded people can agree are relevant (even though, if placed in charge, they might make different choices)", Syrett, *Law, Legitimacy and the Rationing of Healthcare* (2007) pp. 137-138.

1924 See Chapter 2, sec. B.I.1.

1925 See Chapter, secs. B.I.2.b and B.I.3.

ethical considerations from the legal system that were incompatible with it. Its judgments no. 151/2009 and no. 96/2015 are exemplary in this regard.[1926] In judgment no. 151/2009 the Court declared that the requirement to simultaneously implant all of the embryos created in fertility treatment into the uterus – which effectively constituted a legal obstacle to the performance of PGD – was unreasonable. In its later judgment no. 96/2015 the Court again applied the criterion of reasonableness to the provisions of Law no. 40/2004. In particular, the Court considered the ban on access to fertility treatment by fertile couples seeking PGD unreasonable. Had the ethical interest of the absolute protection of the life of the embryo – assumed by the legislators in drafting Law no. 40/2004 – been a constitutionally protected value, then the Constitutional Court could not have declared these provisions unreasonable. They would have been justified by the need to pursue the ultimate aim of protecting the embryo. This indicates how the Court purged the law on fertility treatment from religious influences external to the legal system which could not be properly operationalised by it. The cases also show that the legislature had failed to meet the requirements of neutrality of justification.

The legitimacy of PGD regulation was challenged in Germany too. Here a compromise was reached through Parliament that made access to PGD conditional on strict medical criteria. However, some factors in this process contributed to undermining both the first and the second element of legitimacy.

Firstly, the analysis of parliamentary and academic discussion has shown that the interpretation of some fundamental constitutional principles, namely the right to life and dignity, has often been determined by ethical coordinates concerning the status of the embryo in vitro. These have not been transposed into law and are not widely agreed upon. The interpretation of legal norms on the basis of unshared ethical principles has also been considered problematic insofar as it could lead to an outcome that is incompatible with the legal system.[1927] The ethical concerns regarding PGD have converged in the provision that each procedure must be approved by an ethics commission. However, this scrutiny creates an excessive burden on couples given that the ethics commission's function could be performed by a physician who is in a personal dialogue with the patients.[1928] As indi-

1926 See Chapter 2, secs. B.I.2.b and B.3.
1927 Spranger, *Recht und Bioethik* (2010) p. 41.
1928 See Chapter 2, sec. A.I.3.d.iii.

cated by the Federal Administrative Court, the interpretation of the legislative criteria for access to PGD can be conducted following the established rules of legal interpretation and with the assistance of medical expertise.[1929] The acceptability of the approval requirement by an ethics commission has been rightly questioned in the literature.[1930] Moreover, the requirement that the commission should take 'ethical aspects' into account when deciding what constitutes a serious illness does not guarantee that the individual decision is based on reasons that can be considered relevant and acceptable to all. The thesis found that the inclusion of ethics commissions as gatekeepers to PGD fails to meet the requirement of neutrality of justification.

2. Between Ethical Concerns and Legitimate Legal Interests

Despite these legitimacy criteria, a closer investigation of the case studies through an epistemological perspective has shown that tracing a clear line between particular ethical concerns and legitimate legal interests is not always straightforward. The boundaries between reasons that are generally acceptable as relevant and those that are only comprehensible when adopting a particular ethical stance are not easily drawn.[1931]

One obstacle to a clear definition of what constitutes a neutral norm is the fact that ethical views in society are far from static. The definition of 'neutral' is continuously evolving, as the reasons that can be recognised as acceptable by virtually all members of society change over time. This dynamism in the field of health technology is fuelled not only by cultural and social changes but also by continuous scientific developments and the emergence of new technologies. Consequently, the scope of the neutrality

1929 From this point of view, should this task be deemed too 'normative' to be left to the medical profession, an alternative solution could be to entrust the control of the requirement to access PGD to a judge. The application to a judge is the instrument used in Italy by Law no. 194/1978 to authorise minors to have an abortion in cases where it is either not advisable to consult the persons exercising parental authority or said persons have refused to consent.

1930 See Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013) p. 52; Bögershausen, *Präimplantationsdiagnostik* (2016) p. 278; Landwehr, *Rechtsfragen der Präimplantationsdiagnostik* (2017) p. 141; Kersten, 'Regulierungsauftrag für den Staat im Bereich der Fortpflanzungsmedizin' (2018) 37(17) NVwZ p. 1248, 1252; Dücker, *Die Regelung der Präimplantationsdiagnostik in Deutschland und in England* (2019) p. 195; Brade and Tänzer, 'Präimplantationsdiagnostik vor dem Bundesverwaltungsgericht' (2021) 40(14) NVwZ p. 1037, 1041.

1931 Huster, *Die ethische Neutralität des Staates* (2017) pp. LX-LXI.

standard evolves in parallel to changes in the ethical beliefs shared by members of society.[1932] The legal assessment of controversial health technologies will thus need to accommodate these changes to maintain legitimacy and acceptability.

Another factor challenging this distinction between legal and ethical concerns is the variety of interests that the legal system is required to protect. This potentially allows for any ethical stance to be translated into a legally protected interest. Such a possibility is all the more relevant where the interests protected by the constitutional framework are vaguely formulated and open to interpretation. As a result, it might be possible to bend legal or constitutional arguments in support of any rule so that the requirement of neutrality would lose practical relevance.[1933]

Illustrations of this can be found in the German constitutional framework. Dignity and the right to life are supreme constitutional principles in this system. In analysing the scholars' discussions on PGD it was found that these tend to be invoked as a vehicle for particular ethical views.[1934] Another striking example is the Federal Constitutional Court's second ruling on abortion.[1935] Here the Court stated that the state has a duty to protect the unborn child's right to life from conception. At the same time, however, it defined this position as a neutral one. Indeed, this judgment is often cited[1936] as demonstrating that the Court upholds the neutrality requirement. However, it is questionable whether the statement that life begins at conception is neutral. It appears, instead, that this can only be

1932 The case of the ban on homosexuality, reported by Huster, is exemplary in this regard. The ban was justified on the grounds of the immorality of the behaviour. This, however, with the evolution of ethics in society, lost its neutrality. It could no longer be justified without referring to ideological convictions that were not widely shared, see Huster, *Die ethische Neutralität des Staates* (2nd edn 2017) pp. 569-570.

1933 Huster notes that this already frequently happens as there is widespread agreement that legislators should try and give reasons that translate religious arguments into secular terms and thus make them generally acceptable, see Huster in Kopetzki and others, *Körper-Codes* (2010) p. 11.

1934 See Chapter 2, sec. A.I.3.c.

1935 BVerfG, 28.5.1993 - 2 BvF 2/90, 2 BvF 4/90, 2 BvF 5/92 (BVerfGE 88, 203 - *Schwangerschaftsabbruch II*).

1936 Even in this very thesis, see Chapter 1, sec. B.I.1. See also, *inter alia* Huster, *Die ethische Neutralität des Staates* (2017) p. 15; Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 126.

considered acceptable by those who adhere to particular ethical or religious principles.[1937]

In response to the observation that neutral justifications for a given norm are often conceivable Huster counters that these will have to be subjected to a plausibility test.[1938] This entails, *inter alia*, an analysis of the empirical assumptions on which the justification rests. Among the arguments that fail this plausibility test,[1939] and which have limited legal relevance,[1940] are the slippery slope arguments against the admissibility and financing of PGD and NIPT.

Even if a plausible neutral justification was virtually always available, the theoretical framework and case studies have shown that it is valuable in itself to ensure that measures in the field of healthcare are always to be justified neutrally. Ultimately, ethical neutrality is not so much about the content of a norm as it is about its possibility of being recognised as valid and justified independently form the adherence to a certain ethical or religious faith.[1941] The neutrality standard aims, if only that, to hold legal actors accountable for issuing or implementing legal measures solely based on a specific religious or ethical stance. The legal and constitutional obligation of neutrality aims to push state institutions towards measures that are more widely acceptable and best protect both autonomy and ethical pluralism.

It remains unavoidable that a neutrally justified solution may still be disputed in its content or details and that those with a more permissive or restrictive ethical approach may find it inconsistent with their own standards. However, the purpose of neutrality is for everyone to be able to recognise the reasons behind state decisions as generally acceptable without having to subscribe to an ethical position they do not share. Members of society do not need to compromise on their moral convictions, which they must be able to maintain, but only on what they can expect the state to impose as binding for all in a pluralistic society.[1942]

1937 See also Czermak, *Siebzig Jahre Bundesverfassungsgericht in weltanschaulicher Schieflage* (2021) pp. 68-71.

1938 Huster, *Die ethische Neutralität des Staates* (2017) p. LXIII. See Chapter 1, sec. B.I.1.

1939 Huster in Kopetzki and others, *Körper-Codes* (2010) p. 30.

1940 See Chapter 2 secs. A.I.3.c and D.IV.2.

1941 Fateh-Moghadam, *Die religiös-weltanschauliche Neutralität des Strafrechts* (2019) p. 86.

1942 On the fundamental difference between compromising one's own moral standards and making compromises by recognising as valid a solution widely accepted by

3. Relevance of the Institutional Interplay

This thesis has been mainly focused on the question of the legitimacy of the consideration of ethical concerns in regulating and funding health technologies. In answering this research question, the case studies have also adopted a separation-of-powers and an institutional perspective to show the relevance of the interaction between different state institutions and other actors in the reaction to the emergence of novel technologies. Not only the constitutional framework of the individual jurisdiction but also each actor in the system with their respective (non-)interventions influenced the legitimacy and acceptability of state regulation in this ethically controversial field. In this respect the case of PGD is particularly telling. Here a wide variety of actors, including legislators, courts, medical associations, ethics councils, and expert bodies, were involved in the reaction to the emergence of this technology in all three jurisdictions. In shaping PGD regulation the interaction between institutions has proved necessary to guarantee legitimacy in several ways.

First, the comparative analysis shows how the cooperation of different institutions was necessary to issue legislation responding to the emergence of new technologies and to the current ethical and scientific landscape.[1943] Adaptation of the legal framework in this sense is not only necessary to keep the law abreast of technological developments but it also has a normative component. An "outdated law" is nothing short of a legislative failure and likely problematic in a constitutional democracy.[1944] This is undoubtedly because it affects the democratic principle[1945] and the principle of legal certainty, but also because ethical and scientific developments result in a constantly changing scope of the standard of neutrality. Thus, following the requirement of neutrality of justification, a constant revision and updating of state regulations is essential to ensure the maintenance of a legitimate regulation and practice.

When a new controversial technology is developed, a reaction might be expected from the legislature. Its intervention is especially essential in cases where the existing legal framework does not give precise provisions on the

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other members of society, see Zanetti, *Spielarten des Kompromisses* (2022) pp. 106-113.

1943 Rodotà, *Perché laico* (2010) p. 26.

1944 Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 113 (author's translation).

1945 ibid, p. 116.

restrictions placed on the implementation of the technology, thus leaving room for uncertainty.

An initial scenario of regulatory uncertainty was experienced in both Germany and Italy in relation to PGD. The German Embryo Protection Act of 1990 originally did not contain any provision to regulate PGD. Although the German Medical Association and the 'Benda Commission' had expressed an opinion favourable to PGD, a statutory regulation was still considered premature at the time by the legislature as the technique had not yet been fully developed.[1946] As a result of this failure to pursue the outcome of the exchange between institutions with regard to PGD, the Embryo Protection Act was unequipped to accommodate this new technology's emergence. This was also a consequence of the underlying intention of the law, which was precisely to ensure that the human embryo would be protected against the emergence of new controversial technologies.[1947] Parliamentary oversight was considered a necessary instrument to guarantee this constitutional protection.

When PGD was ready for clinical practice a situation of uncertainty arose in which legislative intervention would be required. The scientific community once again argued in favour of legislation that would allow its use in limited cases. The German Parliament established a study commission for this purpose. Yet, it seems that the role of this expert consultation was once again to ensure that sufficient legislative barriers could be put in place to protect the embryo against developments in modern medicine.[1948] The majority of the commission supported a blanket ban on PGD because of the fear of a 'slippery slope'.[1949]

This flawed institutional interplay and the resulting restrictive approach failed to take into account the developments that had occurred in the ethical perception of society.

In Italy Law no. 40/2004, regulating medically assisted reproduction, also failed to provide a clear legal framework for PGD. Unlike in Germany, however, this was not because the technique was not sufficiently developed at the time. On the contrary, PGD was already performed in the country. Rather, this was the result of the Catholic Church's extensive influence

1946 See Chapter 2, sec. A.I.1.
1947 Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1020.
1948 Jasanoff, *Designs on Nature* (2005) p. 184.
1949 See Chapter 2, sec. A.I.2.a.

on the legislative process and the fact that parliamentary discussions were primarily based on hearings and opinions obtained in 1997.[1950] Parliament failed to establish cooperation with other actors in order to seek more evidence from expert committees or to secure a broader societal consensus. As a result Law no. 40/2004 appeared already obsolete at the time of its enactment.

The situation in the UK was markedly different. Here too the Fertilisation and Embryology Act of 1990 did not provide explicit regulation of PGD. However, unlike in Germany and Italy, the legislature had integrated mechanisms into the HFE Act that were intended to ensure the continuous adaptability of the legislation through the involvement of experts.[1951] The Human Fertilisation and Embryology Authority was entrusted with the power to authorise new treatments, which it used to regulate access to PGD.

This leads to the consideration of a further way in which the interaction between institutions may be relevant. Namely, where the legislature fails to maintain the legislative framework ethically neutral and up-to-date, the intervention of other actors can compensate for this. This happened in the UK because the legislature consciously decided to assign the authority to regulate future technological developments to the HFEA. By contrast, a remedy was brought about by other institutions in Germany and Italy as they responded to pathological legislative inactivity. In these two jurisdictions, in the absence of legislative intervention, claims from the scientific community and individuals had to be addressed by the judiciary.

In Germany an update of the legislation was finally initiated thanks to the intervention of a member of the medical profession who self-reported the use of PGD.[1952] This forced the courts to confront the question of the legal admissibility of the technique. The BGH was thus required to act as

1950 Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 13.

1951 See Franklin, 'Developmental Landmarks and the Warnock Report' (2019) 61(4) Comp Stud Soc Hist p. 743, 771; Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1016.

1952 As put by Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1021, "[i]t took an individual act of conscience by a member of Germany's respected medical profession".

a substitute for the democratic legislature at a time of uncertainty over the regulation of PGD.[1953]

The Italian legislature also failed to provide a mechanism for adapting to the changing scientific landscape. While the law left room for uncertainty, ministerial guidelines intervened to confirm the ban on PGD.[1954] Ultimately it was only possible to update the legal framework for PGD thanks to citizens and to representatives of medical associations who had recourse to the courts. After the intervention of the ordinary courts and the European Court of Human Rights, the Italian Constitutional Court finally managed to recognise the developments in ethical convictions and to implement corresponding norms. By depriving the law of its ideological and religious perspective and by declaring that access to PGD was a part of the essential core of the right to health the Court ensured that the regulation was acceptable, reasonable and that it respected the principle of laicity.[1955]

The crucial role of the Italian Constitutional Court in this case resulted from the confluence of two trends. First, the Constitutional Court had recently embarked on its journey to achieve a "stronger, more active and central role" in the Italian legal system.[1956] This required the Court to be able to grasp the changes in the ethical and societal landscape and translate them into its judgments.[1957] Second, the Italian legislature had exhibited the first indications of a pathological inactivity in ethically controversial matters.[1958] The case of PGD offered a perfect opportunity for the Court to exercise its stronger role given the inability of the legislature to keep the legislation up-to-date and the resulting lack of legitimacy and acceptability.

These two cases demonstrate that where state actors fall short of their legal obligation of neutrality, by either actively promoting particular ethical views or passively omitting to adapt regulation, respect for the standard of neutrality depends on the separation of powers enabling other actors, such as the judiciary, to compensate. In concrete cases the courts could directly

1953 Arguably, an update of the legal framework finally came about, but at the expense of the principle of democracy, see Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 130.

1954 See Chapter 2, sec. B.I.2.a.

1955 See Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 20.

1956 Tega, 'The Italian Constitutional Court in its Context: A Narrative' (2021) 17(3) Eu Const Law Rev p. 369, 375.

1957 Rodotà, *Perché laico* (2010) p. 26; Tega, *La corte nel contesto: Percorsi di ri-accentramento della giustizia costituzionale in Italia* (2020) p. 91.

1958 See Chapter 2, sec. D.I.1.

adapt legislation to new ethical and scientific requirements within the margin of interpretation left open by the legislature. If necessary, constitutional courts have the power to verify whether obsolete legislation complies with scientific reasonableness and ethical neutrality. In this sense the principle of neutrality activates the rule of law's system of checks and balances.

Institutional interaction through dialogue also strives to ensure the acceptability of the regulation. Acceptability can be a suitable measure for assessing the validity of the compromise reached in a pluralist society on ethically controversial issues. It ensures that decisions have been made on grounds that are accepted as reasonable by virtually all members of society.[1959] Dialogue between the involved stakeholders is thus also an instrument of compliance with the requirement of neutrality.

In the Italian legislation on medically assisted reproduction the highly ideological approach and a total disregard for scientific evidence also derived from a parliamentary failure to enter into a dialogue with the scientific community and society.[1960] The aim of the legislation was, similarly to the German Embryo Protection Act, to assert ideological and religious values by protecting the embryo from being used in fertility treatments. Differing views were deliberately excluded from the parliamentary process. This jeopardised the acceptability of the legislation, as demonstrated by the several claims brought to ordinary and constitutional courts by citizens and representatives of medical associations.

The soon obsolete German legal framework also increasingly lost acceptability. Here the courts and scientific associations addressed the demands of civil society and the scientific community before the legislature. After the BGH's ruling the German Medical Association and the German Academy of Sciences Leopoldina again argued in favour of authorising PGD in limited cases. The German Ethics Council also reflected the changes in scientific and ethical developments when intervening in the parliamentary debates following the ruling.[1961] The minority of the Council supported a legislative ban on PGD out of a concern that a slippery slope would emerge. Its majority, however, supported the most permissive of the three drafts introduced into Parliament to regulate PGD and was influential in bringing about its adoption.

1959 Rodotà, *Perché laico* (2010) p. 82.

1960 Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1. See also Chapter 2, sec. B.I.

1961 Deutscher Ethikrat, 'Präimplantationsdiagnostik' (2011). See Chapter 2, sec. A.I.3.a.ii.

In the UK the HFE Act's ability to respond to scientific and ethical developments in a way that was acceptable to society as a whole was based squarely on two premises. First, the involvement of a committee of experts before drafting the legislation guaranteed the acceptability of the initial compromise. The very aim of the work of the Warnock Committee was to find a compromise that everyone could accept as grounded on reasonable premises.[1962] Second, the HFEA went about the licensing of new technologies by taking into account the existing legal framework and conducting several public consultations with other public bodies.[1963] This ensured consideration of possible changes in the ethical landscape. Moreover, institutional dialogue was kept open after the emergence of particularly ethically controversial techniques, such as preimplantation tissue typing combined with PGD. In this case courts were called upon to contribute to the adaptation of the legal framework. They were able to do this by sanctioning the results of the HFEA's assessments rather than by imposing their rulings as substitutes for an inactive legislature. The legislature also promptly intervened to ensure that the ethical implications of new technologies would be taken into account by a democratically elected body.[1964] The most challenging aspects of the regulation were reconsidered and submitted to public consultation. The legislative intervention confirmed the legitimacy of previous developments and the appropriateness of maintaining the HFEA as the licensing body for human fertilisation techniques.[1965]

This overview shows how many different actors in the legal system are well placed to guarantee the acceptability of the legislation by interacting and liaising with society or by providing scientific expertise. The involvement of expert commissions in drafting legislation contributes to legitimacy if it is not merely aimed at representing a particular ethical perspective but genuinely seeks to garner societal consensus. Upon legislative mandate expert committees and public consultation bodies can play a role in responding to ethical and scientific developments. The role of ethics committees is essential to inform the public and interpret the changing ethical landscape.[1966]Together with acceptability, a well-functioning institutional

1962 The "embodiment of a common moral position", as described in Warnock, 'Report of the Committee of Inquiry into Human Fertilisation and Embryology', London 1984, p. 3.
1963 See Chapter 2, sec. C.I.2.a.
1964 See Chapter 2, sec. C.I.3.
1965 See Chapter 2, sec. C.I.3.b.
1966 Rodotà, *Perché laico* (2010) pp. 28-30.

interplay promotes the scientific reasonableness and ethical neutrality of the legislation.

In the various ways illustrated here – be it institutional dialogue, compensation for the inaction of other actors, or consultation with the scientific community and society – institutional interaction has proved essential to the legal system's ability to legitimately address ethical issues in the field of health technologies.

4. Ethical Considerations in the Public Funding of Health Technologies

a Neutrality in Coverage Decisions

Access to health technologies not only depends on the lack of a state ban on them, but also on their public funding. As the case studies have shown the hesitancy surrounding the ethical desirability of a certain technology also affects its reimbursement in the public healthcare system. For this reason it is also imperative to develop a legitimate way of dealing with ethical concerns at this stage of decision-making.

The fact that the state generally has broad discretion in deciding which treatments to publicly fund in the healthcare system does not mean that ethical concerns can be used to justify withholding funding for a certain technology. On the contrary, in this area of state action the scope for legitimately considering ethical concerns is particularly limited. This thesis has demonstrated that the decision on public funding must be made in accordance with strictly neutral coordinates. This conclusion derives from a number of observations.

First of all, this field of state action is also subject to the requirement of ethical neutrality. Indeed, such a guarantee becomes even more essential in the context of welfare state action, given the traditionally wide discretion enjoyed by the legislature in this area. As some commentators have pointed out, fundamental rights will not necessarily have a strong "steering capacity" in the sphere of the entitlement to healthcare benefits.[1967] This can be observed in all three jurisdictions. An entitlement to health care benefits derived directly from the German Basic Law, first identified in the so-called

1967 As observed by Schuler-Harms in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 153 (author's translation).

'*Nikolaus*' decision, only exists in exceptional cases.[1968] With this ruling the constitutional right to life and bodily integrity was given an essential core, insofar as patients acquired a constitutional right to healthcare services in the event of a life-threatening or typically fatal disease.[1969] In Italy there is no obligation to list a benefit that is not included in the minimum essential core of the right to health in the Essential Levels of Care. It can therefore be left to the discretion of the individual Regional Healthcare Systems.[1970] Article 32 of the Italian Constitution states that free medical care is only guaranteed to the most deprived and that the possibility of patient co-payment always remains open.[1971] The determination of which health services are to be provided by the English NHS is left to public bodies whose decisions can only be quashed by the courts in very exceptional cases. In general the courts maintain a certain deference to public decision-makers.[1972]

This means that it is relatively difficult for patients to successfully argue that they have a right to access health care services within the public healthcare system when they have not been included in the benefit basket. Given the narrow scope of the protection offered by the positive dimension of the right to health it is all the more imperative that there is a guarantee for the individual that the state will adopt a position of neutrality of justification when deciding on the public funding of health treatments. Only then can the state's function of protecting the fundamental autonomy of the individual, particularly in the field of health, be fulfilled.

This does not mean altogether disregarding the fact that there are certain paramount interests to be preserved when making a public funding

1968 BVerfG, 06.12.2005 - 1 BvR 347/98 (BVerfGE 115, 25); see Kingreen, 'Verfassungsrechtliche Grenzen der Rechtsetzungsbefugnis des Gemeinsamen Bundesausschusses im Gesundheitsrecht' (2006) 59(13) NJW p. 877.

1969 Huster, 'Anmerkung' (2006) 61(9) JZ p. 466; Becker in Steiner and others, *Nach geltendem Verfassungsrecht* (2009) pp. 66-67; Schuler-Harms in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 154; Huster in Brune, Lang and Werner, *Konzepte normativer Minimalstandards* (2016) pp. 130–131; Ströttchen, *Verfassungsrechtliche Ansprüche auf konkrete medizinische Leistungen* (2019) pp. 260-ff.

1970 However, it has also been observed that the content of the right to health is interpreted rather broadly. This point will be touched on below.

1971 D'Arrigo, 'Salute (diritto alla)' (2001) V Enc dir p. 1009, 1010-1011; Zagrebelsky in Rossi and Bottari, *Sanità e diritti fondamentali in ambito europeo e italiano* (2013) p. 12; Iadicicco, 'La lunga marcia verso l'effettività e l'equità nell'accesso alla fecondazione eterologa e all'interruzione volontaria di gravidanza' [2018](1) Rivista AIC p. 1, 19.

1972 See Chapter 1, sec. B.III.2.b.

decision. The NIPT case study has shown that ethical concerns can be effectively addressed through the principles which have already been widely agreed upon and are protected in the legal system. Indeed, ethical concerns regarding the possible routinisation of the screening or the social pressure potentially exerted on women to undergo testing also exist as a legal concern. The corresponding values have been transposed into the legal system in a form in which all reasonable subjects in the legal system can be expected to agree with. These include legal principles such as women's reproductive autonomy, their informed consent and right to know or not to know. For this reason, for instance, the emergence of NIPT has not been considered ethically problematic in Italy insofar as it is possible to ensure that full informed consent can be maintained when accessing screening.[1973] The detailed design of the screening programme must be made consistent with the principle of informed consent, on the one hand, and with the more general statutory framework of abortion regulation on the other. This implies that a woman's right to know – but also to refuse the information – must be guaranteed and that screening must not be aimed at providing knowledge which cannot be relevant to reproductive choices, such as aesthetic or non-medical features of the future child.[1974] To maintain full informed consent the design of the screening programme must aim to "increase the offer, not the uptake, of the test".[1975] As regards

1973 "To the extent that policy recommendations by bodies such as NICE or professional bodies such as the ACOG serve the purpose of facilitating individual choice, such policies do not have the negative connotations of state-led eugenic programmes of the last century. What is crucial, however, is that women are well informed about a condition that is the subject of screening and testing, such as Down's syndrome, and do not feel pressured to accept screening in the first instance", Scott, *Choosing Between Possible Lives* (2007) p. 177.

1974 "For instance, in deciding what information to disclose to prospective parents as the result of a range of tests, in England health professionals will inevitably be mindful of the scope of the Abortion Act and its requirement of a 'serious handicap'", Scott, *Choosing Between Possible Lives: Law and Ethics of Prenatal and Preimplantation Genetic Diagnosis* (2007) p. 176.

1975 According to Ravitsky, 'The Shifting Landscape of Prenatal Testing' (2017) 47(Suppl 3) Hastings Cent Rep S34-S40, S38-S39 it is imperative to "[e]nsure that the objective and performance measure of any government-run prenatal screening program is to *increase the offer, not the uptake*, of the test. Increasing the offer of screening is a measure that aligns perfectly with the promotion of reproductive autonomy, since it allows more women to have a choice regarding testing. In contrast, increasing the uptake of testing is a measure that reflects a public health rationale and that represents a direct threat to reproductive autonomy. It puts

the question of a potential increase in abortion cases, this is not legally relevant as long as the balancing of fundamental interests carried out by the legislature in regulating abortion is respected. Provided that abortion regulation is still considered as being accepted by society as a whole, or its terms are constitutionally fixed, the increase in the number of women who benefit from this statutory framework is not legally relevant. If the problem lies in the legitimacy and acceptability of abortion as such then this cannot be solved by restricting women's access to prenatal care. Rather it requires an argument that, given the change of opinion in society, the agreement on abortion legislation should be amended.[1976]

Refusing public funding for health technologies would also go against the principle of autonomy, as it would introduce an economic barrier to accessing them.[1977] Pursuing the objective of quantitatively limiting the use of the test by excluding it from statutory health insurance is especially detrimental to people on lower incomes. In the case of NIPT this would result in the use of the least risky technology being guaranteed only to those who can afford to bear the cost out of their own pocket.[1978] While it could be argued that it is natural that the exclusion of any benefit from public healthcare is to the detriment of less affluent patients,[1979] in the case of ethically controversial technologies such as NIPT this effect is unjustified. The barrier to accessing the service would not be based on neutral justifications, such as lack of efficacy, safety or cost-effectiveness, but rather on reasons with ethical connotations that the state, according to the standard of neutrality of justification, cannot legitimately adopt. In sum, healthcare rationing can only be legitimately justified if it is based on neutral reasons.

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explicit pressure on clinicians to push women toward testing so that they can meet the expectations set by the screening program", emphasis added by the author.

1976 Admittedly, attempts to review the compromise on abortion have been made but without success. For the UK, for instance, see the legal challenge to the Abortion Act 1967 brought in the case of *Crowter & Others, R v Secretary of State for Health And Social Care* [2021] EWHC 2536 (Admin) (23 September 2021).

1977 Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194, 197.

1978 This approach was strongly criticised by the chairman of the G-BA, who warned that it would lead to a "Two-tier healthcare", Deckers and Mihm, '"Das wäre Zwei-Klassen-Medizin" Im Gespräch: Josef Hecken, Vorsitzender des Gemeinsamen Bundesausschusses' *Frankfurter Allgemeine Zeitung.* 14.12.2016. See Bunnik and others, 'Should Pregnant Women Be Charged for Non-invasive Prenatal Screening?' (2020) 46(3) J Med Ethics p. 194, 196-197.

1979 Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1715.

b Legal and Institutional Settings

As shown in the previous paragraph, the decision on public funding of ethically controversial health technologies must be made in compliance with a broader legal and statutory framework.[1980] This ensures that they are justified by criteria that are considered relevant and acceptable to society as a whole.

However, the possibility of legitimately dealing with ethical concerns also depends on the instruments that jurisdictions can use to define the benefit basket of the public healthcare system. Here again the adoption of a separation-of powers and institutional perspective is crucial. The different ways in which institutions collaborate to define the basket of health services influence the extent to which ethical concerns might inform public funding decisions in violation of the standard of neutrality. Additionally, the different regulatory contexts, such as different models of healthcare systems and varying conceptions of health and illness, must be considered.

First, institutional considerations prevent ethical concerns from being legitimately included in the funding decision. Indeed, the public authorities of the healthcare system will have to comply with the normative construction enacted by Parliament as the democratically legitimised body. Other public bodies would thus not be legitimised to include new ethical considerations in the decision-making process and reach a divergent normative assessment.[1981]

In Germany ethical interference was excluded from the decision on the reimbursement of NIPT through the scrupulously statutorily regulated process before the G-BA. Indeed, the authority is bound by clear statutory criteria under § 135 of the Fifth Book of the Social Law Code. The reference to this legal framework enabled the G-BA to settle the ethically controversial question of whether NIPT should be included in the Maternity Guidelines of the statutory health insurance.

However, the German model of statutory health insurance is not always capable of adapting to the changing scientific and ethical landscape. It is indeed affected by a certain degree of rigidity in that, in order to qualify for GKV benefits, it is necessary to incur an 'insured risk'. Therefore only

1980 Brownsword and Wale, 'Testing Times Ahead' (2018) 81(4) Mod Law Rev p. 646, 662.

1981 See Huster, 'Der Gemeinsame Bundesausschuss als Ethikbehörde?' (2017) 35(4) MedR p. 282, 285.

those services falling under the notion of the medical treatment of an illness (*Krankheit*) under statutory health insurance law are covered by statutory health insurance funds. Although German scholarship maintains that the lack of a definition of illness in the Fifth Book of the Social Law Code is adequate to leave room for possible shifts in the societal conception of health,[1982] this notion has remained the same since the beginning of the last century.[1983] Moreover, the definition of medical treatment for the purposes of health insurance remains rather limited in scope, as it has been used by the courts to justify limitations on entitlements to healthcare services, particularly in the field of reproductive technologies.[1984] The Federal Constitutional Court, for instance, denied an application for the constitutional review of the provision limiting the reimbursement of IVF to only 50% of the costs by arguing with the notion of a 'medical treatment for a disease'.[1985] The reasoning of the decision argued that IVF does not aim at curing a state of disease but rather circumvents it.[1986]

Similar reasons were given in the case law that denied public funding for PGD. As it does not fall under any of the relevant definitions of the SGB V, this procedure was not considered a health treatment for the purposes of the statutory health insurance.[1987] German social courts, including the Federal Social Court, also confirmed that PGD does not constitute a medical treatment that is owed to the patient by the GKV. This resulted especially from the definition of 'medical treatment of an illness', as PGD was not considered a treatment capable of alleviating suffering or curing a

1982 Lang in Becker and Kingreen, *SGB V: Gesetzliche Krankenversicherung Kommentar* (7th edn 2020) para. 3; Nolte in Körner and others, *Kasseler Kommentar: Sozialversicherungsrecht* (2021) para. 9.

1983 Bieback, 'Zur Neubestimmung des Krankheitsbegriffs in der GKV' (1978) 27(12) Sozialer Fortschritt p. 265. For the current definition of the prevailing literature and case law, see Lang in Becker and Kingreen, *SGB V* (2020) para. 6; Nolte in Körner and others, *Kasseler Kommentar* (2021) paras. 9a and 9b.

1984 For a criticism of the (mis-)use of the concept of illness in the rulings on the reimbursement fertility treatments (BVerfG, 28.2.2007 - 1 BvL 5/03, in BVerfGE 117, 316 and BVerfG, 27.2.2009 - 1 BvR 2982/07, in BVerfGK 15, 152), see Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1715.

1985 BVerfG, 27.2.2009 - 1 BvR 2982/07 (BVerfGK 15, 152).

1986 See Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, 1714–1715.

1987 It is not a measure of early detection of a disease under §§ 25 and 26 SGB V, nor a health treatment necessary to recognise or cure a disease, to prevent its aggravation or to alleviate its symptoms, according to § 27 SGB V, see Chapter 2 sec. A.II.1.

condition. The inclusion of PGD in the GKV would thus require explicit intervention by the legislature. Given the ethical problematic nature of the issue such an intervention is long overdue.

This exemplifies a certain conundrum. While the G-BA could use the ethically neutral statutory framework as a stable point of reference to legitimately decide on NIPT, the legal structure for decision-making in the statutory health insurance has prevented actors from living up to their obligation to recognise shifts in the ethical and scientific landscape in the case of PGD. In particular, the courts have so far succeeded in using the concept of 'medical treatment of a disease' to limit the scope of treatments that must be reimbursed by the GKV. However, this has resulted in implausible and unacceptable reasoning.[1988] In this regard these legal definitions of illness and treatment seem hardly adequate to deal with the emergence of new health services and new forms of medicine, especially in the field of genetic and reproductive healthcare.[1989] It will thus no longer be possible for courts to persuasively apply the stringent notion of medical treatment currently relevant to statutory health insurance.[1990] For the purpose of this thesis it is worth noting that a strict interpretation of this notion prevents courts from intervening to ensure compliance with the constitutional standards of neutrality in the reimbursement of new ethically controversial health technologies.

By contrast, the constitutional concept of illness and health adopted in Italy can be used by the Constitutional Court to adapt to new developments in the ethical and scientific landscape and to implement laicity. The wide scope of the notion of the right to health as well as its distinctive patient-centeredness, for instance, helped the Court to overcome the decidedly Catholic background of Law no. 40/2004. The right to health is of primary importance in the Italian constitutional framework and is the only one expressly defined as fundamental in the constitutional text.[1991] Combined with the individual's right to self-determination and the 'personalistic' approach of the Italian constitution, this notion of the right to health guarantees its adaptability to reproductive health needs. Article 32 of the Italian

1988 Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713, p. 1715-1716.

1989 ibid, p. 1716.

1990 ibid.

1991 See Ferrara in Rodota, Zatti and Ferrara, *Trattato di biodiritto* (2011) pp. 53-55; Busatta, *La salute sostenibile* (2018) p. 41; Morana, *La salute come diritto costituzionale* (2018) pp. 64-65.

Constitution has proven to have a particularly far-reaching scope when used by the courts to expand the right to access health treatments that, due to ethical considerations, have either been prohibited by the legislature or not yet covered by the National Health Service. Thanks to this constitutional provision the regulation of PGD has been *de facto* dictated by the Constitutional Court, whereas access to NIPT remains uncontroversial in view of its undeniable benefits for the right to health and self-determination.[1992]

In Italy, however, the devolution of a residual part of funding decisions to the healthcare systems of the individual Regions undoubtedly risks leaving a gap in the national protection when it comes to ethically controversial health technologies. In the absence of national regulation individual Regions have tended to use their margin of discretion to refuse funding to services that they consider ethically problematic. In the Region of Lombardia this has happened, for instance, with regard to heterologous IVF and in the case of the interruption of life-sustaining treatments. [1993] In this regard it is imperative for this jurisdiction to find mechanisms to ensure the quicker adaptation of the national Essential Levels of Care, especially when the jurisprudence of the Constitutional Court demands it. In the absence of an intervention that updates the benefit basket at the national level, individual ordinary and administrative courts are once again called upon to act as a substitute for the responsible state bodies.[1994]

In England, unlike Italy, there is no general recognition of a right to health and healthcare.[1995] The definition of the health services that need to be granted by the NHS is mainly left to the discretion of NHS bodies and what they consider appropriate. The National Health Service Act, for instance, states that ICBs must arrange health services to the extent they consider necessary to meet reasonable requirements.[1996]

While this discretion is coupled with a model that requires such bodies to be accountable for the reasonableness of their decisions, which ensures legitimacy, the English approach requires a certain amount of trust in the observance of procedural principles by NHS bodies. In this regard, judicial review allows for the striking down of decisions that are based on irrelevant or unreasonable ethical or religious considerations and the courts have re-

1992 See Chapter 3, sec. B.II.
1993 See Chapter 1, sec. B.II.2.b.
1994 See Chapter 2, sec. B.II.2.
1995 McHale and Fox, *Health Care Law* (2007) p. 7. See Chapter 1, sec. B.III.2.b.i.
1996 National Health Service Act 2006, sec. 3 (1).

cently tightened their scrutiny of health authorities' decisions.[1997] Admittedly, however, the likelihood of a court overturning an ethically or religiously motivated decision not to publicly fund a health service remains difficult to assess. As a result, unlike the other two investigated jurisdictions, English courts are only limitedly suitable to act as substitutes for the health authorities in this field. Religious and ethical neutrality of the decision-making can thus not be legally enforced and it is only guaranteed by the adherence to a procedural model of accountability for reasonableness.

5. Towards a Procedural Approach to Neutrality

The comparative analysis of the institutional interactions has shown how successful the different solutions adopted in the three jurisdictions have been in guaranteeing legitimacy when dealing with ethical concerns in the constantly developing field of new health technologies. By answering the main research question, this thesis adds to a body of research that has already touched on the issue[1998] and contributes to addressing some of the challenging questions that arise next.

Guided by the different perspectives mentioned in the Introduction, the study provides insights into the optimal design of collaboration between the legal system's different actors to reach an acceptable and legitimate compromise in a pluralistic society. In doing so, it offers a tool for assessing the legitimacy of decisions concerning the introduction of novel technologies into the public healthcare system.

Ethical concerns about new reproductive health technologies were raised and considered in all three countries. However, from a constitutional law angle, while Italy and Germany adopted a primarily substantial value-driven approach, England grounded its regulation on principles of procedural legitimacy. Unlike in Italy and Germany, the ethical point of view adopted by the English regulation resulted from an effort to find a widely accept-

1997 See Chapter 1, sec. B.III.2.b.

1998 See, *inter alia,* Spranger, *Recht und Bioethik* (2010); Werner in Rothhaar and Frewer, *Das Gesunde, das Kranke und die Medizinethik: Moralische Implikationen des Krankheitsbegriffs* (2012); Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300; Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1; Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015); Huster in Albers, *Bioethik, Biorecht, Biopolitik* (2016); Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001.

able solution, which was validated by scientific evidence and continuously adapted to it. As the institutional perspective has shown, expert and public involvement were two prominent features of this model and they have positively influenced the extent to which the normative approach of the legislation could be operationalised and integrated into the legal system.[1999]

The thesis demonstrates that the adoption of a model of procedural legitimacy for the institutional interaction helps to find a reasonable compromise that can be widely agreed upon in a pluralist society.[2000] In turn, the neglect of procedural elements in the relations between the actors involved has negatively influenced the legitimacy and acceptability of the regulation.

This can be observed when analysing the two case studies in Germany. Here public acceptance of the Embryo Protection Act is especially fragile. It suffers both from the fact that the legislation has sought to adopt a standpoint that offers absolute protection to the embryo, a position which is not widely shared by society, and from its lack of mechanisms for adapting to new scientific and ethical coordinates. In other words: acceptance is undermined by the lack of instruments of procedural legitimacy both at the time of its adoption and in its continuous implementation. As evidence of this there is a growing criticism in the legal scholarship and there are calls for the reform of the Embryo Protection Act that are increasingly being voiced.[2001]

In the case of NIPT some elements of a procedural model were included in the decision-making. The G-BA, an expert body, was the leading player in the procedure. Recognising the ethical issues behind the new test, it directly confronted the public through press releases and gave Parliament

1999 Penasa, 'Regulating ART. The Rise of a (Common?) 'Procedure-Oriented' Approach within EU' (2012) 12(1) Global Jurist p. 1, 2.

2000 The consensus achieved with such a model is fundamentally different from the one established by a large parliamentary majority, as noted by Rodotà, *Perché laico* (2010) p. 82.

2001 *Inter alia*, Rosenau, *Ein zeitgemäßes Fortpflanzungsmedizingesetz für Deutschland* (2013); Gassner and others, *Fortpflanzungsmedizingesetz Augsburg-Münchner-Entwurf (AME-FMedG)* (2013); Hübner and Pühler, 'Systematische Rechtsentwicklung für die Reproduktionsmedizin' (2017) 35(12) MedR p. 929, 933; Dorneck, *Das Recht der Reproduktionsmedizin de lege lata und de lege ferenda* (2018); Kersten, 'Regulierungsauftrag für den Staat im Bereich der Fortpflanzungsmedizin' (2018) 37(17) NVwZ p. 1248; Lindner, 'Ein zeitgemäßes Fortpflanzungsmedizinrecht für Deutschland' (2019) 52(6) ZFR p. 171; Taupitz, 'Zur Notwendigkeit eines Fortpflanzungsmedizingesetzes' (2022) 50(1) Pro Familia Magazin Frankfurt p. 6 .

room for a consultative debate. The opinions of several scientific organisations and the German Ethics Council were gathered through a formal consultation procedure. This positively influenced the chances for the G-BA to reach a broadly acceptable compromise, avoiding the routinisation of the test but still guaranteeing access and respecting patients' autonomy.

In Italy the complete failure to provide procedural instruments capable of ensuring adaptability has negatively affected the legitimacy of the legislation on fertility treatments. Notably, the refusal to involve medical experts in the decision-making process has resulted in the scientific unreasonableness of the adopted measures.[2002] The adoption of one particular religious stance in the Italian legislation on fertility treatment also ran against the principle of laicity and undermined its acceptance. The regulation was not widely agreed upon, as is shown by the comments of legal scholars[2003] and the frequent recourse to ordinary, administrative and constitutional courts.[2004] NIPT in this country has so far not generated extensive public debate. The main actors in its regulation are the Regional Health Systems, while at the national level scientific expertise is ensured by the regularly updated guidelines of the Italian National Health Council. Public funding of NIPT has been justified on the basis of constitutional provisions concerning the right to health and self-determination in health and it thus respects the standard of neutrality.

In England the set of procedural principles outlined in Chapter 1 have been respected throughout the whole regulatory development. First, the procedural model facilitates adaptability to scientific developments thanks to the openness to scientific expertise as a component of procedural legitimacy. This guarantees the flexibility of the regulation and its scientific

2002 A striking example of this is the provision requiring simultaneous implantation of all embryos in the uterus, which was deemed unreasonable by the Constitutional Court in its judgment no. 151/2009. See Casonato, *Introduzione al biodiritto* (2012) pp. 96-97; Penasa, 'Converging by Procedures' (2012) 12(3-4) Med Law Int p. 300, 317.

2003 *Inter alia*, Manetti, 'Profili di illegittimità costituzionale della legge sulla procreazone medicalmente assistita' [2004](3) Pol dir p. 453; Tripodina, 'Il "diritto" a procreare artificialmente in Italia: una storia emblematica, tra legislatore, giudici e Corti' [2014](2) BioLaw Journal – Rivista di BioDiritto p. 67; Casonato in Camassa and Casonato, *La Procreazione medicalmente assistita: Ombre e luci* (2005); Dolcini, 'Legge sulla procreazione assistita e laicità dello stato: da sempre, un rapporto difficile' (2013); Penasa, 'La sentenza n. 96 del 2015 della Corte costituzionale: l'insostenibile debolezza della legge 40' [2015](3) Quaderni cost p. 755.

2004 See Chapter 2, sec. D.II.3.

reasonableness. Moreover, ongoing public consultations and the search for a compromise that is acceptable as reasonable to virtually everyone have imbued the choices on the ethical admissibility of new reproductive treatments with a lasting legitimacy. While it is true that it may not be possible to find a consensus in these ethically controversial areas,[2005] the principles of procedural legitimacy provide a reasonably acceptable justification for the measures taken.[2006] Not everyone might agree with the outcome. However, this is the acceptable result of a political process that remains open to changes according to societal shifts.[2007] Admittedly, the fairly unified utilitarian approach of English society might have played a relevant role here. Nonetheless, the involvement of the Warnock Committee and the described procedural safeguards surely helped to ensure the continued acceptability of the regulation.[2008]

This model of procedural legitimacy was also applied in the case of NIPT where the UK NSC took into account public consultations and the stance of advocacy groups, while the public's opinion was informed and gathered through the work of the Nuffield Council of Bioethics.

In both cases an interaction based on procedural mechanisms took place between the legislature, NHS bodies and society. This was mediated through the work of experts in ethics and science, including in particular the HFEA and the Nuffield Council of Bioethics. The role of the courts in this interplay has been to monitor compliance with procedural legitimacy mechanisms.

The success of the English regulatory model confirms the hypothesis that, while finding complete agreement on substantive principles – or on their interpretation in the case of a written constitution – might be unattainable in a pluralist society, it is possible to find a frame of reference

2005 Fovargue and Bennett, 'What Role Should Public Opinion Play in Ethico-Legal Decision Making? The Example of Selecting Sex for Non-Medical Reasons Using Preimplantation Genetic Diagnosis' (2016) 24(1) Med Law Rev p. 34, 54–56.

2006 "The long-standing British approach, exemplified by the Warnock Committee's proposal of the 14-day limit on embryo research, has tended to assume that public policy should be driven by acceptability as much as principle", Montgomery, 'Bioethics after Brexit' (2018) 18(2-3) Med Law Int p. 135, 153.

2007 See Chapter 1, sec. B.III.2.a.ii.

2008 See Franklin, 'Developmental Landmarks and the Warnock Report' (2019) 61(4) Comp Stud Soc Hist p. 743, 771; Jasanoff and Metzler, 'Borderlands of Life' (2020) 45(6) Science, Technology, & Human Values p. 1001, 1016.

in procedural principles that can give legitimacy and acceptability to the grounds on which legislation is adopted.[2009]

Adopting a procedural approach may also be a suitable response to the shortcomings mentioned above with regard to the concept of medical treatment in the German statutory health insurance. Indeed, the procedural model could positively contribute to a definition of the concept of illness and medical treatment that remains appropriate for purposes of defining and restricting health insurance benefits while also meeting the requirements of justification neutrality. A similar solution has been advocated by Huster, who argues that it has become necessary to allow some decisions on the scope of statutory health insurance coverage to be left to deliberative decision-making and the political process.[2010] In this regard, including elements of the procedural justice method adopted in England, as shown in this thesis, seems well suited to accommodating changes in society's attitudes towards notions of disease and health. In emphasising the need to establish ethically neutral criteria for the definition of health Micha H. Werner also pointed to the strategy of 'proceduralising' existing institutional mechanisms as a possible way forward.[2011] This dissertation joins these proposals by indicating that, in order to comply with ethical neutrality, it is necessary to interpret the concept of health according to coordinates that are acceptable as reasonable to virtually all individuals participating in the public healthcare system. The autonomy of the individual patient can play an essential role in this determination, as seen in the case of NIPT.

In consequence it is argued that Italy and Germany[2012] should also consider including more principles of procedural legitimacy in their substantial

2009 Indeed, in pluralistic societies where reaching an ethical consensus on the content of the regulation appears difficult or impossible, agreement might be more easily found in terms of procedural requirements. See van der Burg in Kuhse and Singer, *A Companion to Bioethics* (2009) p. 62. On the importance of the guarantees provided by the procedural approach, see Casonato in Casonato and Piciocchi, *Biodiritto in dialogo* (2006).

2010 Huster, 'Die Leistungspflicht der GKV für Maßnahmen der künstlichen Befruchtung und der Krankheitsbegriff' (2009) 62(24) NJW p. 1713.

2011 Werner in Rothhaar and Frewer, *Das Gesunde, das Kranke und die Medizinethik* (2012) pp. 221-223.

2012 In the course of the thesis, however, it became apparent that Germany already tends to include more procedural elements than Italy in its decision-making. Apart from the already mentioned consultations conducted in the case of NIPT (Chapter 3, sec. A.II.2.), on the structures existing in Germany for expert consultations in the democratic process, see for all Münkler, *Expertokratie* (2020) pp. 540-ff.

and value-driven approach. The adoption of procedural principles can assist in the interpretation of constitutional standards, in continuously adapting to shifts in the ethical attitudes of society and in ensuring the constant inclusion of experts in decision-making procedures. This could obviate the need for court intervention to rectify the coordinates of legislation that is uncertain, incompatible with the rest of the legal system or inconsistent with scientific evidence. Clearly this would only be legitimate insofar as the principles of democracy and of the separation of powers are preserved in entrusting different institutions with the task of guaranteeing the ethical neutrality of legislation.[2013]

Concurrently, the English model is based on an equilibrium of political constitutionalism that, at least on paper, could be considered precarious. For instance, there is no constitutional guarantee that the principle of neutrality of justification will always be respected in decisions on health technologies. Judicial review is not very powerful against decisions of NHS bodies when it comes to defining the health benefit basket. Moreover, the state's neutrality remains threatened, at least on a formal level, by the connections with the Church of England and the presence of the Lords Spiritual in Parliament.[2014] In other words, the English model of procedural legitimacy requires a certain trust in the ability and willingness of institutions to follow it.

In light of these circumstances hardly any element of the procedural model could be legally included in Italy and Germany unless the prevalence of a fundamental value-based approach is maintained. This follows from several considerations. A first reason is the fundamental difference between the constitutional model in Germany and Italy compared to England. That the constitutional traditions in the investigated jurisdictions are essentially different can be seen from the comparative analysis of the constitutional frameworks in Chapter 1. The constitutional principles of the two jurisdictions must under no circumstances be violated when introducing procedural elements into the decision-making on ethically controversial health technologies.

Second, the ethical background of the three countries is very different and might influence societal acceptance of a procedural model. Whereas in

2013 Kersten in Rixen, *Die Wiedergewinnung des Menschen als demokratisches Projekt* (2015) p. 131.

2014 See Chapter 1, sec. B.III.1.b.

England diffuse pragmatism and utilitarianism[2015] lend themselves particularly well to this, the dignitarian and human rights-based[2016] perspectives, respectively found in Germany and Italy, might call for more strictly regulated legal frameworks. The confidence placed on statutory regulation precludes placing the updating of the legislative framework in the hands of expert committees. When a technology emerges that is particularly ethically controversial the legislature may promptly be called upon to intervene. Looking at the fear of the slippery slope for instance, this concern is deeply rooted in the German ethical discussion, but it is hardly relevant in the English one.[2017] As a reaction to the concern for slippery slopes, a resolute intervention of the legislature might be advocated. Once again the case of NIPT in Germany proves this. Despite the inclusion of elements of procedural legitimacy in the G-BA decision and the eventual achievement of a broadly acceptable compromise, certain groups still advocate for intervention by the legislature.[2018] They argue that the ethically controversial decision to include NIPT in statutory health insurance should be made by the legislature and not by the health administration.[2019] While there is an evolution towards accepting a more procedural approach, it hardly seems that a sufficient trust in the procedural model has developed in Germany at this point.

Third, several tools for guaranteeing neutrality are also effective in these two jurisdictions and mitigate the need to introduce more procedural elements. Although the value-based approach struggles to guarantee increasing ethical pluralism, the steering potential of the written and binding constitution in these two jurisdictions is relevant in this regard. In Italy ordinary and constitutional courts can always rely on the fundamental right to health combined with the principle of laicity to redress ethical and religious biases of other state institutions. In Germany the respect of the principle of neutrality is checked by the Federal Constitutional Court. Furthermore, the inclusion of services within the statutory health insurance is carried out under a highly regulated system which, to a large extent,

2015 Brownsword in Busatta and Casonato, *Axiological Pluralism* (2021) p. 144.
2016 Referring here again to the 'bioethical triangle' theorised in Brownsword, *Rights, Regulation, and the Technological Revolution* (2008) p. 32. More on this in Chapter 1, sec. A.I.1.
2017 Jasanoff, *Designs on Nature* (2005) p. 279.
2018 'Pränatale Diagnostik:"Wir stehen erst am Beginn einer besorgniserregenden Entwicklung"' *Süddeutsche Zeitung*. 28.7.2022.
2019 ibid.

ensures that legal criteria are followed and excludes the relevance of ethical criteria.

In conclusion, while not intending to offer simple solutions, this thesis supports the argument that more elements from the procedural model should be adopted in order to legitimately address ethical concerns in the field of reproductive health technologies. However, the legal culture in different jurisdictions and the preparedness of society to embrace a procedural turn cannot be overlooked.

III. Closing Remarks

In a recent editorial of the *Journal of Medical Screening* Nicholas Wald[2020] made the provocative statement that "it may be unethical" to have ethical oversight on the public funding of screening programmes.[2021]

Although the criteria applied in this thesis are legal and not ethical, I endorse this view. This thesis has shown that the state cannot legitimately impose certain ethical standpoints through a refusal to publicly fund ethically controversial health technologies. In other words, decisions on the coverage and reimbursement of health technologies cannot depend on their ethical desirability. The function of the legal system in modern pluralistic democracies is to enhance the moral choice of the individual rather than

2020 Wald was a pioneer in the field of prenatal screening. He introduced the idea of screening pregnant women for congenital disorders and discovered that neural tube defects in the foetus could be prevented by increasing folic acid intake. See, *inter alia*, Wald and Bower, 'Folic Acid and the Prevention of Neural Tube Defects' (1995) 310(6986) BMJ p. 1019; Wald and others, 'Maternal Serum Screening for Down's Syndrome in Early Pregnancy' (1988) 297(6653) BMJ p. 883; Wald, Cuckle and Royston, 'Antenatal Screening For Down Syndrome' (1988) 332(8624) Lancet p. 1362; Wald, Gilbertson and Doyle, 'Folic Acid in Prevention of Neural Tube Defects' (1995) 345(8946) Lancet p. 389.

2021 "To even suggest that it may be unethical to have ethical committee oversight may seem strange, but such a requirement replaces individual choice with institutional decision making in areas where individual choice should prevail. It denies autonomy because one cannot choose to have a screening test that is not available. Provided that a screening programme is lawful and is also justified on scientific and medical grounds, the individual is sovereign in determining the ethical position. The decisions of such a committee could not only deny public access to useful medical advances but also could offend some people by giving ethical endorsements that conflict with their own views", Wald, 'Are Screening Practice Ethics Committees Needed?' (2021) 28(4) J Med Screen p. 377.

to impose external ethical views. The public healthcare system must also strive in this direction. Those who argue for the need to include more ethical evaluations in decision-making processes on the public funding of new health technologies[2022] overlook this key premise.

This argument also derives strength from the circumstance that agreement on acceptable values is reached during the democratic process. To legitimately operationalise this agreement the bodies that decide on the inclusion of new technologies in the public healthcare system should include more legal expertise rather than ethical evaluations. This would be in line with the findings of this study, which has shown how important it is for the public funding of health services to comply with the fundamental legal and constitutional framework. It would also help to ensure that there is a coherent normative approach within the legal system that is and must remain separate from ethics.

2022 See Introduction, as well as Chapter 3 secs. A.3 and C.3.