Alma Mater Studiorum – Università di Bologna
in collaborazione con LAST-JD Consortium
Università degli studi di Torino
Universitat Autonoma de Barcelona
Mykolas Romeris University
Tilburg University

DOTTORATO DI RICERCA IN

Erasmus Mundus Joint International Doctoral Degree in Law, Science and Technology

Ciclo 28 – A.Y. 2012/2013

Settore Concorsuale di afferenza: 12H3

Settore Scientifico disciplinare: IUS20

TITOLO TESI

Contesting rights: bioconstitutionalism and the debate on preimplantation genetic diagnosis in Italy

Presentata da: VOLHA PARFENCHYK

Coordinatore	**Relatore**
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Esame finale anno 2017

Contesting rights: bioconstitutionalism and the debate on preimplantation genetic diagnosis in Italy

Proefschrift
ter verkrijging van de graad van doctor aan
Tilburg University op gezag van de rector magnificus,
prof.dr. E.H.L. Aarts, en University of Bologna op gezag van de rector magnificus,
prof.dr. F. Ubertini, in het openbaar te verdedigen ten overstaan van een door het college voor promoties aangewezen commissie in de aula van Tilburg University op woensdag 28 juni 2017 om 14.00 uur

door

Volha Parfenchyk

geboren te Minsk, Wit-Rusland

Alma Mater Studiorum – Università di Bologna
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To my dearest mother Anna

and Alexander

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List of abbreviations

ART – Assisted reproductive techniques
BÄK – Bundesärztekammer (German Medical Association)
BverfGE – Bundesverfassungsgericht (German Constitutional Court)
BGH – Bundesgerichtshof (German Federal Court of Justice)
CC – Corte Costituzionale (Constitutional Court)
CDU/CSU – Christlich Demokratische Union Deutschlands/ Christlich-Soziale Union in Bayern (German Christian Democratic parties)
CLS – Critical Legal Studies
CNB – Comitato Nazionale per la Bioetica (National Committee on Bioethics)
DC – Democrazia Cristiana (Political party Christian Democracy)
DFG – Deutsche Forschungsgemeinschaft (German Research Foundation)
ECtHR – European Court of Human Rights
EPA – Embryonenschutzgesetz (German Embryo Protection Act)
hESC – human Embryo Stem Cell
IVF – In vitro fertilisation
Law on MAR – Law on medically assisted reproduction (Legge sulla procreazione medicalmente assistita)
Law 40/2004 – see Law on MAR
OHSS – Ovarian hyperstimulation syndrome
PCI – Partito Comunista Italiano (Italian Communist Party)
PGD – Preimplantation genetic diagnosis
SCA – Stammzellgesetz (German Stem Cell Act)
SNS – Servizio Sanitario Nazionale (National Health Service)
SPD – Sozialdemokratische Partei Deutschlands (German social-democratic party)
STS – Science and Technology Studies
TAR – Tribunale Amministrativo Regionale (regional administrative court)
UNESCO – United Nations Educational, Scientific and Cultural Organization

CHAPTER 1

Introduction

1.1. Introduction

The advances in biomedicine sparked a renewed interest in rights. The contemporary development of practices of law-making illustrates that in an era where new biomedical practices and technologies cause much fear and anxiety, it is through the appeal to rights that citizens seek to shield themselves against potentially dangerous new technologies. For example, the UNESCO set of declarations on genetics, bioethics and human rights, namely, the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005), as well as the Convention on Human Rights and Biomedicine (1997) suggest that human rights often act as criteria for developing law regulating new technologies and setting standards for the type of new technologies that should be practiced.

However, the appeal to and use of rights as benchmarks for the development of new biomedical practices and technologies is not unproblematic. Rights critique has been a topic of proliferous legal research since the emergence of legal realism in the beginning of the XX century. Critical legal scholars brought to light such previously unnoticed and unexplored characteristics of rights as indeterminacy, instability and the ability to conceal and mask rather than reveal and transform political inequality and injustice (Kennedy 1997; Tushnet 1983). Duncan Kennedy, one of the founders of the critical legal studies (hereafter CLS) movement, famously declared that he lost faith in rights (Kennedy 1997). Despite that, over time, it has nevertheless been recognized that ‘there is something too valuable in the aspiration of rights … to abandon the rhetoric of rights’ in order to achieve some important social transformations (Minow 1990, 307; see also Williams 1991) and the critique of rights has softened, the critical approach to rights has surely undermined an overly optimistic faith in rights and demonstrated the need for a more complex analysis of rights discourse.

Several consequences emerge if we take a critical perspective upon rights when they are used as regulatory benchmarks for regulating new technologies. First, the appeal to rights may contain a hidden agenda different from the one that those who appeal to the relevant rights claim they have. For example, as Jackson (2008) illustrated, in countries' technoscientific controversies, pro-life movements often appeal to the need to protect women's health, wishing to shore up an old paternalism and protect unborn life, and therefore resisting the development of new practices such as egg donation and stem cell research, instead of genuinely caring about women's health. Therefore, taking a critical stance is important to make sure that the use of rights discourse is geared exactly towards those social and moral ends that the relevant society or international community wishes to achieve through biomedical and biotechnological innovations and not to mask some political or moral stances by referring to a 'neutral' rights discourse.

The second reason why the appeal to rights is not unproblematic relates to the transformation of rights themselves. Specifically, as the meaning of 'human' in human rights can no longer be taken for granted because new biomedical and genetic technologies provide much opportunity for intervening into and transforming what we used to regard as 'human nature', it is no longer clear who exactly the holder of (human) rights is. In science and technology studies (hereafter STS), the possibilities and consequences of reprogramming 'human nature' do not raise eyebrows, since scholars have long accepted that what we treat as natural or cultural is a product of social processes and not an intrinsic quality of the world (Latour 1993). Yet, the appeal to 'human nature' often figures in political controversies where the notion of 'human' is treated as a constant and the only process that warrants concern is the unsettling of entitlements of 'human nature' by technoscience. The critical approach to rights, coupled with the insights from STS, can help expose how the assumingly stable nature and rights, that are needed to protect it, are mobilized, which (political, religious, or economic) ends those who mobilize them seek to achieve, and whether these are the values that the relevant society wishes to ensure.

Finally, the third reason is that rights might actually act, not as a protection against new technologies with dangerous or unknown implications, but as incentives promoting and further expanding their use. For example, with respect to human embryo stem cell research (hESC), Rubin (2008, 22) argued that despite that many countries such as Germany opposed it as violating human dignity, what she called 'therapeutic promise', or the medical and health benefits of hESC, in fact 'prevailed in ethical discourses within different national contexts as a strong and universally applicable moral coin' and paved the way for a more liberal use of human embryos in biomedical practices. Similarly, in the so-called 'bioethical triangle' (Brownsword 2008), human rights are an empowering ethical perspective, favoring the development of new biomedical practices. Therefore, the use of rights as benchmarks for the regulation of new biomedical technologies may act not as a normative value enabling a more reflexive discussion of the use of new biomedical technologies, but only favouring their broad use.

These are only some of many reasons why the appeal to rights may raise problems. Yet they suffice to show that — in light of their social importance, with rights being the core element of countries' constitutional orders and with the role that they are consequently called on to play in the development of new biomedical practices in modern democratic societies — an in-depth exploration is warranted of how rights are used in social controversies around new technologies. The main **objective** of this work is to explore how rights figure in social controversies around new technologies as well as to highlight the possible advantages, problems and difficulties that the use of them may involve.

Although others have also explored this problematic, the present work differs from existing research in two ways. First, whereas previous research discussed the interplay between human rights and new developments in biomedicine from either an EU regulatory perspective (Flear 2008, 2015; Flear and Vakulenko 2010) or a medical, and therefore private law, perspective (Jackson 2008), this work seeks to enlarge our understanding of how *constitutional* rights interact with biomedicine. Second, it explores rights from a critical angle using three overlapping disciplinary perspectives, namely, CLS, STS, and the Foucauldian theorization on biopolitics, law and the state. Hence, this work will engage and further develop the concept of *bioconstitutionalism*. This concept was proposed by several scholars in science and technology studies, all affiliated with the J. F. Kennedy School of Government at Harvard University, at a panel discussion at the 2010 annual meeting of the Society for Social Studies of Science in Tokyo and was further developed in a book (Jasanoff 2011b). Bioconstitutionalism emerged as a concept to provide a nuanced and comprehensive theoretical framework for exploring how new technologies affect the relationships between states and their citizens, institutionalized in constitutional rights. Bioconstitutionalism, as developed by these scholars, builds on ideas from STS, the Foucauldian critique of state and power, and CLS, which are applied to analyze the influence of new biomedical practices and technologies on the construction of legal personhood, subjectivity, constitutional rights, citizenship, and the problems of legitimacy and accountability. This thesis builds upon the concept of bioconstitutionalism, but applies it to the exploration of problems related to the use of rights as benchmarks for the development of new biomedical technologies and practices. Furthermore, as bioconstitutionalism is a new and underdeveloped concept, this work will further develop the concept to provide a better understanding of how rights interact with new developments in biomedical science and technology.

The exploration of the role of rights for the regulation of biomedical sciences and technologies can hardly be performed in the abstract. Therefore, much of bioconstitutional investigation and other research exploring the interplay between new science and technology and society has looked into concrete cases and controversies (Nelkin 1984; Jasanoff 1995; Martin and Richards 1996; Jasanoff 2011b). Controversies, their emergence, development and closure, represent a useful site for analysis, because they show how the intertwining of technoscience, laws, politics, rights and values emerges and is forged, by means of which elements and along which pathways. As Jasanoff argued, social controversies [work] as 'laboratories' for studying how science and technology work in society (Jasanoff 2012, 439). They provide answers to questions not only 'who wins and who loses in particular struggles over representation, but who benefits, to what ends, by what means, and at how great a cost' (Jasanoff 2012, 439).

This work will be mainly based on the exploration of the debate around the technology known as preimplantation genetic diagnosis (PGD) in Italy. PGD is usually sought to detect for genetic abnormalities in the embryo before implantation in order to start pregnancy with an already healthy embryo. In Italy, the acceptability of PGD was a vexed issue. Together with other reproductive technologies, it had been freely practiced up till 2004 when the Italian Parliament passed a law on medically assisted reproduction (Law 40/2004) and prohibited many reproductive technologies, including PGD. All this was considered necessary to protect the rights of human embryos created through IVF, which were granted legal personhood and turned into 'citizen subjects' by Law 40/2004 (Metzler 2007, 2011). However, the adoption of the Law was followed by a massive litigation campaign initiated by Italian citizens who had predispositions to various genetic diseases and supported by patient and scientific associations. As a result, in a series of decisions, the Italian Constitutional Court repealed the most contested provisions of the Law that prohibited PGD as they violated the right to health of Italian citizens. Thus, unlike other European countries, which, despite being engaged in hot debates on the ethics of PGD, nevertheless managed to draft regulations governing its application (Mulkay 1997; Bleiklie, Hoggin and Rothmayr 2004; Metzler 2017), the acceptability of PGD in Italy for more than 30 years has been, and still remains to some extent, an unresolved issue, not covered by country-wide legislative provisions.

Importantly, and this is the main reason why I chose to discuss rights-biomedicine interaction using the Italian debate around PGD as a case study, rights have been the central element of the entire controversy, not only by sparking it (PGD was prohibited by Law 40/2004 to ensure the protection of the rights of embryos) but also by closing it (the right to health of the woman was recognized by the Constitutional Court as the reason why PGD should be allowed). The fact that rights both caused and closed the controversy, whose scope and intensity sets Italy apart from its European neighbors, already points to a potential difficulty of using rights as benchmarks for regulating new technologies in that such benchmarks can point to different (or even opposite) approaches to how new biomedical technologies should be governed.

The second reason relates to the fact that the debate on and the enactment of embryos' rights and of the respective prohibition of PGD capture the second of those 'new' issues mentioned above that new biomedical technologies raise for rights, that is, how assumingly stable and clearly defined human nature, grounding legal rights, is mobilized by powerful political actors to achieve certain objectives. Specifically, in Italy the emergence of a new technoscientific object/subject – an embryo outside its mother's body – both urged the Italian Parliament to grant legal personhood to IVF embryos whose 'human nature' and natural rights made them akin to born persons and therefore entitled them to the same degree of respect and protection, and turned the rights (of embryos) into benchmarks according to which the acceptability of PGD and other assisted reproductive technologies (hereafter ART) must be evaluated. However, this position was mostly put forward and promoted by the Catholic Church with the help of political parties using Catholic moral imperatives to promote their own agenda. As the controversy evolved, it turned out that it was far from clear which exact aspects of this 'human nature' made humans humans and which exact rights this human nature implied or engendered.

The third reason relates to the period spanning from the mid-1980s to 2004 when the regulation of IVF and PGD was practically non-existent in Italy. This period of an almost unrestricted freedom reminds one of the type of freedom discussed by sociologists of medicine (Rose 2006) as one of the ways in which modern politics is performed, that is, not through the 'state', but through non-state institutions such as medicine and the governance of individuals through their subjectivation. The existence of this freedom, followed by an almost total prohibition of new ART by Law 40/2004, and its partial dismantling by the Constitutional Court makes it worthwhile to explore the different ways in which rights are implicated in the governance as well as the problems related to their central stage in governance. Hence, taking into account the different roles that rights had played in the Italian controversy, as well as different ways in which they had been used, appealed to, shaped, and implemented, I seek to explore the problematic of using rights in social controversies around new technologies.

1.2. Research questions

This thesis asks the following two main questions.

1. How have rights been used (identified, created, transformed, balanced, etc.) in the debate around PGD in Italy and how has this process been connected with the regulation of PGD? The use of the 'how' question in this work means that it will attempt to examine both the process of intertwining of rights and PGD ('how' as a trajectory and methods) and the result of the process ('how' as a form that this intertwining ultimately took). For example, I will address such questions as: What were the reasons (political, moral, historical) why Parliament granted rights to IVF embryos and through which rhetorical mechanisms did it do so? How was human dignity and the natural (human) rights mobilized by those seeking to attribute legal personhood and legal rights to the embryo?

2. To what extent can rights ensure a 'right' regulation of new technologies? The tinge of normativity in the second question means that this work is an exercise in contextual self-reflexivity. Rather than giving a definite answer in the abstract whether rights are a 'good' or 'bad' tool for shaping new biomedical technologies such as PGD, it more seeks to elucidate possible advantages, problems and difficulties of using rights in regulating new biomedical technologies in their particular context. Hence, I will address such questions as: What can the fact that rights were the reason why the controversy was not only sparked but also eventually closed tell us about the role of rights for biotechnological regulation? What do the litigation and the appeal to rights in technoscientific controversies such as the controversy over PGD in

Italy tell us about the allegedly apolitical nature of rights? Which problems can the use of rights in technoscientific controversies create, in light of the value systems prevailing in a certain society? Which other possible and (perhaps unexpected) roles does the use of rights in technoscientific controversies play?

1.3. Theory

In the introduction to the edited volume on bioconstitutionalism, Jasanoff describes the rationale of developing the idiom of bioconstitutionalism and the theoretical framework bioconstitutionalism builds upon. She observes that the effects of the biotechnological revolution, which had started with the discovery of DNA, on law were so profound that they 'should be seen as constitutional or, more precisely, bio-constitutional in their consequences' (Jasanoff 2011a, 3). And further,

> [r]evolutions in our understanding of what life is burrow so deep into the foundations of our social and political structures that they necessitate, in effect, a rethinking of law at a constitutional level (Jasanoff 2011a, 3).

However, according to Jasanoff, constitutional lawyers have been slow in addressing these changes (for example, see Goldberg 1994). In particular, she points to the reluctance of constitutional lawyers to grapple with new entities such as genes, embryos, human embryonic stem cells, or hybrids/chimeras. In addition, in those accounts in which constitutional lawyers do address this problem, they do so from a technology-deterministic perspective known as 'law lag', and which in other accounts has been defined as a problem of 'regulatory connection' or the 'problem of the new' (Brownsword 2008). According to this approach, new science and technologies 'race ahead' of society and constantly create new challenges that society, including morality and law, seem always to need to catch up with.

With respect to constitutional rights, the interaction between rights and biomedicine has been approached from what Jasanoff calls the 'classical' constitutional thought perspective. The latter operates with an essentialist understanding of rights, treating them as stable constitutional guarantees with well-defined meanings and definitions that should be protected and reasserted against erosion and violation. As a result, constitutional theorizing has used the vocabulary of 'impact' and dedicated efforts only to exploring how rights and other constitutional guarantees must be protected against threats posed by biomedical advances. For example, the concept of geneticization has gotten traction (Nelkin and Lindee 1995). Similarly, those wishing to protect human dignity have been particularly vociferous, claiming that the very human dignity of people is under threat (Kass 2002). Hence, by using the vocabulary of impact, this research overlooked important aspects of rights-biomedicine interaction, including the transformation of rights themselves, the multiplicity of sites where rights emerge and are being forged, hidden ideological and political interests that ground assumingly neutral judicial constitutional decisions, as well as the problematic nature of rights themselves unmasked by CLS.

The main aim of using and developing the idiom of bioconstitutionalism is to confront the misconceptions about the modes of interaction between science and constitutional law. To address this point, Jasanoff stressed the importance of the following moves. The first concerns the change of the currently prevailing view on *what constitution and constitutional rights are*. Jasanoff observed that it is important to abandon the 'classical' view of constitutional rights as products made by judges as it fails to account how individuals themselves work out their biopolitical relations with the state in other sites. To do so, she suggested to expand the notion of bioconstitutionalism. Specifically, Jasanoff proposed to explore 'constitution' 'with a small c' that would encompass 'the full range of sites and processes in which individuals work out their biopolitical relationships with the institutions that regulate them' (Jasanoff 2011a, 10). Regarding rights, this broad definition would include 'quasi-constitutional rights that no court has declared nor legislature decreed, but that are created (or constrained) through everyday practice and thought in technologically advanced societies' because a 'right in practice emerges not only at the moment when a court declares it, but also when people (and institutions) assume that they or others own the right and can assert it through their actions' (Jasanoff 2011a, 15). This broad understanding of the constitution taps into recent discussions in postnational, societal and democratic constitutional theory, which have also dealt with radical reconceptualization of constitutionalism (Teubner 2004). In addition, it also resonates with performative forms of citizenship (Isin and Nielsen 2008) and rights claiming (Zivi 2012) that do not necessarily have courts and litigation as the sites and means of ensuring rights.

Second, it is important to overcome the prevailing view on *how constitutional rights work* and how they interact with science and technology. To do this, she stressed that it is important to abandon the deterministic view of science in its relationship with law, including constitutional law and constitutional rights. Instead, she argues, it is important to take into account how the two traditionally separated worlds of the normative and the epistemic 'have supported each other for centuries in patterns of mutual construction, stabilization, and reinforcement'. In this way, her claim resonates with the well-known concept used in STS – the co-production of social and technoscientific orders – of which she is one of the main authors (Jasanoff 2004a; Latour 1993). Furthermore, she stressed the importance of adopting a critical perspective upon rights in order to debunk 'the neutrality and validity of the "baselines" against which we consider constitutional questions' (Jasanoff 2011a, 12) such as the neutrality of private-public distinction.

Finally, Jasanoff and others emphasized that the insights of Foucault, and his concepts of biopower and biopolitics, are needed to better understand how life itself had become the object of different ways and modes of political governance. The latter include not only those performed by the state through commanding the death of citizens, but also those through subjugating their bodies and controlling populations (Sunder Rajan 2011, 193-194, Jasanoff 2011a, 6).

The subsequent sections of this Chapter are concerned with situating bioconstitutionalism in this broad theoretical domain, in order to highlight how it can inform our thinking about the interplay between constitutional rights and new biomedical sciences and technologies. In Section 1.3.1, I will attend to the concept of biopower, biopolitics and biological citizenship. In Section 1.3.2, I will explore the critical approach to rights, including the approach of Foucault and CLS. In Section 1.3.3, I will describe the idiom of co-production. In Section 1.3.4, I will describe the insights from technology regulation studies. Finally, I will also highlight some current inconsistencies and gaps in the theorization of bioconstitutionalism, both of which this thesis will seek to correct.

1.3.1 Biopower, biological citizenship and bioconstitutionalism: the Foucauldian approach

Bioconstitutionalism is informed by the Foucauldian notion of biopower, which underlies how in late modernity, power is focused on regulating and enhancing life itself (Sunder Rajan

2011, 193-194, Jasanoff 2011a, 6). In what follows, I will describe the idioms of biopower and biopolitics and will critically address the ways in which bioconstitutionalism draws on and seeks to further develop these concepts.

Biopower and biopolitics

Foucault made his perhaps most famous distinction, namely, between the 'juridical mode' of power and what he termed 'biopower' (Foucault 1990) in his book *Will to knowledge*, in chapter V entitled 'Right of Death and Power over Life'. According to Foucault, the juridical mode of power could be characterized as the power of the sovereign to seize 'things, time, bodies, ultimately the life of subjects' (Rabinow and Rose 2006, 195). In contrast, since the seventeenth century, this 'deduction', or the deprivation of things, time, body and life, was to be integrated into and subordinated to a new form of power. This power, which he called biopower, acted 'to incite, reinforce, control, monitor, optimize, and organize the forces under it' (Foucault 1980, 136).

Foucault proposed a by now rather familiar diagram of biopower. In this diagram, one focus is the anatomo-politics of the human body or the disciplinary power. It is performed over an individual body through disciplinary techniques in such institutions as schools, prisons, army and hospitals, both to increase the economic productivity of the human body and '[weaken] its forces to assure political subjection' (Lemke 2011a, 36), turning individuals into 'docile bodies' (Foucault 1977, 1990). The second form of biopower, the biopolitics of population, emerged in the second half of the eighteenth century and focused 'on the species body, the body imbued with the mechanisms of life: birth, morbidity, mortality, longevity' (Rabinow and Rose 2006). Similar to anatomo-politics, Foucauldian analysis of biopolitics also focused on disciplinary techniques and therefore was reduced to body politics. The two poles can be interconnected into what Foucault calls 'apparatuses' (*dispositifs*). One of them is sexuality: on the one hand, it is located on the microlevel of the body and, on the other hand, on the macrolevel of a population (Foucault 1980).

Governmentality

Foucault would later come back to discussing biopolitics in his lectures at the Collège de France. Before proceeding to exploring biopolitics, Foucault first dedicates his lectures to government, governmentality and to liberalism as one of the modes or 'families' of governmentalities (Miller and Rose 2008). It must be stated at the outset that Foucauldian thinking on governmentality and government is fragmented and at many points contradictory and incoherent therefore does not constitute a well elaborated theory. However, for the purpose of this work several elements of his explorations on governmentality must be pointed out and fleshed out.

First, the idea of developing the concept of governmentality is to explore 'how the modern sovereign state and the modern autonomous individual co-determine each other's emergence in the long-term processes of co-evolution of modern statehood and modern subjectivity' (Lemke 2007, 44). Foucault thus explores different 'arts of government'. However, unlike the politicized meaning of the word used today, Foucault understands government as conduct, or better 'conduct of conduct', performed in different, and not necessarily political, settings, such as home, school, administration, as well as self-conduct. Government thus ranges from 'governing others' to 'governing self'. In the center of government Foucault places not the omnipotent and homogenous state, but the process of government. Political power is thus exercised through a number of institutions and practices, including both formal bureaucratic bodies and a number of non-governmental institutions, practices, knowledges, techniques, expertise, and rationalities, which he calls governmentality. The more societies aspire towards liberalism, hence limiting the scope of the state in governing life of citizens, the more the importance of these non-state institutions grow, as they claim their legitimacy exactly by existing beyond the state. They influence the behavior of individuals, but not through the rule and command, but through subjectification and the use of 'the technologies of the self' and 'technologies of the social'.

For example, this understanding of the mutual constitution of the state and subjectivities was employed by scholars to differently conceptualize and describe the societal transformations taking place in the twentieth century. One of them is the shift from the Keynesian welfare state toward 'free market' policies and the rise of neo-liberal political projects in Western democracies. Looking at these developments through the governmentality lens, scholars concluded that these political changes should be seen not as a retreat of the state but the favoring of other forms of government, such as self-government by responsible, prudent and entrepreneurial individuals, as well as 'privatized risk-management, empowerment techniques, and the play of market forces and entrepreneurial models in a variety of social domains' (Lemke 2012, 84; Miller and Rose 2008). In other words, in order to advance the governmentalization of the state, liberalism produces, or subjecfies, individuals with particular identities that would enable them to be directed and governed, namely, as individuals having the ability to exercise freedom along some structured pathways. Thus, freedom is a precondition for government. However, this freedom is not absolute but is, using Rose's apt expression, 'regulated autonomy'. Governmentality also produces 'free' subjects via rights and I will come back to this question in Section 1.3.2.

Second, liberalism represents one of the 'families' of governmentality. In other words, liberalism is not an economic theory or a political ideology but as a specific art of governing which involves two types of legitimation and limitation of political power. The first type includes those instruments that are 'external and excessive in relation to government' (Foucault 2008, 9). By these instruments, Foucault primarily meant the concepts of 'original or natural rights' and 'social contract'. As Foucault (2008, 39) stated, 'this approach consists in starting from the rights of man in order to arrive at the limitation of governmentality by way of the constitution of the sovereign'. In other words, according to this approach, individuals resign some of their natural rights and submit to the authority of the sovereign, in exchange for obliging the latter to protect the remaining essential natural rights against other people or the state itself. This way of limiting state power was implemented by the French revolutionaries and found its most explicit theoretical elaboration in the idea of the 'social contract' of Rousseau.

The second type of limitation derives from governmental practice itself and from the 'de facto limits that can be set to this governmentality' (Foucault 2008, 40). This is where Foucault starts to develop his view on a new rationality of government that differs from previous historical rationalities of government such as state reason (*raison d'état*): the idea of a nature of society that constitutes the basis and the internal limits of governmental practice. Nature here is not a carryover of tradition and therefore differs from 'natural rights' acting as an external limit to government. Instead, it represents a form of self-regulation of a society that the government should respect if it does not want to act 'clumsily'. The main intellectual element used to know society's nature is political economy. As Foucault (2008, 15) states, political economy

> considers [governmental practices] in terms of their effects rather than their origins, not by asking, for example, what authorizes a sovereign to raise taxes, but by asking, quite simply: What will happen if, at a given moment, we raise a tax on a particular category of persons or a particular category of goods?

Because the limits to political power are set from within by nature, the 'coordinates of governmental action are no longer legitimacy or illegitimacy but success or failure; rejection focuses not on the abuse or arrogance of power but rather on ignorance concerning its use' (Lemke 2011a, 46). Therefore, in order to learn whether the government is acting properly, 'it is necessary to investigate the "natural order of things" that defines both the foundations and the limits of governmental action' (Lemke 2011a, 46). According to Foucault, this second conception of legitimation and limitation of power has been dominant, although the first one has not entirely disappeared

Third, government is usually a consequence of an emerged problem. As Miller and Rose (2008, 14) put it, 'if the conduct of individuals or collectivities appeared to require conducting, this was because something in it appeared problematic to someone'. Importantly, problem is not treated as given but emerges as a result of different tactics of problematization. Therefore, in conducting analysis from the perspective of governmentality, one first should start with a question of how the rendering of things became problematic and therefore should focus on the process of problematization and the respective search for solutions to the problem. With respect to biopolitics, it means that different corporeal existence such as bodily experiences and biological characteristics (e.g. sexuality or madness) are not treated as given that should be uncovered by 'objective' scientific knowledge and corrected by medicine. Instead, they should be treated as outcomes of problematization. As Lemke put it, it explores how 'certain objects of knowledge and corporeal experiences become a moral, political, or legal problem' (Lemke 2011a, 178).

Biopolitics and governmentality

In his lectures at the Collège to France, Foucault never comes back to biopolitics again and never explicitly developed the connection between biopolitics and governmentality due to his death. However, according to Lemke, the two should be discussed together because for Foucault biopolitics was 'an art of government'. Here, one should recall the previous conceptualization of biopolitics as merely performed through disciplinary power. In other words, he first treated biopolitics as including only 'technologies of the body' and therefore biopolitics was a kind of 'body politics', performed on the *zoē*, the bodies, of individuals (Agamben 1998). However, in his lectures at the Collège do France, Foucault corrects his conclusions in the earlier studies where he explores subjectivity as the construction of 'docile bodies' as he focused only on the processes of discipline. With the notion of government, he thus explores the connection between the technologies of the domination and technologies of the self.

> I think that if one wants to analyze the genealogy of the subject in Western civilization, he has to take into account not only techniques of domination but also techniques of the self. Let's say: he has to take into account the interaction between those two types of techniques – techniques of domination and techniques of the self. He has to take into account the points where the technologies of domination of individuals over one another have recourse to processes by which the individual acts upon himself. And conversely, he has to take into account the points where the techniques of the self are integrated into structures of coercion and domination. The contact point, where the individuals are driven by others is tied to the way they conduct themselves, is what we can call, I think government. Governing people, in the broad meaning of the word, governing people is not a way to force people to do what the governor wants; it is always a versatile equilibrium, with complementarity and conflicts with complementarity and conflicts between techniques which assure coercion and processes through which the self is constructed or modified by himself" (Foucault 1993, 203-4).

The account for the 'technologies of the self' as a technology of power allows to apply biopolitics to the investigation of biopolitical processes in liberal democracies. Thus, Foucault asks: 'How can the phenomena of "population," with its specific effects and problems, be taken into account in a system concerned about respect for legal subjects and individual free enterprise?' (Foucault 2008, 317). Or, in other words, 'how are free subjects— subjects of law — governed when they are simultaneously understood as living beings?' (Lemke 2011a, 175). Consequently, viewing biopolitics as an art of government gives important advantages for it allows to account, not only of how the biological existence of people *zoē,* but also their moral and political existence *bios* are implicated in contemporary biopolitics. It thus allows to connect, not only two poles of power (individuals and population), but also two dimensions of human existence, that is, *zoē* and *bios*.

Hence, biopolitics includes three elements which together participate in biopolitical governance (Lemke 2011a, 2011b; Rabinow and Rose 2006). The first element is truth discourses and experts authorized to speak truth. These truth discourses include systematic knowledge about life and living beings and are required to 'provide cognitive and normative maps that open up biopolitical spaces and define both subjects and objects of intervention' (Lemke 2011a, 119). The second element is power strategies, including 'strategies for intervention upon collective existence in the name of life and health' (Rabinow and Rose 2006, 197) and strategies of power that 'mobilize knowledge of life and how processes of power generate and disseminate forms of knowledge' (2011a, 119). The first type of strategies also encompasses the strategies of subjectification. They include both bodily disciplining and regulation of the population and the self-constitution of individuals as individual and collective subjects. Subjectification in this second sense is performed with the help of 'technologies of the social', through which individuals identify themselves as part of a society, and 'technologies of the self', through which individuals shape a particular attitude towards their bodies, their health, and their conduct. The third element is the types of identities that subjectification produces. They include, for example, new biosocial communities such as patient groups (Rabinow 1996) and the new type of identity termed 'somatic individuality' (Rose 2006).

Biological citizenship and 'biopolitics from below'

Due to recent developments in biomedical and genetic sciences, biopolitics is undergoing transformations. Rabinow (1992) proposed the concept of 'biosociality' as an extension of Foucauldian biopolitics. By biosociality Rabinow means 'a new type of autoproduction' in which 'nature will be modeled on culture understood as practice' (Rabinow 1992, 241). Rabinow suggests that due to growing knowledge about genetic diseases and genetic predispositions to diseases, new individual and collective identities emerge. People start describing themselves and others using biological and genetic terminology. He further goes on to suggest that technical innovations also create new forms of socialization and identity politics. Thus, citizens are not passive recipients of bioscientific information and medical care but build communities such as self-help groups and patient associations through which they seek to understand themselves and their disease.

Besides leading to new forms of individual and collective identity, the growth and diffusion of biomedicine and genetics also lead to new forms of political activism and the demand of recognizing one's 'vital rights' related to one's genetic abnormalities. Heath, Rapp, and Taussig (2004) proposed the concept of 'genetic citizenship', and Rose and Novas (2004) introduced the term 'biological citizenship', which is similar but wider than genetic citizenship. Political activism which 'biological' or 'genetic citizens' would exhibit thus represents a 'biopolitics from below'.

To understand the role that citizenship plays in biological citizenship, Rose (2006) argues that one must break away from the political-philosophical considerations of citizenship and instead locate the different forms of contemporary citizenship within the political history of their 'citizenship projects', that is, the ways in which authorities thought about and acted upon certain groups of people as citizens. According to Rose, biological citizenship refers to 'all those citizenship projects that have linked their conceptions of citizens to beliefs about the biological existence of human beings, as individuals, as families and lineages, as communities, as population and races, and as a species' (Rose 2006, 132). Rose and Novas use the expression of 'making up' citizens, that is, constituting citizens with particular subjectivities, identities and self-understanding by authorities. In this way, they align the concept of citizenship with those theories of citizenship that treat citizenship not only as a formal connection between citizens and the state but as a lived experience of self-identification and participation, hence the term 'performative citizenship' (Butler 2011; Isin and Nielsen 2008).

Importantly, building upon the Foucauldian view of dispersed form that power assumes, in their conceptualization of biological citizenship Rose treats authorities not as the formal state apparatus but different experts. Doctors have been 'central to the development of the arts of government; not only the arts of governing others, but also the arts of governing oneself' (Rose 2006, 26). In recent years, these experts proliferated and include various 'counselors' – genetic, reproductive, family planning councilors – as well as nutritionists, fitness experts, physiotherapists as well as others 'pastors of the soma' under the sway of which individuals construct their subjectivities. The expansion of expertise is one of the key elements of contemporary liberal governance of individuals, which is exercised ‘at a distance’ (Rose 1993), that is, not directly through a formal state apparatus but indirectly through expertise and knowledge. Therefore, Rose states that biological citizenship is primarily a ‘regime of the self’ when ‘individuals shape their relations with themselves in terms of a knowledge of their somatic individuality’ (Rose 2006, 134). Biological citizenship also has a collectivizing dimension, of which ‘biosociality’ is the most obvious example. Activism, which may involve the state and political authorities, which Rose calls ‘rights biocitizenship’ and which will be the topic of Chapter 5 of this work, is part of this second collectivizing form of citizenship (Rose 2006, 134). Yet it is important to remember that authorities involve also ‘experts’ and that therefore the shaping of biological citizens’ identities, rights, duties and responsibilities may and does also take place in more mundane places such as fertility clinics.

The extension of sites where people exercise their entitlements makes an important contribution to the work on rights, as it helps illustrate how rights practice also figures ‘beyond the state’ (Petersen 2013, 268). The need to pay attention to such unconventional sites to see how technologies are being accommodated has been the call of scholars (Murphy 2009a, 2009b). According to Murphy (2009a, 2009b), ethnographic exploration of these sites and practices taking place there can disprove the claim of legal scholars that new technologies create only threats for rights. Indeed, in their often quoted study regarding PGD Franklin and Roberts (2006, 14) argued that

> Contrary to the image of genetic medicine ‘racing ahead’ of society, or impacting upon it like some wayward meteor, the description here reveals an intensely social activity that is very much in our midst. Many of the choices and challenges described in this book may be ‘new’ scientifically or medically, but the relationships involved — within families, between individuals and the medical profession, or between scientists and governmental regulatory authorities — are well established, and in some cases very old.

These practices, I argue, also constitute an important site of biological citizenship in the Italian case and the ‘vital rights’ that citizens will acquire in it will become the basis of those legal rights that will be litigated in courtrooms (Chapter 5).

Despite the enormous value of this reconceptualization of biopolitics, it has several shortcomings. First, according to Lemke (2011b), it does not pay attention to the different ways in which biopolitics from below is integrated into politics or biopolitics from above. For example, Heinemann and Lemke (2014) showed how the state has not entirely disappeared from the arena and biological citizenship is affected by the biopolitical imperatives of the state. Second, Sunder Rajan (2011) argued about the importance of paying attention to the context in which these processes take place and looking at other sites beyond 'advanced liberal democracies'. Third, it pays little attention to how exactly these 'vital rights', their claiming and satisfaction, are implicated in the process of government by producing a subject with a particular identity. I will come back to this particular issue in Section 1.3.2.

Bioconstitutionalism, biological citizenship and biopolitics/biopower

As I stated earlier, bioconstitutionalism draws on the ideas of biopower and biopolitics and is interested in exploring how life becomes the object of governance in a constitutional order. For example, Sunder Rajan points to the importance of 'biopower and biopolitics in helping us conceptualize the ways in which life became a particular subject of political understanding in modernity' (Sunder Rajan 2011, 194). In addition, the authors of bioconstitutionalism also draw on the idea of 'biological citizenship' to emphasize 'the self-molding and creative self-reinvention that occur in response to new biomedical knowledge, even when the subjects of this knowledge are disciplined, exploited, or suffering in various ways' (Sunder Rajan 2011, 195), and thus to 'celebrate the opening up of agency from below' (Jasanoff 2011a, 6).

However, and this is where bioconstitutionalism remains underdefined, the authors do not clearly define where biopolitics ends and where bioconstitutionalism begins. One potential difference between the two is the role of law. For example, Jasanoff defines bioconstitutionalism as 'fundamental understandings about the state's responsibility for life that are articulated and enacted through law and policy' (Jasanoff 2011b, 67), hence emphasizing the importance of law in articulating bioconstitutional rules. A similar interpretation is given by Winickoff (2015, 16) according to whom bioconstitutionalism is 'the especially deep entanglements of biology, constitutional law and the rights-bearing subject'. However, as I mentioned earlier, Jasanoff (2011a) also emphasized the importance of expanding the text of the constitution and to explore 'not only as these are formally construed by courts, but also as they are tacitly understood and worked out by scientists, lawyers, and policymakers, articulated in research practices; hardened into material technologies, or built into professional discourses' (Jasanoff 2011, 16). Similarly, as bioconstitutionalism also involves other sites where rights are forged and exercised and thus includes biological citizenship, bioconstitutionalism is broader than citizenship defined in legal terms. This broad definition of the constitution blurs the boundaries between strictly speaking law and non-law and draws bioconstitutionalism closer to biopolitics/biopower, as the latter also employs the 'legal complex', as well as to its reconceptualization expressed in 'biological citizenship'.

I suggest that bioconstitutionalism should be treated as one of the elements of biopolitics seen as a liberal way of governing (Lemke 2011a, 2011b). It belongs to its second element, namely, power strategies, and as such is a technology of power (Lemke 2011a, 2011b; Rabinow and Rose 2006, 197). More specifically, it can be defined as a strategy of intervention upon biological existence of citizens, articulated in the form of claiming, attributing, implementing, or exercising constitutional rights. Bioconstitutionalism as a 'strategy of intervention' should thus include, for example, *vital rights*, which are part of biological citizenship as 'biopolitics for below' (e.g. when citizens exercise their rights through using a particular biomedical technology or contest the exercise of political power through litigation, Chapter 5) and *positive rights* that the government grants 'from above' (e.g. when a parliament accords rights to new entities such as IVF embryos and implements restrictive regulations to protect such rights, Chapter 4, or when the judiciary recognizes the rights claimed by citizens during litigation, Chapter 5). This definition of rights (including the right to health and right to life) brings them into the domain of politics and therefore means that the definition of rights, of their ontological premises, subjects, objects and other 'building blocks of rights' (Jasanoff 2011a) are negotiable, changeable and subject to the influence of the local political and cultural factors. By exploring the social controversy around PGD in Italy, the rationalities used, the knowledges appealed to, the powers involved, and the outcomes achieved, it will become possible to understand the role that the appeal to constitutional rights plays in controversies around new biomedical technologies and practices. I will come back to examining and refining bioconstitutionalism in the Conclusion where I will discuss how this work will benefit from treating rights as technologies of power over life.

The importance of acknowledging that bioconstitutionalism is a particular form of making biological life an object of political concern is not sufficient for exploring how exactly rights participate in social controversies around new biomedical technologies and practices. It is important to explore the specificity of rights themselves as a legal and political artifacts. In what follows, I will describe the Foucauldian approach to law and rights and will show how it was taken up by other scholars. I will also illustrate the CLS approach to rights.

1.3.2. Law and rights: a critical approach

Foucauldian approach to law and rights

As Foucault himself said little concerning law, different interpretations of the Foucauldian view on law co-exist. The first main interpretation was given by Hunt and Wickham (1994). According to them, law in the Foucauldian view is an instrument associated with pre-modern monarchical sovereignty and therefore is defined in terms of commands, prohibitions and punishments. Foucault thus views law differently from the accounts of other scholars who both pluralize law and argue about the blurring of boundaries between law and regulatory forms of control (Hunt and Wickham 1994). In addition, in interpreting Foucault's position, Hunt and Wickham (1994) argued that Foucault attributes to law a subordinate role that supports another, more powerful form of power – disciplinary power.

> I do not mean to say that law fades into the background or that institutions of justice tend to disappear, but rather that the law operates more and more as a norm, and the judicial institution is increasingly incorporated into a continuum of apparatuses (medical, administrative, and so on) whose functions are for the most part regulatory (Foucault 1978, 144).

The second main interpretation is given by Ewald (1990) and Rose and Valverde (1998). According to them, Foucault interprets law both as an instrument of the sovereign and as an instrument of the 'legal complex', thereby decentering law and rejecting its unity. Law thus represents an 'assemblage of legal practices, legal institutions, statutes, legal codes, authorities, texts, norms and forms of judgment' (Rose and Valverde 1998, 542). According to Rose and Valverde (1998, 542), Foucault saw this legal complex as being 'pervaded by forms of knowledge and expertise that were non-legal' or, in other words, as being increasingly governmentalized. This legal complex operates not through juridical power but through norms. As a result, disciplinary and governmental power 'colonize' law, which as a result tends to reproduce and legitimize the former. For example, in his lectures at the Collège de France, he was exploring the connection between specific modes and forms of truth speaking, or what he called 'regimes of veridiction' and modes and forms of governance, or 'regimes of jurisdiction'. For Foucault, this connection is fundamental: the history of truth is coupled with the history of law (Foucault 2008, 35). He says: 'When penal practice replaced the question: "What have you done?" with the question: "Who are you?" you see the jurisdictional function of the penal system being transformed, or doubled, or possibly undermined, by the question of veridiction' (Foucault 2008, 34-35). Here we see a parallel with the idea that Rule of Technology might undermine and displace the Rule of Law (Brownsword 2008). However, in the case of governmentality, law is not displaced by technical reason but rather legitimates it, and the technical reason starts acting under the auspices of law.

Similarly to law, rights have an ambiguous position in the Foucauldian philosophy. On the one hand, rights were largely disregarded by Foucault because he did not treat them as shields able to protect individuals against the exercise of power. Because Foucault saw power as being exercised, not only though the formal state apparatus, but through other non-state practices, knowledges and techniques of governmentality, claiming the protection of rights from the state would only reify the effects of governmental power acting through law. Similarly, speaking about identity and identity-based rights (such as for gay people, women, disabled people, etc.), he warned against the dangers of the regulatory powers of identity and of identity-based rights as they further translate into life the effects of disciplinary power (Foucault 1980). Therefore, if we come back to the view of Foucault about the first type of limitation of political power in liberalism, that is, natural rights, even if such rights are implemented in law and do perform the function of the limitation of political power, in practice their liberating potential is undermined because through rights other forms of power such as disciplinary power of governmentality take shape.

The convergence of human rights with governmentality was also explored by scholars (Brown 1995, 2000; Guilhot 2008; Odysseos 2010; Sokhi-Bulley 2011a, 2011b). For example, Odysseos (2010, 748) argued that human rights produce a subjectivity *homo* *juridicus* which ‘is a subject amenable to self-government and, as such, acts as a partner, indeed a predicate, to neoliberal governmentality’. In this way, she criticizes Foucault for giving only marginal attention to human rights by showing how the latter even further enables neoliberal governmentality. Similarly, Wendy Brown concludes that rights do not simply act as instruments that the right claimant freely uses to achieve their own objectives. In discussing identity-based rights, Brown observes that ‘the more highly specified rights are as rights for women, the more likely they are to build that fence insofar as they are more likely to encode a definition of women premised upon our subordination in the transhistorical discourse of liberal jurisprudence’ (Brown 2000, 232). Hence, on the one hand, she builds on the Foucauldian critique of rights but, on the other, corrects it by saying that rights do not simply converge with disciplinary power but are ‘from the beginning a potentially disciplinary practice’ (Brown 1995, 99).

This research provides a valuable and missing contribution to the exploration of biological citizenship and the solidification of ‘vital rights’ by showing how the use of legal rights, via claiming, granting and implementing, is involved and further translates into life governmentality by creating a ‘legal subject’ endowed with legal freedom and capacity to act. However, as I will show in this work, rights can nevertheless work as a limit to governmentality. For example, when the Italian Parliament, pushed by the Catholic Church, enacted the rights of embryos, it acted exactly in order to withstand the governmental power of biomedicine. Although this act of Parliament can be criticized for other reasons, it nevertheless demonstrates the possibility of resisting the governmental power through the appeal to natural rights and human dignity.

On the other hand, Foucault personally participated in many political demonstrations. Telling is his participation against the war in Vietnam and the letter he wrote calling on the governments to protect rights. According to Lemke (2001) and Biebricher (2012), such actions of Foucault did not mean that he recognized the liberal view on rights as shields. Instead, he used them politically to gain freedom through practice. As Lemke (2011, 3) put it, ‘freedom does not take shape in institutional arrangements or legal texts. Rather, freedom is a practice, and the only way to preserve it is to claim it’. As Foucault himself stated: ‘the freedom of men is never assured by the laws and the institutions that are intended to guarantee them (...). “[F]reedom” is what must be exercised’ (Foucault 1980).

Critical approaches to rights

Critical socio-legal studies have been important in contributing to the discussion of legal rights and their ability to ensure states' recognition and satisfaction of their citizens' demands. Some scholars developed an extensive critique of rights, emphasizing such characteristics of rights as abstractness, indeterminacy, and individualism, foreclosing real social and legal progress (Tushnet 1983; Rosenberg 1991; Scheingold 2004). The 'crits' argued that the appeal to rights in judicial and political settings does not only fail to empower the weakest and the disempowered members of society but in fact reinforces and deepens existing relations of power and dominance. Assumingly positive rights such as the right to privacy of freedom of contract, so the crits argued, do not liberate but, in contrast, subordinate weak members of society and subject them to the power of the strong (MacKinnon 1987). Furthermore, the appeal to rights fails to bring to tangible legal and social changes because the judiciary is bound by the constraints of their legal culture (Rosenberg 1991). Specifically, legal precedents, grounding the very 'continuity scripts of the law' (Rosenberg 1991, 11), limit the judiciary's discretion and their power, for example, to declare new rights or extend old rights to new situations.

Probably the most famous 'loss of faith' in rights was expressed by Duncan Kennedy (2002). He argued that he lost his faith in rights because rights turned out to be just like any other type of rhetorical or policy arguments and therefore were not 'trumps' in the Dworkian (1977) sense. Even if they are used as 'trumps', rights have the ability to produce counter-claims and therefore the need to balance them will again reduce the dispute to some political or subjective arguments, as there is no objective criterion through which this balancing can be performed. As Kennedy observed, once 'the case requires a balancing of conflicting rights claims, it is implausible that it is the rights themselves, rather than the "subjective" or "political" commitments of the judges, that are deciding the outcome' (2002, 198).

The criticism of the use of rights was also the subject of much feminist critique (Petchesky 1987, 1995; MacKinnon 1987, 1991; Smart 2002; Brown 1995, 2000). For example, feminist legal scholars criticised rights based on their ability to produce counter-claims The abortion case has been used as one of the most illustrative examples. For example, Carol Smart (2002), following Kingdom, argued that winning rights could not lead to women's emancipation because of the tendency of rights claims to produce counter-claims related to other rights, such as men's rights, fetal rights and children's rights. According to Smart, these counter-rights could be, and are being, used to restrict women's access to abortion and constitute a disguised support for patriarchy. Therefore, for Smart, the use of rights by women is, in fact, counterproductive because instead of liberating women they simply reinforce and reproduce patriarchy.

Other scholars, being aware of the critical approaches to rights, nevertheless rejected the complete discarding of rights and emphasized the role of rights in bringing about positive social and legal changes and impoving legal and social position of disempowered social groups (Dworkin 1997; Minow 1990; Williams 1991; Cornell 1991). They generally subscribe to the idea of classical political philosophy, similarly grounding much of the contemporary human rights philosophy, that individuals possess some inalienable and universal rights based on the simple fact of being human. Rights thus represent a claim for having a space where individuals can exercise their interest and capability 'to will, to act, to choose' (Langlois 2010, 254). They sustained that a necessary element of a just political order is a work of translating of these natural and inalienable rights, already enacted in the countries' constitutions, into positive law, for example, through judicial decisions and legislation.

In order to bring such positive changes into law though rights, many feminists and critical race theorists engaged in the project of reconstructing rights. For example, critical race theorists emphasized the importance of using rights strategically to achieve political changes. What does it mean to use rights strategically? To begin with, it is to 'rhetorically invoke the "trump" aspect of rights discourse-capturing a sort of historical residue of rhetorical meaning' (Roithmayr 2000, 1127), without necessarily subscribing to the Dworkian idea that rights are indeed trumps. Further, according to Williams (1991), communities may use rights as tactical means to achieve material gains. Framing their demands through a language that the majority still adheres to could improve their material position.

Other feminist scholars, for example, sought to tackle the individualism that characterizes the traditional – liberal – conception of rights. They suggested that rights should be reconsidered and seen not as shields protecting the individual space against intrusion but, in contrast, as relations. For example, Nedelsky (2011) proposed to regard rights as tools that structure relationships among people in such a way that they foster certain values. Thus, she puts in the centre of her reconstructed definition of rights values and relationships that promote those values. Further, Herring (2013) suggested that rights could be seen as an instrument protecting relational values such as care and responsibility. While rights can and, for the most part, do protect individual values and interests, according to Herring, they can promote relational values and interests as well. However, despite these attempts to reconceptualize rights, the conceptualization of rights as instruments clearing a space for individuals ‘to will, to act, to choose’ (Langlois 2010, 254) remains the prevailing one.

Bioconstitutionalism and rights

One of the main omissions of current research on bioconstitutionalism, is that its authors do not engage sufficiently with critical legal scholarship, feminist studies and other studies that have explored rights from a critical perspective. In particular, none of the authors engaged in the project of bioconstitutionalism explore rights-biomedicine interaction from the critical perspective on rights. However, such work can significantly benefit the theorization of bioconstitutionalism by showing the political and ideological underpinnings of how rights are claimed and defended in technoscientific controversies. This issue will be the topic of Chapter 5 of this thesis.

1.3.3. Co-production of law and technology

Bioconstitutionalism as developed by Jasanoff and others (2011b) builds on the idea of the co-production of social and technoscientific orders (Jasanoff 2004a). The underlying meaning of the idiom of co-production is that science and technology, on the one hand, and society, including law, on the other, do not develop independently but, in contrast, mutually produce and reinforce each other. As Jasanoff observed, ‘knowledge and its material embodiments are at once products of social work and constitutive of forms of social life; society cannot function without knowledge any more than knowledge can exist without appropriate social supports’ (Jasanoff 2004, 3b).

Regarding law, the idea of co-production, unlike deterministic thinking, implies that while law might indeed be in need of being fine-tuned to grapple with new questions, law is nevertheless ‘already present as a conceptual and cultural resource, governing responsible human behavior and conditioning the terms in which people imagine the normative organization of their worlds' (Jasanoff 2011). For example, scholars developing the idea of co-production build on the works of Shapin and Shaffer (1995) or Ezrahi (1990). According to them, the ideas of what democracy is have been intertwined with the conception of 'good science'. Both authors illustrate how the understanding of 'good science' and the understanding of democracy went hand in hand. With respect to rights, this position means the need to abandon deterministic thinking regarding rights. As stated above, it is important to see rights not as mere passive guarantees that should be protected against erosion but as flexible social and legal instruments.

The idea of co-production has affinity with two philosophies. First, it traces back to Latour and to his view of the world as being essentially 'hybrid' rather than composed of clearly separated or separable pure elements of nature and culture (Latour 1993). However, Jasanoff observes that while co-production builds on this perspective, it overcomes Latour's overemphasis on material products and also takes into account the many ethical norms, political interests and legal commitments that participate in the mutual stabilization process of technoscientific and social worlds (Jasanoff 2004). However, she criticized this approach as not paying enough attention to agency and moral commitments. Therefore, with the idea of co-production, Jasanoff is more interested in exploring the role of law and its normative power. In this sense, co-production draws closer to the late Foucauldian thinking on governmentality in which he asserts his argument about the mutual constitution of the regime of jurisdiction and the regime of veridiction and explores the possibility for and the conditions of freedom.

Boundaries

An important implication of the mutual construction of science and society is the acknowledgment that the existence and drawing of *boundaries* – between human and inhuman, nature and culture – is a social and therefore contingent process and not an automatic application of their pre-given definitions (Latour 1993). Boundaries are needed because they help maintain social order, and the separation of objects and practices of external reality from their opposites help maintain or at least create the illusion of this order's presence. In reality, however, all these categories are essentially 'hybrid' and mixed up (Latour 1993). The recognition that boundary drawing is an essentially social process allows us to look differently at the taken-for-granted boundary between science as a self-contained and bounded body of objective knowledge about the world, on the one hand, and society, including law, as a domain of values, economic interests and political rationales, on the other. Unsurprisingly, researchers working both in public policy and academia have acknowledged that this boundary is a myth. They merely differ in views whether it has always been a myth that has recently taken on a new form (Shapin and Shaffer 1985; Jasanoff 2004a) or whether it is a particular characteristic of the latest trends in scientific development due to its rising complexity, uncertainty and risk (Funtowicz and Ravetz 1993). In any case, all agree that things are mixed up.

The recognition that boundary drawing is an essentially social process has given ground to much work exploring how exactly this boundary work is performed. A number of concepts emerged, such as ‘boundary-work’ (Gieryn 1983, 1999; Wainwright and others 2006), ‘boundary organization’ (Guston 1990), and ‘boundary objects’ (Star and Griesemer 1989). In addition, their methodological potential in uncovering the intricacies of the science/politics demarcation has led to the expansion of issues studied through the lens of boundary work. For example, the concept entered into the methodological toolkit of scholars interested in the production of scientific knowledge for policy purposes called ‘regulatory science’ and the role of non-scientists, including policy-makers, in drawing the dividing line between science and policy (Bijker et al. 2009; Jasanoff 1990; Wynne 2002; Guston 1999).

Bioconstitutionalism and co-production

Bioconstitutionalism builds on the idea of co-production of social and technoscientific orders. For example, it dedicates a lot of attention to the problem of boundaries. Thus, one of the interests of bioconstitutionalism is how countries deal with ‘boundary-crossing’ objects created by science and technology, such as entities produced via somatic cell nuclear transfer, human-animal chimeras or IVF embryos, are classified by state regulatory agencies, as a form of top-down bioconstitutionalism. For example, it is relevant to analyze whether regulatory agencies will place these new techno-scientific objects in the domain of constitutional law, where they will be regulated as members of the relevant political community, or in the domain of science, where the language of risk will reign (Metzler 2011). These boundary-crossing entities are in themselves hybrid, produced via technological means and owing to human ingenuity. Yet, for the purpose of regulation, regulators seek to fix their identity in order to know what to do with them. Consistent with the main idea within STS of co-production, bioconstitutionalists attempt to show how this classification of objects into 'objects' or 'subjects' follows countries' important constitutional traditions. This work will also engage with the idea of boundaries. In Chapter 4, it will illustrate the importance of rights for such fundamental boundaries as those drawn around medical professions and knowledge.

1.3.4. Technology regulation and future-proofing of rights

The conclusion that rights should not be regarded as mere passive guarantees in need of protection is reminiscent of much European scholarship in human rights law and technology regulation (Brownsword 2008, Murphy 2009, Hildebrandt 2008, Yeung and Dixon-Woods 2010, Flear and Vakulenko 2010, Flear 2015), which the authors of bioconstitutionalism almost entirely neglect. Furthermore, scholars in technology regulation, and this is where they add to the further elaboration of the idea of bioconstitutionalism, explore not only how rights change due to biomedical advances, but they are also interested in how rights could and *should* be recast in order to withstand challenges posed by biomedicine. For example, much concern in this literature has been expressed with respect to the risk that the Rule of Technology might displace the Rule of Law and become new ways of governing (Brownsword 2008). This 'revolutionary sting' is reminiscent of the Foucauldian studies on governmentality, which point to a similar relationship between new technologies and the Rule of Law. Both scenarios underline the potential for human rights to become merely one of several 'technologies of hubris' (Jasanoff 2004; Flear and Vakulenko 2010), an empty shell that is designed to quiet public dissent.

Authors in technology regulation also explore how rights are being challenged by other normative discourses such as dignitarianism and utilitarianism, making part of the so-called 'bioethical triangle' (Brownsword 2009). According to Brownsword, human rights represent a point of departure in the emerging international regulatory framework on new technologies that has been pioneered by UNESCO, but they do not stand alone. They are instead one part of an ethical plurality, or 'bioethical triangle', sharing the regulatory terrain with both a dignitarian ethic and a utilitarian one. Moreover, although the dignitarian ethic and the human rights one share a commitment to human dignity, they differ radically as to what is needed in order to protect and promote this commitment. In the rights ethic, dignity is linked to autonomy and empowerment whereas, for the ‘dignitarian alliance’ (Brownsword 2009), dignity is invoked as the reason why we must say ‘no’, ‘no more’, or ‘enough’ to particular technologies (Murphy 2009). This difference of opinion on human dignity, and more generally the existence of three different ethical frameworks, will not be always problematic; sometimes utilitarians, dignitarians and rights advocates will be in agreement. But it does suggest that a regulatory framework might be less viable over the longer term and because also challenges the idea of human rights as law’s main ‘hope technology’ (Murphy 2009).

1.4. Method

1.4.1. Discourse analysis

The main method used in this thesis is discourse analysis. It applies the idea of performing two-level analysis of discourse elaborated by Hajer (1995). This approach enables the researcher to approach the analysis of abstract political processes through the analysis of concrete political events, individual strategic actions and speech acts. Following Foucault (1980) and Hajer (1995), I understand language not only as a means of communication, but also as a practice that shapes reality. For example, calling an embryonic entity ‘a human person’ does not mean a neutral description of objective reality, but effects a construction of reality according to the normative stance of the speaker.

Following Hajer (1995), I pay attention to individual actors and therefore perform discursive analysis on the level of interpersonal communication. Specifically, I explore two elements. First are subject-positions. Subject-positions differ both from Foucauldian ‘subjectivity’ and conventional psychological ‘roles’. Subject-positioning represents ‘an integral part of the processes by which people construct accounts of themselves in interaction with others ... as people actively take up positions within different, and sometimes competing, discourses’ (Jorgensen and Phillips 2002, 110). It sees people as ‘active, selecting and adapting thoughts, mutating and creating them, in the continued struggle for argumentative victory against rival thinkers’ (quoted in Hajer 1995, 54). As a result, they seek ‘not only to make others see the problems according to their views but also seek to position other actors in a specific way' (Hajer 1995, 53). This view of a subject as 'decentered' allows us to understand logics of the argumentation of a specific actor that may at first glance seem unintelligible, but also to illuminate how a subject through argumentation can sustain or transform discourses. For example, politicians appealing to strong normative principles can be accused by their opponents of religious 'fundamentalism' and unwillingness to accept and account for the multiplicity of different opinions on the issue. Therefore, these politicians may appeal not to religious truth as a justification for their position but to science. However, the 'discursive affinity' of their argument with religious teaching nevertheless leads their opponents to position them as religious dogmatists and discard their arguments as illiberal.

Second, I analyze how the production, reproduction, transformation and change of discourses happen through concrete utterances—something that Foucauldian analysis has largely neglected. 'The fact that there are similarities between statements (i.e. historical continuity) is to be explained by memory or historical references that people draw upon in a new speech situation.' And, further 'the rules and conventions that constitute the social order have to be constantly reproduced and reconfirmed in actual speech situations, whether in documents or debates' (Hajer 1995, 55). Here metaphors can be very important: as illustrated in the following Chapters, 'Procreative Far West', 'the embryo is one of us', 'a son at any cost' have been metaphorical 'anchors' that sustained and steered the controversy over PGD in Italy.

This reproduction of a discourse often leads to 'blackboxing': the process through which things start appearing 'natural' and fixed (Latour 1987). Blackboxed things or practices are usually taken for granted and are not challenged, reconsidered or changed. Opposition to blackboxed things or practices is either not possible or hampered. Questioning routinized practices that are taken for granted is difficult, because opponents can easily undermine the viability and credibility of alternative modes of thinking by referring to historical memory and traditions – 'we have always done it that way'. For example, state prohibition of clinical practices such as PGD that were wide-spread in Italy can lead to the objection that, since these practices are so wide-spread, both nationally and internationally, they are widely supported by the public and do not contradict public morals. However, the dependence of discursive change on the degree of its routinization and 'blackboxing' remains salient and cannot claim absolute predictive power. For example, an opposing party can always interpret routinized practices differently, by saying that they developed exactly because there had been no state intervention in their regulation and that the fact they are so wide-spread is the main reason for needing to outlaw them. Indeed, this challenge to blackboxed clinical use of embryos in Italy was successful and resulted in the prohibition of any sort of embryo manipulation in 2004. Therefore, the analysis of concrete statements uttered in public but also expressed through written documents, be they laws, law drafts, proposals or government opinions, is important to understand how and why particular ideas, understandings or values reproduce, transform or change.

1.4.2. Primary and secondary sources of analysis

The primary sources of analysis in this work are bills, parliamentary debates and court proceedings. I have extracted the texts of all bills submitted to the Italian Parliament (71 bills in total) and the minutes of the parliamentary debates in the period from 1984 till 2004, from the website of the Italian Senate, www.senato.it. Despite the voluminous data, I have performed traditional text analysis of the minutes of parliamentary debates using manual analysis and close reading of the texts, both to trace (potential) gradual changes in argumentative techniques and the meanings invested by speakers in their speech acts. I have also extracted court rulings (20 rulings in total) from the websites www.altalex.it and www.cortecostituzionale.it. Similarly to the legislative debates, I have applied manual, close-reading text analysis of the court rulings.

To help understand the primary sources and place them in the broader social context in which the relevant debates took place, I have furthermore analyzed the secondary Italian literature, which has widely discussed the pre-Law and post-Law debates.

1.5. Contribution

The main contribution of this thesis consists in providing much-needed exploration of the role of rights for the regulation of biomedical practices and technologies from the critical and not strictly legal perspectives of CLS, STS and Foucauldian philosophy. The importance of researching the role of rights for biomedical regulation from such perspectives has been already much emphasized by lawyers interested in investigating this topic (Murphy 2002). For example, Murphy and Ó Cuinn (2013) proposed to use ‘STS as a human rights method’ to read and interpret courts' jurisprudence, its effects and consequences. According to Murphy and Ó Cuinn (2013, 289), STS 'seems a great deal more engaged and engaging, and a great deal more reflexive, than their international human rights law counterpart' in the analysis of people's dealings with new technologies. Thus, they praised the work on 'biological citizenship' (Rose 2006) as well as stressed the importance of ethnographic research (Franklin and Roberts 2006) to provide an alternative understanding of how individuals deal with new biomedical practices to the one accepted in mainstream legal thinking. Such an understanding, according to them, would help to dispel the fears prevailing in legal scholarship about 'science racing ahead' and jeopardizing some important legal guarantees.

The work on bioconstitutionalism has been an important step towards such alternative explorations. Indeed, Murphy and Ó Cuinn (2013) also mention it as a valuable contribution to more nuanced research on rights-biomedicine interaction. However, as I stated above, the idiom of bioconstitutionalism remains underexplored in several ways. First, it is not entirely clear how bioconstitutionalism relates to biopolitics/biopower/biological citizenship. Second, authors do not engage with CLS to explore the ideological underpinnings of rights discourse. Third, and perhaps most importantly, they are more interested in exploring the patterns along which bioconstitutional transformations evolve and are less interested in pinpointing the problems of using rights as benchmarks for biomedical regulation. Therefore, further work is much needed to take on and further explore bioconstitutionalist approaches to the analysis of rights.

This thesis attempts to address these gaps. First, it elaborates the definition of bioconstitutionalism, suggesting that it could be defined a strategy of intervention upon the biological existence of citizens, articulated in the form of claiming, attributing, implementing, or exercising constitutional rights. This clarification does not only make bioconstitutionalism more analytically tractable, but also adds to the theorization on biopolitics by illustrating that the rights and sovereign power have not waned in modernity but are 'alive and well' (Smith 2000, 285). Second, it engages with CLS (Chapter 5) and explores the advantages and shortcomings of using rights litigation as an instrument that 'biological citizens' can use to withstand biopolitics from above. Third, in the Conclusion (Chapter 7), this thesis explores the pitfalls and the positive aspects of using rights for the regulation of biomedical technologies. Fourth, it adds to the research on the regulation of biomedicine through rights by expanding the notion of constitutionalism and exploring the different sites in which rights can originate and citizenship can be practiced.

The Italian controversy around PGD serves as a productive methodological site for exploring this problematic. Although all chapters of this work relate to Italy (with the exception of Chapter 6, which is a comparative chapter), they all discuss the problematic of rights from different, partly overlapping, perspectives and engage with different concepts (boundary-work, natural rights, governmentality, biological citizenship, rights vs. counter-rights). This combination of perspectives on the same case allows a deep and nuanced analysis of the controversy and the role of rights in it and prevents a flattened and simplified account of the debate (which in my view characterizes the work of many scholars writing about the debate, such as Patrick Hanafin). In order to overcome the limitations of a one-country case study method and to illustrate the importance of context for bioconstitutional transformations, Chapter 6 provides a comparison of how ART and human embryo stem cell (hESC) research have been approached by regulators in Italy and Germany.

1.6. Chapters outline

This work consists of four academic articles that have been submitted (Chapter 3) or accepted for publication (Chapters 4, 5 and 6). After explaining related theories and methodologies in the present chapter, this work first provides a brief overview of the events surrounding PGD in Italy in Chapter 2, which can serve as a point of reference for the reader to keep an overview of the different debates and events. The following three Chapters explore the three crucial instances in which rights have been involved and debated in the Italian controversy on PGD: the debate on and enactment of restrictive provisions of Law 40/2004 to protect the rights of IVF embryos (Chapter 3); the debate around the provision that allowed the implantation of the maximum of three embryos, both in Parliament and courts (Chapter 4), and the litigation campaign of Italian citizens (Chapter 5). These three elements of the controversy are covered in the Chapters in largely chronological order. Therefore, each Chapter allows to not only get a deeper understanding of how rights figured in the controversy, but also tells a story about a specific stage of the controversy and, taken together, they reconstruct the history of the debate on PGD. Finally, Chapter 6 compares the regulation of IVF, PGD and hESC in Germany and in Italy. In Chapter 7, I draw conclusions from the analysis in all these Chapters.

More specifically, Chapter 3 explores how a rationality of government – natural rights as an external legitimation of political power – was employed to classify IVF embryos either as entities having a mere biological existence as *zoē*, or as human persons, capable of moral and political existence, as *bios.* I show how through the appeal to natural rights of embryos, the latter were granted legal subjectivity and rights, and how the implementation of the restrictive regulation of ART to ensure the 'making live and letting die' (Foucault 1980, 70) of these new Italian citizens was performed. In this way, I contend that natural rights have not been displaced by other rationalities for the exercise of political power such as nature as an internal self-limitation of power. This conclusion may fit with the acknowledgment of other scholars that the argument in favor of protecting human nature or human dignity, broadly termed 'dignitarianism', has increased because of fears that the new biomedical technologies may erode the fundamental basis of humans – human dignity (Brownsword, 2008). Finally, I argue that the three elements of biopolitics suggested by Lemke – knowledge, power and subjectification – also help structure the exercise of biopolitics in cases where natural rights act as external limits to government, but they take a different shape if biopolitics is exercised according to this modality than they often do in biopolitics as described so far in most literature.

Chapter 4 focuses on the debate around the provisions of Law 40/2004 that prescribed a uniform method of performing IVF in Italian fertility clinics. Specifically, the Law obliged the treating practitioner to fertilize no more than three oocytes during one IVF cycle and to transfer all the embryos created into the patient's uterus simultaneously. By setting this 'three embryo standard as the constitutive element of IVF, the pro-life members of the Italian Parliament sought to prevent the creation of surplus embryos and their cryopreservation, and thereby to ensure the rights of IVF embryos. Drawing on the concept of boundary-work (Gieryn 1983, 1995), I explore how the Italian Parliament justified the expansion of the jurisdictional powers of the State into a domain traditionally occupied by the medical profession, namely, the prescription of treatment methods, and how the Italian Constitutional Court established and motivated the constitutional illegitimacy of the Parliament's actions. I argue that the demarcation of the jurisdictional domains of the medical profession and the

Italian State depended upon how the latter tipped the balance between the conflicting rights of IVF embryos and the rights of adult Italian citizens, and the procedures of embryo surplus production and cryopreservation acted as a terrain where both the State and the medical profession came to defend their interests. As such, the demarcation of the jurisdictional and occupational boundaries of the medical profession and the State, and the definition of constitutional rights, formed two sides of the same bioconstitutionalist governing project.

Chapter 5 explores the Italian litigation for access to PGD as an example of biological citizenship. It pays particular attention to how exactly the interests of citizens have been recognized through rights litigation and therefore engages with the critical approach to rights. It illustrates that the recognition of citizens' interests in the Italian litigation process was partial, because the Constitutional Court accepted only the protection of mothers' health as a justification for having access to PGD. Instead, relational values and interests of biological citizens such as responsibility and care for the health of their future children, the core element of biological citizens' identity, that the plaintiffs displayed during litigation, were not recognized by the Italian Constitutional Court. It links this partiality to the prevailing (bio)ethical construction of the embryo as a person whose rights the State was obliged to protect, which was consolidated in the Italian legal doctrine. It argue that what was at stake in the Italian litigation for PGD was a dispute which right – a more individualistic right (to health) or right that encompassed also relational values (the right to reproductive self-determination) – should legitimize the access to PGD. The former, however, prevailed over the latter due to the high value attributed to unborn life in the Italian constitutional order, urging the Constitutional Court to recognize that right that would better promote this value. Hence, the recognition of biological citizens' 'vital rights' claimed vis-à-vis the state through litigation in Italy was partial; however, this was so not because the existing relations of power affected how individualistic rights would be balanced, but because certain important societal values, consolidated in the constitutional jurisprudence of Italy, prevented the participants of the debate from reconceptualizing the right to PGD from an individualistic into a more relational one.

Chapter 6 puts the Italian controversy on PGD in a comparative perspective and compares the ways in which Germany and Italy, countries with comparably strong bioethical reservations against new biomedical technologies, debated and enacted regulations on IVF, hESC and PGD. It is directed towards analyzing human dignity because exactly the protection of human dignity, conceptualized as sanctity of life in Italy, was the main purpose for adopting the restrictive Law 40/2004. It explores the debate on these technologies in Italy and Germany from a comparative perspective to shed light on when and under which circumstances the appeal to human dignity in public debates around new technological and scientific practices becomes problematic. The main argument of this Chapter is that in both countries, ‘human dignity as constraint’ played a key role in the political debate around the new ART and hESC research, mainly because these were framed as a potential assault on human dignity. Yet, the two countries differed in terms of their success to build their policies regarding ART and hESC research upon the principle of human dignity. Two factors were responsible for this difference. The first factor was whether dignitarianism is the dominant bioethical perspective in the relevant country. The second factor was the degree to which the regulators were willing to strike compromises with their opponents if dignitarianism was not the dominant bioethical perspective or was competing with other bioethical perspectives for regulatory relevance.

Finally, in Chapter 7, I draw conclusions from previous Chapters to answer the main research questions. I first conclude how rights figured in the debate on PGD and then discuss the advantages, problems and difficulties of using rights for regulating new biomedical technologies such as PGD.

CHAPTER 2

The debate on preimplantation genetic diagnosis in Italy

2.1. Parliamentary debate[1]

2.1.1. IX Legislature (1983-1987)

Santosuosso Commission

First attempts to regulate the application of reproductive technologies in Italy date back to mid-1980s. In 1984 the then Minister of Health Costante Degan set up a special interdisciplinary commission to inquire into technical, scientific, ethical, social and legal issues raised by homologous insemination and to produce a text that could subsequently serve as the basis for a law. The Commission included doctors, biologists, philosophers, lawyers and public officials and was presided by the then judge Fernando Santosusso. The debates of the Commission lasted one year and resulted in the presentation of two bills preceded by explanatory reports. They prohibited heterologous insemination, gamete donation, the access to reproductive technologies to single women and homosexual couples, but allowed the production of surplus embryos and their following cryopreservation if that was necessary to protect woman's health.

Degan Circular

The Government did not implement the proposals of the Santosuosso Commission. Instead, two months prior their publishing, he issued a ministerial circular entitled "Limits and conditions of legitimacy of services for artificial insemination in the domain of SSN". The Circular prohibited the creation, freezing and preservation of embryos for research and industrial purposes, as well as for deferred implantation. It was more restrictive than the proposals of the Santosuosso Commission which allowed embryo cryopreservation. An important feature of the Circular consisted in that it applied to public IVF clinics only, that is, to those that belonged to the National Health Service ("Servizio Sanitario Nazionale", SSN).

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[1] Since the following Chapters only discuss parts of the Italian PGD debate that are relevant for the purpose of the Chapter at issue, this Chapter offers a more comprehensive, descriptive overview of the Italian PGD debate, which the reader can use for reference purposes. This Chapter thus integrates various descriptive parts that feature in the following Chapters.

The provision of IVF services by private clinics therefore remained beyond the regulatory scope of the Circular.

First bills

Alongside governmental attempts to bring ART under state control, the intention to initiate parliamentary discussion of the future law also came from the Italian Parliament. Several parliamentarians engaged in the drafting of a number of bills which expressed alternative visions of how reproductive technologies ought to be regulated. In total 9 bills were submitted to both the Chamber of Deputies and the Senate. The main purpose of the majority of the presented bills was to avoid abuses which the unregulated sector of assisted reproduction could give rise to. These abuses boiled down to the commercialization of reproductive technologies, 'exploitation' of patients, infliction of harm on women and newborns and a number of controversial practices as eugenics and surrogacy. Unlike the Santosuosso reports, the need to outlaw these detrimental practices was framed without any explicit reference to establishing certain normativities.

Donum Vitae

In 1987, the Congregation for the Doctrine of the Faith, the highest-ranking department of the administrative apparatus of the Roman Catholic Church, published the Instruction for Human Life in Its Origin and on the Dignity of Procreation *Donum Vitae*. The Instruction contained the official position of the Roman Catholic Church on the issues of human assisted reproduction. The only reproductive technology that the Instruction approved was homologous insemination. IVF was condemned, together with other technologies (heterologous insemination, surrogacy) because they violated firm principles of Catholic teaching: 'the life of the human being called into existence and the special nature of the transmission of human life in marriage'. A notable feature of the Instruction was that it included the requirements with regard to assisted reproduction addressed both to those who used them (patients, clinicians, scientists) and to regulators. Furthermore, it created an explicit link between moral values and positive law.

2.1.2. X Legislature (1987-1992)

Petition 'For life and dignity of the man'

In September 1987, a petition 'For life and dignity of the man' signed by 2.5 millions of Italian citizens was presented to the Italian Parliament. The Parliament was asked to extend legal protection to the embryo from the moment of conception that could guarantee "respect for life being born and dying" ('la vita nascente e morente'). The draft of the petition's text and the collection of signatures have been organized by the Movement for life and personally by its president Carlo Casini.

Bills and the parliamentary motion

Later, the text of the popular petition became the basis of two important legal documents which set the stage for further deliberation of reproductive technologies. In July 1988, a number of parliamentarians presented a parliamentary motion which appealed to the Italian government and called it 'to promote a moratorium on all types of research and experimentation related to the manipulation of embryos'. Later, in December of the same year, 23 parliamentarians, including Carlo Casini and the president of the Christian Democracy Mino Martinazzoli drafted and presented to the Parliament a bill also building upon the text of the petition. The main purpose of the Martinazzoli bill was to 'extend the protection of the right to health and to physical integrity onto the initial phase of human existence' and thereby to recognize human embryo as a subject of rights, particularly of the right to life. Besides Martinazzoli bill, another seven bills, both of liberal and more restrictive disposition, were submitted to Parliament.

Establishment of the National Committee on Bioethics

Another way of establishing state control over the development and use of reproductive technologies consisted in setting up an institution that would discuss and pronounce decisions on ambiguous issues raised by new scientific and technological developments, including reproductive technologies. A number of parliamentarians suggested to establish a Committee (or Commission) charged with a task of considering 'bioethical' topics. According to them, this institution should be composed of members with high scientific record and act independently from the Parliament but be accountable to the Presidency of the Council. Other groups of parliamentarians stressed that a body with similar competences should be instituted but it should be accountable to the Parliament. A third motion was made to institute a Commission within the Ministry of Health. The latter has been immediately discarded as similar and 'unsuccessful' attempts have been already made through the institution of the Santosuosso Commission. The motions were consolidated into a parliamentary resolution that paved the way for the institution of a national Italian bioethics committee - the National Committee on Bioethics instituted in 1990.

2.1.3. XI (1992-1994) and XII (1994-1996) Legislatures

Busnelli Commission

In XII The Ministry of Grace and Justice established another inquiry commission presided by Francesco Busnelli in the XII Legislature. The Commission issued a report which had a rather liberal frame: it recognized the right to access heterologous and post-mortem insemination, gamete donation and did not forbid embryo cryopreservation. However, the report of the Busnelli Commission was met with an arduous opposition from the Vatican. According to Busnelli himself, this was the reason why the project was not passed to the parliament: "the work had been done, but the results have been put on the shelf".

Bills

Beside the work of the Busnelli Commission, the Parliament received a number of bills from various parliamentarians. Thus, in XI Legislature in total five bills were submitted and sixteen bills during XII Legislature. However, all of them had the same destiny: with the fall of parliamentary coalitions, their discussion had not even started.

2.1.4. XIII Legislature (1996-2001)

'Progetto Bolognesi'

The task of elaborating a bill was assigned to the Commission on Social Affairs of the Chamber of Deputies presided by Marida Bolognesi, a member of the 'Democrats of the Left' ('*Democratici di Sinistra - L'Ulivo*'). The Commission received in total seventeen different proposals elaborated by individual parliamentarians and parliamentary groups. To make the process of deliberation more efficient and smooth, Bolognesi set up a special Restrictive Committee. After several months of intensive deliberation, the Restrictive committee came up with a bill. The Bill represented a clear attempt to find a compromise between opposing views on the right way of regulating ART. Among its most significant provisions were the prohibition of the access to IVF to singles and to homosexual couples and the restriction of the number of embryos to be produced to four in order to avoid the problem of surplus embryos. At the same time the Bill allowed heterologous insemination and embryo cryopreservation. In addition, it did not oblige the doctor to implant all the embryos simultaneously, which meant the possibility to select embryos without general and chromosomal abnormalities in the case PGD was sought. During the discussion of the Bill in the Commission of Social Affairs, it was amended. In particular, the provision that restricted the number of produced embryos was modified: the embryos had to be implanted simultaneously. However, the overall spirit of the law remained the same.

Several parliamentarians, including the most active opponent to this bill, a member of the ultra-right conservative party North League Alessandro Cè published a Report of the minority group. Cè became the main and most active opponent to Bolognesi when the bill was passed to the Chamber of Deputies for further deliberation. Cè promoted the granting of legal personhood to the human embryo. Almost immediately after the bill was passed to the Chamber of Deputies, art. 1 of the bill was amended to include the embryo in the list of subjects whose rights the future law had to protect. Marida Bolognesi refused to support the bill and her position as a Reporter for the majority group was substituted by Cè. The Chamber of Deputies voted for the amended bill in its restrictive formulation.

When the bill was passed to the Senate for deliberation, some of its provisions that had been amended by the Chamber of Deputies, were amended again. One of them was the provision that granted rights to the embryo. However, the approved bill was abandoned because of the fall of the coalition government.

2.1.5. XIV (2001-2006) Legislature

Law 40/2004

Similarly to the XIII Legislature, in the XIV Legislature, the work on a bill on ART was delegated to the Commission on Social Affairs of the Chamber of Deputies. The Commission received in total sixteen bills from different parliamentarians and parliamentarian groups. Again, similarly to the previous Legislature, the Commission established a Restrictive Committee to examine them and to elaborate a unified bill. The Committee held a number of informal meetings with two experts in biomedicine, doctors Carlo Flamigni and Bruno Dalla Piccola, who provided the Committee with technical details about the use of reproductive technologies. As a result of the internal meetings of the Committee and taking into account the opinions of medical experts, the Commission elaborated a unified bill. Its spirit and text were very similar to those of the bill voted for by the Chamber of Deputies in the XIII Legislature. It prohibited heterologous insemination, embryo cryopreservation, PGD, the access to IVF to single women and homosexual couples and laid down the obligation to produce no more than three embryos and to implant them simultaneously. The Chamber of Deputies adopted the Bill without introducing any amendments. After the Senate introduced slight changes regarding the rights of embryos, it was passed for approval to the Chamber of Deputies. On 10 February 2004 the Chamber of Deputies approved the bill, which became Law 40/2004.

In art. 1, the Law recognized the human embryo as a right-holder. It allowed the access to ART only to infertile couples if other methods of treating infertility resulted unsuccessful.[2] Further, in art. 13, the Law forbade embryo experimentation,[3] prescribed that

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[2] Law 40/2004, art. 4 para. 1. ‘Il ricorso alle tecniche di procreazione medicalmente assistita è consentito solo quando sia accertata l'impossibilità di rimuovere altrimenti le cause impeditive della procreazione ed è comunque circoscritto ai casi di sterilità o di infertilità inspiegate documentate da atto medico nonché ai casi di sterilità o di infertilità da causa accertata e certificata da atto medico’.

[3] ibid, art. 13, para. 1. ‘È vietata qualsiasi sperimentazione su ciascun embrione umano’.

clinical and experimental research must be performed only for the sake of the embryo itself,[4] and forbade the creation of embryos for scientific and experimental research and eugenic embryo selection.[5] Finally, in art. 14 it prohibited the discarding and cryopreservation of embryos,[6] and further prescribed that the doctors must not 'create embryos in a number higher than the one strictly necessary for a single and simultaneous transfer, and in any case not more than three'.[7] The only exception to the general rule of the prohibition of embryo cryoconservation were serious health issues of the female patient, 'unforeseen at the moment of fertilization', which allowed doctors to freeze embryos, but after addressing these health issues, the doctor was obliged to proceed with embryo implantation.[8] Thus, whereas the Law

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[4] ibid, art. 13, para. 2. 'La ricerca clinica e sperimentale su ciascun embrione umano è consentita a condizione che si perseguano finalità esclusivamente terapeutiche e diagnostiche ad essa collegate volte alla tutela della salute e allo sviluppo dell'embrione stesso, e qualora non siano disponibili metodologie alternative'.

[5] ibid, art. 13, para. 3. 'Sono, comunque, vietati: *a)* la produzione di embrioni umani a fini di ricerca o di sperimentazione o comunque a fini diversi da quello previsto dalla presente legge; *b)* ogni forma di selezione a scopo eugenetico degli embrioni e dei gameti ovvero interventi che, attraverso tecniche di selezione, di manipolazione o comunque tramite procedimenti artificiali, siano diretti ad alterare il patrimonio genetico dell'embrione o del gamete ovvero a predeterminarne caratteristiche genetiche, ad eccezione degli interventi aventi finalità diagnostiche e terapeutiche, di cui al comma 2 del presente articolo'.

[6] ibid, art. 14 para. 1. 'È vietata la crioconservazione e la soppressione di embrioni, fermo restando quanto previsto dalla legge 22 maggio 1978, n. 194'.

[7] ibid, art. 14 para. 2. 'Le tecniche di produzione degli embrioni, tenuto conto dell'evoluzione tecnico- scientifica e di quanto previsto dall'articolo 7, comma 3, non devono creare un numero di embrioni superiore a quello strettamente necessario ad un unico e contemporaneo impianto, comunque non superiore a tre'.

[8] ibid, art. 14 para. 3. 'Qualora il trasferimento nell'utero degli embrioni non risulti possibile per grave e documentata causa di forza maggiore relativa allo stato di salute della donna non prevedibile al momento della fecondazione è consentita la crioconservazione degli embrioni stessi fino alla data del trasferimento, da realizzare non appena possibile'.

did not specifically outlaw PGD, these provisions made it impossible in practice. In the same year, these provisions of the Law were implemented into the guidelines of the Ministry of Health introducing a new medical protocol of performing IVF both for public and private Italian clinics.

2.2. Abrogative referenda (2005)

Immediately after the Italian Parliament approved the Law on MAP, several political parties led by the Radical Party initiated a campaign for calling an abrogative referendum to repeal the Law. The referendum committee collected the required number of signatures (500,000) for a total of five referendum proposals. The first proposal called for entirely repealing the Law. The other four proposals concerned the repeal of various of the Law's provisions and were drafted in case the Court would not endorse the first proposal. They concerned the repeal of the most controversial provisions: the provision outlawing embryo cryopreservation and experimentation (first proposal), the duty of transferring the produced embryos simultaneously and the prohibition to access reproductive technologies by fertile couples (second proposal), the provision granting legal personhood to the embryo (third proposal) and the prohibition of donor insemination (fourth proposal). The Constitutional Court endorsed the last four proposals and rejected the proposal calling for repealing the entire Law.

In 2005 the Italian Bishops' Conference installed a special committee called 'Science and Life Committee' (*Comitato Scienza & Vita*). The main objective of the Committee was to act as the Church's official spokesperson on the issues put to vote at the referenda, to coordinate Catholic associations and movements and influence Catholic Italians' positions though instructing them how to vote. The main political tactic employed by the Church was to call for abstentionism. '*Sulla vita non si vota*' ('Life cannot be put to vote') was the main slogan used by the Church to stress that crucial social and ethical values are simply not those that can be discussed via such mundane political means as popular referenda. The campaign of the Church proved successful. The voters' turnout was twenty-five percent, while the Italian Constitution stipulates a threshold of fifty percent as the condition for validity of a referendum. The provisions of the Law remained in force.

2.3. Litigation

Catania case 3 May 2004

The plaintiffs (husband and wife) were healthy carriers of beta thalassemia and were infertile. They sought PGD to screen out affected embryos and start pregnancy with healthy embryos. They started proceedings against the fertility center, claiming the violation of the wife's rights under art. 2 (the guarantee of inviolable human rights) and art. 32 (the right to health and the right not to be forced to submit to unwanted medical treatment) were violated. The court held that the plaintiffs claimed not the right to health but the 'right to a healthy child', which the Italian constitution does not guarantee, and dismissed the case.

Cagliari case 16 July 2005

Similarly to the Cagliari case, in the present case the husband and wife were carriers of beta thalassemia and were infertile. The first IVF cycle at the fertility center was performed without PGD. When after prenatal testing the couple learned the fetus was affected with beta thalassemia, the woman performed abortion. Due to abortion, the wife developed an 'anxiety depressive disorder' and wished to perform IVF and PGD to prevent any further negative impacts on her mental state. However, the fertility clinic refused to perform PGD. In courts proceedings, the couple claimed that the prohibition of PGD created harm to her mental health and therefore infringed upon her constitutional right to health (art. 32). The court questioned the constitutionality of the PGD prohibition. According to the court, PGD should be allowed if and only if the health of the woman was at stake. The court submitted the case to the Constitutional Court for adjudicating art. 1. para 1. of Law 40/2004 upon its constitutionality.

Constitutional Court case 24 October 2006

This case was a follow-up to the Cagliari case. The Constitutional Court found the request of the Cagliari judge inadmissible on procedural grounds. It held the Cagliari court had not correctly formulated the appeal.

Florence cases 17 December 2007, 23 August 2008, 11-12 July 2008 and Tribunale Amministrativo Regionale of Lazio case 31 October 2007

All the couples involved were carriers of genetically mutated genes. In these instances, other aspects of the constitutionality of Law 40/2004 were raised. In the cases decided by the Florence court, other adverse health effects the Law entailed were emphasized, such as ovarian hyperstimulation syndrome, ovarian cancer, or multiple pregnancy. The TAR Lazio court also concluded that Law 40/2004 in fact provided limited rather than absolute embryo protection. It stated that the 'three embryo' rule meant that the protection of embryos was not absolute, because by allowing to implant three embryos and not one, the Law acknowledged the need to reduce embryo protection to ensure better prospects of a pregnancy. Therefore, it concluded that, because Parliament implicitly considered embryo protection not to be an absolute value, it was unreasonable to limit the number of embryos to three and to prohibit the cryopreservation of embryos. Furthermore, these restrictions created health risks to the female patient and therefore might violate art. 32 of the Constitution. The Florence court and TAR Lazio asked the Constitutional Court if art. 14 paras. 1, 3 and 4 were unconstitutional.

Constitutional Court case 1 April 2009

As a follow-up to the Florence and Lazio cases, the Constitutional Court decided that art. 14 (paras. 2 and 3) were unconstitutional as they violated the right to health of the woman. However, the Court did not find unconstitutional art. 14 para. 1 of the Law, which prohibited embryo cryopreservation as a general rule.

Cagliari case 9 November 2012

This court case also concerned the access to PGD. The court decided PGD was only allowed if the health of the woman would otherwise be at risk, declining to grant access to PGD as a right to a healthy child.

Salerno case 13 January 2010 and Rome cases 15 January 2014 and 28 February 2014

These cases concerned the right to access ART and PGD by fertile couples. The courts acknowledged both the right to health (art. 32) and the right to a healthy child, part of the right of self-determination, (open-ended art. 2 of the Italian Constitution) as justifying access to PGD. They submitted art. 4 para 1. (allowing access to ART only to infertile couples) to the Constitutional Court to decide on its constitutionality with respect to art. 2 (as including the right to self-determination and right to a healthy child), art. 3 (right to equality) and art. 32 (right to health) of the Italian Constitution.

Constitutional Court case 14 May 2015

The Constitutional Court found that art. 4 para. 1 violated only two articles of the Constitution, namely, art. 3 and art. 32. It concluded that it was unreasonable to prohibit access to ART and PGD to fertile couples while at the same time allowing access to prenatal testing and abortion. This unreasonable prohibition violated art. 3 of the Constitution. Furthermore, since abortion was much more traumatic than PGD, the prohibition of access to ART and PGD also violated art. 32 on the right to health. As a result, the Court concluded that women should be allowed to access ART and PGD on the same grounds as they are allowed to perform abortion, that is, when the health condition of the embryo or pregnancy creates ‘grave risks’ to mothers’ health, as stipulated by art. 6 para. 1b of Law 194/1978.

Naples case 3 April 2014

The Naples court was asked to decide a case in which the doctors of a fertility center in Naples were accused of committing a crime that consisted in embryo destruction. Specifically, doctors performed PGD, requested by a number of Italian couples, and following the results of PGD and IVF discarded embryos with detected pathologies instead of freezing them. The defenders of the doctors asked the Naples court whether the provisions of Law 40/2004 prohibiting embryo selection (art. 13 para. 3) and embryo destruction (art. 14 para. 1) violated, respectively, art. 32 (right to health) and art. 2 (right to self-determination) of the Constitution. The defenders also asked the Court to submit the case to the Constitutional Court for adjudication on the matter of its constitutionality. The Court agreed with the defenders and submitted the case to the Constitutional Court.

Constitutional Court case 21 October 2015

The Constitutional Court declared the provision forbidding the selection of embryos (art. 13 para. 3) unconstitutional, because the prohibition to select and implant only healthy embryos would cause harm to women’s health and therefore would violate art. 32 of the Constitution. However, it did not find that the prohibition of destroying embryos (art. 14 para. 1) was unconstitutional and violated the right to self-determination. Specifically, it concluded that ‘the embryo, in fact, irrespective of the amount of subjectivity that is attributed to the genesis of life, is definitely not a mere biological material’. Its protection could be limited only if necessary to protect a value of greater legal and moral weight, such as women’s health. Since Law 40/2004 no longer obliged the doctor to transfer an embryo with a genetic disease into the patient’s uterus, it did not create risks to her health and therefore was not in violation of the Constitution.

CHAPTER 3

Back to natural rights: artificial reproductive technologies and biopolitics in Italy

3.1. Introduction[1]

The success of *in vitro* fertilization (IVF) techniques in late 1970s prompted many countries in Western Europe to regulate IVF and IVF-based assisted reproduction technologies (ART) and bring them under state control. Belatedly, Italy became the last country to introduce a law (Law 40/2004) regulating the provision of ART services in Italian fertility clinics. Before that, the legislative vacuum had *de facto* rendered all ART techniques lawful. That vacuum was then filled by a controversial and restrictive Law 40/2004. The Law allowed access to ART to stable heterosexual couples of a fertile age, who could use only their own gametes to initiate pregnancy. The Law also prescribed that, irrespective of their morphological and genetic characteristics, all embryos produced during one IVF cycle (which should not exceed three) must be implanted into the woman's uterus. Together with the prohibition of embryo cryopreservation, the Law sought to prevent the creation of surplus embryos, that is, embryos which would not eventually be implanted into their genetic mother.

The enactment of these restrictive norms was meant to make clinical practices involving the use of human embryos consistent with the principle first introduced in art. 1 of the Law. This article recognized the human embryo as a right-holder and prescribed that the techniques of ART should henceforth be performed 'under the conditions and according to the modalities foreseen in the present law which ensures the rights of all the involved subjects, including the conceptus'. Embryos thus were included in the scope of 'citizen subjects' (Metzler 2011) and became full-fledged Italian citizens whose rights to life and health the State had to guarantee, in particular, by restricting the scope of ART that could be practiced on Italian territory.

In this article, I explore the debate on, and enactment of, the restrictive provisions of Law 40/2004 through the conceptual lens of biopolitics (Foucault 1980, 2007, 2008; Lemke 2011a, 2011b). In his lectures at the Collège de France, Foucault observed that 'the general framework of biopolitics' is liberalism (2008, 22). For Foucault, liberalism is not as an economic theory or a political ideology but as a specific art of governing which involves two types of legitimation and limitation of political power. The first type includes those instruments that are 'external and excessive in relation to government' (Foucault 2008, 9). By

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[1] Article submitted to the journal *Biosocieties.*

these instruments, Foucault primarily meant the concepts of 'original or natural rights' and 'social contract'. As Foucault (2008, 39) stated, 'this approach consists in starting from the rights of man in order to arrive at the limitation of governmentality by way of the constitution of the sovereign'. In other words, according to this approach, individuals resign some of their natural rights and submit to the authority of the sovereign, in exchange for obliging the latter to protect the remaining essential natural rights against other people or the state itself. This way of limiting state power was implemented by the French revolutionaries and found its most explicit theoretical elaboration in the idea of the 'social contract' of Rousseau.

The second type of limitation derives from governmental practice itself and from the 'de facto limits that can be set to this governmentality' (Foucault 2008, 40). This is where Foucault starts to develop his view on a new rationality of government that differs from previous historical rationalities of government such as state reason (*raison d'état*): the idea of a nature of society that constitutes the basis and the internal limits of governmental practice. Nature here is not a carryover of tradition and therefore differs from 'natural rights' used as an external limit to government. Instead, it represents a form of self-regulation of a society that the government should respect if it does not want to act 'clumsily'. The main intellectual element used to know society's nature is political economy. As Foucault (2008, 15) states, political economy

> considers them [governmental practices] in terms of their effects rather than their origins, not by asking, for example, what authorizes a sovereign to raise taxes, but by asking, quite simply: What will happen if, at a given moment, we raise a tax on a particular category of persons or a particular category of goods?

Because the limits to political power are set from within by nature, the 'coordinates of governmental action are no longer legitimacy or illegitimacy but success or failure; rejection focuses not on the abuse or arrogance of power but rather on ignorance concerning its use' (Lemke 2011a, 46). Therefore, in order to learn whether the government is acting properly, 'it is necessary to investigate the "natural order of things" that defines both the foundations and the limits of governmental action' (Lemke 2011a, 46). According to Foucault, this second conception of legitimation and limitation of power has been dominant, although the first one has not entirely disappeared.

In his lectures at the Collège de France, Foucault started to discuss biopolitics as an art of government that employed this second type of rationality – nature as a *de facto* limitation of political power. According to Foucault, biopolitics emerged in the eighteenth century and largely superseded the previous and pre-modern – the 'juridico-discursive' – mode of power. This latter consisted in the power of the sovereign to seize 'things, time, bodies, ultimately the life of subjects' and operated according to a rather simple binary code of the sovereign's right over the life and death of its subjects (Rabinow and Rose 2006, 195; Lemke 2011). Instead, biopolitics takes places on the threshold of modernity and signals the passage to liberalism and therefore operates according to a different – liberal – mechanism. First, 'life and its mechanisms' moved into the realm of politics. As Foucault (1980, 142) observes, 'for the first time in history, no doubt, biological existence was reflected in political existence'. This meant that the *zoē*, the biological life of men, became the concern of political life: 'Western man was gradually learning what it meant to be a living species in a living world (Foucault 1980, 142). The concern for the biological life of men prompted the state to ensure the 'fostering' or 'investing (of) life through and through' with a purpose of 'normalizing' the population and its health. Second, liberalism means the use of particular instruments of government which was dictated by the 'naturalness of the human species' (Foucault 2008), that is, by the fact that life of the population – birth, death, diseases, etc. – evolves according to some natural laws. Biopolitics thus includes such regulatory mechanisms as forecasting, statistics, measuring mortality and birth rates, the use of human sciences such as biology with a main aim to 'prescribe norms, adjust anomalies to an equilibrium and maintain an average among the "general population"' (Klein 2010, 402). Foucault stresses that 'nature' of the population does not represent an entirely autonomous reality that governmental action should respect. In contrast, it is a particular focus for governmental intervention. However, as it develops according to its own logic, the government should 'know' it in order to be able to influence it.

Although Foucault connected biopolitics with liberalism, he did not explore this connection any further. However, according to Lemke (2011a, 2011b), these few explorations represent an important step in how Foucault regarded biopolitics. His first writings on biopolitics, for example, in *Discipline and Punish*, first treated biopolitics as including only disciplinary power; therefore, biopolitics was a kind of 'body politics', performed on the *zoē*, the bodies, of individuals (Agamben 1998). Viewing biopolitics as an art of government instead gives important advantages for it allows one to connect two dimensions of human existence – biological existence (*zoē*) and moral and political existence (*bios*) – and to explore how they are intertwined. The importance of connecting these two dimensions is important because liberalism gives rise to a particular question: 'how are free subjects — subjects of law — governed when they are simultaneously understood as living beings?' (Lemke 2011b, 175). Hence, biopolitics includes three elements which together participate in biopolitical governance (Lemke 2011a, 2011b; Rabinow and Rose 2006). The first element is knowledge and experts authorized to speak truth. Systematic knowledge about life and living beings is required to 'provide cognitive and normative maps that open up biopolitical spaces and define both subjects and objects of intervention' (Lemke 2011a, 119). The second element is power strategies, including 'strategies for intervention upon collective existence in the name of life and health' (Rabinow and Rose 2006, 197) and strategies of power that 'mobilize knowledge of life and how processes of power generate and disseminate forms of knowledge' (2011a, 119). The first type of strategies also encompasses the strategies of subjectification. They include both bodily disciplining and regulation of the population and the self-constitution of individuals as individual and collective subjects. Subjectification in this second sense is performed with the help of 'technologies of the social', through which individuals identify themselves as part of a society, and 'technologies of the self', through which individuals shape a particular attitude towards their bodies, their health, and their conduct. The third element is the types of identities that subjectification produces. They include, for example, new biosocial communities such as patient groups (Rabinow 1996) and the new type of identity termed 'somatic individuality' (Rose 2006).

The Foucauldian concept of biopolitics, understood as the type of biopolitics whose shape and form of exercise are determined by the 'natural' basis of the population, has been particularly interesting for scholars exploring the social implications of the transformation of 'life itself' by new biotechnological practices (Franklin 2000; Rose 2006). One of the main conclusions deriving from this type of research is that biopolitical strategies are now 'democratized', and political goals for ensuring health protection of the population intertwined with the personal individuals' aspirations for good health. For example, Rose suggested that biopolitics should be now regarded as 'ethopolitics'. Ethopolitics is

> the ways in which the ethos of human existence—the sentiments, moral nature or guiding beliefs of persons, groups, or institutions—have come to provide the "medium" within which the self-government of the autonomous individual can be connected up with the imperatives of good government… If discipline individualizes and normalizes, and biopower collectivizes and socializes, ethopolitics concerns itself with the self-techniques by which human beings should judge themselves and act upon themselves to make themselves better than they are. (Rose 2001, 18)

The emphasis on individuals as agents of biopolitics is in line with Foucauldian theorizations on liberalism and represents a logical solution to the question: 'how are free subjects — subjects of law — governed when they are simultaneously understood as living beings?'.

In this article, using the Italian debate around Law 40/2004, I explore an alternative way in which the physical being of *zoē* became intertwined with the moral and political existence of *bios*. Specifically, I illustrate how another rationality of government – natural rights as an external legitimation of political power – was employed to classify IVF embryos either as entities having a mere biological existence as *zoē*, or as human persons, thus capable of moral and political existence as *bios.* I show how through the appeal to natural rights of embryos, the latter were granted legal subjectivity and rights, and how the implementation of the restrictive regulation of ART to ensure the 'making live and letting die' of these new Italian citizens was performed (Foucault 1980, 70). In this way, I contend that natural rights have not been displaced by other rationalities for the exercise of political power such as nature as an internal self-limitation of power. This conclusion may fit with the acknowledgment of other scholars that the argument in favor of protecting human dignity, broadly termed 'dignitarianism', has increased because of fears that the new biomedical technologies may erode the fundamental basis of humans – human dignity (Brownsword 2008). Finally, I argue that the three elements of biopolitics suggested by Lemke – knowledge, power and subjectification – also help structure the exercise of biopolitics in cases where natural rights act as external limits to government, but they take a different shape if biopolitics is exercised according to this modality.

3.2. Italian politics, Catholic bioethics and embryo as a human person

The public debate on the law on ART in Italy has been significantly influenced by Catholicism. One of the main ways in which Catholicism affected the debate on ART in Italy was its influence on how ART were problematized (Fischer 2000). Specifically, and unlike in many other European countries (Parfenchyk and Flos 2017; Hermann 2009; Mulkay 1997), the dominant problematization of ART was its potential assault on human life and dignity in which the 'human' largely meant one concrete entity – the human embryo.

The reasons why the problematic that ART raise was reduced to the 'embryo question' were related to the two guises that the Catholic Church had taken in Italy, namely, its acting both as a morality-setting institution and a political actor. Although there has been a break between how the Vatican affected politics before the 1990s and after, the Vatican was acting as an important and powerful political actor and thereby was setting its ethical norms on an institutional level, supporting this by implementing positive laws. In this way, a particular – Catholic – *bioethical* perspective also became a dominant *biopolitical* strategy of governing the Italian population, including IVF embryos.

Thus, in the period between the end of the Second World War and the beginning of the 1990s, the Vatican had been supporting the main Italian Catholic political party Christian Democracy (*Democrazia Christiana,* DC) and therewith had had a political ally in its campaign to defend core Catholic ideals. One of the most substantial impacts that the Vatican had had on the activities of the DC was its support of a network of Catholic organizations associated with the DC (these have been called 'collateral' because of their tight connection with the party (Galli 1978; Giorgi 2013)). These associations had supported the DC through political activism and mobilization of Catholics in the social and political life of Italy (Giorgi 2013). The Catholic presence therefore has been strongly institutionalized, which affected both the forms of involvement of the Italian citizenry in social and political life of the country and their political convictions.

In 1994, following corruption scandals and the '*Mani pulite*' ('Clean hands') campaign, the DC disintegrated. This changed the relationship between the Church and Italian politics. On the one hand, the corruption scandals and failure to remain the central political force led the Vatican to abandon its direct support of political parties. In 1995 the Italian

Bishops Conference at its meeting in Palermo declared the impartiality of the Church and its political non-alignment. This impartiality, however, did not mean neutrality. One of the results of the Palermo meeting was the establishment of the Cultural Project, which had as its goal the 're-Christianization of Italy' based on firm Catholic principles (Italian Episcopal Conference 1997). The Church, therefore, did not abandon its aim to spread Catholic values, it merely changed its methods. Instead of acting through the DC, it increased its public presence without political mediation through a single party and continued its activism in protecting core Catholic values.

On the other hand, the Church's moral judgement and vocal appeal to implement it through secular laws found a responsive audience among Italian politicians. Unlike the DC, its main successor the Italian Popular Party failed to become the center of the Italian political Catholic world or gather it around itself. A number of smaller parties with a Catholic orientation mushroomed (the United Christian Democrats, the Christian Democratic Center and so on), forming multiple coalitions among each other or with nationalist right parties such as the North League for the Independence of Padania (*Lega Nord per l'Indipendenza della Padania*). In their search for political identity and a means to gain public support, the reference to the moral teaching of the Church became a useful instrument to achieve these ends. As a result, right-wing parties, such as Berlusconi's *Forza Italia* and the ultra-right *Lega Nord*, turned for support to the Vatican, both to 'acquire a political identity and to share the cultural legitimacy of Catholicism among the population' (Beltrame 2016, 7).

In these political perturbations, a key goal for both the Church and Catholic politicians was to ensure that new scientific and technological developments did not harm the life or health of embryos. In 1987, the Congregation for the Doctrine of the Faith issued an instruction on biomedical issues, called the Instruction for Human Life in Its Origin and on the Dignity of Procreation *Donum vitae* (Congregation for the Doctrine of the Faith 1987). Later, in 2008, an Instruction on certain bioethical questions *Dignitas Personae* was issued to complement the teaching of the Church on new biomedical technologies that emerged after *Donum vitae* had been issued (Congregation for the Doctrine of the Faith 2008). Both assert that an embryo should be treated as a human person from fertilization onwards. According to *Dignitas Personae*, this ethical principle is part of the existing natural moral law and 'presupposes a truth of an ontological character, as Donum vitae demonstrated from solid scientific evidence, regarding the continuity in development of a human being' (Congregation for the Doctrine of the Faith 1987). By 'solid scientific evidence', the Instruction meant genetic science and the possession by the embryo of a unique and unchangeable genetic code, from the moment of fertilization till death. Therefore, because embryos should be treated as persons, their lives from the moment of fertilization were inviolable and could not be compromised, relativized, or overridden by other interests.

A notable feature of both Instructions was that they included requirements with regard to ART addressed both to those who used them (patients, clinicians, scientists) and to regulators. It is part of the duty of the public authorities to ensure that the civil law is regulated according to the fundamental norms of moral law in matters concerning human rights, human life and the institution of the family. Furthermore, they created an explicit link between moral values and positive law. According to *Donum vitae* 'human rights depend neither on single individuals nor on parents; nor do they represent a concession made by society and the State: they pertain to human nature' (Congregation for the Doctrine of the Faith 1987). These moral teachings of the Vatican and prescriptions to implement natural law into positive law will be taken up by Italian politicians in their struggle to implement Law 40/2004.

This introduction gives a preliminary illustration of the constellation of powers in Italy when ART entered into Italian laboratories. The important role of the Church that it traditionally played in Italy, both in politics and social life, and that was reinforced by the political processes of that time, would be the main factor determining why the Catholic bioethical perspective on ART and embryo protection would also dominate on the political level. Yet, while the Catholic Church actively participates in Italian public life and Italian politicians attempt to exploit Catholicism for their political objectives, Catholicism as a dominant cultural framework of Italy cannot be taken for granted. As Garelli (2010) observed, Italy is characterized, first, by a deep secular-Catholic cleavage that runs through politics and society alike. In addition, there is division not only between secular and Catholic sections of Italian society, but also within its Catholic section. This latter includes a Catholic majority that accept the generic definition of Catholic but do not practice Catholicism, and a Catholic minority that is intensely religious and practices it. Within this last group, only one-tenth actively participates in various Catholic movements or associations. This division was one of the reasons why Italian politics were unable to produce a law regulating ART for twenty years. The absolutist position of the Church regarding embryos and their protection precluded the possibility of a consensus in a society where Catholicism no longer enjoyed a monopoly on ethical issues.

Another factor was related to the legislative decision-making process of the Italian Parliament known as ‘perfect bicameralism’. According to this process, both parliamentary chambers – the Chamber of Deputies and the Senate – have identical rights in designing and passing laws. The consequence of this rule is that, before a law can be passed, both chambers must approve the law in its identical form. If one of the two chambers changes a bill previously approved by the other, the changed provisions must once more be debated and approved by that chamber. This legislative process, known as *navette*, continues until a compromise is reached and passed by both chambers. The absolutist stance of Catholic politicians regarding embryo protection and their reluctance to forge consensus prevented such a compromise being reached. As a result, for many years the Italian Parliament was unable to produce any law regulating ART in Italy.

3.3. Human dignity, natural rights and the beginning of life

As stated above, according to the official position of the Catholic Church, IVF embryos are regarded as full-fledged persons from conception. The Church asserts that this view is part of natural moral law, confirmed by the latest discoveries of genetic science. Embryos are thus ‘objectively’ full-fledged persons, simply because they are human. Similarly, embryos have human dignity and natural (human) rights, with the main right being the right to life. The key biopolitical goal of the Church was to translate these natural rights into positive rights and to forbid all those ART that might infringe on these natural rights through restrictive legal provisions.

Obviously, the Catholic Church has not always had this stance (Pasnau 2002; Hastings, Mason, Pyper and Lawrie 2000). In the Middle Ages, and long before the discovery of genetic code, the theory of ensoulment elaborated by Thomas Aquinas dominated. According to this theory, before the ensoulment, which happened at the fortieth day of pregnancy and was usually associated with quickening, abortion was considered a sin and a crime against marriage. In contrast, after ensoulment, which meant that the embryo already had an intellective soul, abortion considered a homicide. After the discovery of human gametes and the process of fertilization, and later of the genetic code, the Church's position was to take into account the scientific discovery. However, according to Cooper (2009, 147), its position was not 'discredited' but 'destabilized' and was thought to be simply reconsidered to account for the facts provided by genetic science. The Catholic Church adopted fertilization as the moment when a human person comes into existence, hence abortion was to be considered homicide if performed after fertilization.

The Catholic position towards embryos and their rights infiltrated into politics via different means. First, it was affecting politicians directly when they were debating ART. In 1985, the then Minister of Health Costante Degan set up an expert commission entrusted with a task to elaborate the draft of a bill on ART. Degan was a member of DC and an active participant of *Azione Cattolica*, the main Catholic lay association in Italy. Following his Catholic commitments and the intention to protect embryos' life through law, he included mostly Catholic members into the commission. Its president, judge Fernando Santosuosso (hence the name – Santosuosso Commission), was also a Catholic, author of a number of books on Catholic faith. The composition of the Commission was immediately criticised for being too one-sided, which led Degan to modify it and include some non-Catholic members. Yet, the reports produced by the Commission reflected the Catholic spirit of the majority of the Commission's members, in particular through their attitude towards the embryo (Santosuosso Commission 1985). The reports suggested that embryos must be protected through law as they were 'subjects' and by no means 'objects' (Santosuosso Commission 1985, 6). Building on this view on embryos, the Reports suggested that a restrictive regulation should be adopted to ensure embryo protection, such as a prohibition to create surplus embryos, and cryopreservation should be allowed only if it was needed for *force majeure* reasons related to women's health.

The Reports were not taken into account by Parliament and no law was produced. Instead, Degan issued a ministerial circular to regulate the provision of ART practices in the Italian public ART sector. The Circular was more restrictive than the Reports as they entirely prohibited cryopreservation. However, because the Circular applied only to public fertility clinics, private clinics remained beyond its regulatory reach. Therefore, there was a clear need for a law that would regulate the provision of ART on the entire Italian territory.

The debate on a law proceeded with tens of bills being presented to Parliament by various politicians and parliamentary groups. One of these bills that was representative of many other bills presented by Catholic politicians was the bill drafted by 23 parliamentarians, including Carlo Casini, president of the Italian pro-life association Movement for Life and member of the DC, and DC president Mino Martinazzoli (CDD 1988). This bill built on the petition ‘For life and dignity of man’ signed by 2.5 millions of Italian citizens and presented to Parliament in September 1987, which asked to extend legal protection to the embryo from the moment of fertilization. Similar to the petition, the main purpose of the bill was to ‘extend the protection of the right to health and to physical integrity onto the initial phase of human existence, within the scope of the protection of inviolable human rights ensured by art. 2 of the Constitution’ (CDD 1988, 1) and thereby to recognize human embryos as legal subjects endowed with rights, particularly of the right to life and health.

The Martinazzoli bill stated that the IVF embryo must be given the status of a legal subject from fertilization because fertilization marks the coming into being of a new human person. According to the bill, the fact that exactly through fertilization a new person comes into existence is a proven scientific fact. During fertilization, the ‘unique genetically unrepeatable information’ (CDD 1988, 3), that is, the genetic code, is established. This genetic code will both allow the embryo to autonomously and continuously develop without external stimuli and will determine all its individual characteristics (CDD 1988, 3). They also rejected the possibility of connecting the moment when a new person comes into existence with other biological episodes. By these episodes, the authors meant such biological criteria as the appearance of the primitive streak on the fourteenth day of embryonic development or the moment of the so-called nidation when the embryo attaches itself to the uterine wall. For the authors, connecting the moment when a new person comes into being with these events would be arbitrary and completely disregard the existing scientific evidence.

This discursive analysis of the Martinazzoli bill illustrates well the argumentative strategies the authors used to argue that human embryos were in fact full-fledged human persons and therefore should be accorded rights and legal personhood from fertilization. First, they referred to an essentialist conception of human nature, the possession of unique and unchangeable human genetic code that embryos acquire during fertilization. Neither embryo viability, nor other biological criteria, nor embryo dependence upon the mother to be born could be used to decide from which moment their life becomes politically qualified and hence becomes of concern for the state.

Second, the drafters did not refer to religion as a source of their normative position, but to science. Tellingly, the drafters of the bill did not explain why human embryos should necessarily be seen as full-fledged human persons. There is a big difference between classifying unborn life as 'human life', on the one hand, and 'human person', on the other. Indeed, many jurisdictions as well as the jurisprudence of the European Court of Human Rights illustrate that unborn life is generally recognized as 'human life' worthy of protection and respect (Evans v UK. 2006. 43 EHRR 21). Yet, doing so does not mean putting embryos on the same level as born individuals and including them into the moral community of people endowed with a possibility of political existence, or *bios*. Similarly, the presence of the genetic code in the embryo was not an undisputed evidence that embryos are persons. Later, when the adoption of Law 40/2004 would be underway, a number of other scientists, including Nobel Laureate Rita Levi-Montalcini, famous oncologist Umberto Veronesi and doctor Carlo Flamigni published a petition expressing an entirely different position. In the petition, they stated: 'we humbly say that we don't know when human person comes into being but we are sure that this does not happen during fertilization' (Manifesto 'Embrioni e ricerca', 2002). However, there is a noticeable affinity between the argumentative strategy used by Catholic parliamentarians and by Catholic teaching, although the authors used the most secular and therefore credible type of evidence – science – to justify their position.

Third, they framed the obligation to attribute legal personhood and rights to the embryo not as a moral duty but as recognition through law of what has been already discovered and defined through science. The appeal to science and not to morality made this extension appear 'natural' and ethically neutral: it was nothing more than a simple act of 'juridical recognition' of a scientifically proven fact and not a normative definition (CDD 1988, 4). This understanding of law as 'institutional clothing' (Pottage and Mundy 2004) of a naturally existing ontological architecture of the world entitled policy-makers to grant legal subjectivity to the embryo.

Importantly, according to the Martinazzoli bill, these natural rights were already implemented in the Italian Constitution. Specifically, art. 2 that the Bill referred to states: 'The Republic recognizes and guarantees the inviolable rights of the person, both as an individual and in the social groups where human personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled'. According to the judgment of the Italian Constitutional Court on abortion, the fetus is a holder of a constitutional entitlement for state protection and enjoys rights according to art. 2. In this sense, the Martinazzoli bill was just a further enactment of natural rights, already recognized by the Constitution, in Italian positive law. Yet, there was one important difference. In the same judgment, the Court stated that 'there is no equivalence between the right to life and health of the person and life of the one who is yet to become a person'. Put differently, the Court recognized that the fetus was not a person and therefore its entitlements underweighted the entitlements of those who were already persons such as the right to health of the pregnant woman. In this sense, on the one hand, the position of Catholic politicians in the debate on IVF assumingly built on the Italian constitutional law but, on the other hand, by claiming that IVF embryos were persons and therefore should be attributed legal personality, they introduced important changes into the regulation of artificial reproduction compared to how natural reproduction was approached by the Constitutional Court.

The analysis of this bill illustrates how science was used by Catholic politicians, similarly to the Church, in arguing why embryos have to be recognized as legal subjects from conception. In political debates, genetics became an important 'truth discourse' (Lemke 2011a, 2011b), which Italian politicians would heavily rely on to 'prove' that an embryo was a person. The reference to expertise and not to the divine decree is indicative of the importance that modern liberal democracies attach to science in governing populations and its role in biopolitics. However, the use of genetic science in this case significantly differs from its use as discussed by Foucault and the role it is generally assigned in current biopolitical regimes. As I stated above, the role of science in the Foucauldian account of biopolitics was to know the nature and use the knowledge to optimize and improve the health of populations—in other words, to make it manageable and transformable. As Rabinow stated with regard to the human genome, 'the object to be known—the human genome—will be known in such a way that it can be changed' (Rabinow 1996, 92). Instead, the use of genetics in the Italian debate on IVF embryos was used to 'discover' the essence of things, to identify their inherent value and foreclose the possibility of undermining it in order to allow the potential of an embryo, which is already present in the embryo, to develop. In this sense, the appeal to genetics was nothing more than an appeal to a natural moral law couched in genetic terms through which Italian Catholic politicians wished to set limits to the evolving biomedical practices.

In addition, Catholic teaching itself was soon to become a form of expertise, when it started influencing the nature of an emerging discipline, now famously known as bioethics, in Italy. Unlike secular bioethics, Catholic bioethics has been flourishing in Italy over the past 30 years (Mori 2004). One of the issues that has received much scholarly exploration by Catholic bioethicists was the 'moral and legal status of the embryo'. In Italian bioethics, the so so-called 'ontologically grounded personalism' (Sgreccia 1988, 1991) dominated. According to it, the embryo was 'a person with potential' and not 'a potential person', a position advocated by 'functionalism personalism' (Ford 1988, 1991). The theory of 'functionalist personalism', prevailing, specifically, in Britain, assumed that the possession of certain characteristics and traits was necessary to attribute a moral status of personhood to an entity (Ford 1988; Warnock 1984). In contrast, the theory of ontologically grounded personalism builds 'on the objective value of the dignity of every human person' (Sgreccia 1988, 1991), with no distinction whatsoever, but for the only reason of being human and having human dignity.

Similar to Catholic Church, an important aspect of 'ontologically grounded personalism' is that it builds on science – genetics – to prove that embryos are persons. Specifically, it proposes a triangular method analysis, which includes scientific data collection, constituting the cognitive level, ethical analysis, representing the justifying level, and ethical evaluation and deliberation, representing the deliberative level. Hence, this position heavily relies on science, namely, genetics. This made many Italian bioethicists engage with scientific debates to prove that the embryo was a person. According to Mori, this is an important and distinctive characteristic of Italian bioethics (Mori 2005). For example, *Donum vitae* itself did not refer to science as a source of justification but, instead, to an act of God such as the infusion of the soul into an embryo or a fetus. In addition, it stated that the question of whether the human embryo was a person or not was not a scientific question but a philosophical one. Genetic science was an important yet not necessary factor to prove that embryos are persons. In contrast, authors like Sgreccia and many other Italian Catholic bioethics scholars dedicated a lot of attention exactly to scientific analysis to come to normative conclusions.

Hence, similarly to genetics, bioethics as a form of expertise became an important device to legitimize the position of those who sought to defend the protection of life from its beginning. In this way it became another – indirect – instrument affecting Italian political decision-making on ART. This was so when bioethics became an official bioethics. In 1990, the National Committee on Bioethics (*Comitato Nazionale per la Bioetica*, CNB) was set up. Initially, its purpose was to create an institution, composed of people of a high scientific record, that could be entrusted with the task of discussing and pronouncing expert decisions on ambiguous issues raised by new scientific and technological developments. However, from the very beginning of its institution and functioning, the CNB was mostly Catholic. Due to the political processes of that time and to the willingness to forge alliances with the Church and get its political support, the government designated mostly Catholic bioethicists to the CNB. As a result, during many years, members of the CNB were Catholics suggesting the spirit of reports the CNB would issue. Some of the CNB members, such as Elio Sgreccia, were also Vatican officials, pointing to an even tighter interpenetration of the Church with politics. Further, in December 1994, Silvio Berlusconi, who ruled a center-right coalition, nominated a majority of Catholic members in the CNB, which incited civil society to dub CNB the 'Bishops' committee' because of its overwhelming majority of Catholics.

The view that embryos are human persons was adopted by the CNB in its report *Identity and status of the human embryo* issued in 1996 (CNB 1996). As stated before, at that time CNB was composed of mostly Catholic members assigned by Berlusconi. It was this composition that affected the nature of the report. The Commission unanimously concluded that the embryo had to be treated like 'one of us', that is, as a human person. According to the report, 'a simple possession of human nature implies for every individual the fact of being a human person' and 'the human nature of the embryo, the progressive and continuous character of embryonic development are the elements that entitle us to attribute the "ontological" concept of person to the embryo' (CNB 1996).

This report played an important role in political debates. For example, in 1998 the bill was adopted by the Commission on Social Affairs of the Chamber of Deputies that would pave the way for the further decision-making on ART, dubbed the Bolognesi project. The bill was sent to the Commission on Constitutional Affairs of the Chamber of Deputies for assessing its text on the matter of its consistency with the Italian Constitution. Rosa Iervolino Russo, president of the Commission and a former DC member, concluded that it was constitutional because it provided enough protection to IVF embryos. Mainly relying on the purported science-based argumentation in the CNB report to legitimize her position, she argued that she 'thought, naturally, about the laic ethics that makes reference to the same human nature and to human rights because only to them the legislator can appeal, whereas every choice related to faith remains a personal issue of individuals' (CDD 1998).

Thus, one of the main effects of Catholic teaching and Catholic bioethics on politics was the imposition of its essentialist view on embryos as human persons. Their natural right to life, similarly to that of born individuals, was to be transposed into positive law and therefore become the positive right to life and serve as an external limitation to the development of biomedical practices and technologies. The use of expertise was connected with the appeal to natural rights as external limitation. First, unlike the traditionally discussed view of genetics that it is or can be used to transform the genome, the use of genetic science in Italy was used to 'prove' that an embryo was a person having human dignity and to foreclose the development of biomedical practices that would harm it. Second, bioethics was also used to restrict the use of genetic and biomedical sciences, in contrast to other countries where it has been geared towards encouraging self-transformation such as through improving one's health and managing one's genetic predispositions. As I will illustrate in the following section, similarly to genetics, the approach of Italian political actors to the biomedical technologies of ART would eventually result in a political regime rather distinct from the one adopted in what is now usually called 'advanced liberal democracies' (Miller and Rose 2008).

3.4. IVF as a 'public space', the adoption of Law 40/2004 and biopolitics through natural rights

The appeal to natural rights of embryos, and the respective implication that they were persons and legal subjects, became the main argument why restrictive regulation of ART had to be adopted. As stated above, in 1998, the Commission on Social Affairs of the Chamber of Deputies was assigned the task to produce a bill on ART. Marida Bolognesi, president of the Commission, created a Restrictive Committee that had to draft a unified bill on ART based on

21 bills submitted by parliamentarians. The unified bill resulting from the Bolognesi project stipulated that a doctor was allowed to create a maximum of four embryos in one IVF cycle, transfer as many embryos as deemed appropriate in a concrete case to initiate pregnancy, and cryopreserve the remainder (CDD 1997a). Four was chosen as a maximum number of embryos to tackle the problem of surplus embryo production.

However, when the Bolognesi project reached the floor of the Chamber of Deputies, criticism was voiced that because an embryo was a human person, a more restrictive regulation of ART was needed to protect embryos against technological manipulation. The main and most active supporter of maximum embryo protection was Alessandro Cè, a member of the *Lega Nord*. Cè introduced an amendment into the bill that extended legal personhood to the embryo. However, through a technical maneuver undertaken by President of the Chamber of Deputies Luciano Violante, this amendment was not put to the vote. In particular, Violante found the amendment of Cè to the Bolognesi project inadmissible because he believed that the question of embryos' legal personhood and ART had to be discussed separately, for they concerned different, albeit overlapping, topics. Cè disagreed. According to Cè and his supporters, the question of embryos' legal personhood could and should be discussed precisely during the debates around the law on ART. According to him, it was exactly the right place to do so: an embryo created *in vitro* was different from a child created naturally. As he claimed,

> procreation in this new version would lose its connotation of naturalness in which the responsibility for the life of the embryos is assumed by parents, as it is stated in Law 194[2]. In fact, it will fall, at least partially, upon the state, indirectly involved via administrative disciplines and sanitary authorizations, in the implementation of procedures necessary to allow the procreation' (Cè, Seduta 395, 20.07.1998).

Thus, according to Cè, owing to the involvement of third parties, ART were an 'empirically' or 'de facto' public sphere. The State, therefore, had to assume a greater role in protecting embryos, particularly through granting rights to them. A similar position was voiced by many other parliamentarians as well as the main pro-life association of Italy, Movement for Life.

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[2] The law on abortion passed in 1978 (Law 194/1978).

The second reason why natural reproduction was considered different from artificial and which required a more stringent regulation of ART than natural reproduction was related to an apparent lack of interests that conflict with embryos' interests in the case of ART. The possible risks to mothers' health were represented as non-existent. According to Cè, because in the case of ART 'there are no interests conflicting with mothers', it is necessary to introduce absolute protection of the embryo' (Cè, Seduta 395, 20.07.1998). In addition, stressing the absence of such competing interests was important in order to counter the arguments that, if adopted in this restrictive form, the law on ART would be inconsistent with the Law 194/1978. The latter allowed the termination of pregnancy if it was needed to prevent negative impacts of pregnancy on women's health. However, an assumed difference between IVF embryos from fetuses conceived naturally meant that the law on ART did not have to be consistent with abortion, as these were completely different cases. Thus, according to Cè, 'without necessarily revising at the same time the law 194, it is necessary to provide a better protection to the embryo produced in vitro, that is, to the one outside the body of the woman' (Cè, Seduta 395, 20.07.1998).

According to Cè and his supporters, the implementation of two legal changes was necessary to ensure the protection of life and health of embryos. The first one was granting legal personality and rights, including the right to life and to health, to IVF embryos. Similar to the authors of the Martinazzoli bill, Cè and others represented legal rights as positive law equivalents of naturally existing entitlements, namely, human rights, which all human persons, including embryos, had for the mere reason of being human. Instead, adult citizens had only duties with respect to embryos. The desire to have a child was not a 'right to have a child'. A right to have a child would mean reducing the embryo to a 'res' (thing), which was illegitimate because embryos were persons.

The second way of ensuring embryo protection was the imposition of restrictive rules on the practice of ART. According to Cè, only one embryo must be created an implanted (CDD 1998). Others believed that more embryos could be created, but in the latter case they all had to be implanted into the woman's uterus in order to avoid the creation of surplus embryos. In addition, procedures that could harm embryos such as cryopreservation or preimplantation genetic diagnosis (PGD) should be forbidden. Not only would they harm the embryo, they would also be unnecessary due to the absence of countervailing interests. Finally, the supporters of restrictive regulation of ART suggested that women should be prohibited from withdrawing consent after fertilization of embryos to ensure their subsequent implantation (CDD 1998).

During the further debate of the bill, negative aspects of such restrictive regulations on mothers' health were nevertheless voiced and emphasized. Specifically, liberal politicians argued that the prohibition to create more than three embryos would force the doctor to perform repeated ovarian stimulations of the woman, thus raising the risks of such health conditions as ovarian hyperstimulation syndrome (OHSS) and ovarian cancer (CDD 1998; SDR 2000). Furthermore, the duty to implant all created embryos simultaneously would raise the risk of causing triple and therefore significantly more dangerous pregnancies (CDD 1998; SDR 2000). Finally, the duty to implant embryos that were non-viable, that is, incapable of development, as well as embryos with different genetic pathologies that could be screened out through PGD would force the woman to either perform abortion or to experience miscarriage or stillbirth. However, these risks were either disregarded by their pro-life opponents, or acknowledged but considered to be less important than the need to preserve the life of another participant of the treatment – the IVF embryo (SDR 2000).

The further discussion of the bill would eventually allow the Catholic politicians to win over their liberal counterparts. During the debates Cè, together with a number of other conservative parliamentarians, proposed to amend art. 1 of the Bolognesi project in the following way: 'The present law protects the rights of all the involved subjects, *in particular* of the conceptus' (emphasis mine). This amendment was accepted with 223 votes in favor and 202 votes against it. However, with the fall of the parliamentary coalition, the bill failed and the idea of granting rights to the embryo was not fulfilled. In 2001 Italy held elections, and central-right parties occupied the majority of seats in Parliament. The Commission on Social Affairs of the Chamber of Deputies elaborated a new bill. It significantly built on the Bolognesi bill, but it was amended by Cè who replaced Bolognesi as the representative for the parliamentary majority. The new bill received parliamentary approval of the Chamber of Deputies and was in limbo awaiting discussion in the Senate. Although the Government appeared in no hurry, according to Valentini (2004) the situation changed with the intervention of the Vatican, which openly urged Parliament to adopt the law in its then form. In December 2003, the Government obtained the Senate's approval of the bill. However, the

Senate, which has traditionally been more liberal than the Chamber of Deputies, modified the provision of embryos' rights. The formulation of the article voted for by the Senate was 'the law ensures the rights of all the involved subjects, *including* the conceptus' (emphasis mine). To ensure embryo protection, the bill also prohibited embryo cryopreservation, testing, selection, PGD, and prescribed that all created embryos, irrespective of their health status, must be implanted into the woman. After the second approval of the bill by the Chamber of Deputies, on 10 February 2004, it was passed as Law 40/2004.

Hence, what the debate on Law 40/2004 shows is the ways in which new biomedical technologies may lead to very different biopolitical regimes if deployed in different political settings. In these different regimes, the 'analytics of biopolitics' (Lemke 2011a, 2011b) allows to trace the ways in which life becomes the object of politics, however, the constitutive elements were at work differently in Italy comparing to other 'advanced liberal democracies'. First, as I argued above, the 'truth discourse' in the Italian case was also human science (i.e. genetics), and bioethics. Therefore, similarly to their counterparts from other countries, Italian politicians based their political decisions on science. Yet, regarding the ways in which knowledge was used, hence the second element of the 'analytics of biopolitics', Italy substantially differed from other countries. In particular, unlike other countries, in Italy the use of expert knowledge was used to promote an essentialist view on human life and foreclose the development of biomedical and genetic sciences and technologies that could jeopardize life and to learn from nature in order to know how to transform it. This made genetics an ontological, 'conservative' source of knowledge, in contrast to the 'transformative' source of knowledge that it played in many other countries.

Another strategy of intervention in 'advanced liberal democracies' have been technologies of the self and technologies of the social. According to Rose, 'the developments in biomedicine have become deeply intertwined with prevailing technologies of the self, and the contemporary biopolitics is *ethopolitics*' (Rose 2001, 2). However, these technologies of the self or technologies of the social do not have a single calculating center, such as the state, where they are designed and from which they are exercised. As Rabinow and Rose (2006) argued regarding ART, 'it is hard to discern some unified biopolitical strategy underlying these developments'. A parallel development is the contraction of the state and the spread of non-state actors that Rose called ‘experts of the soma’, advising people how to live happier, healthier and more satisfying lives.

Instead, due to the crucial role of Catholicism, the Catholic Church as a political actor and the political climate of the time, in Italy, new biomedical technologies led to the employment of a different strategy of intervention – a direct and unified imposition of legal rules by the sovereign. Starting from the implementation of embryos’ rights and ending with the restrictive provisions regulating ART, law with its binding force and direct state regulation were used to exercise biopolitics in Italy. Through law, the Italian Parliament implemented those rights that it considered of key importance – the rights of embryos and the duties of parents. As a result, it led, not to the contraction of political power, but to the expansion of political power, as represented by the state.

According to the arguments of Italian politicians, the expansion of political power, in the form of the translation of human rights into positive law and the adoption of restrictive regulations of ART, was warranted due to the specificity of the site in which they existed, that is, the fertility clinic. The ‘public’ nature of IVF as well as the exposure of IVF embryos to the ‘violence’ of women, doctors and scientists that their creation *in vitro* enabled, justified the expansion of sovereign power. Clearly, one can doubt whether Italian politicians who stressed the difference between ART and natural reproduction indeed believed that this difference warranted a more stringent regulation of ART than of natural reproduction. For example, according to Biondi (2013), by enacting a more stringent regulation of ART than of natural reproduction, the Italian Parliament, urged by the Church, simply wished to use this inconsistency to question the constitutionality of the law on abortion and make the policy on abortion as restrictive as ART.

Irrespective of what the true motives were, the Italian debate on ART is indicative of several facts. To begin with, with the development of new technologies, unresolved moral controversies such as those around the ‘moral and legal status of embryo’ might spark anew and provide new arguments to those who wish to ensure the protection of unborn life. Further, ‘nature’ might be far from the only legitimation and limitation to the exercise of political power in liberal democracies exactly because new biomedical technologies allow, not only to control ‘nature’, but also to reprogram it. Hence, as Lemke put it, ‘the idea of a natural origin of all living beings is beginning to be replaced by the idea of an artificial plurality of living beings that are more technical artifacts than natural entities' (Lemke 2011b, 170). Due to these developments, there is an increasing appeal to restrict such practices as they violate human dignity and erode human nature, the position that received the name of 'human dignity as constraint' or 'dignitarianism' (Brownsword 2008). Hence, in modern liberal societies, there may be a reemergence of the conservative discourses of human dignity or as in the present case – of natural rights that build on an essentialist view on human nature as determined by the human genetic code. Natural rights thus may act as a shield against governmentality of science and medicine. Coming back to Foucault (2008, 39), these are the 'rights of man' that allow 'to arrive at the limitation of governmentality by way of the constitution of the sovereign', but also, as we have seen in the Italian case, allow the expansion of sovereign power.

In addition, in Italy disciplinary power was used as a strategy of intervention upon life and health of Italian women. In their relationships with embryos, women's role was in fact reduced to a mere *zoē* needed to gestate embryos. Women's bodies were needed to 'make embryos live'. This approach is particularly visible in the example of the Law's provision that prohibited to withdraw consent after fertilization and before embryo implantation. As Weir (2011, 6) observed, in such situations pregnancy becomes 'a time for routinely conserving and optimizing population at and prior to birth'.

Finally, the third element of the analytics of biopolitics is subjectification. In 'advanced liberal democracies' the rhetoric of choice, autonomy and rights dominated. Instead, in Italy, we can observe a rather different process. During the debate, two 'participants' of IVF were subjectified. The first were IVF embryos. By according legal personhood and rights to them, Parliament reclassified them from being a mere *zoē* and included them into the community of political subjects whose life and health the state had to care about. However, as an IVF embryo itself cannot act, 'it forms the lower limit of subjectification, being culturally understood as capable of being acted upon but not as capable of managing its own conduct' (Weir 2006, 12); their subjectification thus forced changes in the modes of behavior of other people towards IVF embryos. The second group were, clearly, women. The passage of the Law was accompanied not by the rhetoric of choice, but by the duty to care about life of new unborn citizens. This attempt to make adult citizens 'responsible' before IVF embryos resonates with the conclusion of feminist scholars according to whom women are turned into responsible citizens that should care about the health of their future children (Rapp 2000). Yet, in the Italian case women were called on as devoid of any entitlements and possessing only duties with regard to the life of embryos. Coupled with the disciplinary power, the restrictions of women's freedom and their reduction to subjects needed to gestate embryos was necessary to ensure the protection of 'life' as embodied in new Italian citizens, regardless of whether or not they are viable or healthy. As I will illustrate in the following section, the debate on how death of embryos should be determined similarly disregarded the importance of women's consent to carry pregnancy.

3.5. 'Abandoned embryos' and the debate on the end of life

Famously, IVF embryos are used not only for overcoming individuals' fertility issues and hence for bringing new life into existence. IVF embryos are also the source of human embryonic stem cells (hESC) that have a great scientific and medical potential. However, the derivation of hESC from embryos involves their destruction. In what follows, I will explore an attempt of Italian politics to find a solution to this challenge. Although the solution has not (yet) been found and hence no legal regulation of this conflict exists so far, I suggest that the ways in which Italian state authorities approached the problem is indicative of the possible solution that might be adopted in the future.

As mentioned above, before the adoption of Law 40/2004, the practice of IVF in Italian private fertility clinics was unconstrained and Italian doctors were free to create as many embryos as they saw fit. Therefore, after the Law was adopted, it was no longer clear what to do with these 'persons-non-persons' dwelling in fertility clinics (Burani-Procaccini, CDD 1998). One suggestion was to use them for hESC research (Associazione Luca Coscioni 2005). However, Minister of Health Girolamo Sirchia rejected this possibility appealing to the right to life of embryos. Therefore, he issued a Circular that obliged fertility clinics to keep all embryos remaining from fertility treatment frozen (Ministro della Salute 2004).

However, the Circular made an important distinction. It distinguished between embryos that should be implanted and those that have been 'abandoned' by their parents (*stato di abbandono*), that is, those embryos whose parents have rejected to implant them as well as those embryos for which the relevant fertility center could not contact the couple for minumum one year. In the summer of 2006, this latter category of embryos triggered debates in the Italian Senate. The debate was provoked by an announcement that the Minister for University and Research Fabio Mussi made in May 2006. Mussi stated that he did not have an intention to strictly oppose the financing of hESC through European sources of funding, which has been the policy of former Italian governments. Specifically, Italy, together with Austria, Germany, Malta, Poland and Slovakia signed the 'declaration of ethics' in which they opposed the legitimacy of funding hESC research with European sources of funding. Mussi declared he could withdraw the signature of Italy from the declaration and allow the use of European funding to conduct research on hESC in Italy. Mussi's announcement in Brussels raised controversy in Italy. After almost two months of highly emotional debates, the right to make a final decision on this issue was entrusted to Parliament (Gottweis, Metzler and Griessler 2006, 81-82).

The discussion in Parliament revolved on whether some of these cryopreserved embryos might no longer be implantable and therefore used in hESC research. In other words, the topic of the debate was the possibility of drawing a boundary that, if crossed, would mark that embryos could be considered 'dead' (Senato della Repubblica 2006c). How and by whom could and should this boundary be drawn? To address this question, three resolutions were presented and discussed in the Senate. The first one, signed by Rocco Buttiglione and others (center-right alliance *Casa delle Libertà*), prohibited financing projects and research that would involve the destruction of embryos (SDR 2006a). The second one, proposed by the center-left parliament group *Gruppo per le Autonomie*, generally prohibited research involving the destruction of embryos but allowed only the use of frozen embryos for research (SDR 2006a). Finally, the third resolution, proposed by Anna Finocchiaro (center-left alliance *l'Ulivo*), in general urged the Italian government to oppose those types of research that 'do not lead to the destruction of embryos', but also urged it 'to explore the possibility of research on frozen embryos that are no longer implantable' (SDR 2006a). According to the supporters of the third resolution, what was needed is the establishment of a cut-off line beyond which embryos would be considered dead, or, in other words, criteria for the 'death' of embryos. On July 19, 2006, with 152 voices in favor and 150 voices against, the third resolution was voted for by the Senate (SDR 2006b).

This resolution was an obvious compromise between the Catholic and liberal members. In general, it called for promoting other ways of performing research. Furthermore, and importantly, it contains what Metzler has defined as an Italian solution to the problem of the ethics of performing research on embryos (Gottweis, Metzler and Griessler 2006). It suggested the possibilities of defining the threshold which, when passed, would mean that embryos are no longer alive and therefore might be used for research. What exactly this threshold meant, however, was not clear. Was it some biological conditions of the embryo? Or was it its abandonment by its parents?

In 2007, the CNB approached these issues by presenting its opinion entitled *Destiny of embryos derived from ART and that are no longer implantable* (CNB 2007). Members of the CNB were asked to answer two questions. The first one was whether it was possible, and if so, under which conditions and subject to which requirements, to donate embryos that are no longer implantable for research. Embryos that are no longer implantable included both embryos with 'grave and irreversible anomalies' and healthy embryos, including those 'cryopreserved, remaining in the state of abandonment and for which the parental project is no longer possible' (CNB 2007, 7). The second question was whether it was possible to determine the death of embryos, after which 'dead embryos' could be used for research.

The members of the CNB split on both issues. Answering the first question, some members agreed to donate for research only embryos 'with grave and irreversible pathologies', others decided that also healthy but 'abandoned' embryos could be given for research, while yet others rejected both possibilities. According to the last group, embryos were persons whose life must be protected, even if their parents did not want them. The second question on the possibility of determining the criteria for the death of embryos received two different answers. The first was given by members who proposed to establish 'organismic death' as a criterion of death. By 'organismic death', its proponents meant the 'loss of the capacity to develop in an integral, self-regulating way, via a progressive cell differentiation' (CNB 2007, 8). The second answer was offered by members who argued that it would be difficult to use this criterion as it would be arbitrary and would be established in such a way as to make possible the use of embryos for research. Instead, more research should be done to ascertain with full precision the criteria that would 'objectively' mark the death of embryos.

Interestingly, for all the CNB members the mere fact that embryos for any reason could not be implanted into their genetic mother and therefore did not have any prospects for life, did not mean they should be regarded dead. In other words, they did not equate the impossibility of implanting embryos into the woman with their death. The female embodiment through which embryos could be born (and not be dead) was entirely absent in the debate. Only some internal processes of the embryo itself that could preclude it from further development such as ‘organismic death’ could serve as criteria of death. This importance of the role of women for making a decision on the death of embryos was only voiced in a dissenting opinion by a famous Italian feminist scholar, Gloria Zuffa, who was also a member of the CNB. She first agreed that non-implantable embryos could also be given for research. Yet, she criticized both liberal and Catholic members for the way they answered the second question, namely, on the definition of the criteria of death. According to her, the criteria for defining embryos’ death could not be determined in the same way in which the criteria of death of born people are determined, exactly because embryos are not born yet. This means a complete disregard of the role of women in their very possibility to be born and to be alive (CNB 2007, 14).

At the moment, it is not clear what the Italian State will decide regarding both the destiny of non-implantable embryos and the definition of the criteria of embryos’ death, nor how hESC will be regulated in Italy. However, the discussions both in the Senate and the CNB suggests that the debate on the legality of hESC might shift to the debate on the scientific (biological or genetic) criteria of establishing embryos’ death. First, establishing death through reference to some biological processes would reinforce the Italian essentialist approach to embryos whose ‘human nature’ is the main source of their entitlements and would preserve and reinforce the discursive and legal construction of IVF embryos as full-fledged human persons, as it has been institutionalized in Law 40/2004. Similarly, just as the beginning of life of a human person is a fact established by science, so would their death be a scientific fact. As a result, embryos’ right to life should not be jeopardized by new biomedical technologies. In contrast, the right to perform hESC only on embryos who are already ‘dead’ would reinforce their moral personhood and the possession of an inalienable right to life.

What does the disappearance of women mean and how does it relate to the conclusion made above about the exercise of disciplinary power over them? I suggest that the disregard for the role of women in giving birth to embryos is a reverse side of the disciplinary power exercised by Law 40/2004. The disciplinary power turns individuals into ‘docile bodies’

(Foucault 1977, 1980) by supervising, controlling and commanding their behavior, hence disregarding their agency. The prohibition to withdraw consent after fertilization means exactly this dismissal of women's freedom in autonomously controlling their bodies. Similarly, the disregard of women's role in carrying pregnancy to term for identifying the moment of embryos' death means that the availability of women's bodies for gestating embryos is simply taken for granted and that their consent in having the embryos implanted is apparently irrelevant. Women are seen as always present if needed to give life to new Italian citizens.

3.6. Conclusion

In this article I have sought to show, using the Italian debate around Law 40/2004, how natural rights as the legitimation of political power have been employed to perform biopolitical governance in Italy, in particular by including IVF embryos into the moral and political community of humans. Whereas the Italian case might be a somewhat extreme example of how natural rights of embryos are implemented into actual policy, it can point at two important conclusions for our understanding of biopolitics. First, natural rights as the limits for new biomedical practices may experience a revival due to the fears that human dignity may be uprooted by new biomedical advancements. It thus confirms the conclusions of already existing research that points at the importance of dignitarianism as a third type of ethical reasoning alongside liberal human rights and utilitarian thinking (Brownsword 2008). Second, the elements of the 'analytics of biopolitics', namely, knowledge, power, and subjectivity, also structure and help implement biopolitical strategies in cases where natural rights act as a key element of governmentality rationality, but they take a different shape than is usually seen in other cases of biopolitics.

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CHAPTER 4

Redrawing the boundary of medical expertise: medically assisted reproduction and the debate on Italian bioconstitutionalism

4.1. Introduction[1]

As a consequence of recent advancements in biomedical sciences, many countries across the world have had to reconfigure their constitutional arrangements. As "life itself" (Rose 2006) has become the object of increasing scientific and technological examination, intervention and manipulation, societies' most basic and fundamental legal settlements have had to be redefined in order to respond to new techno-scientific developments. Redefining constitutional frameworks has included the acknowledgment of new legal rights (Scott 2013), the extension of legal personhood to new artificially-created life forms (Metzler 2007, 2011), and the emergence of biological citizenship as a new "citizenship project" (Rose and Novas 2004). In legal scholarship, these transformations have been defined by the portmanteau term "bioconstitutionalism" (Jasanoff 2011a), a term which underlines the increased importance of the "*bios*" in the constitutional governance of life in the modern world.

In many countries, bioconstitutional transformations have been accompanied by intense public controversy. Because biomedical and biotechnological innovations such as cloning, xenotransplantation, or the more conventional preimplantation genetic diagnosis (PGD), have touched upon a number of important ethical and legal values, bioconstitutional deliberations have often been embroiled in persistent debates about the normative aspects of technoscience and how these should be translated into law (Metzler 2011; Testa 2011). In this article, I focus on one such controversy that has evolved around defining the place and role of medical expertise in state's government programs in light of the increasing number of reproductive opportunities offered by the new assisted reproductive technologies (ART). I explore this debate under the rubric of bioconstitutionalism to illustrate how the renegotiation by the State of its constitutional obligations towards its citizens, provoked by ART, influences the redrawing of the boundary of medical expertise. I build my analysis on the Foucauldian concept of governmentality (Foucault 1991), as applied by Johnson (2003, 2005) to the analysis of professions, according to which professions and the State are not discrete and

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[1] Article published as: Parfenchyk, Volha. 2016. "Redrawing the Boundary of Medical Expertise: Medically Assisted Reproduction and the Debate on Italian Bioconstitutionalism." *New Genetics and Society* 35 (4).

independent actors, but simultaneously participate in the same governing project. Specifically, Johnson (2003, 2005) argued that the tensions between the State and the medical profession should be seen, not in terms of the autonomy/intervention dualism (Freidson 1988), but as techniques of governmentality. In this article, I further advance the Foucauldian approach to the analysis of professions and their role in the process of state formation by illustrating the role that legal rights play in this process.

To do this, I examine the debate around the provisions of the Italian Law 40/2004, which prescribed a uniform method of performing IVF in Italian fertility clinics. Specifically, the Law obliged the treating practitioner to fertilize no more than three oocytes during one IVF cycle and to transfer all the embryos created into the patient's uterus simultaneously (Repubblica Italiana 2004). By setting this "three embryo" standard, the pro-life members of the Italian Parliament sought to prevent the creation of surplus embryos and their cryopreservation, the constitutive elements of IVF (Gianaroli et al. 2000; Hillier 2013) and thereby to ensure the protection of a new technologically-created entity – the embryo outside the women's body (Metzler 2011). Drawing on the concept of boundary-work (Gieryn 1983, 1995), I explore how the Italian Parliament justified the expansion of the jurisdictional powers of the State into a domain traditionally occupied by the medical profession, namely, the prescription of treatment methods, and how the Italian Constitutional Court justified the constitutional illegitimacy of the Parliament's actions. I argue that the demarcation of the jurisdictional domains of the medical profession and the Italian State depended upon how the latter tipped the balance between the conflicting rights of IVF embryos and the rights of adult Italian citizens, and the procedures of embryo surplus production and cryopreservation acted as a terrain where both the State and the medical profession came to defend their interests. As such, the demarcation of the jurisdictional and occupational boundaries of the medical profession and the State, and the definition of constitutional rights, formed two sides of the same governing project.

This article starts by setting out the analytical framework. It identifies the transformation of the relationship between the State and the medical profession, which resulted in the latter taking over the role of medical expert, as a tactic of governmentality. The subsequent analysis of parliamentary debates and litigation foregrounds the role of constitutional rights in the redefinition of the jurisdictional and occupational terrains of the medical profession and the State. More specifically, it illustrates how redrawing of the boundary between the domains of the medical profession and the State and re-defining the constitutional commitments of the Italian State towards its citizens, prompted by the emergence of new ART, became part of the same governing project. Further, confirming the conclusions drawn by other works on the transformation of the governance of biosciences and biomedicine (Jasanoff 2005; Salter and Jones 2007), this analysis recognizes that the appeal to knowledge can no longer legitimize the development of biomedical practices and that other ways of legitimizing them are now required.

4.2. Bioconstitutionalism, governmentality and boundary-work

Bioconstitutionalism, as a defining term, was introduced into academic literature to theoretically conceptualize the relationship between constitutional law and the new developments in biological sciences, medicine and technology and thus provide an instrumental toolkit to support a systematic theorization of their interactions (Jasanoff 2011a). Bioconstitutionalism builds on Jasanoff's research on the co-production of science and social order (Jasanoff 2004) and is influenced by the ideas of biopower and biopolitics (Rabinow 1992; Foucault 1998; Rose 2006) in that it acknowledges the importance of the life sciences in the governance of life. Yet, by engaging with such traditional constitutional law categories as legal rights, legal personhood, and citizenship, bioconstitutionalism attaches itself to legal analysis and legal theory, enriching them with philosophical reflections on the significance that science and technology have in regard to constitutional governance. Specifically, Jasanoff mentions two bioconstitutional transformations, which were prompted by new biomedical practices. According to the first, top-bottom perspective of bioconstitutionalism, states grant legal recognition to "new entities, new subjects, or new rights" (Jasanoff 2011, 289) created by techno-scientific advancements. The second, bottom-up bioconstitutionalism, represents the articulations of new right claims by individual subjects towards their governments, and the use of biological knowledge as a means of legitimizing them. The second type of bioconstitutionalism relates to what, following Petryna (2002), Novas and Rose called biological citizenship (Novas and Rose 2004).

In this article, the notion of bioconstitutionalism is employed to advance the understanding of how changes in the constitutional commitments that state governments have towards their citizens, prompted by biomedical advances, interact with the establishment of the jurisdictional boundaries of medical expertise. The theories emanating from the sociology of professions traditionally explained the relationships between professions, including the medical profession, and the state in terms of the autonomy/intervention dualism (Freidson 1988). According to such conceptualizations, the main reason for granting autonomy to professions is the latter's exclusive possession of objective, credible and highly complex expert knowledge, training and skills (Parsons 1949; Abbott 1988; Freidson 1988). The highly complex and "esoteric" (Freidson 1988) nature of this knowledge justified the exclusion of lay and untrained people because "only properly trained men can know and evaluate it" (Freidson 1988, 360). Conversely, in such works, the knowledge possessed by the professions automatically received the seal of approval by virtue of it being the product of the work of professional social groups.

Johnson (2005) opposed this conception of professions and drew on the idea of governmentality propounded by Foucault to lay ground for his understanding of professions. In the lectures Foucault gave at the *Collège de France* (Foucault 1979), he drew on his earlier work about biopower and began to develop an understanding of the development of the modern bureaucratic state and the role that expert knowledge had in state formation. He suggested that, from the beginning of the nineteenth century, political power has been exercised through a number of institutions and practices, including both formal bureaucratic apparatuses and a number of non-governmental institutions, practices, knowledges, techniques, and rationalities. It was this ensemble of apparatus that he called governmentality (Foucault 1979, 20). At the center of the exercise of political power he thus located, not the homogenous and omnipotent State, but the process of government, exercised through multiple forms, techniques, and institutions, in which the State was only one agent (Miller and Rose 2003, 77). These non-governmental practices, which could be loosely defined as expertise, became integrated into a state apparatus, which justified and legitimized its policies and political programs by relying upon the "neutral" language of expertise. Yet, the neutrality of expert knowledge was the product of a mutual stabilization process of the State and expertise, and not a characteristic of its essential and transcendental nature.

Applying the idea of governmentality to the analysis of professions, Johnson (2005) argued that expertise, embroiled in the process of governance, was ultimately institutionalized in the form of professions and was thus a product of government programs. Put differently, the institutionalization of professions and the formation of the State were the outcomes of a single state-expertise stabilization process. Johnson, therefore, agrees with Larson (1977) and Abbott (1988) that professions are not pre-constituted entities, but, in contrast, acquire their jurisdictional boundaries as an outcome of the struggles they undergo to expand their jurisdictional domains. Yet, following Foucault, Johnson challenges the role and nature of the expert knowledge possessed by the professions. Building his analysis on the idea of the mutual constitution of expertise and the State, he argues that knowledge is a product of the mutual participation of expertise and the State in the process of government. Therefore, the attribution of "correctness" to expert knowledge is also a *result* of government, and not an intrinsic quality of knowledge (Johnson 2005, 10).

One implication of the mutual constitution of expertise and the State is that the government has the opportunity to transform the "arenas of professional neutrality and autonomy" (Johnson 2005, 10), into the political object, if such a transformation is needed to implement new government objectives. In this way the State is able to redraw the boundary between its own jurisdictional domain and the domain of expertise, and expand its jurisdiction over issues which had previously been within the sole purview of the profession. However, transformations such as this are never easy as the State can be accused of politicizing knowledge for its own political objectives. The State and the profession may, therefore, be engaged in boundary disputes over the domains that the competing parties hold important and where they "return to defend, assert or extend their interests" (Thomson 2013, 194). Gieryn's (1983, 1995, 1999) concept of boundary-work provides a good analytical framework for advancing this analysis.

Gieryn employs the term boundary-work to explore the discursive practices which scientists use to draw a "rhetorical boundary between science and some less authoritative, residual non-science" (Gieryn 1983, 783) and to initiate action to establish epistemic authority over the disputed domains (Gieryn 1999, 23). Boundary-work is thus a strategic activity which scientists perform to pursue their ideological objectives because much is at stake – "authority, jobs, fame, influence, nature" (Gieryn 1999, 15) – when the disputes on the locus of the boundary are in play. Gieryn (1995) distinguished four strategies which scientists use to establish their epistemic authority over a disputed domain. First, scientists may seek to expel some claims to knowledge from the domain of science as “bad” science, a strategy Gieryn called “expulsion”. Second, scientists may seek to expand their epistemic authority to a domain, previously occupied by non-science, such as art, politics, or religion. The task here is to “distinguish science from other forms of knowledge deemed to be less reliable, less truthful and/or less relevant” (Petersen, Tanner and Munsie 2014, 193). Third, they may compete for a more truthful representation of reality, attaching authority to their scientific conceptions and denying it to their rivals, the boundary-work Gieryn called monopolization.

Finally, the last type of boundary-work, which Gieryn defines as “keeping politics near but out” (Gieryn 1995, 435-436), refers to scientists’ efforts to protect science from the attempts of outside powers to control or use science for their own objectives. This type of boundary-work is particularly evident in the boundary disputes between scientists and politicians. As Gieryn details, scientists seek to draw science close to politics, particularly, because when a political judgment builds on science, it is “simultaneously measuring and reproducing the authority of science over claims about reality” (Gieryn 1995, 435) and thereby reinforcing science’s “epistemic authority”. But, if science is drawn too close or a “spillover” of politics into science occurs, it threatens the monopoly of scientists over science. Importantly, politicians also seek to maintain a fence between politics and science. Politicians draw legitimacy from science, but they can do so only if science remains “neutral” and “objective”, which it can only be if it remains independent and untainted by political choices.

In recent years, the concept of boundary-work has been employed in a variety of fields, including biomedical sciences, medicine and healthcare. This research illustrates the importance of normative discourses and ethics in undertaking boundary-work. Wainwright et al. (2006) illustrated how scientists perform “ethical boundary-work” to legitimize stem cell research. Ehrich et al. (2006) explored how the staff of reproductive clinics employ the ethical principle of the “welfare of the child” in making decisions on whether or not to provide IVF and PGD treatment. Kelly (2003) demonstrated the role that bioethical deliberation has in public bioethics committees on deciding upon the legitimacy (or lack thereof) of embryo research. Research on interprofessional competition has explored different types of legitimation discourses, which the professions use to expand their professional authority, such as holism and patient-centeredness (Timmons and Tanner 2004). Little research, however, has been done to explore how the normative discourses are employed in the boundary-work undertaken between medical professions and government bodies. Applying the concept of boundary-work to the case at hand, I illustrate the importance of State constitutional obligations towards the citizens in the boundary disputes between the medical profession and the State. Using this approach to explore the mutual constitution of medical expertise and the State (Johnson 2005), I therefore foreground the role that bioconstitutionalism plays in assigning the respective place to medical expertise as an instrument of government.

4.3. Stage 1. The institution of the Santosuosso Commission, the Degan Circular and the "Far West *procreativo*"

IVF made its debut in Italian laboratories in mid-1980s. In 1983, less than 5 years after the birth of Louise Brown, the first girl conceived with the help of IVF, an Italian gynecologist Vincenzo Abate successfully performed the first IVF in a private Italian clinic (Valentini 2004). Immediately following Abate's team success, other Italian university clinics repeated and surpassed it. In 1986 the first frozen IVF cycle was performed (*La Repubblica*, April 12, 1987) and, a few years later in another clinic, a child conceived with a donated oocyte was born.

The deliberation within the Italian government on how to accommodate IVF in the country's healthcare arrangements immediately faced ethical and legal hurdles. The main reason was the use of human embryos in IVF treatment, their creation outside of the women's body and the respective possibilities of manipulating them. Similarly to other countries, where the use of embryos in IVF brought religion back to the fore in public debate (Mulkay 1997; Bleiklie, Goggin, and Rothmayr 2004), the traditionally strong role of Catholicism in Italy, with its uncompromising position with respect to human embryos, affected the first attempts to legislate on IVF (Flamigni and Mori 2005). This was particularly evident in 1984 when, both as a response to the first Italian IVF and to the establishment of the Warnock Committee in Great Britain, the current Minister of Health, Costante Degan, set up a special interdisciplinary commission to inquire into issues raised by ART and to produce a text of a future law. The Commission included doctors, biologists, philosophers, lawyers and public officials and was presided over by Judge Fernando Santosuosso. As a member of the Christian Democrats, Degan first decided to appoint individuals to the Commission who were known for supporting traditional and conservative views, in particular, on matters such as divorce and abortion (Flamigni and Mori 2005). Fernando Santosuosso himself was a catholic and author of a number of books on the catholic faith. This composition of the Santosuosso Commission was immediately criticized by civil society, leading Degan to modify it and appoint some more liberal members, including a well-known clinician and gynecologist Carlo Flamigni and one of the founders of IVF in Italy, Ettore Cittadini (Valentini 2004).

Despite these attempts to "liberalize" the Commission, the conservative mood prevailed, leading to the adoption of a rather restrictive text of the reports. On the one hand, the Commission recognized the unique potential of medicine to find causes and treat human ailing, such as infertility, and therefore help citizens fulfil their legitimate and "worthy" desire of having progeny. On the other hand, if left unregulated, the new medical developments might lead to the "instrumentalization of human life" (Santosuosso Commission 1985, 38). By human life the members meant the human embryo; although they did not specify what exact moral status the human embryo had, they concluded that they "hoped that the legal status of the embryo would be defined soon" (Santosuosso Commission 1985, 47), as it was definitely "a subject" and by no means "an object". The acknowledgement of both medicine's promises and its growing powers to "instrumentalize" life underpinned the decision of the Commission on what role medicine should be allowed to play in the management of the life, health and reproduction of Italian citizens.

First, the Commission found that only a limited range of procedures were legitimate, namely, artificial insemination and IVF using the gametes of the requesting couple. The existing technological limitations in inducing pregnancy with only one embryo and the threat to women's health, caused by recurrent hormonal stimulations, such as ovarian hyper stimulation syndrome (OHSS) and ovarian cancer, justified the creation of surplus embryos and embryo cryopreservation. However, if the doctor did create surplus embryos, then the embryos which were not transferred in the first cycle, must be transferred to the same woman in later cycles. Second, following the opinion of the majority of the Commission's members, the Commission prohibited research on surplus embryos to better understand the factors leading to infertility as being contradictory to the principle of human dignity. Third, it prescribed that IVF must only be performed by doctors holding knowledge in "gynaecology, physiopathology of human reproduction, seminology, with collaboration of sanitarians with competences in the biology of human reproduction with experience in in vitro culturing" (Santosuosso Commission 1985, 59).

The conclusion of the Santosuosso Commission serves as a good introduction to an analysis of how the Italian Government first attempted to define the place and role of medical expertise in the fulfilment of government objectives, in light of the opportunities provided by the new ART. On the one hand, the Commission acknowledged the unique power of the medical profession to secure one of these objectives, namely, health protection, because of the possession of expert knowledge. Therefore, it entrusted all matters, for which such knowledge was required, to doctors. On the other hand, the controversial aspects of IVF, and the ensuing risk of "harming" embryos, urged the Commission to place limits on the professional aspirations of doctors. The boundary-work was particularly evident in the way in which the Commission restricted the use of embryo surplus production and embryo cryopreservation to protect both the embryos' life and women's health, and in how, this limited the jurisdictional power of the medical profession. The result of this balance between the State's obligation to protect embryos and the health of adult citizens was translated into assigning the respective place to medical expertise in the State government plans.

The position of the majority of the Commission members on how new advancements in biomedicine should be used to protect the entitlements of Italian citizens caused two different reactions. The difference between these reactions was related to the opposing views on how to balance the interests of the embryo with the interests of adult citizens, the problem that plagued the debate on all issues related to human reproduction in Italy, particularly, on the regulation of abortion (Calloni 2001; Cesaritti 2011). For example, the more liberal members of the Commission, such as Ettore Cittadini and Carlo Flamigni, argued against the prohibition of embryo research as it could provide important knowledge on embryo development, improve the techniques of IVF and therefore better address citizens' fertility issues (Santosuosso Reports 1985, 56). In this way, they performed the expansion-type of boundary-work described by Gieryn (1999), seeking to further expand the jurisdictional domain of medicine and bring embryo surplus production and cryopreservation into the focus of medicine, appealing to patient's health as a legitimizing instrument.

Another position was supported by Degan himself. Specifically, Degan took into account neither the view of the Commission's liberal members, nor the Reports themselves and refused to deliberate them with the Government. Instead, two months prior their publication, he issued a ministerial circular named "Limits and conditions of legitimacy of services for artificial insemination in the domain of SSN" (MDS 1985). The Circular aimed at regulating artificial insemination alone, but also contained a number of provisions regulating the procedures over embryos. Specifically, the Circular prohibited embryo cryopreservation entirely and only allowed the creation of embryos that were required for implantation. The boundary-work, performed by Degan, thus resulted in the contraction of the professional jurisdiction of the medical profession and was the result of the Government's intent to ensure greater embryo protection.

The subsequent institutionalization of the results of boundary-work followed an even more interesting trajectory, however. The Circular only applied to public fertility clinics, that is, to those that belonged to the National Health Service (*Servizio Sanitario Nazionale,* SSN). This left private clinics beyond its regulatory reach. As a result, a two-tier system of provision of ART developed in Italy. On the one hand, the professional freedom of doctors working in the public fertility centers was substantially restricted by the State. Whilst, on the other, doctors working in the private sector received a high degree of autonomy and were only limited by their deontological codes and the general rules of Italian law. Their professional autonomy, a product of the Degan Circular, was further reinforced by the persistent political debates on the legitimacy of embryo surplus production and cryopreservation. For more than ten years the failure to reach consensus on this issue precluded any attempt to even start the parliamentary deliberation on the law, despite the fact that numerous bills had been presented to both chambers of Parliament. The Vatican, whose position on human embryos has been one of the firmest among other religions, used the existing political crisis in Italy to impose its values on the Italian society through affecting the party politics (Hanafin 2007). In contrast, the political parties used the Vatican's support to promote their political agendas. The regulatory limbo turned the Italian private sector of reproductive medicine into one of the most permissive in the world, giving Italy the nickname of "Reproductive Far West" (Neresini and Bimbi 2000).

The different roles that the medical profession played in Italy was a direct outcome of the opposing views held by Government members on how embryos' rights should be balanced with the rights of adult citizens and, therefore, which ART should be held legitimate. As the research on boundary-work has shown, boundary-work does not always lead to stability and, unless there are factors that help to stabilize the results of boundary disputes, the latter may may remain fluid and volatile (Star and Griesemer 1989; Moore 1996; Guston 1999). The split system of the provision of ART services in Italy illustrates how the impossibility of reaching consensus on how the boundary-work should be ultimately performed and translated into the respective healthcare arrangements, created an entirely different outcome, namely, the simultaneous co-existence of two different models of state/expertise relations. As Franklin argued with respect to a similar situation in the United States, the lack of comprehensive legislation and the unregulated provision of ART are a direct outcome of government attempts to give clear answers to the abstract and complicated question of the "moral and legal status" of the embryo, instead of taking a "sociological" approach and accommodating as many views of its citizens as possible, a position adopted by the Warnock Committee in the UK, for example (Franklin 2010). Yet, the Italian government had been consistently trying to define the place of human embryos in the Italian constitutional order, thereby laying ground for the never-ending debates around the status of the embryo and leading to the institutionalization of the split system of regulation.

4.3. Stage 2. The rise and the fall of the Bolognesi bill. Adoption of Law 40/2004

The impulse for further governmental deliberation on the regulation of ART was caused by the international progress that had taken place in cell biology. The high profile case about cloning the first mammalian animal, Dolly the sheep, in 1997, created strong emotional turmoil in the Italian media who urged Parliament to set limits on runaway scientific developments (Neresini and Bimbi 2000). Unsurprisingly, the regulation of an almost unregulated sector of ART came top of the list of government priorities in the area of science and technology policy.

The government assigned the task of elaborating the text of a bill to the Commission on Social Affairs of the Chamber of Deputies. The then parliamentary coalition was centrist-left which suggested that a more permissive bill on ART would be adopted. Furthermore, the president of the Commission, Marida Bolognesi, herself a member of the Italian social-democratic political party "Democrats of the Left" ("*Democratici di Sinistra - L'Ulivo*"), was known for her feminist and rather liberal views on matters related to ART and abortion

(Valentini 2004). The course of action, which Bolognesi would take in the discussion of the bill, was already reflected in her position on the moral status of the embryo, which she expressed in her opening speech. Resonating with the position adopted by Warnock, Bolognesi stated that, although the human embryo was "worthy of respect" in virtue of it being the "project of life", people's views on it differed and therefore a "shared social ethics" ("*etica sociale condivisa*") should serve as the basis of any future laws on ART.

To draft the first version of the bill, Bolognesi set up a special Restrictive Committee and assigned to it the representatives of a wide array of normative positions regarding ART. To a large extent, the debate in the Committee reflected the debate in the Santosuosso Commission, where individual views on the "moral and legal status" of the embryo underpinned the boundary-work they performed with respect to the procedures of embryo surplus production and cryopreservation. However, the existing situation with unused frozen embryos flooding Italian clinics because of the absence of any targeted regulation regarding their storage and disposal, exacerbated the skepticism of the pro-life politicians towards these procedures. Maria Burani Procaccini, for example, a member of the center-right party *Forza Italia*, argued for the prohibition of the creation of surplus embryos in order "to prevent the production of eighty thousand and more cryopreserved human embryos who are threatened because nobody knows what purpose they serve" (CDD 1996a). Thus, the pro-life parliamentarians claimed that the doctor must be allowed to create only that number of embryos that should be implanted into the woman according to the most recent clinical evidence, in order to avoid the creation of surplus embryos and their cryopreservation (CDD 1996a; CDD 1999b). They pointed out that due the existing limitations in the ART techniques the creation and implantation of one embryo might not initiate pregnancy; doctors therefore should be allowed to fertilize several oocytes, subject to the simultaneous transfer of all the created embryos into the patient's uterus. In contrast, the liberal politicians insisted that doctors should be given full liberty in terms of the creation of embryos and their preservation as such liberty was indispensable for the "good" discharge of their professional duties (CDD 1996b).

Following her commitment to "shared social ethics", Bolognesi sought to reconcile the different ethical positions regarding surplus embryos and searched for a compromise solution. As a result, she endorsed the text of a unified bill, later dubbed the "Bolognesi project" ("*Progetto Bolognesi*"). This bill stipulated that a doctor was allowed to create a maximum of four embryos in one IVF cycle, transfer as many embryos as deemed appropriate in a concrete case to initiate pregnancy, and cryopreserve the remainder, but that these remaining must be transferred into the same woman in the following cycles (CDD 1997a). The "four embryo" standard was another result of the boundary-work, in which a different view on how the Italian State should protect the constitutional entitlements of its citizens resulted in a differently drawn boundary between the professional domain of the State and the medical profession.

Yet, the "four embryo" standard represented a step forward in how the boundary-work was performed by the Restrictive Committee, compared to the Santosuosso Commission. The former not only balanced State commitments as it saw fit and translated this balance into a particular configuration of the medical profession and the State, but also attributed to it a form of clinical evidence. Four as a maximum number of embryos to create and implant was borrowed from the unfolding debates among clinicians about the appropriate number of embryos that should be implanted to increase the chances of pregnancy but which would also reduce the risk of multiple pregnancies to minimum (Murdoch 1998). The pro-life politicians, after having explored the existing international IVF practices, transposed into law the evidence, which, according to them, was shared by the majority of the clinicians themselves. However, unlike the medical profession, they employed this evidence not only to protect the health of the aspiring mother, but also to prevent embryo surplus production and cryopreservation. As a result, the "four embryo" standard was not about the implantation of embryos, but their creation.

This move represents a tactic of governmentality (Johnson 2005), through which the Restrictive Committee redefined the jurisdictional boundaries of expertise to address the constitutional obligations of the Italian State. On the one hand, the locus of the boundary was partially predicated on the availability of knowledge concerning the appropriate number of embryos to implant and the professional capacity of the doctor to autonomously decide how many embryos should be created and implanted in each individual case to better account for the patient's health condition. This illustrates how expertise was again made part of governance in order to respond to the constitutional obligations of the Italian State, such as its duty to protect the right to health (Johnson 2005). On the other hand, the involvement of expertise in governance was also performed to ensure the protection of the new obligations of the State, namely, towards IVF embryos, which in medical practice do not enjoy the same status as adult patients. The result of balancing the State duties towards its citizens was translated into granting that jurisdictional power to the medical profession, which was necessary to enable the fulfilment of both State duties. However, this move of the Italian Parliament was not without problems.

The first sign that the "four embryo" standard would create controversy came immediately after the bill was presented to the other members of the Commission on Social Affairs. First, the differences in normative commitments led to different understandings of what number it should be. Some conservative members of Parliament proposed that a limit be put on the maximum number of embryos that a doctor should be allowed to create, from one (CDD 1997b), to two (CDD 1998) or three (CDD 1998) and that these should be implanted simultaneously, thereby precluding any possibility of embryo manipulation and denying the doctors any medical discretion. The key requirement in these proposals was the prohibition of the creation of surplus embryos and their cryopreservation as such measures represented, according to the deputy Cesare Ercole, "a fundamental protection of embryo's life" (CDD 2002). As the debates progressed, the "three embryo" standard, together with the prohibition of embryo surplus production and cryopreservation, became the most frequently claimed requirement of the pro-life politicians.

Second, an attack came from liberal politicians, supported by the Italian medical community. They performed the type of boundary-work that Gieryn called "keeping politics near but out" (Gieryn 1995). Specifically, the doctors and liberal politicians argued that the state-produced standards represented a "spillover" of politics into clinical knowledge. First, the pro-life politicians incorrectly interpreted the clinical evidence, because "four" should refer not to the number of created embryos, but to those implanted. Second, since the medical community does not only produce, but also applies knowledge as part of its practice, these standards would force the doctors to apply this "incorrect" and "one-fits-all" treatment in different clinical situations and inflict harm on women's health, for example, through increasing the risk of developing OHSS and ovarian cancer. Tacitly many of the doctors and politicians recognized in these state-mandated clinical standards the embedded normative principles and the attempts of the pro-life politicians to protect embryos against harm which was reflected in the speeches of some politicians (CDD 1999a). Yet, this time they also emphasized the apparent incorrectness of the state-produced clinical knowledge and thus added this type of boundary-work to the former "expansion" type. In the debates that followed, the standards, their claimed incorrectness and the resulting adverse health effects on female patients, would become the main leverage, used by doctors and liberal politicians, to oppose the attempts of the supporters of embryo protection to limit the jurisdictional domain of medicine.

However, the recourse to knowledge for legitimizing the expansion of medical expertise on the procedures of embryo surplus production and cryopreservation would prove unsuccessful. In 2004, the Italian Senate voted for the restrictive draft of the law. Interestingly, as Valentini (2004) suggests, the intervention of the Vatican had a decisive impact upon the eventual form of the Law which prescribed that, irrespective of their morphological and genetic characteristics, all embryos produced during one IVF cycle, and which should not exceed three, must be implanted into the women's uterus. The Law also outlawed cryopreservation and selective embryo reduction. These norms were meant to restrict doctors' discretion with regard to treatment options and make the application of IVF consistent with the principle introduced in Article 1 of the Law. The article recognized the human embryo as a rights-holder and prescribed that ART should henceforth be performed "under conditions and according to the modalities foreseen in the present law which ensures the rights of all the involved subjects, including the conceived" (Metzler 2011). In the same year these provisions were implemented into the guidelines of the Ministry of Health introducing a new medical protocol for performing IVF in both public and private Italian clinics (Ministro della Salute 2004).

This failure to refute the state-produced standards through recourse to knowledge fits squarely with the acknowledgement from scholars that biomedicine and bioscience, due to their ethically controversial nature, particularly related to the use of human embryos, proved no longer capable of maintaining public trust by referring to their scientific authority (Salter and Jones 2007). Both nationally and internationally, this resulted in the search for additional strategies of legitimizing biosciences and rendering them accountable to the public, and the normative language of bioethics become a key instrument in achieving this (Rose 2004; Salter and Jones 2007; Wilson 2011). The involvement of bioethics in assessing the legitimacy of new biomedical practices represented another example of the erosion of science's boundaries (Funtowicz and Ravetz 1993; Nowotny et al. 2001). In Italy, State constitutional obligations became a normative benchmark for assessing the legitimacy of IVF and thereby defining the jurisdictional domain of medical expertise.

Yet, the tactics used by the pro-life politicians were not unproblematic, either. First, the intense controversy around them points at the difficulty of accepting the authority of such state-produced clinical standards, because they rested on knowledge produced by expertise for other state political projects, namely, to protect patient's health (Foucault 1979; Johnson 2005). Specifically, by giving a different interpretation to this knowledge and applying it to different state goals, namely, to protect IVF embryos, the pro-life politicians drew expert knowledge "too close" to politics and thereby undermined the "neutrality" of their political judgment (Gieryn 1995; Johnson 2005). This explains the attempts of both the medical community and liberal politicians to refute the "standards" as both "incorrect" and politically charged. Second, when knowledge is used to meet new state goals, the debate over it may become pervasive, because of the disagreements about what these goals exactly are and how they should be met, especially in such longstanding debates as those involving human embryos. As shown above, it was precisely the disagreement about the scope of State duties towards its citizens that created a two tier system of the regulation of ART and the debate among the members of Parliament as to how many embryos future law should allow to be created. Third, because this knowledge is openly non value-neutral, it can be subject to contradictory interpretations, for example, when the interpreting subject disagrees with the values, inculcated in such knowledge, or interprets them differently. As I will further illustrate, it was just such a different interpretation of the state-produced "three embryo" standard that allowed the Court to invalidate it as unconstitutional.

4.4. Stage 3. Litigation and the judgment of the Italian Constitutional Court

Predictably, it was soon clear that Law 40/2004 was unable to promote a nation-wide compromise on regulating IVF. In 2005, the debate around the "three embryo" standard shifted to a different – judicial – setting. In the majority of cases the plaintiffs were Italian couples, claiming that the prohibition of embryo surplus production and cryopreservation violated a number of their constitutional rights, including the right to health, because the restrictions led to a higher risk of OHSS and ovarian cancer. In one case (TARL 2007) the plaintiff was the World Association of Reproductive Medicine.

Among the six submitted cases, only one was unconditionally satisfied in favor of the plaintiffs (TF 2007). The judge gave a “constitutionally oriented interpretation” of Law 40/2004, as the plaintiffs requested, and allowed the creation of surplus embryos to protect the health of the pregnant woman. In the remaining cases the judges either did not sustain the complaint (TC 2004) or considered that, before proceeding, the Law’s constitutionality should be assessed by the Constitutional Court (TC 2005; TARL 2007; TF 2008a; TF 2008b).

The plaintiffs’ main strategy rested on displaying the lack of scientific credibility underlying the “three embryo” standard. Fertility centers, which were formally the defendants in the trials, and medical experts, participating in the trials as third parties, supported the plaintiffs and claimed that the “three embryo” standard was not evidence-based medicine and contradicted international good practice guidelines. The lack of scientific credibility of the standard was, according to them, the main reason why its application by doctors in practice would cause harm to patients’ health and violate their right to health.

The reaction of the courts was remarkably consistent. The judge of the Florence court, for example, agreed that the “three embryo” standard was not entirely consistent with the prevailing medical standards regarding infertility treatment (TF 2008b). But he added that, in designing the “three embryo” standard, the Italian Parliament sought not only to build it on the most credible medical evidence, but also to strike a fair balance between protecting the rights of adult Italian citizens and those of embryos. Therefore, the “constitutionality” of the “three embryo” standard could not be assessed by its consistency with the international clinical standards only, but, instead, by how fairly it balanced different constitutional entitlements, in particular, the right to health of the woman and the right to life of the embryo, and whether the result of this balancing was in conformity with the Italian constitutional law. This conclusion of the court shifted the assessment of the “three embryo” standard from the epistemic to the normative, or better constitutional, terrain, because it required elucidating not only what was “correct”, but also how the Italian Parliament conceived of its constitutional obligations towards its citizens. In other words, he sought to clarify which bioconstitutional arrangements underlay the role assigned to the medical expertise by Parliament and whether this decision of Parliament conformed to the Italian Constitution. Because this assessment could not be performed by local courts but required the intervention of the Constitutional Court, the Florence court passed the case to the latter.

The Constitutional Court was presented with the conflicting evidence about the clinical acceptability of the “three embryo” standard. On the one hand, in a similar manner to the cases decided by local courts, the medical associations sought to display the causation between the legal restrictions on performing IVF and the infliction of harm on women’s health, a direct outcome of the clinical “incorrectness” of the “three embryo” standard. On the other hand, pro-life and catholic associations, followed by the Avvocatura dello Stato, the Italian state body representing the interests of the Italian government in legal proceedings, countered these arguments. They argued that there was no clinical evidence that the decision of Parliament, to limit the number of implantable embryos to three, inflicted harm on women’s health. Specifically, the Committee for the Protection of Women provided the Report of the Minister of Health about the state of the implementation of Law 40/2004. The Report contained statistics according to which, after the Law entered into force, a sudden decrease in complications from ovarian stimulations was detected. This, according to the Committee, proved that the “three embryo” standard could not cause more adverse effects on women’s health than the traditional IVF, at least as far as OHSS was concerned. Importantly, they stressed that the “three embryo” standard represented the position of Parliament on how the conflicting rights of the embryo and adult citizens should be balanced and what role medicine should play to ensure the protection of these rights. As Movement for Life argued “even the discretion of the doctor must respect the rules deriving from the requirement to protect international human rights” (CC 2009).

In 2009, the Constitutional Court passed its milestone judgment repealing the ban on the creation of surplus embryos and their cryopreservation. The baseline of the Court’s judgment was the conclusion that the medical community was the only social institution that was cognitively and technically capable of performing infertility treatment. Implicit in the Court’s judgment was the privileging of the evidence provided by the plaintiffs over the evidence provided by the pro-life associations. And yet the Court’s judgment was not the result of it accepting the epistemic arguments provided by the plaintiffs. The entry point here is the first passage of the judgment, in which the Court directed its gaze at a possible contradiction between a seeming intent of Parliament to ensure maximum embryo protection and the right granted to doctors to create three embryos. The Court suggested that Parliament granting permission to create three embryos instead of one was not intended to make triple pregnancies possible, but to ensure that there were better prospects of initiating a single healthy pregnancy. Therefore, Parliament had tacitly accepted “that some of them [embryos] might not initiate pregnancy” (CC 2009), which in practice implied Parliament’s consent to limit embryo protection to “ensure concrete expectations of pregnancy” (CC 2009). The Court concluded that, if Parliament limited embryo protection for particular therapeutic purposes, it implicitly relinquished its powers to protect IVF embryos and entrusted them to the authority of a different social institution: medicine. As a result, all subsequent medical prescriptions set down by Parliament, such as the limitation of the number of producible and transferable embryos and the ban on cryopreservation, constituted both a paradoxical contradiction to Parliament’s own intention to limit embryo protection and an intrusion into the medical profession. Importantly, the latter could create adverse health risks for female patients’ health. The expulsion of the State from medical practice and granting doctors the autonomy to treat was the only possible way that Italian medicine could ensure the right to health of Italian female patients. In short, while the “three embryo” standard was reasonable and not self-contradictory for the individual parliamentarians, as exemplified in the opinion expressed by Ercole (CDD 2002), it was self-contradictory for the Court. It was precisely this apparent contradiction that was used by the Court to invalidate the “three embryo” standard as unconstitutional.

The judgment of the Constitutional Court leads back to the opening paragraphs of this article and to its underlying idea about the mutual constitution of bioconstitutional arrangements and the state/expertise formation. The Court’s automatic deference to medicine after acknowledging the priority of citizens’ procreative rights over the rights of embryos shows how State constitutional duties and the assigning of the respective place to medical expertise, were co-dependent and co-constitutive (Jasanoff 2004, 2013). Just as the recognition of the priority of adult citizens’ rights over the rights of embryos implied a greater place of medical expertise in the government of citizens, the deference to medicine required legitimation, and the language of rights acted as just such a legitimizing technique. Importantly, it also shows how the appeal to knowledge was insufficient in invalidating the “three embryo” standard in the courtrooms too, thus confirming previous research on the inability of biomedical practices to legitimize themselves through reference to scientific authority (Salter and Jones 2007).

The pronouncement of the Constitutional Court was a key event in re-settling the arrangements between medicine, patients and the State, that had been so easily unsettled by the advent of the new ART. The latter problematized the relationships between the three by creating a new entity – an embryo outside the women's body – and made from it one of the central objects of medical practice. In this way they introduced an old and contentious issue of the "moral and legal status" of the embryo into the debate about the governance of medicine. The Constitutional Court, through the move of co-production (Jasanoff 2004), *simultaneously* addressed the issue of how the rights of IVF embryos should be balanced with the rights of adult citizens, and decided on the role that medical expertise should play in the government of Italian citizens. Italian bioconstitutionalism thus framed the relationship between medicine, Italian citizens and the State, which, in turn, reinforced the re-settled bioconstitutional arrangements.

4.5. Conclusion

Analysis of the relationships between the medical profession and the State has traditionally regarded the two as discrete and independent entities, where the former struggles for autonomy, and the latter seeks to establish control over it. This article sought to provide an alternative understanding of this relationship and illustrate how medical expertise becomes involved in the process of government to fulfil a specific range of duties (Foucault 1979; Johnson 2003, 2005). Drawing on Gieryn's (1983) concept of boundary-work and the notion of bioconstitutionalism (Jasanoff 2011), the analysis of the debate around embryo surplus production and cryopreservation in Italy showed how the role, assigned to expertise, was constitutive of the view on the Italian bioconstitutionalist settlements, namely, on the place in the Italian constitutional order of a new artificially-created entity – an embryo outside the women's body – and its connection with the rights of adult citizens. It also illustrated how the "three embryo" standard became one of the outcomes of this debate. This analysis thus highlights the interplay and co-productionist (Jasanoff 2004) relations between countries' bioconstitutional arrangements and the place of medical expertise therein.

This article draws attention to two particular aspects. First, confirming the results of the works on "ethical boundary-work" (Wainwright et al. 2006), it shows the importance of normative discourses, specifically, of the state's constitutional obligations, in performing boundary-work. As illustrated in this article, constitutional rights were the key benchmarks in deciding on both the legitimacy of medicine's "expansion" of its jurisdictional boundaries and on the need to keep the "three embryo" standard out of "good" medical practice as scientifically unfounded (Gieryn 1995). By exploring how boundary-work was performed by public authorities, including the Constitutional Court, this article also contends that the language of rights acted as an indispensable instrument, legitimizing the new ART, because the latter could not legitimize themselves through reference to their scientific authority (Salter and Jones 2007).

Second, it illustrates how some techniques of government, such as the creation of the "three embryo" standard, which the State may use to comply with its newly assumed constitutional duties, may be problematic and remain highly contested. Specifically, when the government transforms the "arenas of decision making once considered realms of neutral, objective fact" (Johnson 2003, 148) into a political issue, it may be accused of the politicization of expertise. This points at the importance that societies attach to the drawing and maintaining of the discursive boundaries between the areas of knowledge and the areas of politics, even if in reality they are "ambiguous, multiple and overlapping" (Starr and Immergut 1987, 251).

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CHAPTER 5

The right to preimplantation genetic diagnosis: biological citizenship and the challenge to the Italian law on medically assisted reproduction

5.1. Introduction[1]

In recent years, there has been an increased interest in the ideas of 'genetic'[2] and 'biological citizenship'.[3] The concepts were introduced into academic literature to conceptualize the type of relationships between authorities and citizens that build upon the recognition of citizens as biological creatures whose health, treatment, maintenance and improvement, is the key value. Although the authors use the traditional concept of citizenship, most of them stress that recent developments in biological and genetic sciences have led to the creation of new forms of political participation, civic engagement and a pluralization of political spaces in which the activities to improve citizens' health take place. Thus, Rose emphasizes that biological citizenship in 'advanced liberal democracies' does not have a 'nationalized form' but instead represents a new 'regime of the self',[4] or an outcome of the process of subjectification of citizens and constructing their identities.[5] Under the guidance of various 'experts of the soma',[6] modern individuals increasingly tend to understand themselves as personally entitled to, and responsible for, enhancing and maintaining their vitality, for example, by individually managing their genetic risks. Importantly, if an illness has genetic roots, it becomes 'familial,

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[1] Article accepted with some major and minor changes by the *European Journal of Legal Studies*.

[2] Deborah Heath, Rayna Rapp and Karen-Sue Taussig, 'Genetic Citizenship' in David Nugent and Joan Vincent (eds), *A Companion to the Anthropology of Politics* (Blackwell Publishing 2007).

[3] Nikolas Rose and Carlos Novas, 'Biological Citizenship' in Aihwa Ong and Stephen Collier (eds), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Blackwell Publishing 2004). Adriana Petryna, *Life Exposed: Biological Citizens After Chernobyl* (Princeton University Press 2002). Nikolas Rose, *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century* (Princeton University Press 2006).

[4] Michel Foucault, *Histoire de La Sexualité* (Gallimard 1976).

[5] Thomas Lemke, *Biopolitics: An Advanced Introduction* (New York University Press 2011); Paul Rabinow and Nikolas Rose, 'Biopower Today' (2006) 1 BioSocieties 195.

[6] Rose (n 3).

a matter both of family histories and potential family futures'.[7] Thus, possessing genetic information creates genetic entitlements and responsibilities, not only regarding one's own health, but that of one's family and future children too. Using Rose's apt expression, in the contemporary 'regime of the self', health has become 'a desire, a right and an obligation', not only towards one's health but also towards the one of one's children.[8]

Along with this 'individualizing' aspect of biological citizenship, there is its 'collectivizing' aspect as well; this includes the formation of biosocial communities such as patient and self-help groups.[9] These communities make alliances with scientists to shape the direction of scientific research and lobby their governments to assign more funds for financing research on their health condition. They often choose transnational forms of organization and cooperation and the Internet is becoming one of the main instruments of sharing information and cooperating, thus overcoming the limits of the nation-state.

Other scholars, however, emphasize that biological citizenship can, and does, have more traditional forms and involve the state apparatus. Specifically, biological citizens also actively formulate and make rights claims upon their governments in the name of their life and health, and ask the state to protect their 'vital rights', for example, by providing better access to biomedical benefits. Rights litigation is one of the most frequent mechanisms used to enable citizens to satisfy their rights claims. For example, in her research, Petryna showed how citizens of post-Chernobyl Ukraine demanded compensation for their damaged health.[10] Further, Biehl showed how, in Brazil, by litigating, 'patients-citizens' achieved 'a democratization of medical sovereignty ' enabling alternative health care practices' to thrive.[11] Finally, Hanafin explored rights litigation in Italy against a restrictive law on medically assisted reproduction (Law 40/2004)[12] for examples of citizens trying to gain

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[7] Rose (n 3) 108.

[8] Nikolas Rose, 'Molecular Biopolitics, Somatic Ethics and the Spirit of Biocapital' (2007) 5 Social Theory & Health 3, 11.

[9] Paul Rabinow, *Essays on the Anthropology of Reason* (Princeton University Press 1996).

[10] Petryna (n 3).

[11] Joao Biehl, *Will To Live: AIDS Therapies and the Politics of Survival* (Princeton University Press 2007) 135.

[12] Legge 19 febbraio 2004, n.40, in G.U. 24 febbraio 2004, n.45 (Law 40/2004).

access to preimplantation genetic diagnosis (PGD), an artificial reproductive technology (ART) performed to test for the presence of genetic abnormalities in the human embryo before embryo implantation in the uterus of the female patient.[13] Hanafin concluded that the use of rights and litigation helped citizens to resist the 'politics from above' and have their interests, ignored by the 'ideologically indifferent' Parliament, recognized by the Italian judiciary.[14]

Hence, for the authors, rights litigation was employed by citizens to fulfill their hopes and have their claims 'in the name of their damaged biological bodies'[15] satisfied, whether it was a claim for financial compensation, as it was in the case of Chernobyl workers, or for access to a forbidden technology, as it was in Italy. Indeed, as researchers argue, hope is another key aspect of biological citizenship. Hope grounds political activism in all its forms, whether this be the making of alliances with scientists to shape the direction of scientific research, political participation through lobbying, or the organization of public referenda.[16] Furthermore, and importantly, biological citizenship operates within what Rose called the 'political economy of hope'.[17] The hope that patients have to find cures for their illness triggers the funding of research and treatment institutions and fuels the commercial aspirations of companies involved in procuring the relevant services and products. Thus,

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[13] Usually PGD is performed to search and detect genetic mutations in genes responsible for either monogenic diseases (cystic fibrosis, beta thalassemia, Huntington's disease) or for certain polygenic diseases (such as breast and ovarian cancer).

[14] Patrick Hanafin, 'Rights, Bioconstitutionalism and the Politics of Reproductive Citizenship in Italy' (2013) 17 Citizenship Studies 9*42.* Patrick Hanafin, 'The Embryonic Sovereign and the Biological Citizen: The Biopolitics of Reproductive Rights' in Conor Gearty and Costas Douzinas (eds), *The Cambridge Companion to Human Rights Law* (Cambridge University Press 2012).

[15] Ingrid Metzler, 'Between Church and State: Stem Cells, Embryos, and Citizens in Italian Politics' in Sheila Jasanoff (ed), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (MIT Press 2011).

[16] Rose (n 3).

[17] Ibid.

because of hope, 'life itself is increasingly locked into an economy for the generation of wealth',[18] or indeed biovalue.[19]

Yet, whereas hope might well drive biological citizens to look for cures for their illnesses, the hope that rights can be used as an instrument to attain this goal needs further exploration. Belief in rights as an instrument to remedy social ills has not always enjoyed support from lawyers and legal scholars. Starting with legal realists and following critical legal studies (CLS) scholars, rights became criticised as a useless and overinflated idea. For example, Rosenberg argued about the 'hollow hope' in the ability of courts to bring about social change through the pursuance of rights.[20] Probably the most famous loss of hope, or rather faith, in rights was expressed by CLS scholar Duncan Kennedy.[21] He argued that he lost his faith in rights because rights turned out to be just like any other type of rhetorical or policy argument and, therefore, were not 'trumps' in the Dworkian sense, that is, special claims which could override the interests of a political majority and lead to the closure of the debate.[22] Even if they were used as 'trumps', rights have the ability to produce counter-claims, and the need to balance them would, therefore, again reduce the dispute to some political or subjective argument, as there is no objective criterion through which the balancing could be performed. As Kennedy observed, this balancing renders the 'rights argument indistinguishable from the open-ended policy discourse it was supposed to let us avoid'.[23] Therefore, what leads to a closure of a controversy is not the claiming of the rights as such, but the relationship between the rights claims, the identity of the rights claimer and their rhetorical mastery, the political viability of supporting arguments, and many other contingent local and historical circumstances.

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[18] Rose and Novas (n 3) 452.

[19] Catherine Waldby, 'Stem Cells, Tissue Cultures and the Production of Biovalue' (2002) 6 Health: 305.

[20] Gerald Rosenberg, *The Hollow Hope : Can Courts Bring about Social Change?* (University of Chicago 1991).

[21] Duncan Kennedy, 'The Critique of Rights in Critical Legal Studies' in Wendy Brown and Janet Halley (eds), *Left Legalism/Left Critique* (Duke University Press 2002).

[22] Ronald Dworkin, *Taking Rights Seriously* (Harvard University Press 1977).

[23] Kennedy (n 21).

The criticism of the use of rights based on their ability to produce counter-claims was also the subject of much feminist critique. The abortion case has been used as one of the most illustrative examples. For example, Carol Smart, following Kingdom, argued that winning rights could not lead to women's emancipation because of the tendency of rights claims to produce counter-claims related to other rights, such as men's rights, fetal rights and children's rights.[24] According to Smart, these counter-rights could be, and are being, used to restrict women's access to abortion and constitute a disguised support for patriarchy. Therefore, for Smart, the use of rights by women is, in fact, counterproductive because instead of liberating women they simply reinforce and reproduce patriarchy.[25] Similarly, according to Lacey,[26]

> rights may operate, in Dworkin's memorable phrase, as trumps: but trumps are of little use if there are many trumps in the pack. And this multiplicity of rights increasingly brings with it a reliance on a coercive framework of enforcement which, as Carol Smart has argued, inevitably depends on violence of legal power: rights are a creature of the state and hence a function of existing configurations of power. This means, it is argued, that they are of limited use to the politically marginalized or for the construction of claims oppositional to prevailing power relations.

At a closer approximation, such criticism of rights contains two main elements. First, rights are criticised due to their main ontological presumptions, particularly, due to the definition of the right-bearing individual seen as a separate, atomistic and self-sufficient being and of rights as shields intended to protect this autonomous self against intrusion and harm.[27] As a result, rights do not account for the relationality and interdependence among people and alienate

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[24] Carol Smart, *Feminism and the Power of Law* (Routledge 2002).

[25] Ibid.

[26] Nicola Lacey, 'Feminist Legal Theory and the Rights of Women' in K. Knop, ed., *Gender and Human Rights* (Oxford, UK: Oxford University Press, 2004), pp. 13-56 at p. 39. Carol Smart, *Feminism and the Power of Law* (Routledge 2002).

[27] Jennifer Nedelsky, *Law's Relations: A Relational Theory of Self, Autonomy, and Law* (Oxford University Press 2011), Karpin, Isabel. 1992. "Legislating the Female Body: Reproductive Technology and the Reconstructed Woman." *Columbia Journal of Gender and Law* 3 (1): 325–49.

them.[28] Such criticism was particularly developed by feminist and communitarian scholars. Following the idea of relational autonomy, feminist scholars argued that individuals are to a large extent relational beings whose identity and bodies are shaped by the relationships and connections between them and other people.[29] Family has been used as an example of an entity whose members are particularly strongly bound by the relational ties such as responsibility, care and collective interests. Similarly, pregnancy has been discussed as an example *par excellence* of relational autonomy.[30] Pregnant women's personal boundaries are intertwined with the boundaries of the fetus and the latter, in turn, at least in the first stages of pregnancy, entirely depends upon the mother. The emphasis on relationality has been particularly important to undermine the viability of views on a disembodied embryo as a value in itself, or as a person having legal personality and rights, that should be protected against harm and violation.

The second element of rights criticism is that what influences how such competing rights, protecting the autonomous and self-sufficient individual, will be balanced is the existing relations of power, the strength of the arguments used, and other contingent local, legal and political factors. Therefore, particularly for women, as a traditionally marginalized societal group, the use of rights is not helpful, as the relations of power will even further entrench the existing subordination of women.

This full-blown critique of rights was later complemented by more contextual analyses of rights. Scholars working in the tradition of feminist and race critical studies were particularly involved in attempting to provide a more nuanced account of rights. According to Wendy Brown,

> [w]hile rights may operate as an indisputable force of emancipation at one moment in history – the American Civil Rights movement – or the struggle for rights by subjects of colonial domination such as black South Africans or Palestinians – they may

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[28] Kairys, David, ed. 1998. *The Politics of Law: A Progressive Critique*. New York: Basic Books.

[29] Ibid, Nedelsky (n 27), Karpin (n 27).

[30] Karpin (n 27).

> become at another time a regulatory discourse, a means of obstructing or coopting more radical political demands, or simply the most hollow of empty promises.[31]

Hence, according to Brown, it is not possible to say anything specific about rights apriori because the costs and benefits of rights are context-dependent. Nevertheless, according to Brown, both in practice and in legal scholarship, rights still figure as the universal language of emancipation and empowerment.

Other scholars, including race and feminist scholars, also engaged into the process of reconstructing rights. Specifically, some authors developing the idea of relational autonomy, proposed the relational approach to rights. For example, according to Herring, rights could be seen as claims protecting not only individual but also relational values and interests.[32] While rights are still claimed to protect individual values and interests, there is no reason why they cannot also be claimed with respect to 'relational values' and interests such as care, responsibility and parental duty. For example, rights such as the right to respect for private and family life, protected by art. 8 of the ECtHR, can act as such a right, promoting relational values. Further, Nedelsky proposed to regard rights as tools that structure relationships among people that foster and protect certain important societal values.[33] Thus, she puts in the center of her reconstructed definition of rights values and relationships that promote those values. The values that are more important for the relevant society for the most part underlie the respective rights. This can act as a response to Herring that the reason why rights might not be able to promote relational values relates to the fact that those relational values do not enjoy support in the relevant society.

With respect to new biomedical technologies, the critique of rights is pertinent because these new technologies raise many ethical and legal questions and controversies. On the one hand, criticism has been mounting in regard to the free use of technologies such as PGD or prenatal testing, as there are concerns that whether they are misused or not, they create threats to constitutional rights and guarantees, specifically, by creating circumstances that lead to discrimination against people with disabilities, to stigmatization and to increased

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[31] Wendy Brown, *States of Injury: Power and Freedom in Late Modernity* (Princeton University Press 1995) 98.

[32] Herring, Jonathan. 2013. "Forging a Relational Approach: Best Interests or Human Rights?" *Medical Law International* 13 (1).

[33] Nedelsky (n 27).

inequality.[34] These fears are representative of a broader anxiety about geneticization, that is, the reduction of individuals to their genetic constitution and the tendency to treat similarities between, and differences among, people predominantly in genetic terms.[35] In addition, since PGD involves the destruction of embryos, PGD might raise ethical and legal concerns in those countries in which unborn human life enjoys legal protection such as Italy or Germany.[36] Therefore, the use of technologies such as PGD and prenatal testing should be either restricted by the State, allowing only their use for detecting serious diseases with high penetrance, an approach followed by the British regulator,[37] or entirely forbidden, an approach we can witness in Italy regarding PGD.

Yet, on the other hand, some citizens argue that a restrictive regulation of technologies, enacted to safeguard certain rights in the face of new technologies, violates *their* rights, for example, their right to autonomy and self-determination. In this respect, the requirement to provide more liberal legal grounds for using new biomedical technologies is related to the evolving governmental 'regime of the self' which subjectifies citizens as responsible and prudent, with respect to their health and that of their children; the use of advances in biomedicine is then not only desirable but also necessary if these obligations are to be fulfilled. The conflict between the competing rights is reminiscent of the competition between the two ethics, namely, liberal human-rights based ethics and disempowering human dignity ethics. Both, together with a utilitarian ethic, form the three corners of a 'bioethical

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[34] Tonny S Petersen, 'Just Diagnosis? Preimplantation Genetic Diagnosis and Injustices to Disabled People' (2005) 31 Journal of medical ethics 231. Tom Shakespeare, *Disability Rights and Wrongs* (Routledge 2006).

[35] Abby Lippman, 'Prenatal Genetic Testing and Geneticization: Mother Matters for All' (1993) 8 Fetal diagnosis and therapy. Dorothy Nelkin and M Susan Lindee, *The DNA Mystique : The Gene as a Cultural Icon* (Freeman 1995).

[36] Parfenchyk, Volha, and Alexander Flos. 2017. "Human Dignity in a Comparative Perspective: Embryo Protection Regimes in Italy and Germany." *Law, Innovation, and Technology* 9 (1), pp. 26-30.

[37] House of Commons (2005a) Human Reproductive Technologies and the Law: Fifth Report: Session 2004–2005, Volume 1 (London: House of Commons Science and Technology Select Committee), HC7 1, available at: http://www.publications.parliament.uk/pa/cm200405/cmsctech/491/491.pdf

triangle'.[38] Yet, what we witness here is also the competition between two competing rights, namely, the rights of individual citizens to shape their reproductive lives as they see fit, and the rights claimed by other people not to be stigmatized or discriminated against because of their disability or gender. Therefore, the emancipatory potential of legal rights might be undermined not only by their being overridden by a competing bioethical discourse, but also by their own ability to produce counter-claims. However, despite these questions and fears, many scholars working in the area of technology regulation still retain 'hope' in rights litigation.[39] Yet, like those engaged in the critical analysis of rights, they call for a more nuanced thinking about the ability of rights to lead to human emancipation and empowerment.

In light of the need for a more nuanced view of 'hope in rights', in this article, I explore the extent to which rights can ensure the recognition of citizens' interests in using new biomedical technologies, as well as the costs and disadvantages of using rights to achieve these ends, by paying more attention to the problematic nature of rights. To do so, I reconstruct the story of Italian litigation for citizens' access to PGD, paying particular attention to how exactly the interests of patients were recognized through rights litigation. I illustrate that the recognition of citizens' interests in the Italian litigation process was partial, because the Constitutional Court accepted only the protection of mothers' health as a justification for having access to PGD. Instead, relational values and interests of biological citizens such as responsibility and care for the health of their future children, the core element of biological citizens' identity, that the plaintiffs displayed during litigation, were not recognized by the Italian Constitutional Court. I link this partiality to the prevailing (bio)ethical construction of the embryo as a person whose rights the State was obliged to protect, which was consolidated in the Italian legal doctrine. I argue that what was at stake in

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[38] Roger Brownsword, 'Ethical Pluralism and the Regulation of Modern Biotechnology' in Francesco Francioni (ed), *Biotechnologies and international human rights* (Hart Publishing 2007).

[39] E.g., Mark L Flear and Anastasia Vakulenko, 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies' (2010) 10 Human Rights Law Review 661. Marie-Andree Jacob and Barbara Prainsack, 'Embryonic Hopes: Controversy, Alliance, and Reproductive Entities in Law and the Social Sciences' (2010) 19 Social & Legal Studies 497.

the Italian litigation for PGD was a dispute which right – a more individualistic right (to health) or right that encompassed also relational values (the right to reproductive self-determination), which is an example of such a reconstructed right as proposed by Herring – should legitimize the access to PGD. The former, however, prevailed over the latter due to the high value attributed to unborn life in the Italian constitutional order, urging the Constitutional Court to recognize that right that would better promote this value. Hence, the recognition of biological citizens' 'vital rights' claimed vis-à-vis the state through litigation in Italy was partial; however, this was so not because the existing relations of power affected how individualistic rights would be balanced, but because certain important societal values, consolidated in the constitutional jurisprudence of Italy, prevented the participants of the debate from reconceptualizing the right to PGD from an individualistic into a more relational one.

5.2. The law on medically assisted reproduction and the IVF embryo as a 'citizen subject'

The Italian PGD litigation was a consequence of the adoption by the Italian Parliament of a highly restrictive Law 40/2004 regulating the use of ART in Italy. Heavily influenced by the ethics of life of the Catholic Church, by adopting this law, Parliament clearly wished to ensure full protection of embryos' rights, even at the expense of the interests and rights of adult citizens. In art. 1, the Law symbolically recognized the IVF embryo as a rights-holder.[40] To implement the rights of embryos, the Law prohibited many reproductive technologies and practices. Specifically, it forbade embryo experimentation, prescribed that clinical and experimental research must be performed only for the sake of the embryo itself, forbade the creation of embryos for scientific and experimental research and outlawed eugenic embryo selection (art. 13). Further, in art. 14, it prohibited the discarding and cryopreservation of embryos, and prescribed that doctors must not 'create embryos in a number higher than the one strictly necessary for a single and simultaneous transfer, and in any case not more than

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[40] Law 40/2004, art. 1. 'Al fine di favorire la soluzione dei problemi riproduttivi derivanti dalla sterilità o dalla infertilità umana è consentito il ricorso alla procreazione medicalmente assistita, alle condizioni e secondo le modalità previste dalla presente legge, che assicura i diritti di tutti i soggetti coinvolti, compreso il concepito'.

three'. Hence, the doctor was obliged to create not more than three embryos and all the resulting embryos, including those not capable of development and the sick ones, had to be implanted into the women's uterus. The only exception to this rule was if the female patient had health issues that were unforeseen at the moment of fertilization of the eggs. Even in this case, however, after the patient's health improves, the doctor is obliged to proceed with implantation. Combined, all these provisions technically made PGD impossible.

To further restrict the possibilities of embryo manipulation, the Law directly regulated some adult citizens' rights concerning the use of, and access to, ART. First, it prescribed that only infertile married couples could have access to ART in Italy. Therefore, fertile couples wanting to avail themselves of the opportunities offered by the new technologies were excluded. Similarly, single citizens, homosexual couples and unmarried heterosexual couples did not have the right to use them. Second, in art. 4, the Law prohibited women from withdrawing their consent after the fertilization of her eggs which meant she could formally be forced to undergo coercive treatment if she changed her mind after the IVF process had started.

The Italian Law 40/2004, with its focus on the IVF embryo, and its negative implications on the lives and health of adult citizens, has been much discussed and criticized elsewhere.[41] The Law was a product of a 20-year-long controversy spurred on and sustained by the intervention of the Catholic Church in political decision-making in Italy.[42] The Church's moral judgement and vocal appeal to implement it through secular laws found a responsive audience among Italian politicians due to the political circumstances of that time.

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[41] Ingrid Metzler, '"Nationalizing Embryos": The Politics of Human Embryonic Stem Cell Research in Italy' (2007) 2 BioSocieties 413. Herbert Gottweis, Brian Salter and Cathy Waldby, *The Global Politics of Human Embryonic Stem Cell Science: Regenerative Medicine in Transition* (Palgrave Macmillan 2009); Lorenzo Beltrame, 'The Therapeutic Promise of Pluripotency and Its Political Use in the Italian Stem Cell Debate' [2014] Science as Culture 1. Volha Parfenchyk, 'Redrawing the Boundary of Medical Expertise: Medically Assisted Reproduction and the Debate on Italian Bioconstitutionalism' (2016) 35 New Genetics and Society 329.

[42] Patrick Hanafin, *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy* (Ashgate Publishing 2007); Carlo Flamigni and Maurizio Mori, *La Legge Sulla Procreazione Medicalmente Assistita* (Net 2005).

In the beginning of the 1990s, Italian politics was undergoing profound changes as a result of *Mani pulite* (Clean Hands), a massive judicial investigation of corruption cases among Italian politicians, which led to the disintegration of Christian Democracy, the leading party, and to the emergence of new smaller parties. These latter, especially right-wing parties, such as Berlusconi's *Forza Italia* and the ultra-right *Lega Nord per l'Independenza della Padania*, used the Church's moral teaching to foster their political identity and gain public support. This connection between the political interests of Italian politicians and the bioethical interests of the Church constituted the main political factor pushing for restrictive regulation of ART.

The main bioethical issue in the debate on ART was the 'moral and legal status of the human embryo'. According to Catholic teaching,[43] an embryo is a person from conception and the protection of its life, like that of born persons, is of utmost importance and must be safeguarded through positive law. Hence, the Catholic hierarchy pressed Italian politicians to adopt restrictive regulations of ART to ensure the embryo was protected against technological and scientific manipulation. As Flamigni and Mori argued,[44] the Church gave up its intent to ensure the protection of other catholic values through law such as the prohibition of human procreation 'outside of the conjugal act'.[45] As they argue, the Church agreed that it would not find support for this principle in an increasingly liberal society. However, the protection of embryos remained of paramount importance. In the war against the 'culture of death', or ethical relativism, and fighting for the reinstallation of the 'culture of life',[46] embryo protection remained the key guidepost for the Church.

However, this absolutist view of human embryos was not shared by all, as a deep secular-Catholic cleavage had been embedded in Italian society, including the political sphere, for several decades. The lack of consensus regarding the status of the embryo and how ART should be governed, led to a failure to quickly produce a law regulating ART. As a result, the only document that regulated the provision of artificial reproduction services was a

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[43] Instruction for Human Life in Its Origin and on the Dignity of Procreation '*Donum Vitae'*, 1988.

[44] Flamigni and Mori (n 42).

[45] Ibid.

[46] The papal encyclical on the Value and Inviolability of Human Life '*Evangelium Vitae'*, 1995.

Circular issued by the Minister of Health in 1988. However, the Circular only applied to public fertility centers, leaving private ones beyond its regulatory reach and leading to the establishment of a rather liberal approach towards ART. Private Italian clinics offered a wide array of ART procedures, ranging from more widespread ones such as the creation of supernumerary embryos and embryo cryopreservation to surrogacy, egg donation, and the fertilization of menopausal and single women. Thus, while Italian politicians were debating about how ART ought to be accommodated in Italian healthcare arrangements, Italian biological citizens were reaping the benefits of new technologies in quite an unconstrained way. PGD, for example, was widely used in Italy, because of the wide spread of diseases such as beta thalassemia in Mediterranean regions.[47]

The Law was eventually adopted in 2004 when the Berlusconi-led coalition won the majority of seats in Parliament. After it's passing, it was immediately labelled the 'Catholic law', due to its restrictiveness, its emphasis on embryos and its complete neglect of women's rights. Multiple assaults on women's rights were apparent. Thus, the provision obliging doctors to create a maximum of three embryos, without the right to cryopreserve them, forced them to repeat harmful hormonal stimulations, which created the risk of causing such adverse effects as ovarian hyperstimulation syndrome (OHSS) and ovarian cancer. Also, the difficulty in estimating how many embryos would be created following oocyte insemination could result in a multiple pregnancy, which also put women's health at risk too. Furthermore, the outlawing of PGD meant that couples faced a difficult choice between raising a baby with severe genetic pathologies or undergoing a psychologically and physically traumatic abortion procedure.

The enactment of Law 40/2004 provoked a great outflow of Italian citizens seeking treatment abroad. The *Osservatorio Turismo Procreativo* (Observatory of Procreative Tourism), a project launched in 2005 to monitor the consequences of Law 40/2004, reported that the number of couples going abroad to receive treatment in 2005 was almost four times as high as it was in 2003.[48] In 2010, the European Society of Human Reproduction and

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[47] Sandrine Chamayou and others, 'Attitude of Potential Users in Sicily towards Preimplantation Genetic Diagnosis for Beta-Thalassaemia and Aneuploidies' (1998) 13 Human reproduction 1936.

[48] Osservatorio sul turismo procreativo. Turismo procreativo: fotografia di una realta (225). Press Conference.

Embryology performed a survey of foreign patients treated in 46 clinics in six European countries.[49] It found out that 31.8% of the forms were filled in by Italian patients and 70.6% of them referred to legal restrictions as their reason for seeking treatment abroad. Among the most frequent procedures were IVF, gamete and embryo donation and PGD. Not all citizens decided to go abroad to receive the forbidden treatment, however. Some of them, instead, decided to pursue their rights, with hoping for a better outcome.

5.3. The first local cases

The Law's prohibition on using the benefits of science and technology to fulfil one's personal reproductive interests prompted citizens to mobilize their efforts and to change the Law 'from below'. They used the mechanism of rights litigation to challenge the constitutionality of the Law and to have their interests recognized by the State. Specifically, the mobilization was undertaken by individual citizens who were susceptible to various serious genetic pathologies such as beta thalassemia or cystic fibrosis and wanted to use PGD to enable them to have pregnancies with healthy embryos. The interests of the majority of plaintiffs were represented by two renowned Italian specialists in biolaw, namely, Gianni Baldini, attorney at law and a lecturer at the University of Florence, and Filomena Gallo, attorney at law and secretary of the Italian association for the liberty of scientific research, Luca Coscioni. Litigants were supported by several patient and scientific associations acting in courts as third parties; these included the Luca Coscioni association, the association of aspiring parents 'Cerco un Bimbo' and the association for the study of infertility, CECOS Italia. In addition, and importantly, the fertility centers, which had formally denied the plaintiffs PGD and acted as defendants in the trials, mostly testified in favor of the plaintiffs. Hence, a strong coalition of individual citizens and their collectives emerged and acted together to restore rights taken away by Parliament.

In 2004, the first complaint was brought against a fertility center in the local court in Catania.[50] The plaintiffs, husband and wife, were healthy carriers of beta thalassemia and were infertile. During the course of their fertility treatment, Law 40/2004 came into force and the plaintiffs signed the consent form which the Law required. A month later the couple asked

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[49] Francoise Shenfield and others, 'Cross Border Reproductive Care in Six European Countries' (2010) 25 Human Reproduction 1361.

[50] Trib. Catania, 3 maggio 2004.

the center to proceed with PGD and to have only healthy embryos implanted and the rest frozen. The wife also attempted to withdraw her previous consent to having all the embryos implanted. In her written request to the director of the fertility center asking him or her to proceed with PGD and have only healthy embryos implanted, the wife described her ‘hope to conceive a baby that could fulfill and complete our existence and fulfill our desire to be a family in the full and complete meaning of this word’. Further, she described the painful feelings she would have if she gave birth to a baby who would endure ‘atrocious suffering’ for which she would feel responsible.[51] She also added that if she conceived a sick baby, she would be forced to have an abortion. The director of the center, however, rejected the request, referring to the restrictions established by Law 40/2004. The couple initiated legal proceedings, claiming that the fertility center’s refusal to perform PGD violated the inalienable constitutional rights of the wife stipulated in art. 2 (the guarantee of inviolable human rights) and art. 32 (the right to health and the right not to be forced to submit to unwanted medical treatment) of the Italian Constitution.

The judge, however, did not sustain the complaint. First, he concluded that the prohibition of PGD did not violate the wife's right to health (art. 32 para. 1). According to the judge, the recourse to abortion, allowed by the law on abortion (Law 194/1978),[52] was permitted only to prevent risks to the mother’s health that a health condition of the fetus or pregnancy could create. However, in the case of PGD, her health could not be harmed because the procedure is performed before the pregnancy is established. Second, he addressed the argument of the plaintiffs that the implantation of embryos against the mother’s will would violate art. 2 and art. 32 para. 2 of the Italian Constitution. According to the plaintiffs, together these norms meant that if a person is the title-holder of a right (in this case, the right to health), then the person’s will cannot be subordinated to another interest and that the will of the individual is the only measure for deciding if, when and how treatment is to be performed. But the court responded that, in the case of PGD, the interests of two subjects were in conflict: the mother and the unborn child. In this case, it is illogical that the mother alone can decide how to balance these interests. Therefore, it was up to the Parliament to decide how to balance these rights, and the prohibition on withdrawing consent, stipulated in Law 40/2004, represented nothing more than the Parliament’s view on how the two must be balanced.

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[51] Ibid.

[52] Legge 22 maggio 1978, n.194, in G.U. 22 maggio 1978, n.140

Finally, he concluded that the plaintiffs' claim was, in fact, simply their 'desire-interest to have a healthy child', which they only masked by referring to other rights. However, he continued, this right could not be sustained because the Italian Constitution did not guarantee the 'right to have a healthy child' or to a 'virtual baby that lives only in a mental representation of its parents'. This, according to the court, was a eugenic practice, which Italian law forbids. Instead, together with Law 40/2004, the constitution protects the child 'that will in fact live as a result of the fertilization of the eggs, even [if it is] possibly sick'.

Thus, the court's reasoning and the outcome of the litigation provide us with first and rather vivid illustration of how rights-claiming against the state can affect the recognition of biological citizens' demands to ensure the protection of their or their family's health and use the advances of biomedicine and genetics to achieve these ends. As the analysis above illustrates, the plaintiff's position was abundant with claims about the interdependence between her and her future baby and the care for its health and well-being that urged her to seek PGD. The plaintiff referred to the suffering she would experience if she would need to give birth to a severely handicapped and suffering baby, as well as the sense of an unfulfilled responsibility because of failing to ensure its good health. Thus, it was, not only an individual harm afflicted on her that urged her to seek PGD, but also, and particularly, the suffering of her future baby that she wanted to prevent via PGD. In such a view, exactly *caring* for the future baby entitled the woman to select embryos without pathologies and discard those carried defected genes. Her personal feelings of suffering are only a part of deep emotional ties that bound her and her future baby.

However, caring for the health of the future baby as a reason for accessing PGD first had to be translated into a right whose violation might justify the access to PGD. Yet, translating it into a right was not unproblematic because care that the mother described in her appeal implied not only a relatively understandable desire to enhance the baby's health, but also the selection of embryos with good genes and the destruction of affected embryos. PGD, in fact, while allowing women to fulfill their caring obligations, inflicted harm upon other entities – existing sick IVF embryos. Exactly the protection of *their* life against violation and the prevention of harm was the reason behind the prohibition of PGD. Therefore, care for the health of the future baby, a relational desire and responsibility, also implied the affliction of individual harm upon those embryos that would bear defected genes.

In the court's view, motives such as the wish to give birth to a healthy baby out of responsibility for its health or simply to have a 'normal family' did not qualify as good enough reason for having access to PGD. Although the couple did not explicitly claim the right to a healthy child, the court 'discerned' this right in the couple's complaint, particularly in the wife's letter to her doctor, and dismissed it. According to the judge, satisfying this request would entitle the couple to 'eugenically select only healthy children' and mean a complete negation of the embryo's right to life. The embryo was recognized as a legal subject by Law 40/2004, therefore its interests and rights deserved the same protection and recognition as those of adult citizens. Therefore, no selection, let alone destruction of embryos should be allowed by law, even if performed for apparently positive and well-justified reasons such as care for the health of the baby eventually to be born.

Importantly, the court acknowledged, by referring to Law on abortion 194/1978, that an embryos' right to life could be limited if the competing right to health of the mother was at risk. However, in the case of PGD, the court took the position that the wife's health could not be harmed in this way, so no rights conflicting with embryo rights could be violated. In other words, attempting to be consistent with the Italian law on abortion, which attributes strong protection to unborn fetuses, the court applied an individualist approach to rights, seeing the mother and the embryo as competing rivals with conflicting interests, because this approach would better promote and guarantee the protection of the embryo's life. If the plaintiff would prove how the mother's right to health is violated, then it would satisfy the plaintiff's complaint. However, because she failed to do so, the Court had to dismiss the complaint.

The next case was brought by a couple from Cagliari in 2005.[53] Like the previous case, the husband and the wife were healthy carriers of beta thalassemia and could not conceive a baby naturally. The first IVF cycle was performed without PGD. Following prenatal testing, the couple learned that the fetus was affected with beta thalassemia and the woman had an abortion. After the abortion, she developed an 'anxiety depressive syndrome' that lasted for over a year and the couple decided to make use of PGD to prevent a recurrent negative impact upon her mental state caused by a similar experience. But the doctor at the clinic refused to perform PGD, referring to art. 13 para. 1 of Law 40/2004 prohibiting embryo experimentation. The couple asked the Cagliari court to perform a 'constitutionally oriented interpretation' of the Law and oblige the clinic to perform PGD, because not doing so would

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[53] Trib. Cagliari, 16 luglio 2005, n. 5026.

constitute 'a grave threat to the psychophysical health of the woman deriving from a well-founded fear that the embryo might be affected by a serious genetic disease' and therefore violate her right to health.[54] To substantiate the claim, the couple submitted a report from the wife's psychiatrist to the court which indicated that the woman had developed a mental health condition that could re-occur if she was prevented from using PGD. The couple also asked the court to submit the Law to the Italian Constitutional Court for adjudication on the matter of its constitutionality if it decided that the first two requests could not be satisfied.

The judge considered the requests of the plaintiffs and decided that the clarity of the Law's intent to prohibit PGD did not allow a 'constitutionally oriented interpretation' of art. 13 of the Law to be made and thus he could not instruct the clinic to perform the procedure. However, the court found that there was a possible contradiction between art. 13 and the Italian Constitution, specifically, art. 32 on the right to health. First, the judge referred to a judgment of the Constitutional Court on abortion (Abortion Ruling 27/1975) that addressed the issue of the conflict between the women's right to health and the rights of the fetus, ruling in favor of the former.[55] According to the judge, in the case of PGD, where the rights of IVF embryos similarly conflicted with women's right to health, the protection of the latter should also be prioritized over embryo's interests. Second, according to the judge, the plaintiffs demonstrated, having submitted the necessary evidence, how the legal prohibition of PGD could be harmful to the wife's mental health. Hence, in this case, the reference to health was successful, because the plaintiff succeeded in proving how her health might be jeopardized by the prohibition of PGD. Third, the judge specified that legal access to PGD was warranted by the State's constitutional duty to protect the right to health of the plaintiff and not the 'interest of the parents in having a healthy child', as eugenics was forbidden by Italian law. Therefore, access to PGD should be provided on exactly the same grounds as access to abortion, that is, only if the health condition of the embryo or pregnancy would cause adverse effects to women's health. Like the Catania court, safeguarding the mothers' health was again listed as the only reason that could outweigh the conflicting rights of the embryo.

The Cagliari case is thus also illustrative of the interdependence that exists between the embryo and the pregnant woman. The harm caused upon the mental state of the woman is related not only to her individual interest, but also to the care for the future baby and its

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[54] Ibid.

[55] C.C., 18 febbraio 1975, n. 27.

health. However, unlike the former case, rights invoked by the plaintiff were acknowledged by the judge because the plaintiff was able to translate this interdependence and care into the type of right that would take priority over embryos' rights. This was done through reframing the mother's suffering into illness. This allowed her to appeal to her right to health of the mother that could be violated if PGD remained prohibited.

The analysis of the two cases is informative because it gives a preliminary illustration of how legal institutions struggle with carving out space for new biomedical technologies in their countries' constitutional order. Both CLS and feminist scholars argued in their analysis of legal rights, one of the main issues that rights claims face is that they can always give rise to counter-claims.[56] Because there is no objective criteria for deciding how the balancing of conflicting rights must be performed, the result of the balancing process depends on contextual factors, including political, moral and other variables. As I have shown above, what is important is not only how local factors affect the balancing of individual rights, but also how they affect the ways in which rights, their definition and their ontological presumptions are defined in courts in the first place. For example, the Cagliari court, similarly to the Catania court, did not recognize the 'interest of a couple in having a healthy child' as deserving state recognition. Although in both cases the plaintiffs did not claim this right or did not mention this interest, the judges discerned them while considering the plaintiffs' accounts of their experience of care and responsibility. The main reason for this was the fact that entrusting parents with this 'right' or fulfilling this interest would imply the affliction of harm on sick embryos. According to both courts, Italian law and constitutional doctrine on abortion saw embryos as entities in and of themselves, separable and disconnected from the female body and having value and rights merely due to the mere fact of their existence. Therefore, women's discretion on what they could do with these embryos, even if driven by the feelings of care and responsibility for their family, should be limited by law. The only legitimate reason for limiting embryos' right to life would be the affliction of a harm of a greater moral weight such as harm to the health of the woman.

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[56] Smart (n 24).

As much research has shown, attitudes towards embryos vary, both geographically and over time.[57] Therefore, the recognition by the State of women's interests in using PGD will also vary and depend on how strongly unborn life is valued, in itself and in its relationship with the pregnant woman. In Italy, the constitutional jurisprudence and the laws regulating abortion and ART have accorded a high degree of protection to unborn life, particularly when compared to the majority of other European countries, including Great Britain, Spain, the Netherlands and Sweden.[58] Italian law does not provide a clear-cut answer with respect to the legal and moral status of the embryo. Whereas Law 40/2004 recognizes the embryo as a rights-holder and elevates its interests over those of adult citizens, the Abortion Ruling 27/1978 stresses that the embryo is 'not a person but is yet to become one'. Yet, the entire body of Italian law, including the jurisprudence of the Constitutional Court, builds upon the position that unborn life deserves significant respect and is entitled to protection by the State. Clearly, with respect to the status of embryos, Italian law takes the most restrictive – dignitarian – perspective in the so-called 'bioethical triangle'. Therefore, using the rights mechanism in defending women's interests in those cases in which embryo protection is implicated is replete with negative expectations, leading, at most, to only a partial recognition of reproductive rights. This is exactly what we shall observe later.

5.4. The first cases decided by the Constitutional Court and the right to health

The judge of the Cagliari court asked the Constitutional Court whether art. 13 of the Law 40/2004 violated art. 32 of the Constitution on the right to health. However, the Constitutional Court declared the question of the constitutional legitimacy of art. 13 inadmissible on procedural grounds,[59] and that the prohibition of PGD also derived from other articles of Law 40/2004 which the local judge had not submitted for consideration. He also held that prohibition of PGD reflected the 'spirit' of the Law. Put in another way, the local judge had failed to correctly formulate the appeal, which entitled the Constitutional

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[57] Dorothy McBride Stetson (ed), *Abortion Politics, Women's Movements, and the Democratic State : A Comparative Study of State Feminism: A Comparative Study of State Feminism*, vol 15 (Oxford University Press 2001).

[58] Ibid.

[59] C.C., 24 ottobre 2006, n. 369.

Court to dismiss it. Importantly, the Constitutional Court did not take a stance on the legitimacy of PGD; its decision to keep the Law intact was a result of the local court's failure to fulfil the procedural requirements of the appeal procedure.

This failure by the local court to fulfill the procedural requirements used by the Constitutional Court as a reason not to discuss the Law's constitutionality is very significant in our discussion of 'hope in rights'. According to Italian constitutional law, a failure of the local courts to formulate a complaint cannot prevent the Constitutional Court from judging on the merits of the dispute, because of the constitutional law principle of derived constitutionality.[60] According to this principle, the Constitutional Court also had a right to repeal those provisions that were not directly questioned by the Cagliari court, if it saw a direct violation of constitutional rights. However, the Constitutional Court left the Law 40/2004 intact by using a procedural flaw as the reason for not judging on its merits. Several reasons can purport to explain the court's 'decision not to decide'.[61] First, it might have been a political move, as the court may have wanted to avoid an explicit confrontation with Parliament, especially with respect to the problematic Law 40/2004. Second, its rejection might have derived from the recognition that Parliament indeed had a right to accord greater protection to IVF embryos than to fetuses and to prioritize them over a mother's right to health (Chapter 3). Whatever the real reason was, the key implication of the court's decision is that it points to the importance of embryos' rights for defining the entitlements of other – born – citizens. In the present case, even mother's right to health, individualist right, did not override the rights of the embryo. Otherwise, the court should have used the principle of derived constitutionality and repealed the disputed provision as violating the right to health.

However, success came later, in 2009. The local Florence court[62] and *Tribunale Amministrativo Regionale* (TAR) of Lazio,[63] following complaints by the plaintiffs, who were also carriers of mutated genes, submitted the Law 40/2004 to the Constitutional Court for

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[60] D'Amico Marilisa, 'Il Giudice Costituzionale E L'alibi Del Processo' [2006] Giurisprudenza Italiana 3859.

[61] Alfonso Celotto, 'La Corte Costituzionale «decide Di Non Decidere» Sulla Procreazione Medicalmente Assistita' [2006] Giurisprudenza Italiana 3849.

[62] Trib. Firenze, 17 dicembre 2007; Trib. Firenze, 23 agosto 2008, n. 382; Trib. Firenze, 11-12 luglio 2008, n. 323.

[63] Tribunale Amministrativo Regionale del Lazio, 31 ottobre 2007, n. 398.

adjudication upon its constitutionality. This time, however, they provided the Constitutional Court with arguments about other reasons why the Law might be unconstitutional. To begin with, they emphasized that it was not only mothers' mental health that could be harmed. Specifically, art. 14, prohibiting embryo cryopreservation and obliging the doctor to implant all embryos simultaneously, created adverse effects on women's health like OHSS, ovarian cancer and multiple pregnancy do. The most substantial contribution, however, was the conclusion by TAR Lazio about the degree of protection the embryo was accorded by the Law itself. According to the Tribunal, Law 40/2004 had already established by its own terms that the protection of embryos was not absolute. In particular, by allowing a doctor to create three embryos, the Law did not intend to cause a triple pregnancy, but sought to increase the chances of (at least) one successful pregnancy. Parliament had thereby accepted, albeit implicitly, that only the healthiest embryo would give rise to pregnancy, while the rest would perish. Hence, for the Tribunal, the possibility of creating three embryos and not one meant that embryo protection was limited and that their 'lives' could be sacrificed to achieve certain important goals such as the protection of the procreative rights of Italian citizens. Therefore, limiting the number of producible embryos to three, which Parliament obviously introduced to protect embryos against technological manipulation and overproduction, was illogical as it contradicted the intention of Parliament itself to limit embryo protection. In addition, it created risks to women's health by increasing the risks of OHSS, ovarian cancer and multiple pregnancies. Therefore, the doctrine of the Constitutional Court on abortion, according to which a woman's right to health had priority over an embryo's life, should apply also to the case of ART. Together with the Florence court, TAR Lazio referred the case to the Constitutional Court for adjudication on its constitutionality, specifically, with regard to art. 32 of the Italian Constitution on the right to health.

In 2009, the Constitutional Court passed judgment, repealing as unconstitutional the prohibition to create no more than three embryos (art. 14 para. 2) and the exception to the prohibition of embryo cryopreservation (art. 14 para. 3), because these provisions violated the right to health of Italian female citizens.[64] The Constitutional Court used the reasoning put forward by TAR Lazio about the limited embryo protection accorded to the embryos by Parliament itself. As a result, the court found that a number of the words of art. 14 para. 2,

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[64] C.C., 1 aprile 2009, n. 151.

namely, ‘a single and simultaneous transfer, and in any case not more than three’, and art. 14 para. 3, in which it prescribed that embryo cryopreservation could be performed only if the woman had serious health issues, ‘unforeseen at the moment of fertilization’, were unconstitutional.

The judgment was praised by many lawyers, citizens, doctors and scholars as a triumph of constitutional rights over political voluntarism. Although the court did not explicitly rule on PGD, many clinics started to introduce it into their practices. But as far as our ‘hope in rights’ is concerned, the judgment was obviously not the type of act that can fully satisfy this hope. First, bottom-up governance succeeded not (only) because the right to health acted as a trump but (particularly also) because the court was provided with a suitable rhetorical argument to recognize that embryo protection had, in fact, been limited already by the Law itself. As Kennedy argues, what often enables courts to recognize the claimed rights and leads to a closure of the debate on rights is the rhetorical mastery of the plaintiffs. In the present case, it was the argument about Parliament’s own intent as to how much protection embryo was granted. Second, like the reasoning and judgments of the local courts and the first judgment of the Constitutional Court, it again points to the importance of embryos’ individual rights for how successful plaintiffs’ appeal to *their* rights will be. In fact, it was only because the Court was able to reduce embryo protection using a suitably presented argument, that the litigation was successful.

Tellingly, the judgment already contained the signs of how other cases on Law 40/2004, and the claim made by plaintiffs that other experiences justifying access to PGD should be acknowledged, would be approached in future. For example, the Constitutional Court declined to declare that art. 14 para. 1, which prescribed the prohibition of cryopreservation as a general rule was unconstitutional. Instead, it found that limiting the possibility of cryopreserving embryos to only ‘serious’ health issues that were ‘unforeseen at the moment of fertilization’ was unconstitutional; instead of repealing the prohibition on cryopreservation as such, the court only extended the range of health issues that justified embryo cryopreservation. Similarly, it only partially repealed art. 14 para. 2: embryos still had to be created in a number ‘strictly necessary’ for implantation. Using the metaphor of Italian lawyers, in repealing the disputed provisions, the Court operated with a ‘chisel’ rather than an ‘axe’, thus allowing only that degree of embryo manipulation that was essential to prevent adverse risks to women’s health.[65]

5.5. The last cases and the right to self-determination

The following cases concerned PGD explicitly, hence they give additional information on how the Constitutional Court took into account the Italian citizens’ interests in, and reasons for, using PGD. The plaintiffs in these legal cases were fertile couples with various genetic pathologies who wanted to use PGD to become pregnant with healthy embryos and therefore needed recourse to IVF. They complained that the Law was unreasonable in preventing fertile citizens from accessing PGD, while at the same time allowing prenatal testing and abortion to be performed – procedures significantly more potentially harmful and risky than PGD. As a result, they argued that Law 40/2004 violated several constitutional rights, including the right to self-determination which was protected by the open-ended art. 2, the right to health (art. 32), and the right to equality before the law (art. 3).

These cases were considered by local courts and had different outcomes. The Cagliari court explicitly distinguished between the two rights that legitimized the couple’s access to PGD, namely, the right to health and the right to a healthy child, and recognized only the right to health as justifying access to PGD.[66] In the next three cases, however, the right to have a healthy child and the right to self-determination were acknowledged for the first time. Local courts in Salerno[67] and Rome[68] sustained that the ‘right to a healthy child’, as part of the right to self-determination and guaranteed by the open-ended art. 2 of the Constitution, also justified access to PGD. They, therefore, illustrate just how judicial decision-making evolved towards the acceptance of a more liberal regulatory regime for PGD, allowing access to it, not only to prevent health risks to the female patient, but also to ensure the couple’s right to self-

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[65] Daniele Chinni, ‘La Procreazione Medicalmente Assistita Tra “detto” E “non Detto”. Brevi Riflessioni Sul Processo Costituzionale Alla Legge N. 40/2004.’ (2010) 2 Giurisprudenza Italiana 289; Lara Trucco, ‘Procreazione Assistita: La Consulta, Questa Volta Decide, (Almeno in Parte) Di Decidere’ (210AD) 2 Giurisprudenza Italiana 281.

[66] Trib. Cagliari, 9 novembre 2012, n. 5925.

[67] Trib. Salerno, 13 gennaio 2010, n. 12474.

[68] Trib. Roma, 15 gennaio 2014, n. 69. Trib. Roma, 28 febbraio 2014, n. 86.

determination on reproductive issues and the fulfillment of other – relational – values and goals.

The position of the Constitutional Court, however, remained unchanged. The Rome Court asked the Constitutional Court whether prohibiting the use of PGD by fertile couple was in violation of art. 2 (as it included the right to self-determination and the right to a healthy child), art. 3 (right to equality) and art. 32 (right to health) of the Italian Constitution. The Constitutional Court passed its judgment in May 2015[69] declaring that art. 4 of Law 40/2004 prohibiting the use of ART by fertile couples was unconstitutional. However, unlike the Rome court, the Constitutional Court found that this prohibition violated only two articles of the Italian Constitution, namely, art. 3 and art. 32. It concluded that it was unreasonable to prohibit access to ART and PGD by fertile couples while, at the same time, allow access to prenatal testing and abortion. This unreasonable prohibition violated art. 3 of the Italian Constitution. Furthermore, as abortion was much more traumatic than PGD, the prohibition of access to ART and PGD also violated art. 32 on the right to health. As a result, the court concluded that women should be allowed to access ART and PGD on the same grounds as they are allowed to have an abortion, namely, when the health condition of the embryo or pregnancy creates 'grave risks' to mothers' health, as stipulated by art. 6 para. 1b of Law 194/1978.

An analysis of the court's reasoning is interesting for a number of reasons. First, the court did not discuss whether 'the right to have a healthy child' and the right to reproductive self-determination were violated; in fact, in its ruling it did not mention these rights at all. This 'elegant silence', as Italian scholar Ianuzzi defined it, suggests that these rights found no support within the Constitutional Court.[70] Rather predictably, and in a similar manner to its previous judgments, the court quashed another controversial provision of Law 40/2004 by finding that it violated only the right to health and thus allowed access to PGD if it was needed solely to prevent adverse health effects for the female patient.

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[69] C. C., 14 maggio 2015, n. 96.

[70] Antonio Ianuzzi, 'La Corte Costituzionale Dichiara L'illegittimità Del Divieto Di Accesso Alla Diagnosi Preimpianto E Alla Procreazione Medicalmente Assistita per Le Coppie Fertili E Sgretola L'impianto Della Legge N. 40 Del 2004' (2015) 60 Giurisprudenza Italiana 805.

Second, the court ruled that access to PGD should be allowed on the same grounds as abortion was allowed, according to art. 6 para 1b of Law 194/1978, that is, to prevent 'grave risks' to women's physical and mental health. According to Law 194/1978, abortion is legitimate within the first 90 days of pregnancy if abortion creates a risk to mothers' health (art. 3), and after 90 days, if abortion creates 'grave risks' to women's health (art. 6). In the first case, the woman is free to have an abortion and does not need to ask the doctor's permission, whereas in the second case the doctor's permission is required. Hence, without discussing the reasons for its decision, the court allowed PGD not on the same conditions as abortion is allowed in general, but on the strictest conditions. It limited the type of health issues which could be prevented by performing PGD and obliged female citizens to ask for a doctor's permission to perform it. In this way, the possibility of accessing PGD was obviously curtailed by these requirements.

Third, the Constitutional Court rejected building on the judgment on the *Costa and Pavan v. Italy* decision that the European Court of Human Rights (ECtHR) had passed in 2013.[71] A brief description of the case is in order here. This complaint against Law 40/2004 was brought by an Italian couple claiming that art. 8 of the ECHR (right to respect for private and family life) was being violated. The ECtHR upheld the applicant's claim. It held that since Italian law allowed prenatal testing and therapeutic abortions, the prohibition of PGD was unreasonable. Therefore, the government's interference in the applicants' private and family life was disproportionate. During the trial, the Italian government objected to the applicants' claim that their complaint was, in fact, a claim to the 'right to have a healthy child', which the ECHR does not guarantee. The ECtHR rejected the government's objection, stating that the right claimed by the applicants was not the right to have a healthy child. Instead, 'the right relied on by the applicants is confined to the possibility of using ART and subsequently PGD for the purposes of conceiving a child unaffected by cystic fibrosis, a genetic disease of which they are healthy carriers'.[72] The former, according to the ECtHR would be impossible as PGD cannot exclude other factors that can affect the health condition of the future child such as other genetic disorders or complications during pregnancy. In this way the ECtHR distinguished between a 'right' to have a child unaffected by a particular

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[71] *Costa and Pavan v. Italy* [GC], n. 54270/10, ECHR 2013.

[72] Ibid, 9-10.

genetic disease, which is protected by the right to respect for private and family life, and the 'right to have a healthy child', that is, an entirely healthy baby.

In addition, by emphasizing this difference, the ECtHR also made an important correction to other local courts' rulings suggesting the potential violation of the right to a healthy child, discussed above. In these rulings, the courts did not discuss what exact meaning they attributed to the 'right to a healthy child'. Hence, it is not clear whether they indeed meant the right to have a baby unaffected by a particular disease or the right to have an entirely healthy baby, the right to a highly implausible outcome. In any case, and despite this clarification, the Constitutional Court opted for carving out space for PGD in the same way in which it legitimized abortion, that is, only to prevent negative impacts on mothers' health, and not out of respect for citizens' private and family life. The ECtHR, by specifying, that the right to have PGD is not tantamount to a 'right to have a healthy child', clarified through which right the right to PGD could be recognized.

Of a particular importance for this paper is the right to the violation of which the plaintiffs in *Costa and Pavan v. Italy* appealed to, that is, the right to respect for private and family life. According to proponents of the idea of relational autonomy, one of the ways through which relational values could be promoted is the endorsement by courts of the right to respect for private and family life (article 8 ECHR). For example, Herring praised the ruling in the case *K v. LBX*,[73] in which the British Court of Appeal urged courts to take into account the right to respect for private and family life of the ECHR when it should be decided if a person should be taken care of at home or at a relevant medical institution. Building a ruling on article 8 of the ECtHR in cases involving human reproduction, courts could also promote relational values and give more discretion to women and their partners in reproductive decision-making.

Thus, on the one hand, through litigation Italian citizens achieved their goal of making access to PGD legitimate. The bottom-up governance made the provision of PGD and other ART in Italy less restrictive. Indeed, there is an important parallel to be drawn between these and similar cases such as litigation for access to medicine in Brazil or the right to financial compensation for health damage in Ukraine.[74] And yet, on the other hand, the use of rights

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[73] [2012] EWCA 79

[74] Hanafin, The Embryonic Sovereign and the Biological Citizen: The Biopolitics of Reproductive Rights (14).

yielded much more modest results in the present context. By failing to recognize that the prohibition of PGD might violate, not only the right to health, but also the right to reproductive self-determination, the court did not acknowledge other reasons that might urge citizens to want PGD. To begin with, there could be financial reasons for having PGD as the couple would be financially incapable of raising a child with a severe genetic disease. More importantly, it ignored other ethical and relational values, duties and responsibilities unrelated to health issues, that might urge biological citizens to seek PGD. Here, the letter of the wife from the Catania case, in which she refers to her responsibility towards the future baby as well as her and her husband's wish to create a 'normal' family, is telling.

Indeed, as much sociological research has shown, couples often choose PGD not for the sake of their own health or their interests but out of 'parental obligation' towards their future children and their health.[75] Similarly, as Rapp has shown in her analysis of women having prenatal testing, women navigate within a complex ethical decision-making space, and the responsibility for the future baby and for other family members was often one of the reasons they sought prenatal testing.[76] These conclusions suggest that particularly in the relationships between close family members such as between parents and children, individuals, albeit driven by parental self-determination, tend to build their decisions on relational autonomy and the feelings of mutual responsibility rather than the feeling of unlimited personal freedom, even if their decisions do not lead to a direct infliction of harm upon others.[77] They were further confirmed by other authors exploring parents' views on sex selection. For example, Scully *et al.* showed the majority of interviewed parents regarded voluntary self-limitation of their choices as constitutive of their identity as 'good parent', and

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[75] Celia Roberts and Sarah Franklin, 'Experiencing New Forms of Genetic Choice: Findings from an Ethnographic Study of Preimplantation Genetic Diagnosis' (2004) 7 Human Fertility 285. Sarah Franklin and Celia Roberts, *Born and Made: An Ethnography of Preimplantation Genetic Diagnosis* (Princeton University Press 2006).

[76] Rayna R Rapp, *Testing Women, Testing the Fetus : The Social Impact of Amniocentesis in America* (Routledge 2000).

[77] Ehrich, Kathryn, Clare Williams, Bobbie Farsides, Jane Sandall, and Rosamund Scott. 2007. "Choosing Embryos: Ethical Complexity and Relational Autonomy in Staff Accounts of PGD." *Sociology of Health & Illness* 29 (7).

felt that parental autonomy was only possible within the limits set up by relational values.[78] Similarly, in Petersen's study of the experiences of people with genetic disabilities, many participants expressed concerns about the future of their offspring, which induced them to make reproductive choices that would favor what was fair or right for the child's future, rather than their own desires.[79] In other words, in such intimate relationships as between parents and children, the feeling of mutual responsibility, care and interdependence abound. However, such personal and relational family-related interests, values and responsibilities that Italian biological citizens might have had as part of their 'regime of the self' were not regarded by the Italian Constitutional court as deserving of state recognition.

Clearly, one can suggest that this limitation is insignificant and couples will be able to circumvent it, for example, by referring to their health as the reason for wanting PGD. The fact that the Italian Law 194/1978 also allows access to abortion to protect the mother's mental health will definitely provide quite wide grounds for accessing PGD. Like the plaintiff in the Cagliari case, women will be able to refer to 'depression' or 'anxiety' as their health grounds for having PGD. And yet, two implications are nevertheless significant. First, practically speaking, women will always need to ask permission from their doctors if they want PGD and prove they would be at risk of damaging their (mental) health, which automatically gives full decision-making power to the medical profession and runs the risk of them being denied. Second, and importantly for our discussion of rights, by distinguishing between the grounds that can legitimize the access to PGD and assessing their value, the court did not recognize the complexity involved in relationships between the pregnant woman and her embryos. Formally, Italian law still forbids the performing of PGD for reasons other than the female citizens' health. Some citizens may find it unfair that the law does not allow them to follow their ethical convictions and fulfill their moral duties in reproduction as well as use new developments in science and technology to achieve these ends. Reproductive self-determination, together with many different ethical choices, responsibilities, and hopes which

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[78] Scully, Jackie Leach, Sarah Banks, and Tom W. Shakespeare. 2006. "Chance, Choice and Control: Lay Debate on Prenatal Social Sex Selection." *Social Science & Medicine* 63 (1): 21–31.

[79] Petersen, Alan. 2006. "The Best Experts: The Narratives of Those Who Have a Genetic Condition." *Social Science & Medicine* 63 (1): 32–42.

Italian citizens had had as a result of a rather unconstrained provision of ART and PGD before Law 40/2004 was enacted and which they had embraced as an element of their ‘regime of the self’, was excluded from the scope of interests that the Italian State was committed to protect.

Litigation and rights-claiming through courts played a key role in determining how exactly biological citizens’ ‘vital rights’ should be accommodated in Italy. They acted like millstones, through which these ‘vital rights’ had to pass before receiving legal and formal country-wide recognition. The outcome of this process was rights that were accepted but transformed; ‘vital rights’ encompassing relational values and interests were defined as an individualist right to health. Clearly, the main reason for achieving this partial recognition of plaintiffs’ rights was the competing interests and rights of embryos whose protection the Italian Constitutional Court also sought to ensure by imposing constraints on adult citizens’ freedom of action, including the freedom to follow their convictions and use the benefits offered by biomedicine.

Of course, most other countries also restrict the scope of genetic diseases that can be tested via PGD and therefore also limit citizens’ self-determination in terms of the reproductive choices they make. Hence, reproductive autonomy can and, according to many people, should be limited in order to avoid the wider negative social implications of biomedical and genetic technologies, such as the eugenic consequences, for example. As stated in the beginning of this article, this argument is used by disability movements to protect *their* rights, such as the right not to be stigmatized or discriminated against based on their disability. Thus, on the one hand, this general restriction of PGD testifies to the argument advanced in this paper that rights, by creating counter-claims, might be a less reliable mechanism for winning autonomy than is often assumed. Yet, on the other hand, an analysis of how PGD is regulated in other countries shows that the use of rights can lead to different outcomes and that rights are not inherently strong or weak, but that their success depends on the context. Specifically, in Great Britain, the genetic diseases that can be tested via PGD are limited to serious genetic pathologies with high penetrance which have been previously approved by the Human Fertilization and Embryology Authority for testing. However, British law does not limit access to PGD only to prevent adverse health effects on women’s health. As a result, the British State makes it possible for citizens to follow their relational commitments and seek PGD, which they do, as much anthropological research mentioned above has illustrated.[80] In addition, women are not obliged to demonstrate and prove to their doctors how the genetic diseases of their embryos would harm their health.

Therefore, despite the limitations on using PGD, the access to PGD in Britain is significantly more liberal than in Italy. This is so because utilitarian, hence more pragmatic and liberal, thinking is the main and dominant bioethical perspective in Great Britain which affects the regulatory policy on biomedicine, including PGD.[81] This utilitarian thinking was specifically applied to defining the degree to which *in vitro* embryos must be protected against technological manipulation. According to the British Human Fertilization and Embryology Act adopted in 1990, embryos are only accorded protection from the 14th day of development from conception. Therefore, embryo research and use in medical treatment in Great Britain is among the most liberal in Europe as the law allows rather a lot of freedom to manipulate embryos for medical purposes (such as PGD) or research purposes (such as the derivation of human embryo stem cells). Hence, limited embryo protection allowed citizens' reproductive autonomy to have a much greater scope in Great Britain than in Italy, as well as to implement their relational values.

The following, and last, two litigation cases, although they do not concern health of the embryos, give a good illustration of what the circumscription of citizens' procreative rights can entail in practice. The Naples court was asked to decide a case in which the doctors of a fertility center in Naples were accused of committing the crime of embryo destruction.[82] Specifically, doctors performed PGD, requested by a number of Italian couples, and following the results of PGD and IVF they discarded the embryos with detected pathologies instead of freezing them. The defense council for the doctors asked the Naples court whether the provisions of Law 40/2004 prohibiting embryo selection (art. 13 para. 3) and embryo destruction (art. 14 para. 1) violated, art. 32 (right to health) and art. 2 (right to self-determination) of the Italian Constitution. The defenders also asked the court to submit the

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[80] Ehrich *et al* (n 77); Scully *et al* (n 78); Petersen (n 79).

[81] Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005); James Mittra, 'Marginalising "eugenic Anxiety" through a Rhetoric of "liberal Choice": A Critique of the House of Commons Select Committee Report on Reproductive Technologies' (2007) 26 New Genetics and Society 159.

[82] Trib. Napoli, 3 aprile 2014, n. 149.

case to the Constitutional Court for adjudication on the matter of its constitutionality. The court agreed with the defense and submitted the case to the Constitutional Court.

Predictably, the Constitutional Court declared the provision forbidding the selection of embryos (art. 13 para. 3) to be unconstitutional, because the prohibition on selecting and implanting only healthy embryos would cause harm to women's health and therefore would violate art. 32 of the Italian Constitution.[83] However, it did not find that the prohibition of destroying embryos (art. 14 para. 1) was unconstitutional or that it violated the right to self-determination. Specifically, it concluded that 'the embryo, in fact, irrespective of the amount of subjectivity that is attributed to the genesis of life, is definitely not a mere biological material'. Its protection could be limited only if it was necessary to protect a value of greater legal and moral weight, such as women's health. As Law 40/2004 no longer obliged the doctor to transfer an embryo with a genetic disease into the patient's uterus, it did not create any risk to her health and was, therefore, not in violation of the Italian Constitution.

The plaintiff's request for the embryos to be destroyed refuted the notion that they were treating their embryos as mere biological material. For example, the so-called 'compassionate transfer' is a widely used practice in fertility clinics in Italy, with embryos being placed into the women's cervix or vagina rather than the womb allowing them to die there rather than be flushed down the sink. This practice makes clear that the woman acknowledges the embryos' high value. In addition, these rituals play an important role for women themselves, because they

> represent attempts to recognize and register value in women's experience of the creation of these embryos; the physical and emotional effort that has gone into wanting and making them. In this way, both life and death for embryos are by no means objectively, scientifically, legally identifiable moments. Instead, they might be described as investments—made typically by women but also by other parental figures—in that which is desired.[84]

Indeed, the disposition of surplus embryos after the end of fertility treatment is another widely discussed topic in sociological research. As much research has shown, what happens to their

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[83] C. C., 21 ottobre 2015, n. 229.

[84] David Ellison and Isabel Karpin, 'Embryo Disposition and the New Death Scene' (2011) 17 Cultural Studies Review 81.

embryos is very important to couples.[85] In countries with more liberal regimes, couples are given the right to dispose of the embryos as they see fit, and may donate them to other couples or for research. In these countries, citizens might feel that depriving them of this opportunity is too great a restriction of their reproductive freedom and responsibility, including for supernumerary embryos. But the Constitutional Court did not have the option of considering any personal circumstances and relational values. Following its dignitarian position towards embryos, it accepted that only the right to health justified the limitation of embryo protection.

Therefore, on the one hand, Hanafin was right in arguing that Italian biological citizens managed to contest their 'exclusion from full legal citizenship' and, in this bottom-up governance rights indeed acted as "important weapons in a counterhegemonic 'tactical biopolitics'".[86] And yet, on the other hand, the extent to which citizens secured the 'writing of the law from below' and managed to have their interests and rights recognized by the State was significantly more limited, particularly compared with the scope of those 'vital rights' that have become the key elements of the contemporary ethical 'regimes of the self', dominating in countries with liberal regulatory approaches towards ART and PGD, such as Great Britain, and in Italy before the adoption of Law 40/2004. This limitation was a direct outcome of the Constitutional Court's biopolitical responsibilities towards the IVF embryo, established in the constitutional law doctrine, which prevented the Italian biological citizens from having their relational values recognized by the state through legal rights.

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[85] Erica Haimes and others, '"So, What Is an embryo?" A Comparative Study of the Views of Those Asked to Donate Embryos for hESC Research in the UK and Switzerland.' (2008) 27 New genetics and society 113. A Lyerly and others, 'Factors That Affect Infertility Patients' Decisions about Disposition of Frozen Embryos' (2006) 85 Fertility and Sterility 1623. Kristina Hug, 'Motivation to Donate or Not Donate Surplus Embryos for Stem-Cell Research: Literature Review.' (2008) 89 Fertility and sterility 263. Erica Haimes and K Taylor, 'Fresh Embryo Donation for Human Embryonic Stem Cell (hESC) Research: The Experiences and Values of IVF Couples Asked to Be Embryo Donors.' (2009) 24 Human reproduction 2142.

[86] Hanafin, The Embryonic Sovereign and the Biological Citizen: The Biopolitics of Reproductive Rights (n 14) 194.

5.6. Conclusion

In this article, I sought to show the limitations of using rights and rights litigation to gain the freedom to make personal choices related to one's own health and that of one's children and family and to use new advances in biomedicine to achieve these ends. I did not mean to suggest that we should abandon our hope, or faith, in rights, as Kennedy has done. The use of legal rights does play an important role in democratic governance and in making State authorities recognize and fulfill their citizens' health-related needs, rights and responsibilities. Instead, I sought to suggest that a nuanced and more critical approach towards rights should be adopted. This critical attitude would help both scholars and citizens engaged in bottom-up governance to remain aware of the constraints inherent to rights and not to be overly optimistic about their liberating potential, hence sparing themselves from a disappointment and an eventual loss of faith in rights.

CHAPTER 6

Human dignity in a comparative perspective: embryo protection regimes in Italy and Germany

6.1. Introduction[1]

Advances in human fertilization and embryology have brought immense opportunities for medicine and human health. Technologies such as *in vitro* fertilization (IVF), preimplantation genetic diagnosis (PGD) and human embryonic stem cell (hESC) research have contributed to managing serious health conditions and their further development is now widely associated with improved health.

However, such ‘promised futures’[2] of improved health have not been the only vision of what these biomedical advances may bring. Both in philosophical and ethical debates and in more down-to-earth political discussions, criticism has been mounted that these technologies might lead to the violation and erosion of human dignity.[3] One of the criticisms that ‘dignitarianism’, as this position has been called,[4] raises with respect to these technologies is that they involve the use of human embryos. Regardless of how human embryos are regarded, either as full-fledged human persons or as just one of the stages in the development of human life, their use for medical or scientific purposes is nevertheless seen as problematic because embryos due to their ‘humanity’ deserve respect and therefore cannot be treated as objects of scientific or biomedical research. Hence, the requirement to protect human dignity can imply the prohibition of commodification, instrumentalization and commercialization of human life. It thus derives from the philosophy of Kant, according to

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[1] Article was published as: Parfenchyk, Volha, and Alexander Flos. 2017. “Human Dignity in a Comparative Perspective: Embryo Protection Regimes in Italy and Germany.” *Law, Innovation, and Technology* 9 (1).

[2] Sarah Franklin and Margareth Lock, ‘Animation and cessation: the remaking of life and death’ in Sarah Franklin and Margareth Lock (eds), *Remaking Life and Death. Towards an Anthropology of the Biosciences* (SAR Press 2003).

[3] Leon Kass, *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics* (Encounter Books 2002); Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (Farrar, Straus and Giroux 2002).

[4] Roger Brownsword, ’Ethical Pluralism and the Regulation of Modern Biotechnology’ in Francesco Francioni (ed), *Biotechnologies and International Human Rights* (Hart Publishing 2007).

whom no human life can be used merely as a means to an end but only as an end in itself.[5] Dignitarianism can also include the principle of 'sanctity of life' which has religious roots.[6] Sanctity of life implies that the dignity of human life entails its inviolability and sacredness and therefore requires respect for every human life, including patients in a 'vegetative state' and unborn life.[7] In the discussion on whether a relevant technology violates human dignity, the appeal to dignity often acts as a 'conversation stopper'.[8] All possible therapeutic benefits that embryo use in medical treatment and scientific research offers are regarded as irrelevant if such technological and scientific practices violate human dignity.

However, the extent to which the principle of human dignity can effectively shape regulatory policy on controversial biomedical issues is in need of exploration. Specifically, human dignity as described above constitutes the basis of only one and the most restrictive and disempowering ethics out of three strands of bioethical reasoning in the so-called 'bioethical triangle'[9]. Besides dignitarianism, the bioethical triangle includes liberal, emancipatory human rights ethics and pragmatic, utilitarian ethics. The problem hence emerges when these three bioethical perspectives start competing for regulatory relevance, thus urging policy-makers to determine which of the three should shape policy and whether dignitarianism has some particular importance that could trump the two other ethics.

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[5] Timothy Caulfield, and Roger Brownsword, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?' (2006) 7 Nature Reviews Genetics 72.

[6] This connection between human dignity and sanctity of life was most clearly expressed by John Paul II in the encyclical *Evangelium Vitae*, according to which 'the Gospel of the dignity of the person and the Gospel of life are a single and indivisible Gospel'. John Paul II, Evangelium Vitae (1995) <http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html> accessed 9 December 2016.

[7] Doris Schroeder, 'Dignity: One, Two, Three, Four, Five, Still Counting' (2010) 19 Cambridge Quarterly of Healthcare Ethics 118.

[8] Kurt Bayertz (ed), *Sanctity of Life and Human Dignity* (Springer Netherlands 1996).

[9] Brownsword (n 4).

Furthermore, and to complicate things further, human dignity constitutes the basis of not only dignitarianism, but also of the human rights perspective.[10] These two ethical perspectives build on two different versions of human dignity. Dignitarianism builds upon the restrictive version of dignity, or 'dignity as constraint'. As stated above, it is rooted in religious beliefs or it is based on Kantian philosophy. Therefore, this principle entails that technologies such as human therapeutic and reproductive cloning, sex selection, tissue-typing and PGD may erode human dignity because they instrumentalize, commodify and destroy human life. Instead, the human rights perspective builds upon a liberal version of human dignity, or 'dignity as empowerment', which can be defined as autonomy and self-determination. This perspective does not treat new biomedical technologies as necessarily problematic and conditions their legitimacy upon the need to obtain the informed consent of the concerned patients.

The fact that human dignity underlies both bioethical perspectives, dignitarianism and the human rights approach, further aggravates the problem for policy-makers. For example, this problem is particularly pertinent when the interpretation of laws that build on human dignity is required. In the absence of a clear definition of human dignity, it is not clear whether the legislator implied human dignity as constraint or human dignity as empowerment. Therefore, even if the intent to protect human dignity might be uncontested by the parties to the debate, competition between several bioethical perspectives might still take place due to the intention of the promotors of different bioethical perspectives to interpret human dignity in a more liberal or more restrictive way.

Taking the aforementioned problems into account, we explore how, when and under which circumstances the appeal to human dignity in public debates around new technological and scientific practices becomes problematic. To do this, we compare how Italy and Germany discussed and adopted policies on assisted reproductive technologies (ART) and hESC. Italy and Germany are commonly used as examples of countries whose restrictive policies on ART and embryo research have been influenced by the presence of strong dignitarian traditions. However, despite this apparent similarity, the two countries differ in terms of the timing of the adopted laws and their durability. The German Embryo Protection Act

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[10] Ibid.

(*Embryonenschutzgesetz*, hereafter EPA) was passed in 1990 after five years of deliberation of its text. It has been in force since its inception and has since only been modified and complemented to regulate new technologies, including PGD and hESC. In contrast, the Italian Parliament deliberated the law on medically assisted reproduction (*Legge sulla procreazione medicalmente assistita*, hereafter Law on MAR) for 20 years after the first bills on IVF had been drafted, and adopted it only in 2004. However, within five years, almost all its restrictive provisions were repealed by the Constitutional Court as unconstitutional. Thus, while the dignitarian tradition led to the adoption of a workable and enduring law in Germany, the Italian law, similarly influenced by the value of human dignity, was subject to a lengthy discussion, only to see many of its articles invalidated as unconstitutional in a short period. Summarised bluntly, in Germany, the dignitarian tradition led to an enduring and workable EPA, while in Italy it led to a controversial and, ultimately, unconstitutional Law on MAR.

The main argument of our article is that in both countries human dignity as constraint played a key role in the political debate around the new ART and hESC research, mainly because these were framed as a potential assault on human dignity. Yet, the two countries differed in terms of their success to build their policies regarding ART and hESC research upon the principle of human dignity. We suggest that two factors were responsible for this difference. The first factor was whether dignitarianism was the dominant bioethical perspective in the relevant country. The second factor was the degree to which the regulators were willing to strike compromises with their opponents if dignitarianism was not the dominant bioethical perspective or was competing with other bioethical perspectives for regulatory relevance.

While the focus of this paper is on human dignity and the possible difficulties in implementing it through policy, we argue that its conclusions are also indicative of general patterns of the relationships between particular bioethical configurations and regulatory outcomes. Indeed, much research has shown the connection between countries' bioethical landscapes and the eventual regulatory outcomes of the debate on new biomedical technologies.[11] This article contributes to this research in two ways. First, it illustrates the

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[11] Tanja Krones and Gerd Richter, 'Preimplantation Genetic Diagnosis (PGD): European Perspectives and the German Situation' (2004) 29 The Journal of Medicine and

importance of not only the presence of dominant bioethical perspectives, but also the ability and willingness of their supporters to strike compromises and to form coalitions with opponents. Second, it provides a more detailed account of how exactly such bioethical configurations translate into policies. In the conclusion, we will draw three broad patterns of how exactly bioethical configurations may shape regulatory policy.

We shall proceed as follows. In Section 2, we will describe the debate around the Italian Law on MAR, both its discussion in Parliament and its invalidation by the Constitutional Court. In Section 3, we shall explore how the German government discussed the EPA and how it amended it to account for new technologies such as PGD and hESC. In Section 4, we will analyse and compare the two countries and conclude why human dignity succeeded in materialising in the German EPA and Stem Cell Act (*Stammzellgesetz*, hereafter SCA) and failed to do so in the Italian Law on MAR. Finally, we will derive three broad patterns in the relationship between countries' bioethical landscape and their regulatory policy.

6.2. Italy, sanctity of life and the debate on the Law on MAR

Italy opened its laboratories to ART in 1984 when Italian doctors performed their first IVF procedures. At the same time, the Italian State made its first attempts to regulate the provision of ART services on its territory. As ART were still new technologies, raising ethical, legal and safety concerns, the then Minister of Health Costante Degan instituted an interdisciplinary commission entrusted with exploring various aspects of ART and issuing reports that could subsequently be used as the basis for a law on ART. The commission included doctors, scientists, philosophers, and legal scholars and was presided over by judge Fernando Santosuosso.

Philosophy 623; Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005); Stefan Sperling, *Reasons of Conscience* (University of Chicago Press 2013).

The reports produced by the Santosuosso Commission had a rather restrictive approach towards ART and embryo research, employing a clearly deontological reasoning.[12] IVF embryos were defined as 'subjects' whose primary legal entitlement was the right to life. Therefore, the reports prohibited embryo selection and the creation of embryos for other purposes than the initiation of pregnancy, such as scientific research. Finally, they also suggested that only as many embryos should be created as would be implanted into the woman, in order to prevent the creation of supernumerary embryos. In case the implantation of embryos would fail, the non-implanted embryos could be cryopreserved for later implantation into the same or another woman. In the latter case, equating embryos with born children, it prescribed that the implantation should be performed under the supervision of the Juvenile Court, similarly to the adoption procedure.

The reports of the Santosuosso Commission were not implemented by the Minister of Health. As Flamigni and Mori ironically suggest, he found them too liberal.[13] Instead, two months prior to their publication, he issued a ministerial circular named 'Limits and conditions of legitimacy of services for artificial insemination in the domain of the National Health Service'.[14] The Circular aimed at regulating artificial insemination alone, but also contained several provisions regulating the procedures regarding embryos. Specifically, the Circular entirely prohibited embryo cryopreservation and only allowed the creation of embryos that were required for implantation. However, the Circular applied to public centres only, thus leaving private centres beyond its regulatory reach. The adoption of the Circular thus addressed the need for regulation; however, due to its limited scope of application, it satisfied this need only partially.

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[12] Commissione Santosuosso, 'Proposte di disciplina della nuova genetica umana' (1986) 2 Giurisprudenza Italiana 33.

[13] Carlo Flamigni and Maurizio Mori, *La Legge Sulla Procreazione Medicalmente Assistita* (Net 2005).

[14] Circolare 1 marzo 1985, n. 100/119657/32.2.14, *Limiti e condizioni di legittimita dei servizi per l'inseminazione artificiale nell'ambito del Servizio Sanitario Aziendale*.

6.2.1 Sanctity of life, the Catholic/secular cleavage and underregulation

Simultaneously with the governmental attempts to regulate ART and embryo research, Parliament also wished to place these under state control. From the very beginning of the debate, a substantial number of bills, mainly drafted by the members of Christian Democracy (*Democrazia Christiana*, hereafter DC), had been presented to Parliament that called for the prohibition of any type of clinical and scientific manipulation of human embryos from the moment of fertilisation, including the creation of supernumerary embryos, their cryopreservation, testing, selection based on morphological or genetic conditions, scientific research and destruction. This prohibition was warranted because, according to the bills' drafters, embryos from the moment of fertilisation were already full-fledged human persons. The belonging of the '*nascituri*' ('those to be born'), as embryos have been interchangeably called, to the moral community of people meant that they possessed human dignity and that their life was therefore inviolable. For example, the bill presented by Mino Martinazzoli, president of DC, and Carlo Casini, president of the Italian pro-life association Movement for Life (*Movimento per la Vita*, hereafter MpV) and a DC member (Martinazzoli bill), which was to be resubmitted many times throughout the debate, explicitly stated that there exist no interests that could outweigh the importance of preserving human life, including the life of the embryo.[15]

Another purpose of these bills, including the Martinazzoli bill, was to explicitly recognize IVF embryos as legal subjects and holders of the right to life. According to the Italian law on abortion, foetuses are neither 'persons' nor legal subjects enjoying the right to life,[16] but they do 'enjoy the inalienable rights of human beings' and are thus protected by general art. 2 of the Italian Constitution.[17] Unsatisfied with the partiality of legal protection of

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[15] Camera dei Deputati, *Proposta di legge* (*Norme a tutela dell'embrione umano*), n. 3486. X Legisatura, 22 dicembre 1988. <http://legislature.camera.it/_dati/leg10/lavori/stampati/pdf/34860001.pdf> accessed 9 December 2016.

[16] Corte cost. 18 febbraio 1975 n. 27, in *Giur. cost.*, 1975, p. 117 ss.

[17] Art. 2 of the Italian Constitution: 'The Republic recognizes and guarantees the inviolable rights of the person, both as an individual and in the social groups where human

embryos, the Martinazzoli bill stated that its main goal was 'to extend the protection of the right to health and to physical integrity onto the initial phase of human existence'[18] and thereby to recognise human embryos as a subject of rights, particularly of the right to life. Along with the prohibition against clinical and scientific manipulation of the embryo, the recognition of IVF embryos as legal subjects, whose primary right was the right to life, was regarded as the best means for ensuring their protection by the State.[19]

This framing of embryos as human persons and legal subjects was attacked by more liberal politicians, largely belonging to the Italian Communist Party (*Partito Communisto Italiano*, hereafter PCI). One of the main discursive strategies they employed was to to oppose religion and the state. They stressed that the issue of an embryo's moral status was a personal and subjective value, influenced by one's religious views, and therefore could not serve as the basis for secular laws. Instead of focusing on the need to protect embryos against manipulation, they emphasised other risks that ART raise, especially if left unregulated, and thereby sought to re-problematise ART. Specifically, they stressed the need to prevent the commercialisation of reproductive technologies, 'exploitation' of patients, infliction of harm on women and new-borns, medical malpractice and a number of controversial practices such as eugenics and surrogacy.[20]

Thus, from the very beginning, the deliberative space on ART and embryo research in Italy was characterised by two ways in which ART and embryo research were problematised. These problematisations built on two different understandings of what should be the basis for

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personality is expressed. The Republic expects that the fundamental duties of political, economic and social solidarity be fulfilled.'

[18] Camera dei Deputati (n 15).

[19] Camera dei Deputati. Assamblea, *Resoconto stenografico*. XIII Legislatura, 395 Seduta, 20 luglio 1998. <http://leg13.camera.it/_dati/leg13/lavori/stenografici/sed395/s030r.htm>accessed 9 December 2016

[20] Camera dei Deputati, *Proposta di legge* (*Norme sulla inseminazione artificiale e sulla fecondazione in vitro*), n. 1304. IX Legisatura, 17 aprile 1985. <https://www.senato.it/service/PDF/PDFServer/DF/277857.pdf> accessed 9 December 2016.

laws on ART and embryo research, that is, the protection of embryos' dignity and life or, in contrast, the prevention of medical malpractice and the protection of patients' health. The presence of these two different problematisations was an expression of a deep secular/religious cleavage running throughout both Italian politics and society alike. In the political debates, these problematisations were advanced and supported by two groups of politicians. DC members supported full embryo protection and an absolute right to life of the embryo. In their struggle for implementing this principle through laws, they were supported by the Catholic Church, which retained its role of an influential political actor and opinion-maker despite the secularisation of Italian society.[21] Its influence on the Italian politics would be further reinforced in the beginning of the 1990s, when the corruption scandals led to the dissolution of the main political parties and emergence of smaller political parties, many of which would turn to Catholicism in search for their political identity.[22] In contrast, PCI members rejected that human embryos necessarily had human dignity and instead emphasised the need to protect women's health. This secular/Catholic cleavage of the Italian party system was to be the main principle structuring the debate around embryo use in medical and scientific practices in Italy. Furthermore, running through the entire Italian society alike, it split both lay citizens and the Italian medical and scientific community on the issue of the 'moral and legal status of the embryo' and thus on how ART and embryo research should be regulated.[23]

One of the main consequences of this cleavage was a difficulty in achieving consensus on how to regulate ART and embryo research. This led to the incapacity of the Italian Parliament to come up with any law on ART and embryo research for 20 years. As a result, the Circular remained the only instrument regulating the provision of ART services and

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[21] Franco Garelli, 'La rilevanza concreta e pubblica del cattolicesimo italiano' (2005) 5 Il Mulino 823.

[22] Alberto Melloni, 'Tre fasi nel rapporto fra Chiesa, episcopato e politica' (2006) 6 Il Mulino 1056.

[23] Celina Ramjoué and Ulrich Klöti, 'ART Policy in Italy Explaining the Lack of Comprehensive Regulation' in Ivar Bleiklie and others (eds), *Comparative Biomedical Policy. Governing Assisted Reproductive Technologies* (Routledge 2004).

embryo research in the country. However, because it applied to public fertility clinics only, private centres remained outside its regulatory reach and instead were subject to self-regulatory governance.[24] The self-regulation of doctors practising ART in the private sector led to a rather liberal approach towards ART. Private Italian clinics engaged in practising a wide range of ART procedures, ranging from more widespread ones such as creating supernumerary embryos and embryo cryopreservation to more controversial ones such as surrogacy, egg donation, and the fertilisation of menopausal and single women. Due to this permissibility, sceptical observers defined Italy as a 'Procreative Far West' country.

As a result of this permissive approach towards ART, large numbers of embryos got accumulated in Italian private clinics. This situation had a substantial impact on the approach of pro-life politicians towards ART and embryo protection. Embryos, besides being framed as full-fledged human persons and having an absolute right to life, started to be framed as weak, little and still unprotected little children whose life and health was at stake due to the 'deviant egoism of those who want to have a child at any cost'.[25] Women, instead, were regarded as the main subjects responsible for transgressing the established boundaries and putting at stake the interests of IVF embryos. In the discussion of the law's text in Parliament, this urged pro-life politicians to emphasise even more strongly the need for an absolute protection of embryos' right to life even against the entitlements of prospective mothers to procreate and have their rights protected.[26]

The debate around ART and embryo research in Italy was therefore taking place around a problem that interpretative policy analysis defines as 'wicked problems'. According to Fisher, 'wicked problems' are problems 'in which we not only don't know the solution but

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[24] Isabelle Engeli and Christine Rothmayr Allison, 'When Doctors Shape Policy: The Impact of Self-Regulation on Governing Human Biotechnology' (2016) 10 Regulation & Governance 248.

[25] Senato della Repubblica, *Proposta di legge* (*Norme in materia di procreazione assistita*), n. 112. XIV Legisatura, 6 giugno 2001, 2. <https://www.senato.it/service/PDF/PDFServer/DF/63552.pdf> accessed 9 December 2016.

[26] Ibid.

are not even sure what the problem is'.[27] Often, wicked problems can emerge in debates around moral and therefore frequently irreconcilable values. Italian society, split around the issue of the 'moral status of the embryo' and hence embryos' entitlements, was similarly engaged in discussing what exact problem ART and embryo research actually raised. Was it the problem of violating the sanctity of life or was it possible risks to citizens' health? The inability to reconcile views on the issue of the 'moral status of the embryo' led to the failure to adopt a law and to a *de facto* permissive regime.

6.2.2 The debate around the Bolognesi bill, sanctity of life and the regulation of fertility treatment

The discussion of the co-called Bolognesi bill provides a vivid illustration of what the idea to protect human dignity conceptualised as sanctity of life meant in practice. In 1998, largely due to the high-profile case of cloning the first mammalian animal Dolly the sheep, the government renewed its attempts to bring ART and embryo research under state control. It assigned the task of preparing the first draft of a unified bill to the Commission on Social Affairs of the Chamber of Deputies. The parliamentary coalition at that moment was centrist-left, which suggested that a more permissive bill on ART might be adopted. Furthermore, the president of the Commission, Marida Bolognesi, herself a member of the Italian social-democratic political party Democrats of the Left (*Democratici di Sinistra - L'Ulivo*), was known for her feminist and rather liberal views on matters related to ART and abortion.[28] However, as a result of the corruption scandals of the beginning of the 1990s, the dissolution of the main DC and PCI, and the emergence of a large number of smaller parties, political parties were no longer representative of either religious or secular views. Instead, the latter were dispersed across the entire political spectrum. Therefore, Marida Bolognesi, attempting to attract the voices of Catholic members of the party, approved a compromise text of the 'Bolognesi bill'. It allowed a doctor to create a maximum of four embryos in one IVF cycle, transfer as many embryos as was deemed appropriate to initiate pregnancy, and cryopreserve

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[27] Frank Fischer, *Citizens, Experts, and the Environment* (Duke University Press 2000) 128.

[28] Chiara Valentini, *La Fecondazione Proibita* (Feltrinelli 2004).

the remainder; however, the remaining embryos must be transferred into the same woman in the following cycles. The bill also prohibited embryo research. Thus, it did allow some form of embryo manipulation such as the creation of supernumerary embryos and cryopreservation; yet, responding to the voices of the Catholic members of the party and to their moral reservations about creating supernumerary embryos, it limited the number of producible embryos to four and prohibited embryo research.

However, absolutist voices precluded adoption of the law. Almost immediately after the bill was passed to the Chamber of Deputies, it was amended by including the embryo in the list of subjects whose rights the future law had to protect. In addition, to ensure absolute protection of embryos' right to life, the amended bill prohibited embryo cryopreservation and selection, and mandated the creation of a maximum of three embryos during one IVF cycle, all of which, even those holding pathologies, had to be implanted into the woman's uterus. Furthermore, pro-life politicians stressed the need to prohibit both women and men to withdraw consent after the fertilisation of the patient's eggs. The main reason for this amendment was to protect embryos' right to life from the moment of fertilization till implantation, if the couple would change their mind regarding the implantation of embryos.[29] Finally, pro-life politicians proposed to prohibit PGD. According to them, PGD would involve the selection of human embryos based on their genetic profile, or in other words, a 'eugenic practice'.[30] Furthermore, PGD did not simply treat different forms of life differently, but presupposed the discarding and elimination of embryos that bore pathological genes. PGD thus represented a double offence against human life: not only did it imply

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[29] Senato della Repubblica. Assamblea, *Resoconto stenografico*. XIII Legislatura, 852 Seduta (pom.), 7 giugno 2000. <http://www.senato.it/service/PDF/PDFServer/BGT/6064.pdf> accessed 9 December 2016.

[30] Camera dei Deputati. Assamblea, *Resoconto stenografico*. XIV Legislatura, 421 Seduta, 10 febbraio 2004. <http://leg14.camera.it/_dati/leg14/lavori/stenografici/sed421/00470b04.htm> accessed 9 December 2016.

selection, but it also built upon 'the affirmation that diseases can be treated by killing the sick'.[31]

Liberal politicians criticised these restrictions as not paying enough attention to the interests of adult Italian citizens involved in ART, especially to those of women, as women's bodies were the main object of treatment. They argued that the prohibition to create more than three embryos would force the doctor to perform repeated ovarian stimulations of the woman, thus raising the risks of such health conditions as ovarian hyperstimulation syndrome (OHSS) and ovarian cancer. They criticised the provision prohibiting withdrawal of consent after egg fertilisation, as it would violate the principle of informed consent and amount to forced treatment of women. Furthermore, the prohibition of PGD would cause 'true family tragedies'[32] and require 'from couples a heroism that the law cannot require',[33] as it would force couples to raise children with severe genetic pathologies or force women to perform abortion, a much more harmful procedure than PGD. Yet, all attempts by liberal politicians to reduce the restrictiveness would fall short in face of the reluctance of pro-life politicians to negotiate the value of embryo life with other values, including health of the mother.

6.2.3 Embryo and hESC research

The regulation of embryo and hESC research in Italy was another hotly contested topic. During the discussion of the Bolognesi bill, how embryo research should be regulated in Italy was a secondary issue, yielding primacy to the issue of fertility treatment. It got prominence

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[31] Senato della Repubblica. Assemblea, *Resoconto stenografico*. XIV Legislatura, 499 Seduta (ant.), 03 dicembre 2003. <http://www.senato.it/japp/bgt/showdoc/frame.jsp?tipodoc=Resaula&leg=14&id=00114374&part=doc_dc-ressten_rs-ddltit_rdddddl1514eapa&parse=no&stampa=si&toc=no> accessed 9 December 2016.

[32] Ibid.

[33] Senato della Repubblica. Assemblea, *Resoconto sommario*. XIV Legislatura, 504 Seduta (ant), 10 dicembre 2003. <http://www.senato.it/japp/bgt/showdoc/frame.jsp?tipodoc=Resaula&leg=14&id=00090770&part=doc_dc&parse=no> accessed 9 December 2016.

only in 2000, when the British government decided to amend the Human Fertilisation and Embryology Act to allow research on stem cells. This led to a full-blown controversy on whether hESC research should be allowed in Italy.

First, a brief explanation of what embryonic stem cells are is warranted. Stem cells have been isolated from an embryo and grown for the first time in 1998. They are taken from an embryo at the blastocyst stage, normally five days after fertilisation of an egg cell. At this stage the embryo cells are pluripotent (capable of growing into many but not all types of cells) and therefore cannot become embryos. This makes them a useful and promising tool for curing diseases, such as Parkinson's disease. However, because the extraction of stem cells from embryos involves their destruction, it raises similar concerns as research on embryos.

Similar to the discussion of fertility treatment, the debate around the legitimacy of performing hESC research was first problematised as an assault on human dignity and a violation of the right to life. The views of discussants, who included both politicians and scientists, split along the secular/Catholic cleavage. The proponents of hESC emphasised the therapeutic benefits of hESC and the potential of such research to provide new cures for presently untreatable diseases. In contrast, the opponents claimed that hESC violates human dignity and embryos' right to life. Similarly to the debate on fertility treatment, the second group of politicians was backed by the Vatican, which used the debate on stem cells to further advance its goals on the 're-Christianisation' of Italy.[34] Furthermore, in addition to employing ethical arguments in the debate, they also argued that hESC research gives worse results than research on adult stem cells. As Beltrame argued, by engaging in the discussion about therapeutic benefits of different types of research, Catholic politicians and scientists attempted to shift the debate from the ethical to the epistemic domain and thus to problematise the debate on hESC further by calling into question the therapeutic efficiency of hESC research.[35]

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[34] Alberta Giorgi, 'Ahab and the White Whale: The Contemporary Debate around the Forms of Catholic Political Commitment in Italy' (2013) 20 Democratization 895.

[35] Lorenzo Beltrame, 'Disputing the Boundary of Pluripotency. The Italian Public Debate on Amniotic Fluid-Derived Stem Cells' (2013) 32 New Genetics and Society 385; Lorenzo Beltrame 'The Therapeutic Promise of Pluripotency and Its Political Use in the Italian Stem Cell Debate' (2014) 23 Science as Culture 493.

However, such reproblematisation was indeed anything but uncontroversial; instead of de-moralising hESC, such reproblematisation indirectly asserted a moral status of the embryo as a full-fledged human being. Instead, the polarisation was reinforced as it was no longer only about the moral status of the embryo, but also about scientific evidence and knowledge.

In 2000, the then Minister of Health Umberto Veronesi instituted an ad hoc commission, including 25 members and presided over by the Nobel prize winner oncologist Renato Dulbecco, in order to explore the ethical implications of hESC research. The final report was published in 2003.[36] The members of the commission agreed that hESC provides significant benefits for medicine. However, they split on the issue of ethics of using hESC for medical purposes. While the majority of the Commission's members supported the use of surplus embryos for deriving hESC, seven Catholic members opposed the use of all embryos, even of surplus ones. They argued that the embryo was a full-fledged human person, whose right to life and human dignity had to protected, and no other benefits, including medical ones, could outweigh the value of its life.

One of these Catholic members was Girolamo Sirchia, an outspoken proponent of research on adult stem cells. In 2001, when Italy had its parliamentary elections and the Berlusconi-led coalition won, Sirchia was appointed a new Minister of Health. After he took the post, Sirchia 'promised' to institute a new expert commission that would provide an 'alternative' expert report. Despite that this alternative commission was not established, the reports of the Dulbecco Commission were not taken into account by the new Italian government and ended up in a drawer. Instead, immediately following his appointment, Sirchia issued a regulation on funding schemes of Italian science. The regulation did not include funding for hESC and covered only adult stem cells. Despite that no official regulation of hESC was produced, the governmental decision not to assign funds for hESC research was indicative of the then government's reluctance to find ethically ambiguous hESC

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[36] Ministero della Sanità, *Relazione della Commissione di studio sull'utilizzo di cellule staminali per finalità terapeutiche*. XIII Legislatura, 28 dicembre 2000. <http://salute.aduc.it/staminali/documento/relazione+della+commissione+studio+sull+utilizzo_2082.php> accessed 9 December 2016.

research. The prohibition of conducting hESC research would be fully implemented with the enactment of the Law on MAR.

6.2.4 The adoption of the Law on MAR and the institutionalisation of sanctity of life

In the elections of 2001, central-right parties occupied the majority of seats in Parliament. After the restrictive text of the bill was approved by the Chamber of Deputies, the bill was in limbo awaiting discussion in the Senate. The Government appeared in no hurry, however. The situation changed with the intervention of the Vatican.[37] In February 2003, representatives of the Government met with the Vatican clergy on the occasion of the anniversary of the signing of the Lateran Pacts. The Pope expressed the Vatican's concerns with the Government policy such as its support of the war in Iraq and the implementation of discriminatory laws on immigration. He stressed that the Vatican could provide political backing if the law on assisted reproduction in its restrictive version would be approved as soon as possible. [38] After this meeting the position of the Government changed drastically. In December 2003, the Government obtained the approval of the Bill by the Senate. After the second approval of the Bill by the Chamber of Deputies, on 10 February 2004, it was passed as the Law on MAR.[39]

In art. 1, the Law recognised the human embryo as a right-holder, although it did not give a definition of the embryo. It allowed access to ART only to infertile couples if other methods of treating infertility proved unsuccessful. Further, in art. 13, the Law forbade embryo experimentation, prescribed that clinical and experimental research must be performed only for the sake of the embryo itself, and forbade the creation of embryos for scientific and experimental research and eugenic embryo selection. Finally, in art. 14 it prohibited the discarding and cryopreservation of embryos, and further prescribed that doctors must not 'create embryos in a number higher than the one strictly necessary for a single and

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[37] Chiara Valentini, *La Fecondazione Proibita* (Feltrinelli 2004); Patrick Hanafin, *Conceiving Life: Reproductive Politics and the Law in Contemporary Italy* (Ashgate Publishing 2007).

[38] Ibid.

[39] L. 19 febbraio 2004 n. 40, *Norme in materia di procreazione medicalmente assistita*.

simultaneous transfer, and in any case not more than three'. The only exception to the prohibition of embryo cryopreservation were serious health issues of the female patient, 'unforeseen at the moment of fertilisation', which allowed doctors to freeze embryos. However, after solving these health problems, the doctor was obliged to proceed with embryo implantation. In the same year as it was enacted, the Law's provisions were implemented into guidelines of the Ministry of Health introducing a new medical protocol for performing IVF both for public and private Italian clinics.

Furthermore, three years later, another Circular was issued that specified what is meant exactly by 'embryo'.[40] As stated before, art. 1 of the Law on MAR did not specify this. As a result, doctors interpreted it as an entity that is formed with the fusion of the two pro-nucleuses. This means that from the moment the sperm meets the egg until the fusion of their pro-nucleuses, the entity was not an embryo, and therefore the restrictive provisions of the Law on MAR did not apply to it. Therefore, doctors could create a large number of oocytes, fertilise them and cryopreserve these 'pre-embryos', as they have been called by Italian doctors. In this way, they did not have to repeat the detrimental ovarian stimulation of the woman and jeopardise her health. In addition, this procedure gave comparable pregnancy rates as a regular IVF. Finally, they could perform polar body biopsy, an alternative to PGD, although it had a narrower scope of application and could detect only the mother's genetic diseases. However, the Circular prohibited these practices. It built its decision on a common line of reasoning employed in the debate around the Law on MAR, according to which life should be protected from the beginning, hence with the penetration of the sperm into an egg and not with the fusion of the two (pro-)nucleuses. As will be seen later, in Germany both procedures were allowed, which made IVF significantly less restrictive there.

6.2.5 The challenge of the Law on MAR, abrogative referenda and litigation campaign

Predictably, the Law on MAR was not a legal instrument able to function as a compromise on the issue of IVF regulation. Instead, the debate shifted to other institutional settings.

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[40] Manuela Perrotta, 'Il Pre-Embrione (Non) È Uno Di Noi: Breve Storia Di Una Innovazione Inter-Organizzativa Tra Istituzioni, Comunità Professionali E Tecnologie' (2011) 122 Sociologia del Lavoro 194.

Referendum

The enactment of the Law urged citizens who disagreed with the Law to organize an abrogative referendum against the Law.[41] Several questions were put to vote that concerned the liberalisation of fertility treatment and the possibility to perform scientific research on supernumerary embryos. This campaign was supported by many Italian researchers and scientific associations, such as the Luca Coscioni Association for the Freedom of Scientific Research. They claimed, first, that absolute embryo protection was a religious principle that could not be the basis for a law in a secular country. In addition, they emphasised the principle of scientific freedom that was violated by prohibiting embryo research. The referendum failed, however, as the quorum was not met. The Catholic Church influenced this outcome. It organised a massive campaign against the referendum, calling Italian citizens to abstain from voting as 'life cannot be put to vote'. This strategy proved successful and only 25,7 percent of Italian citizens went to the polls. The threat posed to embryo's life by referenda and the possibility of repealing the newly enacted Law was forclosed.

Litigation

In the same year, the debate around the Law shifted to a different – judicial – setting. Individual citizens, unsatisfied with the restrictive nature of the Law on MAR, continued to debate the law's granting of absolute protection to the IVF embryo's rights. They were supported by patient associations and fertility centres. The plaintiffs' main legal complaint was that the Law on MAR prohibits PGD and thereby violates women's right to health. Thus, the relationship of the mother and the embryo, whose opposing interests figured prominently during the debate on the Law on MAR and eventually underlay the Law's text, again became the topic of debate, this time in the courtrooms.

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[41] Ingrid Metzler, '"Nationalizing Embryos": The Politics of Human Embryonic Stem Cell Research in Italy' (2007) 2 BioSocieties 413; Ingrid Metzler, 'Between Church and State: Stem Cells, Embryos, and Citizens in Italian Politics' in Sheila Jasanoff (ed), *Reframing Rights: Bioconstitutionalism in the Genetic Age* (MIT Press 2011).

In 2009, only five years after the Law on MAR had been adopted, the Italian Constitutional Court acknowledged that the Law violates women's right to health.[42] The question of the appealing courts concerned the constitutionality of art. 14 of the Law on MAR that obliged doctors to implant all created embryos simultaneously and prohibiting cryopreservation. The Constitutional Court concluded that this restriction could harm women's right to health, because it significantly limited the freedom of the treating doctor to apply individual treatment to every patient, that is, decide on the number of embryos to create and to implant. As a result, the Constituional Court repealed the restriction that at most three embryos could be created and implanted simultaneously as well as the provision forbidding cryopreservation. Henceforth, embryos could be created in a 'scientifically justified number' to ensure good prospects of pregnancy and protect women's health.

Hence, the mechanism of litigation was used by those citizens and their collectives, including patients and medical associations, who disagreed with the value system upon which the Law on MAR was based, that is, the principle of the sanctity and inviolability of life of embryos. Furthermore, it attributed this value to a wide scope of embryonic entities, including fertilised eggs. Therefore, the Law on MAR excluded the voices of much of its constituency, such as patients, doctors, and scientists, whose activities and interests had been substantially curtailed. Those citizens who disagreed, believing that the law unreasonably prioritised the sanctity of embryo life over the mothers' right to health, used the mechanism of constitutional law to protect their entitlements. This mechanism was successful and the interests of the patients and doctors were recognized by the Constitutional Court, repealing the most

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[42] Corte cost., 1 aprile 2009 n. 151. <http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2009&numero=151> accessed 9 December 2016.

restrictive provisions of the Law.[43] In fact, such citizen resistance enabled a parallel a significantly more liberal rewriting of the Law.[44]

6.2.6 ART and stem cells: back to underregulation

One consequence of the Constitutional Court's judgment was that the regulation of ART was again entrusted to doctors themselves. This resulted in a situation of significant legal uncertainty, which the Italian government made several attempts to address through regulation. First, the Minister of Health set up two expert commissions to update the Ministerial guidelines on ART by 2010. However, up till now, updates have not been published. Second, liberal parliamentarians introduced a number of bills to regulate the access of both fertile and infertile couples to PGD. Yet, none of them reached the parliamentary floor. Thus, the Italian ART sector, having existed without any state regulations for 20 years to be suddenly overregulated when the Law on MAR was passed, returned to its pre-law state within only 5 years. Such issues as whether PGD was legitimate or not, which health conditions justified access to PGD as well as how, where and for how long supernumerary embryos should remain frozen did not have clear and precise legal answer. Some of these questions were addressed by the Constitutional Court when it repealed the prohibition for fertile couples to use PGD (art. 4) and the prohibition of 'eugenic selection' (art. 13) through its judgments in 2015.[45] Others, such as the destiny of cryopreserved embryos and the

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[43] Volha Parfenchyk, 'Redrawing the boundary of medical expertise: medically assisted reproduction and the debate on Italian bioconstitutionalism' (2016) 35 *New Genetics and Society* 329.

[44] Patrick Hanafin, 'The Embryonic Sovereign and the Biological Citizen: The Biopolitics of Reproductive Rights' in Conor Gearty and Costas Douzinas (eds), *The Cambridge Companion to Human Rights Law* (Cambridge University Press 2012).

[45] Corte cost., 14 maggio 2015, n. 96. <http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2015&numero=96> accessed 9 December 2016; Corte cost., 21 ottobre 2015, n. 229. <http://www.cortecostituzionale.it/actionSchedaPronuncia.do?anno=2015&numero=229> accessed 9 December 2016.

indication of the types of diseases that could be selected out via performing PGD, remained unregulated. Medical self-regulation again became the main instrument governing the provision of ART in general and PGD in particular in Italian fertility clinics. However, this mode of governance came into being not as a result of the State purposefully delegating power to the medical profession, but rather as a consequence of the State's failure to regulate ART and agree on how the wicked problem of the moral status of the embryo should be incorporated into laws, entailing legal uncertainty and insecurity, both for patients and the medical community.

A rather similar thing happened with the import of hESC. To begin with, the failure to repeal the Law on MAR's restrictive provisions and the fact that the latter remained in force did not make embryonic stem cell research entirely impossible. Specifically, the Law on MAR said nothing with respect to the possibility of importing hESC from abroad. In the absence of a clear state position, scientists used the loophole in the Law and began importing hESC from abroad. In their permissive interpretation of the Law, they were backed by a substantial number of legal scholars.[46] However, the legitimacy of importing stem cells was not supported by many Italians, both lay citizens and scientists. For example, as Elena Cattaneo, a famous Italian researcher and supporter of stem cell research, stated in an interview, Italian scientists were willing to perform stem cell research and made frequent visits to her laboratory.[47] However, as they did not wish to be called 'unethical' scientists, in public they denied the fact that they performed such research. In addition, several organizations, mostly Catholic, insisted that the loophole in the Law should be interpreted restrictively, accusing the researchers who were importing stem cells of committing a criminal offense, which led to a further worsening of the societal debate with respect to stem cell research.

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[46] Emilio Dolcini, 'Ricerca Su Cellule Staminali Embrionali Importate Dall'estero e Legge penale Italiana' (2006) 49 Rivista Italiana di Diritto e Procedura Penale 450.

[47] Giuseppe Testa, Elena Cattaneo and Assunta Viteritti, 'The Italian Pathways of Stem Cells' (2013) 4 Tecnoscienza 145.

Thus, the lack of clear state regulations on stem cells entitled Italian scientists to autonomously decide whether they wished to perform research on hESC and, if so, how they wished to perform it. This freedom resembles the self-governance of Italian doctors before the adoption of the Law on MAR and after the invalidation of its provisions by the Constitutional Court in 2009. However, the lack of any regulations was far from a positive outcome. It led to various negative consequences, including the insecurity which Italian scientists experienced with respect to the legality of performing research on imported hESC.

6.2.7 Conclusion

ART and embryo research, including hESC research, were ultimately problematised in Italy as a potential assault on human dignity. Therefore, the Law on MAR that was eventually adopted represented a solution to the problem that ART and embryo research raised. This problematisation as well as the conceptualisation of human dignity itself as ‘sanctity of life’ emerged as a result of historical, cultural and political factors, among which the presence of the Catholic Church as an important political actor played a key role.

However, dignitarianism was not the main perspective in the Italian bioethics. The requirement to protect human dignity, or sanctity of life, of embryos was not supported by many lay people nor by decision-makers who adhered to more liberal views. In addition, the affinity of dignitarianism with the Catholic teaching raised objections on the part of the secular sections of Italian society, triggering even deeper disagreements among its supporters and opponents. Similarly, it entailed absolute and unrestricted protection of embryos’ right to life even against the competing interests of the future mother. Embryos included all embryonic entities, including non-viable and sick ones, from the moment of penetration of the sperm cell into an egg. Such an encompassing scope of entities that had the right to life substantially restricted treatment possibilities of Italian doctors, increased health risks for their patients and therefore further narrowed down the scope of those citizens supporting this ethical perspective and its implementation in law.

Despite this disagreement, the supporters of dignitarian ethics made little or no attempt to strike a compromise with their opponents. All attempts of finding a middle-ground solution, such as the one undertaken by Marida Bolognesi, failed. As a result, this prevented the adoption of a law for 20 years. Italian patients were unprotected and clinics were stuffed with supernumerary embryos. Furthermore, even after the Law had been adopted, the debate did not stop but shifted to the courtrooms, and in no more than five years, the most restrictive provisions were repealed by the Italian Constitutional Court, hence reverting to a situation of *de facto* underregulation after a short period of overreguation.

6.3. Germany, non-instrumentalisation of life, and the debate on ART, hESC research and PGD

Similar to Italy, in 1984 the German Government instituted an interdisciplinary commission to study ethical aspects of ART. The Commission was presided over by the former German Constitutional Court president Ernst Benda, illustrating the importance of the commission's work. The produced report was restrictive in nature, prohibiting the manipulation and instrumentalisation of embryos as a general rule.[48] According to it, embryos were entities worthy of protection because they constituted human life and therefore possessed human dignity, and the protection of the latter was the constitutional duty of the German State as envisaged by art. 1 para. 1 of the Basic Law. Specifically, it indicated that research on embryos might lead to such horrible scientific practices as Nazi experiments and eugenics and thereby violate the constitutional principle of human dignity. The report therefore prohibited germline engineering, embryo and sperm selection, surrogacy, the creation of embryos for scientific research, and the creation of more embryos than would ultimately be implanted into the woman. Unlike the Santosuosso Commission, it did not prescribe that embryos must be necessarily implanted, and if the woman for any reason would change her mind with respect to implantation, the embryos could be cryopreserved. Moreover, and importantly, the Commission allowed research on supernumerary embryos for 'medical findings of great value'. By indicating that such research must be of 'great value', the Benda Commission attempted to make sure that embryos are not routinely used in laboratory experiments. However, the fact that it allowed their use for research meant that embryo protection was important, yet not absolute.

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[48] Benda Kommission, In-vitro-Fertilisation, Genomanalyse und Gentherapie: Bericht der gemeinsamen Arbeitsgruppe des Bundesministers für Forschung und Technologie und des Bundesministers der Justiz (J. Schweitzer Verlag 1985).

6.3.1 Parliamentary discussion, human dignity and adoption of the EPA

The report of the Benda Commission was not fully implemented when the German Government proposed its bill in 1989. Its aim was to establish boundaries for the use of IVF and genetic engineering when applied to humans, specifically by prohibiting any kind of manipulation during the initial stages of human life.[49] According to the Government, such a prohibition was required by the need to ensure the protection of human dignity (art. 1 para. 1 of the German Basic Law) and the right to life (art. 2 para. 2). Although the Government acknowledged the constitutional right to perform research (art. 5), this right was limited by the need to protect human dignity.

To prevent the manipulation of human life at its initial stages and to thereby protect constitutional principles of human dignity, the Government included in the list of the forbidden procedures a rather wide range of techniques. They included the creation of embryos for purposes other than initiating pregnancy (in order to avoid the creation of embryos for research purposes), the use of embryos for scientific research, modifying germlines or fertilised eggs till the moment of fusion of the nucleuses, the fertilisation of more eggs than can be implanted in one cycle, cloning, the production of chimeras, choosing the gender of future children, the use of donor gametes, and surrogate motherhood. All these procedures were defined as crimes punishable by prison sentence or fines.

The government bill was also specific in defining what exactly it considered as ‘human life’ whose dignity the State had to protect. Specifically, according to art. 8 the protection was accorded to embryonic entities from the moment of the fusion of the gametes’ nucleuses (i.e. zygotes), including totipotent cells (i.e. cells that can grow into all cell types) that could be derived from an embryo, because a totipotent cell has the potential to become an embryo. In addition, to be protected by the State embryos had to have the potential to develop

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[49] Deutscher Bundestag, Entwurf eines Gesetzes zum Schutz von Embryonen des Bundesregierung, 25 Oktober 1989, Drucksache 11/5460, <http://dipbt.bundestag.de/doc/btd/11/054/1105460.pdf> accessed 9 December 2016.

and thus to be born.[50] Art. 8 of the bill also stipulated that within the first 24 hours after fusion, when it is not certain whether an embryo will be able to develop, it is considered to be capable of development and therefore is also protected by the law. After these 24 hours, it can be already determined with full precision whether the embryo can develop. Thus, only embryos capable of developing and hence becoming individuals were protected by the law.

Finally, the bill sought to protect not only the dignity of embryos, but also the dignity of women. Thus, the bill criminalised the insertion of embryos into the woman against her will, as it would violate the principle of autonomy. Furthermore, it acknowledged the possibility that a woman might not want to have the embryos implanted, or could not have them implanted, for example, in case of illness. In such cases, the bill allowed embryos to be cryopreserved and even destroyed, if the woman would not want to proceed with implantation.[51]

The German Senate, the Bundesrat, agreed that embryos should be protected according to the Basic Law and, similarly to the Government, based its judgment upon the State’s duty to protect human dignity and human life. Is also feared a *Dammbruch* – the breach of a floodgate: if research on embryos would be allowed, then it would only proliferate as new forms of research goals would appear in the future. However, it asked itself whether embryos produced to initiate pregnancy, but that are not implanted in the genetic mother and therefore not capable of developing into human beings, should be banned from research. These supernumerary embryos, according to the Bundesrat, are not protected by the law because they do not fit within the definition of embryos stipulated in art. 8 of the law, as they do not have the capacity to develop. So too can it be questioned whether performing medical research on them would violate human dignity.

Responding to its own quandaries, the Bundesrat deemed a prohibition to perform research to be necessary, however. Performing research on supernumerary embryos could be dangerous because it could lead to a development that would ultimately be irreconcilable with

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[50] Hans-Ludwig Günter, Jochen Taupitz and Peter Kaiser, *Embryonenschutzgesetz. Juristischer Kommentar mit medizinisch-naturwissenschaftlichen Grundlagen* (W. Kohlhammer GmbH 2014) 354.

[51] Jochen Taupitz, ‘The German Stem Cell Act’ (2010) 11 German Law Review 1381.

the ‘objective idea of human dignity’. Specifically, it could incite doctors to overproduce supernumerary embryos in order to satisfy the increasing demands of scientists to have more embryos at their disposal. Additionally, it could incite scientists to require the right to create embryos for research purposes if they do not have a sufficient number of supernumerary embryos. Therefore, the Bundesrat, though questioning whether research on supernumerary embryos violates the human dignity of embryos, nevertheless advised the Government to prohibit research also on supernumerary embryos. This suggestion was accepted by the Government and incorporated in the bill before it was sent to Parliament.

During the parliamentary debates, the bill was modified to include a limitation of three embryos for implantation during one cycle in order to prevent the creation of supernumerary embryos. Three was chosen as a maximum because medicine at that time did not need more than three embryos to initiate pregnancy. Another amendment concerned the right to select sperm cells in order to avoid the transmission of a serious hereditary genetic disease from parents to children. The proposal of the Government did not contain this exception because sperm selection based on gender chromosomes was outlawed out of fear of eugenic practices.[52] In the Bundestag the need to allow sperm selection was proposed by the Christian Democratic parties (CDU/CSU) in order to prevent the transmission of grave hereditary diseases to the children, e.g. Duchenne disease, or, if the woman would decide to abort a diseased foetus, to spare her the traumatic experience of abortion. After accepting the proposed amendments, Parliament voted in favour of the bill and on 1 January 1991, the Embryo Protection Act entered into force.

Hence, the debate around the EPA lasted only five years and was not particularly controversial. The constitutional value of human dignity and the shared agreement that human dignity also applied to unborn life, including embryos, played a key role in the rather speedy enactment of the EPA. As observed before, the EPA was rather widely supported by the political parties (apart from the Green Party (*die Grünen*)).[53] This shared agreement emerged

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[52] Günther, Taupitz and Kaiser (n 50) 268.

[53] Deutscher Bundestag, ’Beslußempfehlung und Bericht des Rechtsausschusses (6. Ausschuß)’, 8 Oktober 1990, Drucksache 11/8057 13, <http://dipbt.bundestag.de/doc/btd/11/080/1108057.pdf> accessed 9 December 2016.

to a large extent due to the reluctance of the entire German society to repeat the mistakes of its Nazi past, which the inclusion of the principle of human dignity in the German Basic Law was meant to prevent.[54] This reluctance led to acknowledging that the instrumentalisation and commodification of all human life to which practices such as human embryo research, cloning or gender selection might lead must be prohibited.

6.3.2 The debate around hESC in Germany

A subsequent debate in Germany, on embryo research and hESC research, was provoked by the news about cloning Dolly the sheep in 1997 and was further intensified by announcements about the derivation of hESC in an American clinic.[55] In Germany, the EPA did not clearly prohibit research on hESC, as hESC were pluripotent and not totipotent cells and therefore were not embryos. Although derivation of hESC involves the destruction of embryos, a practice prohibited by the EPA, German researchers could perform research on imported hESC and thus would not violate the general prohibition against embryo destruction. However, for some this would still involve the destruction of embryos abroad and therefore violate the spirit of the EPA. This legal loophole triggered an intense debate in German society about the legality of performing hESC research in Germany and how the EPA should be amended to accommodate new research possibilities.

The debate around hESC included many actors, which could be roughly divided into two groups. The first group, opposing hESC research, was rather heterogeneous, including Catholics, the Green Party and feminists.[56] Unlike Italy, where the Vatican imposed one main frame on embryo use in ART and hESC, hESC research was problematised in many ways in Germany. Thus, while Catholics framed it as a problem of embryo dignity and right to life, feminists emphasised socio-political consequences such as the use of women’s bodies as raw

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[54] Sperling (n 11); Herbert Gottweis, 'Stem cell policies in the United States and in Germany' (2002) 30 Policy Studies Journal 444.

[55] James A. Thomson and others, ‘Embryonic stem cell lines derived from human blastocysts’ (1998) 282 Science 1145.

[56] Svea L. Herrmann, *Policy Debates on Reprogenetics : The Problematisation of New Research in Great Britain and Germany* (Campus Verlag 2009) 169.

material for research. On the other hand, medical and scientific associations such as the German Research Foundation (*Deutsche Forschungsgemeinschaft*, hereafter DFG) suggested that embryo research was promising because it could bring new cures.[57] DFG, specifically, appealed to a more liberal regulatory approach to hESC and even suggested changing the EPA. However, compared with opponents of hESC research, such liberal voices were in a clear minority.

However, in the end the debate around hESC focussed only on the moral status of the embryo. This result was provoked by an interview of a newly instated Minister of Cultural Affairs, Julian Nida-Rümelin, in *Tagesspiegel* in January 2001. He stated that embryos do not have self-esteem and therefore do not have human dignity, therefore the latter could not be violated. This led to public upheaval, for it was in direct contradiction with the publicly held opinion that embryos do have human dignity, as any other human being regardless of specific qualities. As a result, President Johannes Rau intervened with a speech and in sharp words defended human dignity and condemned the commodification of embryos. He stressed that the value of human dignity was a lesson learned from the crimes of Nazi-Germany.[58] In another of his speeches, in May 2001, he claimed that medical research should never decide when human life should be protected, thereby pointing at the illegality of embryo research.[59]

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[57] Deutsche Forschungsgemeinschaft, Empfehlungen der DFG zur Forschung mit menschlichen Stammzellen‘ (2001) <http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/download/empfehlungen_stammzellen_03_05_01.pdf> accessed 9 December 2016.

[58] Speech president Rau at the special meeting of the German Bundestag on the occasion of the memorial day for the victims of national socialism (Rede bei der Sondersitzung des Deutschen Bundestages aus Anlass des Gedenktages für die Opfer des Nationalsozialismus am 26. Januar 2001), <http://www.bundespraesident.de/SharedDocs/Reden/DE/Johannes-Rau/Reden/2001/01/20010126_Rede.html> accessed 9 December 2016.

[59] Berlin Speech president Rau ("Wird alles gut? - Für einen Fortschritt nach menschlichem Maß"), <http://www.bundespraesident.de/SharedDocs/Reden/DE/Johannes-Rau/Reden/2001/05/20010518_Rede.html> accessed 9 December 2016.

The problem of the moral status of the embryo also underlay the reports of the two commissions – Enquiry Commission on Law and Ethics in Modern Medicine (*Recht und Ethik der modernen Medizin*) created by the Bundestag and the National Ethical Council (*Deutscher Ethikrat*) created by Chancellor Gerhard Schröder – set up to explore ethical and legal problems related to hESC research.[60] Calls for a deliberate investigation of hESC were voiced when a German researcher, Oliver Brüstle, wishing to perform research on imported human embryonic stem cells, applied for funding at the DFG and the public debate turned into a political debate. Both commissions stated that the main ethical problem of hESC research was the destruction of embryos; since for many citizens, embryos had a right to life and dignity, their destruction might be ethically dubious as it would involve embryo instrumentalisation for the sake of performing scientific research. Yet, on the other hand, for other people embryos do not have dignity. They concluded that the problem of the embryo's moral status is thus unsolvable, as it is impossible to reconcile different ethical views. As a result, both commissions proposed to prohibit general research on embryos in Germany and the derivation of hESC in Germany. Yet, they differed with respect to importation of hESC; whereas the Enquire Commission was against any hESC research (26 to 12 votes)[61], the Ethical Council was in favour of hESC research by importing them from abroad (15 to 10 votes).[62]

The political debate on hESC finally led to a debate in Parliament. In January 2002, three motions (*Anträge*) on hESC research were discussed in Parliament. The first was from a politician of the social-democratic party (SPD). In line with the report of the Commission on Law and Ethics in Modern Medicine, it argued that human life starts at fertilisation with the fusion of two nucleuses, therefore it was the duty of the State to protect human life and

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[60] Sperling (n 11).

[61] Deutscher Bundestag, Zweiter Zwischenbericht der Enquete-Kommission Recht und Ethik der modernen Medizin (2001) Drucksache 14/7546, <http://dip21.bundestag.de/dip21/btd/14/075/1407546.pdf> accessed 9 December 2016.

[62] Nationaler Ethikrat, 'Zum Import menschlicher embryonaler Stammzellen', Dezember 2011, <http://www.ethikrat.org/dateien/pdf/zum-import-menschlicher-embryonaler-stammzellen.pdf> 58 accessed 9 December 2016.

human dignity of embryos against misuse and instrumentalisation. This requirement entailed the protection of embryos against third parties who would kill them to produce hESC for research and thus turning them into mere instruments. No distinction should be made between embryos created inside and outside of Germany, therefore import of embryos and stem cells should also be prohibited.[63] In addition, the motion sought to safeguard the dignity of women, to protect them from being turned into suppliers of raw materials for science, echoing others' arguments that were used in the public debate. Though the motion did acknowledge the constitutional right to freedom of research, it considered this right had to yield to the more important 'universal principle' of human dignity of human beings, independent of their stage of development and capabilities.[64] The second motion was from the liberal party (FDP).[65] It proposed the use of imported hESC derived from embryos created to initiate pregnancy. Being of a utilitarian nature, it suggested that hESC research should be endorsed because it would be beneficial for medical research and promote the public good.[66] The third motion, put forward by CDU/CSU member Horst Seehofer, former Green Minister Andrea Fischer and by the chairperson of the Law and Ethics of Modern Medicine Inquiry Commission and SPD member Margot von Renesse, also allowed the use of only imported hESC.[67] However, unlike

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[63] Deutscher Bundestag, Antrag Wodarg, Schutz der Menschenwürde angesichts der biomedizinischen Möglichkeiten –Kein Import embryonaler Stammzellen, 29 Januar 2002, Drucksache 14/8101 2-3, <http://dipbt.bundestag.de/doc/btd/14/081/1408101.pdf> accessed 9 December 2016.

[64] Ibid 4.

[65] Deutscher Bundestag, Antrag Flach, Verantwortungsbewusste Forschung an embryonalen Stammzellen für eine ethisch hochwertige Medizin, 29 Januar 2002, Drucksache 14/8103, <http://dipbt.bundestag.de/doc/btd/14/081/1408103.pdf> accessed 9 December 2016.

[66] Jasanoff (n 11) 197.

[67] Deutscher Bundestag, Antrag Seehofer, Keine verbrauchende Embryonenforschung: Import humaner embryonaler Stammzellen grundsätzlich verbieten und nur unter engen Voraussetzungen Zulassen, 29 Januar 2002, Drucksache 14/8102 2-3, <http://dipbt.bundestag.de/doc/btd/14/081/1408102.pdf> accessed 9 December 2016.

the former, it included a substantial number of restrictions. This motion acknowledged that, on the one hand, hESC were not embryos and therefore their use was not in violation of the EPA and of the principle of human dignity. Therefore, the constitutional principle of freedom of research did not affect any constitutionally protected rights and principles. On the other hand, hESC research was ethically and constitutionally problematic because the derivation of hESC involved the destruction of embryos and therefore led to their instrumentalisation and destruction. Specifically, by approving the import of hESC, the law would violate the Basic Law if it would create a demand for new hESC and hence would lead to the destruction of embryos. To tackle this issue, its promoters suggested to allow the import of hESC created before the discussions of the motions in Parliament. To be fully consistent with the ethics enshrined in the EPA, they further limited hESC research to those that were derived from embryos created to induce pregnancy and not for research.

The debate around the three motions was highly emotional and lasted five hours.[68] Due to the ethical nature of the issue, the politicians were allowed to vote according to their conscience and not to their party ideology. The views split around the issue whether hESC would violate human dignity. The politicians opposing hESC research emphasised that hESC research would turn embryos into objects of research and thus violate their human dignity. They made no distinction between supernumerary and regular embryos, nor between German and imported embryos. Similarly, they feared that allowing hESC research would lead to a *Dammbruch*, in the future allowing cloning, more exceptions for the import of hESC or production of embryos for research.[69] In contrast, the politicians favouring hESC research stressed that by setting the cut-off date, the law would ensure that embryos 'will not die for German research'.[70] As hESC themselves were not embryos, they were not protected by the

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[68] Herbert Gottweis, Brian Salter and Catherine Waldby, *The Global Politics of Human Embryonic Stem Cell Science*: *Regenerative Medicine in Transition* (Palgrave Macmillan 2009).

[69] Deutscher Bundestag, Stenographischer Bericht, 214. Sitzung, 30 Januar 2002, Plenarprotokoll 14/214 21209, 21213, 21214, 21218, <http://dipbt.bundestag.de/doc/btp/14/14214.pdf> accessed 9 December 2016.

[70] Sperling (n 11).

Basic Law and therefore research on them would not violate human dignity.[71] They also put forward the promises of hESC research and downplayed the fear of a *Dammbruch*, pointing out the strict conditions for researchers to perform hESC research. At the end of the day, the third motion got the majority vote in Parliament, with 340 votes in favour and 265 against.[72]

Thus, as a general rule, the SCA outlawed hESC research, because such research would violate the principle of human dignity. Yet, it allowed importing hESC lines if they were created from supernumerary embryos before the cut-off date, which was set at the 1st of January 2002. This cut-off date was chosen to make sure that Germany would not stimulate the destruction of embryos anywhere in the world for German research purposes. Further, the SCA stipulated that to import hESC, scientists should first prove that the research could only be performed with hESC and not, for example, with animal stem cells. Lastly, the law contained a provision that obliged German researchers to submit proposals for hESC research to the Central Ethics Commission on Stem Cells for approval, before being allowed to actually import stem cells. This mechanism was intended to act as an additional safeguard against excesses or misuses.

Thus, the constitutional principle of human dignity significantly affected the outcome of the debate around hESC in Germany. Because it revolved around a principle that was widely shared, that embryos could not be used as objects and be destroyed for German research, the German Parliament managed to overcome the differences in views and quickly pass a law. Tellingly, none of the motions discussed in Parliament called for allowing the derivation of hESC from German embryos. Despite the attempts of German scientists, represented by the DFG, to liberalise the policy on embryo research in Germany and oppose the German *Sondermoral* to the value of scientific research, the general consensus about the importance of protecting the constitutional principle of human dignity was deeply entrenched in German society. The absence of a deep cleavage like in Italy ensured a speedy passage of

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[71] Deutscher Bundestag, Stenographischer Bericht, 214. Sitzung, 30 Januar 2002, Plenarprotokoll 14/214 21200, 21220, <http://dipbt.bundestag.de/doc/btp/14/14214.pdf> accessed 9 December 2016.

[72] Thomas Banchoff, 'Path Dependence and Value-Driven Issues: The Comparative Politics of Stem Cell Research' (2005) 57 World Politics 220.

the SCA. By allowing the use of stem cell lines only from supernumerary embryos initially created for pregnancy and by setting the cut-off date, the German Parliament thus created an image of a responsible regulator, loyal to the fundamental ethical principles of German society.

Despite its consensual success, the SCA can be criticised for many reasons. It can be seen as hypocritical, protecting German supernumerary embryos from being used as material for stem cells while allowing to use foreign embryos for this purpose. Interestingly, in 2008, six years after passing the SCA, Parliament amended it by choosing a new cut-off date for the use of embryos, that is, May 2007, which might again suggest hypocrisy of the German regulators. Furthermore, it can also be criticised for creating regulatory incoherence through combining in the same regulatory order two contradictory value systems.[73] One of them builds upon the restrictive 'dignity as constraint' value, whereas the other has a more utilitarian nature, allowing German scientists to reap the benefits from research on embryos that in any case will be turned into hESC lines in countries with more liberal policies. Finally, a potential criticism is that by gradually increasing the number of such 'exceptions', the German regulator may in the long run betray the very idea of human dignity.[74] However, exactly this alleged 'hypocrisy' or 'incoherence' enabled the German regulator to pass the SCA and regulate hESC research on its territory. Unlike Italy, which came to a *de facto* liberal outcome on the regulation of hESC research as a result of a failure to compromise, Germany allowed the import of stem cells after a deliberate negotiation process and as a result of a willingness to account for different ethical views of its citizenry.

6.3.3 The debate on PGD in Germany

It was generally considered that the EPA, though not explicitly naming PGD, did not allow its use because the selection of embryos would violate the constitutional principle of human

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[73] Roger Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford University Press 2008).

[74] Kathrin Braun, 'From Ethical Exceptionalism to Ethical Exceptions: The Rule and Exception Model and the Changing Meaning of Ethics in German Bioregulation' (2016) Developing World Bioethics.

dignity upon which the EPA was built. However, since as early as the mid-1990s, German society had been deliberating the possibility to legitimise PGD. The main strategy for this was to attempt to re-problematise it. Specifically, according to the German Society of Human Genetics (GfH), the prohibition of PGD was not consistent with parents' interests as it would force pregnant women to perform abortions.[75] A similar conclusion was reached by the ethics committee of a clinic in Lübeck, which was approached by two clinicians for advice on the issue of PGD. According to this committee, the EPA prohibited PGD. However, it wondered if such a prohibition would be ethical if it would force women to perform harmful abortions and thus create negative impacts upon their health.[76] Finally, in 2000 the German Medical Association (*Bundesärztekammer*, hereafter BÄK) published a discussion paper on PGD.[77] The BÄK framed the problem of PGD as a conflict between the embryo's right to life and the rights of parents, and concluded that because PGD was needed to protect the health of the future mother, it would not amount to eugenic practice and hence should be allowed.

In 2010, a crucial event happened affecting the legality of PGD in Germany. The Federal Court of Justice (*Bundesgerichtshof*, hereafter the BGH) had to decide upon a case of a German gynaecologist who performed PGD to prevent the passing of genetic disorders if these would lead to miscarriage, stillbirth or early death of the child. The gynaecologist performed three PGD operations and later turned himself in to the authorities. The BGH, however, acquitted him.[78] First, the BGH concluded that all the doctor's actions did not involve the misuse of embryos, strictly forbidden by the EPA. Instead, he performed PGD to make pregnancies possible, the only purpose that allowed the use of embryos according to the EPA. Second, it took into account that the EPA permitted sperm selection to avoid the creation of sick embryos. Drawing upon this analogy, it equated embryos with sperm cells and concluded that if sperm selection was allowed, then embryo selection should be allowed

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[75] Herrmann (n 56).

[76] Ibid.

[77] Bundesärztekammer, Diskussionsentwurf zu einer Richtlinie zur Präimplantationsdiagnostik, in Sigrid Graumann (ed), *Die Genkontroverse. Grundpositionen* (Herder Spektrum 2001) 157.

[78] Bundesgerichtshof (BGH), Urteil vom 6. Juli 2010 – 5 StR 386/09.

as well to prevent the passing of genetic disorders. Third, the German regulation on abortion permitted a termination if the foetus carried certain kinds of pathologies. Therefore, for the Court it was unreasonable to forbid PGD, given that abortion was significantly more intrusive and damaging than PGD. As a result, the Court decided that PGD was not a criminal offence under the EPA.

The ruling created legal uncertainty with respect to the legality of performing PGD in Germany and Parliament was quick to remove it. During the Parliamentary debate around PGD, three types of bills were presented. The first proposal, put forward by Green Party politician Katrin Göring-Eckardt, entirely prohibited PGD.[79] Its proponents argued that according to the values of the Basic Law, every human being has the same dignity and the State cannot make decisions on which life is worthy of living and which is not, as it can lead to eugenic practices. This value system would be jeopardised if PGD were allowed. The second bill was put forward by SPD politician Peter René Röspel. It allowed PGD only to check the presence of serious genetic hereditary diseases in the embryo if these would lead to stillbirth, miscarriage or death of the baby in the first year of life and thus was similar to the BGH ruling.[80] The third proposal, proposed by FDP politician Ulrike Flach, was substantially more liberal. It allowed PGD to perform screening both to check the presence of genetic abnormalities if they would lead to miscarriage, stillbirth or the death of the baby in the first year and when the parents have a severe hereditary disease with a risk of at least 25% of passing it on to their offspring.[81]

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[79] Deutscher Bundestag, Entwurf eines Gesetzes zum Verbot der Präimplantationsdiagnostik, 11 April 2011, Drucksache 17/5450, <http://dipbt.bundestag.de/dip21/btd/17/054/1705450.pdf> accessed 9 December 2016.

[80] Deutscher Bundestag, Entwurf eines Gesetzes zur begrenzten Zulassung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG), 12 April 2011, Drucksache 17/5452, <http://dipbt.bundestag.de/dip21/btd/17/054/1705452.pdf> accessed 9 december 2016.

[81] Deutscher Bundestag, Entwurf eines Gesetzes zur Regelung der Präimplantationsdiagnostik (Präimplantationsdiagnostikgesetz – PräimpG), 12 April 2011,

In 2011, only one year after the BGH ruling, Parliament voted for the third proposal, thus allowing PGD in both cases, that is, to check for genetic abnormalities in the baby if they would lead to miscarriage, stillbirth or death of the baby in the first year and when the parents have a severe hereditary disease. The amendment was incorporated into the EPA. According to the new art. 3a of the EPA, PGD remained a crime. However, it was not unlawful to perform PGD to prevent passing a serious hereditary disease to the embryo, including if such a disease would lead to stillbirth or miscarriage. The amendment also instructed that the woman had to undergo counselling beforehand and stipulated the institution of ethics committees that had to provide oversight over PGD.

During the parliamentary debates in the Bundestag, the politicians opposing PGD argued that the selection of embryos for implantation violated human dignity as it constituted eugenic practice.[82] Echoing the fear of Nazi eugenics, they stressed that the State should not decide which life would be worth living (*lebenswert*) and which life would not be (*lebensunwert*). In contrast, the politicians favouring PGD argued that allowing PGD would give German families a chance to avoid the psychological and social burden of raising children with severe genetic pathologies. They engaged in telling personal stories about people they knew whose lives were affected by similar experiences—for example, experiences from burying a baby of a few days old to the woman who lost six brothers due to the same genetic disease.[83] More importantly they stressed that is was not a question of a life *worth* living or not, but having the possibility for parents to have a baby *capable* of living (*lebensfähig*).

Interestingly, in their speeches, they made no reference to human dignity but chose a different technique. They stressed the obligation of the State to protect not (only) unborn life, but (also) adult German (female) citizens from heavy physical or mental burdens that might

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Drucksache 17/5451, <http://dipbt.bundestag.de/dip21/btd/17/054/1705451.pdf> accessed 9 December 2016.

[82] Deutscher Bundestag, Stenografischer Bericht, 105. Sitzung, 14 April 2011, Plenarprotokoll 17/105 11947, 11954, 11956, 11967, <http://dipbt.bundestag.de/dip21/btp/17/17105.pdf> accessed 9 December 2016.

[83] Ibid 11946, 11955, 11972.

result from performing an abortion or raising a child with a severe genetic disease, allowing them to have a baby capable of living. Put differently, the main strategy of the German regulators in legitimising PGD was its re-problematisation. Instead of discussing how exactly PGD should be accommodated in order to be consistent with the German constitutional order and the principle of human dignity, the supporters of PGD ignored the discussion of the principle of human dignity altogether. Rather, they emphasised how the prohibition would affect German couples who would be forced to raise children with severe genetic pathologies or women who would be forced to perform an abortion. In other words, they emphasized that the German state was obliged to care not only about the dignity of embryos but also about the dignity of adult women. Hence, dignity as empowerment was brought to the fore in the debate on PGD, implying the need for a more liberal regulation of new biomedical practices.

And yet, the constitutional ideal of human dignity as constraint was not entirely absent. The amendment introduced in the EPA is reminiscent of how the German Constitutional Court allowed abortion.[84] As a general rule, abortion was considered a crime as performing it would violate human dignity. However, the State was obliged to take into account and protect not only the right to life of unborn foetuses, but also the life and health of women. Unlike human dignity, according to the German Basic Law, the embryo's right to life was not absolute, as according to the Basic Law it could be limited by law. Therefore, the Constitutional Court, while maintaining the definition of abortion as a crime, made it unpunishable if the woman would undergo counselling, and if her health condition would be affected by the embryo's pathologies. Thus, the Court made abortion possible, yet without abandoning the State's commitment to protecting human dignity.

In a rather similar way, the German Parliament allowed PGD. As a general rule, it recognised PGD as a crime. PGD was still regarded as a practice incompatible with the German *Sondermoral* and the principle of human dignity. However, by redefining the scope of subjects whose dignity the State must protect, the proponents of PGD managed to carve out a space for PGD in the German constitutional arrangements, to protect the interests of adult citizens alongside the interests of unborn life.

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[84] Bundesverfassungsgericht (BverfGE), Urteil vom 28. Mai 1993, BVerfGE 88, 203.

6.3.4 Conclusion

ART and embryo research, including hESC research, are problematised in Germany as a potential violation of the constitutional principle of human dignity, enshrined in art. 1 of the German Basic Law. Whereas the Basic Law itself says nothing concerning the legitimacy of embryo manipulation and whether it violates human dignity, due to historical reasons, and mainly to the Nazi past of Germany, embryo research and experimentation were problematized as an assault on human dignity. Similarly, due to the memory of Nazi experiments, human dignity was conceptualised as the principle of non-instrumentalisation of human life. This implied that unborn life enjoyed strong protection in Germany. However, it was not absolute and did not entail an unrestricted right to life. This conceptualisation affected the way in which the EPA defined human life that the State was obliged to protect, that is, as human life from the moment of the fusion of the egg and the sperm and having the ‘capacity to develop’.

The memory of the Nazi past was also the reason why there was a general consensus in German society about the need to prohibit embryo experimentation out of respect for human dignity. This general consensus underlay a speedy and rather unproblematic adoption of the EPA and a broad endorsement of its restrictive nature. Importantly, there was an agreement with respect to another value that also played an important role in the speedy passage of the Law and in its support. Of the utmost importance was the consent of women, needed to prevent forced medical treatments. Hence, the EPA already contained the two bioethical principles, dignity as constraint, underwriting the general prohibition of embryo experimentation, and dignity as empowerment, prohibiting forced IVF treatment and allowing women to withdraw their consent any time during the treatment. These two bioethical perspectives enjoyed wide societal support making the EPA almost entirely criticism-proof.

With the advent of new technologies, the extent to which the principle of human dignity encompassed embryo protection started to be questioned. The proponents of hESC research emphasized that the import of hESC from abroad would not violate human dignity if strong norms against such violation were embedded in the law and stressed another constitutional principle, the freedom of research. Similarly, the proponents of PGD emphasized the need to prevent negative impacts of raising children with severe genetic pathologies on women's lives, thereby invoking the dignity as empowerment principle. Importantly, the proponents of both technological advancements did not argue against the need to protect embryos from scientific experimentation as such. At stake was the degree to which the competing interests and values could and should be taken into account.

The eventually adopted SCA and the amendments to the EPA on PGD illustrate that a well-debated compromise was struck between the competing bioethical perspectives. Hence, the German regulator, while staying truthful to its constitutional values and historical memory, nevertheless approached and solved the problem of 'regulatory connection'[85] and therefore stayed in touch with new techno-scientific realities, keeping them under its vigilant watch. In addition, by embracing different views on the ethical legitimacy of new technologies, it took into account different normative positions of its constituency.

6.4. Discussion and conclusion

The comparison between Italy and Germany provides a good illustration when the appeal to human dignity in public debates on new technologies involving the use of embryos becomes problematic. First, the appeal to human dignity raises significant controversy when dignitarianism does not constitute the main bioethical perspective in the country at stake. Specifically, the comparison of the policies of Italy and Germany showed differences in terms of their efficiency and durability exactly because of a different degree of support that this principle enjoyed in the two countries. Seeking not to repeat the horrors of Nazi-Germany, German society broadly accepted that the regulation of new biomedical technologies must be in conformity with the principle of human dignity, conceptualised as the principle of non-instrumentalisation of human life. This enabled the speedy enactment of laws regulating ART and hESC research, which were seldom contested after their enactment. In contrast, in Italy, due to the secular/religious cleavage, only the religious part of Italian society fully supported human dignity of embryos, conceptualised as sanctity of life. Moreover, the attempts of Italian politicians to embed this principle into law were rejected as inappropriate in a country where the Church is separated from the State. As a result, it led to a regulatory stalemate and underregulation of ART, both in the long period before the adoption of the Law on MAR and

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[85] Brownsword (n 73).

after the invalidation of the most restrictive provisions of the Law by the Constitutional Court. A similar underregulation also characterised the legal situation with hESC.

Second, the appeal to human dignity raises problems when the supporters of this principle may not be willing to compromise with their opponents. As has been demonstrated, the supporters of sanctity of life in Italy refused to seek out compromises with the supporters of more liberal views on ART and hESC research. In a country where this principle is not widely shared, the absolutism further exacerbated the controversy. In Germany, in contrast, the parties were open to compromises. Human dignity remained the main principle governing the development of policies. However, those who appealed to other principles such as freedom of research and dignity as empowerment also managed to have their position accommodated by law. Thus, 'human dignity as constraint' was combined with 'human dignity as empowerment' in the German policy on PGD. Although the outcome achieved by the German regulator may be criticised as incoherent, it had the advantage that it led to the closure of the controversy and the establishment of a tight and reliable mechanism of oversight on new technologies. In addition, through combining different perspectives, the German regulator undertook an attempt to stay in touch with techno-scientific realities and hence address the problem of 'regulatory connection'.[86] More importantly, such an outcome provided sufficient certainty for all the involved actors about their entitlements, duties and responsibilities.

While the focus of this paper is on human dignity, we suggest that its conclusions can be also indicative of general patterns of the relationships between particular bioethical configurations and countries' policy on new biomedical practices. In what follows, we will draw three broad patterns of how exactly bioethical configurations may shape regulatory policy. Clearly, in teasing out these patterns, we acknowledge that they do not work as uniform and regid templates for how bioethical sensisbilities of the relevant country shape its policy and therefore must be applied with an utmost caution in further analysis. However, by drawing them we believe that they can make further research on this topic more analytically tractable and therefore act as useful methodological resources for other scholars exploring the connection between countries' bioethical landscapes and their regulatory policy.

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[86] Ibid.

The first pattern is the correspondence of the regulatory environment of a country with the country’s dominant bioethical perspective. Put differently, if a specific bioethical perspective clearly dominates the bioethical landscape, the regulatory policy will reflect this perspective. Great Britain, where the utilitarian perspective is dominant, can exemplify this pattern. The second pattern is that in those countries where (a) several bioethical perspectives co-exist and (b) the supporters of competing perspectives are willing to make coalitions or strike compromises, the regulatory environment will reflect the terms of the compromise or coalition. We suggest that Germany might instantiate this principle. Although the ‘dignity as constraint’ principle remained the main regulatory principle, regulatory policy nevertheless accommodated ‘the dignity as empowerment’ perspective. Third, in countries where (a) several bioethical perspectives compete for regulatory relevance and (b) their proponents are not willing to form coalitions or strike compromises, the regulatory outcome will be unpredictable and uncertain. We suggest that Italy followed this pattern; the reluctance of Catholic politicians to strike compromises with respect to the regulation of ART and hESC research led to significant periods of underregulation and legal uncertainty.

CHAPTER 7

Conclusion

In this concluding section, I will answer the two research questions that I posed in the Introduction to this work. Section 7.1, drawing on Chapters 3-5, will describe how rights figured in the debate around PGD in Italy and how this process has been connected with the regulation of PGD. Further, building on this analysis and also drawing on Chapter 6, Section 7.2 will address the issue to what extent rights are a ‘right’ instrument for regulating new biomedical technologies such as PGD.

7.1. Problematization and bioconstitutionalism as a ‘technology of power’ over life

In countries around the world, the possibility of creating embryos *in vitro*, that is, outside their mothers’ bodies, and the associated possibility to test and select embryos before implantation have raised many issues. On the one hand, they provided important possibilities for individuals to overcome fertility issues. In addition, to individuals with genetic pathologies, PGD allowed to start pregnancy with already healthy embryos and to avoid undergoing risky procedures of prenatal testing and abortion. On the other hand, they provoked many fears about the use of embryos, science ‘racing ahead’, and resurrected the specter of eugenics and ‘designer babies’. Furthermore, unlike IVF, PGD as such is not performed to overcome health issues of citizens themselves but to screen out and eliminate affected embryos. As Franklin and Roberts (2006) argued, whereas IVF might be seen as more natural because it is a ‘helping hand’ to what nature would do otherwise, in case of PGD, its purpose is exactly to prevent nature to take its course. These aspects of IVF and PGD have raised questions on how they should be governed.

7.1.1. Problematization: embryos’ life, adult citizens’ health and reproductive autonomy as objects of political concern

To decide on how to govern ART and PGD, Italian society had to answer several questions that were at the same time legal, political, medical, ethical, and social. What is the constitutional obligation of the Italian State to respond to technological developments in medical care? Whose rights and constitutional entitlements do IVF and PGD allow to fulfill and protect? What kind of negative legal and social consequences do IVF and PGD entail? And how should the existing constitutional arrangements be transformed in order to respond to the challenges created and opportunities provided by these new ART? These questions were answered differently by different sections of Italian society depending on what physical aspects of life were problematized in light of the new extracorporeal fertilization techniques (Rose and Valverde 1998; Lemke 2011, 2011b). As I showed throughout the thesis, after IVF entered the Italian fertility clinics, the biological existence of two types of beings became a matter of legal and political concern. On the one hand, it was adult citizens' health and the health of their future children, which IVF and PGD could help improve and optimize, if performed under strict state control. On the other hand, it was embryos' biological existence, which IVF and PGD, in contrast, undermined. These two problems were expressed and promoted by two different groups of people, both of which included patients, politicians, scientists, doctors, and non-governmental institutions. Thus, from the very beginning, the biological life of two groups of human beings became an object of politics for which the respective sections of the Italian society sought to propose their own solutions. Crucially, from the very beginning, both the problems and the solutions to them had been couched in terms of the need to protect constitutional rights.

7.1.2. Governing through rights in Parliament: embryos' rights and the redrawing of medicine's boundaries

In Chapter 3, I explored the debate revolving around embryos' classification as entities having mere biological existence of *zoē* or as human persons, hence capable of political and moral existence, as *bios*. I illustrated how the Italian Parliament, prompted by the Catholic Church and its life ethics on embryos, which sees embryos as human persons that are endowed with human dignity and natural (human) rights, included embryos into the community of 'citizen subjects' and accorded legal personhood and rights to them. In addition, I showed how the role of women's rights in the Italian constitutional order was negotiated. I showed how women were eventually subjectified as citizens having only duties regarding their embryos and how their bodies were subjected to disciplinary power. In Chapter 4, I also showed how Parliament deliberated and ultimately enacted 'the three embryo' standard and therewith redrew the boundary of medical expertise.

I suggest that the attribution of rights to the embryo as well as the enactment of restrictive regulations on ART was the first important bioconstitutional transformation in the Italian controversy on PGD. It was performed through the use of sovereign power and a particular type of subjectification of two groups of Italian citizens. First, IVF embryos were classified as citizen subjects having, not only the capacity for biological existence *zoē,* but also moral and political existence *bios*. Second, Italian female citizens were subject to disciplinary power performed by the state which regulated their bodies and reproductive behavior.

7.1.3. Governing through rights in fertility clinics: knowledge, the constitution of 'biological citizens', and 'vital rights'

While the Italian parliament was discussing what problem PGD and other ART raise and how to address this problem, both techniques were widely practiced in Italian fertility clinics. According to the medical code of the National Federation for the Orders of Doctors and Dentists (FNOMCeO), the main code of medical practice of Italian doctors, the only procedures that it outlawed were surrogacy and commercialization of gametes. In addition, Italian fertility clinics were performing IVF and PGD using the same clinical guidance for IVF as in other countries, albeit often violating them in the absence of any regulatory oversight (Valentini 2004). Thus, they created embryos in surplus, froze them, practiced multiple embryo transfer to increase the chances of pregnancy, tested and selected embryos during PGD.

I suggest that this medical practice performed in Italian fertility clinics was the second key bioconstitutional transformations taking place in Italy as a result of the emergence of extracorporeal fertilization. Due to the lack of any regulatory oversight, reproductive and genetic medicine in fact was the only form of government (Foucault 1980) regulating practices performed in Italian fertility clinics. This practice consisted of both normative and epistemic elements: adult citizens' procreative and health rights were prioritized over embryo protection and a particular knowledge about how to ensure these rights was produced and employed. It also employed a particular technology of power over patients, 'technologies of the self', thereby acting upon the biological existence of individuals in a 'liberal' way, that is, not by disciplining their bodies, controlling and oppressing them, but via 'conducting their conduct'. Hence, a particular technology of power, knowledge and norms (i.e. rights) were co-produced, addressing a particular problem: the health of patients and of their children.

The main outcome of this co-production was the constitution of patients' identities and subjectivities (Foucault 1980; Rose 2006), including their entitlements. I suggest that this subjectification was an important bioconstitutional process that would later translate the assumed entitlements into positive rights during litigation. The rights that were claimed in courts during the final, litigation, stage of the PGD debate, did not come out of nowhere. Instead, they had been embedded in the practices evolving in Italy for decades until they suddenly became illegal in 2004. Yet, of course it was not clear what kind of entitlement the 'vital rights' (Rose 2006) actually constituted. Only with the involvement of the Constitutional Court was the entitlement framed as a right to health and not as a right to reproductive self-determination. The consequences of this framing I will explore in Subsection 7.2.

7.1.4. Governing through rights in courtrooms: adult citizens' rights, litigation and 'biological citizens' in courtrooms

The transformation performed by Law 40/2004 dissatisfied many Italian citizens. The Law, clearly, erased all those entitlements that citizens thought they had and that they had forged throughout the period of unregulated ART. The identities they had as a result of governmental power of medicine as responsible citizens, understanding themselves partially as carriers of genetic diseases and acting on themselves to prevent passing these to their children, henceforth had to be transformed to conform to new political, legal and medical realities. As a result, they sought to claim back their rights to the now forbidden technologies. Some citizens went abroad, triggering a massive wave of reproductive tourism. Others sought to claim their rights through legal means and engaged in a long and not always successful process of litigation, claiming a violation of their right to health and of a right to reproductive self-determination. Hence, acting as active 'biological citizens', they engaged into another bioconstitutional process of asserting their entitlements, either via courts or moving abroad to perform treatments forbidden domestically. The first step in this process was the reestablishment of the boundaries of medicine and the acknowledgment of the constitutional legitimacy to produce more than three embryos (Chapter 4). The second step was the debate on which right (the mother's right to health or the right to self-determination) justifies the access to PGD (Chapter 5).

I suggest that the judge-made law resulting from the citizens' litigation was the third key bioconstitutional transformation triggered by the emergence of an *in vitro* produced embryo. It was a compromise and an attempt to bridge the two bioconstitutional transformations mentioned above: the subjectification performed in Italian fertility clinics and the institutionalization of embryos as citizen subjects. It was performed and achieved through legal rights claimed in courts, which performed a tactical and instrumental role (Foucault 1980; Golder 2015).

7.1.5. Bioconstitutionalism as a technology of power: mechanism of governing

As I illustrated in the Section above, depending on whose physical aspects of being the relevant section of the Italian society saw as threatened or protected by the new ART, the respective right was prioritized and the respective bioconstitutional approach to governing IVF and PGD was chosen. In this sense, the type of bioconstitutionalism – performed through the enactment of embryos' natural rights, prohibitions, and disciplinary power (Parliament), or through codes of medical practice and 'vital rights' (fertility clinics), or, finally, through the (partial) satisfaction of legal rights claimed by citizens from below (courts) – was connected with the view on whose physical being mattered more for the relevant Italian authorities (Rose and Valverde 1998; Lemke 2011a, 2011b). Here, I would like to come back to the definition of bioconstitutionalism and to refine it.

7.1.5.1. Rights as a technology of power: connecting four poles of human existence within the state

Drawing from the analysis in this work, it is possible to see the mechanisms through which the use of rights, seen as a technology of power, govern. I suggest that rights represent that technology of power that bind and shape the four poles of human existence within the state. These four poles include *an individual subject and the state*, on the one hand, and *physical and moral-political existence of human beings*, on the other. The first connection Foucault elaborated in his theorizations on governmentality, whereas the second one represents a particular importance for his discussions on biopolitics.

Regarding the need to account for both *biological and moral-political existence*, Foucault stated (2008, 22) that

> with the emergence of political economy, with the introduction of the restrictive principle in governmental practice itself, an important substitution, or doubling rather, is carried out, since the subjects of right on which political sovereignty is exercised appear as a population that a government must manage.

Therefore, rights (such as the right to life, the right to health as well as, as in the present case, the right to reproductive autonomy) represent that form of governing biological existence of individuals that also allows to take into account their political and moral existence as ‘free’ but also relational beings. The granting of legal rights ‘from above’, for example, when Parliament grants rights to new technoscientific entities (Chapter 3), or rights-claiming ‘from below’, including the satisfaction of rights claims by the judiciary (Chapter 5), is a way of biopolitically governing population in such a way that it *simultaneously* recognizes them as full-fledged members of the relevant political community, having connections with other members, and acknowledges the biological aspects of their existence.

For example, in Chapters 5 and 6 I showed how the plaintiffs submitted evidence (e.g. psychiatrist records) demonstrating the negative impact on their health by the restrictive provisions of Law 40/2004. The submission of these documents shows that individuals also displayed the biological aspects of their existence that were affected by the disputed provisions of the Law. At the same time, they were legal subjects possessing the ‘right to health’ which they could claim vis-à-vis their government. Further, in this Chapter 5 I also argued that individuals acted not only as free but also as relational beings. Finally, an embryo was ultimately recognized as a human being possessing both biological and moral-political existence (Chapter 3).

Further, in order to have significance, the realization of rights must be secured by the state, either through positive (adoption of the necessary measures to ensure the realization of rights) or negative means (non-interference). Therefore, rights also connect *individuals with the state*, thus presupposing a particular type of statehood within which these rights exist. For example, the decision that embryos’ rights should be ensured and, as a result, biomedical developments that violate these rights be prohibited, turns the state into a more conservative and absolutist one than the state that decides not to establish moral truths through law. Similarly, it also shapes the boundaries of the state with other social institutions such as medicine. As I showed in Chapter 4, the decision on whose right should take priority simultaneously shaped the locus of the boundary between the state and the medical expertise.

7.1.5.2. The ontologies of rights: types of inalienable rights

In Italy, the governance of life through rights included another important element: the appeal to legal rights as based upon some inalienable entitlements of individuals that they have due to the simple fact of being human, that do not depend on being enacted in positive law, but that could be better ensured if such enactment would have been performed. This position has been developed in classical political philosophy, grounds liberal rights theory (Dworkin 1977; Minow 1990), underlies international human rights law and characterizes rights discourse in the majority of countries, including the debate on PGD in Italy. Specifically, the Italian Parliament appealed to embryos' natural rights and to art. 2 of the Italian Constitution as enacting these natural rights in order to further translate these inalienable rights into positive law (i.e. Law 40/2004). The plaintiffs appealed to the Constitution, as enacting *their* inalienable rights, to change Law 40/2004 after it was passed. In other words, it was the appeal to some 'outside' rights (Kennedy 2002), enacted in the Constitution, that, according to the participants of the controversy, entitled them to change existing positive law, either by passing a new legislative act (Law 40/2004) or by repealing it (through a judicial decision). However, in the controversy around IVF and PGD in Italy, several and rather different types of these inalienable rights emerged.

a) 'Vital rights' of biological citizens and natural rights of embryos

The first type of right was the biological citizens' 'vital rights' which emerged as a result of practicing IVF and PGD in mostly private fertility clinics and which were largely co-extensive with governmental power of medicine. In Italy, these 'vital rights' concerned the interest of parents in having a child unaffected by a particular genetic disease. These rights, although with some modification (Chapter 5), were recognized by the Constitutional Court and thus translated into positive law (judicial decision). The second type of right was the natural rights of embryos which were translated into positive law 'from outside' in order to protect human dignity and life of embryos by Parliament (legislative act) (Chapter 3). They, in fact, were not subjected to disciplinary or governmental power.

Comparing these two types of rights, we can see that despite their inherent similarity, in that both existed as part of being human, they were very different with respect to the degree of transformation through biomedicine that they implied. The 'vital rights' implied change and transformation of human vitality and human biological characteristics, made practically unlimited by new genetic technologies. In contrast, the rights of embryos invoked to shield life and health of embryos from outside influence resisted the transformative power of biomedicine. Therefore, while similar in some respects, they were also very different, particularly with respect to the degree of transformation of biological aspects of human life and health that they implied and with respect to the associated degree of acceptability of new biomedical technologies that made these changes possible. This difference played a key role in the governance of new biomedical technologies which I will come back in Section 7.2.1.

Returning to the first conclusion about the different mechanisms through which rights work, we can see that each right – the 'vital rights' as they were defined by the plaintiffs or by the Constitutional Court and embryos' natural rights translated into positive law by Parliament – presupposed a particular understanding of the state about its own responsibilities towards life in its care, the locus of the boundary with the medical institution, particular relationships between state and citizens and the relationships (as well as rights and duties) between citizens themselves (e.g. between the mother and the embryo).

b) Individual and relational rights

As I showed in this work, after Law 40/2004 was passed and limited the exercise of citizens' 'vital rights', citizens appealed to the Constitution as a legal act enacting these inalienable entitlements (Chapter 5). According to the plaintiffs, these 'outside' rights were recognized by the Constitution but were not recognized by Law 40/2004. However, what exact 'outside' entitlement the Constitution protected in this context – the right to self-determination or the right to health – turned out to be unclear. Plaintiffs appealed to both rights, seeking to get access to PGD to also protect their relational values. However, the Constitutional Court, building upon its doctrine, ultimately recognized that the entitlement at issue was the constitutional right to health. As a result, the 'vital rights', recognized by the Court, were different from those 'vital rights' that citizens thought they had and which might have been part of their ‘regime of the self’. As I stated in Chapter 5, the outcome of the litigation was the ‘vital rights’ that were accepted but transformed.

This points to another difference between rights. The ‘vital rights’ exercised by the citizens and appealed to by them during litigation were relational rights because they favored the fulfillment of relational values and responsibilities. Instead, the Constitutional Court defined them as a type of individual rights. That rights are individual is another theoretical contribution of the liberal rights theory and classical political philosophy. The rights-bearing subject is primarily an individual subject, whose capacity ‘to will, to act, to choose’ (Langlois 2010, 254) is its most important one. Despite the attempts of feminist and communitarian scholars to reconceptualize rights, rights primarily figure as claims to have a space where this individual may exercise this capacity ‘to will, to act, to choose’. In Italy, despite that Italian plaintiffs sought to define their entitlement as a more relational right, emphasizing their relational values that could be pursued through such a relational right, the Constitutional Court defined it as a traditional individual right. This points to the fact that the same inalienable right was conceptualized differently in different institutional settings and by different parties invoking it, thereby leading to different conclusions which constitutional right was exactly at stake. I will come back to discussing this issue in Section 7.2.2.

7.2. Rights as a ‘right’ instrument for the regulation of PGD

By answering the question to what extent rights can ensure a ‘right’ regulation of new technologies, I will add to an already existing literature discussing the challenges that rights face in regulating new technologies (seminally, Brownsword 2008). I acknowledge that building my conclusions on one country case-study is tricky, as these problems might not emerge in other countries. Indeed, as I showed in Chapter 6, even such a slight difference as the exact conceptualization of human dignity, either as non-instrumentalization of human life or as sanctity of life, might significantly affect the degree of skepticism or conservatism towards adopting new technologies. Yet, in what follows, I will try to derive those conclusions that in my view might emerge in other contexts as well and which therefore scholars should be attentive to in their exploration of the role of rights in the regulation of new biomedical technologies.

7.2.1. The vital rights of biological citizens and embryos' rights: conflicting rights and their effect on the policy on new biomedical technologies

As I stated above and as I sought to show in this work, rights do act as external limits to governmental power. As I described in Chapter 4, positive rights of embryos, based on 'natural rights' and human dignity, were limits to governmentality. Similarly, in Chapter 6, I showed that the Constitutional Court provided access to PGD on much more modest grounds than was claimed by some plaintiffs and in a more limited scope than probably existed in practice before Law 40/2004 was adopted in order to ensure the rights of embryos. This conclusion taps into recent discussions about the importance for law to exercise a proper symbolic and normative function and not merely reflect technoscientific developments. Similarly, in the age when the transformation of 'life itself' knows few limits, as Brownsword (2008) stated, human dignity may be an important moral reference point in assessing those biomedical transformations that affect the most fundamental existential assumptions that people have long taken for granted, such as what it means to be human. In addition, as I showed in Chapter 6, in countries such as Germany, human dignity may also play an important role as an element of national identity and enable a more critical reflection on new biomedical technologies.

Yet, these positivized natural rights of embryos also co-exist with other more 'transformative' rights, that is, those vital rights that imply transformation and change and that new biomedical and, particularly, genetic technologies make possible. Both types of rights have a close relation with new biomedical technologies; yet, while the embryos' rights presume the need to limit them, the second one, in contrast, presume their further development.

The co-existence of these two types of rights has several consequences. First, the presence of two different types of rights introduces an uncertainty into the debates on new technologies, as it is not clear which or whose rights the regulation of new technologies must seek to protect most. This uncertainty is similar to the twofold conceptualization of human dignity, as empowerment or as constraint. In the case of rights as a regulatory benchmark, we can redefine the problem as a competition between 'rights as empowerment' (such as the right to health) and 'rights as constraint' (such as the rights of embryos). In the first approach, rights would be claimed by citizens wishing to have freer access to new technologies. In the second approach, entities such as embryos, protected as holders of rights, might call for constraints on scientific or medical experimentation. Indeed, as I showed in Chapter 3, the proponents of embryo protection very often appealed to human rights (and not to human dignity) as the main reason why the law on reproductive technologies should have a restrictive character.

Second, and similarly to the problem of the twofold meaning of human dignity, the problem of regulatory range emerges. If we agree on, say, rights as empowerment as a regulatory approach, does this mean that embryos do not deserve any protection whatsoever? Should, for instance, surplus embryos be treated as biological waste? Should parents have the right to decide on what do with them, for example, to destroy, to donate for research, etc.? May the State nevertheless constrain citizens' freedom on what to do with embryos, similarly to how it constrains citizens' freedom if they wish to sell their body parts, in order to prevent their commodification? Finally, due to the competition of rights, the problem of balancing emerges. As I showed in this work, there are no undisputed, objective and self-evident criteria how the right to life of IVF embryos (regarded as full-fledged human persons by Parliament) must be balanced with the rights (to health or self-determination) of women. In the Italian litigation for access to PGD, even the right to health did not act as a trump, because it was far from self-evident whether this right should outweigh IVF embryos' interests.

This suggests that the appeal to rights does not lead to one – permissive – outcome with respect to regulating new biomedical technologies as Brownsword suggested. In fact, because two different types of rights exist, they rather lead to a further debate about rights and the acceptability of new biomedical technologies rather than close it. As this work has shown, the debate can be quite extended, producing no long-term solutions.

7.2.2. Judicial review and framing: regulating new technologies through rights 'from below'

Another aspect that must be taken into account in exploring the problematic nature of the use of rights in regulating new technologies is that when constitutional rights are claimed, discussed or accorded in courtrooms, their definitions and their building blocks do not preexist judicial review but, are, in contrast, its outcome. Two examples discussed in this work should be mentioned here. First, in Chapter 5, I showed how suffering was defined differently, either as a mere psychological experience or as ‘depressive and anxiety syndrome’, that is, illness, by the judiciary, depending on whether plaintiffs submitted the reports of their psychiatrists or not.

The second example is the definition of ‘vital rights’ of citizens, that is, the entitlements they thought they had, in courtrooms. In Chapter 5, I showed that the plaintiffs sought to define their ‘vital rights’ both as a right to self-determination and as a right to health. However, the Constitutional Court acknowledged only that this entitlement involved the right to health. In other words, it was far from clear to the participants of the controversy which exact inviolable right the Italian Constitution protected and which right the plaintiffs could claim.

The recognition by the Constitutional Court that the inviolable right at stake was the right to health had several important implications. Despite that it recognized that the right to health might be jeopardized by the prohibition of PGD and thereby captured some of the experiences of Italian women, by choosing the right to health the Constitutional Court failed to acknowledge many other interests of Italian women, such as relational values of care and responsibility for the health of the future baby, as deserving state recognition and thus as protected via constitutional rights. Despite the fact that the judgments repealed many of the Law’s provisions, only health of the woman and not her reproductive interests were recognized as being at risk. As such, it was not the health of the future children that justified the access to PGD, nor the women’s interest in securing it, but the health of the mother that could be harmed if PGD remained prohibited. Therefore, physical experiences were not straightforwardly defined as falling within the scope of constitutional rights protection and thus having relevance for the moral and legal existence of citizens or not. As seen above, several factors may affect this process. The first is how individuals themselves define it, for example, by submitting the medical records to the judiciary or failing to do so. Second, the judiciary may feel constrained by its own jurisprudence to qualify the claimed entitlements as particular constitutional rights.

This process of defining which right the issue of access to PGD in fact concerned, reminds one of the idea of framing. Framing is largely used in post-positivist policy analysis and has roots in the sociology of Erving Goffman (1974). Goffman (1974, 21) famously defined it as a construction of meanings through which individuals ‘locate, perceive, identify, and label' elements of external reality. An important aspect of framing consists is that by interpreting social reality, individuals focus on some of its aspects while concealing others. Consequently, through framing, 'actors not simply describe but create the world' (Hajer 1993, 44). In the post-positivist policy analysis, framing has received much attention because of a shared assumption that policy development critically depends on how the relevant political problem is defined or framed (Stone 1989). Framing, therefore, has an important role for public policy, because it involves formulating 'the social meaning of an issue domain, where meaning implies not only what is at issue but what is to be done' (Schön and Rein 1994; Hajer 1993, 1996). However, in legal analysis, let alone the analysis focusing on legal aspects of the use of biotechnological developments, this concept has received only marginal attention. An exception to it is the work of Smith (2016) who analyzed same-sex litigation in the United States and Canada using the concept of frame. She illustrated how in the debate over the problem of legality of same-sex marriage social movements in both countries used three frames, namely, the political right frame, the queer culture frame and the morality frame. She argued that due to political traditions, in both countries, the political right frame was successful and thus allowed the plaintiffs to win the case owing to the long-standing legal traditions in both countries in upholding civil rights claims. However, Smith did not focus on how different rights themselves can act as different frames.

I suggest that in the Italian litigation for PGD, the right to have access to PGD was in fact framed as either of these two rights: the right to health and the right to reproductive self-determination. Since through framing some aspects of social reality are made visible and others are concealed, framing the right to PGD as either of these rights also makes some aspects of social (or, for the purpose of this work, biological and, related to that, moral-political) reality visible, while concealing others. Framing the right to PGD as a right to health conceals the importance of relational values of care and responsibility. In contrast, framing the access to PGD as a right to self-determination conceals the importance of embryos' biological existence as an end in itself.

For our discussion of the role of rights for regulating new biomedical technologies, this conclusion may imply several consequences. First, due to such indeterminacy of rights, when citizens seek to receive access to a particular biomedical technology, they may be surprised to find out that those values or those experiences, that the relevant technology could protect and the protection of which they thought they are entitled to, are not or cannot be covered by the existing rights regime. For some, this partial outcome may look like a failure, particularly when some important values are not recognized through law. Second, participants may use rights strategically by framing their demand to a new technology in such a way that it would bring about the desired outcomes regarding the access to the relevant technology. For example, they can take into account the context such as the judicial doctrine in order to frame their experiences through rights in a strategically advantageous way. I will come back to the strategic use of rights in the next section.

7.2.3. The double role of legal rights and the regulation of new biomedical technologies

As I stated in the Introduction, according to the critical approach to rights, propounded for example, by Foucault and feminist legal scholar Wendy Brown, rights do not simply act as instruments that the right claimant freely uses to achieve their own objectives, such as the access to new technologies. Rather, rights have 'political ambivalence' (Golder 2013, 10) in that they 'are both political tools for the contestation and alteration of mechanisms of power and simultaneously mechanisms of capture and inscription' (Golder 2013, 6-7). As I argued in Chapter 5, the claim to and an ultimate guarantee by the judiciary of the women's right to health also allowed plaintiffs to contest the power exercised by Parliament and at the same time imposed constraints on the plaintiffs in that they 'constitute[d] the very identities of those who deploy them' (Golder 2013, 7). What does this mean for our discussion of the role of rights in regulating biomedical advances?

Reification of identities

First, the definition of the plaintiff's identity in a single court proceeding 'will not be limited to the litigant asserting the right: they will instead be deployed to regulate all members of the group' (Ford 2002, 56). Therefore, by configuring the subject of rights as a female patient, it would mean that, first, it would exclude male citizens from the category of subjects qualifying for access to PGD. Second, female citizens might be able to receive PGD, but only if they prove that PGD is needed to prevent negative impacts on their health by the health condition of the embryo. Hence, they will need to formally *represent* themselves as sick patients, for example, by providing the required proofs to fertility centers that their bodily or mental health is indeed at risk. Similarly, they are dependent on an assessment of their health condition by the doctor and therefore, formally and officially, are not entitled to autonomously decide on whether or when to perform PGD. They are not 'agents' in the full sense of this word, as they are officially deprived of full decision-making power. Using the language of CLS, their identities as sick patients lacking full autonomy will be repeatedly reiterated in their encounters with doctors, and symbolically they will be represented as using PGD for therapeutic reasons. Importantly, women who did not participate in litigation will still have to follow these requirements: the disciplinary power of rights will affect not only the individual claimants, but the entire population, or that part of it that wants access to PGD. Biopolitics thus is exercised on the Italian citizenry through the disciplinary effects that bioconstitutionalism has in reifying the identities of rights-holders.

Strategic use of rights

Despite the reification of their identity as female patients, as I also showed in Chapter 5, women will probably still be able to receive a rather liberal access to PGD due to the ability of interpreting the 'mental health' justification broadly. For example, experiences such as anxiety and depression can be qualified as health issues: The Diagnostic and Statistical Manual of Mental Disorders (DSM-V), for instance, treats them as mental disorders. Therefore, Italian women might make use of this broad definition of health as an escape route and perform PGD on the grounds that they choose. I suggest that this is an effect of the 'tactical' or 'instrumental' use of rights in the litigation for PGD, performed by plaintiffs and by courts (Golder 2015, Foucault 2007). As Golder, building on the Foucauldian critique of rights, stated:

> [t]o employ law as a tactic is to approach it not as a substantive ideal or a normative system binding on all, but rather as an assemblage of power-knowledge available for appropriation by various social actors that can be, and is, put to varying uses. An instrumental deployment of law (or any other assemblage) is a kind of insubordinate, disobedient, and potentially subversive deployment that plays the game in a way that does not respect the stated purpose of the game and hence troubles and possibly undermines it (Golder 2015, 117).

Thus, on the one hand, the need to guarantee the right to health might be seen as compatible with the intention of the state to recognize embryos as persons and therefore as subject of strong constitutional protection. On the other hand, the use of rights was an instrument strategically deployed by those who disagreed with the biopolitical intentions of Parliament and wished to make use of new advances in science and technology to achieve their own goals. Thus, their instrumental value in achieving the desired social or legal ends is strong if they are deployed in a strategically ‘right’ way. This aspect of rights might therefore be taken into account by those who wish to ensure that new technologies will enable the ‘right as empowerment’ framework to win over competing discourses such as dignitarianism or ‘rights as constraint’.

7.2.4. Private clinics, Parliament and courts: institutional setting and its influence on the regulation of new technologies through rights

In this work, I showed that it matters a lot for the regulation of new technologies, not only their regulation through rights as such, but also the context in which these rights are exercised, discussed or claimed. In order to appreciate this importance, it is necessary, first, to see rights broadly as including not only positive rights but also the entitlements that make part of citizens’ identity and, second, to consider that rights shape the four poles of human existence within the state. Through these moves, it is possible to see how human life and its biological and moral aspects are recognized by the relevant state authorities and, hence, how they treat the role and impact of new technologies for the protection of these rights.

First, speaking about private fertility clinics, we can see that here IVF and PGD were highly demanded because citizens’ vital rights were prioritized above all. In the situation of a non-existent state, that is, when it did not exercise any supervisory function, biomedicine, with its promises to give birth to healthy children, was reigning, shaping and fulfilling the entitlements of Italian patients. Second, in Parliament, both IVF and PGD were ostracized. The state qua Parliament saw them as threatening its duty to ensure the protection of its ‘little’ and ‘vulnerable’ unborn citizens and their rights. At the same time, biological existence of women was valued relatively low and their rights were deemed less significant for the state. The rights of both embryos and women received this particular degree of protection because of the influence of powerful moral actors such as the Catholic Church as well as due to the political ambitions of Italian political parties. Third, and finally, in courts, women’s rights were vindicated and PGD was reintroduced into Italian healthcare arrangements. This was done through acknowledging the importance of women’s health, which should take priority over embryo's life. However, only health was recognized as justifying access to PGD and not reproductive self-determination. Here, the court's jurisprudence played a key role in pronouncing this judgment.

What this triangulation of spaces where rights are claimed, exercised and conferred shows is the importance of an institutional setting where such practices take place for how the relationships between the state and its citizens, which concern the biological aspects of human existence, will be structured in the form of legal rights and how, respectively, this will affect the acceptability of new biomedical technologies. Arguably, the most liberal setting is a fertility clinic: here, the transformative power of biomedicine shapes 'vital rights' of citizens, inculcating freedom and choice into them and making them part of biological citizens' identity. Parliament is prone to different political interests and influences of strong morality-setting institutions such as the Catholic Church. Instead, courts are bound by legal precedents, which ground 'continuity scripts of the law' (Rosenberg 1991, 11) and limit the judiciary's discretion in terms of the type of judgments they could pronounce.

An important aspect of how rights figured in these three spaces is that they were represented as some inalienable entitlements of individuals that should be translated into the country's positive law. Citizens were performing PGD because they thought they had this entitlement and, in courts, referred to the Constitution as legalizing this inalienable entitlement. Parliament also referred to the Constitution as well as to natural rights of embryos. The Constitutional Court built its judgment on a particular interpretation of the Constitution, which legalizes inalienable rights of Italian citizens (Italian Constitution; Barsotti *et al* 2015). In this way, all the involved actors were implementing 'outside' rights into positive law, seeking to achieve a just political order. Indeed, exactly such natural rights, whose existence is independent on state power and positive law, have been the underlying idea behind the international human rights regime and national constititutional law, particularly, in Italy (Italian Constitution; Barsotti *et al* 2015). However, as I sought to show in this work, in Italy, the appeal to such inalienable rights did not lead to a single decision about how they should be defined and translated into policy and hence regulate PGD. As a result, as this work shows, the appeal to natural (or inalienable rights) in bioconstitutional debates may expose life to a decision-making process with inherently unpredictable outcomes and boil down to a debate about subjective normative or political commitments or interests of those who participate in the debate.

7.2.5. Vital rights, 'biological citizens' and the regulation of new biomedical technologies

I stated in the Introduction that anthropologists and social scientists have concluded that the simultaneous development of a neoliberal form of government and the development of biomedical practices in 'advanced liberal democracies' led to the emergence of a particular type of identity (Rose 2006). This identity includes 'vital rights', or the assumption that one has an entitlement to claim the protection of one's right to health and life vis-à-vis the state, engage in political activism for funding a particular type of research, etc., as a key component. The development of Italian fertility treatment practices, regardless of their vexed legal existence, also took this route.

I suggest that this view on 'vital rights' as elements of personal and collective identities may mean that posing the question whether rights are a 'right' instrument of regulating new technologies may be inappropriate in the first place. Since identities, including the assumptions about one's rights, are an outcome of the mutual constitution of personhood and the state, the problem then is not whether rights can be 'law's hope technology', but whether broader political processes, producing a particular type of identity and rights, should be judged as positive. The productive assessment of rights and their role for the regulation of new biomedical technologies can only be performed if the entire socio-political landscape is taken into consideration. In other words, such rights as the right to access new biomedical technologies or the right to practice them will be considered 'right' as long as the neoliberal form of governance is regarded as a preferred form of governance. New biomedical technologies such as PGD take the central stage in this neoliberal form of governance because the exercise of 'vital rights', which are an essential part of this form of governance, in fact presupposes and favors their use.

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Summary

1. Background, aim and research questions

The contemporary development of practices of law and policy-making making related to biomedical issues, e.g. the UNESCO set of declarations on genetics, bioethics and human rights, illustrates that in an era where new biomedical practices and technologies cause much fear and anxiety, it is through the appeal to rights that citizens seek to shield themselves against potentially dangerous new technologies.

The main objective of this work is to explore how constitutional rights figure in social controversies around new biomedical technologies and to highlight the possible advantages, problems and difficulties that the use of rights as benchmarks for their regulation involves. It does so by drawing on the concept of *bioconstitutionalism*. Bioconstitutionalism builds upon the ideas from science and technology studies, the Foucauldian critique of state and power, and the critical approach to legal rights, to analyze the influence of new biomedical practices and technologies on the construction of legal personhood, subjectivity, constitutional rights, citizenship, and the problems of legitimacy and accountability. Drawing on bioconstitutionalism research, this thesis seeks to address the problems related to the use of rights as benchmarks for the development of new biomedical technologies and practices, thereby also contributing to the further development of bioconstitutionalism research.

To address this issue, this work is mainly based on a case study: the exploration of a social controversy around a technology known as preimplantation genetic diagnosis (PGD) in Italy. Together with other reproductive technologies, PGD had been freely practiced for a long time up to 2004, when the Italian Parliament passed a law on medically assisted reproduction (Law 40/2004) and prohibited many reproductive technologies, including PGD. This was considered necessary to protect the rights of human embryos created through IVF, which were granted legal personhood and turned into ‘citizen subjects’ by Law 40/2004. However, the adoption of the Law was followed by a massive litigation campaign initiated by Italian citizens who had predispositions to various genetic diseases and who were supported by patient and scientific associations. As a result, in a series of decisions spanning over a decade, the Italian Constitutional Court repealed the most contested provisions of the Law that prohibited PGD, as they violated the right to health of Italian citizens. Exploring the different roles that rights have played in the Italian controversy, as well as the different ways in which they have been used, appealed to, shaped, and implemented, this work thus seeks to contribute to exploring the problems of using rights in social controversies around new biomedical technologies.

To fulfil this aim, the thesis addresses two research questions.

1. How have rights been used (identified, created, transformed, balanced, etc.) in the debate around PGD in Italy and how has this process been connected with the regulation of PGD? The use of the 'how' question in this work means that it will attempt to examine both the process of intertwining of rights and PGD ('how' as a trajectory and methods) and the result of the process ('how' as a form that this intertwining ultimately took).

2. To what extent can rights ensure a 'right' regulation of new technologies? The tinge of normativity in the second question means that this work is an exercise in contextual self-reflexivity. Rather than giving a definite answer in the abstract whether rights are a 'good' or 'bad' tool for shaping new biomedical technologies such as PGD, it more seeks to elucidate possible advantages, problems and difficulties of using rights in regulating new biomedical technologies in their particular context.

2. Different perspectives on PGD in Italy

This work starts with a brief overview of the events surrounding PGD in Italy (Chapter 2). As such, it can serve as a point of reference for the reader to keep an overview of the different debates and events. Subsequently, the thesis analyzes three crucial instances in which rights have been involved and debated in the Italian PGD controversy, applying different conceptual lenses (Chapters 3-5), and puts it in a comparative perspective (Chapter 6).

Chapter 3 explores how a rationality of government – natural rights as an external legitimation of political power – was employed to classify IVF embryos either as entities having a mere biological existence as *zoē*, or as human persons, capable of moral and political existence, as *bios*. It shows how through the appeal to natural rights of embryos, the latter were granted legal subjectivity and rights, and how the implementation of the restrictive regulation of assisted reproductive techniques (ART) to ensure the 'making live and letting die' (Foucault 1980, 70) of these new Italian citizens was performed. In this way, it contends that natural rights have not been displaced by other rationalities for the exercise of political power, such as nature as an internal self-limitation of power.

Chapter 4 focuses on the debate around the provisions of Law 40/2004 that prescribed a uniform method of performing IVF in Italian fertility clinics, namely to fertilize no more than three oocytes during one IVF cycle and to transfer all created embryos into the patient's uterus simultaneously. Drawing on the concept of boundary-work (Gieryn 1983, 1995), it explores how the Italian Parliament justified the expansion of the jurisdictional powers of the State into a domain traditionally occupied by the medical profession, namely, the prescription of treatment methods, and how the Italian Constitutional Court established and motivated the constitutional illegitimacy of the Parliament's actions. It shows that the demarcation of the jurisdictional domains of the medical profession and the Italian State depended upon how the latter tipped the balance between the conflicting rights of IVF embryos and the rights of adult Italian citizens, and how the procedures of embryo surplus production and cryopreservation acted as a terrain where both the State and the medical profession came to defend their interests.

Chapter 5 explores the Italian litigation for access to PGD as an example of biological citizenship. It pays particular attention to how exactly the interests of citizens have been recognized through rights litigation and therefore engages with the critical approach to rights. It shows that the biological citizens' 'vital rights' that litigants claimed vis-à-vis the state in Italy were only partially recognized; however, this was so not because the existing relations of power affected how individualistic rights are balanced, but because certain important societal values, namely a high value accorded to unborn life, as consolidated in the constitutional jurisprudence of Italy, prevented the participants of the debate from successfully reconceptualizing the right to PGD from an individualistic into a more relational one.

Chapter 6 puts the Italian controversy on PGD in a comparative perspective and compares the ways in which Germany and Italy – countries with comparably strong bioethical reservations against new biomedical technologies – debated and enacted regulations on IVF, human Embryo Stem Cell (hESC) research and PGD. It is directed towards analyzing human dignity because exactly the protection of human dignity, conceptualized as sanctity of life in Italy, was the main purpose for adopting the restrictive Law 40/2004. It explores the debate on these technologies in Italy and Germany from a comparative perspective to shed light on when and under which circumstances the appeal to human dignity in public debates around new technological and scientific practices becomes problematic. It shows that in both countries, ‘human dignity as constraint’ played a key role in the political debate around the new ART and hESC research, mainly because these were framed as a potential assault on human dignity. Yet, the two countries differed in terms of their success to build policies regarding ART and hESC research upon the principle of human dignity. Two factors were responsible for this difference. The first factor was whether dignitarianism is the dominant bioethical perspective in the relevant country (which was the case in Germany but not in Italy). The second factor was the degree to which the regulators were willing to strike compromises with their opponents, particularly if dignitarianism was not the dominant bioethical perspective or was competing with other bioethical perspectives for regulatory relevance (and German regulators turned out more willing to agree on compromises than Italian regulators).

3. Conclusion

Based on the previous chapters, Chapter 7 draws conclusions to answer the main research questions. It first concludes how rights figured in the debate on PGD and then discusses the advantages, problems and difficulties of using rights for regulating new biomedical technologies such as PGD.

3.1. Governing life through rights

Drawing upon the analysis performed in this work, I suggest that constitutional rights work as a strategy of intervention upon the biological existence of citizens, articulated in the form of claiming, attributing, implementing, or exercising constitutional rights and, as such, rights are a technology of power over life. The ways in which rights work include several important elements. First, rights bind and shape the four poles of human existence within the state: the *physical and moral-political existence of human beings*, on the one hand, and *the individual subject and the state*, on the other. Specifically, rights (such as the right to life, the right to health as well as the right to reproductive autonomy) represent that form of governing biological existence of individuals that also allows taking into account their political and moral existence as ‘free’ but also relational beings. The granting of legal rights ‘from above’, when Parliament grants rights to new technoscientific entities (Chapter 3), or rights-claiming ‘from below’, including the satisfaction of rights claims by the judiciary (Chapter 5), is a way of biopolitically governing a population in such a way that it simultaneously recognizes them as full-fledged members of the relevant political community, having connections with other members, and acknowledges the biological aspects of their existence.

Further, in order to have significance, the realization of rights must be secured by the state, through either positive means (adoption of the necessary measures to ensure the realization of rights) or negative means (non-interference). Therefore, rights also connect *individuals with the state*, thus presupposing a particular type of statehood within which these rights exist. For example, the decision that embryos’ rights should be ensured and, as a result, biomedical developments that violate these rights be prohibited, turns the state into a more conservative and absolutist one than the state that decides not to establish moral truths through law. Similarly, it also shapes the boundaries of the state with other social institutions such as medicine. As Chapter 4 showed, the decision on whose right should take priority not only affected the balance between mothers’ and embryos’ rights, but also simultaneously shaped the locus of the boundary between the state and medical expertise.

Finally, as this work showed, the governance of life through rights may include another important element: the appeal to legal rights as based upon some *inalienable entitlements* of individuals that they have due to the simple fact of being human and that do not depend on being enacted in positive law. However, this work showed that this appeal to natural (inalienable) entitlements is not unproblematic. Inalienable rights can be of quite different types with respect to the degree of transformation through biomedical technologies they imply or allow (e.g. ‘vital rights’ of biological citizens and natural rights of embryos). While similar in that they both can be regarded as inalienable entitlements of citizens (both born and unborn), they are also very different, particularly with respect to the degree of transformation of biological aspects of human life and health that they imply and with respect to the associated degree of acceptability of new biomedical technologies that make these changes possible.

Moreover, the same entitlement can be defined differently by the partipants of the controversy. For example, this work showed that biological citizens’ ‘vital rights’ for citizens themselves were relational rights because they favored the fulfillment of relational values and responsibilities. Instead, the Constitutional Court defined them as a type of individual rights. This points to the fact that the same inalienable right can be conceptualized differently in different institutional settings and by different parties invoking it, thereby leading to different conclusions which constitutional right is exactly at stake.

3.2. Governing life through rights: difficulties and advantages of regulating new biomedical technologies through rights

Based on the analysis in this work, I suggest there are several reasons why the use of rights for the regulation of new technologies may be problematic. The first problem that the use of rights as an instrument of governing new technologies may create concerns the fact that natural (inalienable) rights can be of two different types. The co-existence of these two types of rights has several consequences. First, it introduces an uncertainty into the debates on new technologies, as it is not clear which or whose rights the regulation of new technologies must seek to protect most. This uncertainty is similar to the twofold conceptualization of human dignity, as empowerment or as constraint. Second, and similarly to the problem of the twofold meaning of human dignity, the problem of regulatory range emerges. This suggests that the appeal to rights does not lead to one – permissive – outcome with respect to regulating new biomedical technologies as, for example, Brownsword suggested. In fact, because two different types of rights exist, they rather lead to a further debate about rights and the acceptability of new biomedical technologies rather than close it. As this work has shown, the debate can be quite extended, producing no long-term solutions.

The second problem connected with the problematic nature of the use of rights in regulating new technologies is that when constitutional rights are claimed, discussed or accorded in courtrooms, their definitions and their building blocks do not preexist judicial review but, are, in contrast, its outcome. As this work showed, it was far from clear to the plaintiffs and Constitutional Court which exact inviolable right the Italian Constitution protected and which right the plaintiffs could claim. As a result, due to such indeterminacy of rights, when citizens seek to receive access to a particular biomedical technology through appealing to constitutional rights, they may be surprised to find out that those values or those experiences that the the use of the relevant technology could ensure and the protection of which they thought they are entitled to, are not or cannot be covered by the existing rights regime. For some, this partial outcome may look like a failure, particularly when some important values, such as relational ones, are not recognized through law.

The third aspect concerns the double role of rights. On the one hand, rights reify citizens' identities and exercise disciplinary power, not only on those citizens who participate in litigation, but also on those who will be affected by the legal force of the pronounced judgment. For example, in the Italian controversy, female citizens' identities as patients will be reiterated in their enounters with doctors and state authorities. On the other hand, participants may use rights strategically by framing their demand to a new technology in such a way that it will likely bring about the desired outcomes regarding their access to the relevant technology. As this work shows, despite the fact that, formally, Italian citizens' demands were only partially recognized, they nevertheless will be able to have access to PGD on quite similar grounds as they had before Law 40/2004 was passed.

The fourth aspect concerns the importance of the institutional setting in which constitutional rights are exercised, discussed or claimed for how the relationships between the state and its citizens, with respect to the biological aspects of human existence, will be structured in the form of legal rights and how, respectively, this will affect the acceptability of new biomedical technologies. As this work showed, in all the discussed spaces – fertility clinics, Parliament, and courts – rights figured as some inalienable entitlements of individuals that should be translated into the country's positive law. However, and importantly, the appeal to such inalienable rights did not lead to a uniform decision about how they should be defined and translated into policy and hence regulate PGD. As a result, the appeal to natural (or inalienable rights) in bioconstitutional debates may expose life to a decision-making process with inherently unpredictable outcomes and boil down to a debate about subjective normative or political commitments or interests of those who participate in the debate.

Finally, the fifth aspect concerns the fact that posing the question whether rights are a 'right' instrument of regulating new technologies may be inappropriate in the first place. This particularly concerns 'vital rights' as elements of personal and collective identities. Since identities, including the assumptions about one's rights, are an outcome of the mutual constitution of personhood and the state, the problem then is not whether rights are 'right', but whether broader political processes, producing a particular type of identity and rights, should be judged as positive. The productive assessment of rights and their role for the regulation of new biomedical technologies can only be performed if the entire socio-political landscape is taken into consideration. In other words, such rights as the right to access new biomedical technologies or the right to practice them will be considered ‘right’ as long as the neoliberal form of governance is regarded as a preferred form of governance. New biomedical technologies such as PGD take the central stage in this neoliberal form of governance because the exercise of ‘vital rights’, which are an essential part of this form of governance, in fact presupposes and favors their use.