Science, Technology, & Human Values
000(00) 1-27

DOI: 10.1177/0162243911411195
http://sthv.sagepub.com

Beyond the Geneticization Thesis: The Political Economy of PGD/PGS in Spain

Vincenzo Pavone[1] and Flor Arias[2]

Abstract

In the last decade, preimplantation genetic testing (preimplantation genetic diagnosis [PGD] and preimplantation genetic screening [PGS]) have become widely used and in 2005 constituted 5 percent of all in vitro fertilization (IVF) cycles performed in Europe. Their diffusion, however, is not homogenous; while in some countries they are prohibited and in others hardly implemented, Spain performs 33 percent of all the PGD/PGS. While policy guidelines and mainstream bioethics address PGD from a patient choice perspective, disability studies insist on PGD's potentiality for discrimination. Alternatively, other authors have explored PGD/PGS from the perspective of geneticization but little work has been done on how PGD/PGS are framed by the members of national regulatory bodies. Combining the analysis of juridical documents with semistructured interviews with members of the Spanish National Assisted Reproduction Committee

[1] Institute of Public Policies (IPP), Madrid, Spain
[2] University of Extremadura, Caceres, Spain

Corresponding Author:
Vincenzo Pavone, Institute of Public Policies (IPP), Centro de Ciencias Humanas y Sociales, Consejo Superior Investigaciones Cientificas, calle Albasanz 26-28, 28037 Madrid, Spain
Email: vincenzo.pavone@cchs.csic.es

(CNRHA), this study suggests that the remarkable diffusion of PGD/PGS in Spain may be largely due to the interaction between the growing momentum enjoyed by embryonic stem cell research and a vibrant expansion of IVF business along the Mediterranean coast. In this process, genetic issues per se seem to play a minor role, although the prevention of genetic diseases now constitutes the master narrative underpinning the extension of PGD from monogenic, early onset, diseases to polygenic, late-onset, ones.

Keywords
expertise, markets/economies, other, politics, power, governance

Introduction

Recent advances in human genetics have had a far-reaching impact on biomedical research and health care policy prospects (Andrews 1994; Kaufert 2000; Abel et al. 2005; Patlak and Levit 2010). As a result of the initial accomplishments of the Human Genome Project (HGP), several countries foresaw important changes in future health care practices and therapeutics, such as personalized medicine and gene therapy (Royal Society 2005; Soo-Jin Lee 2005) but, ten years after the completion of the HGP, many of these prospective changes have actually failed to materialize (Hedgecoe 2004). Genetic testing, though, is one of the few biomedical sectors in which significant advances have been made, paving the way to the gradual introduction into health care practices of a number of new genetic testing technologies (GTTs), mostly as diagnostic tools but also as susceptibility and predictive tests (Organisation for Economic Co-operation and Development [OECD] 2007). The field in which most new GTTs have been introduced is reproductive medicine (Lippmann 1991, 1992; Nelkin and Lindee 1995; Hoedemakers and ten Have 1997; Parens and Asch 1999; Katz Rothman 2002).

In reproductive medicine, preimplantation genetic diagnosis (PGD) and screening (PGS) have raised enormous expectations not only because they represent an important step forward in the prevention of hereditary genetic diseases but also because they promise to improve the success rate of IVF techniques (Human Fertilization and Embryology Authority [HFEA] 2002; Pehlivan et al. 2003). Yet, they also raise significant ethical and social concerns (Lippmann 1991; ten Have 2001; Robertson 2002; Pembrey 2002; Kerr, Shakespeare and Varty 2002; Franklin and Roberts 2004). According to the geneticization thesis, for instance, the introduction of new genetic tests in reproductive practices is likely to promote a gradual shift from a

complex, sociobiological view of human life to one in which differences among individuals would be increasingly reduced to their genetic characteristics (Lippmann 1991, 1992, 1994; Nelkin and Lindee 1995; Hoedemakers and ten Have 1997; ten Have 2001).

However, the implementation and diffusion of preimplantation genetic testing vary significantly from country to country. Whereas Germany and Italy have prohibited them, countries with equally permissive legislation, like the United Kingdom and Spain, show remarkably different patterns of use: in the United Kingdom, PGD and PGS are very selectively performed, but Spain alone performs nearly one third of all the European PGD/PGS (European Society for Human Reproduction and Embryology [ESHRE] 2007). These remarkable differences suggest that geneticization dynamics might be strongly mediated by local, institutional, social, and cultural factors, which arguably play a constitutive role in the process of coproduction between science, technology, and social order at work in any given national space. In this article, therefore, we explore the social and institutional landscape of geneticization through an empirical analysis of the remarkable diffusion of PGD/PGS in Spain, from the privileged viewpoint of the members of the National Assisted Reproduction Committee (CNRHA).

The article is divided into three sections. First, we outline and discuss the main arguments of the geneticization thesis as well as some of the most important empirical contributions focusing on PGD and PGS. A methodological note presenting the research questions paves the way to the second section, in which we reconstruct the actual development and implementation of PGD/PGS in Spain, including the main legislative and institutional changes affecting reproductive technologies. The final section seeks to identify the main social and institutional factors contributing to the remarkable growth of PGD/PGS in Spain during the past decade. In the conclusion, we suggest directions for future research on geneticization and genetic testing and discuss the policy implications related to their future prospects.

PGD/PGS: Toward a Socio-Institutional Landscape of Geneticization

PGD and PGS are GTTs associated with IVF and intracytoplasmic sperm injection (ICSI), which explore the genetic and chromosomal characteristics of a single cell extracted from a pre-embryo before the implantation in the uterus. PGD searches mainly for genetic mutations responsible for particular diseases, both monogenic (e.g., cystic fibrosis) and high-penetrance polygenic (e.g., BRCA1/2 for hereditary breast cancer). PGD

constitutes a formidable technique to allow fertile couples at risk of transmitting serious genetic hereditary conditions to have genetically unaffected offspring, and represents a potential alternative to prenatal testing (PNT; Lavery et al. 2002). PGD can also be employed to select histocompatible embryos for future transplantation to sick siblings, such as in the case of Fanconi's anemia (Verlinsky et al. 2001). PGS, in contrast, is used to screen for chromosomal alterations and aneuploidy in order to select the embryos with the highest chances to develop into a normal pregnancy and is usually associated with advanced maternal age (AMA) and repeated implantation failure (RIF; Thornhill et al. 2005). Recent medical literature, however, suggest that PGS either does not increase success rates (Yakin and Urman 2004; Mastenbroek et al. 2007; Harper et al. 2010) or affects it negatively (Hardarson et al. 2008). In 2005, PGD/PGS have reached in Europe more than 6000 interventions (Nyboe et al. 2009), which show not only that preimplantation genetic testing is becoming an important component of IVF and ICSI cycles (King 2008) but also that genetic information is becoming central to reproductive medicine.

It has been argued that genetic information may be playing a constitutive role in the process of biomedicalization, promoting a shift from enhanced control over external nature to the harnessing and transformation of our internal, genetic nature. Consequently, genetic information seems to be encouraging a *geneticization* of medical research and clinical practice through an overemphasis on the genetic aspects of human life and body (Clarke et al. 2003; Clarke et al. 2009). Geneticization was originally defined by Lippmann as "*an ongoing process by which differences between individuals are reduced to their DNA codes, with most physical and behavioral diseases defined at least in part as genetic in origin. It refers as well to the process by which interventions employing genetic technologies are adopted to manage problems of health*" (1991, 19).

However, geneticization and biomedicalization are not necessarily intertwined and they may not be consistently observed in all fields of biomedicine. Social research on geneticization should, therefore, abandon the abstract ground of theory driven polemics, seek empirical evidence of socially relevant change (Hedgecoe 2001), and pay more attention to the variety of cultural, social, and political factors in which medical research and clinical practice are embedded (Hedgecoe 1998, 1999). For instance, some authors have explored the gradual construction of specific diseases into overtly genetic conditions (Hedgecoe 2001, 2002; Hall 2005; Weiner and Martin 2007) or the impact of genetic testing in the job and insurance markets (Dodge and Christianson 2007; Goven 2008; Markel and Barclay

2007; Sedo 2007; Van Hoyweghen, Horstman, and Schepers 2007, 2010), in health care policy as well as in health care and clinical practices (Kerr 2005; Skully et al. 2006; Vailly 2006, 2008). Others have suggested that geneticization dynamics may be affecting some sectors more than others (Pavone 2010), while it has also been denied that any meaningful geneticization process is actually taking place (Condit and Williams 1997). Although yielding somewhat mixed results, these studies have focused on a common research question, asking where geneticization could actually be seen at work and whether it played a dominant role.

As preimplantation genetic testing is increasingly adopted as a tool for prevention, our society may be experiencing a shift from a *social view of welfare*, which sought to reconstitute the environment in order to accommodate the special needs of given social groups, to a *new biomedical welfare* that seeks to biologically refashion the problem by selecting the embryos of future individuals according to the biological standards currently upheld by society (Ehrich et al. 2006). Organizational and institutional pressures to retrieve and deliver genetic information have also been detected. What is often presented as the "right to know" is increasingly becoming a "duty to know," that is, a moral obligation for prospective parents to bring to life only children free from harmful genetic mutations (Ehrich and Williams 2010). As a result, PGD is currently being extended to late-onset polygenic diseases with high penetrance (Verlinsky et al. 2004), allegedly endorsing a genetic reframing of complex medical conditions, which reduces complex biological phenomena to their genetic mechanisms while attributing to the genes a disproportionate predictive power: "*when a neo-ontological conception of disease is combined with the reductionist element of geneticization* [. . .] *we get a most curious identification of disease and one's very being* [. . .] *We no longer have a disease, we are a disease*" (Stempsey 2006, 198).

While these studies confirm that prevention of hereditary diseases, patient choice, and reproductive autonomy deeply contribute to the master narrative endorsing the growing diffusion of PGD/PGS, others pointed out that the increasing availability of genetic information is more likely to produce complex and articulated responses. While PGD may be shifting the focus of assisted reproduction from the achievement of successful pregnancies to the delivery of "healthy babies" (Ehrich and Williams 2010), ethnographic work on PGD shows that prospective parents might consider access to genetic information as an opportunity to manage their own uncertainty, rather than having it managed by others (Franklin and Roberts 2006). In the context of private market insurance, instead of simply being an object of discrimination, genetic information can also be an important operator of solidarity (Van Hoyweghen 2010).

Tensions and inconsistencies have also emerged around the impact of genetic information on the social construction of the PGD embryo, which is constructed either as a potential object of research or as a potential "baby" depending on whether research staff, gynecologists, and parents are involved (Ehrich, Williams, and Farside 2008). Competing frames have been detected around whether discarded PGD embryos should be considered as "viable" or should rather be considered ready for research on the ground of their alleged non-viability (Williams et al. 2008). Discarded PGD/PGS pre-embryos are more likely to be donated for research and constitute, therefore, a valuable resource for the development of stem cell lines (Franklin 2003; Franklin et al. 2005; Verlinsky et al. 2009; Svendsen 2007). Finally, because of their genetic profile, PGD embryos have recently become the source of human embryonic stem cells for specific disease research and drug discovery (Stephenson, Mason, and Braude 2009).

The diffusion of preimplantation genetic testing, thus, emerges as a composite phenomenon, in which the increasing availability of genetic information plays a crucial role in the multifaceted set of interactions between reproductive and regenerative medicine (Franklin 2006a, 2006b; Waldby 2008; Waldby and Cooper 2010) but it does not necessarily produce a one-way, unequivocal overemphasis on genetic traits or on genetic aspects of human life, disease, and reproduction (Roberts and Franklin 2004; Williams et al. 2007). In this broader picture, geneticization dynamics emerge as part of a complex, multi-actor process in which the master narrative normatively supports the extension of PGD in the name of "disease prevention" but is strongly mediated by institutional, social, and economic factors at national level, which Felt et al. (2010) have captured through the concept of *techno-political cultures*.[1] This hypothesis is also consistent with recent works on public engagement showing the relevance of different *institutional rationalities* (Bickerstaff et al. 2010).

The unevenness and heterogeneity of PGD and PGS national practices, therefore, constitute an interesting opportunity to explore, from a socio-institutional perspective, how the deployment and articulation of geneticization processes are actually embedded in reproductive practices. In this socio-institutional reconstruction, PGD/PGS can be approached as a technosocial site through which it becomes possible to explore not only the empirical relevance of geneticization (Hedgecoe 1998, 1999) but also its theoretical power as a heuristic tool (ten Have 2001).

Aims and Method

Given the magnitude of the phenomenon and the peculiarity of the institutional context, Spain represents a unique case to explore the social, economic, and institutional dynamics that discipline PGD and PGS within the broader political economy of IVF practices. This study combines sociological, historical, and legal perspectives to explore if and to what extent there exists a mutually constitutive relation between geneticization dynamics and the diffusion of PGD/PGS, and to cast some light on the coproduction of technology and social order that is emerging around IVF, PGD, and reproductive practices.

In this study, we address four research questions. First, why did Spain develop a technological trajectory leading Spain to perform more PGD/PGS than any other country in Europe? What role did geneticization dynamics play in this process? Did other factors play a constitutive role in the actual unfolding of the process? And finally, how were geneticization dynamics mediated by these other factors? Our main hypothesis is that while geneticization dynamics have indeed been at work in the Spanish IVF context, they did not represent the main driving force, and have themselves been strongly mediated and shaped by broader economic pressures and by local institutional factors.

We interviewed fourteen of the twenty-nine members of the CNRHA, the Spanish regulative body in charge of authorizing PGD/PGS; four members refused to cooperate and the other members remain unidentified, because CNRHA membership is not made public. The interviewees are experts in the fields of regenerative medicine, embryology, genetics, gynecology, bioethics, law, and psychology, drawn not only from private and public IVF centers but also from civil society organizations, regional authorities, and professional orders. We complemented interviews with legal documents, data from the ESHRE and the Spanish Fertility Society (SEF), and reports from national newspapers. The interviews contained two different parts, whose outcomes inform, respectively, the following two sections of the paper. The first part addressed the history, the mission and the composition of CNRHA, while the second part specifically explored the nature, the diffusion, and the future prospects of PGD and PGS in Spain.

Introduction and Regulation of PGD/PGS in Spain: The Role of the CNRHA

The first Spanish law regulating assisted reproduction dates back to 1988. Preimplantation genetic testing was then an experimental technique, whose

potential applications had only been identified recently (McLaren 1987). The 1988 Act considered preimplantation genetic testing both as a tool to improve the success rate of assisted reproductive techniques and as a diagnostic tool for the detection of hereditary diseases. Given the experimental stage, the 1988 Act did not actually regulate PGD/PGS but envisioned a future regulatory framework based on three measures: the licensing and the monitoring of authorized assisted reproduction centers; the setting up of a consultative body to inform the government and to elaborate appropriate legislative measures on the advances of assisted reproduction techniques; and the creation of a National Registry, in which assisted reproduction activities and gametes and embryo donation could be recorded.

The actual implementation of these measures followed very different trajectories. The licensing of IVF introduced by the 1996 Act attributed the authority to license IVF centers to the regional governments but, in contrast to the U.K. licensing system, did not establish any specific authorization procedure for PGD and PGS: until 2006, IVF centers could offer and perform these techniques in the absence of regulation. A National Registry, in contrast, has yet to be created. Negotiations are being held among the Ministry of Health and the Spanish Society for Fertility and recent press commentary suggests that the registry will actually be set up by the SEF on behalf of the Ministry and that participation in it will be voluntary.

The National Assisted Reproduction Committee (CNRHA), that is, the consultative body envisioned by the 1988 Act, was constituted only in 1997. Since then, the mission, functioning and composition of the CNRHA have shifted dramatically. Originally, the Committee mainly discussed the ethical issues related to the status of supernumerary embryos and to the legitimacy of embryo and stem cell research. During 2003 and 2004, the Committee elaborated important guidelines to allow research on embryos and on embryonic stem cells. Although the 1997 Act attributed to the CNRHA the power to authorize PGD and PGS, it was not until 2006 that some specific regulation criteria for PGD and PGS were introduced:

> The new Act regulates PGD. PGD was without any regulation and the 2006 Act introduced one article and clarified when it was possible to use it, but if you want to do other things now you have to make a request and it has to be approved by the Committee. (Gynecologist 2)

In the meanwhile, these techniques had been largely carried out in private IVF centers, which had experienced a remarkable proliferation. In 1988,

there existed only 14 centers, 10 private and 4 public, but in 2003 the overall number reached 203, 165 private and 38 public.[2]

The 2006 Assisted Reproduction Act framed PGD and PGS in broader terms, introducing a regulatory regime flexible enough to accommodate future technological advances and new genetic conditions without the need to modify the normative framework. More specifically, the 2006 Act permitted the use of PGD for all genetic hereditary conditions considered "serious, early-onset and for which no treatment exists" and approved the use of PGD and PGS "to detect the alterations that may affect negatively the viability of the embryos." When cases clearly meet these criteria, IVF centers and hospitals are simply expected to inform, through their regional authority, the CNRHA. Controversial cases require an explicit authorization by the CNRHA.

As noted by one of the members of the CNRHA, the 2006 Act simply legalized the ways in which PGD/PGS had been performed so far, with the notable exception of Human Leukocyte Antigen (HLA) matching.

> [The law confirmed] the use that had been done before, except for the HLA which was not permitted before, and so the law left the door open to do it. The new regulation opens the possibility of different techniques and allows the assessment of which special cases may or may not be admitted. (Embryologist 2)

As a result of the changing regulatory regime, the CNRHA shifted from a consultative body, which was meant to advise public authorities and the government, into a regulatory body in charge of the authorization of controversial assisted reproduction practices, mainly PGD. In assuming these regulatory functions, the CNRHA was also *technicized*.

> [The Committee's mission] has changed from an advisory body in a time when there were legislative changes, changes in the assisted reproductive laws, to a current role of giving more technical than ethical advice, whose main task is to approve pre-implantation genetic diagnosis [...] this is the most important function that the Committee does in this moment. (Embryologist 2)

Legislative changes after 2006 further reinforced the process of technicization. In 2007, the number of scientific members was increased and the preliminary work of assessment has been effectively entrusted to a technical subcommittee, which now prepares the reports and submits them

to the plenary for approval and/or modification. However, as one interviewee noted, the interpretation of these requirements is not merely a technical task:

> In the Committee, technical opinions prevail [. . .] we mainly discuss whether a given particular case is included in the law or not [. . .] In order to apply a law, it is commonly understood that a technically competent body is enough, helped by lawyers, but for advising the government it will be necessary to do more ethical reflection than what we do now. (Biologist 1)

As a consequence, several nontechnical members felt marginalized and complained that the original mission of the CNRHA had been radically altered:

> When the Committee was created, the idea was that all social, professional and scientific actors related to assisted reproduction had to be represented. Yet, after the 2006 Act the committee was increasingly busy with PGD, focusing on issuing reports on a case-by-case approach. Now, I have the feeling we are doing much more technical consultancy than anything else. (Psychologist 1)

In 2010, despite internal resistance, the government reduced the overall members of the CNRHA by eliminating representatives of civil society and professional orders. The rationale presented by the Ministry was the need to obtain a more flexible and more effective body

> What I can see is that there is pressure from the Ministry to make the committee more technical, more efficient. (Bioethicist 1)

Finally, to speed up the process of approval, the 2010 Act encourages the CNRHA to elaborate a list of specific diseases for which PGD can legitimately be performed without specific compulsory authorization. The interviewed members agreed about the difficulty of elaborating such list:

> [. . .] It sets out a list of diseases, but for now the view is that we must analyze case-by-case because what the law says is not clear and the basic standards are not defined. It is easier to issue case-by-case decisions than to make a list that can be manipulated [. . .] and there are economic interests that would prefer to avoid setting real limits. (Jurist 1)

PGD/PGS in Spain: The Perspective of the CNRHA Members

Until 2006, the absence of an effective regulatory regime encouraged a steady growth of PGD and PGS as part of the IVF cycles performed. The regulatory regime introduced in 2006 de facto legalized the ways in which PGD/PGS had been performed so far and turned the CNRHA into a technical body in charge of authorizing controversial PGD cases. Against this background, we will now present and discuss how the members of the CNRHA framed and explained the trajectory of PGD and PGS in Spain, and how they envisioned the future prospects of these technologies.

The Master Narrative: PGD, Technological Progress, and Reproductive Choice

The interviewed members, especially the medical and scientific ones, expressed a vision of technological advance that strongly emphasizes the inevitability of technological progress.

> The technological evolution is unstoppable. In a short time we will understand the human genome. So, PGD will be everywhere in IVF. That sets up an Orwellian society maybe but it is impossible to avoid it. When we will have tools you can forbid it but people will go to the neighboring country. (Embryologist 1)
>
> What was originally a technique to help infertile couples will soon be mainly associated with fertile couples with hereditary conditions, like breast cancer, or to couples who want to give birth to a child with histocompatibility to save the other child [. . .] and it will grow further because new reasons to apply PGD will be discovered until it will probably become the main assisted reproduction procedure. (Embryologist 2)

This progressive, and generally positive, view of technological advance also informed their view on the extension of PGD and PGS to high-penetrance, late-onset diseases with limited treatment. The criterion adopted by the majority of the members to authorize PGD was a 60 percent penetrance associated with recurrence in family history:

> Finally, we adopted [. . .] let us say a Solomonic solution. All diseases related to genetic factors with a 60 per cent penetrance, that is more than 60 per cent probability to develop the disease, means to have a Damocles' sword threatening you. (Embryologist 1)

Some members also identified ambiguity in the law, for example, the 2006 Act's limitation of PGD/PGS to "serious" conditions:

> For example, the concept of "serious" is complicated. Is it necessary to be life threatening to be a serious disease? Serious diseases are those that determine your life. Who is entitled to define the concept: those who suffer from the disease or those who see their relatives suffer? (Gynecologist 3)

PGD also seems to be encouraging a radical redefinition of "early onset" diseases. Whereas in the past, *early onset* was mainly related to a disease that would develop in childhood or before reproductive maturity was reached, as a result of PGD it is now increasingly associated with adult diseases that may develop earlier than in the average population:

> If breast cancer is normally developed around 50, and the hereditary one appears around 30, this disease can be considered early-onset. (Gynecologist 2)

> Before, early onset was applied to children's diseases, but it was not correct, because adults have their own diseases, and the early-onset ones are those that are developed before its usual time in the population. This is clear, no? (Gynecologist 3)

The interaction between a positive view of technological advance, the growing expectations about PGD and the redefinition of the concepts of "early-onset" and "serious" diseases, seem to confirm that geneticization dynamics do play a constitutive role not only in the emerging master narrative supporting the expansion of PGD but also in the current redefinition of diseases, reproduction, and identity that is taking place in the perspective of the Spanish regulators.

However, the actual trends in PGD/PGS evolution in Spain suggest a partially different scenario: the geneticization process is indeed part and parcel of the master narrative supporting the current extension of PGD in both policy choices and regulatory frameworks, but it is not the driving force behind the spectacular amount of genetic testing performed. According to the data of the SEF in 2008, only about 6 percent of all PGD/PGS in Spain was related to molecular diseases, that is, conditions associated with genetic variations or single-nucleotide polymorphisms (SNPs). As shown by Tab.1, 40 percent of the pre-implantation genetic testing actually was pre-implantation genetic screening for AMA, RIF and recurrent abortion, while nearly 38 percent were pre-implantation genetic diagnoses for cytogenetic diseases.

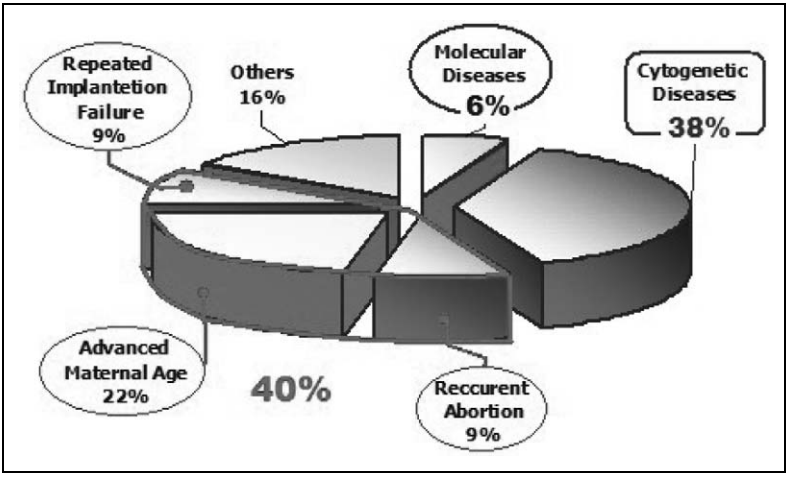

Figure 1. PGD/PGS in Spain in 2006 (our own elaboration from SEF 2009).

Rather than an emphasis on mutations associated with genetic disorders, the diffusion of PGD/PGS seems to be more connected either to the prevention of chromosomal abnormalities or to the avoidance of miscarriages and RIF:

> In fact, more than 80 per cent of PGD are actually PGS for aneuploidy. In the European Registry (the ESHRE) they are wondering why in Spain we perform much more PGS for aneuploidy than we are expected to perform. (Gynecologist 2)

In fact, when PGD for genetic mutations is removed from the picture, Spain presents an impressive amount of PGS performed, which stands in stark contrast to the figures in UK (179 PGD/PGS in 2005), a country with a similar legislative framework. Hence, the question remains: if genetic variations are not the main issue at stake, why do IVF centers in Spain offer and perform such an impressive amount of PGS?

An Alternative Reconstruction of the Technology's Trajectory

During the Nineties, a number of major and technologically advanced private IVF centers were established in Spain. These centers were located in those areas of the country that looked more promising from a scientific

but also from a business point of view, such as Madrid, Barcelona, Valencia, and Andalusia. Although little research has been carried out on this issue, the proliferation of private IVF centers during the Nineties is likely to have emerged as a result of different factors. First of all, as pointed out by the biologist Ana Veiga,[3] private centers were the earliest to set up clinically successful assisted reproduction in Spain in 1984, and for several years they remained the sole option, given that public ones only engaged in assisted reproduction for experimental purposes. IVF treatments were introduced into the public health system only in 1995, with a slow and uneven process providing public hospitals with limited funds and serious restrictions in the scope of the services offered (Matorras 2002).[4] In turn, this produced very long waiting lists, often up to three years (Gynecologist 3). Cultural factors also played a crucial role, for sexual and reproductive behaviors became crucial battlefields of women's liberation during the transition after the fall of Franco's regime, favoring a rather permissive, unregulated approach to emerging reproductive technologies (Alcorta-Idiakez 2006), which in turn encouraged a private-oriented institutional setting of assisted reproduction. Finally, IVF private centers provide the most advanced technological options and also guarantee very high-privacy levels (Farnós-Amorós 2010). Facing a proliferation of private IVF centers along the Mediterranean coast, the Spanish government tried in 1996 to enforce consistently high-quality standards across the country through the introduction of the licensing system above mentioned. Yet, in the absence of specific regulation and of an official registry, private centers were free to offer PGD/PGS as part of their IVF treatments, which constituted the core of an "IVF tourism" from Germany, Italy, and other countries where IVF is more strictly regulated and PGD and PGS are forbidden: 20 percent of IVF cycles performed in 2007 related to nonresidents (SEF 2008).

The technique most frequently performed was PGS for aneuploidy, for three main reasons. First, as suggested by the very same debate occurring in the HFEA in 2000–2002, PGS was a viable alternative to prenatal screening for prospective parents who did not want to undergo amniocentesis and abortion. Second, increasing evidence in the medical literature suggested that PGS could improve success rate in IVF cycles, especially insofar miscarriages and RIF were concerned (Kuliev and Verlinsky 2008). Finally, any information relevant to PGD began to emerge from the HGP only by the end of the Nineties. Although these elements influenced the implementation of PGS all over Europe, we can find a remarkable proliferation only in Spain, Greece, Turkey and, to less extent, Belgium (ESHRE 2007).

National factors, therefore, play a crucial role in this process. The interviewees singled out some specific factors, which have, in their opinion, facilitated and encouraged the massive diffusion of PGS in Spain. The first factor related to the powerful economic interests of IVF private centers, which often introduced PGS as part of their IVF treatments:

> In an IVF cycle, PGD and PGS is what costs more [. . .] this is why there is a business of PGS, which is better not to question, because this is a remarkable business and we all want to make money. (Embryologist 2)

A related factor is the dominance of private centers in the IVF medical context in Spain and the late introduction of IVF (and PGD) into the public health care service.

> The share of private IVF is remarkable because it has been considered a problem of public health only recently, and IVF has been hardly incorporated into the public health system. Moreover, PGS, among reproductive techniques, is the one that generates more money in Spain [. . .] Imagine that in Andalusia there are only 7 public hospitals but 50 private ones, which often offer PGS to raise the cost of their products. (Gynecologist 3)

> When we talk about PGD and PGS, there are very few public centers that offer this service. Therefore, the vast majority of these interventions, whether PGD or PGS, are paid directly by the users. [. . .] I believe that no more than 20 per cent of PGD/PGS are actually performed in public hospitals and centers. (Gynecologist 2)

The actual validity of PGS was a contested issue among the CNRHA members and revealed an ongoing conflict between gynecologists and embryologists. In the presence of AMA, RIF, and miscarriages, embryologists encourage an extensive use of PGS because their main goal is the identification of viable and chromosomically healthy embryos. In contrast, gynecologists aim at achieving the highest number of successful pregnancies and oppose PGS on the grounds that it runs the risk of harming pre-embryos, reducing overall success rate.[5] For embryologists, the risk is more than compensated by the selection of chromosomically healthy embryos, while gynecologists, generally, contest that any such compensation occurs:

> There are three reasons: Spain's role in Europe is quite relevant; the embryologists are strong and very powerful; and there has been an abuse of preimplantation screening for AMA and RIF. (Gynecologist 3)

> With regards to PGS, which is used to enhance the chances of pregnancy of those couples that have special problems to succeed . . . There are colleagues that believe it doesn't work, but I disagree, I believe it does work [. . .] sure this is a sensitive issue, because it is offered to the couples and they have to pay for it . . . and in Spain this is especially common, because you know [. . .] it means a lot of money for private centers. (Embryologist 1)

> There are many of us who disagree with this use of PGS [. . .] I do not believe this is good, and in the conferences I went to I was getting angry at embryologists and they were getting angry at me. (Gynecologist 4)

The economic interests of private IVF centers and the supportive attitude of the embryologists, have certainly sustained the proliferation of PGS, but they alone are not sufficient to explain why countries like the United Kingdom, with similar business interests and reproductive trends, did not experience similar outcomes. The relatively low number of public IVF centers and the exclusion of IVF from public health services in several Autonomous Regions partially explain why the impact of private business has been more powerful here than elsewhere, but again it is not sufficient to account for the magnitude of the phenomenon. In Spain, cheaper prices and the touristic appeal of the Mediterranean coast contributed to the overall picture:

> We are the country that performs the highest number of PGD and PGS in Europe. This means something. The point is that there are countries where this is not permitted, and people come here . . . imagine that there are centers that only perform PGD and PGS! (Gynecologist 1)

The Mediation of Local, Cultural, and Institutional Factors

The diverging patterns between private and public centers also illustrates how the trajectory of PGS, and indeed of a technology in general, can be shaped by crucial economic pressures in a context where these remain unregulated for a long time. One of the reasons behind the slow implementation of a regulatory regime, in fact, seems to be related to existing and yet unacknowledged conflicts of interests affecting the CNRHA. Several members of the Committee come from the most important private IVF centers in Spain. It is not by coincidence that the 2006 Act permitted PGS "to detect alterations that may negatively affect the viability of the embryo," without requiring authorization by the CNRHA. The subsequent technicization process affecting the Committee made technical experts from private centers more influential than ever.

A similar conflict of interests originates from the pressures of the Department for Cell Therapy and Regenerative Medicine of the Research Institute Carlos III, which conducts stem cell research in Spain. The CNRHA is placed under its direct authority and its researchers, who are represented in the CNRHA, directly benefit from the production of "spare" embryos for research.[6] This problem was mentioned in the interviews:

> Yes, we have debated about this (the use of PGD embryos for research) because more embryos were necessary to develop stem cell lines and this research was a priority. (Embryologist 3)

> [. . .] A PGD embryo with a genetic hereditary condition, like Fanconi's anemia [. . .] this embryo can be used for research but we should be careful with the definition of 'non-viable' embryos. (Gynecologist 2)

Economic factors related to private IVF businesses and the scientific pressures related to stem cell research are by no means peculiar to the Spanish context. In Spain, however, these economic factors and scientific pressures could fully exert their influence unbalanced by the weak and ineffective regulatory regime and in the total absence of transparency. Perhaps, the trajectory of the technology might have been different if the CNRHA had set up the National Registry in 1998. Indeed, the failure of the CNRHA to set up a Registry for more than twenty years represents per se evidence of how influential these socioeconomic pressures have been. Some members actually admitted to having received pressures from some private centers, which did not want their success rate to be known to the public:

> There is fear, there is fear, as I mentioned earlier, that examples like this "Woman, aged 55 is undergoing her sixth IVF cycles" could become widely known among the public. With a registry the situation will change because the people will be able to know the data and say: "How strange that this center performs so many PGD and patients have to repeat the cycle so many times." With the registry, all this mess will come to an end. (Embryologist 3)

> The reality is that nobody in the Ministry or in the CNRHA wanted to tackle this issue [i.e. the registry]. Eventually they decided to make an agreement with the SEF and set up a voluntary registry so that those centers that felt like participating could do it. The ESHRE get the Spanish data from this voluntary registry. (Ministry Representative 1)

> One of the main factors behind this [i.e. the diffusion of PGS] is the absence of a Registry, because one thing is the law and another thing is the actual enforcement of the law. It is clear that the absence of a Registry indirectly reveals that several centers do not behave in a correct way. (Bioethicists 1)

Conclusion

Limitations and Policy Implications

While the remarkable technological advance of preimplantation genetic testing has facilitated its increasing inclusion in IVF cycles, there has been a general tendency to extend PGD to common polygenic hereditary diseases with high penetrance, like breast cancer, and perhaps even beyond life-threatening diseases. This trend is also provoking a redefinition of "early-onset" and "serious" diseases, broadening the actual scope of the technology. While this seems to confirm the constitutive role played by geneticization dynamics in assisted reproduction, the actual implementation of PGD and PGS has followed different trajectories not only among countries with different legislative restrictions but also among countries that have adopted similarly permissive legislation, notably the United Kingdom and Spain. In the European political economy of IVF practices, these disparities suggest that, even when general trends of geneticization are at work, they are largely mediated by social and institutional factors and deeply shaped by national discourses and practices.

A closer look at the Spanish case study suggests that while the potential of PGD for the prevention of hereditary genetic diseases constitutes the master narrative endorsing an increasingly broader application of this technique, its actual diffusion has been so far quite moderate. In contrast, business interests associated with out-of-pocket PGS and scientific pressures associated with the urgency to secure embryos for research have played a major role in the diffusion of preimplantation genetic testing. While these interests and pressures were not unique to Spain, they have been able to produce these outcomes because of the specific interaction between the peculiar Spanish IVF landscape, dominated by private IVF centers, and the institutional deficiencies of the 1988 and 2006 regulatory regimes.

These institutional deficiencies have been further aggravated by the actual functioning of the CNRHA, the Spanish national regulatory body, whose activity has been consistently characterized by a lack of accountability, due to its limited democratic connection with elected bodies, and by a remarkable lack of transparency: although annual reports are mandatory, the CNRHA has issued one only in 1998 and 1999. Besides, not only has

the CNRHA never organized public consultations on preimplantation genetic testing, it also never bothered, until recently, to discuss the implications and effectiveness of PGS in IVF cycles. This remarkable lack of attention seems to originate from two main conflicts of interests affecting the composition and the functioning of the CNRHA, such as the presence of experts from leading IVF private centers and the dependence from the research institute Carlos III. Finally, as a result of the 2006 Act the CNRHA has also been affected by an increasing process of technicization that has reduced nontechnical members and is now forcing the Committee to merely focus on the approval or rejection of controversial PGD requests.

In this process, a crucial role seems to have been played by the growing influence of embryologists in both the private IVF centers and within the CNRHA. From the data we present, it is clear that a major impetus to the expansion of PGD/PGS has been driven more by embryologists than by gynecologists, and that the "geneticization" narrative fails to explain their respective use of, and approach toward, the value of PGD/PGS. Finally, Spanish private IVF centers have successfully combined "regulatory" IVF tourism (Kovacs 2010), wherein patients seek access to clinical facilities that may be unavailable in their own country (Spar 2005; Mladovsky 2006), with affordable conventional tourism, which private centers both exploit (in terms of its infrastructure and location) yet also contribute toward (in terms of increasing its level of activity).

From this analysis, it seem plausible to conclude that the impressive amount of preimplantation genetic testing in Spain is a complex phenomenon, in which a combination of specific cultural, social, and economic factors has made it possible for private IVF centers and the established stem cells research community to shape dominant institutional and regulatory practices, preventing, for instance, a full enforcement of the 1988 and 2006 laws but also deeply influencing the functioning of the CNRHA. If science and social order are permanently engaged in a process of coproduction (Jasanoff 2004, 2005), the technological and institutional trajectory of preimplantation genetic testing in Spain clearly illustrates how the remarkable proliferation of PGS (compared to PGD); the dominant position of private IVF centers; the technicization of the CNRHA; the growing influence of the embryologists and of the stem cell research community within the CNRHA, and the progressive adaptation of the regulatory framework to meet their respective needs and interests, are all aspects of science and social order that have been coproduced. In this process of coproduction, institutional, cultural, and economic factors have played a constitutive role and need, therefore, to be fully addressed when geneticization dynamics are studied.

Yet, the Spanish case appears to be a peculiar one and therefore these conclusions may not be easy to generalize. Future research is needed not only to explore PGD and PGS trajectories in a comparative way, comparing perhaps Spain and the United Kingdom, but also to explore the actual dynamics of interaction between medical staff and prospective parents around PGD and PGS, which may be very different depending on whether they take place in private or public clinics, or in conservative or progressive regional settings. Although *de iure* inspired by the same principles and ideas sustaining both the U.K. regulatory framework and the HFEA (Williams et al. 2007), the Spanish regulatory framework and the CNRHA—affected by unresolved conflicts of interests and powerful economic and scientific pressures—have de facto not only endorsed a remarkably different PGD/PGS implementation trajectory but also failed to ensure sufficient standards of transparency and accountability to provide for the necessary amendments. Consequently, this study also clearly illustrates that when policy guidelines and regulatory frameworks are being elaborated, sociological, empirically grounded research is required to ensure not only that these guidelines and rules may be appropriate to tackle the social and the ethical concerns that a given technology is likely to raise but also that these guidelines may actually produce the intended policy outcomes *in the particular context in which they will be introduced.*

Acknowledgments

We would like to thank Andrew Webster, Nick Brown, Michael Morrison and all the staff at SATSU, University of York for the excellent comments, suggestions and support received during Vincenzo Pavone's visiting stay at SATSU in spring and winter 2010. We also wish to thank Joanna Goven and Sara Degli Esposti for their highly valuable comments, suggestions and remarks on earlier versions of this paper.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article:

This paper is the outcome of the research project "Bioethics beyond Ethics: Evaluating the social impact of genetic testing,", reference number SEJ2007-67465,

financed by the Ministry of Science and Education, through the National R&D Plan 2004-2007.

Notes

1. Techno-political cultures, note Felt et al. (2010), "capture the ways in which technologies are interwoven into specific societies" (p. 528).
2. See: http://www.msc.es/ciudadanos/prestaciones/centrosServiciosSNS/centroReproHumAsist.htm. The four public centers in 1988 only engaged in experimental IVF. There are no official data after 2003. The most recent data collected by the SEF only proceed from about ninety centers (SEF 2008).
3. Luz Sánchez-Mellado, Interview to Ana Veiga, El País, 20th March 2011.
4. As a general rule, preimplantation genetic diagnostic is subsidized by public health care only in those regional health care systems providing public IVF treatment, such Andalucía, Cataluña, and Canarias. In 2005, the Andalusia Regional Government took the lead and authorized PGD to avoid the implantation of an embryo presenting a genetic profile related to a closed list of specific monogenic diseases and made PGD accessible through the public health care system. No public center, though, performs PGS.
5. The tension between embryologists and gynecologists over PGS, *mutatis mutandis*, reminds of a similar tension between embryologists and geneticists over PGD, detected and discussed by Ehrich and Williams (2010).
6. It is well known (Franklin et al. 2005; Wainwright et al. 2006; Williams et al. 2008; Svendsen and Koch 2008; Verlinsky et al. 2009) that PGD has traditionally been one of the main sources of "spare" embryos, and couples who undergo PGD are more prone to donate their "spare" embryos to research than the average IVF couples (Franklin et al. 2005).

References

Abel, E., S. D. Horner, D. Tyler, and S. A. Innerarity. 2005. "The impact of genetic information on policy and clinical practice." *Policy Politics and Nursing Practice* 6:5-14.

Alcorta-Idiakez, I. 2006. "Los derechos reproductivos de las mujeres basca nel cambio de siglo: de la anticoncepción a la reproducción asistida." *Vasconia* 35:345-71.

Andrews, L. B. 1994. *Assessing Genetic Risk: Implications for Health and Social Policy*. Washington, DC: National Academy Press.

Bickerstaff, K., I. Lorenzoni, M. Jones, and N. Pidgeon. 2010. "Locating Citizenship: The Institutional Contexts and Cultures of Public Engagement." *Science, Technology, & Human Values* 35:474-500.

Clarke, A. E., J. K. Shim, L. Mamo, J. R. Fosket, and J. R. Fisherman. 2003. "Biomedicalization: Technoscientific Transformations of Health, Illness, and U.S. Biomedicine." *American Sociological Review* 68:161-94.

Clarke, A. E., J. K. Shim, S. Shostak, and A. Nelson. 2009. "Biomedicalising Genetic Health, Diseases and Identities." In *Handbook of Genetics and Society: Mapping the New Genomic Era*, ed. P. Atkinson, P. Glasner, and M. Lock. London: Routledge.

Condit, C. M., and M. Williams. 1997. "Audience Responses to the Discourses of Medical Genetics: Evidence against the Critique of Medicalization." *Health Communication* 9:219-35.

Dodge, J. H., and D. J. Christianson. 2007. "Genetic Testing and Disability Insurance: An Alternative Opinion." *The Journal of Law, Medicine and Ethics* 35:33-5.

Ehrich, K., and C. Williams. 2010. "A 'Healthy Baby': The Double Imperative of Pre-Implantation Genetic Diagnosis." *Health* 14:41-56.

Ehrich, K., C. Williams, and B. Farside. 2008. "The Embryo as Moral Work Object: PGD/IVF Staff Views and Experiences." *Sociology of Health and Illness* 30: 772-87.

Ehrich, K. et al. 2006. "Social Welfare, Genetic Welfare? Boundary-Work in the IVF/PGD Clinic." *Social Sciences and Medicine* 63:1213-24.

Farnós-Amorós, E. 2010. "European Society of Human Reproduction and Embryology 26th Annual Meeting." *Revista Para el Análisis del Derecho* 3:1-17.

Felt, U., M. Fochler, and P. Winkler. 2010. "Coming to Terms with Biomedical Technologies in Different Technopolitical Cultures: A Comparative Analysis of Focus Groups on Organ Transplantation and Genetic Testing in Austria, France and the Netherlands." *Science, Technology, & Human Values* 35:525-53.

Franklin, S. 2003. "Ethical Biocapital: New Strategies of Stem Cell Culture." In *Remaking Life and Death: Towards an Anthropology of Biomedicine*, ed. S. Franklin and M. Lock, 97-129. Santa Fe, NM: School of American Research Press.

Franklin, S. 2006a. "The IVF—Stem Cell Interface." *International Journal of Surgery* 4:86-90.

Franklin, S. 2006b. "Embryonic economies: The Double Reproductive Values of Stem Cells." *Biosocieties* 1:71-90.

Franklin, S., and C. Roberts. 2004. "Experiencing New Forms of Genetic Choice: Findings from an Ethnographic Study of Pre-Implantation Genetic Diagnosis." *Human Fertility* 7:285-93.

Franklin, S., and C. Roberts. 2006. *Born and Made: An Ethnography of Preimplantation Genetic Diagnosis*. Princeton, NJ: Princeton University Press.

Franklin, S., C. Roberts, K. Throsby, P. Braude, J. Shaw, and A. Lashwood. 2005. "Factors Affecting PGD Patients' Consent to Donate Embryos to Stem Cell

Research." Paper presented at the Sixth International Symposium on Pre-implantation Genetics, London, 19-21 May (See Conference Programme and Abstracts, Reproductive BioMedicine Online, 10, Suppl. 2, 31).

Goven, J. 2008. "Assessing Genetic Testing: Who are the "Lay Experts"?". *Health Policy* 85:1-18.

Hall, E. 2005. "The "Geneticization" of Heart Disease: A Network Analysis of the Production of New Genetic Knowledge." *Social Sciences and Medicine* 60:2673-83.

Hardarson, T., C. Hanson, K. Lundin, T. Hillensjö, L. Nilsson, J. Stevic, E. Reismer, K. Borg, M. Wikland, and C. Bergh. 2008. "Pre-Implantation Genetic Screening in Women of Advanced Maternal Age Caused a Decrease in Clinical Pregnancy Rate: A Randomized Controlled Trial." *Human reproduction* 23:2806-12.

Harper, J., K. Sermon, J. Geraedts, K. Vesela, G. Harton, A. Thornhill, T. Pehlivan, F. Fiorentino, S. SenGupta, C. de Die-Smulders, C. Magli, C. Moutou, and L. Wilton. 2010. "What Next for Pre-Implantation Genetic Screening (PGS)? A Position Statement from the ESHRE PGD Consortium Steering Committee." *Human Reproduction* 25:821-3.

Hedgecoe, A. 1998. "Geneticization, Medicalization and Polemics." *Medicine, Healthcare and Philosophy* 1:235-43.

Hedgecoe, A. 1999. "Transforming Genes: Metaphors of Information and Language in Modern Genetics." *Science as Culture* 8:209-29.

Hedgecoe, A. 2001. "Schizophrenia and the Narrative of Enlightened Geneticization." *Social Studies of Science* 31:875-911.

Hedgecoe, A. 2002. "Reinventing Diabetes: Classification, Division and the Geneticization of Disease." *New Genetics and Society* 21:7-27.

Hedgecoe, A. 2004. *The Politics of Personalized Medicine: Pharmacogenetics in the Clinic*. Cambridge: Cambridge University Press.

Hoedemakers, R., and H. ten Have. 1997. "Geneticization: The Cyprus Paradigm." *Journal of Medicine and Philosophy* 23:217-24.

Human Fertilization and Embryology Authority (HFEA). 2002. HFEA Report 2002. Accessed http://www.hfea.gov.uk/docs/Annual-Report-12th-2002-03.pdf

Jasanoff, S. (ed.) 2004. *States of Knowledge: The Coproduction of Science and Social Order*. Oxon, UK: Routledge.

Jasanoff, S. 2005. *Designs on Nature, Science and Democracy in Europe and the United States*. Princeton, NJ: Princeton University Press.

Katz Rothman, B. 2002. *The Book of Life–A Personal and Ethical Guide to Race, Normality and the Implications of the Human Genome Project*. New York: Beacon.

Kaufert, P. 2000. "Health, Policy and New Genetics." *Social Sciences and Medicine* 51:821-9.

Kerr, A. 2005. "Understanding Genetic Disease in a Socio-Historical Context: A Case Study of Cystic Fibrosis." *Sociology of Health and Illness* 27: 873-96.

Kerr, A., T. Shakespeare, and S. Varty. 2002. *Genetic Politics: From Eugenics to Genome*. Winchcombe, UK: New Clarion Press.

King, D. S. 1999. "Pre-Implantation Genetic Diagnosis and the "New" Eugenics." *Journal of Medical Ethics* 25:176-82.

King, J. 2008. "Predicting Probability: Regulating the Future of Pre-implantation Genetic Screening." *Yale Journal of Health Policy Law & Ethics* 8:283-358.

Kovacs, P. 2010. Seeking IVF Abroad: Medical Tourism for Infertile Couples, *Medscape Ob/Gyn & Women's Health.* Accessed http://www.medscape.com/viewarticle/723224

Kuliev, A., and Y. Verlinsky. 2008. "The Impact of Pre-implantation Genetic Diagnosis for Chromosomal Disorders on Reproductive Outcome." *Reproductive Medicine Online* 16: 9-10.

Lavery, S. A., R. Aurell, C. Turner, C. Castello, A. Veiga, P. N. Barri, and R. M. Winston. 2002. Preimplantation Genetic Diagnosis: Patients' Experiences and Attitudes. *Human Reproduction* 17:2464-67.

Lippman, A. 1991. "Prenatal Genetic Testing and Screening: Constructing Needs and Reinforcing Inequities. *American Journal of Law and Medicine* 15:15-50.

Lippman, A. 1992. "Led (astray) by Genetic Maps: The Cartography of the Human Genome and Health Care. *Social Sciences and Medicine* 35:1469-76.

Lippman, A. 1994. "The Genetic Construction of Prenatal Testing: Choice, Consent or Conformity for Women?" In *Women and Prenatal Testing: Facing the Challenges of Genetic Testing*, ed. K. H. Rothenberg and E. J. Thomson, 9-34. Columbus: Ohio State University.

Markel, K. S., and L. Barclay. 2007. "Discrimination and Stigmatization in Work Organizations: A Multiple Level Framework for Research on Genetic Testing." *Human Relations* 60:953-80.

Mastenbroek, S., M. Twisk, J. van Echten-Arends, B. Sikkema-Raddatz, J. C. Korevaar, H. R. Verhoeve, N. E. A. Vogel, E. G. J. M. Arts, J. W. A. de Vries, P. M. Bossuyt, C. H. C. M. Buys, M. J. Heineman, S. Repping, and F. van der Veen. 2007. "In Vitro Fertilization with Pre-Implantation Genetic Screening." *The New England Journal of Medicine* 357:9-17.

Matorras, R. 2002. "La reproducción asistida en el sistema sanitario publico español." *Revista Iberoamericana de Fertilidad* 19:103-8.

McLaren, A. 1987. "Can We Diagnose Genetic Diseases in Pre-Embryos?" *New Scientists*, December 10, 42-7.

Mladovsky, P. 2006. "IVF and Reproductive Tourism." *Euro Observer* 8:5-7.

Nelkin, D., and M. S. Lindee. 1995. *The DNA Mystique: The Gene as a Cultural Icon*. New York: Freeman.

Nyboe, Andersen, A., V. Goossens, S. Bhattacharya, A. P. Ferraretti, M. S. Kupka, J. de Mouzon, and K. G. Nygren. A. 2009. "Assisted Reproductive Technology and Intrauterine Inseminations in Europe, 2005: Results Generated from European Registers by ESHRE." *Human Reproduction* 24:1267-87.

Organisation for Economic Co-operation and Development (OECD). 2007. *OECD Guidelines for Quality Assurance in Molecular Genetic Testing*. Paris: OECD Press. Accessed www.oecd.org

Parens, E., and A. Asch. 1999. "Special Supplement: The Disability Rights Critique of Prenatal Genetic Testing Reflections and Recommendations." *The Hastings Center Report, 29(5) (September–October, 1999),* S1-S22.

Patlak, M., and L. Levit. 2010. *Policy Issues in the development of Personalized Medicine in Oncology: Workshop Summary*. Washington, DC: The National Academies Press.

Pavone, V. 2010. "Genetic Testing, Geneticization and Social Change." In *Assessing Life: On the Organization of Genetic Testing*, ed. B. Wieser and W. Berger, 101-32. München: Profil and Verlag.

Pehlivan, T., C Rubio, L. Rodrigo, J. Romero, J. Remohi, C. Simón, and A. Pellicer. 2003. Impact of Pre-Implantation Genetic Diagnosis on IVF Outcome in Implantation Failure Patients. *Reproductive BioMedicine Online* 6:232-7.

Pembrey, M. 2002. "Social Sex Selection by Pre-Implantation Genetic Diagnosis." *Reproductive Biomedicine Online* 4:157-9.

Roberts, C., and S. Franklin. 2004. "Experiencing New Forms of Genetic Choice: Findings from an Ethnographic Study of Preimplantation Genetic Diagnosis." *Human Fertility* 7:285-93.

Robertson, J. A. 2002. "Sex Selection for Gender Variety by Pre-Implantation Genetic Diagnosis." *Fertility and sterility* 78:463.

Royal Society. 2005. *Personalized Medicine: Hopes and Realities*. London: The Royal Society.

Sedo, K. 2007. "Workers' Compensation, Social Security Disability, SSI, and Genetic Testing." *The Journal of Law, Medicine & Ethics* 35:74-9.

Skully, J. L., Banks, S., and T. W. Shakespeare. 2006. "Chance, Choice and Control: Lay Debate on Prenatal Sex Selection." *Social Sciences and Medicine* 63: 21-31.

Soo-Jin Lee, S. 2005. "Racializing Drug Design: Implications of Pharmacogenomics for Health Disparities." *American Journal of Public Health* 95: 2133-38.

Spar, D. 2005. "Reproductive Tourism and the Regulatory Map." *New England Journal of Medicine* 352:531-3.

Stempsey, W. E. 2006. "The Geneticization of Diagnostics." *Medicine Healthcare and Philosophy* 9:193-200.

Stephenson, E. L., C. Mason, and P. R. Braude. 2009. "Preimplantation Genetic Diagnosis as a Source of Human Embryonic Stem Cells for Disease Research and Drug Discovery." *British Journal of Obstetrics and Gynaecology* 116:158-65.

Svendsen, M. N., and L. Koch. 2008. "Unpacking the "Spare Embryo": Facilitating Stem Cell Research in a Moral Landscape." *Social Studies of Science* 38: 93-110.

Ten Have, H. A. 2001. "Genetics and Culture: The Geneticization Thesis." *Medicine, Healthcare and Philosophy* 4:295-304.

Thornhill, A. R., C. E. de Die-Smulders, J. P. Geraedts, J. C. Harper, G. L. Harton, S. A. Lavery, C. Moutou, M. D. Robinson, A. G. Schmutzler, P. N. Scriven, K. D. Sermon, and L. Wilton. 2005. "ESHRE PGD Consortium: Best Practice Guidelines for Clinical Pre-Implantation Genetic Diagnosis (PGD) and Pre-Implantation Genetic Screening (PGS)." *Human Reproduction* 20:35-48.

Vailly, J. 2006. "Genetic Screening as a Technique of Government: The Case of Neo-Natal Screening for Cystic Fibrosis in France." *Social Sciences and Medicine* 63:3092-101.

Vailly, J. 2008. "The Expansion of Abnormality and the Biomedical Norm: Neonatal Screening, Prenatal Diagnosis and Cystic Fibrosis in France." *Social Sciences and Medicine* 66:2532-43.

Van Hoyweghen, I. 2010. "Taming the Wild Life of Genes by Law? Genes Reconfiguring Solidarity in Private Insurance." *New Genetics and Society* 29:431-55.

Van Hoyweghen, I., K. Horstman, and R. Schepers. 2007. "Genetic "Risk Carriers" and Lifestyle "Risk Takers"—Which Risks Deserve our Legal Protection in Insurance?" *Health Care Analysis* 15:179-93.

Verlinsky, Y., J. Cohen, S. Munne, L. Gianaroli, J. L. Simpson, A. P. Ferraretti, and A. Kuliev. 2004. "Over a Decade of Experience with Pre-Implantation Genetic Diagnosis: A Multicenter Report." *Fertility and Sterility* 82:292-4.

Verlinsky, Y., S. Rechitsky, W. Schoolcraft, C. Strom, and A. Kuliev. 2001. "Pre-Implantation Diagnosis for Fanconi Anemia Combined With HLA Matching." *Journal of American Medical Association* 285:3130-33.

Verlinsky, Y., N. H. Zech, N. Strelchenko, V. Kukharenko, A. Shkumatov, Z. Zlatopolsky, and A. Kuliev. 2009. "Correlation between Pre-Implantation Genetic Diagnosis for Chromosomal Aneuploidies and the Efficiency of Establishing Human ES Cell Lines." *Stem Cell Research* 2:78-82.

Wainwright, S. P., C. Williams, M. Michael, B. Farsides, and A. Cribb. 2006. "Ethical Boundary-Work in the Embryonic Stem Cell Laboratory." *Sociology of Health & Illness* 28:732-74.

Waldby, C. 2008. "Öocyte Markets: Women's Reproductive Work in Embryonic Stem Cell Research." *New Genetics & Society* 27:19-31.

Waldby, C., and M. Cooper. 2010. "From Reproductive Work to Regenerative Labour—The Female Body and the Stem Cell Industries." *Feminist Theory* 11: 3-22.

Weiner, K., and P. Martin. 2007. "A Genetic Future for Coronary Heart Disease?" *Sociology of Health and Illness* 30:380-95.

Williams, C., K. Ehrich, B. Farsides, and R. Scott. 2007. "Facilitating Choice, Framing Choice: Staff Views on Widening the Scope of Pre-Implantation Genetic Diagnosis." *Social Sciences and Medicine* 65:1094-105.

Williams, C., S. P. Wainwright, K. Ehrich, and M. Michael. 2008. "Human Embryos as Boundary Objects? Some Reflections on the Biomedical Worlds of Embryonic Stem Cells and Pre-Implantation Genetic Diagnosis." *New Genetics and Society* 27:7-18.

Yakin, K., and B. Urman. 2004. "What Next for Pre-Implantation Genetic Diagnosis?" *Human reproduction* 23:1686-90.

Bios

Vincenzo Pavone is research fellow at the Institute of Public Goods and Policies (IPP) of the Consejo Superior de Investigaciones Científicas in Madrid, Spain. His main research interests include the public assessment of biotechnologies, as well as the social and political aspects of genetic testing. Currently, he is investigating the interaction between reproductive and regenerative medicine and the role of bio-objects in the so-called bio-economy.

Flor Arias is associate professor of public law at the Law Department of the University of Extremadura, in Caceres, Spain. Her research interests include normative changes in the regulation and governance of new biotechnologies as well as the dynamics of innovation of public research centres. Currently she has been investigating the normative changes associated with genetic testing and new biomedical technologies in assisted reproduction.