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

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In 2004, the Italian Parliament passed a controversial law on medically assisted reproduction (Law 40/2004). The Law obliged clinicians to create a maximum of three embryos during one in vitro fertilization (IVF) cycle and transfer them simultaneously into the patient’s uterus. With this “three embryo” standard, the Parliament sought to secure the realization of rights of IVF embryos. Drawing on the concepts of boundary-work [Gieryn, T. F. 1983. “Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists.” *American Sociological Review* 48 (6): 781–795] and bioconstitutionalism [Jasanoff, S., ed. 2011. *Reframing Rights: Bioconstitutionalism in the Genetic Age*. Cambridge, MA: MIT Press.], this article explores the role that the constitutional obligations of the Italian State towards its citizens, including IVF embryos as its new “citizen subjects,” played in how it envisaged and demarcated the professional boundaries of medical expertise. It argues that the latter depended upon how it balanced its commitments to protect the rights of IVF embryos and those of adult citizens. As such, the demarcation of the jurisdictional boundaries of medical expertise, and the definition of constitutional rights, formed two sides of the same governing project.

**Keywords:** boundary-work; bioconstitutionalism; Italian human embryo debate

Introduction

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 2005). In legal scholarship, these transformations have been defined by the portmanteau term “bioconstitutionalism” (Jasanoff 2011), 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 1979), as applied by Johnson (2003, 2005) to the analysis of professions, according to which professions and the State are not discrete and 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 in vitro fertilization (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 2005), 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.

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 2011). 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), Rose and Novas called biological citizenship (Rose and Novas 2005).

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 (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 homogeneous 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 2015, 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” (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” (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.

Stage 1. The institution of the Santosuosso Commission, the Degan Circular and the “Far West procreativo”

IVF made its debut in Italian laboratories in the mid-1980s. In 1983, less than five 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, 12 April 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 fulfill 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 fulfillment 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 10 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 remain fluid and volatile (Star and Griesemer 1989; Jasanoff 1990; 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.

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, 1). 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, 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 fulfillment 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, 32). 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, 434). 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” (Repubblica Italiana 2004). 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 2005). 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 (Salter and Jones 2005; Rose 2006; 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, Scott, and Gibbons 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.

**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 nationwide 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, 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, 2011). 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 2005).

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.

**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 fulfill 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 2005).

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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