

'Sidestepping the Embryo'

The Cultural Meaning and Political Uses of Ethical Stem Cells

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Abstract In many countries, stem cell research is embroiled in heated ethical and political debates because the most valued stem cell types are human embryonic stem cells (hESCs) taken from a few-days old human embryo which is destroyed during the harvesting procedure. 'Ethical stem cells' is the label commonly used to denote an array of cellular reprogramming techniques, biological artifacts, and somatic stem cells which make it possible to obtain pluripotent stem cells while avoiding the use of human embryos. This paper, by focusing on the Italian case, analyzes the cultural meaning and the political uses of these bio-objects which incorporate in their ontology the social and ethical quandaries raised by stem cell research in order to sidestep them. The debate on ethical stem cells shows a new way to deal with ethical commitments in biosciences and throws light on the process of regulatory ordering and normativity production in regard to biotechnological innovations.

Keywords: ethical stem cells, human embryo, bioethics, biotechnologies, Italy.

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I. Introduction

In many countries, stem cell research is embroiled in heated ethical and political debates because the most valued stem cell types are human embryonic stem cells (hESCs) taken from a few-days old human embryo which is destroyed during the harvesting procedure. The ethical dilemma springs from the fact that hESCs are highly valued because they are *pluripotent* (i.e. able to develop into almost any cell type) and thus regarded as able to yield a renewable supply of organs and tissue for the treatment of degenerative diseases (Hauskeller and Weber 2011), while the destruc-

tion of the human embryo is morally condemned by those who grant it the status of a human being. The political debate revolves around the management of these two opposing values: that of the 'therapeutic promise' of hESCs, and the so-called 'embryo question' (Rubin 2008).

One of the political means most widely adopted to deal with the moral dilemmas raised by stem cell research has been the development of bioethics committees (Gottweis *et al.* 2009). Bioethics has emerged as the main way to fulfill 'the political need to reconcile the promise of new health technologies with the cultural costs of scientific advance' (Salter and Salter 2007, 555) and as 'a new language of deliberation, geared to the analysis of human values' (Jasanoff 2005, 172). In its interplay between institutional mechanisms and expert discourse, bioethics seemed to provide a solution to both the 'moral problematization' and the 'more general problematization of scientific governance in terms of public trust' (Moore 2010, 202). Another way to cope with ethical issues related to bioscientific innovations is what Wainwright and colleagues (2006) call 'ethical boundary-work', a process of social demarcation between more or less ethical ways of conducting scientific research which involves a set of perspectives, processes and practices referring to a 'practical ethics' which 'takes the form of a number of choices over how to conduct oneself in a complicated political, moral and epistemic context' (Wainwright *et al.* 2006, 745).

In this paper I shall explore a third way to deal with ethical issues in stem cell research; one in which, instead of delegating the moral evaluation to expert bodies or to the direct commitment of scientists in their practices, the moral problematization is incorporated in the biological objects themselves, whose ontology would be constructed precisely in order to solve ethical quandaries through an epistemic discourse, thereby challenging or reinforcing an existing regulatory regime on stem cell research. I refer to so-called 'ethical stem cells', which is the label introduced both in scientific literature and in mass media discourses to denote an array of cellular reprogramming techniques, biological artifacts, and somatic stem cells which would make it possible to obtain pluripotent stem cells while avoiding the use of human embryos. Indeed, the embryo question has dominated the public debate, overshadowing other ethical and social concerns (Prainsack *et al.* 2008). Especially (but not only) in countries such as Italy, where the human embryo has been legally defined as possessing the status of a fully human subject, the embryo question has monopolized the ethical debate, becoming *the* ethical issue in stem cell research. Therefore, ethics has come to coincide with avoiding the use of human embryos, and pluripotent stem cells harvested from non-embryonic sources have been publicly defined as 'ethical'. Both in the scientific literature and mass media discourses, it has been hoped that ethical stem cells would defuse political and moral conflicts. Italy provides a paradigmatic example to study of the cultural significance of ethical stem cells and their political use in challenging or reinforcing the cur-

rent Italian stem cell regulation. By focusing on the Italian case, I shall explore what can be learned from the debate on ethical stem cells in regard to the making of regulatory orders in biotechnologies in general.

In this paper I critically develop some insights of Sarah Franklin, in particular her claim that in our biotechnological era ‘the social is literally being reinstalled within the biological’ (Franklin 2001, 342), and also that ethics ‘can be “built in” to new life-forms’ because one way to allay public anxiety ‘is to re-engineer an ethically sensitive biotechnology’ (Franklin 2001, 342). I shall similarly consider the work of Giuseppe Testa, who has defined ethical stem cells as attempts ‘to solve ethical quandaries through technological means’, since they ‘must be constructed, genetically and conceptually in such a way that [they are] visibly, self-evidently ... biological artefacts’ (Testa 2008, 441). In this regard, I consider ethical stem cells and their sources to be what Webster terms ‘bio-objects’, that is, technoscientifically created life forms and ‘technologically enacted vital materiality’ emerging from the process of bio-objectification in which the boundaries of life ‘are questioned and destabilized, though sometimes can be re-established or re-confirmed’ (Webster 2012, 1-2). Ethical stem cells sources as bio-objects have ‘considerable fluidity and mobility across different socio-technical domains ... or even contrasting cultural meanings’ (Webster 2012, 3), and they leave many questions open, rather than simply solving problems. This paper aims to address some of these questions. In particular: have ethical stem cells been successful in defusing political and ethical quandaries in Italy? Or has their ontology (i.e. as non-embryonic sources of pluripotent stem cells similar to embryonic ones) been called into question? Have they allowed a research trajectory conjugating the therapeutic promise of pluripotent stem cells with the safeguarding of the human embryo? Or have they instead simply changed the terms of the debate, by inaugurating a new language and moving ethical and political quandaries to a different terrain? In other words, what have been their cultural meanings and political effects in the Italian stem cell debate and regulation?

In order to answer these questions I shall trace the trajectories of the different kinds of ethical stem cells from scientific journals to the Italian public sphere. Indeed, even if ethical commitment is at the core of scientific work, it is not circumscribed to the social space of laboratory practices, since the discussion on ethical stem cells is also pursued in the public sphere and is involved in attempts to modify or reinforce existing regulations. The mass media are considered an important arena for the construction of policymaking in biotechnologies (Nisbet and Lewenstein 2002; Kitinger and Williams 2005). Here, however, I shall follow the network of interconnections from the laboratory to the public discourses and regulations (Horst 2005). My purpose will be to trace the evolution and transformation of definitional work on the ontology of ethical stem cells in different social spaces: from its construction in the scientific literature, through its discussion in the public sphere, to its implementation in

regulatory and normative devices. In this sense the paper also follows a second trajectory: from the framing of scientific and ethical issues in the worldwide scientific literature, to their translation in the public debate and the regulatory process in Italy. The Italian debate it is used as a paradigmatic example of the problems arising from the development of novel stem cell technologies. The discussion will then return to the more general meaning of ethical stem cells, and to the questions left open in the debate on stem cell research regulation in general. This paper is based on discourse analysis carried out on articles published by scientific journals, policy texts and documents produced by bioethical advisory committees, as well as newspapers articles. I collected articles published by the three most widely circulating Italian newspapers (*Corriere della Sera*, *La Repubblica*, *Il Fatto Quotidiano*), the main fora of hESC opponents (*Il Foglio*, *L'Osservatore Romano* and *Avvenire*), and other relevant journals (e.g. the left-wing *L'Unità* and *Tempi*, the magazine of the Catholic movement *Communion and Liberation*). Using the electronic archives of these newspapers, I collected all the articles published in their printed version from 16 October 2005 (the publication date of the first scientific articles on ethical stem cells) to 8 October 2012 (the announcement of the Nobel Prize awarded to Shinya Yamanaka, the discoverer of the induction of pluripotency technique), on which I conducted qualitative discourse analysis.

2. The political meaning of ethical stem cells in the Italian stem cell debate

According to Gottweis and colleagues (2009), the ethical reasoning implemented by bioethics committees has played an important role in the political management of the regulatory challenges of hESC research. Public bioethics is defined as ‘a complex of institutions, practices and discourses, whose purpose is to connect policy making with ethical considerations... in order to improve political decision-making’ (Moore 2010, 198). Bioethics, as a neutral and authoritative discourse on ethical conflicts concerning biomedical innovations, presupposes that the tensions among different normative views, values and worldviews may be resolved through the formulation of a unifying and consensual normative culture. Moreover, bioethics, with its reference to scientific knowledge, claims to be a device producing normativity, that is, a typical truth discourse which legitimates political decisions in modern biopolitics (see Foucault 1976; Rabinow and Rose 2006). Therefore, bioethics bodies are institutions and bureaucratic devices – established as state-sanctioned authorities – which through the deployment of an expert discourse set the decision-making agenda and legitimize governments’ regulatory decisions (Salter and Salter 2007; Gottweis *et al.* 2009).

However, bioethics is not always able to resolve conflicts, and the re-

sulting regulations are contested rather than being consensual. In many countries, the tension between the therapeutic promise of hESCs and the embryo question has not been settled through the adoption of a normative framework harmonizing the competing standpoints. Rather, it has been resolved through arbitrary decisions whereby hESC research is forbidden or seriously hampered, so that the emerging regulations are strongly challenged. Furthermore, the conflict has not been merely ethical, regarding the moral and ontological status of the human embryo – and therefore the underlying normative views of the society deemed desirable – but in most cases also the scientific knowledge on which the regulation is grounded has been seriously contested as not having sufficient epistemic robustness.

When the controversy on hESC research has become intractable, ethical stem cells have been presented in scientific articles as a suitable means to circumvent the impasse. Indeed, under the umbrella of the label ‘ethical stem cells’ it is possible to gather a wide array of bio-objects whose aim is to obtain pluripotent stem cells avoiding the destruction of human embryos. In the case of ethical stem cells, the commitment to ethics is not delegated to an institutionalized moral expertise, nor to the practical choice and the conduct of scientists; it is instead incorporated directly into the biological objects. It would thus be the ontology and biological features themselves of these objects that solve the ethical quandaries of stem cell research by sidestepping the passage through the biological entity which embodies the moral dilemma: the human embryo. As Testa (2008) pointed out, these bio-objects offer a technical solution to political problems and ethical quandaries, since controversies would be resolved not through the outcome of a confrontation between ethical stances and political choices, but through the alleged neutrality of a biotechnological procedure which depoliticizes the ethical quandary through the ‘belief in the power of objective facts’ (Testa 2008, 441). Moreover, the discussion on such bio-objects, as will be shown in more detail in the next sections, does not take the form of an ethical confrontation on the morality of the biotechnological procedure employed; rather, it is an epistemic evaluation of the ontology, the scientific reliability and therapeutic effectiveness of these objects. In other words, these bio-objects avoid the problem of developing a consensual normative culture – by embedding ethical and political quandaries into their ontology – and they delegate the question of normativity to the authority of the truth discourse on stem cell biology. But, as we shall see, this is not an unproblematic process, since the ontology of ethical stem cells is not *hic et simpliciter* accepted; rather, it entails complex and contested definitional work on both their biological ontology and their ethicality.

Italy is a suitable case for studying the cultural meaning and the political uses of ethical stem cells. Italy, in fact, has enacted one of the most restrictive regulations on stem cell research which seriously hampers hESC research (Metzler 2007; Gottweis *et al.* 2009). Notwithstanding the re-

course to bioethics, the resulting stem cell research regulation has been strongly contested as the outcome not of a shared consensus, but of merely political decisions based on scientific knowledge not regarded as authoritative.

Indeed, at the beginning of the debate in August 2000, the Italian government delegated the task of formulating policy suggestions for the regulation of stem cell research to the National Bioethics Committee (Comitato Nazionale di Bioetica, henceforth CNB) and to an *ad hoc* commission appointed by the former Health Minister Umberto Veronesi and chaired by the Nobel-prize winner Renato Dulbecco (known as the Dulbecco Commission). The delegation to expert bodies – usually seen as a way to de-politicize complex issues and to obtain authoritative knowledge for policy-making – failed to solve the conflicts over stem cell research. Both committees were accused of ideological partisanship, and both of them split on the embryo question because the Catholic members of both committees opposed the use of human embryos for stem cell research (CNB 2000; Dulbecco Report 2000). The policy suggestions contained in the two documents were never discussed by the Italian parliament.

The Italian stem cell regulation emerged in the period 2001-2005 during government of the centre-right coalition. Firstly, in 2001 the former health minister Girolamo Sirchia decided to allocate public funding only to research on non-embryonic stem cells (the so-called adult stem cells, ASCs henceforth). Secondly, enacted in 2004 was the Italian law on medically assisted fertilization (Law 40/2004), which forbids the use of human embryos for research purposes, the somatic cell nuclear transfer (SCNT) technique, and the production of hybrid and chimeras mixing human and animal gametes. Therefore, Italian stem cell scientists cannot derive embryonic stem cell from embryos left over from IVF treatments, nor can they produce embryos via SCNT for research purposes (Metzler 2007). Finally, in 2005 the Italian government, together with the ministers of other European countries opposed to European Union financing of hESC research, and, if this decision had succeeded, Italian researchers in the field of the hESCs would have excluded from not only national but also EC funding. The entire Italian regulatory regime of stem cell science is grounded on a particular declination of the dilemma between the embryo question and the therapeutic promise. On the one hand, law 40/2004 considered the human embryo to be not only a human being but also a public citizen subject (Metzler 2007, 417) protected by the law; on the other hand, the research funding policies stated that ASCs were the most credible therapeutic promise in regenerative medicine.

The ASC/hESC opposition in the competition for the most credible future source for therapies is common across countries (Parry 2003; Kitzinger and Williams 2005; Hauskeller and Weber 2011), but in Italy it has assumed a distinctive central role (Beltrame 2012; Testa 2012), entering into the lay/Catholic cleavage – one of the most performative socio-

political oppositions in Italian public life (Rusconi 2000). By prohibiting the use of human embryos and research on hESCs, Catholic actors used this debate as a means to affirm the Christian roots of the polity and to shape the social and political order according to their worldview. But they also affirmed that ASCs were more effective in clinical applications and, albeit non-pluripotent, perfectly able to fulfill the therapeutic promise of regenerative medicine (Beltrame 2012). The biological discourse on ASCs clinical effectiveness has been the scientific basis for the Italian regulation, firstly because it conjugates the principle of the defense of human dignity with the value of protecting and improving the health of the population, secondly because it provides an epistemic justification for political choices grounded on ethical orientations.¹ As a consequence, the struggle for hESC research has been framed as a fight to assert the secular nature of the Italian social order, and the hESC/ASC opposition has overlapped with the lay/Catholic cleavage: the struggle between two different views of the normative culture underpinning the social order has been embedded in an epistemic discussion on the most credible therapeutic promise in stem cell research.

Because the Italian regulation did not emerge from shared consensus but instead from contingent power relations in the parliament and key institutions (the centre-right coalition was in power and it was close to Catholic positions), and because its scientific base was considered not epistemically robust, it was strongly criticized. In 2005 a popular referendum was held to abrogate some articles of the Law 40/2004, including the ban on the use of human embryos for research purposes. The referendum failed because the turnout was only 25.9%, very distant from the *quorum* required by the Italian Constitution for a referendum to be considered valid (i.e. 50% plus one of the Italian electorate must have cast votes). Given the political strength of the actors who opposed the use of human embryos and supported ASCs, as well as the failed challenge against the regulation, the advent of ethical stem cells seemed a way to circumvent the Italian regulatory regime in order to make research on pluripotent cells possible while avoiding a direct confrontation on the legal status of the human embryo – whose outcome appeared inevitable amid the power relations of the time.

3. The advent of quasi-embryos in the Italian public sphere

In exploring the cultural and political meaning of ethical stem cells in the Italian public sphere, it is useful to draw an analytical distinction between two main groups: the first comprises cellular reprogramming tech-

¹ The improvement and protection of health and life itself is the central value in modern biopolitics, and (scientific) truth is the legitimizing principle of contemporary (bio)power (Foucault 1976; 1980; Rabinow and Rose 2006).

niques involving biological entities with a contested status because they appear similar to an embryo but are defined as not proper embryos (i.e. parthenotes, cytoplasmic hybrids, and embryoids produced by altered nuclear transfer); the second includes non-embryonic stem cells characterized as pluripotent, as well as so-called induced pluripotent stem (iPS) cells. This distinction is necessary because in the Italian public debate the former group has been proposed and defended by hESC research supporters, while pro-ASC actors have strongly criticized it and promoted the second group. Therefore, the overlap between hESC/ASC and the lay/Catholic cleavage reappears in the opposition between these two groups of ethical stem cells.

The starting point of the debate on ethical stem cells can be dated to 16 October 2005 when *Nature* published on-line two papers reporting two famous experiments: one concerning the Altered Nuclear Transfer (ANT) technique – a procedure of somatic cell nuclear transfer which silenced the *Cdx2* gene to produce an embryo unable to implant in the uterus (Meissner and Jaenisch 2006) – and the other – carried out by a research team led by Robert Lanza at the biotech company Advanced Cell Technology (ACT) – presenting a single cell embryo biopsy which would make it possible to establish embryonic cell lines without interference with the embryo's development (Chung *et al.* 2006). Both experiments were conducted on mouse embryos and both directly addressed the ethical commitment to avoiding the embryo question and the need to obtain pluripotent stem cells. Indeed, in *Nature* the two experiments were presented in these terms:

In this issue are two new methods for producing pluripotent stem-cell lines — the great future hope of regenerative medicine ... The protocols each aim to satisfy the religious, ethical and/or political objections of groups that are opposed to some of the methods used in embryonic stem-cell research. (Weissman 2006, 145)

The ANT technique was described as ethically sensitive because, whilst the conventional nuclear transfer produces a '*reconstructed human blastocyst*' which 'lack[s] the potential to develop into normal human beings', ANT 'further cripples an *already compromised blastocyst* and eliminates the developmental potential to implant into the uterus to establish the fetal-maternal connection' (Meissner and Jaenisch 2006, 214, *emphasis added*). Here we can observe careful definitional work in which the cloned embryo is renamed a '*reconstructed blastocyst*', and the human status is identified with 'embryo development' and 'the fetal-maternal connection'. Since the bio-object produced morphologically fails to fulfill these two aims, according to its proponents, it cannot be considered an embryo, so that its deployment appears to be ethical. The ANT paper is particularly interesting because it was encapsulated in a discursive reper-

toire replete with cultural implications which could be named the ‘discourse on quasi-embryos’. Indeed, ANT produces an entity which pro-HEsCs actors define as a quasi-embryo because it lacks the capacity to develop.

The discourse on quasi-embryos in Italy was first developed with the release of the Dulbecco Report (2000). As Testa (2012) noted, the most important epistemological contribution of the Dulbecco Commission was its unanimous endorsement of somatic cell nuclear transfer (SCNT). This technique was deemed exempt from ethical problems because its product was defined as ‘*an oocyte reconstituted with the nucleus of an adult somatic cell*’, which ‘cannot be considered a zygote in the usual sense in that it does not derive from the union of two gametes’, and it ‘is proven by the fact that *such a reconstructed oocyte does not develop spontaneously into an embryo*, and this happens only following artificial stimulations that force it to develop into a blastocyst’ (Dulbecco Report 2000, 8, emphasis added).

Similarly, this discourse was deployed also in the case of an experiment in artificial parthenogenesis – a technique that forces an oocyte to develop into an embryoid without sperm fertilization – conducted by an Italian research team led by Fulvio Gandolfi (Paffoni *et al.* 2007). Parthenotes were defined ‘*embryo-like structures that develop from eggs without the need for fertilization*’, and since mammalian parthenotes ‘always die before implanting in the womb, but they survive long enough to be a potential source of stem cells’, they appeared to be ‘an ethically acceptable source of stem cells’ because they do not involve the human embryo (Marchant 2006, 1038, emphasis added). Gandolfi’s team defined human parthenotes as ‘parthenogenetically activated oocytes’ (Paffoni *et al.* 2007, 81) and the newspaper *La Repubblica* presented this bio-object as a ‘mock embryo... entirely formed from stem cells... [and] incapable of growing in the uterus and generating a new life’, according to the principle that ‘If it does not initiate a new life, it cannot be defined an embryo in every effect’ (*La Repubblica*, 29 June 2006). In 2006 the stem cells obtained by Meissner and Jaenisch, and by Lanza’s and Gandolfi’s teams, were labeled ‘ethical stem cells’ (see Marchant 2006; Abbot 2006), and this definition entered scientific and public discourse as well.

Another case of quasi-embryos deployed to circumvent the Italian regulatory regime has been that of human-animal cytoplasmic hybrid embryos (cybrids). These are biological entities created through SCNT in which a human cell nucleus is implanted in a previously enucleated animal oocyte, so that the resulting embryo has a human nuclear DNA and an animal cytoplasmic DNA (mitochondrial DNA); or, in other words, it is 99.9% human. The Italian debate was sparked by the corresponding debate in the UK, where the Human Fertilisation and Embryology Authority (HFEA) and then the British parliament allowed the creation of transpecies cybrids under license, defining them as prevalingly human in order to permit their creation under the British law (Brown 2009). In Ita-

ly, by contrast, since the Italian law prohibits the use of human embryos for research purposes, these entities should be characterized as not properly human. Moreover, because the Italian law 40/2004 also bans 'the insemination of human gametes by gametes from different species and the production of hybrids and chimeras' (Law 40/2004, art. 13 sec. d), the proposal of cybrid research required more complicated definitional work. The proponents had to demonstrate that cybrids are simple biological artifacts incapable of embryonic development – that is, they are quasi-embryos. Developmental biologist Carlo Alberto Redi declared that 'the cybrid is a kind of *laboratory in miniature, a fantastic tool*' (*Corriere della Sera*, 6 September 2007, emphasis added), and geneticist Giuseppe Novelli explained that cybrids are simple biological artifacts as 'the incompatibilities between the cell's nucleus and the surrounding part, the cytoplasm, are too great: the foetus would never develop' (*La Repubblica*, 6 September 2007).

In general these bio-objects were constructed and defined as artifacts permitting research on pluripotent stem cells similar to embryonic ones without involving human embryos. Their ontology was constructed both materially (in the lab) and discursively (from scientific journals to mass media and policy documents) to emphasize their non-embryonic nature. These various objects – SCNT reconstructed oocytes, ANT embryos, parthenotes, and cybrids – share a common feature: the lack of a biological component, which configures them as not proper embryos because it impedes the normal embryo development. According to Testa (2008), these quasi-embryos could solve the ethical quandaries, by presenting themselves as merely technological means, since they are 'genetically and conceptually' constructed, as 'biological artifacts' (Testa 2008, 441), skipping the living entity around which the controversy revolves: the human embryo. The focus on embryo development is the centre of the quasi-embryo discourse and, therefore, the cornerstone of its contestation.

Indeed, in the Catholic and pro-life discourse the humanness of the embryo is located in its capacity to develop into a human being: for example the Pontifical Academy for Life (PAL 2000) defined the human embryo 'a *human subject* with a well defined identity' which from the union of the gametes 'begins its own *coordinated, continuous and gradual development*'. Therefore, sidestepping the embryo question implies avoiding natural fertilization and embryo development. According to Testa (2008), in the quasi-embryo discourse, embryo development is decomposed into the biological components and organized structures which make it possible. The lack of one of these components implies an entity which cannot be defined as a living human being because it is incapable of the 'coordinated, continuous and gradual development' characterizing the *true* embryo in the pro-life discourse. These quasi-embryos are intentionally constructed in the lab with these features, and they are discursively presented in the public sphere through a definitional work emphasizing a particular ontology, that of artifacts created only to allow the establishment of plu-

ripotent cell lines sidestepping the embryo. There is an awareness of the set of social issues, ethical stances, and power relations involved in the stem cell debate which is reflexively embedded in the construction of these bio-objects. According to Testa (2008, 442), this 'what component part question' is 'epistemic in nature' and an 'attractive route to depoliticize the conflict over nascent human forms'. With these bio-objects, the stem cell controversy would not be solved through negotiation on ethical stances and political choices, but instead through the alleged neutrality of a biotechnological procedure.

However, these bio-objects were not undisputed: the debate took the form of an epistemic evaluation of the ontology, scientific reliability, and therapeutic effectiveness of these objects. The ANT technique was criticized on the grounds that the silencing of *Cdx2* was not sufficient to solve the ethical problem because, according to molecular biologist (and priest) Roberto Colombo, ANT produces 'a *human embryo* with a deficiency artificially and intentionally made by the researcher' (*Avvenire*, 18 October 2005, emphasis added). In the case of the SCNT technique presented in the Dulbecco Report, Vatican spokesperson monsignor Elio Sgreccia declared that the fact that SCNT does not produce embryos is 'a simple hypothesis not yet corroborated by any research published in a scientific journal' (*L'Osservatore Romano*, 10 January 2001). The human-animal cybridization technique was discussed in 2009 by the CNB and the majority opinion discarded it doing so on the grounds that, since SCNT creates living entities with 'developmental defects and anomalies' when applied among the same species, inter-species cybridization would increase these problems. It would generate 'cells with genetic anomalies' which would be 'useless... as models for the study of a disease, and they could not have any therapeutic application', and 'owing to their contamination with animal material... they would have limited or no importance for the study of diseases ... with the risk of interspecies transmission of viral agents' (CNB 2009, 22).

Since the proposal of SCNT contained in the Dulbecco Report was never discussed by the Parliament, the majority opinion of the CNB rejected the human-animal cybridization technique, and since Law 40/2004 prohibited 'cloning procedures through nuclear transfer' and the 'creation of hybrids and chimeras' (Law 40/2004, art. 13, sect. 3c), we can conclude that these novel bio-objects failed as means to circumvent and defuse ethical quandaries, as well as to challenge the existing Italian stem cell research regulation. Also their ontology as quasi-embryos was called into question, as well as their ability to produce therapeutically useful pluripotent stem cells for human clinical settings. Nevertheless, these bio-objects introduced a new language in which the ethical dimension was incorporated into bio-objects, so that the public discussion took the form of an epistemic discourse.

4. Non-embryonic pluripotent stem cells and the significance of pluripotency

Whilst the prospect of carrying out research on quasi-embryos was proposed mainly by supporters of hESCs, the other group of ethical stem cells seemed to pertain to ASCs proponents. The second group of ethical stem cells comprises non-embryonic pluripotent stem cells (i.e. discovered in somatic tissues) and cellular reprogramming techniques which, through genetic manipulations, reverse somatic cells into embryonic-like pluripotent stem cells. Even if ASC supporters justified the Italian regulation by stating that ASCs were more clinically effective and useful than hESCs – to the point that during the 2005 referendum campaign hESCs were defined as therapeutically useless and dangerous (Beltrame 2012, 219) – the discourse on pluripotency remained a critical and contradictory point in this discursive articulation. To be sure, during the referendum campaign, while pluripotency was being defined as therapeutically useless and dangerous, stem cell scientist Angelo Vescovi (one of the most important spokespersons for the anti-hESC front) favorably cited two techniques of cellular reprogramming developed by Douglas Melton's and Yuri Verlinsky's research teams (Cowan *et al.* 2005; Strelchenko *et al.* 2006), which had used hESCs cytoplasm to dedifferentiate somatic cell nuclei in order to transform somatic cells into pluripotent stem cells. In other words, the same scientists and commentators who criticized pluripotency acclaimed cellular reprogramming techniques aimed at transforming ASC into pluripotent cells similar to hESCs. Hence, pluripotency regained primacy, and hESCs indirectly became the 'gold standard' for evaluating the potency of any kind of stem cell.

The most discussed and relevant source of non-embryonic pluripotent stem cells – i.e. opposed to contested quasi-embryos – were the pluripotent stem cells discovered in the amniotic fluid (De Coppi *et al.* 2007) and the famous induced Pluripotent Stem (iPS) cells (Takahashi and Yamanaka 2006). Amniotic Fluid-derived Stem (AFS) cells were defined as representing 'an intermediate stage between pluripotent ES cells and lineage-restricted adult stem cells' (De Coppi *et al.* 2007, 103); but, in another part of the article, the authors sought to blur the boundary between multipotency and pluripotency by stating that 'AFS cells are indeed broad-spectrum multipotent (*that is, pluripotent*) stem cells' (De Coppi *et al.* 2007, 101, emphasis added). Nevertheless, AFS cells failed to 'overcome the ethical obstacle blocking this strand of research' (*La Repubblica*, 9 January 2007). Some contested their ethical status by highlighting the fact that the amniotic fluid is obtained through amniocentesis, a prenatal genetic diagnosis criticized as risky for the fetus and as a new form of eugenics. But the most interesting controversy concerned the biological status of these cells. Whilst Catholic actors and pro-ASC newspapers defined AFS cells as pluripotent, hESC research supporters highlighted the

definition of a ‘intermediate state’ between hESCs and ASCs. Finally, in March 2008 *Nature Biotechnology* published an article in which the Italian research team led by stem cell scientist Elena Cattaneo explained that the results of Atala and De Coppi’s work (De Coppi *et al.* 2007) were not sufficient to demonstrate that AFSc ‘can give rise *in vitro* to neurons’ (Toselli *et al.* 2008, 269). The boundary between pluripotency and multipotency, made porous and flexible by the definitional work on AFSc cells, was thus re-established, restoring these cells to the rank of multipotent stem cells. As in the case of quasi-embryos, the discussion rotated around the biological status, and ethical and political implications were embedded in an epistemic discourse.

Publicly considered to be ethical stem cells *par excellence* are iPS cells. Indeed, the cellular dedifferentiation technique developed by the Japanese team led by Yamanaka consists in reprogramming somatic cells into pluripotent stem cells similar to hESCs by artificially forcing the expression of certain genes. In 2012, Yamanaka was awarded the Nobel Prize in physiology and medicine ‘for the discovery that mature cells can be reprogrammed to become pluripotent’ (Nobelprize.org 2012), and not only Catholic newspapers and magazines, but also secular newspapers carried the headline ‘ethical stem cells awarded Nobel Prize’ (e.g. *Il Fatto Quotidiano*, 8 October 2012). This testifies to how, in the public imagery and discourse, iPS had come to coincide with ethical stem cells and moved to the centre of public discussions on this non-embryonic source of pluripotent cells.

The first breakthrough came on 25 August 2006, when the journal *Cell* published a famous article on the induction of pluripotency in mouse somatic cells (Takahashi and Yamanaka 2006), but the public’s attention was directed to iPS cells on 20 November 2007 when *Cell* and *Science* published two articles – one by the Yamanaka team (Takahashi *et al.* 2007) and the other by a team led by James Thomson (Yu *et al.* 2007), which in 1998 had derived the first hESC line (Thomson *et al.* 1998) – reporting the induction of pluripotency on human cells. The fact that one of the research teams was led by the person who had given rise to hESC research was seen as the end of the stem cell war and as the capitulation of hESC research. Indeed, the newspaper *Il Foglio* commented: ‘The cultural war on embryos has probably ended’ (*Il Foglio*, 23 November 2007).

Nevertheless, another article in *Il Foglio* highlighted that, in Italy, the discovery of iPS cells did not defuse the struggle over stem cell research. Indeed, as Hauskeller and Weber (2011) have noted, iPS cells were subject to a debate on the legacy of hESC research. While ASC supporters argued (and continue to do so) that iPS cells belong to the family of ASCs,² hESC scientists highlighted that the discoverers of iPS cells had

² For example, when Yamanaka won the Nobel Prize, the Catholic news magazine *Tempi* carried the headline: *Nobel Prize to adult stem cells* (“Tempi”, October 8, 2012).

'longstanding experience with and in-depth knowledge of culturing and experimenting on hES cells' that rendered 'hES cell researchers as a privileged epistemic group in the study of iPS cells and present iPS cells as a direct follow-on from hES cell research' (Hauskeller and Weber 2011, 424). Indeed, whilst for *Il Foglio* the discovery of iPS cells belonged among 'results that arrive from the adult stem cells front' (*Il Foglio*, 21 November 2007), geneticist Giuseppe Novelli declared that 'research on embryo stem cells is still indispensable, for without it these results would not have been achieved' (*La Repubblica*, 21 November 2007). Although *Il Foglio* declared that iPS cells rendered the use of embryos obsolete (*Il Foglio*, 13 December 2007), Yamanaka stated that 'the recent advancements in iPS cell research would not be possible if it were not for the many years of dedicated hES cell research that preceded them' (Hyun *et al.* 2007, 368) and, therefore, 'it would be a serious mistake to conclude that recent developments in iPS cell research (or, for that matter, any other so-called "alternative" source of pluripotent stem cells) avert the need for ongoing research on hES cells' (Hyun *et al.* 2007, 367). HESCs remained the gold standard with which to evaluate the real pluripotency of any given stem cell, because several studies had shown that the factor-based reprogramming used in iPS method can leave an epigenetic memory of the tissue of origin that may influence efforts directed at the differentiation of the reprogrammed cell (Kim *et al.* 2010) and there were doubts about the equivalence between iPS cells and hESCs (see Hanna *et al.* 2010). Moreover, on discussing the human-animal cybridization technique, even though the majority of the CNB stated that iPS cells 'appear more promising and effective than SCNT', it also recognized that 'these are not cells identical with embryo stem cells ... they raise safety problems from a therapeutic standpoint because all the significant factors in the reprogramming are oncogenic' (CNB 2009, 18).

Despite the doubts concerning the biological ontology of AFS cells and the controversy on the legacy of hESC research in iPS technique – both centered on the significance of pluripotency – these ethical stem cells were enlisted in political controversies. Indeed, in the summer of 2006, the new University and Research Minister Fabio Mussi (a member of the centre-left political coalition which won the 2006 national elections) removed Italy's signature from the document which excluded research projects involving human embryonic stem cells from financing under the EC Seventh Framework Programme (FP7). This decision provoked a heated parliamentary debate with demands that the so-called Mussi Act should be withdrawn and that the Italian Government should impose limits on hESC research under the FP7. However, these demands were rejected. The discovery of AFS cells was used in this debate. For example, the left-wing Catholic politician and activist Luigi Bobba declared: 'In light of this discovery... Minister Mussi should draw the consequences from the breakthrough. The EU must not finance the destruction of embryo cells' (*La Repubblica*, 8 January 2007). Similarly, on 21 November

2007, in a leading article in *Avvenire*, Eugenia Rocella (a pro-life activist and future Deputy Minister in the centre-right government in 2008) used the announcement of the discovery of human iPS cells to call for a five-year moratorium on embryo research in Europe. The moratorium was promptly supported by pro-life advocates, Catholic actors and centre-right politicians, and it was proposed to the European Parliament by Deputy Mario Mauro (centre-right), although the response of the European Commissioner for Science and Research Janez Potocnik was negative. For Catholic actors and members of the centre-right political coalition, AFS and iPS cells served both to defend the previous Italian legislation and to challenge the new policy choices, because they demonstrated that there existed non-embryonic pluripotent stem cells which rendered hESC research obsolete. By contrast, for lay activists, such as the bioethicist Maurizio Mori, the fact that ‘Yamanaka developed a method to bring back adult cells to an embryonic state’ was proof that ‘embryonic cells are better than adult ones’. Hence the previous Italian Government’s decision to fund only ASC research was completely wrong (*L’Unità*, 23 November 2007).

Like other ethical stem cells, rather than defusing the stem cell war, also AFS and iPS cells generated conflicts and were used as weapons in the political confrontation. In particular, iPS cells entered into the hESC/ASC opposition, first with demonstration that pluripotency is the most prominent and promising feature of stem cells (on which depends the hope of therapies and clinical applications), and second with the controversy on the role of hESC research into the lineage of iPS cells. Therefore, the struggle between hESCs and ASCs to define the most effective and promising research trajectory in stem cell research did not end but continued through iPS cells.

5. Conclusion: the cultural meaning of ethical stem cells and their political significance

What, therefore, were the cultural and political effects of ethical stem cells? Their ability to defuse political, ethical, and social conflict appeared to be scant; rather, as we have seen, they became the subject of new quarrels and controversies. Likewise, if we consider their function of conjugating the therapeutic promise of pluripotent stem cells with the safeguarding of the human embryo, their general effect was marginal. Especially in the case of the first group of ethical stem cells, i.e. that of quasi-embryos, the attempt to circumvent the embryo question failed, because their ontology and scientific reliability was called into question. Similarly, also the other group of ethical stem cells – apparently less controversial – was unable to defuse the stem cell war because it created a debate on their pluripotency. In part this was due to the fact that these techniques and artifacts were (and still are) in the experimental stage, even if they were pre-

sented in the mass media as 'just around the corner' technologies. On the other hand, debates and quandaries both on their biology and their ethicality reveal to the extent to which their ontologies were instable and open to discussion and contestation.

Does this mean that the effect of ethical stem cells was pointless? No it does not. On the contrary, they were victims of their own success. Indeed, ethical stem cells have incorporated social issues to such an extent that previous controversies have been translated into the more epistemic language that they introduced. This has deep cultural significance. It testifies to the capacity of biotechnologies and the life sciences to create new forms of life which challenge established cultural categories such as life and death (Franklin and Lock 2003). Indeed, a substantial group of techniques to produce ethical stem cells fabricate entities producing living *things* (such as cell lines) without creating living *beings*. According to Testa (2008, 444), this means that 'molecular biology is recruited to reinforce pre-existing moral commitments'. The debate on ethical stem cells shows how cultural values and moral commitments can be embedded, camouflaged and implicitly evoked in epistemic and technological practices and in the discussion on them. The fact that the debate takes the form of an epistemic evaluation of the ontology of these bio-objects – indeed, their moral evaluation depends on and follows their stabilization as non-embryos or as functional and effective sources of pluripotent stem cells – shows how, in modern societies, 'truth is centered on the form of scientific discourse', and how the 'battle for truth', and for 'power attached to the truth', (Foucault 1980, 131-132) is conducted through the deployment of scientific discourses. Moreover, this embedding of ethical issues in epistemic practices, by 'rebuilding embryonic cell lines *without embryos*', testifies the reinstallation of 'the social' within 'the biological', since ethical stem cells appear as epitomizing the re-engineered 'ethically sensitive biotechnology' with which ethics 'can be "built in" to new life-forms' (Franklin 2001, 342; see also Franklin 2005). In the case of ethical stem cells, the therapeutic promise of pluripotent hESCs 'has installed itself so firmly in the discourse on hESC research that ethics is repositioned as a discourse guiding the conduct of embryo/hESC research' (Rubin 2008, 25). In ethical stem cells, the tension between therapeutic promise and the embryo question is not resolved by a moral trade-off (Salter and Salter 2007) between the two values; rather, both are incorporated into bio-objects which are constructed and defined to solve the tension by fulfilling both purposes at the same time. A side effect it is that the moral status of the human embryo as a fully human subject is not called into question. In other words, the attempt to sidestep the embryo question takes for granted the moral status of the early human embryo, so that the embryo question remains the cornerstone of the debate. Indeed, what I have called quasi-embryos are constantly compared to the human embryo, and if their definition fails to denote them as non-embryos they are also regarded as non-ethical sources of stem cells (i.e. they are not ethical

stem cells providers).

The Italian case then throws light on the general problem of regulatory ordering in the field of biotechnologies. On the one hand, it shows how bioethics mediation appears to be insufficient: ethical values and worldviews may be so irreconcilable that they cannot be included in a common and more general normative framework. On the other hand, it suggests that the foundation of such a framework on an alleged natural normativity is equally problematic. The attempt to incorporate ethical quandaries into bio-objects which bypass social conflicts generates new conflicts, because these objects are hybrids (Latour 1991) which constantly switch between nature and culture (Brown *et al.* 2006) and display how the normativity of the natural, the meaning and the boundaries of life are called into question and are open to intervention and manipulation (Nowotny and Testa 2010; Webster 2012). Contrasting definitions and discussions on the ontology of ethical stem cells reveal how Agamben's (1995) problem of the demarcation between *zoé* and *bios* – that is, the inclusion of bare life in the realm of politically qualified existence – is at stake for these bio-objects as well: are they simple artifacts and living *things* or are they living *beings* which have to be included in the bios? This is a problem that cannot be solved simply by invoking the alleged neutrality and authority of epistemic practices. Indeed, according to Nowotny and Testa, in the biotechnological era, nature can no longer be seen as a source of authority – so that 'what is natural is from then on subject to the contingency' of biotechnological intervention, to the point that it 'is becoming a substantially political issue' (Nowotny and Testa 2010, 6). Therefore, how can a biological ontology defuse conflict and underpin a social order only by the objectivity of scientific knowledge about 'the natural', if the natural has lost its moral authority?

Contrary to the idea of the possible emergence of a unifying and consensual normative framework grounded on common values (e.g. the protection of life) and on cognitive categorizations of the natural world (Parsons 1961), this debate supports the Weberian contention that the general ideals of life and the universe which rule human conduct can never be the products of empirical knowledge, but are always and only formed in the struggle with other ideals (Weber 1949). The process of regulatory ordering thus consists in what Jasanoff (2004) terms 'co-production': that is, the mutual process by which knowledge of the (natural and social) world and social formations come symmetrically into being, influencing and reinforcing each other. In particular, we witness the emergence of novel objects whose stabilization in the epistemic domain is strictly connected with the ordering of society because they embed ethical, cultural, and political issues: in this sense, 'solutions to the problem of knowledge are solutions to the problem of social order' (Shapin and Shaffer 1985, 332). Hence, insofar as the scientific (truth) discourse remains the (epistemic) source of legitimacy of any political ordering, the natural order and the normativity of 'the biological' are only evoked as the bedrock un-

derpinning the regulatory order of 'the social'; instead, politics fabricate political-epistemic normativities that simultaneously order 'the social' as well as 'the natural'. The Italian debate on ethical stem cells has tried to shift itself to the terrain of a merely epistemic discussion, but its outcome displays how the regulatory order in biotechnology is nothing but a temporary and local arrangement of tightly intertwined ethical values, worldviews, power relations, epistemic practices, and bio-objects.

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