

Participatory Governance and Institutional Innovation [PAGANINI]
Contract No. CIT2-CT-2004-505791 . Deliverable Number 12

Work Package 2 _ Defining Human Life

HUMAN EMBRYONIC STEM CELL RESEARCH BETWEEN POLITICS AND ETHICS

Herbert Gottweis, Ingrid Metzler & Erich Griessler



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The Paganini Project

Focussing on selected key areas of the 6th EU Framework Programme for Research and Technology, PAGANINI investigates the ways in which participatory practices contribute to problem solving in a number of highly contentious fields of EU governance. PAGANINI looks at a particular dynamic cluster of policy areas concerned with what we call “the politics of life”: medicine, health, food, energy, and environment.

Under “politics of life” we refer to dimensions of life that are only to a limited extent under human control - or where the public has good reasons to suspect that there are serious limitations to socio-political control and steering. At the same time, “politics of life” areas are strongly connected to normative, moral and value-based factors, such as a sense of responsibility towards the non-human nature, future generations and/or one’s own body. In these areas traditional mechanisms of governance can be seen to hamper policymaking and much institutional experimentation has been taking place.

The overall objective of the proposed research is

- to analyse how fields of governance related to the “politics of life” constitute a new and particular challenge for citizen participation and the generation of active trust
- to illuminate how citizens’ participation in key areas of European research and technology policy that are connected to the “politics of life” can be made more effective and appropriate,
- to investigate the changing role of civic participation in the context of multi-level governance in the European Union,
- to contribute to institutional re-design in a the emerging European “politics of life”.

Work package 2 – Defining human life: Human embryonic stem cells between politics and ethics

Work package 2 studies the conflict about human embryonic stem cell research and therapeutic cloning in Austria, Germany, Italy, the United Kingdom, on the EU and international level, and against the background of the situation in the United States. At the centre of this WP is to study whether and how the highly contentious fields of stem cell research and cloning have led to the creation of new forms of institutional deliberation that combine ethical consensus-finding and reflection with public participation and governance.

This report

This report is the final report of Work package 4.

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Acknowledgements

This report is the product of our shared research and efforts.

Herbert Gottweis was responsible for research conducted about Germany, the United Kingdom and the United States; Ingrid Metzler for Italy and Israel; and Erich Griessler for Austria and the European Union. All authors contributed to chapters three and five of this report. The introduction, chapter two and chapter four were authored by Herbert Gottweis and Ingrid Metzler. Herbert Gottweis wrote the conclusion of this report.

We wish to thank all members of the PAGANINI consortium for their insightful and useful comments on previous draft versions of this report. We are especially grateful to our many interview partners, who were essential for helping us to understand the nature and development of emerging stem cell regulations. Ingrid Metzler is grateful to Nik Brown and Lena Eriksson from the Science and Technology Studies Unit at the Department of Sociology, University of York, for their comments on drafts and presentations related to this report. In addition, she would like to acknowledge the help of Barbara Prainsack from the University of Vienna, whose comments have helped to shape her work in an indirect but nevertheless important way. Last but not least many thanks to Chris Dematté for his vital assistance in the preparation of this manuscript.

Obviously, all shortcomings or mistakes of this report are our own responsibility

Executive Summary

Our report focuses on the comparative study of the governance of human embryonic stem cell research. We address some of the key challenges for how to govern in this complicated field in the politics of life

Our comparison indicates that there seems to be a relationship between the *early, proactive and coherent effort to deal with new challenges in the new politics of life* as opposed to half-hearted, delayed, and contradictory approaches. Our in-depth case studies of the United Kingdom and Italy provide clear examples of this.

The idea of a coherent, pro-active approach towards life science governance should not be confused with modernist, hierarchical top-down political decision-making. The case of stem cell politics is not especially characterized by the adoption of novel, participatory decision-making mechanisms, neither during the political decision-making process, nor as a reaction afterwards. But it demonstrates well the importance of *creating trust through a variety of discursive and institutional mechanisms, designs and strategies*. Here, interactions with the various publics form an important element. Our case study on the EU strategy towards stem cell governance reveals an increasing realization on the part of policy makers that engaging with various publics today is a key element in any viable approach towards life science governance.

However, the creation of trust goes well beyond an engagement and shaping of publics. Within Britain, the HFEA, an already “trusted institution”, an institution with “ethos” was designated as the key institutional actor in HESC regulation in that country. Whereas in the United States, Germany, Austria and Italy *new* bioethics institutions were created partially with the idea of facing up to the new governance challenge of stem cell research, in the United Kingdom, an institution established long ago quickly became a strong asset in securing trust for the emerging framework of regulation. This turned out to be a key asset in the regulatory process.

Emotions have played a crucial role in confrontations with stem cell politics in the countries discussed in this report. There were two central axes through which emotions came into the field of stem cell governance. First, the question of whether research with early embryos is acceptable has been key to the debates, not only in the sense of ethical acceptability but also emotional acceptability. Second, the potential of stem cell research to heal dreadful and often

deadly diseases has an emotional power in its own that transcends any logical argument but also can transcend ethical or religious principles. Just as it is with trust and ethos, emotional language can be used in support of stem cell research or in its critique.

The importance of pro-active governance, trust and ethos, and emotions in the policy-making process all point in our view towards the key role of the *setting or staging* of the policy-making process in the field of life sciences. Stem cell governance today operates under general conditions of radical uncertainty and requires the simultaneous mobilization of different publics, the creation of institutional spaces for articulating emotions, concerns, and anxieties and the shaping of narratives that create fixations when boundaries are fluid and architectures of meaning are fragile. Participation does not always and necessarily offer the answer to such constellations, but, as the United Kingdom example shows, can be an important element in life science governance. While participation, deliberation, transparency and, in general, linking up with the citizenry seem to be an important aspect of contemporary stem cell governance, facing up to the stem cell governance challenge requires a more complex intervention.

Contemporary politics of life is hardly one that operates exclusively in the form of “governing through freedom”, that is, the democratic negotiation of self-governed individuals, but one that co-exists with forms of governing through sovereignty, directly through law and the state or through delegated forms of sovereignty, such as through ethical committees that decide on the ethical acceptability of HESC research proposals or through the licensed participation of couples and donors donating embryos and other biological materials. The limits of instrumental expert rationality might not only give rise to new constellations of uncertainty, emotional language and issues of trust-building, but also create the setting for new expressions of state sovereignty, such as bio-nationalism, or the positioning of the state as “last line of defence” of the family. It is not difficult to foresee that life science governance can quickly turn into a question of the “culture of life”, or the “future of mankind”, thematizations that might position the state as a central and dominant actor in the field of the politics of life.

1. Introduction: Stem cells for Europe

In summer 2006 the Commission's proposal for Europe's Seventh Framework Programme (FP7) reached the floor of the European Parliament and the Council of the European Union (EU). The proposal on which the two bodies were to vote allocated a total budget of 50,862 million Euros to European research and technological developments for a period ranging from 2007 to 2013. Similar to its predecessor, the Sixth Framework Programme (or FP6 for short), FP7 was designed to move the European knowledge space towards the Union's "strategic goal" "[t]o become the most competitive and dynamic knowledge-based economy in the world" (Presidency Conclusions, Lisbon European Council, 23 and 24 March 2000).¹ Yet the Commission's proposal contained some controversial elements that threatened to delay the approval of FP7 altogether. One of these tricky details was the proposed eligibility for funding of human embryonic stem cell research. Should Europe integrate this research on her path towards the knowledge-based economy? Or would a European financial incentive to this line of research violate the 'principle of subsidiarity' and hence the rights and authorities of the Union's member states? These questions had already triggered struggles in the context of the shaping of FP6 at the turn of the millennium (Salter 2006). And now, in summer 2006, Europe witnessed a sort of "déjà-vu" (Schwägerl 2006). Just as six years before, the proposed eligibility for European funding of human embryonic stem cell research became the object of fierce controversies. What was this excitement all about?

'Biologically' speaking, stem cells are cells that have the capacity to divide and give rise to more identical stem cells and to more specific cells of somatic tissues at the same time. They can be derived from various types of tissues of adult organisms, such as bone marrow, from the umbilical cord blood of newborns and from (aborted) fetuses. However, at the present time, the most promising type of stem cells are stem cells that are derived from early in vitro embryos. They are named 'human embryonic stem cells' (or HESCs for short), and they are the only agreed upon type of stem cells that are amenable to being cultured in the laboratory without losing their potential to form all cells and tissues of human bodies. Scientists are not

¹ Retrieved from <http://www.europarl.europa.eu/summits/lis1_en.htm?textMode=on> (accessed on April 15, 2007).

alone in their hope that HESC in vitro performance will be transformed into in vivo therapies for a broad range of diseases in a not too distant future. Since their first appearance on the global stage in 1998 (Thomson, Itskovitz-Eldor et al. 1998), patients and patient groups have been following the progression of this line of research with particular anxiety. Indeed, over the last decade, they have had many opportunities to witness the global flourishing of this line of research, with many research groups and companies joining in (Lewis 2007). Yet the development of stem cell research has not only been shaped in laboratories; its progress has also been forged in Parliaments, expert committees and national referenda. While HESCs were embraced without resistance in some settings, in others they were quickly entangled in controversies, stirred emotions, created camps of fervent opponents and stimulated discussions about the very meaning and direction of contemporary biomedicine.

In Europe, we find a broad range of different interpretations that have materialized in national regulations. The United Kingdom, for instance, has drafted regulations that allow British scientists to engage in this cutting-edge field of science and has fostered their research with substantial public funding. In Italy, in contrast, the interpretation of HESC research as an intolerable violation of ‘human life’ has been enshrined into a law that prohibits Italian researchers to derive HESCs from Italian embryos. On the background of these different regulations and interpretations of the very meaning of this line of research, it does not come as a surprise that the issue of whether or not to integrate them in Europe’s path to the world’s most dynamic knowledge-based economy was contested. While Germany’s Research Minister Annette Schavan announced that Germany wanted “no financial incentives to kill embryos” (quoted from BBC News 2006), her Portuguese colleague Jose Mariano Gago, stated:

I hope that none of the colleagues will ever need treatment which does not yet exist for dementia and Alzheimer’s. These are treatment which could be made possible by research with stem cells. If you find yourself in such a position I hope you would be able to say you did not stand in the way of such research (Quoted from Watt 2006)

The vital language of ‘life and death’ shaped the stem cell debates on the European stage and on the national stages alike, rendering stem cells controversial and an unruly challenge for governance. With HESC research, ‘life’ entered the stage of policy making – and became an object of intense political controversy. Therefore, the field of human embryonic stem cell

research constitutes a perfect example for what we have termed in the PAGANINI project the ‘(new) politics of life’. In this report we will pursue the question how policy making in this field was proceeding. How were stem cells eventually being politically ‘tamed’ and ‘re-ordered’? To which extent did HESC research lead to the dislocation of traditional practices of sense-making in the political realm? Which lines of conflict did emerge? And how were these conflicts eventually solved – if at all? Did the constellation of deep uncertainty in stem cell research lead to institutional innovations on the political level? How did national European levels of policy making and the EU level relate to each other in this important field of policy making? And to what extent did participatory practices contribute to the shaping of governance in stem cell research? This report will explore these questions. It is based on empirical field work on the United Kingdom, Italy, Germany, Austria and the European Union, the United States and Israel.

In chapter 2, we engage in a discussion of the ‘sciences’ of HESC and cloning research and map the key contextures and lines of conflict. In chapters 3 and 4, we describe what happened in our case study. After brief discussions of Germany, the United States, Israel, Austria and the European Union in chapter 3, we engage in detailed description of the energy fields and key events in Italy and the United Kingdom in chapter 4. In the final fifth chapter, we discuss the empirical material and flesh out what we see as the key patterns and major innovations in the emerging field of stem cell governance. Finally, we present a concise summary of our key findings in the conclusions of this report.

2. Human embryonic stem cell and cloning research – a science in the making

Imagine a future where the effects of debilitating diseases such as Parkinson's and Alzheimer's are treatable with simple cell therapies, where transplants mean that diabetes patients no longer have to worry about their insulin levels, and where needed organs are readily available.

Alex Zdan (2006), in the "Trenton Times", on October 22, 2006

It's no longer in the realm of science fiction. I really believe that within my lifetime I will see diseases treated by these therapies.

James Thomson, a pioneer of HESC research in 1998 (quoted from Wilmut and Highfield 2006)

The derivation of embryonic stem cells from the inner cell masses of mouse blastocysts was first reported in 1981 (Evans and Kaufman 1981; Martin 1981). Around the same time, Robert G. Edwards, one of the pioneers of assisted reproductive technologies, and colleagues managed to grow human in vitro embryos at five days after insemination, thus overcoming the previous difficulties of obtaining in vitro human blastocysts (Edwards 2001). But it was not before November 1998 that a team of researchers, led by James Thomson from the University of Wisconsin, Madison, announced having successfully derived and cultured HESCs from human blastocysts (Thomson, Itskovitz-Eldor et al. 1998).

Since their first appearance in 1998, HESCs have become a key topic in contemporary 'politics of life'. It is in fact difficult to find a (Western) country that has not in some way ventured into this field, be it approvingly or in a rejecting manner. Unlike many other highly sophisticated biomedical technologies, HESC and cloning research do not demand as a precondition the presence of extremely expensive techno-scientific infrastructures. Any well-equipped laboratory with corresponding know-how can move into this field. The question of whether or not to engage in HESC and cloning research is therefore not preconditioned by past decisions on research strategies and infrastructural investments, but essentially open to choices in the present. Over the last decade, many groups and laboratories have seized the

opportunities of this line of research. And states have facilitated and enabled their endeavour: they have drafted enabling regulations and have also invested considerable public funds (Gottweis, Salter et al. 2007; Salter 2007). Yet other states have resisted this ‘temptation’. Altogether, the field of HESC and cloning research developed rather unevenly over the last decade, giving rise to a heterogeneous stem cell topography.

But how did this all come about? And what are stem cells in the first place? What makes them the object of hopes and promises and fears and anxieties at the same time? We seek to deal with these questions in this section. We start with a detailed discussion of the scientific stakes of stem cell and cloning research. We have decided to give much attention to the science of stem cell research because we think that these facts have themselves a politics, or, perhaps more precisely, are amenable to being politicized in very specific ways. Subsequently, we will seek to embed the field in its political, social and economic contextures.

On stem cells and embryos

On stem cells ...

What is a stem cell? This question cannot be answered easily. Stem cells cannot be reliably morphologically identified; neither do scientists agree on a set of molecular biomarkers that signal the presence of a stem cell. Even the most powerful microscope cannot help to set stem cells clearly apart from other types of cells, and scientists neither know nor agree on the expression of what set of genes marks a cell’s ‘stemness’. In the absence of other agreed upon criteria, scientists rely on functional definitions of stem cells; that is they define stem cells through what they are doing and producing (Zipori 2004; Shostak 2006). From this perspective, a stem cell is a cell that is not yet differentiated and that has the potential to undergo divisions to form other, more specialized cells that perform specific functions in our bodies. Hence, stem cells are, firstly, less specific and less differentiated than other cells. Secondly, stem cells divide in a way that sets them apart from other cells within our bodies. Rather than symmetrically, they divide asymmetrically, giving rise to both a more specialized progeny cell and to an identical stem cell at the same time. Stem cells therefore have the capacity to self-renew for indefinite period of times; when cultured under appropriate conditions stem cells might live forever.

Our bodies contain more than 200 different kinds of specialized and differentiated cells committed to fulfilling a single function within our bodies. Stem cells, in contrast, are cells that have not (yet) specialized. They retain the ability to become some or even all of the more than 200 different cell types in the body, thus performing a crucial role in repairing damaged tissues in our bodies. Whenever specialized and differentiated cells die, and they regularly *do* (either because they have been damaged or because they have simply grown old), the undifferentiated stem cells replace the damaged cells with new differentiated and specific cells. As long as they divide asymmetrically, they provide more specific cells that can develop into the final specific stage and, at the same time, renew themselves as a reserve pool for repairs in the future. For instance, stem cells in the blood, ‘haematopoietic stem cells’ (HSC), generate millions of new blood cells to replenish destroyed or old blood cells each and every day (Bordignon 2006). Similarly, stem cells in the epidermis of our skins regularly generate new skin cells that replace old cells. ‘Intestinal stem cells’ produce the various types of cells in our intestines, and ‘central nervous system (CNS) stem cells’ produce the various types of nerve cells that keep our brain working (Johansson, Momma et al. 1999; Alison, Poulsom et al. 2002). Altogether, our bodies contain a broad range of ‘tissue-specific’ or ‘adult’ stem cells that are located in the various tissues of our bodies and that are committed to regenerating the damaged cells within this particular tissue (McKay 2000; van der Kooy and Weiss 2000; Fischbach and Fischbach 2004; Corrigan, Liddell et al. 2005). ‘Adult’ stem cells can also be isolated from the tissues of aborted fetuses and from the blood contained in the umbilical cord blood of newborn siblings. However, at the present time the most scientifically heralded (and politically contested) type of stem cells are cells derived from in vitro embryos. They are named human embryonic stem cells (or HESCs for short), and they are the only proven type of stem cells that is able to divide and dwell in the laboratory without losing its potential to form all cells of human bodies (Solter and Gearhart 1999).

... and embryos

Textbook stories on embryonic development are likely to proceed as follows (see Figure 2.1): In mammals, fertilization occurs when eggs and sperm fuse into what is named a ‘zygote’, that is a single cell that, once it is transferred into an uterus, is capable of developing into a foetus and eventually into a full-fledged human being. Approximately one day after fertilization, the zygote starts a series of (mitotic) cell divisions, the outcome of which are

identical cells. Each of these cells is classified as ‘totipotent’, that is as a cell that has the potential to become every type of cell in the body as well as every cell of the trophoblast (the fetal placenta) (Fischbach and Fischbach 2004; Gilbert, Tyler et al. 2005).

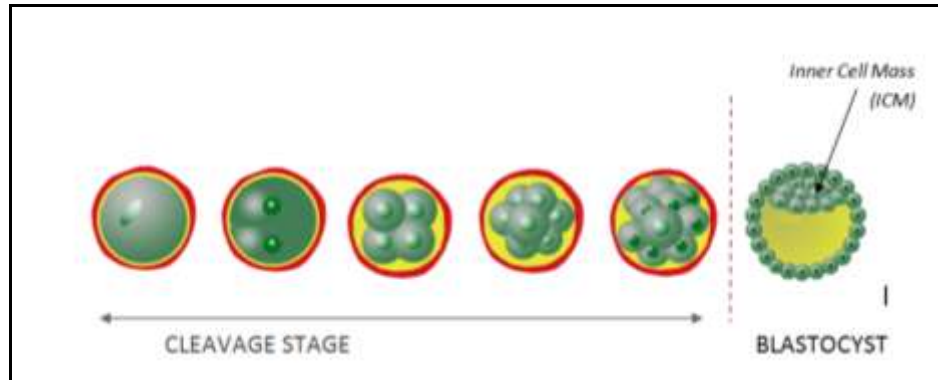


Figure 2.1: The development of early mammalian embryos

On the fourth day after fertilization the embryo passes from the ‘cleavage stage’ to the ‘blastocyst stage’. Then, the embryo’s cells start to be re-arranged, forming an outer layer of cells, the so-called trophoblast, and a cluster of cells called the inner cell mass (ICM). While the cells of the ICM are able to generate all cells and tissues of the ‘embryo proper’, they lack the ability to form the placenta and the supporting tissues. These cells are therefore characterized as ‘pluripotent’ (Alison, Poulsom et al. 2002).²

² The categorization of cells as ‘pluripotent’ cells, as opposed to ‘totipotent’ cells, provides a telling example for our claim that scientific uncertainties or, in this case, scientific facts or agreed upon categories are amenable to be political in very different ways. In this case, scientific categories helped to settle a tricky regulatory issue. If we follow Towns and Jones, we learn that in ‘scientific’ language,

[totipotency] is generally asserted (...) to denote the ability of a cell or group of cells to give rise to a complete individual, whereas pluripotency refers to the capacity to give rise to all the cell types constituting the individual – but not the individual as a whole. (Towns and Jones 2004)

However, in the present the deployment of the two distinct categories is not very consistent. In addition, as Christine Hauskeller (2005) notes, the characterization of stem cells as “totipotent” or “pluripotent” has also “shifted during the few years in tandem with developments in political, legal, and scientific fields.” Yet in one setting, namely in Germany, a sound deployment of these different categories was and continues to be fundamental. There, the differentiation of ‘pluripotent’ HESCs from ‘totipotent’ embryos was instrumental in order to make sure that “embryonic stem cell research with existing cell lines is in accordance with the [German] Embryo Protection Act” (Hauskeller 2005: 823). The German Embryo Protection act qualifies each “totipotent cell” as an embryo and deprives German embryos from research. If HESCs were classified as totipotent, they

The blastocyst stage of the embryo represents a ‘window of opportunity’ for scientists. But the time window is short: When kept in their ‘natural’ environment, the cells of the ICM interact with the trophoblast and differentiate into the so-called embryonic germ layers:

- the ectoderm, which gives rise to skin and neural lineages;
- the mesoderm, which later generates blood, bone, muscles, cartilage and fat, and
- the endoderm, which contributes tissues of the respiratory and digestive tracts.

But when the cells constituting the ICM are disentangled from the outer layer, transferred to a Petri dish and cultured under appropriate conditions, the cells can be kept proliferating and replacing themselves indefinitely. These cells are HESC cells (Thomson, Itskovitz-Eldor et al. 1998; Thomson 2001; Amit and Itskovitz-Eldor 2005).

Box 2.1: Histories of human embryonic stem cell research

The year 1998, which saw the ‘birth’ of the first HESC line, is often heralded as the ‘year zero’ of HESC research. Yet HESC research certainly did not arise out of a vacuum.

Robert G. Edwards (2001), one of the pioneers of in vitro fertilization, traces contemporary HESC research to the beginning of research on human in vitro fertilization in the 1960s in Cambridge. Davor Solter (2006) tells a slightly different and much more ‘esoteric’ story. He traces current stem cell practices to the history of research on ‘teratomata’, ‘teratocarcinomata’, and ‘embryonal carcinoma (EC) cells’ (see also Cooper 2004).

Benign ‘teratomata’ and malignant ‘teratocarcinomata’ are tumors that are composed of a ‘monstrous’ (the Greek ‘teratos’ translates as ‘monster’) mixture of adult tissues. They are composed of teeth, pieces of bones, skin and hair and have therefore triggered fascination and curiosity for centuries (Solter 2006: 319). First fragmentary accounts on teratomata date back to ancient times (Cooper 2004: 15). However, teratomata were very rare and therefore very difficult to study. This changed in the 1950s, when a newly described mouse strain showing an incidence of spontaneous testicular teratoma of about 1% enabled a series of experiments. In one of these experiments, a cell was isolated from a teratocarcinoma and injected into the abdominal cavity. The single cell gave rise to all tissue types that can be found in teratocarcinomata (Solter 2006: 320). In other experiments embryos were grafted to extra-uterine sites and gave rise to teratocarcinomata, from which embryonal carcinoma (EC) cells could be isolated. Once a similarity between EC cells and cells of early embryos was established, scientists were curious about whether EC cells could contribute to the development of chimaeras. They injected EC cells into the mouse blastocyst cavity, and some embryonic stem (ES) cell lines indeed gave rise to ‘normal’ tissues. This finding suggested that EC cells are “in essence identical to embryonic cells” (Solter 2006: 323). However, given that embryonal carcinoma cells could be isolated from embryos grafted to extra-uterine sites, scientists wondered whether similarly powerful cells could also be derived

would be categorized as embryos in Germany. A sound boundary between totipotent embryos and pluripotent HESCs was therefore mandatory in Germany. Scientific classifications, here, make the difference between allowed biomedical research and criminal offense. In other settings (where research on ‘totipotent’ embryos is endorsed, such as in Israel, or where regulatory definitions of embryos do not draw upon totipotency, such as in Italy), it has not been crucial to purify ‘pluripotent’ stem cells from ‘totipotent’ embryos. There, a stringent deployment of terminology was simply less important.

directly from embryos. And in 1981, the first mouse ES cell lines were derived by two independent groups (Evans and Kaufman 1981; Martin 1981).

Once murine ES cells had been isolated, the deployment of EC cells became a thing of the past (Solter 2006: 323). The short period of in vitro studies on EC cells and teratomata were nevertheless foundational for the subsequent work with ES cells. Many techniques to keep ES cells proliferating in the laboratory were in fact developed in the work with EC cells.

The announcement that the first *human* ESC line was alive and well had been anticipated by two decades of work with animal ESC lines, whose results gave rise to narratives on future applications. Many of them related to potential new ways to increase insights on human health and ill health, and to generate truths on human 'life'. Yet the presence of the pluripotent HESCs in a laboratory was also quickly translated into potential applications in biomedicine and an increase in public health.

On the one hand, scientists argued that stem cells could help to improve insights on the causes of birth defects, genetic abnormalities and basic developmental processes, moving the study of disease "from patients to a Petri dish" (Holden 2006a). HESC lines were also presented as an "inexhaustible supply" (ES Cell International 2005) for drug screening and toxicity testing (Okarma 2001; Semb 2005). On the other hand, HESCs were entangled with the prospect of new therapeutic approaches for afflictions and diseases, ranging from diabetes to strokes to neurodegenerative diseases. This perspective was often expressed in revolutionary terms. For instance, the Italian 'Dulbecco Report' claimed that HESCs might even go beyond the importance of the invention of antibiotics in the past century (Ministero della Sanità 2003 [2000]). Others presented the small cells as paths into a new age of biomedicine, in which ailing, injured or degenerated tissues and bodies are no longer only 'fixed' with pharmaceuticals or other artificial devices but permanently cured and 'regenerated' through an alliance with 'nature's own forces' (Okarma 2001; Petit-Zeman 2001; Thacker 2005; Franklin 2007). Such a "regenerative approach", Thomas Okarma, the CEO of Geron Corporation, a California-based bio-tech company, argued, would transform the definition of medical therapies "from simply halting the progression of acute or chronic disease to include restoration of lost organ function" (2001: 3)

[P]atients who suffered a myocardial infarction would be discharged from hospital not only with immediate progression of the infarct stopped, but also with a repaired heart, the function of which would be restored to preinfarct state. Patients with stroke or spinal cord injuries would receive cell-based treatments that would restore central nervous system function,

thereby enabling them to maintain functional independence. *Regenerative medicine would be a totally new value paradigm for clinical therapeutics.* (Okarma 2001: 3; italics added)³

The ‘regenerative promises’ of HESCs were further intensified through the prospect to produce HESCs in such a way as to bypass the problem of immune rejection. HESCs, so the argument went, could be ‘custom-tailored’ (Hochedlinger and Jaenisch 2006) through the combination of HESC with somatic cell nuclear transfer (SCNT).

SCNT involves the injection of the nuclear DNA from a somatic cell, that is, any of an adult’s body’s cells, into an enucleated ‘oocyte’, or egg cell, whose nuclear DNA has been removed. Then, the oocyte is mechanically induced to divide and develop like a ‘standard embryo’ (HFEA 2004).

The feasibility of this technique was first successfully demonstrated by Ian Wilmut, Keith Campbell and colleagues, when they produced Dolly the famous sheep. They removed the egg’s nucleus with its DNA and replaced it with the DNA of a donor cell. Then, they “found a way to fool the egg, by a shock of electricity, into thinking that it was a developing embryo” (Wilmut and Highfield 2006: 93). The oocyte provided signals that reprogrammed the somatic cell DNA, redirecting it to divide and develop like early-stage embryos. Subsequently, the embryo was transferred to a surrogate ewe. The resulting sheep – Dolly – had the same nuclear genome as the sheep that was the source of the somatic cell.

The birth of Dolly triggered a lot of excitement on the potential uses and misuses of cloning (see section four and five). However, scientists and policy makers stressed that the feasibility of SCNT might also be regarded as a blessing for the future of biomedical therapies. They proposed to combine SCNT with HESC technologies. A somatic cell of a patient could be transferred into an enucleated oocyte or egg. The resulting artefact would contain the same nuclear genome as the donor. The aim of this exercise, scientists underlined, would not consist in the production of full-fledged human beings. Rather, the laboratory artefact would be cultured in in vitro conditions until it reached the blastocyst stage, when HESCs could be derived from its ICM (Solter and Gearhart 1999). This research seemed to give shape to a set

³ Please note, neither ‘regenerative medicine’ nor the related field of ‘tissue engineering’ (TE) were altogether new. Both terms predate the announcement of Thomson and colleagues in 1998. TE, that is, the joined application of “principles of engineering and life sciences toward the development of *biological* substitutes that restore, maintain, or improve tissue functions” (The National Science Foundation 2003), in particular refers to a set of practices that are *already* applied in health care and medicine. However, the work of Thomson and colleagues gave these fields a new boost.

of new medical-therapeutic therapies that promised extraordinary possibilities for dealing with serious ailments and diseases, many of which had no alternative treatments. However, while some people framed these prospects as unprecedented opportunities, others regarded them as the crossing of ‘fundamental moral boundaries’ and as the beginning of a public health nightmare.

Adult stem cells

While HESC and cloning research expanded and triggered the first controversies, the field of ‘adult’ or tissue specific stem cell research also produced a host of much discussed advances. In contrast to their embryonic relatives, adult stem cells already have a history of clinical applications. However, the excitement and growing controversies on HESCs gave this field a new boost (De Carli 2003).⁴ In addition, there have also been a number of hotly debated new research findings.

In 2002 there was much excitement about the work of Catherine Verfaillie and her team on multipotent adult progenitor cells (MAPCs). These cells qualify as adult stem cells but display characteristics close to HESCs (Jiang, Jahagirdar et al. 2002). In addition, some research findings suggest that adult stem cells might be more flexible than previously believed. Until recently, adult stem cells were believed to be ‘tissue-specific’ and ‘multipotent’; that is, they were thought to be capable of producing only progeny cells corresponding to their tissue of origin (Alison, Poulson et al. 2002; Wagers and Weissman 2004). But in the late 1990s, a range of research papers suggested that under certain circumstances cells might ‘transdifferentiate’; they might convert from a cell of one tissue lineage into a cell of an entirely different tissue lineage (Bjornson, Rietze et al. 1999; Castellino 1999). These findings

⁴ Haematopoietic stem cells (HSCs), i.e., the cells that replace old or damaged blood cells in our bodies, have been used in blood disorder treatments for decades (Lennard and Jackson 2000). In the past, HS cells were isolated from the bone marrow. More recently, cord-blood transplants have become an increasingly popular alternative to bone-marrow transplants, and in Western countries an ever increasing number of parents decide to store the cord blood of their siblings as a form of ‘fleshy insurance’ for future health risks in one of the exploding number of private cord blood banking facilities (Brown and Kraft 2006; Waldby 2006b). For now, HSCs have only been proven to provide suitable therapies for blood disorders. But they are nevertheless advertised as a hopeful investment for a broad range of potential future therapies that go well beyond the treatment of blood disorders. In December 2005, the British “Guardian” reported that the biotech enterprise Smart Cells International offered “stem cell gift certificates” for Christmas. For an investment of 1,250 Pound Sterling, the company offered to store a baby’s stem cells for 25 years as a “long-lasting insurance policy” (Carvel 2005). More recently, football players engaged in the English Premier League, have been rumoured of having stored their newborn children’s cord blood as a “repair kit” for eventual injuries (Christian 2006).

have given rise to the concept of ‘stem cell plasticity’, the proposition that the lineage determination of a differentiating stem cell might be flexible rather than permanently fixed. Attention increasingly shifted towards what scientists frame as the ‘stem cell niches’, the microenvironments in which stem cells reside and dwell. The molecular signals exchanged between the stem cells and the other cells within these “niches” seem to be crucial factors to understanding the working of a stem cell’s “stemness” (Moore and Lemischka 2006; Scadden 2006).

For now, the concept of ‘stem cell plasticity’ remains a contested concept within the scientific community. Yet some have nevertheless argued that adult stem cells might have “the same developmental potential as ES cells, if given the right cues” (McKay 2000: 363), thus providing a scientifically valid solution that “would effectively sidestep the ethical problem of using ES cells” (McKay 2000: 363; cf. Towns and Jones 2004) (see also Box 2.4).

A promising science in the making

Over the last decade, many research groups have moved in this field of research. Today, more than 400 different HESC lines exist in laboratories around the globe. Yet it would be certainly misleading to conceptualize the field of HESC and cloning research as a stable field of research with firmly stabilized boundaries and stable facts and truths. Rather, stem cell and cloning research reflects the confluence and crossing of the boundaries of a number of disciplines, such as reproductive biology, embryology, cell biology, molecular biology, endocrinology, immunology or transplantation medicine (Kiessling and Anderson 2003). In addition, this vaguely defined field of research is also very much “in its infancy” (Fischbach and Fischbach 2004: 1364; Scott 2006b: 10). At the present, many of the secrets of these cells are still poorly understood. Little is known about the signals that make stem cells differentiate into particular cell types or about how to eventually integrate them into tissues or organs (Zandonella 2005). Similarly, SCNT still belongs to an imagined future. Up to the time of the writing of this report, no group of researchers has managed to derive HESCs from cloned blastocysts.⁵ Experts frequently emphasize that many years of laboratory work will be

⁵ In November 2001, the US-based biotech company Advanced Cell Technology (ACT) announced that it had cloned the first human embryo. The researchers had removed the nucleus from donated oocytes, replaced them with the nuclei from skin cells and so-called cumulus cells and subsequently induced them to divide. However, while the scientists managed to derive embryos, the embryos failed to develop beyond the first few cell divisions, and no stem cells could be derived (Check 2005). In 2002, Hui Zhen Sheng of

required before HESCs can be safely transferred to clinical applications. HESC and cloning research, rather than being “ready made science”, is “science in the making”, as Bruno Latour describe the concept (Latour 1987).

Please note, this does not mean stem cell research is somehow more ‘fabricated’ than other fields of research; it means that stem cell science is characterized by an uncertainty that characterizes any new field of scientific research. Many ‘facts’ about stem cells still need to be established, agreed upon and ‘stabilized’ as facts. While this is true for any ‘scientific fact’ or ‘technological device’ in the making, the dimension that renders the politics of stem cell research different is the dimension of time. Whereas usually the processes and struggles that discern ‘true’ scientific utterances from noises (or hopes and dreams that have not come true) are re-constructed *ex post*, in the emerging stem cell science, the stabilization of what counts as a fact, is occurring in real time now – and in the midst of political controversies (Scott 2006b).

Cells for a healthy and wealthy future?

“Scientific utterances”, Loeber and colleagues argue, “are ‘true’ only to the extent that they are embedded in social practices which feature conventions and supportive problem frames that together define their meaning and ‘truth’” (2005: 20). Hence, neither knowledge production nor technical innovation can be separated from the socio-political contexture in which and by which they are given shape (Loeber, Hajer et al. 2005: 20). So, what are the socio-political contextures that shape stem cell research? What makes them ‘interesting’ to policy makers? And what renders them controversial? The remaining parts of this section seek to tackle these questions.

Shanghai Second Medical University and her colleagues reported to have produced blastocysts by inserting human cells into rabbit oocytes, however, without deriving HESCs from them (Check 2005; Scott 2006a). Finally, in February 2004, a group of South Korean researchers led by Woo Suk Hwang reported they had extracted HESCs from a cloned blastocyst. And in May 2005, the same group of scientists of the Seoul National University in South Korea announced that they had achieved major advances in the efficiency of SCNT, creating 11 ‘patient-specific’ HESC lines. Both papers were hailed as milestones. But in the end of 2005 they amounted to nothing but one of the major scandals of the last years when it turned out that Hwang and his team did not have a single patient-specific HESC line, and all HESCs were fakes (Gottweis and Triendl 2006). However, despite the substantial drawback from the South Korean cloning scandal, research on therapeutic cloning goes on (Holden 2006a; Pearson 2006b).

Catherine Waldby notes that HESC research triggered interest because it seems to provide ‘microbiological’ fixes to at least two problems. First, it promises a new mode in which cells and tissues are distributed between bodies and populations (Waldby 2005: 10; Waldby and Mitchell 2006). In the post-world war tissue economies, tissues and organs were mainly circulated from the dead to the living and mediated through gift relationships between fellow citizens. However, this system had its inbuilt limitations. The number of needed tissues and organs always exceeded the number of actually available ones and the fleshy barriers of immune rejection set severe limitations to the free flow of tissues. Put succinctly, HESC technologies promise to provide bio-technical answers to these limitations. They promise to provide a new *source* of tissues. Rather than from the “dead”, tissues are collected from the surplus vitality of embryos. And the technology of immortalization promises to expand the vitality of embryos into a literally unlimited quantity of pluripotent cell lines that are amenable to be grown in all sorts of tissues, and therefore capable of effectively overcoming the problem of tissue shortage (Cooper 2006). The combination of HESC technologies with SCNT also promises solutions to the problem of immune rejection, providing ‘personalized’ HESC lines. Patients would no longer depend on donors. Rather, the ‘self’, or a sort of extended self, would donate, say, a skin self to herself that is subsequently re-programmed by the powerful cytoplasm of human oocytes, and finally re-transferred in the body of the ‘somatic self’ (Cooper 2006).

However, the promises of stem cell research go further. It seem to be a particularly interesting perspective for Western nation states, the health care systems of which are increasingly burdened by the ill health of their ageing populations (Waldby 2002; Waldby 2005; Cooper 2006). Most post-industrialized nation states are confronted with the consequences of decreased fertility rates and, as a consequence of longer life spans, rapidly ageing populations. From the early 1990s, international bodies such as the World Bank warned that the globe was about to confront a ‘crisis in ageing’ that would trigger dramatic effects on the growth of productivity and the long-term viability of welfare states (Cooper 2006: 2). “Regenerative medicine” seems to offer solutions to this crisis scenario. It is proposed as a field of technologies that offers the prospect of “rejuvenating aging populations” and “extending the viable life of the work force” (Waldby 2005: 12). In addition, “regeneration” is promoted as a new and more cost-efficient way for the administration of the ill health of the ageing population of Western nation states, which is

putting heavy burdens on national welfare systems. In particular, the rising numbers of “‘wear-and-tear’ conditions, such as osteoporosis, diabetes, cardiovascular diseases, and Alzheimer’s and Parkinson’s diseases” (Petit-Zeman 2001), diseases that cannot be cured but that must nevertheless be “managed” and “administered”, put severe financial demands on systems that suffer constantly decreasing public support. From this perspective, then, regenerative medicine’s promise to “permanently fix” diseases rather than to temporarily halt or simply manage their most severe consequences, seems particularly intriguing (Lachmann 2001).

However, similar to other areas of contemporary biomedical research, stem cell research is not only tied to the production of health. While it is no doubt legitimated by its ability to increase human health, it is also connected with its potential to generate new economic wealth (Rabinow 1996; Novas 2006). Stem cell and cloning research seem to be driven by the search for what Catherine Waldby has termed ‘biovalue’, that is a “simultaneous surplus of biological vitality, clinical use-value and commercial profit” (Waldby 2002; Waldby 2005; Waldby and Mitchell 2006). Biological processes, cells and tissues are leveraged in the laboratory so that they become more prolific or useful, through processes like the fractioning of blood, the creation of cell lines, genetic engineering or cell nuclear transfer. More or less marginal, excess or even waste life forms are re-engineered in the laboratory in such a way as to transform them into therapies to enhance the vitality of the living. In addition, these re-engineered biological artifacts are often treated as patentable intellectual property, so that surplus *in vitro* vitality may eventually be transformed into surplus commercial profits (Waldby 2005). HESC technologies, Waldby notes, are also a particularly productive sources of *biovalue*, as they transform “marginal” life processes on the cellular level and fragments of “surplus” embryos into spectacular medical technologies that generate commercial and public value.

Please note, this does not imply that stem cell research is a smooth or linear process. Disputes and different regulations on the patentability of stem cells and ‘life’ (Taymor, Scott et al. 2006) and controversies and outcries on the news reporting of women selling their oocytes demonstrate that the ‘drive for wealth’ also meets considerable resistance. In addition, at the present time HESC and cloning research are still at a very early stage, and the translation of *in vitro* vitality into *in vivo* health and wealth remains speculative and uncertain (Waldby 2005; Rabinow and Rose 2006). So far, venture capitalists have largely stayed away

from HESCs that appear to be too controversial and too far from market readiness. With venture capitalists and biotech companies reluctant, major sources for stem cell research have been donations from foundations and gifts by private individuals (Holden 2006b). And in general, the largest share of funds is still public rather than private (Waldby 2005).

Last but not least, it would be deeply misleading to confine the emerging stem cell ‘energy fields’ to more or less enabling (regulatory) states, more or less transnational biotech enterprises and a handful of more or less radical “pro-life” groups (whom we will discuss shortly). The emerging field of stem cell governance is also shaped by the actions of atomized patients and often transnational patient groups who hope that investments in the present will bring cures and therapies in the future. Stem cells have become the objects of often transnational ‘communities of promise’ (Brown 2003), in which scientists, patients, venture capitalists and other political actors are linked through their hope that today’s science might lead to a better future (Novas and Rose 2000; Novas 2006): Both within the boundaries of national energy fields as well as in transnational settings we find patients and patients’ organizations who argue that bans or restrictions on stem cell research contradict their rights in a specific community, or – overall – their “human right” to health as human beings. As Nikolas Rose and Carlos Novas eloquently note, “claims on political and non-political authorities are being made in terms of the vital damage and suffering of individuals or groups and their ‘vital’ rights as citizens” (Rose and Novas 2005: 441). And “pain”, “suffering” and – altogether “life” – are being rationalized and translated into political resources (Petryna 2002: 15). Please note, we are not talking about the actions of patients’ organizations, who through their actions pressure actions of governments and are sometimes able to direct investments and research strategies, who, as Nikolas Rose and Carlos Novas note, “have [also] been around for many years” (2005: 452). What Rose and Novas “see today” and what was indeed one of the key features of contemporary stem cell debates is the “formation of direct alliances [of patients] with scientists” (Rose and Novas 2005: 452). These alliances and joined identities are then not only forged between persons who suffer from the same disease or who share a similar genetic make-up, but from social actors who invest their hope (for financial or professional gains or a life saving therapy) in the same line of research, transforming it in “a hopeful domain of activity, one that depends upon and intensifies the hope that the science of the present will bring about cures or treatments in the near future” (Rose and Novas 2005). As we will see in the next sections of this report, these investments by patients often

take a rhetorical form, when patients translate their bodies into rhetorical devices and seek to convince opponents and skeptics of HESC research of the vital importance of this research to their lives. However, patients not only speak or collect funds – they also invest their fleshy bodies in clinical trials. Similarly, there could be no HESC research without women being ready to donate oocytes or couples agreeing to donate their “surplus” embryos to this field.

Sacrificing ‘life’

So far, we have put considerable emphasis on those (national and transnational) networks of ideas, hopes, actors and biological artefacts that have helped to constitute, facilitate and shape stem cell research. We have not discussed an equally important part of the emerging stem cell research regime – the actors and networks who reject, oppose, challenge and while doing so also shape (the politics of) stem cell research. From its very inception, stem cell research was in no way uncontested. There were many “matters of concern” (Latour 2004), ranging from the difficulty to tame the growth of HESCs, over the concern that stem cell research could lead to a new exploitation of women’s bodies and women’s reproductive labour to criticism on the commercialization of life itself. However, two topics in particular provoked controversies and debates: the contested status of the most important raw material of HESC research, early human embryos, and the difficulty to purify ‘research cloning’ from the connotations of ‘reproductive cloning’. Both were very prominent in some of our case studies, and strikingly absent in others. We will therefore return to them in more empirical details in the following two sections. For now, we would like to outline them briefly.

Dolly’s legacy

The announcement of the birth of Dolly the sheep in February 1997 led to a global public outcry, and in particular to fears that the birth of the first cloned human being might be imminent. These fears regularly re-emerged, whenever strange figures announced that cloned babies were about or had just been born.⁶ More than ten years after the birth of the first

⁶ The Italian embryologist Severino Antinori announced in November 2002 that the birth of the first cloned human being was immanent and that three women were pregnant with cloned babies;

cloned mammal, ‘human reproductive cloning’ – that is the production of fully fledged human beings through the deployment of cell nuclear transfer – remains globally tabooed. Although not all socio-political actors exclude ‘human reproductive cloning’ as a matter of principle (Prainsack 2006), it is difficult to find an actor or group of actors who embrace human reproductive cloning as a blessing without at the same time risking condemnation as being “irrational” or even completely “insane” or “crazy”.⁷ So far, no national legislation has deliberately endorsed human reproductive cloning, and numerous international declarations have condemned it (see Box 2.2).

Box 2.2: International conventions and declarations against human reproductive cloning

Article 11 of the “Universal Declaration on the Human Genome and Human Rights” adopted by UNESCO in November 1997 invites the states to ban human reproductive cloning as a practice “contrary to human dignity” (United Nations Educational Scientific and Cultural Organization 1997). In March 2005, the United Nations’ General Assembly adopted a (non binding) “Declaration on Human Cloning”, calling upon all member states to take all measures necessary to prohibit all forms of human cloning (including “therapeutic cloning”) and stating that all forms of human cloning are incompatible with “human dignity” and the “protection of human life” (United Nations General Assembly 2005). In Europe, the Additional Protocol on the “Prohibition of Cloning Human Being” of the “Convention on Human Rights and Biomedicine” of the European Council bans the creation of “a human being genetically identical to another human being, whether living or dead”. Finally, the European Union’s Article 3 of the “Charter of Fundamental Rights of the European Union” prohibits reproductive cloning (European Union 2000).

Yet, even with this ‘reproductive’ application of SCNT safely doomed into the category of the tabooed, the birth of SCNT and Dolly was a crucial event in the shaping of contemporary stem cell topographies. The announcement of Dolly’s birth in February 1997 preceded the announcement of the work of Thomson and colleagues in November 1998. More specifically, Dolly set the stage for it. On the one hand, the two technologies were directly linked to each other through the proposal to combine HESC technologies with SCNT technologies. On the other hand, these events were related in a less direct but more incisive way. As we will argue in more details in chapters four and five, the announcement of Dolly the sheep, and the way in which this announcement was handled and dealt with, set the stage for the following HESC debates. Put succinctly, Dolly set the boundaries of life in motion; as a being that was

And in December 2002, Clonaid, a self proclaimed biotechnology company announced the birth of ‘Eve’, the world’s first cloned baby girl.

⁷ For an excellent overview on the bioethical and philosophical discussion of reproductive cloning, see Prainsack and Spector (2006).

both ‘born’ and ‘made’ (Franklin and Roberts 2006), she questioned views on what ‘biology’, as opposed to and distinguished from ‘culture’ is, and what it should be; and as a being born from a fully differentiated adult cell that had been reprogrammed by the cytoplasm of an egg cell, she shattered truths of biological textbooks. Before her birth, it was believed to be biologically impossible to reprogram an adult cell and to ‘revert its biological clock’. Cell differentiation was firmly believed to be both linear and progressive, and an incisive event. Dolly proved this truth to be wrong (Wilmut and Highfield 2006; Franklin 2007). Therewith, Dolly challenged our understanding of the meaning of life and biology. As more biological truths shape the way in which we make sense of our human existence, and more people draw on biological concepts and scientific knowledge to make sense of who they are (Rose 2007a; Rose 2007b), the meaning of this shattering event was not confined to laboratories but quickly spilled to other spaces in which the meaning of ‘human biology’ and its implications for the meaning of ‘humanness’ were discussed and negotiated. Last but not least, Dolly’s birth engendered debates on the very direction of modern biomedicine. To sum up, Dolly set the boundaries of life in motion and gave rise to attempts to re-order them. When HESCs appeared on the global stage at the end of November 1998, this stage was to a large extent already shaped by the attempts of re-ordering engendered by the Dolly debates.

In addition to Dolly, there was another recurring entity that was prominent in most of our case studies: early human embryos.

The embryo debates

As we have noted, HESCs are derived from the inner cell mass (ICM) of *in vitro* pre-implantation embryos. Embryos can either be obtained from in vitro fertility centres, where they had been produced for fertility treatment but are no longer needed for this purpose, or they can be produced on purpose – through ‘normal’ fertilization of an oocyte or through SCNT. Subsequently, embryos have to be grown for at least five days in a medium until they reach the blastocysts stage. Once stem cells are harvested from the inner cell mass of the embryo, the vitality of the embryo is redirected into the formation of immortal HESC lines, and the capacity of the embryo to develop into a foetus is permanently disrupted (cf. Waldby 2002). For some, this is highly immoral and amounts to ‘killing human beings’. Others argue that this language is misleading: as long as embryos do not qualify as human beings, the

language of 'killing' is simply out of place. Still others take a position in between these two 'extremes' and argue that surplus embryos from fertility treatment programs should be used, as they would otherwise be discarded. In other words, the debates on whether human embryos should be used for stem cell procurement imply questions and decisions on what sort of entity human embryos are in the first place. Therefore, the debates on the ethics of HESC research often amounted to debates on the 'ontics' of embryos, on their moral and legal status of the embryo (Williams, Kitzinger et al. 2003; Corrigan, Liddell et al. 2005; Salter 2006).

Box 2.3: Embryo debates

Opponents of HESC (and embryo) research often align stem cell research with eugenics, slavery or the mass murder of European Jews in Nazi Germany's concentration camps. For instance, the Catholic Italian journalist Antonio Socci argues that the "battle for the recognition of the rights of the conceived (*concepito*) is identical to the struggle for the abolition of slavery. Also in this battle (...) a consistent part of culture and public opinion claimed that certain human beings do not have natural rights, that they could be 'used' like things and that their right to life didn't have to be recognised" (Socci and Casini 2005: 12-13). Deploying similar tones, Monsignore Sgreccia, the President of the Pontifical Academy of Sciences, explained, "Frozen embryos are human beings in a concentration camp of ice" (quoted from Flamigni and Mori 2005: 101). For some, stem cell research is only one of the most recent materializations of the long history of racism and the most recent articulation of the bloodsheds conducted in the name of it. However, we think it is analytically misleading to equalize contemporary stem cells and embryo research with slavery, eugenics or the mass-murdering of Jews in German concentration camps.

Racism subdivides the species body of the population into a range of subspecies and re-arranges these subspecies in such a way as to make sure that putting to death one of them makes the 'life' of the population and the species body healthier and more productive. As Michel Foucault put it in his 1976 lecture: "[R]acism justifies the death-function in the economy of biopower by appealing to the principle that the death of others makes one biologically stronger insofar as one is a member of a race or a population" (quoted from Rabinow and Rose 2006: 201). Putting to death those who were deemed to embody a form of vitality that is "inferior", a life "not worthy of being lived" or even a danger and risk to the collective made the life of the collective healthier and more productive. The contemporary debates on embryos and HESCs have little to do with this rationale. The destruction of IVF embryos in the name of the progress of science or in the name of the hunt for vital therapies for patients does not amount to the purification of the population from its enemy from within. Who would ever argue that in vitro embryos endanger the body politic? Furthermore, it is also difficult to find a supporter of HESC research who argues early human embryos embody a 'life that is not worth living'. Rather, proponents of HESC research argue the embryo is not a 'human being' at all. While all actors in the HESC energy fields agree the life of the embryo embodies some sort of human vitality, they disagree on what kind of vitality this is (Waldby 2005). The Italian philosopher Giorgio Agamben provides a set of concepts that enables us to translate this in an analytical vocabulary.

Drawing on the work of Aristotle, Agamben (1998) notes that in ancient Greek there was a linguistic distinction that ceased to exist in modern languages. Instead of the single 'life' we know today, the Greek used two semantically different terms: "*zoē*", which expresses the simple fact of living common to all living beings (animal, men, or gods), and "*bios*", which indicated the form or way of living proper to an individual or a group" (Agamben 1998: 1).

While 'bios' refers to the qualified life of a legally protected citizen and member of a community, 'zoē' refers to the mere fact of biological existence, to 'bare life'. In Agamben's

account, the latter is embodied by the "Homo Sacer". Banned from the polity, this strange figure bears a life that can be killed without committing homicide. As "some kind of 'living dead'" (Lemke 2005: 3), he is the iconic embodiment of "bare life". Importantly, the boundary between the "bare life" of those excluded from the polis and bereft of rights and the "qualified life" of citizens is not given by nature – for Agamben it is sovereign power that is responsible (cf. Dean 2002: 124).

We do not want to give a full account of Agamben's work here, which is much more sophisticated than our brief summary suggests. Rather, our purpose is to propose using Agamben's distinction between bios, the "qualified life of a citizen", and zoē, the bare life of whatever or whoever does not belong to the political community, has no rights and can be killed without the commission of a homicide, as a heuristic tool to re-conceptualize today's embryo debates. For us, it is of little interest whether it is sovereignty that is at work here; it is – no doubt – politics.

Agamben himself makes a mirror-inverted argument when he discusses the establishment in the 1970s of the "brain death criteria" as the new threshold between "living citizens" and dead cadavers. From the late 1950s on, he notes, new life-supporting technologies, such as artificial respiration and the maintenance of cardiac circulation through intravenous perfusion, enabled the "survival" of comatose patients. Up to then, death was determined with the help of two criteria that had remained pretty much the same throughout the centuries (at least in the Western world): the stopping of the heartbeat and the cessation of breathing (Agamben 1998: 161). Hearts of comatose patients could be kept beating and the respiration could be kept working with the help of machines and bio-technical devices, so new criteria to determine death became necessary. The problem, Agamben claims, became "even more urgent and complicated" with the sophistication of transplantation medicine. The "state of the overcomatose person", i.e. a patient who continues to 'survive' only thanks to the new life-support technologies, seemed to be "the ideal condition for the removal of organs" (Agamben 1998: 162). The patient's remaining vitality could be deployed to increase the vitality of the living. However, pending criteria on whether these overcomatose persons were still among the "living", an agreement on an "exact definition of the moment of death was required in order for the surgeon responsible for the transplant not to be liable for homicide" (Agamben 1998: 162). As we know today, new criteria were indeed established, and today it is the "death of the entire brain" that marks the threshold between the "living" and the "dead" – or the boundary between zoē and bios.

The structural similarities of these debates with contemporary embryo debates are striking⁸: First, just as the 'overcomatose patient' dwells in a zone of indistinction between zoē and bios and the patient's precise position becomes meaningful only after a decision, the embryo dwells in a hybrid zone – as a life that is not yet born or actually not even yet conceived. Does the embryo belong to the realm of bios, or is it a form of bare life, only a biological entity? This question is not merely a philosophical one. Similar to the overcomatose patient, who embodies precious organs, the embryo embodies valuable cells, which can be deprived from it only under the condition that the embryo is classified as zoē and not as bios. Life forms classified as zoē can be legitimately deployed and leveraged in laboratories or Petri dishes, but it would be an unbearable provocation to draw upon 'life forms' that are classified as bios and hence as fully fledged members of our political communities. It might therefore be more useful to speak of a search for 'zoē-value' that presupposes an explicit or implicit decision that categorizes embryos as a form of 'bare life'. In other words, the production of 'bio-value' (Waldby 2002; Waldby and Mitchell 2006), the production of an economic or therapeutic surplus from life, presupposes the production and separation of a 'bare life'; and this is a political decision.

Please note this does not imply that such decisions are necessarily made in Parliaments. In Italy, this was indeed the case, but in Israel, these decisions were enacted in a very dispersed way. Lacking enforceable legislation on the status of the early human embryo and regulations on embryo donation, the boundary between embryos as zoē and cell donors and embryos as (potential) bios is constantly being negotiated by the ethical decisions of women and couples.

⁸ Please note that Catherine Waldby and Susanne Squier (Waldby and Squier 2003) draw a similar analogy between IVF embryos and comatose patients, although they do not refer to Agamben's work.

However, although establishing the 'brain death' criterion worked rather smoothly in most Western countries, the same does not hold true for the opposite end of the timescale of life. The 1980s witnessed the emergence of criteria to define a scientifically based boundary between 'pure life' and a 'human being', such as the formation of the "primitive streak", that is the formation of an embryonic nervous system that occurs about two weeks after fertilization and induces the embryo to "feel" and "to be hurt" (private conversation with British scientist), but these criteria were never universally mainstreamed or altogether downstreamed as facts. "Science" was deprived of its monopoly to speak truth on the "embryo" (and 'life'), and a whole range of new voices and practices (re)emerged that sought to step into science's shoes. Religious opinions regained a new prominence, and an increasing number of bioethicists began to deliberate on these questions. Finally, the tricky question was staged in electoral campaigns and referenda.

Of course, these "embryo debates" were not altogether new. Issues such as abortion or in vitro fertilisation have led to similar debates in the past. In the stem cell debates many of these old lines of argumentation and some of the old coalitions and networks were reactivated (Jasanoff 2005a). Yet the emerging controversy went well beyond a simple rehearsal of the abortion and embryo research debates of the 1970s and 1980s. Following Brian Salter, the "second generation" of the embryo debates were, first, embedded in a more economical discourse and narratives of (national and regional) competitiveness, such as "the global economic potential for regenerative medicine and the perceived national and regional advantage to be gained from an early commitment" (Salter 2006). Second, while the abortion debates of the past decades were framed as a clash between the 'vital rights' of embryos and fetuses versus women's reproductive rights and their rights over their own bodies, the embryo debates of the late 1990s were neither characterized by a problematization of the consequences for women's bodies, nor by questions of distributional justice; rather, they were staged as 'ontological' debates. They did not just focus on questions such as under which conditions and for which purposes we are allowed to "sacrifice" human embryos, but focused on the fundamental question of what kind of matter human embryos actually are.

Interestingly, there have been considerable efforts to "scientifically" fix these debates and to find technical solutions to this moral and political problem. Research groups around the globe have sought to either derive HESCs from embryos without disrupting the embryo's 'life course', or to find alternative sources for pluripotent stem cells (see Box 2.4). The controversies on embryos have therefore given rise to the (modernist) practice of fixing social or political problems through scientific and technical answers. However, so far, none of them have proved to be successful. In the meantime, it is up to politics to deal with these

questions. How politics actually dealt with them is the subject of the following two sections of this report.

Box 2.4: Techno-scientific fixes to ethical problems

Andrew Barry (2001) argues that we live in a “technological society” that is not only characterized by the widespread deployment of technological machines and artefacts but also by its tendency to translate ethical, social, moral or political problems into technical challenges. More specifically, Sarah Franklin notes that one of the emerging dimensions of both innovation and market strategies of the burgeoning stem cell complex are the ways in which ethical concerns or – more broadly – “concerns about public opinion are literally being built into new life forms” (Franklin 2003: 98). Given the high stakes of the stem cell complex as well as the intractability of the embryo conflict, it does not come as a surprise that there have been numerous efforts to engineer technical solutions to these tricky moral conflicts or to produce artefacts that can disentangle the stem cell complex from ethical disputes and moral debates. The spectrum of proposed techno-scientific fixes to the moral and ethical problems of HESC research are widespread. Over the last three years, they have also increased in density.

Some have proposed using embryos that have been found to be carriers of genetic mutations and hence unfit for embryo-transfer after pre-implantation genetic diagnosis for HESC research (Pickering, Braude et al. 2003). Others have proposed growing HESCs from a single blastomere of cleavage stage embryos (Chung, Klimanskaya et al. 2006; Marchant 2006; Pearson 2006a; Simpson 2006). More than one decade of embryo-biopsies in the context of pre-implantation genetic diagnostics (PGD) have proven that cleavage stage embryos are capable of mediating the loss of one of their cells.⁹ Growing HESCs from blastomeres, therefore, could allow the procurement of stem cells without “killing” embryos. In addition, scientists have also proposed engineering embryos – or embryo-like structures – in such a way as to exclude that they could ever develop into fully fledged human beings. William Hurlbut, a member of President Bush’s Council on Bioethics, has proposed a technique called “alternative nuclear transfer” (ANT). ANT suggests removing a gene in order to hamper the development of the embryo. Such a “crippled human embryo” (Gibbs 2006) would survive only long enough to allow the derivation of stem cells from its inner cell mass, but it could not develop into a foetus. While ANT has been only theorized, Italian scientists have recently announced that they have derived human ES cells from “parthenotes”, that is, embryo-like structures developed from eggs that are not fertilized but nevertheless start to divide and to develop. Some insects can reproduce in that way, but mammalian parthenotes are believed to be unable to survive past an early stage. However, according to Tiziana Brevini and Fulvio Gandolfi of the University of Milan, they survived long enough to allow for the derivation of ES cells from their inner cell mass (Marchant 2006). A similar experiment was reported to have succeeded a year later, when Elena Razova and Jeffrey Janus from Lifeline Cell Technology, a biotech company in Walkersville, Maryland, reported having derived stem cells from unfertilized eggs that were induced to divide by chemicals (Cyranoski 2007a).

Different groups of scientists were also reported to have grown ‘HESC like’ stem cells without embryos. In 2006, Shinya Yamanaka from Kyoto University and his group induced a cocktail of four genes into somatic mouse cells. The genes triggered the fully differentiated cells back to a pluripotent stage. Yamanaka named them induced pluripotent stem cells (iPS cells). These cells had some characteristics of HESCs (Check 2006; Vogel 2006). In June 2007, Yamanaka presented “a second generation” (Cyranoski 2007b) of iPS cells, which passed all HESC tests. In addition, a group led by Rudolf Jaenisch at the Whitehead Institute for Biomedical Research in Cambridge, Massachusetts, and a collaboration between Konrad Hochedlinger of the Harvard Stem Cell Institute and Kathrin Plath of the University of California, Los Angeles, used the same four genes and got similar results (Holden 2007).

⁹ When Robert Lanza announced that he and his team had – for the first time – created “human embryonic stem cells without destroying the embryo itself” (Gibbs 2006) in Nature’s podcast on August 23, the shares of Lanza’s company Advanced Cell Technology (ACT) leapt five-fold in price (Marchant 2006).

3. Emerging stem cell topographies

On cells, fluid boundaries and national differences

“Biotechnology”, Eugene Thacker notes, “takes place on a global level, be it in terms of exchanging biological information, controlling epidemics, deterring biological attacks, or standardizing intellectual property laws” (Thacker 2005: xv). And the emerging stem cell and cloning technoscapes (that form – no doubt – a part of a bigger biotechnological reality) cut across boundaries and render national frontiers unstable, indeed. Stem cell lines and oocytes are traded across countries (Waldby 2006a), and networks of patients’ organizations and scientists make national boundaries permeable and fluid. Yet ‘national boundaries’ and ‘states’ have nonetheless retained meaning. Rather, somehow puzzling in an age we are used to thinking of as a ‘global(ized)’ one, in the emerging map of stem cell governance it is the ‘nation state’ that has emerged as the key topographical unit. There are, at least, two reasons for this.

First, states actively shape stem cell and cloning research by drafting regulations that secure the proceeding of this line of research and by allocating funds the private sector has only reluctantly invested so far (see section 2). National boundaries and differences between countries are thereby re-affirmed and enshrined into legislations. In countries such as in Israel and the United Kingdom, HESC and cloning research are permitted under the existing regulations. In other countries, such as in Austria, Italy and Germany, these lines of research are either prohibited or seriously restricted. These differences hamper the crossing of materials and knowledge across boundaries or undermine it altogether.¹⁰ Second, the very interpretation and meaning of the seemingly universal cells, embryos and clones differ strikingly from one topographical unit to the next; often, they are also imbued with particular ‘national’ meanings, ranging from narratives of ‘national’ regeneration over ‘national pride’ to a language of national (dis-)advantages in the emerging global stem cell geo-economies (Gottweis 2002; Gottweis and Triendl 2006). The politics of stem cell research are hence a vivid example for what Sheila Jasanoff eloquently notes, namely that

¹⁰ An extreme case is Germany: German scientists who collaborate with colleagues in countries such as the United Kingdom, where HESC lines faces far less restrictions, might be acting illegally (Stafford 2004).

policies concerning the life sciences have become embroiled to varying degrees in more or less self-confident projects of nation-building or, more accurately, projects of reimagining nationhood at a critical juncture in world history. (Jasanoff 2005a: 7)

The European experiences in the context of FP6 and FP7 speak clearly here. Please note, we do not claim that narratives and discourses respect national borders in the sense that they stop in front of a particular border. HESC lines *are* traded from one country to the next, and styles of argumentations travel from one setting to another. Borders and boundaries are fluid and not hermetic, but they do no doubt matter. How can we make sense of these differences?

A closer look at regulatory patterns reveals that certain groups of countries, such as Germany and Japan and the United Kingdom and South Korea, are much closer to each other in terms of regulatory guidelines than typical regional regulatory cluster tradition or religious lines of division would make one expect. This pattern of difference has led to a number of different interpretations with different emphasis, such as on differences in national historical experience, differences in religion (Gottweis and Prainsack 2002) and local salience of earlier conflict, such as the abortion conflict. Much has been written, for example, about the influence of the traumatic experiences during the Nazi period on current perceptions of modern biomedicine in Germany (Gottweis 2002; Brown 2004), as well as about the traditionally important role of religious groups in public debates in the United States (Wertz 2002; Kennedy 2005). In this report, we will nevertheless argue that the substantial differences between different countries in their approach towards HESC and cloning research can only be explained to a limited extent by reference to culture, religion or the particularities of different political systems. Rather, what we need to look at is the way a particular challenge was politically dealt with and governed.

We suggest the birth of Dolly the sheep as the key event in shaping the local regulatory conflicts around HESC and cloning research across all the countries we discuss more closely in this report. Dolly's birth constituted what Ernesto Laclau labels a "dislocatory moment", that is, the

emergence of an event, or a set of events, that cannot be represented, symbolized, or in other ways domesticated by the [dominant] discursive structure – which therefore is disrupted. (Laclau 1990: 41)

The dislocatory moment does not only refer to a "traumatic event" of chaos or crisis (Torfing 1999: 149) that induces a break with dominant structure, but denotes a turning point or

rupture in a discursive structure, calling for a process of policy re-ordering (Loeber, Hajer et al. 2005). As we argue, the somehow ‘sudden’ availability of cloning technology with the potential to ‘replicate’ complex organisms, and many other, unprecedented implications for research and its various applications in the animal and human field, constituted such a rupture of preestablished modes of ordering and sense making.

In the following, we will argue that we can see two ‘basic models’ to deal with the destabilization of biomedical and regenerative medicine discourse caused by Dolly: a coherent approach that involved the relevant actors in an attempt to develop an encompassing system of regulation for somatic cell nuclear transfer and HESC research (UK and Israel); and a heterogeneous approach (United States, Germany, Italy) characterized by fragmented and often delayed regulation. While in the United Kingdom the shaping of HESC regulations was characterized by an extended process of deliberation and negotiation, in the United States, Germany, and Italy stem cell research quickly turned into a highly divisive, national topic. Whereas in scenario one an inclusionary regulatory setting was created with the intention to create trust between key stakeholders, in scenario two fragmentation, polarization and mistrust dominated. There were also different modes of mobilizing emotions in the different countries discussed in this report, and different ways of structuring the political space, in particular, the interaction between publics and policy makers. Whereas in the United States, in Germany, and in Italy the stem cell question was closely associated with the possible adoption of new laws, a process that segmented the public into well-defined pro- and contra groups, in the United Kingdom the stem cell issue was constructed as a matter of gradual adjustment of existing regulations, a definition of agenda that worked against polarization. As we will argue, delayed regulatory response to the new policy challenges, lack of trust in regulatory institutions and emotionalization led to regulatory stalemate in the United States, and to the passing of tight regulations in Germany and Italy, whereas proactive regulation together with a more balanced distribution of mobilization of trust, emotions and rational argumentation in the United Kingdom avoided a strongly antagonistic policy setting and eventually created a more liberal system of regulation. The EU strategy can be seen as an attempt to develop a coherent, pro-active approach towards stem cell governance, a project that faced substantial differences due to widely varying positions among member states.

In this section we give brief sketches of the developments of in Germany, Austria and the level of the European Union, against the background of the United States and Israel. This

brief overview will be followed by “thick descriptions”(Geertz 1973) of key incidence in Italy and the United Kingdom in the next section.

Emerging Regulatory Patterns

*The United States: Stem cells and emotional polarization*¹¹

From the very beginning, HESC research has been a hotly contested topic characterized by emotional polarization in the United States (Green 2001). Being closely linked to embryo research in the bioethical debate both on the public level and among scientists in a context of increasing religious politicization, the issue of HESC research quickly became a subfield of the abortion wars (Wertz 2002). It was precisely this instrumentalization of a topic of medical research in the context of the politics of religion against which patient advocacy groups (Perry 2000) joined forces.

While privately and state-funded research on HESCs continues to be unrestricted, the use of federal funds for this contested field of research has been a fiercely debated issue for almost a decade. In light of earlier presidential and legislative bans on embryo research, the National Institutes of Health (NIH) in 1999 requested a legal opinion from the General Counsel of the Department of Health and Human Services (HHS) on whether federal funds could be used to support research on human stem cells derived from embryos or foetal tissue. HHS's General Counsel Harriet Rabb concluded that then-current legal prohibitions on the use of HHS-appropriated funds for human embryo research did not apply to research using HESCs “because such cells are not a human embryo within the statutory definition” (Rabb 1999). The statute defines an embryo as an “organism” which, when implanted in the uterus, is capable of becoming a human being – which, so the argument went, is not possible for pluripotent stem cells (that are not totipotent). Therefore, HHS concluded that the NIH could fund research on HESCs previously derived from embryos in a privately-funded setting.

This rational argumentation was combined with deliberate attempts to develop trust-building. In November 1998 President Clinton asked the National Bioethics Advisory Commission

¹¹ This section draws upon Gottweis and Prainsack (2006).

(NBAC) for a review of the medical and ethical issues associated with human stem cell research. After a thorough discussion of the ethical, scientific, legal and social implications of stem cell research, the NBAC strongly endorsed the use of federal funds for HESC research (National Bioethics Advisory Commission 2000). The NIH final guidelines were published on August 25, 2000, giving the green light to federal funding of HESC research in the United States. In the middle of a highly emotionalized debate, an argument presented as an instance of logical reasoning, combined with effective trust-building measures, had helped to overcome the ban on federal funding for embryo research of prior years.

However, the issue was not permanently settled and with the change in the presidency in autumn 2000, HESC research resurfaced as a contested political issue. Already during the presidential campaign of George W. Bush, aides had indicated that he would halt the NIH's initiative to support HESC research. Anti-abortion groups had put considerable pressure on Bush to reconsider the Clinton administration's approach to stem cell research regulation. In a nationally televised speech in August 2001, President Bush outlined his government's new policy. "[M]y administration has adopted the following policy", Bush stated:

Federal funding for research on existing stem cell lines will move forward; federal funding that sanctions or encourages the destruction of additional embryos will not. While it is unethical to end life in medical research, it is ethical to benefit from research where life and death decisions have already been made. (Bush 2001)

Federal funds, Bush stated, would be used only for research on existing HESC lines that had been derived with the informed consent of the donors, from embryos that had been created for reproductive purposes but were no longer so needed and those embryos that had been produced without any financial inducements to the donors (Bush 2001). The NIH was to examine all existing HESC lines and set up a registry of those lines that met the criteria outlined by the President. No federal tax funds were to be spent to create additional embryos for research or to study cells derived from new embryos previously created for research purposes with private funds (Cohen 2004). This decision meant serious restrictions and limitations for HESC research in the United States (Philipkoski 2006).

Since 2001, the debate has been characterized by an even stronger clash than in previous years between religiously motivated opponents of HESC research and its supporters, which include scientists' associations and patient advocacy groups led by celebrities such as Michael J. Fox, Nancy Reagan, and Christopher Reeve. While the National Right to Life alliance

presented HESC research as a plan for “baby farming” (National Right to Life 2002), Nancy Reagan countered with a desperate plea to focus on curing patients: “There are so many diseases that can be cured or at least helped. We have lost so much time already and I just really can't bear to lose anymore” (Anonymous 2004).

On July 20, 2006, however, President Bush vetoed a bill that the Senate had passed shortly before with the aim of loosening restrictions on federal funding for HESC research. In a televised speech, surrounded by young children who were born from ‘adopted’ frozen embryos and their parents, the President explained:

These boys and girls are not spare parts (...) They remind us of what is lost when embryos are destroyed in the name of research. They remind us that we all begin our lives as a small collection of cells. (Anonymous 2006)

To sum it up, stem cell politics in the United States was characterized by a ‘vital’ clash between pro-life groups and patients’ organizations. This sort of emotional polarization went hand in hand with the absence of successful trust-building, as no undisputed regulatory authority emerged. Behind all this stands a tradition of sharp separation between governmental competencies and the sphere of individual freedom, making possible the unique distinction between what is permissible for privately and state-funded as opposed to federally funded research in the United States.

Israel – stem cells in a ‘small country in a hostile neighbourhood’

Israel has been described as “one of the centres where researchers from less liberal countries go shopping” (Gross 2003), as “one of the leading countries” in stem cell research (Perrin 2005) and as a “peaceful island for therapeutic cloning” (ADUC 2002b). And our second non-European case study could probably not be more different from the United States.

Despite Israeli researchers and laboratories being at the forefront of this field of cutting-edge science, Israel has not witnessed controversies or public outcries that are in any way comparable to the antagonistic debates in the United States, nor have Israeli socio-political actors ever been confronted with the challenge of finding a common ground on how to tame stem cells – they simply did not become ‘unruly’.

Following the birth of Dolly the sheep, the Knesset, the Israeli Parliament, adopted “The Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law” in December 1998. In 2004, the law was slightly modified and renewed for another five years (State of Israel 1999; Barilan and Siegal 2005; Revel 2005; Prainsack 2006). It prohibits the deployment of reproductive cells “that have undergone a permanent intentional genetic modification (Germ Line Gene Therapy)”, and human reproductive cloning, setting a moratorium on both technologies until March 2009. ‘Therapeutic cloning’ is not mentioned in the law.

In the absence of primary legislation, HESC and cloning research are governed by secondary legislation, the 1980 “Public Health Regulations (Human Experimentation)” and the 1987 “Public Health (Extra-Corporeal Fertilization) Regulations” (Shapira 2002; Shapira nY). Their respect and implementation is monitored by a range of institutional review boards.

Altogether, the current regulatory regime places a ban on the production of embryos for research purposes, but it does not inhibit Israeli scientists from deploying ‘surplus’ embryos for research purposes or from producing embryonic structures through somatic cell nuclear transfer. However, scientists engaging in one of these practices need prior approval from the “(Supreme) Helsinki Committee for Genetic Medical Experiments on Humans”, a monitoring body within the Ministry of Health. In its 2003 report to the Ministry of Health, the committee stated that it was ready to approve both the derivation of HESC from “genuinely surplus” embryos and applications for somatic cell nuclear transfer (Shapira nY).

How can this striking difference to the United States be explained? Scholars often mobilize cultural values and hegemonic narratives to explain the enthusiastic embracement of stem cell research and other fields of cutting-edge techno-science in the small Jewish state. Israel seems to benefit in particular from being embedded in a Jewish, rather than Christian, religious moral system (Kahn 1998; Kahn 2000; Shalev 2003; Prainsack 2006). Judaism, Prainsack (2006: 184) notes, works as an inducement for biomedical research rather than as a barrier. It allocates high values on practices of healing. Following Jewish-religious reasoning, our bodies are a gift from God, and we are therefore invited or obligated to guard, heal and enhance this gift (Wahrman 2002: 18). In addition, in contrast to Christian(-Catholic) reasoning, the Jewish moral system does not regard the early human embryo as in any way comparable to a human person. Judaism believes that rather than at fertilization, humanness is acquired progressively during embryonic and foetal development. Pre-implantation embryos embody a status that is

comparable to that of human gametes: they should not be wasted in vain, but they may be manipulated for therapeutic purposes (Interview 2-50; see also Prainsack 2006). The key argument of the US-American opponents to stem cell research, that this line of research “end[s] some lives for the medical benefit of others” (Bush 2001) and is at odds with “human dignity” is therefore totally devoid of meaning. Rather, as Amos Shapira notes, in the Israeli discourse the concept of “human dignity” is “far more readily associated with aspirations for healing life-threatening diseases ... and enabling couples to beget offspring” (Shapira nY).

In addition to these “sacred” truths and ancient deliverances, the stem cells are also imbued with “secular” truths (Prainsack 2006). Zionism, the founding myth of the State of Israel, allocates high value to science, technology and - in general – “human agency”, as a means to defend the well-being and survival of the Jewish community and as a guarantee for its economic and physical continuity. While scientists and technocrats ranged prominently in the “pantheon of heroes” (Penslar 1991: 241) of the “first Israelis”, in recent decades this reading of science has also been re-enforced through the enduring Israeli-Arab conflict. Following the hegemonic sense-making of the continuing bloodshed, Israel is a small community in the midst of a hostile neighbourhood that constantly threatens the survival of the small Jewish state. In this context, there is “no other choice” (*ein brera*) but to invest in science and technology to guarantee the state’s survival and continuity (Kimmerling 2001). As Nissim Mizrachi notes, the narrative goes as follows: “[A] small country surrounded by numerous Arab nations threatening its very existence defeats its vicious enemies against all odds by using its ‘brain power’” (Mizrachi 2004: 223). Barbara Prainsack notes, in this context, “[e]ndorsing a permissive approach towards technologies that are capable of sustaining the collective body by finding new cures for the sick, or even by creating new life, is the only ‘rational’ solution for both decision-makers and users” (Prainsack 2006: 176)

But please note, this does not mean that the meaning of cells and clones is totally fixed by the mere existence of this discursive economy and that ‘politics’ and governance become meaningless. The events after the birth of Dolly the sheep are cogent here. Both in the occasion of the first passing of the law in 1998 and in its renewal, there have been voices calling for a permanent ban of cloning and the practice of governing through the administration of ordinances through dispersed institutional review boards was threatened. However, in both occasions scientists and bio-ethicists have been able to ‘convince’ these voices that it would be ‘irrational’ and ‘immoderate’ to oppose scientific research in principle

and to impose rash bans. Scientific research, so the story went, should be carefully monitored – and science could be trusted (Gottweis and Prainsack 2006).

*Germany: Ethos Politics*¹²

In Germany, the 1991 Embryo Protection Act (*Embryonenschutzgesetz*, ESchG) strictly prohibits embryo research and human cloning. It prescribes that all eggs fertilised within an IVF procedure must be transferred to the woman from whom the eggs had been taken and the number of embryos transferred is limited to three. No fertilised egg may be stored or destroyed. Consequently, according to the law, *there must not be any 'surplus' embryos in Germany*. Thus, embryo research is not only illegal but also lacks any legal research material.

The 1997 news of the first cloned sheep, Dolly, was met with shock and horror in large sectors of the German public. While HESC research (including cloning for research purposes) was illegal in Germany, some younger German scientists had worked in HESC research in the United States and had started to apply their knowledge on animal models at home. With increasing unease those scientists saw their work on animal models being used in experimental research on human stem cells abroad. Subsequently, the scientific community allied itself with key German research funding agencies and politicians from different parties to convince the German public of the worthiness and necessity of pursuing HESC research in Germany (Stafford 2006). What they had underestimated was the increasing public importance of the question of whether and how HESC research could be compatible with the German self-image of an 'ethical nation.' The latter proved to be an important aspect of German collective identity in light of a collective memory of inflicting suffering and death on millions of people (Schöne-Seifert and Rippe 1991).

A broad coalition of actors considered this an irresolvable conflict and fiercely rejected research on HESCs. Catholic and Protestant churches, the Green Party, major sectors of the Christian Democrats (CDU/CSU), a part of the Social Democrats (SPD), and a broad spectrum of NGOs ranging from feminist groups to green organizations (Braun 2007) conceptualized HESC research as an "attack on life" and "human dignity", an unprecedented undermining of ethical principles, a "dehumanization" of life, and even "cannibalism"

¹² This section draws upon Gottweis and Prainsack (2006). Many thanks to Kathrin Braun for her insightful revision of this section.

(Cardinal of Cologne, Joachim Meisner, quoted in Anonymous 2001). The *Nationaler Ethikrat* (“National Ethics Council”), set up by Chancellor Schröder in May 2001 (exactly at the time when the legalization of importing HESC lines was being discussed), was soon branded a puppet institution intended to generate ad-hoc legitimation for the government’s allegedly bio-liberal decisions. Barely six months after its creation, it issued a recommendation in favour of allowing the import of HESC lines (supported by a 14: 8 vote).

On January 30, 2002, the German Parliament engaged in a five-hour-long debate, after which a majority of 339 versus 266 members favoured the legalization of importing HESC lines for research from abroad. In April of that year, the Parliament passed the new Stem Cell Act which was enacted July 1. It allows the import of HESCs for research purposes under certain strict conditions. A newly founded ethics committee, the Central Ethics Committee on Stem Cell Research, was established to evaluate research proposals on HESC research. The creation of HESCs on German soil remained illegal. In effect, the Parliament had succeeded in outlawing a contested field of research *in principle* but at the same time left a loophole that rendered a potentially profitable field of research possible at the practical level.

Altogether, the German stem cell debates were not shaped by a clear divide between religiously motivated opponents of HESC research on the one hand and its propagators using the rhetoric of scientific progress and empathy with the suffering of patients on the other (Braun 2005). Rather, the lines of antagonism in Germany cut across the religious-secular divide, as well as across the political spectrum. Not only Christian churches, but also many other actors, mobilized narratives of history reminding what the devaluation of human life had led to in Germany’s National Socialist past, referring to a common ethos, which, in their view, lies at the heart of German post-war society: the ethos derived from the historical experience of the Nazi crimes. It implies the common will not to become that sort of people any more who distinguish between “life worth living” and “life not worth living” (Braun 2005).

In stark contrast to the United Kingdom, the United States and Italy, the voices and images of suffering patients were virtually absent from the debate. Instead, much of the controversy unfolded as a search for the morally and ethically proper course of action (Heinemann and Honnefelder 2002), the questioning of the ethical status of institutions and individuals, and the compatibility of the discussed policy measures with different collective self-images in Germany. The strategy of rendering HESC research a topic that one had to oppose – or at

least be very skeptical about – if one did not want to run the risk of being labeled unethical, cold-hearted and greedy, was largely successful. It was also able to succeed because of the greater *ethos* possessed by actors who were seen as driven by genuine moral concerns, independent of political and economic profit considerations, as opposed to, for example, members of the National Ethics Council, or scientists themselves, who were seen as morally reprehensible in weighing research and economic objectives against “human dignity”. As the late President Johannes Rau, one of the participants in the debate who possessed a lot of *ethos*, stated: “Where human dignity is concerned, economic arguments do not count” (Rau 2001).

Austria: A deadlock in the debate on stem cell research

Austria is an example of how past decisions and experiences in politics of life affect present regulation of HESC research. The conservative right-wing government rejected HESC research, as can be observed by Austria’s refusal of the FP6 proposals in 2001 and 2002. In spite of the government’s restrictive position, the legal situation in Austria concerning HESC research is ambiguous. No particular law regulates the status of the embryo, and current legislation has great gaps regarding HESC research. The reproductive medicine law, which regulates in vitro fertilization (IVF), prohibits research on reproductive cells and thus clearly bans embryo research. However, disagreement exists among jurists on whether the law prohibits non-reproductive cloning for research purposes and the import of existing stem cell lines, since it does not cover these issues explicitly (Pichler 2002). In addition, existing legislation is not very rigorous: The reproductive medicine law defines breaches as petty offences and penalizes them only with minor fines. Notwithstanding this unclear legal situation, no HESC research occurs in Austria, and research focuses on stem cells from umbilical cords, adult stem cells and murine stem cells (Gmeiner 2006: 30).

Despite these ambiguities, neither the government nor the opposition took initiatives to clarify the legal situation. Only a limited political debate took place in the narrow sense on HESC research. In Robert Gmeiner’s words, “while the debate on stem cells in Europe and in Austrian media has been quite heated, it has not really touched Austrian political bodies such as the federal government or the parliament” (Gmeiner 2006: 30). As a result, neither a particularly coherent nor a polarized or emotionalized controversy evolved in

Austria, where HESC research was mainly a non-topic, and the de facto moratorium on HESC research remained surprisingly unthematized.

The leading governing party, the conservative Austrian People's Party, dominated the little discussion that did exist. A faction favouring a restrictive approach to HESC research including, for example, the federal chancellor and the science minister, formulated the official party opinion. 'Thus the Peoples' Party as a whole rejects HESC research (Gmeiner 2006: 27). Through their connection to this restrictive group, high-level officials of the Catholic Church, which take a very restrictive position, are rather influential in Austria (Interview 2-27, Interview 2-25). But there is also a permissive group within the party that includes the economics minister and the representative and party speaker for science. In a parliamentary debate on the budget in June 2003 she said:

In the area of gene research, in the area of genetic diagnostic, I wish for a proactive answer to the problems which we have introduced with in vitro fertilisation. With this in vitro fertilisation – and that's what all ethicists say – we have crossed the Rubicon and now – on the other bank of the river – we have to give answers. I think, that it would be appropriate that we, together with all the groups that are assembled in this parliament, face up to, and try to find answers to the problems of embryo research, of embryonic stem cell research and the connected issue of pre-implantation diagnostics. I wish for research proposals from research institutes. On the basis of such a proposal it is possible to state in a transparent manner and accompanied by monitoring and by naming parameters and preconditions, under what conditions this research should be allowed, supported and funded (Stenographisches Protokoll 2003: 90ff).

Both opposition parties, the Austrian Social Democratic Party and the Green Party, take a more permissive stand towards HESC research than the prevailing, restrictive wing within the Austrian People's Party. But neither the Social Democrats nor the Greens were particularly present in a public political debate.¹³

Despite many pleas that a socio-political discussion of HESC research is desirable and necessary, no large public controversial discussion on HESC research has developed thus

¹³ With two exceptions we could not find a statement on the issue. One exception were four identical parliamentary inquiries from Social-Democrat representatives who addressed the Federal Chancellor and the Ministers for Science, Social Security, and Innovation on June 13, 2002 (4063/ J XXI.GP, 4064/ J XXI.GP, 4065/ J XXI.GP, 4066/ J XXI.GP). The representatives asked – using a language that implies critique on the decision – about the reasons for the votes, how the decision came about and the consequences for Austrian science and research.

far.¹⁴ When media has dealt with regulative aspects of HESC research at all, they have neglected its relevance to Austria, instead focusing on international legal developments, mainly in Germany, the United Kingdom and the United States. Although universities, parties and NGOs organised a number of events and bioethical symposia, they reached only a small segment of the public (Gmeiner 2006: 26). In summary, it is fair to say that the discussion remained restricted to a small number of stakeholders from science, theology, ethics and law, as well as a handful of politicians and civil servants.

An elite of scientific experts (e.g., human geneticists, gene researchers) and physicians play an important role within advisory boards and expert commissions such as the bioethics commission (Bioethikkommission) at the federal chancellery (Bundeskanzleramt)¹⁵. But a handful of Catholic and Protestant theologians as well as secular philosophers are also important elite actors in governmental commissions and public debate. So far, expert advice stemming from the bioethics commissions has been important because it has informed or at least legitimated government decisions on HESC research (Interview 2-29).

Two instances played a key role in the unfolding of stem cell policy in Austria: first, the abortion controversy of the early 1970s and, second, the 1998 public initiative on gene technology (*Gentechnikvolksbegehren*). The abortion debate ended in 1975 in a fragile but permanent compromise: Austria has a very permissive abortion law; however, in practice abortion is not openly accessible in all parts of the country (Grießler 2005). Political actors drew from the abortion conflict the lesson to avoid the issue as much as possible so as not to disturb this fragile balance (Interviews 2-25, 2-26, 2-34).¹⁶ The second instance, the public initiative on gene technology (*Gentechnikvolksbegehren*) was extremely critical about 'green biotechnology', demanded very restrictive governmental policy and became one of the most successful civic initiatives in Austrian history since 1945. This very act of civic participation traumatised politicians and civil servants, who wanted to promote research and development

¹⁴ This statement is also valid for most ethical and political debates on biomedicine and 'red' biotechnology in Austria (Grabner 2003; Gmeiner 2006).

¹⁵ <<http://www.bka.gv.at/DesktopDefault.aspx?TabID=3455>>, accessed on October 20, 2006.

¹⁶ "The discourse (or maybe better: the non-discourse) then demonstrates that this controversy on abortion and its outcome reaches into contemporary issues: on the one hand and despite obvious differences, it is difficult not to see the connections between the debate on abortion, and issues such as in-vitro fertilisation (IVF), pre-natal diagnosis (PND) or pre-implantation genetic diagnosis (PGD). On the other hand, one can recognize issues and positions (e.g., of the Catholic Church) in the current discussions which have been presented in the context of the Fristenlösung (...)debate for the first time" (Gmeiner 2006: 25).

for economic growth. Both the *Gentechnikvolksbegehren* and the 1970s abortion debate were important to the debate of HESC research in Austria. Both were very emotional controversies, characterised by seemingly irreconcilable cleavages within society and followed by a political deadlock. As Gmeiner (2006) puts it:

My interpretation is that potential groups of activists (political parties, feminist groups, disability rights groups) would rather not touch a (biopolitical) issue. This approach seems to have its roots in a fear that a broad political debate about biomedicine and biotechnology might bring back disputes which no one wants again (e.g., “Fristenlösung”) or might launch public discussion of a kind (such as GMO conflict) no one wants to face again. Potential participants must also have in mind that a debate could – with regard to their particular goals – change the legal framework in a non-desirable manner. And most of the contributors realise that their previous handling (or better: non handling) of these issues was quite a good way (in German “man fährt gut damit”): so why should one change the approach. (Gmeiner 2006: 25)

One of the few instances resulting in a small-scale debate on HESC research was the negotiation on FP6. At the centre of discussion was the question of whether European public funds should be used for HESC research funding. Together with a number of other EU member states, Austria, represented by the science minister and the minister for transport and innovation, took a restrictive position and voted against public funding of HESC research within the framework programme (Pichler 2005).

Thus, policy making regarding HESC research followed the usual patterns of Austrian politics: Public involvement apart from the usual mechanisms of representative democracy was almost absent. The general public and the media did not participate much in this elite debate. Policy making was concentrated in responsible ministries and marked by elite participation. The responsibilities concerning the reproductive medicine law were scattered among several ministries¹⁷, which had to find a consensus for change (Gmeiner 2006: 27), and civil servants within the responsible ministries did most of the preparatory work to reach that consensus. The National Council and its individual representatives – as in most policy areas in Austria – played only a minor role in political debate and decision making, despite their formal legislative responsibility (Müller 2006). However, the decision to reject funding of HESC research in the context of FP6 shows some different features. The decision was taken by a very small number of top politicians within the Austrian People’s Party. It neglected the majority vote of the bioethics committee. The minister opted for a restrictive

¹⁷ I.e., the Ministry for Science and Culture, the Ministry for Justice, the Ministry for Health and Women and the Ministry for Traffic and Innovation (Gmeiner 2006: 27).

position that a minority within the commission recommended. Moreover, she decided to take a different position than the one her top civil servants had based their work on in Brussels for years (Interview 2-27).

The European Union

Europe is currently at a crossroads: we need to actively develop responsible policies in a forward-looking and global perspective, or we will be confronted by policies shaped by others, in Europe and globally. The technology and its applications are developing rapidly – the Commission believes that Europe’s policy is, therefore, not whether but how to deal with the challenges posed by the new knowledge and its applications
(European Commission 2002: 9).

Among the dilemmas frequently encountered by ethics, there is that born of the confrontation between freedom of research and freedom to conduct business on the one hand, and the respect due to human life on the other
(EGE 2001: 11).

The Commission proposes a strategy that responds with responsible, science-based, and people-centred policies on an ethical bases
(European Commission 2002: 10).

In contrast to ‘green’ biotechnology, EU-competencies in ‘red’ biotechnology are rather limited because health policies¹⁸ and the regulation of ethical issues of medicine and human reproduction are mainly a national domain. Nevertheless, embryo- and HESC research became a very controversial issue within and among the EU Institutions in the context of research and technological development policy and the Sixth Framework Programme (FP6). This controversy is well documented in recent analysis (Abels 2002; Salter and Jones 2002; Abels 2003; Gottweis 2003; Pichler 2005). We will therefore focus on the questions of which participatory spaces emerged in the debate, and in what way, or whether any emerged at all, and under which conditions FP6 funding should include HESC research.

HESC research is mentioned in FP6 in priority 1 “Life Sciences, Genomics and Biotechnology for Human Health”:

focus on the development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies). (Commission of the European Communities 2003b: 4, quoted from Pichler 2005: 262)

¹⁸ This section does not deal with the regulation of pharmaceuticals where the EU has much more competencies.

The Commission perceives biotechnology and life science – and accordingly HESC research – within the context of the Lisbon agenda’s strategic goal “to become a leading knowledge-based economy”. The Commission refers regularly to these goals and expresses its opinion that life sciences and biotechnology are key technologies leading to economic prosperity:

Life sciences and biotechnology have entered a stage of exponential growth, opening up a vast potential to move economies in Europe and globally towards more sustainable development and improved quality of life. They are therefore of strategic importance in Europe’s quest to become a leading knowledge-based economy. Europe cannot afford to miss the opportunity that these new sciences and technologies offer. (European Commission 2001b: 3, see also European Commission 2002a: 8)

[T]he life science revolution was born and is fed and nurtured by research. (...) There is an undisputed link between research, innovation, the competitiveness of industry and the generation of wealth and social prosperity (European Commission 2001b: 11ff.).

The Commission was also concerned that “Europe’s current performance in life sciences and biotechnology is not facilitating the achievements of that objective” (European Commission 2002a: 8). In short, the Commission emerged early on as an institution strongly in favour of HESC research and as a policy actor attempting to build a coherent approach towards HESC research.

The Commission supported stem cell research already during the 5th Framework Programme (1998-2002) within the thematic programme “Quality of Life and Management of Living Resources”. This decision was backed by an Opinion of the European Group on Ethics and New Technologies (EGE).¹⁹ The Commission funded “15 research projects in the area of

¹⁹ On September 11, 1998, the Commission requested an Opinion on embryo research within FP5. In its Opinion No. 12 from November 23 1998, EGE confined embryo research to “experiments on embryos which are not intended for transfer to the uterus, and which do not survive” (EGE 1998: 78). The EGE emphasises that “the progress of knowledge of life sciences, which in itself has an ethical value, cannot, in any case, prevail over fundamental human rights and the respect which is due to all the members of the human family” (EGE 1998: 81). It states that “the human embryo (...) deserves legal protection”, which “falls within the competence of national legislation”. However, the Community authorities “should be concerned with ethical questions resulting from medical practices or research dealing with early human development”. In that they should take into account “the moral and philosophical differences” between Member States, “the respect for different philosophical, moral and legal approaches and for diverse national culture” being “essential to the building of Europe”. The EGE states that “the Community’s Fifth Framework Programme Community funding should not a priori exclude human embryo research (...) but that this funding should, nevertheless, only be granted under strict conditions” (EGE 1998). These are “systematic ethical evaluation, at Community level, of protocols of research on human embryos presented for Community funding”; “priority should be given to the principle of the respect due to human life, as well as, respect regarding the consent of the women or couple concerned”; the project must comply with national regulations; where embryo research is permitted by national legislation, public as

stem cell research and therapy with a total EC contribution of € 27.4 million” (European Commission 2002b: 10).

In preparation of FP6 (2003–2006) the Commission came to the conclusion that the decision whether to include HESC research into research funding should be backed by an Opinion of EGE (Gottweis 2003: 17). In short, the EGE opinion took the position that HESC research should be allowed in principle, however, under certain restrictions (EGE 2000a)²⁰.

well as private research should be carried out “under strict public control” and “maximum transparency”. Such transparency “should be a compulsory requirement of any proposal funded by the 5th Framework Programme, since it provides the best guarantee against major risks of arbitrary experimentation” (EGE 1998). Moreover the Opinion emphasizes the importance of enlarging public debate, which “is just getting underway”. It also asks for additional Community money within FP5 for global scientific and ethical evaluation on research projects involving human embryo research, the results of which should be made public. Finally, the EGE Opinion desires that the Commission should create a system of information “regarding all ethical and legal aspects relative to life sciences, at both national and international level” (EGE 2001: 83).

²⁰ The EGE addresses “ethical issues raised by human stem cell research and use in the context of the European Union research policy and European Community public health competence” (EGE 2002a: 14). It points out several “fundamental ethical principles at stake” such as “respect for human dignity”, “individual autonomy (entailing the giving of informed consent, and respect for privacy and confidentiality of personal data”, the principles of “justice and beneficence”, “freedom of research”, “proportionality (including that research methods are necessary aims pursued and that no alternative more acceptable methods are available”. Moreover EGE points out the “potential long-term consequences of stem cell research and use for individuals and society” (EGE 2002a: 15). Again EGE points out the “respect for different philosophical, moral or legal approaches and for diverse cultures” that are “implicit in the ethical dimension of building a democratic European society”. In that EGE refers to Article 22 of the Charter of Fundamental Rights and on Article 6 of the Amsterdam Treaty (EGE 2002a: 15).

EGE states, that embryo research is forbidden in some Member States, but allowed in others “for the purpose of treatment of infertility. It states that **“it is hard to see any specific argument which would prohibit extending the scope of such research** in order to develop new treatments to cure severe diseases or injuries” (EGE 2002a, emphasis in original). Following from that EGE sees “no argument for excluding funding of this kind of research from the Framework Programme (...) if it complies with ethical and legal requirements as defined in this programme (EGE 2002a). EGE states several requirements which should be considered for funding: Stating the UK HFEA as an example, ES cell research should be carried out in countries, where it is allowed **“under strict public control by a centralised authority”** (EGE 2002a: emphasis in original). Given the sensitivity of the “use of embryonic stem cells”, authorisation for both private and public research should be highly selective and transparent and be based on a case-by-case approach. EGE states that “the creation of embryos for the sole purpose of research raises serious concerns since it represents a further step in the instrumentalisation of human life”. It considers the creation of embryos “with games donated for the purpose of stem cell procurements” as “ethically unacceptable, when spare embryos represent a ready alternative source”. Moreover it states that the **“creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would b premature”** (emphasis in original), since there are alternative sources from spare embryos, foetal tissues and adult stem cells). EGE also appeals for “EU funding (that) should be devoted to testing the validity of recent discoveries about the potential of differentiation of adult stem cells” and states “a specific responsibility (at European Union level within the Framework programme of research) to provide funding for stem cell research” (EGE 2002a). This implies the establishment and provision of sufficient means for ethical ex-ante assessment and monitoring. Moreover, EGE “stresses the necessity **to ensure that the demand for spare embryos and oocyte does not increase the burden on women**” (EGE 2002a: stress in original).

This opinion, as Commissioner Busquin declared, was the bases of the Commission's policy:²¹

In the preparation of future research programmes the Commission will base itself on the opinion of the European Ethics Group, especially on the opinion on the ethical aspects of human stem cell research delivered on 14 November 2000. (IP/00/1501, 20 December 2000)

In his decision Commissioner Busquin was guided by an

anticipated positive response by the majority of Member States, the positive opinion of the EGE, and because of the positive development in his native country, Belgium, where even the Catholic University of Leuven has been in favour of stem cell research under certain conditions. (Pichler 2005: 266)

Subsequently, in 2001 the Commission, which has the right of initiative in this matter, entered negotiations about FP6 with a permissive proposal regarding funding of HESC research.

However, political actors representing Member States in the Council had (and still have) very different perspectives on the use of HESC for research purposes, and national legislations varied (and still varies) to a great extent across Europe (European Commission 2003, Capps 2005). The Council was split into a 'permissive' and a 'restrictive' faction; the first included the United Kingdom, Sweden, Denmark, Finland, France, Belgium, Greece and the Netherlands; the latter group was composed of Germany, Italy, Austria, Luxemburg, Portugal and Spain and Ireland (Pichler 2005: 267). This division roughly mirrors the group of Protestant and Catholic countries in Europe. Religion, however, should not be overestimated and was only one essential factor in this debate. Naturally, there are strong economic and

As all EGE Opinions issued so far also this Opinion was issued as consensual. However, the paper was a compromise within the group: "This Opinion (...) was thus adopted by consensus though some in the Group tended to oppose all human embryo research while others were more favourable to the development of 'therapeutic cloning'" (EGE 2001: 9).

21 "This advice that they gave which said that it was important to support those embryonic stem cell research foetal and adult stem cell research. And that should be supported at the EU level. But what the advice was that it was not justified to create embryos for stem cell research. And also that it was also premature to allow for creation of embryos by nuclear transfer. So that was their recommendation. So meaning that the framework programmes would provide possibilities to work on let's say the three different fields of research on stem cell origins. And this advice has been the basis for the policy that the commission has performed. And when we, when the discussions on the framework programme starts, it is the Commission that put forward a proposal which is then discussed in the institutions" (Interview B).

strategic interests in HESC research (Salter 2006).²² Thus, different beliefs and economic interests were the main centrifugal forces of this conflict within the Council. However, since HESC research was only a very small faction within the programme and international economic competitiveness is a cardinal goal of EU policies, none of the players within the Council wanted to jeopardize the timely resolution of the entire FP6.

A group of representatives of restrictive Members States criticized the Commission's permissive approach in the Council and the Austrian representative even vetoed the Council's common position in June 2006. On September 30, 2002, the restrictive faction requested a moratorium to postpone actual funding of HESC research until December 31, 2003. The compromise stated that no funding for HESC research would be granted until December 3, 2003, except for isolated and banked human embryonic stem cells in culture. Moreover, it was agreed that the Commission would provide a report on HESC research that should be the basis for an inter-institutional seminar in spring 2003. In addition, the Commission should work out funding guidelines.

Salter and Jones perceive the European Parliament as the most active actor in the "expression of the civil society interest" in biotechnology so far (Salter and Jones 2002: 334). The Parliament takes a more skeptical position towards HESC research than the Commission, which was expressed in several resolutions concerning cloning and embryo research (see Salter and Jones 2002: 331; Romeo-Casabona 2002:495). Salter and Jones explain this sensitivity with their dependency on their electorate:

Members of European Parliament are naturally sensitive to the cultural response of their constituencies to human genetics developments. Unlike permanent officials, they are obliged to balance the pressures of the Brussels-based trans-national policy networks with the electoral consequences for themselves and their parties of failing to heed the often strongly held view of the citizens. As a consequence, they act as a conduit for the expression of a diverse range of ethical vies on human genetics and find the achievement of a workable consensus in this field a less than straightforward matter (Salter and Jones 2002: 332).

²² E.g., in the case that the United Kingdom did not sign the Bioethics Convention of the Council of Europe, "UK, non-signature (of the bioethics convention) reflects its need to protect its economic interest and its leading position in human genetics R&D. Signing the convention would prevent the realisation of the UK's ambition to establish a world lead in stem cell research since this technique is dependent on therapeutic cloning which the Convention prohibits" (Salter and Jones 2002: 329). Or: "it is also true that important economic interests are involved in embryo research (including the trading of embryos or ES cell lines and the aim of patenting them), and is certain that these economic interests are playing a role in the political and legislative decisions of some state. It would be disingenuous not to consider this a relevant matter, which is often hidden behind the ethical controversies" (Romeo-Casabona 2002).

Like the Council, the European Parliament was split into restrictive and permissive factions. However, the permissive faction, consisting of Social Democrats, Liberals and a group of conservatives from the European People's Party, finally prevailed in November 2003 in a vote of 298 in favour, 241 against and 21 abstentions.²³

In April 2003 the Commission Staff Paper that was agreed upon in December 2002 (Commission 2003b: SEC(2003)441) was presented and formed the basis of an inter-institutional seminar on HESC research held in Brussels in the same month. The Commission also worked out a proposal, based on Article 166(4) of the Treaty for guidelines “on the principles for deciding on possible Community funding of research projects involving in particular the use of human embryonic stem cells” (Commission 2003: 12). This proposal was submitted to the Institutions in July 2003 and was supported by the European Parliament (Commission 2003: 17).

In November 2003 the Commission (C(2003)2952) adopted procedural modalities for research activities involving banked or isolated human embryonic stem cells in culture to be funded under FP6 (Commission 2004: 17).

At the end of the moratorium, the restrictive and permissive factions within the Council did not agree on the funding condition for HESC research in the Specific Programmes in FP6. In absence of general guidelines, the Commission started to fund HESC research on a case-by-case approach after the expiration of the moratorium. So far only a small number of projects on HESC research have been funded. In its first call the Commission funded 25 research projects involving at least one component of stem cell research, with an EC contribution of ca. € 160 millions.. More than 90% involved the use of adult human stem cell and only 2 use components of HESCs (drawing upon already existing lines). In the second call the Commission expected to support 17 projects involving stem cell research, amounting to € 110 millions. Only 1 project involves a component of HESC research (using existing HESC lines, Commission 2005: 29).

²³ The provisions for funding of HESC were: “The human embryos used for the procurement of stem cells must be supernumerary early stage (i.e. up to 14 days) human embryos (embryos genuinely created for the treatment of infertility so as to increase the success rate of in vitro fertilisation (IVF) but no longer needed for that purpose and destined for destruction); such research may be funded provided that it is legally permitted in the Member State(s) where it will be conducted under the rules and strict supervision of the competent authorities (European Parliament, 2003, AS-0369/2003 Final Amendment). Funding is also allowed for “research on embryo or foetal stem cells deriving from spontaneous or therapeutic abortion” (European Parliament, 2003, A5-0360/2003, Amendment 18, quoted from Pichler 2005: 266).

An interesting feature of these developments were the efforts in the Commission of “seeking new methods of engagement both with the expanding numbers of NGOs in the human genetics arena and the public at large” (Salter and Jones 2002: 326). Commission departments, the Council and the Parliament compete in these efforts “for the pole position in the business of policy agenda setting” (Salter and Jones 2002). The institutions face the challenge to resolve diverging claims of civil society, science and industry in the area of biotechnology policy. Salter and Jones state that

the traditional reliance on that community on technocratic networks as the mainstay of policy formulation and implementation is no longer a sufficient mechanism for maintaining the legitimacy of the process. New policy networks imbued with different value systems are rapidly making inroads into the previously impermeable policy community of EU governance.

Connected to the difficulties of regulating GMO, Salter and Jones perceive a “sea-change in the political culture of governance policy making at EU level” (ibid.), which is expressed, for example, in strategic documents such as the “White Paper on Governance” (European Commission 2001a) or the paper “Towards a Strategic Vision of Life Science and Biotechnology” (European Commission 2001b). The latter strategy papers explicitly state that

transparency, accountability and participatory approaches in public policy making need to be reinforced. These objectives coincide with those of the Commission’s White Paper on European governance and will be pursued through the actions proposed therein (European Commission 2002: 20).

Abels also diagnoses participation as a “remarkable shift” in the Commission’s position on “how to govern biopolitics”:

‘Participation’ is the key word – yet reduced to a very limited concept (...). The proposed ‘participatory’ modes of governance aim at greater *inclusiveness* of social actors, i.e. experts and lay-people, stakeholders and citizens, the public and Eurocrats in supranational policy-making and regulation. The underlying assumption is that the effectiveness and efficiency, i.e. the output side of policy making, can be improved by strengthening the input-side and, in doing so, the legitimacy of EU policy will increase. (Abels 2002: 2)

This sea change is not only fuelled by the “laudatory desire for greater citizen involvement in the governance of biotechnology” but also by the plain fact that consumers decide with their market decisions on economic success or failure of biotechnology products (Salter and Jones 2002: 327).

Abels (2002) notices three features of EU RTD policy making. First, the system is heavily driven by science and relies on expert advice:

The Commission sets up and makes use of scientific advisory committees; it utilizes its organisational resources and experiences to decide who gets access to European policy networks and who doesn't. Policy- and decision-making on issues of science and technology is, above all, a 'politics of expertise'. Epistemic communities, that is networks of professionals with recognized expertise and an authoritative claim to policy relevant knowledge have easy – and above all – privileged access to European policymakers (Abels 2002: 6).

Second, she perceives the rise of bioethics. Third, there is an attempt to “take into account the social prerequisites of technological innovation” (ibid.). However, the notion of participation is in conflict with the “scientification of politics”, i.e. the inflationary use of scientific expertise in public policy making” (Abels 2002: 3).

Thus, the rhetoric of participation, a lesson drawn from the GMO and BSE debates heavily influenced the way in which the Commissions tried to handle the case of HESC research. However, how did European institutions actually come to grips with the “ethical problem” of HESC research, and what was the role of participation in this process? Which participatory practices were actually present in the debate on HESCs in FP6?

Despite the rhetoric of participation and public dialogue, the decision on HESC research was still prepared by a small number of officials within the Commission and finally made by top politicians in the Council, the Commission and the Parliament. In this process, formal competences and procedures as well as informal negotiations and bargaining at the top level played “the” decisive role.

[A] lot was really at high level, between the Ministers. Less than what we usually (...) Because usually it is true. Everything is prepared. The Ministers go and they sign. And it is technical people who do their work. But this time it was not only the technical people who did the work. A lot was done in the discussions between the Ministers, between Commission. (...) It was very much, let's say, it was really a **political** decision. (Interview B, emphasis in the original)

These decision-making processes, not surprisingly, were not at all open to the public and public participation.

One way to deal with the problem posed by HESC research funding was to follow administrative routine, to compile reports on HESC research and international regulation and

to discuss them with other actors from relevant EU authorities. The inter-institutional seminar held in Brussels in April 2003 provided such a deliberative space:

[I]t will be in three institutions Council, Parliament and the Commission. (...) the idea is of course that (...) at this seminar they should be, well, the report is a basis for the discussion. So the report is supposed to give them information about the, well: Where are we with the science? What are the legal situation? What are the main ethical issues? So it should give them the background to try to formulate their opinion on this issue, on as I said whether we should be allowed to fund research involving the use of spare embryos. And also what should be then the guiding principals for such research? If it should be allowed and in general to, to, what should be our policy? (...) What are our needs if we want to try to promote this area of research? At EU level or in the framework of the 6th Framework Programme? How can we contribute, I mean to keep Europe competitive in this area? So let's say also I hope they even have a more also general discussion on the whole issue. And let's say the European policy, because there is also competitiveness in World and or, or, or industries. (Interview B)

The seminar addressed mainly members of the Institutions and some experts and the public was only involved as spectator on the internet.²⁴

Another way to deal with the problems posed by HESC research is to increase expertise by involving experts on ethics as well as biotechnology and life sciences in general and stem cell research in particular.

Salter and Jones identify the establishment of the “European Group on Ethics in Science and New Technologies” (EGE) in 1998 as one of the two main developments for the establishment of bioethics in the EU.²⁵ This group had started already in 1991 as “Group of Advisers to the European Commission on the Ethical Implications of Biotechnology” (GAEIB, 2002: 329, EGE 2001: 2).

The task of EGE is to “examine ethical questions arising from science and new technologies and on the basis to issue Opinion” (EGE 2001: 158). It “is an independent, pluralist and multidisciplinary body” (ibid. 3) and issues its Opinions on request of the Commission, the Parliament, the Council or on its own initiative (ibid. 159). Its Members are appointed by the European Commission “for their specific skills” and come from different disciplines and professions. They “deliberate freely and in total independence in accordance with its rules of procedure. They also communicate the Group’s opinions as they see fit, naturally ensuring

²⁴ http://ec.europa.eu/research/conferences/2003/bioethics/index_en.html (accessed on 21.1.2007).

²⁵ The main development being the Bioethics Convention by the Council of Europe.

the Commission receive them first” (EGE 2001: 4 ff.). The EGE sees its role as the following:

Ethics must (...) help the Community authorities, which are responsible for regulating the market, to take better account of the aspirations of the public in the various aspects of their lives: as consumers, workers, parents, patients etc. With this in mind, the Group intended to reattach to European ethics the principles which are not always directly associated with it; the idea being to create a relationship of trust between science and society. (EGE 2001: 12)

Salter and Jones perceive the EGE as an important and self-confident policy brokers with good links to national bioethics committees and international communities such as the Council for Europe’s Steering Committee on Bioethics and UNESCO’s International Bioethics Committee. They conclude, “[I]n the fluid politics of the EU it is a player to be taken seriously” (2002: 336). The Commission also attributes great importance to the EGE and declares repeatedly its increasing significance.²⁶

The Commission welcomes the key role played by the European Group of Ethics in Science and New Technologies since its creation in the early 1990s and proposes (...) to enhance its role and to reinforce the networking with and between national ethical bodies. (European Commission 2002: 20)

The Commission has stressed that it will enhance the role of EGE by closer collaboration with the Commission services and by increasing the exchanges with other institutions, in particular the Parliament (Commission 2004: 20). The EGE also strengthens its collaboration with National Ethics Committees.

Salter and Jones however, are skeptical about the role of bioethics:

Bioethics presents itself as both expert and as having a hotline to the needs of civil society through its impartial consideration on moral concerns. By linking its claim to legitimacy to a quasi-representative function in this way, bioethics may be able to resolve, or at least to ameliorate the effects of, regulatory conflicts whilst this occurs within the relative cerebral confines of the EU policy community and its immediate network environs. However, whether its legitimacy will survive prolonged public exposure to a media-driven issue in human genetics is unknown and untested. (Salter and Jones 2002: 338)

Also EGE concedes that it has a problem with public involvement in its Opinions:

²⁶ EGE’s high status is also underlined by the fact that it handed over its Opinion about HESC research to the President-in-office of the European Union (IP/00/1293).

Generally speaking, the Group has endeavoured to be as open as possible in its proceedings. It is true that the Group's deliberations on its Opinion are not public, but otherwise the EGE Round Tables are open to representatives of interest groups, MEPs interested in any given matter, delegates from other international bodies. (EGE 2001: 5)

Moreover, Paragraph 25 of its "Rules of Procedure" state explicitly that "the deliberation of the Group are confidential" (EGE 2001: 160). Participatory elements in the EGE setting are restricted to one-day round tables, in which established stakeholders are consulted but not able to vote on an Opinion. Opinion No. 15 on HESC research in the context of FP6 refers to such a Round Table:²⁷

[T]he Round Table organised by the Group on 26 June 2000 in Brussels with members of the European Parliament, jurists, philosophers, scientists, representatives of industries, of religions, of patients' associates, and of international organisations (Council of Europe, UNESCO, WHO). (EGE 2000a: 2)

The participant list of this Round Table had 82 participants: 12 members of EGE, 3 participants from its secretariat, 7 invited speakers, 14 representatives from the Commission, 4 Members of the European Parliament, 3 participants from the Economic and Social Committee, 6 representatives from international organisations (WHO, Council of Europe, UNESCO, European Patent Office, OCDE), 9 representatives of media, 4 from religions and 20 experts (EGE 200b: 223-227). Taking a perspective on participation the round table clearly favoured policy makers and organised interest groups; only 2 participants came from patient groups.

The EGE is surely an institutional innovation, since it raises the "new" topic of ethical questions. However, it still follows a traditional expert model because it involves only a small number of elite ethicists, scientists and jurists who are specialised on biotechnology issues. Public involvement is extremely limited in EGE's setting. The group seems to be aware of this problem and stated in its Opinion No. 15 that "there is a need for continuing dialogue and education to promote the participation of citizens, including patients, in scientific governance, namely in the social choices created by new scientific development" (EGE 2000a: 20). However, it does not state how this objective can be achieved.²⁸

²⁷ Moreover, there were two hearings of representatives of experts and a hearing of representatives of religions on September 8, 2000 (ibid.).

²⁸ The Forum of Presidents of National Ethics Council is another example of how the Commission tries to come to grips with the difficult issue of ethics by taking a top-level expert approach. The Forum

The “Life Science High Level Group”, which later was renamed to “European Group on Life Science” (EGLS), was installed by Commissioner Busquin in 2000 to “provide high-level advice on life science and associated technologies”.²⁹ The group was in office until 2004 and was a typical high-elite scientific expert body. In addition to the task of informing the research commissioner, it also had the goal of supporting “science communication strategies, such as engaging in informed and pluralistic stakeholders debates on life science perspectives” (European Commission 2002: 3).

Within this competence it organised the conference “Stem Cells, Therapies for the Future?”³⁰ in December 2001 and invited 750 people from 36 countries “including expert scientists, clinicians, politicians, industrialists, representatives of interest groups, patient support groups and religions, and interested private individuals” (ibid. 6). According to Commissioner Busquin this conference was “intended as an exercise in the governance of science” (ibid. 6).

Illustrating its will to innovate and to maximise the impact of the debate, the discussion platform was web cast, and members of the public were invited to express their opinions and views via e-mail before, during, or after the forum. After each talk, there was a question-and-answer session, and the programme included two roundtable discussions and a public debate. The aim was to air and publicise the current state of scientific knowledge and medical progress as a basis for further discussion. (ibid. 6)

However, the results of this conference remain vague. An official brochure states it was “not possible to achieve total consensus, but widespread explicit or implicit agreement on several

consists of chairpersons and the secretaries of the National Ethics Councils and shall promote harmonisation and benchmarking by open coordination:

“It is an independent informal platform for exchange of information, experience and best practices on issues of common interest in the field of ethics and science. The NEC Forum follows the method of “open coordination”, and its meetings are always hosted by one of the National Ethics Councils. The Commission (Directorate-General for Research) reimburses the travel and subsistence costs of one representative per National Ethics Council. The NEC that is hosting the meeting and DG Research provide the secretariat. The President of the EGE and the President of the Bureau of COMETH (Council of Europe) are invited to the meetings. The Forum network is developing an important role in exchanging good practices between Member States (http://ec.europa.eu/research/science-society/page_en.cfm?id=3161)”

The Forum was created in the context of the EU’s Science and Society Programme (Commission 2004: 20). Between 2003 to 2006 it gathered eight times in different Member States and at these meetings is often received by top politicians. Stem cell research was an issue several times (current therapeutic possibilities of adult and embryonic stem cells 5th Meeting, p. 2). Supported by the Commission, the Forum might contribute to the establishment of a particular epistemic community and expert network on bioethics in Europe.

²⁹ http://ec.europa.eu/research/life-sciences/egls/index_en.html

³⁰ <http://ec.europa.eu/research/quality-of-life/stemcells.html> (accessed January 21, 2007).

points” (European Commission 2002b: 33). This consensus, however, is formulated rather imprecisely:

It was “generally accepted that the potential value of regenerative medicine involving stem cells is enormous”. Moreover, there was “broad agreement that living human tissues, and human embryos in particular, should be respected”. “Most participants felt that the use of (...) adult and umbilical cord blood stem cell was acceptable”. “Many of those present seemed to feel that reproductive cloning was unethical and should be prohibited”. The rest of the conclusions are even more appellative and fuzzy: “science should not proceed in a vacuum”, the “ethical debate requires input from many diverse elements of society, including the public at large and interest groups, not just scientists and technocrats”, “there is substantial diversity in Europe (...) as concern ethics in this field, and this may make it difficult to lay down common legislation”, “public debate is required”. (ibid. 33)

In contrast to these imprecise formulations, the EGLS’s own recommendations presented at the end of the brochure are much more concrete and policy oriented than the conclusions drawn from the Public Forum: “[R]esearch using cells from both sources should be actively developed and supported” (ibid. 34). “None of the scientists were in favour of prohibiting stem cell research in general, or any particular type of stem cell research” (ibid.). “New lines need to be derived if this approach is to realise its clinical potential” (ibid.). “The EU should continue to support research with all sources of human stem cells, including human embryonic stem cells, to provide new clinical opportunities for therapy” (ibid.: 35). “Reproductive cloning (...) should be prohibited” (ibid.). Derivation of human embryonic stem cells from nuclear transplantation (so-called therapeutic cloning) has not been achieved and appears to raise considerable difficulties, scientific as well as ethical” (ibid.). The group “agrees on the use of spare human embryos for the derivation of embryonic stem cell lines. (...) the Group insists that in those countries where research on human embryonic stem cell is allowed, it should be carefully regulated, peer reviewed, scientifically sound, directed towards substantial goals and ethically controlled” (ibid.).

Thus, although the conference was a major effort to involve the European public on HESC research, it still was expert oriented, only informative, and vague in its outcome.

Another approach to involve the public is simply information provided on the internet. The web-page of DG Research provides information on policy papers and conferences held in Brussels on HESC research.³¹

The Commission also delegated this information task to all researchers: It “support[s] measures to help researchers become communicators and debaters, caring for the conditions in which all parties in society can be involved in embarking in new ways of collective learning” (Commission of the European Communities 2003: 10). The Commissions also addresses the topic of ethics by incorporating it into its administrative procedures of research funding:

A specific ethic review has been implemented for proposals dealing with specific and sensitive issues such as the use of banked or isolated human embryonic stem cells in culture, human foetal tissue or cells, non human primates, animal cloning, human beings, genetic information etc. The recommendations from the ethical review are taken into account in the negotiation of the projects. (European Commission 2004: 19)

In summary, the debate on HESC research was and is still mainly an elite concern and did not include a general and concerned public. However, and this was a major concern for policy makers, the issue of HESC research was potentially highly politically explosive, similar to the issues of abortion, GMO or BSE.

In contrast to the GMO debate, the controversy on HESC research involved primarily elite actors from EU Institutions and traditional stakeholder organisations, which differed in their evaluation of values such as freedom of research, freedom of making business and the moral status of the embryo. This group of elite actors included officials from the EU institutions and the Member States, top politicians, scientific and bioethics experts and representatives of established, well-organised pressure groups and lobbies from science, industry or churches.

By and large the debate is still characterised and decided by the usual inter-institutional conflicts and dynamics within and among EU institutions. In particular it involved a regulatory permissive Commission; the Parliament, that was split, but in the end permissive; a split Council of Ministers; and established pressure groups lobbying either for a permissive or restrictive cause.

³¹ http://ec.europa.eu/research/fp6/index_en.cfm?p=1_stem_dialogue, accessed January 21, 2007.

HESC research posed a disruption within the process of setting up FP6, which officials and policy makers in the institutions tried to remedy by their usual administrative practices such as comparing national regulations, compiling reports and gathering information. Overall there was a clear intention to develop a coherent regulatory approach towards HESC research and to open up the process of decision making for more transparency and interaction with various publics. At the same time, the bitterly divided Member States were neither in the position nor willing to find a full compromise or solution for HESC research. Commission officials and policy makers also tried to increase their expertise and legitimacy by involving elite researchers on life science, biotechnology and stem cell research.³² They addressed the “new” and unruly topic of ethics by efforts to build up, integrate and “harmonise” expert bodies and expertise in bioethics. Moreover, they changed administrative routines by establishing ethics review for sensitive funding decisions. In addition, Commission officials organised deliberative spaces where they could meet and reconcile with other policy makers and experts. Guiding principles in this process were formal competences and rules of procedures but also informal rules and bargaining (e.g., a “trialogue” between the institutions) within and between Commission, Council and the Parliament. All these efforts mentioned so far were aimed at policy makers, politicians and experts.

In the decision-making process on HESC research within FP6, participation and public dialogue were mainly used as means of information. Participatory practices covered only a small part of activities and were never used consultatively for actual decision making. If citizens were addressed at all, they were consulted in a few, well-staged events such as a conference or Round Tables. They mostly remained in the passive role of an audience to be educated. Thus, despite the “participatory” language in some EU documents, the “participatory spaces” in the decision on HESC research in the context of FP6 remained rather limited.

³² See the Conference: “Stem Cell Research at European Level” held on 13./14. September 2001 in Brussels, which involved 12 of the 15 coordinators of research projects on stem cell research, which were then funded by the Commission (European Commission 2001).

Summary

As this first, brief discussion of stem cell politics in a comparative perspective shows, human embryonic stem cell research inside and outside Europe has been a highly controversial topic that “divided nations” into “supporters” and “enemies” of stem cell research. As with the abortion or the euthanasia question, it is impossible to be a “bit” in support of the one or the other, and a clear position pro or contra is necessary. There is also relatively little space for “negotiating” stem cell research, as the question always has been one of permitting or outlawing this type of research.

In the next chapter, we will provide more detailed accounts and discussions of stem cell governance in two countries, Italy and the United Kingdom. We decided to focus on these two countries for two reasons. First, Italy and the United Kingdom display features that can be found in our other case studies in a comparatively explicit way. Second, with the decision to focus on these two countries we follow the logic of “maximum variation” (Flyvbjerg 2001:78), that has been indicated by Workpackage 1 (Loeber, Hajer et al. 2005). And Italy and the United Kingdom could not be more different indeed.

As Sarah Franklin notes, the United Kingdom has provided a series of techno-scientific “firsts” in the field of reproductive biomedicine, embryology and developmental biology, the globe’s first ‘test tube baby’ in 1978, the first successful performance of pre-implantation genetic diagnosis (PGD) and the delivery of the world’s first cloned mammal, Dolly the sheep, in 1996 (Franklin 2006: 74). Today, the British islands harbour a range of prestigious stem cell laboratories and since 2003, the world’s first National Stem Cell Bank (Glasner 2005). At the same time, the United Kingdom is “proud” (personal communication with a British citizen) of its equilibrated regulatory regime. Italy, in contrast, is not famous for its techno-scientific excellence. It has banned research cloning and the derivation of HESCs from Italian embryos. This decision, however, was contested and continues to steer controversies. While Italy is hence an ideal ‘model’ for restrictive stem cell regulation, the United Kingdom seems to be an excellent example for liberal regulation.

But why did one country take one particular direction to deal with the “stem cell challenge” while another European country headed just the opposite direction? The answer to this question will be given below, and it contains interesting insights for the nature, structure and possible future of life science governance.

4. Stem cell and cloning research in Italy and the United Kingdom

Regenerating Italy: From sacred embryos to unruly cells and back again

The stem cell battle is a battle for laicality (*laicità*), a battle for laicality that has the same value as the battles fought on abortion and divorce (...) these things are completely different (...), but [what is at stake] in all of them, is [the issue of] the self-determination of individuals that is deprived by a law of the state.

Interview (2-36)

[The level of] civilization [of a society] manifests itself first of all in the respect for human life.

Interview (2-38)

On July 19, 2006, the members of the Italian Senate busily discussed the topics of HESCs, embryos, and a rather peculiar boundary. At issue was a threshold that, once it was crossed by embryos, marked the permanent disruption of their reproductive trajectory, or in the ambiguous terms of a heavily contested resolution, the threshold from which embryos are “no longer implantable” (Senato della Repubblica 2006c). Is there a meaningful boundary that divides vital frozen embryos from embryos that are no longer vital, that (once they are thawed) no longer divide and develop and are hence ‘non implantable’ embryos or embryos without a reproductive future? And how and by whom can this boundary be drawn? On July 19, members of the Italian Senate passionately deliberated these questions.

For sure, this was not the first time a governmental body sought to draw a boundary to settle the HESC debates. Boundaries that purify biomedical technologies from immoral applications or that disentangle “bare” forms of human vitality from life forms that embody

some sort of belonging are key components in stem cell governance. But the boundary at issue in Italy was nevertheless new: It did not relate to situations, in United States President George W. Bush's terms, in which "life and death decisions" have already been made (Bush 2001, see section 2). Rather, it sought to ensure that such decisions remain a prerogative of nature and that stem cells are only derived from embryonic cadavers. As Senator Ignazio Marino explained:

[W]e have to make an inquiry and define the moment in which these embryos lose their reproductive capacity and transform themselves into blastocysts that do no longer have the capacity to give rise to a foetus. The path that we have to strike is similar to the [path] covered in 1968 in Harvard by a commission composed by scientists, lawyers and representatives of different religious beliefs, [that] led to the 'brain death' definition, a concept that nobody questions and that has allowed the removal of organs from deceased persons and an enormous development of transplantation medicine with the consequent possibility to cure hundreds of thousands of patients (...). When it will be possible to locate the moment from which forward frozen embryos will no longer be implantable, then, I believe, every objection concerning the possibility of donating their cells to a research that might change the history of medicine, will waive away. (Senato della Repubblica 2006a)

It is probably not too farfetched to claim that Marino's reasoning on cell donations from brain dead embryos required an Italian setting and an Italian audience. This argument could not be meaningful in Israel or the United Kingdom, where embryos are not regarded as in any way comparable to human beings, let alone comparable to dying patients (Mulkay 1997; Spallone 1999; Prainsack 2006; Hashiloni-Dolev 2007). But why can this argument have meaning in Italy? And what does this tell us about the governance of HESC research? In this section, we will explore these questions.

In doing so, we seek to shed light on a country that has a comparatively restrictive regulation of HESC and cloning research. Indeed, since the enactment of the 'law forty' (*legge quaranta*) in February 2004, the "norms in matter of medically assisted procreation" (*norme in materia di procreazione medicalmente assistita*) (Repubblica Italiana 2004), Italian researchers may no longer derive HESCs from Italian embryos; they are also barred from producing embryos through SCNT. Please note, this restrictive stance does not imply a total closure towards HESC research. In the absence of other regulations, Italian scientists are still allowed to engage in this line of research provided they draw on HESC lines imported from abroad. But the number of Italian scientists actually working in HESC research is very small, as their work is not encouraged: All 'national' stem cell funds are confined to research projects that draw on

animal stem cells or stem cells derived from adult tissues or aborted fetuses; HESC researchers depend on private money or funding from the European Union. Stem cell research in Italy is therefore neither endorsed and supported nor prohibited altogether. But why? In this section, we will seek to make sense of this.³³

We will argue that Italian HESC politics is best understood as the side effect of the re-ordering of Italy's laboratories of reproductive medicine through the 'law forty' (40/2004) rather than as an explicit or coherent strategy. This law greatly confined Italian HESC research and set the conditions for it to become an unruly political topic (Loeber, Hajer et al. 2005). In other words, in Italy an "act of orthodox statecraft" (Loeber, Hajer et al. 2005) rendered stem cell research controversial. Interestingly, however, these controversies did not lead to new practices of governance. We therefore consider the 'legal void' that ruled for almost two decades as more representative of the Italian approach towards stem cell research – or, in general – towards the 'new politics of life' (Loeber, Hajer et al. 2005) than the present restrictive law that governs Italian laboratories. The HESC example demonstrates the difficulties of the Italian energy field to find common ground on ways to rule unruly matters and the preference for Italian socio-political actors to co-exist with "unregulated monsters" (Jasanoff 2005b), rather than to place them at the center of the political stage.

But let us proceed chronologically and start in summer 2000, when HESCs were not yet controversial but had become the subject of enquiries by two expert committees.

First phase: The ontics and ethics of expert committees

HESCs arrived in Italy in 2000 when two expert committees started to deliberate on the subject. At that time, Italy had no laws covering embryo research. All forms of cloning were banned by a ministerial ordinance in March 1997 (Ministero della Sanità 1997b), yet embryo

³³ Please note, most developments in the Italian stem cell field occurred comparatively recently. A very material consequence of the dynamics in the Italian field is the scarcity of scholarly research engaging with the politics of human embryonic stem cell and cloning research in Italy. This section is therefore almost exclusively based on primary data, our field work and our own interpretations and attempts to make sense of the Italian case. We have participated in two conferences that were organized by the Luca Coscioni Association (in June 2005 and in February 2006), and we have conducted a series of semi-structured interviews with Italian policy makers, patients, bioethicists and scientists in Milan and Rome in February 2006 and September 2006. In addition, our data include a broad range of media data, such as newspaper articles, television and radio broadcasts, and policy documents. (For a complete list, please consult the references at the end of this document.)

research was unregulated. Italian scientists were therefore free to engage in this line of research. At the same time, there was very little ‘stem cell talking’. HESC news was relegated to the science sections of Italian newspapers, and the media only covered events that happened abroad, far away from Italian borders – and far away from Italian politics. In other words, HESCs were not yet unruly in Italy when the two expert bodies started to deal with them.

One of these, the National Committee for Bioethics (“Comitato Nazionale per la Bioetica”, CNB for short), was established in 1990. Composed of more than 40 members who were appointed by the government for a term of four years, the CNB deliberated on the ethics of cutting-edge science (Scuderi 2004; Bompiani 2005; Comitato Nazionale per la Bioetica 2005). It started to ponder about HESC research in April 2000 and approved a final report on this subject at the end of October (Comitato Nazionale per la Bioetica 2000).

In this report, the CNB approved the derivation and usage of stem cells from adult tissues and aborted fetuses. But the Committee’s members were split on the question of the ethical permissibility of HESC research. All members agreed that embryos should not be produced for the purpose of research, but they did not achieve a consensus on how to proceed with ‘surplus’ embryos, embryos initially produced in the course of fertility treatments but no longer needed for that object. A part of the commission sustained that

the removal and laboratory culturing of stem cells derived from an embryo that cannot be implanted does not signify a lack of respect towards [the embryo], but can be considered a contribution from the donating couple to research (...), [that is] based on an act of solidarity. (Comitato Nazionale per la Bioetica 2000: 28)

Parts of the Committee mobilized a recurring argument in the expert discourse, namely that the deployment of surplus embryos in research neither amounts to a lack of respect towards the embryo nor to “killing” but is better framed as the redirection of their vitality towards the enhancement of the vitality of the living (see Waldby 2005), thus rendering even their short “life” meaningful and productive. But 14 members of the Commission disagreed with this reading. They argued that the “direct and intentional suppression of ‘supernumerary’ embryos” was “at odds with the duty to respect human life from conception” (Comitato Nazionale per la Bioetica 2000: 28) and therefore damned HESC research as unethical.

However, while the CNB was still working on its final report, Health Minister Umberto Veronesi gave an ad hoc commission the task of providing evidence on the science and ethics of HESC research. This commission was composed of 25 members, chaired by the Nobel laureate Renato Dulbecco, and therefore known as “Commissione Dulbecco” (Dulbecco Commission). The final report of the Commission was published in December 2000 (Ministero della Sanità 2003 [2000]).

In its long introduction, the report set the techno-scientific stage for its narrative, discussing extensively the state of stem cell research. It argued that the stakes of stem cell research were high indeed. Stem cell research, the report read, could lead to a “real revolution in medicine”, the impact of which might go well beyond the impact engendered by the discovery of antibiotics (Ministero della Sanità 2003 [2000]: 124). Seeking to give concrete numbers to these hopes and promises, the report argued that the suffering of approximately 10 million Italians could be leveraged by stem cell research in the future (Ministero della Sanità 2003 [2000]: 121). But the members of the Dulbecco Commission also underlined that scientific uncertainty of stem cells was still high and argued that more research was needed. Given the high stakes as well as the many scientific uncertainties, the report recommended creating a “national stem cell program”, based on “solid scientific evidence” and “unanimous consent in the scientific community” (Ministero della Sanità 2000: 122). While the members of the Dulbecco Commission agreed on the scientific stakes of HESC research, they were split on the ethics – or actually – the ontics of the early human embryo. All members agreed that embryos should not be produced for the purpose of research, but they could not find common ground on the ethical legitimacy of the deployment of surplus embryos for research purposes. The majority of the Commission’s members favored using surplus embryos for research purposes, arguing that Italian laboratories contained an unknown but nevertheless “elevated” number of frozen embryos that were no longer “designated to be transferred” (Ministero della Sanità 2003 [2000]: 129). “[I]n front of the inevitable destiny of a part of the frozen and no longer implantable embryos”, the report argued,

the Commission believes that the balance tends in favour of the destination of these embryos to a research that is susceptible to save the life of millions of human beings and thinks that such a destinations demonstrates (...) a respect of human life that goes well beyond a “let them perish”. (Ministero della Sanità 2003 [2000]: 129)

However, seven (Catholic) members strictly opposed this argument, arguing that “the embryo is a human being with developmental potentials (and not a potential human being)”, that “the embryo, like every human being, has a right to life” and that an instrumental deployment of embryos would be an offence to human dignity (Ministero della Sanità 2003 [2000]: 128). Similar to the CNB, the Dulbecco Commission was split on the ontological status of the early human embryo and consequently on the ethical permissibility of research lines that imply the destruction of embryos. Yet the ontological ordering of the Dulbecco Commission went further.

The Commission did in fact reach a consensus on how to bypass this conflict. It presented a sophisticated argument on “somatic cell nuclear transfer” (SCNT), positing that the technology could be altered in such a way as to inhibit the creation of human embryos, thus providing a technical answer to ethical problems and – following the wording of the press release of the Ministry of Health – an “Italian way to therapeutic cloning” (Ministero della Sanità 2000). Actually, a closer look at the document reveals that the report did not propose to alter the technology itself; rather, it proposed an *altered reading* or “reframing” of the product of the technology (see Testa 2006).

“[N]uclear transfer”, the report argued, was “a matter of reprogramming the nucleus of the somatic cell derived from the patient, through the contact with the cytoplasm of the oocyte” (Ministero della Sanità 2003 [2000]: 116). The reprogramming of the adult cell did not imply its transformation into an embryo. Rather, the result of this technique could be framed as an *artificial* cluster of cells that had no *natural* potential to develop into a foetus. Or, in the words of the report:

In the contemporary literature, this procedure is called therapeutic cloning, which is actually a term that is clearly open to dispute. In fact, an oocyte that is reconstructed with the nucleus of an adult somatic cell cannot be considered a zygote [i.e., an embryo at its first stage of development] in the classical sense, as long as it does not derive from the unification of two gametes. The fact that such a reconstructed oocyte does *not spontaneously* give rise to an embryonic development proves this. [The development of the reconstructed oocyte into an embryo] can only occur thanks to an *artificial stimulation* that *forces* [the reconstructed oocyte] to develop into a blastocyst. And only just a few of these blastocysts actually have the effective capacity to form an embryo and subsequently a foetus (Ministero della Sanità 2003 [2000]; Italics added)

Cell nuclear transfer, hence, neither produces human embryos nor human beings, but a sort of “cell expansion (...) of the patient” that is comparable to the product of already widely practiced techniques that amplified “bioptic samples” of a patient’s skin in the laboratory (Ministero della Sanità 2003 [2000]: 116). In addition, the report argued, in the future the deployment of human oocytes might also be substituted by the deployment of “cytoplasmic extracts from other animal species, or artificially produced cytoplasm” (Ministero della Sanità 2003 [2000]), thus relieving women from the pressure of oocyte donations. Despite being pretty close to the technique that other commissions labeled “therapeutic cloning”, “research cloning” or “cell nuclear transfer”, the report gave the technique the new label of “nuclear transfer for the production of autologous stem cells” (*trasferimento nucleare per la produzione di cellule staminali autologhe*, TNSA) and presented it as a technical all-rounder, or – quoting the wording of the press release of the Ministry of Health – as a scientifically *and* ethically valid “foundation for cures for a broad range of diseases, that are partly incurable today, and that concern 10 million Italians” (Ministero della Sanità 2003 [2000]).

To sum up, both reports engaged in extensive ‘ontological ordering’ (Jasanoff 2005b) and devoted much attention to the categorization of early human embryos. As we will show below, the focus on the status and meaning of the embryo is one of the key characteristics of Italian stem cell governance. In addition, the Dulbecco Report is ‘Italian’ in another sense: It is saturated with Italian truths and story lines, on what sort of objects are “natural” and which ones are instead “artificial”, and on what this implies in turn for reasonable and morally correct human conduct (Testa 2006). The boundary deployed by the Dulbecco Commission’s members between what is conceived of as being “naturally given” as opposed to what is “artificially engineered” eventually proved to be meaningful and powerful. Altogether, the Dulbecco Commission’s report was well anchored in Italy’s socio-political reality. But it nonetheless failed to pave the way for a future policy narrative.

In the first weeks after the publication of the report, some expressed perplexity on the scientific feasibility of the “Italian way towards therapeutic cloning” or questioned whether TNSA would “really not give rise to human embryos” – after all, “Dolly the sheep was birthed that way” (Interview 2-38). Some doubted the authority of the results, given that it had taken the Commission barely three months to draft the report, or they denounced the Commission as a “puppet institution” of Minister Veronesi. “Driving at an opinion in favour of this research”, one of our interviewees complained,

Veronesi appointed an ad hoc commission instead of asking the national committee [for bioethics], offending all members of the [national] committee [for bioethics] who were in favour of this research. (Interview 2-46)

With the authority of the Commission seriously questioned, Health Minister Veronesi embraced only one of the recommendations of the report and asked the “Istituto Superiore di Sanità” (ISS for short, the Italian “Higher Institute of Health”) to conduct a census on Italy’s frozen embryos. But after a couple of weeks, the report went to the backstage of Italian politics and finally disappeared, quite literally, when general elections brought a change in the Italian government and Girolamo Sirchia took Veronesi’s office in June 2001.

In the long term, the experience of the Dulbecco Commission and the attempt to order stem cell research through their staging in expert committees, proved to be the initiative of a single minister, and the episode was neither anchored in a larger political context (for instance on the strategic importance of this line of research) nor in Italian political culture. Subsequently, stem cells, clones and embryos once again became a marginalized topic in Italy’s socio-political reality.

This changed radically in early 2004, when the passing of Italy’s law 40/2004 provided the conditions of possibility for the emergence of an Italian “stem cell public”, that is, following the definition provided by work package 1, “all those who were affected by the indirect” and direct “consequences of a transaction” to such an extent that “they deemed [it] necessary to have those consequences systematically cared for” (Dewey 1991 [1927]: 15-16; quoted from Loeber, Hajer et al. 2005: 24). Only when the final reading of a bill that would have substantial implications for HESC research was imminent did an Italian “stem cell public” start to emerge. In other words, only with the passing of a law, an institutional innovation, did stem cells become unruly.

In order to understand this, we must return to 1997, the year in which the announcement of the birth of Dolly, the globe’s first cloned mammal, triggered international debates and lasting effects in Italy.

From Dolly the Sheep and Italy's "Wild West of Reproduction" ...

In February 1997, the Italian news agency ANSA was the first to break the news of the birth of the animal with the code name 6LL3, better known as Dolly the sheep. Three weeks of intense puzzling on the meaning and implications of this event followed (Gallese and Toldo 1998; Satolli and Terragni 1998; Neresini 2000). Some scientists appealed to the Italian audience to “keep rational” and to deliberate carefully on the scientific potential of Dolly’s birth. Yet a different interpretation was gradually mainstreamed. Slowly but steadily journalists, bioethicists, scientists and politicians wondered whether the same technology that had given birth to Dolly could also be applied to humans, and they wondered whether Italian scientists were smart and skillful enough to clone a human being. Subsequently, the Italian sociologist Federico Neresini notes, “the focus of attention began to shift decisively toward IVF-related issues and the controversies arising from them”:

The shift in coverage from human cloning to IVF was so marked it suggests that the most important relationship in the cloning issue really revolves around control of the social definition for the reproductive process and the institution that embodies it, that is, the family. (Neresini 2000: 371)

In Italy, therefore, SCNT was linked to human reproduction. Indeed the birth of Dolly provided an opportunity to set an issue on the political agenda that led to substantial anxieties and emotional discussions in Italy for more than a decade: “Italy’s Wild West of Reproduction” (see Box 4.1).

Box 4.1 Italy’s “Wild West of Reproduction”

Italy’s first ‘test tube babies’ were born in 1983 (Flamigni and Mori 2005). Approximately 50,000 others followed in following decades. In addition, techniques such as donor insemination and sperm banking had started to spread after the late 1950s (Bonaccorso 2004; Valentini 2004; Cirant 2005). In the beginning of the 1990s, both practices were firmly established in Italy. But despite their widespread deployment, the new possibilities to achieve motherhood and fatherhood were not always regarded as a blessing. While the leftist newspaper “La Repubblica” had welcomed the birth of Louise Brown, the world’s first ‘test-tube-baby’, with the headline “This fecundation would appeal to Hitler, too”, the rightist newspaper “Il Tempo” simply stated: “It is not licit to violate nature” (quoted from Flamigni and Mori 2005: 16).

In the 1980s and early 1990s, a series of cases that troubled kinship categories and ‘natural boundaries’ were covered intensively in the media. One of these cases was a woman in her mid-60s who asked a fertility expert to help her become mother with the frozen sperm of her husband, who had died 10 years earlier (Valentini 2004). In a similar case, the tribunal of Palermo gave a widow approval to transfer the frozen embryos that had been fertilized

before her husband's death. In 1994, Italian fertility expert Severino Antinori gained global fame when he helped a woman age 62 to become mother, and in 1995 a major uproar was provoked by the birth of a girl in Rome who had been implanted as an embryo into the womb of an aunt more than a year after the death of the embryo's "biological" mother (Keates 1995). These stories about messy genealogical relations, maverick doctors, and births against all odds depicted the realm of techniques of assisted reproduction as a "supermarket of homosexuals who fertilize lesbians, multiple births at request and virgins who birth children" (L'Espresso 1995, quoted from Valentini 2004), in essence, as a situation without rules and norms, which violated the sacredness of reproduction, reducing it to a mere economic enterprise or – in the four words increasingly deployed by Italian actors – to Italy's "Wild West (*Far West*) of reproduction".

One of the conditions of the emergence of the metaphor of the "Wild West" was the substantial lack of regulations and 'legal void' (Neresini 2000) that governed Italian laboratories up to 2004. This legal void should not be mistaken for a complete lack of regulation. Rather, in the absence of primary legislation, Italian laboratories were governed by secondary legislation, by a series of court decisions, by the informal but nevertheless powerful norms and truths of Italian society, as well as by attempts of Italian physicians and scientists to make these norms binding through professional guidelines. But this "dispersed" mode of governance was *not* the product of a decision or a shared consensus that these methods would suffice. It was the effect of a series of failed attempts to find a common ground on how to re-order these tricky issues. The reasons for these difficulties relate to the second source that rendered the metaphor of the "Wild West" meaningful: the slow but steady dislocation that the new ways to achieve motherhood and fatherhood had triggered in Italy.

Techniques of assisted reproduction had not merely challenged the Italian discursive economy; they were particularly challenging to the Italian moral economy, as they threatened to dislocate one of its key components: the family in its "naturally given" boundaries (Neresini 2000; Marchesi 2007). The importance of the Italian family had been shrinking for years, as an ever increasing number of Italians had started to choose alternative life courses (Saraceno 1998). However, the challenge that IVF posed to the Italian body politics had a new quality. What had seemed before the birth of Louise Brown to be given by nature and without alternatives was now open to social negotiations and political re-ordering. "Matters of facts" were transformed into "matters of concern" (Latour 2004). Moreover, Italian socio-political actors were clearly struggling to find a common sense of what kind of "matters of concern" they were dealing with. Was IVF an unprecedented attack on human reproduction? Or was it a legitimate and "normal" biomedical treatment for infertility and sterility? Could

Italian physicians, couples and women be trusted? Were they able to “govern themselves”, re-creating the nation in a responsible way? Or were they acting irrationally and immorally, driven by the mere anxiety to fulfil their personal wishes and interests for financial gains? Or would this be an infringement upon the private choices of its citizens? These questions clearly split Italian socio-political actors. With “natural facts” seriously shuttered, Italian actors struggled to find a shared and agreed upon language to come to terms with these transformations. Indeed an ‘institutional void’ existed (Loeber, Hajer et al. 2005) – a situation in which actors agreed that the rules and norms in place were neither sufficient nor appropriate, and in which these actors disagreed on how and in reference to which common good they could find more appropriate ones. For years, Italian actors seemed to prefer to coexist with this ‘void’ rather than to dare to search for a common ground on how to re-order it.

However, the birth of Dolly no longer made this situation acceptable. After years of inactivity, Dolly led to two emergency ordinances that banned *both* human and animal cloning (Ministero della Sanità 1997b), and the commerce of human gametes and embryos (Ministero della Sanità 1997a). In addition, the Italian Parliament started to prepare a draft bill on reproductive medicine. However, despite agreeing that a law was urgent, the Italian Parliament took an additional seven years to agree on its content.

... to the rise of Italy’s ‘citizen embryos’

In the seven years of powerbroking and puzzling on the rights and obligations in the age of new reproductive choices, a particular ‘policy narrative’ (Gottweis 1998) emerged. This narrative was inscribed into law 40/2004, which made this particular system of meaning binding for all of Italian society.

The narrative’s protagonist was the early human embryo, which was framed as the first embodiment of a small, innocent child and future citizen of the Italian Republic. Despite being not (yet) existent, the child had rights that, so the narrative went, were threatened by the selfishness of its future parents and by the drive for financial gains of maverick doctors. The respect of the embryo’s rights had therefore to be safeguarded by the state. And, indeed, the first article of law 40/2004 solemnly pronounces the very basic aim of the law to be to

ensure the rights of every involved subject, including [the rights of; iM] the conceived (concepito). (Repubblica Italiana 2004: Art. 1, Sec. 1)

The rights of the “conceived” featured, first of all, the right not to be produced for any other purpose than to become a child. For the provisions taken by the Italian legislature, this implies that no more than the “strictly necessary” number and – at any rate – no more than three embryos may be produced, that all produced embryos must be transferred and that no embryo may be frozen. In addition, Article 13 also explicitly bans “[a]ny experiment on any human embryo” (Art. 13), as well as

- a) the production of “human embryos for research or experimentation purposes”,
- b) “any form of eugenic selection of embryos or gametes”, as well as “interventions that, – through techniques of selection, of manipulation or *in any way through artificial procedures* – aim at altering the genetic patrimony of the embryo or of the gamete or at (pre)determining their genetic characteristics” (italics added),
- c) cloning (of human beings) “through nuclear transfer or early division of an embryo or of ectogenesis” for reproductive as well as therapeutic purposes, and
- d) the fertilization of human gamete with gamete of another species as well as the production of hybrids and chimaeras, are strictly forbidden.

Second, drawing on the wording of Carlo Giovanardi, the former Minister of the Relationship with the Parliament, the embryo also had a “natural” right “to have a father and a mother” (Camera dei Deputati 2004), the embryo’s right to be born in a family with two sexually different genetic parents. In the law, this rationality translates into (1) the restriction of the access to techniques of “medically assisted procreation” to married or stable heterosexual couples who are both living, in a potentially fertile age and suffering from proven fertility problems, and (2) a ban of gamete donation, or the deployment of genetic materials that do not belong to the couple.

The rise of this particular policy narrative and the sense-making of Italian parliamentarians did not, of course, take place in a vacuum. The members of the two houses of Parliament did not follow coalition or party alignments; rather, they were led only by their own consciences. But their understandings of rights and wrongs were shaped by the moralities of Italian society. In Italy, an important contexture is the Catholic truth discourse on the meaning of embryos and reproduction (see Box 4.2)

Box. 4.2: The morality of the Catholic Church

The Catholic Church regards the early human embryo as the first embodiment of “human life” (Congregation of the Doctrine of the Faith 1987). As long as this “human life” is a gift from God, humans are not allowed to question it, to manipulate it, let alone to destroy it. The Catholic Church also strongly discourages the whole range of artificial reproductive techniques, as long as the unity of marriage and sexual intercourse is regarded as the only setting worthy of truly responsible procreation (Evans 2002). These Catholic “truths” – no doubt – shaped the emergence of the Italian embryo narrative, providing a horizon of understanding to the senses of rights and wrongs of Italian parliamentarians. In addition, Catholic groups and organizations – such as the Bishops’ Conference CEI (Conferenza Episcopale Italiana) or the Italian “Life Movement” (Movimento per la Vita) – are also reported to have actively sought to “discipline” Italian Parliamentarians in more or less direct ways (Interview 2-35, Interview 2-38, Interview 2-41; see also Valentini 2004).

And, yet, it would be certainly misleading to conceptualize the Italian law as a Catholic rather than an Italian law. Italian parliamentarians were also concerned with the make-up of the Italian collective body, of the care of its future citizens and of the (familiar) environment in which these citizens dwell. They speculated on the best ways to assure a proper re-creation of the nation and how to re-order the micro “cells”, the families, on which the Italian species body rests. The fear of the disruptive consequences of IVF on the Italian family seems to be particularly important. Some parliamentarians appeared to be driven by an anxiety to keep the permitted range of applications of techniques of assisted reproduction as close to “nature” as possible and to make sure that artificial techniques could only be deployed to give “nature” a little boost, re-affirming the traditional boundaries of the family rather than challenging or disrupting them (Testa 2006). “For years we have witnessed *real distortions of nature* with granny-mums and wombs for rent”, Cesare Cursi, the Secretary of Health, explained on the eve of the law’s final approval in February 2004. The law, Cursi went on, was instead a “victory of natural procreation” (quoted from Mingroni 2005).

There was a recurring feature or “story line” that shaped the discussions and debate on the floor of the Italian Parliament, the concern for the risks and dangers triggered by men’s challenging of “sacred natural nature” (*santa natura naturale*). Please note, this “bio-essentialist” story line is not the prerogative of the struggle on embryos and families. It cuts across all areas of the “new politics of life” in Italy. Summarizing the media debates on “wine, alga and mad cows”, the Italian sociologist Massimiano Bucchi (1999) notes that a particular “macro theme” has emerged in Italy over the last couple of years, “‘attaching’ itself whenever to specific events”:

[I]n the discussion on cloning connected to the birth of Dolly the sheep, but also in the recurring issue of assisted procreation in its diverse articulations (old mothers, rented wombs, sperm banks) and in events like [the] Viagra [debates] all focused on the same central problem: *to which extent can man possibly and acceptably modify his own “nature”?* (Bucchi 1999: 88, italics added)

To sum up, the discursive re-ordering of reproduction on the stage of the Italian Parliament was shaped by various Italian narratives, by Catholic truth discourses, the care of the family and its future citizens and a care for “nature”. It was the product of a transversal sense making, and anchored in the Italian discursive economy – but it was nevertheless not shared by all members of the Italian Parliament, let alone by Italian society.

On the “vital rights” of born citizens: from the passing of law 40/2004 to Italy’s bio-political referenda

Dear Italians, Dear Beppe,

I go immediately to the heart of the issue with a strong and nasty statement (...). With the passage of the law on assisted fecundation, this country has accepted the death penalty. I do not see, in fact, how you could otherwise define the destiny to which hundreds of thousands of persons suffering from terrible degenerative disease (such as Alzheimer’s disease, and amyotrophic lateral sclerosis) are condemned to, [patients] whose only hope for recovery consists in scientific research with stem cells.

Paolo Pizzato, a private citizen of Italy in a letter to the editor, February 12, 2004
(Pizzato 2004)

When the law was published in Italy’s *Official Gazette* on February 24, 2004, an enduring and rocky process of legislation finally reached its end. After seven years of waiting, the very enactment of the law was celebrated as an achievement and as the much anticipated end of Italy’s “wild west” of reproduction. For some, the passing of the law marked the end of the story. Yet for others it was just its beginning.

Agreeing in principle with the necessity of a law, many in fact did not agree with the content of this law and often criticized it harshly. Fertility experts warned that the provisions would induce (the more wealthy part of) Italian patients to seek treatment outside of Italian borders, and scientists worried that the provisions would trigger a further brain drain from Italy’s

crisis-ridden scientific community. Altogether, the law was condemned as an enforcement of the Catholic moral system on the Italian society as a whole (Associazione Luca Coscioni 2005; Cossutta 2005) and as an offense of the secular character of the Italian Republic.

Hence, much of the protest followed the “normal” patterns of Italian political struggles. But the protests also featured unusual patterns that set them apart from other political struggles and gave them a decisively “vital” character. Some citizens and citizens’ associations condemned the law as having very material consequences on their lives and their bodies: Infertile couples argued that their chances of conceiving a child were severely handicapped; ‘high risk couples’ saw their hope for healthy children hampered by the sudden ban on pre-implantation genetic diagnosis (PGD); and patients suffering from chronic diseases saw their hopes shattered that HESC research might bring future life-saving therapies into their lives. In the name of their bodily vulnerability and somatic make-up, fully fledged born Italian citizens protested that the state had sacrificed their “Lives” (with a capital L) to protect a very abstract notion of “life” (Novella 2005) and to “gratify” the “moral ordinances” of the Catholic Church (Di Lascio 2005).

The “Association Luca Coscioni”, in particular, mobilized this argumentation. This group is a transversal association that involves a broad range of socio-political actors, such as scientists, physicians, infertile couples and patients affected by chronic pathologies. It is named after its founder, Luca Coscioni, who suffered from amyotrophic lateral sclerosis (ALS)³⁴, a disease still poorly understood but that figures prominently among the potential targets of HESC research³⁵. Following his own terms, Luca Coscioni was an “expert of bioethics” on his “own

³⁴ Luca Coscioni *was* the president of the association in the past, but he died in February 2006. Since his death, his wife, Maria Antonietta Coscioni, succeeded him in the presidency of the association that continues to be named after its founder.

³⁵ Following the definition provided by the Amyotrophic Lateral Sclerosis Association (ALSA), amyotrophic lateral sclerosis (ALS), also known as “Lou Gehrig’s disease” is “a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually lead to their death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed. Yet, through it all, for the vast majority of people, their minds remain unaffected. A-myotrophic comes from the Greek language. ‘A’ means no or negative. ‘Myo’ refers to muscle, and ‘Trophic’ means nourishment---‘No muscle nourishment.’ When a muscle has no nourishment, it ‘atrophies’ or wastes away. ‘Lateral’ identifies the areas in a person’s spinal cord where portions of the nerve cells that signal and control the muscles are located. As this area degenerates it leads to scarring or hardening (‘sclerosis’) in the region. As motor neurons degenerate, they can no longer send impulses to the muscle fibers that normally result in muscle movement. Early symptoms of ALS often include increasing muscle

skin” (ADUC 2002a). His disease confined him to a wheelchair, and he was able to speak only thanks to the help of a computer that transformed his body into a cyborg and a powerful discursive tool. Since 2002 he was the iconic embodiment of a struggle that was engendered by one essential hope, the therapeutic potentials of HESC research, and one essential aim, to facilitate the performance of HESC and cloning research in Italian laboratories. In his intervention in the Health Commission in the Italian Senate, Coscioni reminded the Senators, that their vote was

decisive for the life and death of millions of our fellow citizens, and – in a global world – for hundreds of millions of persons. (ADUC 2002a)

Once law 40/2004 was passed, the association argued that an abolition of the ban on “decent” HESC research could develop cures for approximately 10 million Italians. And it would delete the contradiction of a piece of legislation, that – following the wording of Marco Cappato, the association’s secretary, – “prefers to let decay 30 thousand surplus embryos in the freezer (...) instead of using them in a search for cures for diseases which are today without hope” (Repubblica.it 2005).

The Luca Coscioni association had been founded well before the passing of law 40/2004 in February 2004. But it was the law’s approval that set the conditions for the association’s move to the center of the Italian political stage. The law’s passage enabled the struggles and hopes of Italian stem cell activists to link with the hopes, sufferings or angers of other socio-political actors, who might not have been interested in HESC research but who agreed that the law was “unjust” or even “cruel”. In addition, law 40/2004 permitted HESCs to move from rather dispersed places of civic sense making to a more prominent and institutionalized space of civic participation. Article 75 of the Italian Constitution has, in fact, arranged the possibility for the “sovereign”, the “Italian people”, to cancel the work of its representatives, through an abrogative referendum (“referendum abrogativo”). It permits popular referenda, whereby the Italian electorate can give direct expression of its will about a specific law *after* the law’s approval. Thus, a referendum can nullify an existing law, either partially or completely. But this tool of direct democracy also has some pitfalls: for a referendum to be valid a minimum of 50% +1 of the Italian electorate must cast its vote.

weakness, especially involving the arms and legs, speech, swallowing or breathing. When muscles no longer receive the messages from the motor neurons that they require to function, the muscles begin to atrophy (become smaller). Limbs begin to look ‘thinner’ as muscle tissue atrophies.”

In spring 2004, the Luca Coscioni Association started to collect signatures for a referendum petition to overturn the entire law and that also supported four additional requests that sought to partially cancel the law.³⁶ The first request was to cancel all those passages of the law that hampered HESC and cloning research in Italy, such as the ban on embryo research, on the production of “surplus” embryos and the ban on SCNT, so as to enable “new cures to diseases such as Alzheimer’s, Parkinson, sclerosis, diabetes, heart diseases, tumours”. The second petition “for the protection of the health of the woman” sought to cancel the ban on embryo freezing and all provisions that outlawed pre-implantation genetic diagnosis. The third petition sought to reaffirm “[women’s] auto determination and the protection of women’s health” and to abrogate the passage of the first article of the law that framed the early human embryo as embodying equivalent rights as its future parents. Finally, the fourth petition sought to re-introduce donor insemination to the range of permissible practices in Italian laboratories. Overall, more than a million signatures were collected. The Constitutional Court ruled on the admissibility of the five petitions in January 2005. Although it did not admit the request for the abrogation of the entire law, arguing that a law was constitutionally necessary, it approved moving forward with the four “partial” referenda.

From early 2005 to the June 12 and 13, when the referenda took place, stem cells, clones and embryos ceased to be the stuff of expert committees, parliamentary debates or the dispersed sense-making of activists. Instead, they became the object of electoral campaigns, newspaper headlines and television shows. Let us take a look on how these struggles were played out.

“Life cannot be put for vote”

In the six months between the Constitutional Court’s decision and the referenda in June 2005, the four rather tricky and technical questions were reduced to a single one. Are early human embryos subjects or objects? Are they amenable to be deployed for research, or do they embody a set of fundamental rights? Are they a cluster of mere human vitality, or are they human beings or even human persons? That is, the struggles switched from the rights and freedoms of adult citizens to such a big question as “who or what is an embryo”, or

³⁶ The following section is based on the Italian Ministry of the Interior’s webpage, under http://referendum.interno.it/ind_ref.htm (retrieved on September 2, 2005).

more precisely, “is the embryo a who or a what, somebody or something”? The debates on the rights and liberties of fully fledged adult citizens were thus transformed into debates on the essence of human embryos and hence into exercises of ontological ordering, effectively marginalizing and silencing the personal narratives of those citizens whose life courses had been hampered by the enactment of the law.

The main argument of the “embryo as a citizen” alliance was that the embryo was “one of us” because it had received a genome. As the result of the fusion of the genes of its mother and its father, so the argument went, the genome of the embryo was unique. In addition, the genome contained all the necessary information that makes an embryo progressively become a fully fledged and unique human being and therefore “one of us” (*uno di noi*). However, the status of the embryo was not only based on its potential to become one of us, but also derived from the fact, that, as the president of the CNB Francesco D’Agostino, explained,

[w]e have all went through the various phases of embryonic development. Therefore we cannot not regard the embryo as one of our fellow human beings. (Quoted from Milano and Palmerini 2005: 155)

“We have all been embryos” became one of the major slogans of the campaigns. And as the member of the parliament Francesco Paolo Lucchese, explained in February 2004:

One cannot freeze one of us. The embryo cannot be manipulated for research purposes, because this would be as if we put one of us at the disposition of research. (Camera dei Deputati 2004)

Nor can “one of us” be voted for. “Life cannot be put for vote“, was in fact the principal message of the campaigns: It cannot be scrutinized by citizens in national referenda, nor can it be acted upon by scientists or women and couples who make their own ethical decisions, nor can it be sacrificed for biomedical research or for a more or less likely salvation of Luca Coscionis. The supporter of law 40/2004 hence mobilized the bias of this tool of direct democracy, inviting the Italian electorate not to cast its vote.

The first to propose this strategy was the head of the Italian Bishops’ Conference (*Conferenza Episcopale Italiana*, CEI), Cardinal Camillo Ruini. Immediately after the Constitutional Court decision to allow the referenda to proceed, , Ruini invited the Italian electorate to refrain from voting (La Repubblica.it 2005). This strategy was subsequently embraced by other

socio-political actors. The newly founded Scienza & Vita (Science&Life) association, in particular, invited the Italian electorate to refrain from voting.

It would be misleading to reduce the arguments of the advocates of the status quo with regard to the “most ticklish” (Anonymous 2005a) of the four referenda, the referendum on HESC research, to the “ontological” status of the embryo. Their argumentation was more sophisticated. In their representation, HESC research was not only ethically problematic but also scientifically uncertain and actually a risky enterprise. Rocco Buttiglione, for instance, claimed that HESC are not necessary in order to develop cures to diseases such as “Alzheimer, Parkinson or others”. The best results were achieved with “non embryonic stem [cells]”, a realm in which “Italy is leading”. Thus, while somatic stem cells are highly successful, HESCs have not given “any real and concrete hope”. It is, as Buttiglione underlined, “a line of research that contradicts basic human rights, because one can be a good scientist and at the same time a criminal” (Anonymous 2005b). This particular “truth” was not only uttered by politicians but also by the authoritative and trustworthy voice of scientists. Angelo Vescovi, the deputy director of the Stem Cell Research Institute of the Milan-based San Raffaele Institute (*Istituto di Ricerca sulle cellule staminali dell'Istituto San Raffaele di Milano*), repeated constantly that the “sacrifice of embryos” was scientifically unnecessary, and – given the “intrinsic character of [human] embryonic stem [cells] to produce tumours” – was actually risky (Vescovi 2005).

To sum up, the debates and struggles were organized by the emergence of two transversal alliances. The first alliance – which we could call the “(vital) rights & freedom” alliance – focused on human rights and freedoms: the freedom of reproduction, the freedom from religion, women’s rights over their bodies, the right not to be hindered in someone’s own ethical choice by a national or governmental moral code imposed on the collectivity as a whole, the freedom of research, the right to receive cures and to live a healthy life and the right to have – at least – hope in potential therapies in a not too distant future. Its reference point was the “human being” as a biological citizen whose genetic – or in anyway – somatic corporeality, vulnerability and suffering endows him or her with vital human rights, which the state as a good shepherd must not interfere with but, in fact, must foster. The second alliance, too, referred to “human beings”, radicalising this category to include the “life” of fertilized oocytes and embryos. As this “life” is “one of us”, so their argument went, it needs protection; in extremis, at the expense of the rights and liberties of the qualified life of the

“citizen”. Both alliances performed their own realities, truths and – indeed – visions of society; but they were not equal: one of them was more successful. Considering the turnouts of the referenda, it was obviously the latter. As three-fourths of the Italian electorate chose to stay at home, it turned out to be a merely statistical detail that between 78,2% (for the legalization of gamete donation) and 89,2% (for the legalization of human embryonic stem cell research) decided to vote “yes”.

The threat posed to the Italian embryo regime was averted. And the embryo’s status as a “citizen subject” was no longer only the effect of the powerbroking and decision making of the members of the Italian electorate; rather, it was also embraced by the Italian ‘general public’ – or at least, the vast majority of the electorate chose not to question it.

After the referendum: do ‘orphan’ embryos die?

The failure of the referendum set a clear defeat of Italy’s “stem cell public”, confirming the current regulation that bans the production of embryos for research purposes as well as the deployment of Italian embryos in this line of research. But it did not mark the end of the Italian stem cell story.

Indeed, there is still an unresolved and puzzling question: the future destiny of Italy’s surplus embryos. As we have explained before, since the enactment of law 40/2004, the production of ‘surplus’ embryos is strictly banned. But in the previous two decades, Italian laboratories were at liberty to produce as many embryos as they deemed necessary. In effect, they produced an estimated number of 30,000 ‘spare’ embryos, whose vitality is frozen in the various IVF centres dispersed over the Italian territory. What should be done with them?

The law said nothing about their future and delegated the decision to the Minister of Health. In summer 2004, Umberto Veronesi, a former Minister of Health and prestigious oncologist, proposed to use these “orphan embryos” as cell donors, instead of “chucking them away” (quoted from Pappagallo 2005). Similarly, the Luca Coscioni Association pledged to use these surplus embryos for research purposes, given that they are “anyway designated to be destroyed” (Assiociazione Luca Coscioni 2005: 5). But Health Minister Girolamo Sirchia strongly dismissed this possibility, as “research should be carried out on animals, not on

Christians” (quoted from Lorenzi 2003)³⁷, issuing an ordinance on the subject in August 2004 (Ministro della Salute 2004).

The ordinance introduced a distinction between embryos “waiting” for their future implantation and embryos “in state of abandonment” (*stato di abbandono*), that is, cases in which couples had explicitly resigned to transfer the embryos or in which the IVF centre had been unable to contact the couple for at least one year. While all “waiting” embryos remain at the fertility centres, all “abandoned” embryos will be gathered at a central repository at the “Biobanca Nazionale”, Italy’s “National Biobank” in Milan. However, it is still unknown whether the freezer in the biobank will be a “crypt of ice for Italian embryos” (La Repubblica.it 2004) or the obligatory passage point of Italy’s surplus embryos.

In summer 2006, these embryos triggered debates that reached the Italian Senate (see Box 4.3 for the context of this debate). The discussion focused on whether a part of these embryos might no longer be implantable, and on whether these no longer implantable embryos might be used for HESC research (see the introduction of this section).

Box.4.3: Italy’s place in Europe

The debate was prompted in May 2006, when Italy’s newly appointed Minister for University and Research, Fabio Mussi, announced that he did not intend to insist on the policy of previous Italian governments that had strictly opposed European money for HESC research and that he had therefore withdrawn Italy’s signature from the “declaration of ethics”, in which the delegations of Germany, Austria, Slovakia, Poland and Malta declared their opposition towards the eligibility for European funding of HESC research.³⁸ Mussi’s announcement in Brussels raised a storm of protest in Italy. Some condemned Mussi as having agreed to fund the murdering of embryos, and therefore a form of life that in the name of Parliamentarian Luca Volonté “constitute[s] the origin of all of us” (Volonté 2006). Others stressed that Mussi’s act was not only an offense of ‘life’ but also an infringement of Italian democracy. Laura Bianconi, a Parliamentarian from the centre-left party Forza Italia, declared: “Italy consists of a majority of persons who have different views on stem cells and embryonic cells from Europe. Why should we be ashamed of this position? (Senato della Repubblica 2006b). Others deployed harsher tones: Various Catholic groups issued a declaration in which they denounced Mussi’s decision as an “authoritarian act” (quoted from ZENIT 2006), and “Avvenire”, the daily of the Italian Bishop’s Conference (“Conferenza

³⁷ Please note, in the Italian language “Christian” does not necessarily refer to a religious person. In colloquial Italian it is often used as a (sympathetic) expression for a “human being”. In this sense, also Jews and Muslims can be Christians. We therefore suggest translating Sirchia’s “Christians” as “innocent human beings”.

³⁸ Technically speaking, the “declaration of ethics” was a short note in the minutes of the 2694th meeting of the Council of the European Union for Competitiveness in which the delegations of Germany, Austria, Italy, Slovakia, Poland and Malta declared that they could not agree “that activities that include the consumption of human embryos [could; I.M.] be eligible for funding under the VII Research Framework Programme” (Council of the European Union 2005).

Episcopale Italiana", or CEI for short) denounced Mussi's act as a "[military] coup (*golpe*)" and as an "obvious treason of the will of the people (*volontà popolare*)" (quoted from Padania.online 2006). After almost two months of intense and highly emotional struggles, a final decision on how to direct Mussi's actions was delegated to the Italian Parliament. On July 19, the members of the Italian Senate passed a resolution with a tight majority. This directed the Italian government to stand up for research activities that "do not imply the destruction of embryos, (...) [to promote] scientific research conducted in order to individuate the possible production of totipotent [sic] stem cells that are not derived from embryos (...) [and] to verify the possibility of research on frozen embryos that are not implantable" (Senato della Repubblica 2006d). Hence, the resolution directed the government to stand up for lines of research that did not imply the destruction of embryos, yet it nevertheless did not oblige the government to oppose European funding for such research.³⁹

At the present, it is impossible to predict whether the "death of the embryo" remains a term that allowed putting a political end to the tantalizing conflict on stem cells for Europe, or whether it will be eventually mainstreamed as a way to ethical embryonic stem cell research for Italy. However, it is probably not too far-fetched to claim that in both cases it would constitute an "Italian" solution: First, the "death" of the embryo remains within the boundaries of the discursive construction of early human embryos as deserving the treatment of fully fledged human beings. The donation of one's remaining vitality after the death of a patient is a concept that in other settings is reserved to adult persons. The "death of the embryo" therefore does not break away from the discursive construction of the early human embryo as "citizen subjects"; rather, it forges it ahead. Second, the issue of the "death of the embryo" also sticks to Italy's bio-essentialist story line. As we have seen in the introduction of this section, the wording of the Senate's resolution of embryos that "are no longer implantable" was ambiguous and therefore contested. But the intention of the authors of the resolution was nevertheless clear: In their view, the boundary between vital embryos and embryos that are no longer vital and hence no longer implantable is a boundary given by "nature". It might be interpreted or read through a scientific truth discourse. But it is not set by it.

³⁹ Half a week later, the Council of the European Union reached a compromise. It agreed that the Commission should continue its current practice of not submitting to the Regulatory Committee proposals for projects which include research activities that destroy human embryos, but that the exclusion of funding of this step of research would not prevent Community funding of subsequent steps involving HESCs (BBC 2006; Watt 2006). Backed by a parliamentary vote, Mussi and the Italian delegation could agree to this compromise.

The political task was to facilitate scientific research that would not set the boundary but “detect” or “identify” it. Such research could not experimentally test whether a particular embryo is still among the “living” or not, as it would threaten to kill this particular embryo. But observational studies could help to understand the location of the threshold between vital embryos and dead embryos (Interview 2-42). And once the identification of the “death” of the embryo succeeds, researchers would no longer need to disrupt the vitality of human embryos, “making them die” or “killing” them. Rather, science would be able to deploy only those embryos that have been “let die” or that suffered a “natural death”. For sure, this boundary is still imbued with many questions and uncertainties, such as whether dead embryos are still vital enough to be the source of HESC lines, or how to understand the location of the boundary. However, one thing is for sure: The decision on the death of the embryo is up to “nature” – not to politics, let alone to “the public”.

Reproductive Medicine, Biotechnology, and the Future of Britain

"America does not want stem cell research, we do, we welcome it here."
 Prime Minister Tony Blair in his "Farewell Speech" on September 26, 2006
 (quoted from Stobart 2006)

In Germany and in the United States HESC research had quickly become a highly politicized topic that created boundaries of separation between different segments of society. The presidents of the United States, the German Chancellor, and high-profile leaders of the parliaments in these countries played a key role in the ensuing controversy. The result of these broadly based debates were highly restrictive regulations of stem cell research in Germany for private and public research, and an almost equally restrictive approach in the public sector in the United States, while privately pursued research remained relatively unregulated. Nevertheless, strong political forces in the United States fought also a battle against HESC research and sought a ban on cell nuclear replacement (or 'therapeutic cloning') procedures.

In the United Kingdom, the picture could not be more different: While there was a broad public debate and press coverage on the issue, the language and style of the debate remained comparatively moderate. The discussions were characterized by sober language, deductive reasoning and the attempt to construct the stem cell problematic as a question of pragmatic choice and balancing of arguments. In 2001 the British Parliament endorsed legislation that opened the door not only for public and private human embryonic stem cell research, but also for somatic cell nuclear transfer (SCNT). Briefly afterwards, the launching of a "UK stem cell bank" indicated the government's strong determination to turn the United Kingdom into a global leader in HESC research. Today, the United Kingdom has one of the most liberal regulatory regimes for HESC research and a comprehensive system in place securing the tight oversight of stem cell research to be supported with substantial government resources. *How can this striking contrast be explained?*

A first important feature is the strong interest of British governments and stakeholders in the economic powers of biotechnology (Gottweis 1998). Within this narrative of economic revival and growth through an increase in knowledge of biological materials, stem cell and cloning research were quickly framed as a field of strategic importance. However, the British development in stem cell research was by no way simply predetermined by contextual factors. Rather, it was the result of a discursive struggle and explicit policy strategy to define the nature of the “stem cell question” in a coordinated effort of the medical-scientific establishment together with the government. These two groups were successful in establishing a hegemonic definition of the stem cell problematic that marginalized alternative interpretations in a way so that opposition to the government policy strategy hardly materialized. While the critics of stem cell research initially had tried to polarize the debate as a conflict between Christianity and a post-Christian nation, the dominant policy discourse’s framing of the debate as one between reason and unreason became hegemonic to the extent that the critics had to focus their arguments to question this dominant polarization. In this narrative polarization the question of ‘vital rights’ of embryos as well as of (biologically conceptualized) citizens and related ontological separations were as much at stake as in Italy. But, unlike in Italy, in the United Kingdom an alliance made up of the government and medical interest groups soon emerged as an organizing centre that successfully defined the reality of the stem cell question in Britain.

Key in this context was the build-up of a historical narrative that was highly efficient in organizing a variety of actors and strategies. As we will show below, according to the increasingly dominant policy narrative, any attempt to argue that Britain was facing a major choice for or against HESC research and therapeutic cloning was beside the point. Britain already had made a choice in this question more than ten years earlier with the debate and passing of the HFE (Human Fertilization and Embryology) Act. The only issue was to extend the 1990 decision to allow for embryo research from reproductive medicine to other areas of medical research. Thus, neither was there a major question to be settled, nor a major policy problem to be solved. *In fact, there was no problem.* The main issue was to think and reflect carefully and to help not only those with fertility problems but also those suffering from Parkinson and other diseases. Any other interpretation of the stem cell problematic was simply wrong, far-fetched and unreasonable. In the British discourse, critique of stem cell research was not even precisely identified as such, but somehow as an unspeakable

articulation of unreason. Whereas in the United States the critics of stem cell research were identified as voices of backwardness and irrationality, in the British case the problematic was constructed as a “learning problem”, as a matter of pragmatic choice that mainly seemed to depend on the capacity of all actors to think reasonably. The creation of publics corresponding with this problem definition was a key aspect in the UK stem cell strategy.

The 1980s: From the Warnock Committee to the HFE act

When in 1998 the first reports from the United States on the successful cultivation of HESCs arrived, they were received in a political-cultural environment that was in many respects much better prepared to deal with this news than was the case in the United States, in Germany or in Italy.

In Germany, the highly restrictive Embryo Protection Act had put a de facto ban on all variations of embryo research and thus no regulatory mechanisms existed that could have dealt with the HESC question. As a result, the debate from 1998 until 2003 was characterized by a fundamental consideration of the arguments pro and contra stem cell research, and efforts to develop regulatory mechanisms that could deal in an efficient and respected way with the new regulatory challenge. In the United States, the debate on embryo research and related issues of reproductive medicine had a longer and more complicated history but was also characterized by a split between private and public research. Whereas in the private sector restrictions were relatively loose and permissive, publicly funded research in this field was much more strictly regulated. Tight federal regulations together with a permissively regulated private sector had created a confusing regulatory situation with a continuous stream of reports from private companies such as Advanced Cell Technology (ACT) about ‘breakthroughs’ such as the creation of chimeras paralleled by the much less spectacular federal oversight. As a result, in both countries trust in existing systems of regulation was difficult to build and authorities were under pressure to achieve legitimacy and belief in their actions and policies. The situation was radically different in the United Kingdom.

In Britain the discussion of embryo research dates back to the 1980s, when it had a preliminary culmination in the 1984 Warnock Report that had recommended that embryo research up to the fourteenth day after fertilisation should be continued in the United Kingdom but be restricted in scope and monitored and controlled by a body outside of the

research community (Warnock Report 1985). Initially, the suggestion to create trust in embryo research via oversight was criticized and rejected within the research community. Likewise, those voices and politicians opposed to abortion also considered the conclusions of the Warnock Report as unacceptable (Mulkay 1997: 20-23). In 1985 the anti-embryo research lobby gained the cooperation of the Conservative ex-Minister Enoch Powell, who introduced a Private Member's Bill, the "Unborn Children (Protection) Bill". Powell's bill provided that IVF clinics should be controlled more tightly than in the past and prevented any use of IVF embryos for research purposes. Two pro-life organizations – the Society for the Protection of Unborn Children (SPUC) and LIFE – supported strongly Powell's position. LIFE delivered a petition for the protection of the human embryo with two million signatures (Powell, HC, 15 February 1985, cols. 637-698, Mulkay 1997: 29). In the House of Commons' Second Reading of the Bill, a majority of 238 to 66 votes was in favour of Powell's bill. But the government delayed the vote on the Powell bill, and in November 1985 the Medical Research Council (MRC) and the Royal Society of Obstetricians and Gynecologists (RCOG) established a Voluntary Licensing Authority and began to issue first licenses for externally supervised research on IVF embryos (Mulkay 1997: 28). In 1986 the Unborn Children (Protection) Act was submitted to the Commons once more, by Ken Hargreaves. In the years to follow, a number of similar attempts to stop embryo research in the United Kingdom took place. In 1988 the government produced a White Paper outlining a framework for legislation. The White Paper followed the recommendations of the Warnock Report on embryo research rather closely and proposed to replace the Voluntary Licensing Authority with a Statutory Licensing Authority to regulate infertility treatments. But it took a different approach towards embryo research: It proposed that the eventual bill would use the device of alternative clauses on embryo research to enable Members of the Parliament to decide this issue according to their personal judgment (Mulkay 1997: 33). The Bill eventually introduced by the government followed the White Paper in most respects. After long and protracted debate, the House of Commons voted 364 votes to 193 for the Bill, a vote unexpected with respect to the majority in favour of research (Mulkay 1997: 41).

The Human Fertilization and Embryology Act (HFE Act) is administered by the Human Fertilisation and Embryology Authority (HFEA). The 1990 Act regulates the practice of in vitro fertilisation (IVF) and the creation, use, storage and disposal of embryos formed by this means. The Act also made provision for research to be undertaken on embryos to find out

more about infertility, miscarriages, contraception and developing methods to detect genes that may cause congenital birth defects. With respect to embryo research the Act's Schedule II states that

a licence (...) cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of —

- (a) promoting advances in the treatment of infertility,
- (b) increasing knowledge about the causes of congenital disease,
- (c) increasing knowledge about the causes of miscarriages,
- (d) developing more effective techniques of contraception, or
- (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,

or for such other purposes as may be specified in regulations. Furthermore, the Act states that

[p]urposes may only be so specified with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied.

Finally, the Act also outlawed a number of practices, including replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo. This last provision was directed against the possible cloning of humans based on the state of art of the late 1980s. According to a Department of Health statistic, some 48,000 embryos that were no longer needed for IVF were used in research between August 1991 and March 1998. One hundred eighteen embryos were created in the course of research in the same period.

The existence of the HFE Act and, related, Britain's deep involvement in embryo research might be seen as the central contextual feature for the passing of the 2001 revisions of the HFE Act that cleared the way for one of the most liberal regulatory regimes for HESC research and somatic cell nuclear transfer of cloning research in the world. But, as we will show, the story is more complicated.

Taming Dolly

Just as in most other countries with a strong interest in biomedical research, the birth of Dolly the sheep created a period of uncertainty and questioning in the United Kingdom. As

in the United States and elsewhere, the British public and the mass media did not greet the production of Dolly the (Scottish) lamb with unequivocal enthusiasm. Calls for a ban on “human cloning” also were strong in the United Kingdom (Butler and Wadman 1997: 8-9; Lee 1999: 56) and the government felt a “need for action.” Unlike in Italy and the United States, in the United Kingdom the government immediately took preparations to react decisively to the “dislocatory challenge” of the birth of Dolly. There was the question as to the extent to which the HFEA actually covered cloning as used in Dolly. The first cloned sheep involved nuclear transfer into an egg, not an embryo, the cloning known when the HFE Act was passed.

The announcement of Dolly also prompted an inquiry by the House of Commons Science and Technology Committee, which published its findings in March 1997 in a report, “The Cloning of Animals from Adult Cells” (The Science and Technology Committee 1997). The Committee argued that concerns over the cloning of Dolly may have overshadowed potential benefits. The Committee also suggested that the Human Genetics Advisory Commission (HGAC) would advise on the implications of the work for human genetics. It also recommended that work that would create “experimental human beings” should not be carried out and suggested that the Parliament should reaffirm a ban on human reproductive cloning. The HGAC was established in December 1996 in response to a report by the House of Commons Science and Technology Committee, as a non-statutory advisory body. It provides independent advice to UK Health and Industry Ministers on issues arising from developments in human genetics that have social, ethical and/or economic consequences. The Commission is charged with setting its own priorities, although from time to time it may be requested to provide urgent advice to Ministers. The Commission was also asked to advise on ways to build public understanding of the new genetics. The HGAC and the HFEA decided to explore ways of holding a public consultation exercise into the implications of cloning developments. A joint working group, consisting of members of both bodies, was established to consider the planning, drafting, distribution and analysis of a joint consultation paper on the issues for human genetics arising from advances in cloning technology.

The government response to the Science and Technology Committee’s report was published in December 1997 (Government Response to the Fifth Report of the House of Commons Select Committee on Science and Technology 1997). It reiterated the Minister of State for Public Health’s statement; explained that the HGAC and the HFEA were exploring ways of

holding a public consultation exercise on cloning; and said that the government would consider carefully, in the light of developments, whether the legislation needed to be strengthened in any more specific way, taking into account the views of Members of Parliament, the HGAC, the HFEA and the responses received to a more general consultation on the broader issues (HGAC Papers January and December 1998).

The consultation document, “Cloning Issues in Reproduction, Science and Medicine”, attracted substantial interest. More than 1,000 copies were distributed, and the document was also distributed through the HGAC website. The consultation sought general comments about how the technology that led to Dolly might develop and the opportunities and problems that might be raised by human reproductive cloning and other applications of somatic cell nuclear transfer technology. It also invited views on priorities for the future and the ethical settings in which these scientific developments are taking place. It sought comments on any other ethical issues raised by human cloning that respondents identified. It was requested that responses be structured around replies to six questions. Respondents were also invited to make suggestions about what advice might be offered to Ministers on ways to build public confidence and understanding of the new developments in genetic techniques.

The document drew, apparently, the first time a distinction between two types of cloning:

For the purposes of this consultation we draw the distinction between two types of cloning: on the one hand, human reproductive cloning, where the intention is to produce identical foetuses or babies; and, on the other hand, what may broadly be called therapeutic cloning, which (although not coterminous with conventional scientific usage) includes other scientific and medical applications of nuclear replacement technology. (HGAC 1998b).

This distinction between ‘therapeutic’ and ‘reproductive’ was not based on any pre-existing scientific terminology. It was developed by the committee, and, eventually, shaped in a most powerful way the discussion about the topic of stem cell research and cloning in many countries (Interview 1-12).

The consultation paper raised many fundamental questions concerning cloning such as if there were any areas of medical research that could benefit from cloning research. But the paper also began to outline a particular policy direction. On the one hand, it related what it defined as ‘*therapeutic cloning*’ to the current regulatory practice:

The HFEA's policy is that it will not license any research which has reproductive cloning as its aim. However, it would consider licence applications for other types of research involving embryo splitting or nuclear replacement in eggs, provided that the research falls within one of the purposes specified by the HFE Act, or any regulations, which may be made by the Secretary of State for Health as described above.

On the other hand, the report clearly highlighted to possible advantages of human cloning in a range of applications:

The creation of Dolly represented a further step in the development of nuclear replacement technology. It showed that a nucleus taken from an adult animal could be reprogrammed to allow the full range of gene expression needed to produce a complete animal, so called gene totipotency. Although this research is still in its early stages and has not been reproduced it is a significant scientific breakthrough and offers a number of basic research applications of human relevance. Nuclear replacement research can improve our knowledge about physiological processes and the genotype. For example, it is hoped that this work will offer a greater insight into the origins of cancer and other cellular development processes such as aging and cell commitment. It may also offer the potential to produce better animal models for human disease which would aid research into new or improved therapies. Many of these important questions will be difficult to study unless the procedure shown in livestock animals can be extended to mice, for example. (...) In humans, the possibility of using nuclear replacement technology for reproductive cloning has been raised. However, it could also be used as a means to avoid the transmission of inherited diseases derived from the mitochondria. This possible application need not involve human reproductive cloning. It could involve, for example, taking an enucleated egg from a donor containing normal mitochondria, which would then receive the nucleus from an unfertilised egg taken from the individual with mitochondrial disease. The reconstructed egg could then be fertilised. This type of therapy would not involve the production of a genetically identical individual or foetus.

Nearly 200 responses were received – about 40% from individuals and the rest from a wide range of constituencies – scientists, clinicians, academics, religious groups, ethicists, lawyers, industry and lay groups. As the HGAC paper summarized:

Responses varied enormously, some expressing a horror at the very idea of any form of cloning without addressing the specific issues raised in the document, whilst others were very detailed in their consideration of the issues. Some respondents provided additional questions and arguments to those raised in the consultation document. This wide range of views was welcome, reflecting common reactions, misunderstandings and hopes and fears about this rapidly developing technology.

The final December 1998 HGAC paper (HGAC 1998a) spoke even a clearer language with respect to future policy making:

The Human Fertilisation and Embryology Act 1990 is on the statute book, and despite the concerns of some respondents, the purpose of the consultation was not to reopen old debates about it. What needed to be considered was the effectiveness of the Act in dealing with new developments concerning cloning. The difficulty is in considering the appropriateness of controls in a rapidly changing area where it is difficult to envisage just what direction developments will take and what problems might be encountered. (...) The Government has explicitly ruled out reproductive cloning and the HFEA has stated its policy that it will not license the use of nuclear replacement for this purpose. HGAC and HFEA *recommend* that these safeguards be recognised as being wholly adequate to forbid human reproductive cloning in the United Kingdom. The Government may, nevertheless, wish to consider the possibility of introducing primary or secondary legislation *explicitly* banning reproductive cloning regardless of the technique used, when there is an opportunity to do so in the legislative programme, so that the full ban would not depend upon the decision of a statutory body (the HFEA) but would itself be enshrined in statute. (...) When the 1990 HFE Act was passed, the beneficial therapeutic consequences that could potentially result from human embryo research were not envisaged. We therefore *recommend* that the Secretary of State should consider specifying in regulations two further purposes to be added to the list in paragraph 3(2) of Schedule 2 (as described in paragraph 5.7 of this report) being:

- *developing methods of therapy for mitochondrial diseases*
- *developing methods of therapy for diseased or damaged tissues or organs.*

(...) Finally, because of the pace of scientific advances in the area of human genetics, the HGAC and the HFEA believe that the issues need to be kept under regular review to monitor scientific progress. We therefore *recommend* that the issues are re-examined again in, say, five years time, in the light of developments and public attitudes towards them in the interim.

Despite this clear endorsement of support for therapeutic cloning as a field of vital politics by the joint HGAC/HFEA paper, it was by no means clear that this position would become official government policy. In fact, the BSE scandal and the broad discussion about genetically modified foods had created a discursive context for the shaping of governmental strategies in other sensitive areas of policy making. In June 1999 the government decided to defer its decision on a possible rewriting of the HFEA regulations as suggested in the joint HGAC/HFEA report and suggestions. When the HGAC/HFEA report was drafted, it mainly had focused on cloning issues, but the work by Thomson and Gerhard in human stem cell research had not yet been published and, thus, it was difficult to take these developments into account. Public Health Minister Tessa Jowell told the Parliament:

We believe that more evidence is required of the need for such research, its potential benefits and risks, and that account should be taken of alternative approaches that might achieve the same ends. (Quoted from BioCentury 1999)

It was announced that a new expert group would look into the issue of therapeutic applications of stem cell research and cloning. As a high-level Department of Health officer described the results of the HGAC/HFEA report:

I think government at that time felt that was the right way forward, but that it recognized, that it had come to that conclusion without having necessarily carried out a very substantial analysis to where the science was taking us.(...) The HGAC/HFEA report was already in press when J. Thomson first isolated stem cells, so almost immediately there was this new area, that the report had not covered, so that let the government say, we think this is the right way forward but we really want to put together an expert group, scientists, medical and academic scientists, ethicists, lawyers, specifically to look at the implications of cell nuclear replacement research and stem cell research. (Interview 2-5)

Immediately following this move of the government were threats from the biotechnology industry. Simon Best, the managing director of Geron BioMed, the company with exclusive license to commercialize the technology that created Dolly, said his company had hoped to collaborate with other institutes in the United Kingdom, but this was looking less likely now and that Geron BioMed might conduct its human embryo research in the United States. The UK Bioindustry Association noted that other countries such as France, Germany, and Spain were reconsidering bans previously implemented on the therapeutic use of human embryo cloning, and that money for research would move elsewhere if research were not allowed in Britain (BioCentury 1999, June 28; Independent, June 25, 1999).

It seems it was during 1999 that the government's human embryonic stem cell/human cloning strategy began to take shape. Unlike in the United States and in Germany, where government bodies began to look into HESC research after they had decided that, for the moment, all forms of cloning were, in principle, unacceptable, things seem to have worked the other way around in the United Kingdom. Central policy actors saw no conflict between the HFE Act and human cloning for therapeutic purposes for research covered in the Act, mainly in the context of infertility treatment and reproductive medicine. By contrast, the combined issue of cloning and stem cell research were identified as associated with the vital rights of the British citizenry and the government defined as a defender of these vital rights. This position was officially acknowledged by the HGAC papers on the topic. Viewed from this perspective, HESC research was a relatively unspectacular sub-topic in the regulation of stem cell research technologies. But this view was in no way imposed from above, but carefully presented and developed in a 'controlled' interaction with the public, in particular,

the ‘informed’ publics created through consultation processes. These consultation processes addressed, on the one hand, a ‘generalized’ public of ‘the British’, but also specific stakeholder publics with a special interest in topics such as cloning, on the other.

While there was considerable public concern about cloning, this technology was seen as a ‘British technology’, and further research in this area was not only a matter of regulatory decision making, but also a matter of defending major advances in medical research and of major industrial-strategic interest. From the late 1970s, biotechnology had been defined as a major industrial-strategic goal for the United Kingdom. Following the Spinks report from 1980 about the current state and future strategies for biotechnology in the United Kingdom, a plethora of biotechnology strategies and initiatives were designed (Gottweis 1998: 196-209). In 1996 the Department of Trade & Industry together with a number of other UK government ministries had launched a “Crusade for Biotechnology” to maintain Britain’s position in biotechnology into the 21st century. The idea of this “crusade” was not only to maintain what was seen as Britain’s lead in Europe, but also to strengthen its position as a global leader in biotechnology (Biobusiness, June 1996, 12-13). In November 2000 Tony Blair addressed the European Bioscience Conference and outlined his commitment to building investment in the UK’s science base. He said:

The science of biotechnology is likely to be, to the first half of the 21st Century, what the computer was to the second half of the 20th Century. Its implications are profound, its potential benefits massive.

As populations grow and people's expectations of their health increase, the world will be more and more in need of the kind of solutions that biotechnology can offer. Biotechnology can deliver better, more effective medicines. It can improve food production, including in the developing world. It can help to clean up our environment.

Biotechnology is the next wave of the knowledge economy, and I want Britain to become its European hub. This is an industry whose market in Europe alone is expected to be worth over US\$ 100 billion by 2005. The number of people employed in biotech and associated companies, as well as those whose work will depend on biotech applications, could be as high as 3 million, as we catch up with the US industry – currently 8 times the size of Europe's.

With our excellent science base, our sophisticated capital markets and venture capital industry, the large number of skilled scientists and managers in our pharmaceuticals sector, and the investment in research by Wellcome and others, Britain is well placed to keep our lead in Europe. I want to make it clear: we don't intend to let our leadership fall behind and are prepared to back that commitment with investment.

Under this Government, the Research Councils have spent £600 million a year on biotechnology and medical R&D. In July, we announced that the science budget would increase in real terms by 7% a year to 2004. (...) All in all this will be the largest investment in science over the next few years in peacetime Britain's history.

The DTI have also developed measures to promote biotechnology specifically, in terms of clustering, finance and advice, and deal with industry concerns like planning. The Pharmaceutical Industry Competitiveness Task Force is also helping develop better links between biopharmaceutical SMEs and 'big pharma', as well as providing support for early stage biotechnology manufacturing.⁴⁰

Surely, the UK debate on stem cells and human cloning must be localized with this specific discourse on biotechnology, in which the British government was determined to "defend the position of British biotechnology" in the world. Stem cell and cloning research came to be inseparably connected to a major meta-political goal of the Blair government.

But it must be pointed out that this is only one part of a larger story. The United States and the German government were also committed to their national biotechnology industries, but the governments were much less certain about unequivocal support of human cloning and stem cell research. Within the group of core policy makers the 'GMO scare' began to be articulated as an aspect of the stem cell issue in a very particular fashion. Not only was the stem cell issue seen and defined as a matter of major national interest, but it was also defined as an arena for demonstrating 'Britain's commitment' to the progress of science and its rejection of luddites and irrationality.

In June 1999 the government announced the establishment of an expert group chaired by the Chief Medical Officer, Professor Liam Donaldson

to advise on whether new areas of research could lead to a broader understanding of, and eventually to new treatments for a range of disorders where there is disease or damage to tissues or organs. (Department of Health 2000)

The creation of the expert group was met with some hostility in the scientific community, which feared a delay in advancement for British science and a possible brain drain to the United States. But in a press conference Donaldson dismissed such claims:

We need to proceed carefully. (...) I hardly think there'll be a brain drain in the next six months. (Masood 1999: 4)

⁴⁰ <http://www.bioindustry.org/cgi-bin/contents_view.pl?ID=154>

The expert group was a small high-level body composed of 14 individuals, mostly scientists from reproductive biology to veterinary medicine, an ethicist, a lawyer, and the government's chief scientific adviser, Sir Robert May. Initially, the expert group under the impression it was to study the ramifications of Dolly the cloned sheep and the possible impacts of the technologies developed in animal cloning on humans. In fact, when the group was set up it was called the "Chief Medical Officer's Expert Group on Therapeutic Cloning" (Department of Health 2000: 49).

When we started we thought that we [were] going to produce quite a short, specific report about the particular issues and [it] became apparent almost with the first meeting that the net should be cast more widely and as the report developed the emphasis and the direction of the report became more about [what] was likely to be practical in the next decade, which really concentrated on stem cell research, and some of the wilder suggestion of the media such as cloning organs or whatever was so much science fiction, so the balance of the report evolved and I think it was quite reasonable at the end of the period to say this body, this committee had expanded within its term of reference.

With the launching of the Donaldson expert group, stem cell research and cloning finally had become a highly visible issue of governmental decision making. But it took the Donaldson group much longer to produce and present the report than was initially indicated.

The final report was delayed by several factors. For one thing, it seemed that the government wanted as much of a time distance between the BSE and the GMO crisis that had peaked in mid-1999. Also, there was internal dispute within the governing party. The "Guardian" reported about a row between the Department of Health and Science Minister Lord Sainsbury. While the Department of Health was reluctant to publish the report, as it was concerned about possible critique from religious groups, the Science Minister pressed to go forward. Lord Sainsbury said in an interview that in his view, "the potential medical benefits outweigh any other considerations one might have". These remarks were interpreted as signaling the go-ahead for cloning. Liam Fox, the shadow Health Secretary, said:

This is a huge issue of concern to church groups and religious groups, who are all expecting the very different ethical issues involved to be given maximum scrutiny.

Dr Fox so, the "Guardian" reported, accused Lord Sainsbury of "sweeping away all the complex ethical issues with complete contempt" and of having neglected the consultation that had been promised (Patrick Wintour, The Guardian, July 31, 2000).

After almost a year of deliberations, the expert group issued its report in mid-August 2000. It contained no surprises and, in essence, reiterated policy content and direction of the 1998 HCAG consultation paper. In five chapters and two annexes the report attempted to guide the reader through the main scientific, legal, and ethical implications of stem cell research and human cloning and arrived at nine recommendations for future action. But the report was clear that it did not attempt to take a fresh look at the moral and ethical issues of embryo research. The section preceding the treatment of ethical issues of the report stated clearly:

These morally contentious issues were considered by the Committee of Inquiry into Human Fertilisation and Embryology (the Warnock Committee) and debated at length by Parliament during the passage of the Human Fertilisation and Embryology Act 1990. Parliament decided to allow embryo research to take place, but subject to the considerable safeguards enshrined in the Act. The purpose of this Chapter is not to revisit that earlier debate. It focuses only on whether research involving the extraction of stem cells from embryos, or the creation of embryos for such research using cell nuclear replacement, raises any new ethical issues. (Department of Health 2000: 37)

Quite clearly, the report considered central ethical and moral issues of embryo research to be “settled”, and declared itself only to be interested in a set of “new” questions. In short, the presence of any possible new moral or ethical question was simply and straightforwardly denied. In its recommendations, the Donaldson Report followed precisely the boundaries set up by the initial HGAC consultation paper: Research using embryos should be extended from the strictly defined set of research areas dealing with infertility and reproduction to the general field of medical research, and cell nuclear replacement techniques should be used to develop treatments for mitochondrial diseases. At the same time, research using embryos created by cell nuclear replacement should only be conducted if there were no other means to pursue the objectives of research. Furthermore, the report indicated a strict rejection of the mixing of adult cells with live eggs of any animal species and reproductive cloning. Also, it is quite remarkable that throughout the report, the initial language of “therapeutic cloning” had given way to the “cell nuclear replacement” terminology. After the report was published, the government announced that members of the Parliament would have a free vote to decide on the proposed change in regulations (Tim Radford, *The Guardian*, Thursday August 17, 2000).

With the Donaldson Report the British government had fully entered the politics of stem cells and human cloning. With it, the debate on stem cell research moved from the terrain of “generalized” and “specific” publics to the field of Parliament as site for deliberation and

decision making. In its response to the report, the government stated that it accepted the Report's recommendations in full and would bring forward legislation where necessary to implement them as soon as the parliamentary timetable allowed (Department of Health August 2000: 1). The long duration of the production of the Donaldson Report, its presentation in the middle of the summer when Parliament was not in session, and the following steps to introduce secondary legislation in Parliament and finally pass the law were characterized by a series of unusual moves by Parliament, which indicated a great deal of insecurity and concern with respect to the passing of the reforms. Just as was the case in the 1990 HFEA legislation, the outcome of the vote would be unclear until the final vote in the House of Commons in December 2000. After Parliament finally had voted in support of the bill, it was far from clear how the House of Lords would proceed.

The battle for a 'Christian Britain'

On the side of critics of the proposed legislation there was a number of smaller pro-life groups that fiercely rejected the proposed legislation and, in general, the 1990 HFE Act and the 1976 abortion legislation. These groups included LIFE and SPUC, which had already played an important role in the debate of the HFEA legislation, but also newer groups, such as Comment on Reproductive Ethics (CORE, founded 1994) or the ProLife Alliance (founded in 1997). Other critical organizations included the NGO Human Genetics Alert (London), and the Catholic Church (Ahmed and Hinsliff 2000). To be sure, the critics also comprised representatives from all political parties in Parliament, who, as we will see, either sided with a pro-life agenda, or had other reasons to reject the proposed legislation. While the Catholic Church rejected fundamentally stem cell research and cloning, it remained relatively silent and inactive during the following debate.⁴¹ In particular, the ProLife Alliance and, to a lesser extent, LIFE and SPUC turned out to be the most articulated and active voices on the pro-life side. Their strategic goal was to define the stem cell and cloning question as being tied to fundamentally 'ontological questions' and to tie the stem cell agenda to larger topics and narratives connected with British identity. A countless stream of press releases, statements, reports and strong presence via well-organized internet sites was a characteristic

⁴¹ Probably indicative for this is the following episode: During one of our interviews in 2002, representatives of the Catholic Church referred several time to the "ProLife Alliance" as the best interview partners to get a sense of the position of the Catholic Church in the UK on stem cells and cloning.

of these three latter organizations.⁴² The most recent of these organizations, the ProLife Alliance, was, in fact, a political party that had offered candidates in the 1997 elections. It declared as its central goals: to repeal the Abortion Act 1976 and outlaw all abortion; repeal the Human Fertilisation and Embryology Act 1990, ban cloning, embryo experimentation and destruction, and the laboratory creation of embryos; and outlaw voluntary and involuntary euthanasia (ProLife Alliance 2001: 3). The position of these pro-life organizations and the Catholic Church was very clear and, in the light of its position towards abortion, embryo research and any extension of embryo research and cloning were fundamentally wrong. For example, in its comments on the Donaldson Report, SPUC stated:

“Recommendations by the government’s committee on cloning are not only unethical but could lead to people being cloned without their knowledge or permission.” Paul Tully, general secretary of the Society for the Protection of Unborn Children said: “Implementation of the Donaldson report will mean the creation of carbon copy embryos who will be denied the right to live. The recommendations fly in the face of two votes in the European Parliament against human cloning.” Cell nuclear replacement involves so-called somatic cells, but the report does not recommend that consent should be required for the use of such cells. The report says that consent should be obtained from those whose sperm and eggs are used to create embryos through cell nuclear replacement, yet this technique does not involve sperm. It is nonsense. “The report misrepresents the law on human embryos. It claims that the 1990 Human Fertilisation and Embryology Act does not distinguish between embryos created from eggs and sperm and those created by cell nuclear replacement. However, embryos are defined on the first page of the act as resulting from fertilisation. “We oppose the manufacture and destruction of cloned embryos.(...) The committee seems to want Britain to catch up with other countries in human spare part research, yet it seeks to permit unethical practices which our European and American competitors have avoided. The Charter of Fundamental Rights may contain an explicit and binding prohibition of cloning. “If the research envisaged in this report goes ahead, it will bring the birth of cloned babies much closer,” concluded Mr Tully.⁴³

The construction of the conflict between the pro-life groups and “The Government” suggests a relatively clear structure of the world, which is divided among those who reject

⁴² See: <http://www.prolife.org.uk/>; <http://www.lifeuk.org/>, <http://www.spuc.org.uk/index.htm>.

⁴³ SPUC, August 16, 2000, <<http://www.spuc.org.uk/releases/20000816.htm>>

abortion, stem cell research, and cloning, – and those who support it, a division, that separates “Christians” from “Non-Christians”. As one of the pro-life leaders told us:

The United Kingdom is a profoundly Post-Christian culture. There is definitely no longer any concept at all about Christian heritage, of issues of right and wrong, and in many respects, it is my belief, science has usurped the role of religion (...) and scientists are our Gods, whatever they say is the truth, (...) the whole debate polarized into science versus religion and this very much borne out of this: there is science, and there is religion (...) we never have come to any conclusion what the human embryo is, but the arguments were looked in 1990 subsequent to the Warnock committee rather brushed aside laws and regulations and we were just left alone with that. (...) God has gone from this country (...) it is a country without a soul, totally hedonistic, self-cantered culture. (Interview 2-11)

In the battle for “A Christian nation”, the pro-life movements had few allies:

[T]he Catholic Church is not very strong. Catholicism is a minority religion anyway, but the leadership in the Catholic Church this country is not intellectual leadership, it is quiescent, (...) here the leadership is almost not existent, the battle is fought by the lay people here. (...) I do think, with the greatest respect, that our leaders are not very well educated. (...) the common feeling about the Anglican Church is that they like sitting on fences, the Church has compromised, so you can have a little bit of cloning, and little bit of stem cell research (...) the Anglican leader who is always involved in these issues was the Bishop of Oxford, (...) he couldn't be more liberal and more utilitarian. (Interview 2-11)

But, as we will show below, these views, perceptions, and “divisions of the world” only entered the political debate to a rather limited extent. The idea to define stem cell politics as an attack on the ‘vital rights’ of those who support a broad and emphatic vision of what constitutes life never gained ground in the political discourse. This political debate was dominated by an alternative semantic construction; they interpreted the ‘stem cell/cloning problem’ as one in which pragmatism conflicted with dogmatism. In particular during parliamentary debate, this reasoning was supplemented by an often emotional appeal not to abandon potential cures for the desperately sick in light of dubious religious claims.

Following the HGAC consultation paper and the Donaldson Report, in this alternative interpretation of the problem, there was the highly successful and respected structure of the HFEA system, and some, few, but important, modifications that needed to be brought about to extend the scope of permissible research from fertility and reproductive medicine topics to other areas of medical research, topics such as Parkinson, Alzheimer, and many other serious health conditions. All that was needed now was to allow for this kind of research, to expand

the scope of the HFE Act, and to help more people. What could be more natural and obvious? In fact, “there was no problem” there – and all potential problems, such as the status of embryos, had been discussed and settled many years ago. This “pragmatic view”, shared by many important and respected groups, institutions and individuals in Britain, was misinterpreted, maybe misunderstood, by a small minority who preferred to stick to old dogmas and views and was not prepared to accommodate to the new situation. In this narrative, the “small minority” had respectable values and needed to be listened to. But the critics were simply misled and misinterpreted scientific and political realities.

The critics were viewed as a small group. As one of our interview partners from the Wellcome Trust put it:

We were aware that anything in this country that involves any human embryo always creates fairly strong opposition of fairly small groups, in particular the pro-life alliance (...) if I am honest that seems to be the only focus of opposition, is that small group (...) it is not clear how many people they represent. (Interview 2-10)

But, as it seems from the cautious proceeding of the government in preparing and passing the new HFEA legislation, this small group was taken very seriously. The government did not want either the “BSE scare” or the “GMO experience” to be repeated in the case of stem cell research.

On the other side of the spectrum were the government, representatives from all political parties in parliament, medical, scientific, and industrial organizations, patient groups and a wide range of academic bodies. This broad and powerful alliance comprised, among others, the Royal Society, the British Medical Association, the Medical Research Council, the Biotechnology and Biological Sciences Research Council, the Human Fertilisation and Embryology Authority, The BioIndustry Association, and the Association of Medical Research Charities, Alzheimer’s Society, The British Liver Trust, the Parkinson’s Disease Society, the Juvenile Diabetes Foundation, and the British Heart Foundation, just to name a few of AMRC’s members. The Royal Society, for example, stated in its reaction to the Donaldson Report:

The Royal Society today welcomed the publication of the Donaldson report and called on MPs to support an extension of the 1990 Human Fertilisation and Embryology Act that would allow the use of human embryonic stem cells for research into treatment for disorders such as Parkinson’s disease, hepatitis, diabetes and rheumatoid arthritis.

“We believe the potential medical benefits of permitting research on human embryonic stem cells are so great that an extension of the 1990 Act is entirely justified,” said Professor Patrick Bateson, Vice-President and Biological Secretary of the Royal Society. “If supported by Parliament, the recommendations of the Donaldson report would ensure that research was properly regulated”, said Professor Bateson. “Reproductive cloning would continue to be a criminal offence, but the controlled use of cell nuclear replacement would be permitted to produce embryonic stem cells for research.” Professor Bateson added: “The research may eventually make possible the re-programming of adult cells so that they behave like embryonic stem cells. If that can be achieved, then embryonic material would no longer be needed.” In its evidence to the Donaldson group, the Royal Society recommended that a working party should investigate the feasibility of establishing frozen banks of various categories of stem cell that have been both tissue-typed and screened comprehensively for pathogenic viruses.

In response the Donaldson group recommended that the Research Councils should be encouraged to establish a programme for stem cell research and should consider the feasibility of establishing collections of stem cells for research use. “We are glad that the Expert Group has endorsed our recommendation”, said Professor Bateson. “Much more research is needed on all types of stem cells if patients are to benefit from the new therapies that will be made possible by such work.”⁴⁴

This press release of the Royal Society indicated a considerable shift in the Society’s position towards human embryonic stem cell research and, in particular, cell nuclear replacement. In February 2000 a working group chaired by Richard Garder, had produced a paper, “Therapeutic Cloning”, intended to contribute to the deliberations of the Donaldson expert group. In its submission, the Royal Society discussed the possible benefits of therapeutic cloning as a potential basic research tool, but concluded in a highly skeptical manner:

The techniques of therapeutic cloning is likely to remain inefficient for the foreseeable future, and does raise serious issues about safety, particularly regarding the normality of donor nuclei. If this approach for replacing damaged tissues does work, the cost will be considerable. This may mean that such therapy will only help those individuals who are able to afford an expensive treatment and the majority of patients will be excluded. Therefore, the early

⁴⁴ August 16, Press release, <http://www.royalsoc.ac.uk/templates/press/releasedetails.cfm?file=299.txt>

applications of these techniques are likely to be offered by private clinics. (The Royal Society 2000b)

Such considerations were absent from subsequent statements of the Royal Society, be it in its press releases or its briefing note prepared for Members of the Parliament in November 2000, when the decisive vote about the proposed legislation came closer (The Royal Society 2000a), which emphasized mainly the crucial importance of stem cell and cloning research for the future of medical research, and the position for British science in the world.

The Royal Society's shift in position indicated that the UK research establishment had decided to attribute to the 'battle over stem cell and cloning research' not only high substantive, but also high symbolic importance. As a representative of the Medical Research Council (MRC) told us:

This was one issue we wanted to make a stand on for rational approaches to science, rather than this anti-science lobby we often get in the UK, and for example, if you take GM crops, scientists assumed ten years ago that the case was so overwhelmingly in favour of using GM crops they did not bother to do anything and then Monsanto came along and actually made a few inappropriate remarks and comments, the whole GM cause got lost, and I think everyone is determined with things like stem cells that is one thing where we have learnt (...) that did not get involved because they thought it is so obvious everyone looks at it, but of course, that was naive, and so people were very clear let's get out there and let's make a case, let's get to the press, tell the press what is going on, and let's get the arguments out there, let's get people like Christopher Reeve, Superman, telling the general public what the potential benefits are rather than the scare stories, and let's make sure that scientists get out there and tell the truth about reproductive cloning. Nobody in their right minds believes that reproductive cloning is something that one could contemplate (?) or could even be done scientifically. (Interview 2-6)

During the months from the publication of the Donaldson Report in August 2000 until the decisive vote on the House of Commons in December, the medical, scientific and industrial organizations in support of stem cell and cloning research, together with medical charities and patient groups organized an unprecedented, well-coordinated campaign in support of research, organized by the Wellcome Trust, a medical charity (Interview, 2-10). An internal Wellcome Trust note described this process in the following way:

—the Trust has used a combination of both a proactive and a response-mode approach to the development of a new policy area: Stage 1: The Trust became aware during late spring 2000 that the Chief Medical Officer's expert group reviewing the potential of developments in stem cell research was due to publish its report on 16 August 2000. This was a relatively new area for the Trust to consider and consequently a Project Team was established in July 2000, consisting

of representatives across the Trust. Stage 2: The project team research the scientific, ethical and moral considerations of research using both human embryonic stem cell (ES) and adult stem cells and developed an Interim Position Statement on the subject to ensure that the Trust was in a position to respond publicly when the Chief Medical Officer's report was published. Stage 3: The report from the Chief Medical Officer's expert Group made a series of recommendations (...) Stage 4: The votes took place in the House of Commons and the House of Lords (...) The Trust was keen to support the proposed legislation as it was considered to be beneficial to biomedical science, so a Q&A document was developed to send to the MPs and Lords. The Trust also worked proactively with the Association of Medical Research Charities in order to contact MPs and Lords (...) in addition, the Trust took an extensive round of media activity. (...) This was the first time the Trust had undertaken such an extensive range of activities concerned with a new area of research and the process appeared successful. (Memo, Welcome Trust, August 2002)

In addition to the Trust, the MRC, the Department of Health and other organizations organized briefings and meetings with MPs to communicate their main message: "There is no problem. Pragmatism must win over dogma." As we will see below, this mode of "rational reasoning" was increasingly combined with an emphasis on those who suffered from currently untreatable diseases, and the hope that stem cell research would be a way to secure their vital rights as citizens in the political arena. This well-financed and organized campaign was in no way matched by the critics of stem cell and cloning research, basically a small group of activists who were not even well-coordinated between themselves (Interview 2-10). "The British public" had become the main addressee of this campaign.

Pragmatism versus Dogma

The parliamentary debate of the new HFEA regulations began on October 31, 2000, when the Liberal Democrat Evan Harris introduced a so-called Ten Minute Rule bill

to amend the Human Fertilisation and Embryology Act 1990 to allow the use of early embryonic tissue for the purposes of research into the development of regenerative therapies. (HC Deb 31 October 2000, cc (colume) 626-630).

(Ten Minutes Rules bills are Private Member's Bills and intended for Backbench MPs to introduce a bill of their own. They may give a speech not lasting more than ten minutes to support their bill.) Harris, one of the members of the House strongly in favour of passing the new HFEA legislation, had chosen this rather surprising move to reform the HFEA regulations because he felt the need to put pressure on the government to finally act on the Donaldson Report from mid-August (Harris, HC Deb 17 November, 2000, c 1220.) The

presentation of the bill was followed by a brief discussion and a vote with 83 members in support of the bill, 175 rejecting it. The bill had no chance of success and was mainly meant to put pressure on the government; it was clear that changes would only come about by the government introducing the planned legislation with sufficient time for debate. On the other hand, the critics of stem cell and cloning research viewed the vote on the bill as a sign of encouragement for their battle. John Smeaton, the national director of SPUC, commented: "This is a healthy start to our campaign against human cloning."⁴⁵

On November 17, 2000, a longer debate on the new regulations began, when the Labor MP Tony McNulty made a motion for an adjournment debate on stem cell, human fertilization and embryology regulations. An adjournment debate is a short debate that is introduced by a backbencher and gives backbench members the opportunity to discuss issues of concern to them, and to have a minister respond to the points they raise. (HC Deb 17 November 2000, cc 1175-1230). At this point in time, the new regulations had not been laid out before the government, but based on the Donaldson Report and the response of government, it was already fairly clear what the legislation would look like.

There were a number of themes that emerged during this debate and the subsequent parliamentary debates in December 2000. These themes reflected the strategic priorities of the supporter of the impending legislation but also, to some extent, of the critics. Beginning with the HGAC consultation paper and the Donaldson Report, one of the key strategic decisions of the supporters of the proposed legislation was not to "re-open" the debate that had taken place in Britain around the publication of the Warnock Committee report leading up to the 1990 HFEA regulations. In particular, the 'ontological' question of "what is life" or about the general acceptability of embryo research should not become the centre of the parliamentary debate. And, indeed, the House of Commons debates did not focus on this topic. These "general questions" had become non-issues, and this was certainly not to the disadvantage of the supporters of research. As one of our interview partners put it:

The debate did not go back and reopen as to whether or not human embryos should be used in research or not and this is why I think when it came to debate stem cells and their generation from human embryos things moved easier in the UK, much easier than they did in Germany or

⁴⁵ Quoted from <<http://www.spuc.org.uk/releases/20001031.htm>>

in the States, because to a certain extent we resolved the use of human embryos in research argument ten years ago. (Interview, 2-2).

The clear spin of the statements of the supporting MPs, and the numerous briefing packets of scientific and other organizations in defence of cloning and stem cell research was: “There is, in fact no problem. New legislation is needed in order to help those with serious diseases.” This spin had become so dominant in the months and weeks leading up to the parliamentary debate that the critics of stem cell research had resorted to a defensive strategy: to question the claim that the proposed reform was really not more than a small, incremental change; to complain about the lack of time given to Parliament to come to a decision; and to point to the potentially disastrous consequences of a positive vote by Parliament. This strategy was first put in action via public statements, press releases and so on; then via MPs in the parliament; and finally in the form of court action intended to find judicial support for the core accusations of the stem cell and cloning research critics.

But this semantic strategy was clearly linked to an emotional rhetorical strategy that focused on the fate, the suffering, and the feelings of patients, in short, on ‘vital issues’. One clear line of argumentation in support of the new legislation was the argument that people with serious diseases must be helped. As Liberal Democrat Evan Harris put it:

I am driven to my view on the issue not by the science, although that is an important factor, but by the ethical duty I believe we as representatives have to do what is right. After careful examination, I have judged that, although it will entail the curtailment of the rights of some early embryos, allowing research into life-saving therapies is the right thing to do. (Harris, HC, 17 November 2000, c 1217)

Regulations to specify the announced changes in the HFE Act were laid out on November 27, 2000. Revised draft regulations were issued on December 12, 2000, in particular, involving a re-wording, and a limitation of the purposes of the Act to “serious” disease. This was a response to concerns articulated in the previous parliamentary debate that embryo research might be permitted also for minor ailments or trivial complaints. In particular, the new regulations extended the scope from permitting research in embryos and IVF not only for infertility treatment and the study of the development and treatment of embryos to a sixth area of increasing understanding about human diseases and disorders and their cell-based treatments.

Finally, on December 15 and 19 the decisive debates in Parliament took place. The Parliamentary Under-Secretary of State for Health, Yvette Cooper introduced the debate:

The purpose of the regulations is to promote stem cell research, which has immense potential to relieve the suffering of many people in this country. It is for that reason, and because of the impact that the research could have on hundreds of thousands of people, that the Government support the regulation. (Cooper, HC, 15 December, 2000, c 877)

It was a telling opening of the debate that the second speaker of the day, the Conservative shadow Health Secretary, Liam Fox, responded with a procedural question, indicating one of the major points of critique of opponents of the new legislation, namely, as, they saw it, the way the legislation was rushed through Parliament:

Can the Minister tell the House at the outset why the Government withdrew their draft regulations and produced a new draft regulations this week, and why the House will be given only four working days between their publication and the need to enact them on Tuesday? (Fox, HC, 15 December, 2000, 878)

Later on, the Conservative MP Edward Leigh seconded Fox on the issue of procedural problems of the passing of the Act:

My views are clear: this is an ethical issue and we cannot use embryos in this way. I accept that my view is probably not shared by the majority of hon. Members. However, if we are to change the law, at least let us do it properly. Procedure on the matter has been rather cockeyed. There has been a ten-minute Bill, and Adjournment debate on one Friday and this debate (on Friday, H.G.)— although many Members cannot come on Fridays. We are also to have a short debate on Tuesday. Is not the whole thing a tiny bit confusing and messy. Will the Minister reconsider one last time before Tuesday, taking the matter away and coming back with primary legislation? (Leigh, HC, December 2000, 892)

Fox and Leigh were both, like many other MPs during the debates, pointing to the fact that the government had chosen secondary legislation as the vehicle to rush the new regulations through Parliament, instead of primary legislation, which would have given the opposition much more space for interventions, such as utilizing amendments. This perspective was also shared by Labor MPs, such as Ruth Kelly, who also pointed to one of the possible main weaknesses of the proposed legislation: the fact that the content of the new regulations hardly could have been anticipated during the drafting of the 1990 legislation:

I (...) feel very strongly that a statutory instrument does not the best way to proceed. Although the 1990 debates on human fertilisation and embryology provided for an extension of the purposes for which research on embryos should be allowed, it is clear from reading

those debates that no one envisaged that the Human Fertilisation and Embryology Act 1990 would also allow human cloning to take place: that it was even possible to use cell nuclear replacement to produce a clone was not known until Dolly the sheep was produced. However, the Act prohibited the substitution of one nucleus for another in an embryo. At that time, that was thought to be the method by which clones would be produced. It is not unreasonable to assume that, had the technique of cell nuclear replacement been known, it, too, would have been banned. (Kelly, HC, December 15, 2000, c 899-900)

A good number of speeches by Conservative, but also Labour, members of the House emphasized the “rushed” character of the new legislation, the unhappy timing of the debates on Fridays and at a late hour and, in general, what was seen as the wrong choice of secondary legislation instead of primary legislation. While critics frequently mentioned they rejected embryo research on ethical grounds, the major issue that emerged in parliamentary debate was the question of exactly what it was that was to be regulated by the new legislation: something that had been already available and thus discussed in the debates leading to the 1990 Act, namely embryo research, or something new, embryo research AND cell nuclear replacement, which was neither available in the late 1980s, nor would it have been permitted by the 1990 legislation. The answer to critics’ allegations from a number of speakers was that the new legislation was neither rushed through Parliament, nor was there any reason to view secondary legislation as an inappropriate policy tool. Supporters of the legislation emphasized that there had been broad discussion and emphasized that the suggested way to proceed was absolutely correct. Robert Kelly argued:

The business has not been rushed though. We had the chief medical officer’s report for five months. There has been masses of discussion about the subject in the national press and other media. (...) I am grateful for the many briefs that I have received from many quarters. (...) It has been very helpful to have the views of particular denominations of the Christian faith, for example. It has been very helpful to me, as a fully paid-up member of the Church of England, to understand how other Christians think about the issue (...)

Mr.Swayne: Do Church of England members believe in God?

Mr. Key: Perhaps we can debate that on another occasion (...) (Kelly, Swayne c 236)

And the Parliamentary Under-Secretary of State for Health Yvette Cooper, responded to the allegations of the critics:

This is secondary legislation because the Parliament considered the issue in detail in 1990, and set out a power in the Human Fertilisation Act 1990 to extend the purposes of research in this way (...) Parliament clearly decided at that time to give powers to its successors to extend the

purposes of research through regulations. (...) It is true that Parliament in 1990 did not envisage the possibility of cell nuclear replacement. That technique has been developed since that time, and could not have been anticipated in the debates. However, it was anticipated in those debates that science and medicine would move on rapidly. That is why provisions for regulations were put in place in the 1990 Act. (Cooper, HC, 19 December 2000, cc 211-216)

Apart from defending the chosen procedures to decide about the extension of the HFE Act, many speakers supportive of the new legislation emphasized the enormous medical potential of stem cell and cloning research. The wheel-chair-bound MP Ann Begg delivered one of the most passionate speeches in which she masterfully linked a ‘pragmatic perspective’ with a plea for the ‘duty’ of the Parliament to allow stem cell research to proceed as a ‘moral obligation’.

I must begin by declaring an interest. I have a condition that results from a single gene defect. Ultimately, the cure – if there is to be one – for Gaucher’s disease will be gene replacement therapy, but there is no doubt that my problems, such as osteoporosis, could be helped by the research that we are discussing. Although I have a personal interest, I am speaking not just because of my own experience, but because of approaches I have received from constituents. About five weeks ago, in the middle of a busy advice surgery, a constituent arrived in an agitated state. She sat down. She had great difficulty in speaking and had quite severe tremors in both her hands and her head. She managed to get out that she was there to lobby me about supporting the whole issue of stem cell research. It was at that point that I stopped my constituent and said, “It’s okay, I know the arguments. I am in favour of the research. I understand what you are getting at.” A look of relief came across her face and she said, “You mean that I don’t have to go into the spiel that I have prepared? I’ve had such a morning; I couldn’t get myself together. It’s been very difficult. I’ve prepared everything, but I know that my words don’t come out properly and that, if I had to explain something that was very complicated, I might not be able to do it well”.(...)

Begg continued:

That reminded me of the problems my uncle faced when he, too, had Parkinson’s disease. (...) I am therefore aware of the issues around what had been proposed. I hope that I can articulate some of the thoughts, feelings, and emotions of those who may be helped by the research.(...) We have the technology with the potential to alleviate huge suffering. I believe that the moral argument is on the side of pursuing that technology.(Ann Begg, HC, December 2000, cc 906-908)

In the following debate, on December 20, Begg also spoke:

If the vote is lost today, I and other hon. Members will have to go back to our constituents who have Parkinson’s disease, multiple sclerosis or Huntington’s disease and say, “Sorry,

embryo cells can be used for research into improvements in contraception but cannot be used to find a treatment for what is wrong with you. (...) We will have to tell them, "Sorry, a group of cells in a laboratory dish, which will die because they have no means of sustaining themselves, has the same status as you. These cells are so important that they cannot be used to help alleviate your suffering (...) I would find it impossible to explain the logic of that position to my constituents. (Begg, HC, 19 December, c 229)

Another member, Sally Keeble reasoned:

I have had IVF treatment which, in my case, was successful. I am also a theologian. (...) I have been through a process and know what it is like to look at embryos that are part of one's genetic material. (...) I might not want to give them away as they are part of my genetic material. However, I must ask what the embryos will do if they cannot create life or reproduce something of my husband and me. (...) I believe that the means and ends are justified. I hope that the House will agree to the regulations and enable science to proceed. (Keeble, 20 December, C256-257)

And Yvette Copper concluded the debate:

Watching at home with bated breath and in the Gallery are many who hope that the research will deliver the cures and treatments that turn their lives around. (...) We cannot guarantee to them that the research will transform their lives, but we can tell them that we did not turn our backs on the possibilities that it might. (Cooper, 19 December 2000, c 261)

In this reasoning, suffering human bodies turned into major points of reference to support stem cell research, and these bodies were given voice and a role in a struggle for vital rights. In the decisive vote, the House of Commons gave a clear vote: 366 for the proposed legislation, 174 against it.

After that vote, the proposed legislation moved to the House of Lords. One day after the vote in the House of Commons, the government announced its intention to bring the Statutory Instrument to the House of Lords one day after the beginning of the next parliamentary session. When protest rose against such haste, the debate was postponed to January 22. Pressure continued to rethink the planned legislation. The Archbishop of Canterbury joined forces with the Roman Catholic archbishops of Glasgow and Westminster, the Chief Rabbi and the President of the Muslim College to protest changes to the law that would allow testing on stem cells derived from the cloning of human embryos. In an open letter that was sent to all peers, the religious leaders said the proposals deserved to be examined in more detail than that allowed by a brief parliamentary debate (Guardian, January 22, 2001). Again, the outcome of the vote in the House was considered as uncertain. On January 22 the House discussed the Human Fertilisation and Embryology Regulations 2000.

Before that, Lord Action had tabled an amendment that a Select Committee should be appointed to study the proposed regulations before a decision had been reached. This proposal would have delayed a final decision by the House for up to a year. In response, another amendment was tabled by Lord Walton of Detchant that the order be approved but that a Select Committee would then scrutinize the new regulations. Lord Walton's amendment was backed by the government. In his introductory statement to the Lords' debate the Parliamentary Under-Secretary of State, Department of Health, Lord Hunt of Kings Heath, stated that the government would support Lord Walton's amendment. He promised that the government "will listen to the Select Committee's views and review the regulations in the light of this report" (HL Deb., 22 January 2001, cc 15-21). Lord Hunt argued that any research proposal would take some months to complete and it would take the HFEA considerable time to arrive at a decision. Lord Hunt was suggesting that by agreeing with the government's legislation, research applications would not be delayed, but they might only be positively decided if the Select Committee of the House would arrive at a positive decision concerning the proposed legislation. Again, the government had chosen a highly unusual way to proceed with legislation, and, as a result, the debate in the House focused on what many Lords saw as a rushed and protracted way to proceed. In the Lords' debate, Lord Action commented on Lord Walton's amendment:

Imagine a court of law where the judge gave out the verdict and sentence before hearing the defence, the prosecution and the witnesses. Such a process would be held up to ridicule. I believe that if a Select Committee were to meet after we had agreed on these regulations, we should be in danger of dealing with such a momentous issue in the wrong way. (HL Dev., 22 January 2001, c 23)

This position was not only shared by Lords and Baronesses opposed in general to stem cell and cloning research. The "architect" of the 1990 regulations, Baroness Warnock stated:

There is a belief among the general public that a huge moral step is being taken without the benefit of the normal parliamentary procedures. Once that first step has been taken, they fear that nameless horrors will follow (...) I fear that suspicion grows every year – as regards politicians and scientists which is reaching dangerous proportions. (...) We ought to take every step within our power to increase trust (...) That is the background against which setting up of a Select Committee, whose evidence could be heard largely, perhaps entirely, in public, the membership of which would be known and the members of which therefore could be written to, lobbied and annoyed in every possible way by the general public, is an important consideration (...) In 1990 a number of the issues that we are discussing had not been raised. The possibility of these kind of procedures was thought of by the forward looking scientific

members of the committee that I had the honour to chair but the detailed work was not under discussion, neither was the sense that there was an imminent breakthrough. (...) I believe that there is a real need to set up a Select Committee and for its findings to be taken seriously into account in the regulation that will follow. (Warnock, HL Deb, 22 January 2001, cc 43-45)

Against those positions aired by many members of the House, the supporters of the Walton amendment pointed out the need to act quickly. Lord Hunt of Chesterton argued.

If the delaying amendment of the noble Lord, Lord Alton, is passed, researchers are likely to leave the UK and to continue the work abroad. All scientists know that the application of research, including medical research, is most immediate and effective when it is done alongside the fundamental research. So the expertise in the application of medical research in the UK will therefore be less than in countries where the research is taking place. Is that really the aim of those supporting the amendment tabled by the noble Lord, Lord Alton? (Hunt, HL deb., 22 January 2001, c 94)

In the final vote, Lord Alton's amendment was rejected (by 212 votes to 92). The alternative amendment of Lord Walton, that had asked for a "retrospective" Select Committee to be set up was passed without a division. The new regulations duly came into effect on January 31, 2001. But this was not the end of the story.

Of Select Committees, Judicial Review, and Reproductive Cloning

While the House of Lords decision had opened the door for the first research application to be submitted under the new regulations, the unusual strategy of the government to press through the new legislation began to show its political price in the months to follow.

After allegations in Parliament that legislation had been rushed through, the ProLife Alliance applied for judicial review – and with that move the ontological debate on the status of the embryo re-emerged in the political spectrum. Already on November 2000 ProLife had applied for permission to apply for judicial review. It sought a declaration that human embryos created by CNR were not within the definition of the HFE Act. It also sought a declaration that the Secretary of State had no power to make regulations in this connection. After the passing of the regulations in Parliament, ProLife contended that they were *ultra vires*, because they merely extended the purpose for which a license for research may be issued, without purporting to alter the definition of an "embryo" (High Court of Justice 2000: 3). On January 26, 2001, the application for permission was listed for oral hearing and expert

evidence was filed on both sides, among others by Ian Wilmut, head of the Gene Expression and Development Department at the Roslin Institute for the Department of Health and one of the ‘fathers’ of Dolly the sheep. Justice Crane followed in his judgment the ProLife argumentation. He argued in his judgment:

CNR is a form of cloning. (...) CNR of the kind under consideration does not normally involve fertilisation (...) during the hearing there has been discussion about whether the organisms produced by CNR is properly described as an ‘Embryo’ as a matter of scientific language. The Defendant submits that it is morphologically and functionally indistinguishable from an embryo produced by fertilisation. The Claimant has pointed to certain differences of structure. They point to the fact that on currently available data from animal experiments only a tiny percentage of such organisms will result in live births. (...) The defendant argues for a purposive construction of section 1(1). It argues that the essential concept is ‘a live embryo’. The subsection should be read as if the words were, in effect “a live human embryos where (if it is produced by fertilisation) fertilisation is complete” (...) I decline any invitation to rewrite any of the sections of the 1990 Act to make them apply by analogy to organisms produced by CNR. I accept the Defendant’s argument that the reason for inserting in section 1(1) (a) the words “where fertilisation is complete” and the following words in section 1(1) (b) was to define the moment at which the Act’s protection applied to organism. Nevertheless, the words are there (...) with some reluctance, since it would leave organisms produced by CNR outside the statutory and licensing framework, I have come to the conclusion that to insert these words would involve an impermissible rewriting and extension of the definition (...) (High Court of Justice 2001)

With this decision, both forms of cloning, ‘reproductive’ and ‘therapeutic’ cloning, were outside of the remit of the law. Bruno Quintavalle, the director of the ProLife Alliance stated:

The Human Fertilisation and Embryology Authority has no power to stop this research; it isn't a criminal offence and there is nothing that any public authority can do. The law as it stands is hopeless and we are glad we have shown up the government lie that human cloning is prohibited. (Guardian, November 15, 2001)

The situation was further compounded, when the infamous Italian Dr. Severino Antinori, one of the most prominent advocates of human reproductive cloning, told the BBC’s Newsnight programme that he planned to set up a cloning programme in Britain immediately.

[T]his decision increase my chances very much. (...) We want to begin a programme in the UK. My reaction is happy (...) I will phone my friend in England to establish the collaboration in cloning work. (BBC on line, Friday November 16, 2001)

A few days later, news broke that Advanced Cell Technology (ACT), Massachusetts, had managed to produce the first human embryo clone (Guardian, November 26, 2001). These developments prompted the government to introduce “emergency legislation” to put a ban on reproductive cloning. As the daily “Guardian” commented:

The government last night moved to rush emergency legislation through both houses of parliament and prevent an outbreak of unregulated embryo research in Britain by maverick scientists bent on cloning human beings. (November 26, 2001)

While the House of Lords was still in the process to work on its “retrospective” Select Committee report on the regulations that had come into effect in January 2001, primary legislation was introduced to eliminate a potential loophole in the passed legislation. The “Human Reproductive Cloning Bill” was introduced on November 21, 2001, and it became law on December 4, 2001. At the same time the government appealed against the judgment to try to bring the usage of SCNT within the scope of the Act. The one-page-long bill stated in its key passage:

A person who places in a woman a human embryo which has been created otherwise than by fertilisation is guilty of an offense (...) A person guilty of an offense is liable on conviction on indictment to imprisonment for a term not exceeding 10 years or a fine or both. (Human Reproductive Cloning Act 2001: Chapter 23)

The idea behind the Act, which did not use the language of SCNT or cloning, was to prevent for the time being and in the future any cloning research or treatment that would not be under the HFE Act. As the Parliamentary Under-Secretary of State for Health Hazel Blears put it:

As we have seen with the 1990 Act, the science is developing. What is not thought possible as an embryo today may well be an embryo tomorrow. This Bill concerns reproductive cloning. It addresses those embryos that may develop to become a human being. There is absolutely no reason why we should seek to restrict the definition of what an embryo created other than by fertilisation is, because any such attempt is likely to become out of date in short time. Nor is there any point in trying to define what we mean by an embryo created by fertilisation because that is fully covered by the 1990 Act. (HC Deb, Blears, November 29, c 1168)

The debates in House of Lords (HL, Deb, 26 November 2001, cc 10-60) and the House of Commons (HC, Deb., 29 November 2001, cc 1155-1213) were brief and, again, the rushed character of legislation was criticized, but also the fact, that Parliament was to pass legislation while the government was appealing against the judgment that had triggered the introduction

of the new bill. In fact, briefly after the passing of the Reproductive Cloning Act, the government won its appeal at the Court of Appeal. Sitting with two other judges, the Master of the Rolls, Lord Phillips dismissed the ProLife Alliance's argument that the 1990 HFE Act did not regulate SCNT. Lord Phillips accepted the government's argument that cloned embryos and embryos created by fertilisation were similar enough and that the intentions of the Parliament when it passed the Act was clear enough to stretch the Act's language to cover embryos created by SCNT as well (The Guardian, January 19, 9). On March 13, 2003, the ProLife Alliance's final appeal was rejected by the court, which seemed to have added the final point to the ProLife Alliance's litigation strategy with respect to the 2001 HFE Act.

In the meantime the House of Lords had begun, under the chairmanship of the Bishop of Oxford, its exhaustive investigations into stem cell and cloning research. The committee issued a call for evidence on April 5, 2001, distributed to scientific and research organizations, charities, patient groups and pro-life groups. The major groups involved in the debate were invited to give evidence, and the committee received 52 submissions from representative institutions and 57 from individuals. Twelve sessions of oral evidence were held at which 42 persons representing 17 organizations gave evidence. Over the period of four weeks, from September to October 2001, an internet debate was organized by the Hansard Society on behalf of the Committee. The Committee also undertook two visits, one to the MRC's Clinical Sciences Centre at Hammersmith and at Durham University, and some members met members of the Deutsche Bundestag Commission of Inquiry on Law and Ethics (House of Lords 2002). Based on this exhaustive parliamentary exercise, which took almost a year, the Committee came to conclusions that fully endorsed the 2001 HFE Act and the 2001 Reproductive Cloning decision. The various positions and oral and written evidences essentially and not surprisingly repeated the views and arguments that had been advanced by the various groups leading up to the 2001 legislation. On February 27, 2001, The House of Lords Select Committee officially announced its findings. At a press conference, the Bishop of Oxford, Richard Harris said:

Stem cell research offers real and great hope for the future for a range of common diseases (...) It is very important to keep all avenues of research open and we recommend that for the moment this fundamental research is necessary. (...)The Human Fertilisation and Embryology Authority (...) is the best regulatory authority in the world. (Guardian, February 27, 2001)

Two days after the House of Lords' decision, it was announced that HFEA had granted the first licenses to carry out stem cell research under the new regulations to the Edinburgh's Centre for Genome Research and a group of researchers at King's College, London (Guardian, March 1, 2002). The first license to cell nuclear replacement followed two years later, in August 2004 (Pincock 2004).

5. From Dolly the sheep to unruly cells: Dislocation, institutional ambiguity and the new politics of life

The PAGANINI project started from the proposition that the ‘new politics of life’ are often set off by dislocation that is either a sudden disruptive event or a more enduring process “that cannot be represented, symbolized, or in other ways domesticated by the [dominant] discursive structure – which is [therefore] disrupted” (Laclau 1990: 41; quote in Loeber, Hajer et al. 2005: 41). Dislocatory events challenge our traditional way to make sense of and order the world in which we live. They disrupt categories, concepts and truths we usually draw upon to make sense of events and phenomena. Loeber and colleagues (2005) note that in these occasions actors tend to struggle to find a common sense of what kind of phenomena they are dealing with. Consequently, dislocatory events challenge the practices of ordering we usually engage in and shutter institutional boundaries that are taken for granted. The practices and procedures in which elements and processes had been handled before being dislocated are often de-legitimated or fail to produce trust and to effectively re-order the dislocated realm. In such occasions, Loeber and colleagues note, actors have a tough time agreeing on “clear rules and norms, according to which (...) ground can be regained” (Loeber, Hajer et al. 2005: 12). Dislocation is therefore often expressed in terms of ‘institutional ambiguity’, that is, a constellation in which

on the one hand, the existing rules and norms that shape politics and policy-making with regard to a specific issue are considered problematic and/or unacceptable, while yet, on the other hand, there is evidence that clear rules are considered indispensable by the parties involved to determine who is responsible, who has authority over whom, what sort of accountability is to be expected and so on. As a result, in situations of institutional ambiguity, the ‘rules of the game’ – the way in which a perceived problem can and should be legitimately framed and publicly handled – are themselves the subject of political deliberation and struggle. (Loeber, Hajer et al. 2005: 60-61)

In other words, dislocation usually engenders struggling, puzzling and collective sense making, first, on the type of phenomena now being handled; and – as a consequence – with the type of instruments they can be handled with. However, dislocation does not necessarily

lead to deadlocks. Rather, as Loeber and colleagues argue, dislocation might lead to the emergence of new practices of governance and eventually to institutional innovations.

In this section, we will interpret and compare our data in the light of this perspective.

On cells, embryos and sheep: Going to the “bottom” of stem cells’ unruliness

Our case studies evolved in very different ways. But we think there is nevertheless a ‘unifying’ event that holds the differences of our case study together - the birth of Dolly the sheep.

First, as we have discussed in the third section of this report, HESCs and cloning have been actively and consciously linked by scientists. SCNT, so their argument went, could be deployed to craft ‘personalized’ HESC lines (see section 2 of this report). What initially was conceived as a “positive” because “therapeutic” version of cloning turned out to create a reverse reaction, namely, an apparently inseparable connection between cloning and stem cell research. Opponents of HESC research quickly argued that opening up towards HESC research with surplus embryos would only be the first step on a slippery slope that would inevitably lead to a future in which inhumane scientists would produce fully fledged human clones.

However, the importance of “cloning” goes well beyond this direct techno-scientific link. Because, second, the debates opened up by the birth of Dolly the sheep also set the stage for the future struggles and regulations of HESC research. The 1997 announcement that reproductive cloning had moved from science fiction to science triggered anxiety, fears and suspicion. Worldwide, policy makers, bioethicists, stakeholders, journalists and private citizens sought to make sense of the meaning and implications of this event. Did the birth of Dolly symbolize a further step on humankind’s long journey to represent and intervene in nature? Or was it just an arrogant attempt to “play God”? And, more generally, could the current pace of techno-science and biomedicine be controlled? Or would it inevitably lead to the “end of mankind” and our “humanness”?

No doubt, these questions had started to provoke anxieties well before the birth of Dolly. It is sufficient to think about the struggles on the ‘environment’ from the 1970s, the GMO debates in the early 1990s, the struggles in the context of the human genome project or the BSE debates in the second half of the 1990s. Dolly did not trigger completely new questions.

But she was a ‘discursive event’, in which dispersed questions that were rooted well before her birth were condensed. For many, there seemed to be no question that the “rubicon” had been crossed – and that some sort of big reaction was called upon. While today it has become obvious that animal cloning and certainly human cloning are immensely complicated and little understood endeavours that will probably never become routine practices, in 1997/98 a new brave world of cloned animals and humans seemed to wait just around the corner. In other words, Dolly was a dislocatory event. Yet, as our case studies show, the way this event was handled and governed differed remarkably.

The news of Dolly broke in remarkably different discursive and regulatory contextures. Whereas in the United Kingdom, reproductive medicine and embryo research was governed by the HFE Act and the trustworthy HFEA, in Italy, the news of Dolly broke into an ‘institutional void’. These different ‘mediums’ no doubt mattered. Warnings about the implications of the ‘availability’ of SCNT could be uttered much more meaningfully in Italy, which lacked binding regulations as well as trusted institutions. Yet, as the case of the United Kingdom demonstrates, the mere existence of different regulatory contextures did not make ‘governance’ meaningless.

A comparison of our data reveals that we can see two ‘basic models’ to deal with the destabilization of biomedical medicine discourse caused by Dolly: either by a coherent approach that involved the relevant actors in an attempt to develop an encompassing system of regulation for somatic cell nuclear transfer and HESC research (United Kingdom and Israel); or a more heterogenous approach (United States, Germany, Italy) characterized by fragmented and often delayed regulation. The special case of the European Union strategy in the field of stem cell governance seemed to be caught between attempts towards generating a coherent strategy and resistance from a number of member states to such an approach.

A comparatively early legal moratorium on reproductive cloning in Israel demonstrates that Dolly did matter in a country that is often depicted as a “peaceful island” for researchers and scientists, as much as it shows the successful re-affirmation of the dominant discursive structure. ‘Human reproductive cloning’ was represented as an enterprise too risky to be conducted in the present, but that could nevertheless be controlled and managed by a science worthy of being trusted (Gottweis and Prainsack 2006; Prainsack 2006). Similarly, in the United Kingdom, “British” Dolly was quickly interpreted as a political-technological “opportunity” to be seized rather than as a potential message from hell. While in the United

Kingdom the shaping of HESC regulations was characterized by an extended process of government-led deliberation and negotiation with various publics and an early attempt to deal with the governance challenge of animal cloning, in the United States, Germany, Austria and Italy a proactive, central approach towards Dolly never materialized, and stem cell research quickly turned into a highly divisive national topic, transforming the politics of life into a polarized battlefield with high visibility. In Italy, the birth of Dolly was connected to the field of human reproduction, rather than to scientific research or ‘regenerative medicine’. The small sheep worked as an ultimate reminder that a ‘revolution’ was taking place in Italy’s reproductive laboratories that challenged hegemonic ideas on human reproduction and that must finally be tamed. To sum up: Whereas in scenario one an inclusionary regulatory setting was created with the intention of creating trust in key stakeholders for stem cell governance, in scenario two fragmentations, polarization, and mistrust dominated.

Overall, the sense making and re-ordering on and after the “Dolly event” paved the way for the future stem cell struggles: While the announcement that the globe’s first HESC line was alive and well occurred at the end of 1998 and therefore one and a half years after the Dolly event, the stage for this announcement was set in the weeks and months following the announcement of the sheep’s birth. In some of our case studies, the anxieties on Dolly and “cloning” led to proactive ordering and steering, downscaling the meaning of Dolly’s birth to a “normal” or even “blessing” progress of a science that could be trusted and managed. In other case studies, in contrast, Dolly was interpreted as the product of a science out of control that could neither be trusted nor tamed. Whereas in the former set of case studies, the governance of the later appearing HESC research went comparatively smoothly, in the latter range of cases HESC research tended to be unruly and was characterized by antagonistic or intractable debates.

Here, it is in particular the difference between the United Kingdom and Italy that is telling: Whereas in the United Kingdom, the debates on HESC and cloning research tended to be ‘thin’ debates, in Italy, the debates on HESC were quickly entangled with very fundamental questions. Whereas in Italy, the HESC debates were to a large extent ‘embryo debates’, in the United Kingdom, these questions never gained ground. We do not want to judge whether this is good or bad, yet, no doubt, the absence of these ‘big debates’ facilitated the smooth acceptance of HESC and cloning research in the United Kingdom. In Italy, in contrast, the

focus on these big questions marginalized other concerns and voices, such as the concerns and voices of patient groups, and led quickly to an intractable policy controversy.

Between institutional innovations, participation, and the re-emergence of ‘old’ institutions

One of the propositions of the PAGANINI project was that in light of dislocation and institutional ambiguity, institutional innovations were likely to occur. Developments in the HESC research field challenge this finding. Here, we do not want to argue that our present is a copy of our past, yet we find it quite remarkable that ‘old’ institutions, and organizations were able to handle the life sciences’ ontological innovations. In Italy, dislocation actually led to the re-emergence of ‘old’ practices of governance, such as the implementation of a centrally passed law, or the reference to ‘nature’ as an ontological real. However, the same case also shows the limits and biases of these practices.

A central thesis of the PAGANINI project was that the challenging of traditional ways of governance leads to the emergence of new practices of governance, among which participatory practices were presumed to loom largely. However, what emerges from our empirical data is that their unruliness was neither efficiently tamed nor tackled with “participatory practices”; or, at least “participatory practices” did not exhaust the emerging range of tools and instruments that were deployed to re-order stem cell and cloning research. This of course does not imply that “participation” was altogether meaningless.

In **Italy**, stem cells, clones and embryos became contested objects of national referenda in which the Italian electorate was entrusted to vote on a ‘relaxation’ of the tight embryo regime that its representatives, the Italian Parliament, had passed in February 2004. Yet this was not an instance in which the ‘public’ was invited to participate – this public had invited itself. At the same time, it does not come as a surprise that Italian policy makers did not opt for participatory arrangements, as ‘the public’ was constructed as part of the problem: With their dispersed actions and decisions, they were pushing the boundaries of life and nature.

In **Austria**, policy makers in the area of biotechnology were confronted with the challenge to avoid the political disaster of “green biotechnology” they stumbled into in the late 1990s

when the public initiative against biotechnology was broadly supported within the electorate. One lesson policy makers learned from the rejection of “green biotechnology” was to increase efforts to enter into a dialogue with “a” presumably skeptical public.⁴⁶ However, apart from a singular *café scientifique*⁴⁷, a dialogical game⁴⁸ and the several expert symposia, few initiatives were made in Austria to involve the public into discussion on HESC research. In the **United Kingdom**, a creation of the public of stem cell research dominated in which the public was constructed as a well-informed, democratic audience with needs, passions, emotions and hope for a better future of health care. Only those who had fallen victim to dogmatism would not be able to see through the issue of stem cell research and work towards a balanced understanding of the issue.

Similarly interesting is the phenomenon that instances of opposition and protest went through traditional institutions and innovations, as well. In Italy, the protest against the law 40/2004 was institutionalized through abrogative referenda, and hence through an institution that had been used several times in the past, that stuck to the ‘traditional’ vocabularies and categories of politics, and that might suffer exactly from its biases. Similarly, the UK opposition against the government’s stance towards therapeutic cloning was pushed through institutional review, which is again a traditional mechanism of opposition against specific laws. In other words, even groups who oppose specific policies deploy the mechanisms and institutions of the old ‘polities’, thereby reconfiguring them.

⁴⁶ Policy makers also initiated and supported the foundation of the “Plattform Gentechnik und Wir” (now “Dialog<>Gentechnik”), a platform of scientific societies that should defend the cause of biotechnology by giving science a voice in public debate.

⁴⁷ <http://www.oe-journal.at/Aktuelles/!2005/0505/W1/50305imp.htm>, download 15.11.2006.

⁴⁸ www.playdicide.org

6. Conclusions

The politics of human embryonic stem cell research and cloning is, first of all, characterized by radical uncertainty, ambivalence and an overflow of meaning in its core terminology and semantic architecture. In particular, the boundaries between ‘cells’, ‘the embryo’, and ‘human beings’ and its various associations such as rights, dignity and status have been in a constant state of flux in the countries discussed in this report. The stabilization of the discursive field of stem cell research has been accomplished with varying success in the countries analyzed in this study.

(1) As our comparison indicates, there seems to be a relationship between the *early, proactive and coherent effort to deal with new challenges in the new politics of life* as opposed to half-hearted, delayed, and contradictory approaches. Our in-depth case studies of the United Kingdom and Italy provide clear examples of this. At first glance, it appears we are dealing with strict regulations in a Catholic country and liberal regulations in a Protestant country, something that seems to reflect strongly religiously coded differences in the definition of human life. But the story is much more complicated. Whereas in the United Kingdom the strongly dislocatory event of the birth of Dolly the lamb triggered a unified government response leading to new HESC regulations, in Italy the political response to Dolly lacked a coherent approach, was delayed, and the result was an inconsistent policy approach. Combined with a general regulatory vacuum in the field of reproductive medicine, Italy turned into the ‘Wild West’ of reproductive medicine in the late 1990s, with strange professors such as the infamous Prof. Severino Antinori creating the impression of a ‘world out of control’. This situation played an important role in the rise of groups utterly opposed to HESC research and polarized Italy into two bitterly divided publics. This situation was similar to that of the United States, where a regulatory vacuum in the field of regenerative and reproductive medicine had played an essential role in partially radicalizing the various stakeholders in the energy field.

(2) The idea of a coherent, pro-active approach towards life science governance should not be confused with modernist, hierarchical top-down political decision-making. The case of stem cell politics is not especially characterized by the adoption of novel, participatory decision-making mechanisms, neither during the political decision-making process, nor as a

reaction afterwards. But it demonstrates well the importance of *creating trust through a variety of discursive and institutional mechanisms, designs and strategies*. Here, interactions with the various publics form an important element. If we again look at our two in-depth case studies, we see two contrasting styles in interacting with the variously defined and self-defined publics of stakeholders. Partially shaped by historical pattern, the United Kingdom's policy-making process was characterized by a consultative and deliberative style of communicating through position papers, White Papers, and open public consultations. Also our case study on the EU strategy towards stem cell governance reveals an increasing realization on the part of policy makers that engaging with various publics today is a key element in any viable approach towards life science governance.

(3) However, the creation of trust goes well beyond an engagement and shaping of publics. Within Britain, the HFEA, an already "trusted institution", an institution with "ethos" was designated as the key institutional actor in HESC regulation in that country. Whereas in the United States, Germany, Austria and Italy *new* bioethics institutions were created partially with the idea of facing up to the new governance challenge of stem cell research, in the United Kingdom, an institution established long ago quickly became a strong asset in securing trust for the emerging framework of regulation. In the United Kingdom, the HFEA was neither known for its bioethical expertise nor for its transparency, but for its pragmatic and successful way of dealing with complex matters in reproductive medicine. The early involvement of HFEA in shaping UK stem cell governance is not only a result of path-dependence, but the result of a deliberative and purposeful approach to create a system of regulation that combines competence with success and trust-building. But the aspect of trust and "ethos" has not only come into stem cell governance in the form of creating acceptance for stem cell research. As the case of Germany, in particular, demonstrates, the "ethos" of certain trusted voices, such as of that of German President Rau, in the context of uncertainty, can play a decisive role in tipping the balance of decision-making. Rau's outspoken rejection of stem cell research gained so much weight in the German context because it was a trusted voice in a constellation of deep insecurity, but also because there was a void in which institutions such as HFEA in the United Kingdom simply did not exist.

(4) Emotions have played a crucial role in confrontations with stem cell politics in the countries discussed in this report. There were two central axes through which emotions came into the field of stem cell governance. First, the question of whether research with early

embryos is acceptable has been key to the debates, not only in the sense of ethical acceptability but also emotional acceptability. Deciding about the manipulation and instrumentalization of human cells derived from early embryos or gained through the creation of early embryos is not based on philosophical expertise alone but typically is grounded in a mixture of sentiment and logical reasoning, that lends itself to a type of decision-making that cannot be reduced to mere logical deduction. Second, the potential of stem cell research to heal dreadful and often deadly diseases has an emotional power in its own that transcends any logical argument but also can transcend ethical or religious principles. Just as it is with trust and ethos, emotional language can be used in support of stem cell research or in its critique. In our view, life science governance in the field of stem cell research was not only shaped through emotions but also through the deliberate mobilization of emotional language and the space emotions were given in the regulatory process. As our case studies indicate, there seems to be a difference if emotional language is only mobilized by the critics and supporters of stem cell research (as was the case in the United States, Austria and Germany), or if the political-institutional mechanisms themselves create spaces for bringing in emotions in the field of political decision-making. As we showed, key policy makers in the United Kingdom and in the United States had strongly focused on creating legitimacy for the display of emotionality in the policy-making process, mainly with respect to those who suffer under various diseases that potentially could be healed in the future through stem cell therapies. Although emotional language and articulation were prominent in the various policy settings from campaigns to the parliament in both the United States and the United Kingdom, the contrast between these two countries demonstrates that, as in the United States, emotional language can quickly lead to emotionalization and polarization, whereas in the United Kingdom, the display of emotions together with the creation and existence of trust in institutions created a political space where a topic as delicate and intimate as stem cell research could be debated without polarization. In Germany, all efforts were made to keep emotions out of the stem cell debate and to let the quest for the German ethos determine the style of discussion and exchange. The exchange between the German president, the German chancellor and the German parliament dominated a discussion in which few attempts were made to use policy designs to connect the top decision-makers with the various groups of stakeholders.

(4) The importance of pro-active governance, trust and ethos, and emotions in the policy-making process all point in our view towards the key role of the setting or staging of the policy-making process in the field of life sciences. Who gets the right to speak to which audiences is a question that is not simply decided by constitutions and general characteristics of political systems but often can be decided ad hoc in particular policy constellations. Stem cell governance today operates under general conditions of radical uncertainty and requires the simultaneous mobilization of different publics, the creation of institutional spaces for articulating emotions, concerns, and anxieties and the shaping of narratives that create fixations when boundaries are fluid and architectures of meaning are fragile. Participation does not always and necessarily offer the answer to such constellations, but, as the United Kingdom example shows, can be an important element in life science governance. While participation, deliberation, transparency and, in general, linking up with the citizenry seem to be an important aspect of contemporary stem cell governance, facing up to the stem cell governance challenge requires a more complex intervention. Both the success of HFEA in the United Kingdom and the partial failure of ad hoc created bioethics boards elsewhere vividly demonstrate the importance and the pitfalls of trust-building strategies in life science governance. The role of emotions in policy making and the importance of language and narratives in dealing with stem cell research point to the limitations of instrumental rationality for settling key political questions.

(5) Our case studies seem to offer strong evidence that the contemporary politics of life is hardly one that operates exclusively in the form of “governing through freedom”, that is, the democratic negotiation of self-governed individuals, but one that co-exists with forms of governing through sovereignty, directly through law and the state or through delegated forms of sovereignty, such as through ethical committees that decide on the ethical acceptability of HESC research proposals or through the licensed participation of couples and donors donating embryos and other biological materials. The limits of instrumental expert rationality might not only give rise to new constellations of uncertainty, emotional language and issues of trust-building, but also create the setting for new expressions of state sovereignty, such as bio-nationalism, or the positioning of the state as “last line of defence” of the family. It is not difficult to foresee that life science governance can quickly turn into a question of the “culture of life”, or the “future of mankind”, thematizations that might position the state as a central and dominant actor in the field of the politics of life.

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8. Akronyms

ACT	Advanced Cell Technology
ALS	amyotrophic lateral sclerosis
AMRC	Association of Medical Research Charities
ANT	alternative nuclear transfer
BSE	Bovine spongiform encephalopathy
CDU/CSU	Christian Democrats
CEI	Italian Bishops' Conference (<i>Conferenza Episcopale Italiana</i>)
CNB	National Committee for Bioethics (<i>Comitato Nazionale per la Bioetica</i>)
CNR	cell nuclear replacement
CNS	central nervous system
CORE	Comment on Reproductive Ethics
DG	Directorate -General
DNA	deoxyribonucleic acid
EC	embryonal carcinoma (cells)
EGE	European Group on Ethics and New Technologies
EGLS	European Group on Life Science
ES	embryonic stem (cells)
ESC	embryonic stem cell
EschG	Embryo protection act (<i>Embryonenschutzgesetz</i>)
EU	European Union
FP6	Sixth Framework Programme
FP7	Seventh Framework Programme
GAEIB	Group of Advisers to the European Commission on the Ethical Implications of Biotechnology
GMO	genetically modified organism
HESC	human embryonic stem cell
HFE	Human Fertilization and Embryology (Act)
HFEA	Human Fertilization and Embryology Authority
HGAC	Human Genetics Advisory Commission
HHS	(Department of) Health and Human Services
HSC	hematopoietic stem cell
ICM	inner cell mass
IVF	in vitro fertilization

MAPC	multipotent adult progenitor cell
MP	Member of Parliament
MRC	Medical Research Council
NBAC	National Bioethics Advisory Commission
NEC	National Ethics Council
NGO	non governmental organization
NIH	National Institutes of Health
PGD	preimplantation genetic diagnosis
RCOG	Royal Society of Obstetricians and Gynaecologists
RTD	research and technological development
SCNT	somatic cell nuclear transfer
SPD	Social Democrats
SPUC	Society for the Protection of Unborn Children
TNSA	nuclear transfer for the production of autologous stem cells (<i>trasferimento nucleare per la produzione di cellule staminali autologhe</i>)
UNESCO	United Nations Educational, Scientific and Cultural Organization
WHO	World Health Organization