

**Transnational governance and cultural politics: the case of human embryonic  
stem cells and the European Union's Sixth Framework Programme**

**Professor Brian Salter**

**University of East Anglia**

Address for correspondence:

Professor Brian Salter  
Institute of Health  
Yorkon Building  
University of East Anglia  
Norwich NR4 7TJ  
UK

e-mail: [brian.salter@uea.ac.uk](mailto:brian.salter@uea.ac.uk)  
tel: 0044 1603 593365

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### **Introduction**

On 10<sup>th</sup> June 2004 the European Commission issued the third call within the 'Life Sciences, Genomics and Biotechnology for Health' Priority of its Sixth Framework Programme (FP6 – 2002-06). The designated work programme topics included the functional genomics of human embryonic stem cell differentiation, human stem cells for spinal cord injury, a European human embryonic stem cell registry, and a conference on the state of the art of stem cell research, focusing on the potential and limitations for curing severe diseases, aimed at patients (European Commission, 2004). The issuing of the call was a real and symbolic victory for the proponents of human embryonic stem cell (hESC) research, particularly the UK, following a long and often bitter political conflict spanning the European Commission, the Council of Ministers, the European Parliament, national governments and a host of associated agencies and policy networks. It is not, however, a final victory over the opponents of human embryo research. Nor is it a sure indication of the likely course of the hostilities that are continuing within the confines of the agenda setting exercise for the Seventh Framework Programme commencing in October 2006. The roots of the discord are far too deeply embedded for such a simple resolution to be sustainable.

For the tortuous debate and manoeuvres regarding the funding of human ESC research by FP6 are the expression of a general political problem in the transnational governance of science that has global implications. As the Fifth Framework Programme had already discovered, human embryo research raises cultural concerns with which the European Union's (EU's) governance system is not fully equipped to deal (Salter and Jones, 2002a and 2002b). With dramatic intensity, FP6 focused those concerns around the hESC issue, provided a vehicle for the cultural divisions of Member States regarding the status of the human embryo to become manifest, and in so doing exposed the frailties of the EU's transnational governance of science and its technocratic reliance on the authority of expertise. The demands of science for fresh territories to conquer, buttressed both by the hopes of certain civil society interests for new therapies and the ambitions of the biotech industry, collided with a set of

fundamental cultural values with which there seemed little compromise. As the conflict escalated, not only did it produce institutional struggle across a range of arenas in EU science policy formation but it also embraced the neighbouring policy domain of human tissues.

The politics of the European experience resonate strongly with the global issue of human embryonic stem cell governance. At the United Nations (UN), the continuing debate around reproductive and therapeutic human cloning (the latter a critical element in the development of hESC science) has displayed a similar range of national cultural concerns, interests, intransigence and inventiveness in the search for an acceptable governance solution. In the United States (US), the stem cell issue figured prominently in the 2004 Presidential election and will continue to enjoy a high profile. The Californian decision in November 2004 to invest \$3 billion over ten years in the development of hESC based degenerative medicine poses a direct governance challenge to President Bush's restrictive policy on the Federal funding of hESC research. Meanwhile, transnational companies with an actual and potential stake in the field, be they small biotech firms or large pharmaceuticals, are monitoring the national and transnational policy responses to these conflicts with intense interest since without governance stability their investments will be jeopardised.

Given this context, the purpose of the paper is to explore the nature of the political struggle for control of the future governance of science in the transnational setting of the European Union (EU) using a three stage approach. Firstly, it develops a theoretical understanding of the governance problem so vividly illustrated by the human embryonic stem cell case. Why does this policy field generate such sustained antagonism, what are the primary limitations of the governance response and what frame work should we employ to analyse the dimensions of the policy conflict? Secondly, the paper applies this analysis to the debate and decisions about the funding and regulation of hESC research within FP6 and the consequent impact of these events on the human tissue directive. Why did the conflict take the course that it did and what does this tell us about the balance of power within this particular arena of transnational governance? Throughout, the paper focuses on the political role of bioethics as an emerging epistemic force in the transnational governance of human

ESC research. What insights does the FP6 case provide into the authority and functionality of this new form of expertise?

### **Transnational governance and embryonic stem cell research**

It is the promise of the scientists engaged in embryonic stem cell research that their work will lead to therapies capable of dealing with one of the major challenges of modern medicine: irreversible organ and tissue failure. Their claim is that research on human embryos can enable the production of 'pluripotent' stem cells, undifferentiated cells that have the capacity to develop into almost all of the body's tissue types, and thus provide the ability to create an unlimited supply of transplantable tissues. Whole organ transplants, such as for heart or kidney disease, will no longer rely on a supply of donors, neurodegenerative disorders such as Parkinson's and Alzheimer's disease will become treatable, and chronic conditions such as diabetes will be given new tissues capable of replacing the function of pharmaceutical regimes. Tissue engineering and regenerative medicine, it is argued, will be revolutionised.

Such a vision has both economic and political power. Given the range and size of health consumer demand that may be stimulated by the potential stem cell technologies, transnational life sciences companies such as Geron, StemCells, Advanced Cell Technology and ES Stem Cell International have taken a keen interest in the development of the field. Such companies sponsor biomedical research on a transnational basis and as 'the purveyors and consumers of such research are internationally mobile, taking advantage of transportation and communications technologies to operate transnationally and seek out national environments that are most hospitable to their chosen enterprises' (Cahill, 1999: 5). They constitute important players in the emerging global stem cell economy. Other significant players in the development and shape of that economy are governments themselves. Through their choices on the support they give, or do not give, to ESC research in terms of both investment and facilitative regulation, states can create a global framework of incentives and penalties to which the transnational companies respond. National investment in basic research can provide an attractive platform on which transnational companies can then build a development function to the economic benefit, it is hoped, of both companies and government. Thus in 2003 the UK made a

£40 million allocation for stem cell research and in 2004 the European Commission signalled its intention to fund up to 30 million euros of research in the area (Research Fortnight, 2004). On a grander scale, the Singapore government announced plans to spend \$300 million on Biopolis, a science park focusing on stem-cell technology (Spar, 2004: 211), and, as mentioned earlier, California has announced its \$3 billion commitment to stem cell research.

If state investment in the research infrastructure is one determinant of the stem cell future, state regulation is the other. Regulation may impact on scientific and industrial development through its influence on such factors as R and D costs, the parameters of ownership, product development time, product market life span and, most importantly, consumer confidence. As the experience of GM food and agriculture has so vividly illustrated, markets are dependent on the ability of regulatory regimes to reassure consumers that the benefits of the new biotechnologies are matched by appropriate controls of any risks they might contain (Levidow *et al*, 2000). But consumers are of course also citizens who, in the case of ESC research, have divided cultural loyalties that can generate an intense political dynamic. While the potential therapeutic value of stem cell research may dominate the concerns of some sections of civil society, others are preoccupied by the challenges it may pose to traditional ideas about what is natural and what is social, to the status of human beings, ethics and morality, the boundary between humans and animals, and to 'normal' reproduction and kinship (Gottweis 2002a, 2002c and 2002d; Waldby, 2002; Waldby and Squier, 2003).

There is no ready way of grouping these cultural positions and the narratives associated with them. They are rarely static, they may be rooted in the national historical experience yet they may also flow easily across the transnational sphere. Christian views on the dignity to be accorded the early human embryo (an ill-defined concept) range from radical Catholic positions (the fertilised ovum is to be treated like a fully developed human being – see e.g. Doerflinger, 1999) to more liberal and flexible Protestant approaches based on the conviction that moral questions are determined by individual conscience. But not all Catholic positions are so non-negotiable as this may imply and some thinkers have been willing to recognise the significance of the potential benefits to humankind of embryo research in the ethical

equation (Farley, 2001). On the other hand, non-Catholic conservatives may support the radical Catholic position but use a different terminology replacing the religious concepts of 'sanctity' and 'God's creation' with the secular notions of 'dignity', 'nature' or simply 'life' (Lauritzen, 2001). Among cultural groupings where little or no value is accorded to the early embryo, a variety of values may coincide in support of its scientific and industrial use: most commonly, the health rights of citizens, scientific freedom, medical progress and the national (or regional in the case of the EU) economic interest. In particular countries, historical influences on the national culture can promote a dynamic that brings together unusual cultural groupings. Thus in Germany, for example, the experience of the Third Reich and of Nazi eugenics has joined the Churches, the Green Party and numerous social movements in an alliance against ESC research.

As these cultural dimensions are engaged, and civil society groups play a larger part in biotechnology controversies (Salter and Jones, 2002; Rose and Novas 2003), so the progress of the science becomes politically problematic and attention focuses on regulatory policy as a site for the negotiation of these conflicting pressures. As a result, and in the absence of a world order capable of imposing a single governance solution, nation states compete for economic and political position in the future global stem cell market. Their policies are influenced not only by the promise of the field but also by its scientific, economic and political uncertainties. Despite the interest of governments, the extent of the scientific unknowns have thus far produced a cautious response from industry: in the US in 2003 only 10 firms were actively involved in ESC research in spending a meagre total of \$70 million (Spar, 2004: 212). More generally, the tissue engineering market (of which potential ESC products form a part) shows a similar gap between anticipated markets and present reality. Market estimates for tissue-engineered products range from 80 billion euros for the US alone to 400 billion worldwide by 2007. However, these estimates have to be set against global figures for the sales of tissue-engineered products that do not surpass 60 million euros for 2002 (Bock *et al.*, 2003: 35). Scientific and economic uncertainty is then reinforced by the variety of cultural reactions to human embryo research.

The engagement between human embryonic stem cell research and cultural values takes us into an area of governance quite different from that traditionally dealt with by

the technocratic approach to regulation where apparently calculable quotients of such measures as costs, benefits, and risks are formulaically presented within an organising theme such as the 'precautionary principle' (Jasanoff, 1995). The controversies surrounding the foetus, the right to life and abortion have clearly shown that the political negotiation of conflicting values requires a form of governance different in both form and substance from the customary exercise of scientific authority (Mulkey, 1995). In these situations, governance has to grapple with the inclusion of culturally generated premises and prescriptions into the policy process. Conceptually, this can be described as the point at which cultural theory meets political science with a consequent emphasis on the significance of political culture, or more accurately cultures, in the analysis of political behaviour. Elder and Cobb establish the link as follows:

In defining the range of symbols that are available to give social definition to a situation, a political culture acts to limit the range of problems and problem solving alternatives that are likely to be considered, or for that matter, even entertained or recognised....Culture colours perceptions and constrains problem definition (Elder and Cobb, 1983: 85).

In terms of the competition for control of the policy process, political cultures can then be seen as the symbolic vehicles for both prioritising and legitimating one policy agenda over another (Edelman, 1971).

In the case of ESC research, political cultures compete within an internationalised policy domain for influence over the political meta-narratives that guide and shape the emergent policies of transnational governance (Gottweis, 2002b). Cultural values are translated into arguments that attempt to legitimate one form of regulation, or non-regulation, rather than another. They become political resources that may be traded in the political market of transnational governance. In the case of the EU, cultural trading over ESC regulation usually takes place within the institutions of multi-level governance (Commission, Council of Ministers, European Parliament, etc) that facilitate the operation of sub-national and national actors at the European level (Hooghe and Marks, 2001: ch 1; Jordan, 1998). As a result, the policy networks of civil society, the scientific community and industry have an incentive to organise on

both a national and a transnational basis to exploit the opportunities inherent in multi-level governance, be this to oppose, support or negotiate the terms of ESC research (Ronit and Schneider; Streeck and Schmitter, 1991; Grande, 1996).

The political debate surrounding the cultural value and status of the human embryo is not, of course, a new one. Over the past three decades, the issues of abortion and in vitro fertilisation (IVF) have produced their own kaleidoscope of different national responses. In the case of the UK, Mulkey's seminal work charted in rich detail the variegated patterns of the six-year long policy narrative preceding the enactment of the 1990 Human Fertility and Embryology Act (Mulkey, 1997). However, what is new is that the global economic potential of human ESC research and the consequent national and regional advantages to be gained from an early commitment to the field takes that debate into a different league of transnational competition. Furthermore, the putative inclusion of ESC research into the agenda of FP6 brought together into a single political stream two dominant prerequisites of a successful European R and D policy: the funding of basic research and the regulatory framework necessary to make that research politically sustainable across the Member States. Given the cultural politics of the human embryo, the latter was always going to be a tall order.

### **Analysing the transnational political narrative: national pressures and ethical boundaries**

The propulsive forces of scientific freedom and industrial ambition had encountered substantial cultural opposition to the plans for human embryonic stem cell research from within the institutions of the EU well before FP6 was launched in 2002. In general, the conflict between the cultures of science and industry, on the one hand, and some parts of civil society, on the other, was formalised (and to a degree normalised) through the referencing of 'ethics' as a suitable and legitimate vehicle for the conduct of the continuing political bargaining. Ethical debate became the politically acceptable face of cultural conflict in that it facilitated a way of noting and organising differences between often emotive positions.

Thus when, in the formulation of the research agenda of FP5, DG Research faced a clash between the demands of science for human embryo research and the cultural



opposition of certain Member States it turned to the European Group on Ethics in Science and New Technologies (EGE) for a solution. Since 1991 the EGE has provided advice to President of the Commission on the values that should guide regulatory decisions on biotechnology. Its 1998 Opinion *Ethical aspects of research involving the use of human embryos in the context of the 5<sup>th</sup> Framework Programme* resulted in the FP5 1998-2002 research agenda excluding any ‘research activity which modifies or is intended to modify the genetic heritage of human beings by alteration of germ cells’ and any ‘research activity understood in the sense of the term “cloning”, with the aim of replacing a germ or embryo cell nucleus with that of the cell of any individual, a cell from an embryo or a cell coming from a later stage of development to the human embryo’ (European Council, 1999). Furthermore, and in the context of the EGE recommendation that FP5 should introduce the principle of ethical review for sensitive projects, Article 7 of the Council and Parliament Decision approving FP5 stated that ‘All research activities conducted pursuant to the fifth framework programme shall be carried out in compliance with fundamental ethical principles’ (European Parliament and European Council, 1999). In the same year, both Directive 98/44/EC on the legal protection of biotechnological inventions and Directive 98/79/EC on *in vitro* medical devices emphasised the important role of ethics in their implementation. In addition, Article 7 of the 1998 Patent Directive charged the European Group on Ethics with the evaluation of the ethical aspects of biotechnology in general. As a formal part of the institutional discourse, ethics, *qua* ethics, had arrived. The regulation of science funding and research was no longer a purely technocratic preserve but territory where, it would seem, cultural factors had a legitimate presence.

However, although recognised as a useful vehicle for the formulation of general cultural propositions, ethics had yet to establish itself as a mechanism for the negotiation of cultural differences within the political narrative. Its political utility was therefore limited to one of presentation rather than one of resolution. Given the wide variations between Member States regarding both the definition of the human embryo and the conditions under which research, if any, could be conducted on it, as a political form ethics would have to evolve if it was to perform any kind of brokerage function between opposing cultural positions. Table 1 illustrates how the political cultures of Member States have found expression in a patchwork of legal

arrangements containing numerous shadings of the value of, and the protection to be afforded to, the human embryo. These differences were to form the basis of the conflicts over human ESCs and FP6.

**Table 1**

**Regulations in EU Member States regarding human embryonic stem cell research (March 2003)**

Type of regulatory control	Austria	Belgium	Denmark	Germany	Spain	Finland	France	Greece	Ireland	Italy	Luxembourg	Netherlands	Portugal	Sweden	UK
Prohibition of human embryo research									X						
Prohibition of the procurement of ESCs from human embryos					X		X		X						
Prohibition of procurement of ESCs from human embryos but allowing by law for importation of human ESCs	X		X	X											
Allowing for the procurement of human ESCs from supernumary embryos by law						X		X				X		X	X
Prohibition of the creation of human embryos for research purposes by law or by ratification of the Council of Europe's Convention on Human Rights and Biomedicine	X		X	X	X	X	X	X	X			X	X	X	
Allowing for the creation of human embryos for ESC procurement by law															X
No specific legislation regarding human embryo research		X								X	X		X		

**Source:** European Commission, 2003b: table 1 (amended).

As the agenda setting debate for FP6 got under way, and as the move to establish genomics and biotechnology for health as its first priority became evident, so the

ability of the EU's system of transnational governance to handle the conflicting national pressures came under severe scrutiny. The political atmosphere was already well heated, particularly in the European Parliament. As early as March 1989 a Parliamentary resolution on the ethical and legal problems of genetic engineering had called for legislation prohibiting any gene transfer to human germ line cells and defining the legal status of the human embryo in order to provide unequivocal protection of genetic identity (European Parliament, 1989). Other resolutions followed in 1993, 1997, and 1998 opposing cloning of the human embryo, supporting the Council of Europe's Convention on Human Rights and Biomedicine and calling on Member States to introduce a legally binding ban on the cloning of human beings (European Parliament, 1993, 1997, 1998).

In this context, the publication on 16<sup>th</sup> August 2000 of the UK Department of Health's *Stem cell research: medical progress with responsibility* not only raised the political temperature dramatically, it also succeeded in focusing the European Parliament's attention by recommending that research on human embryos for therapeutic purposes (including somatic cell nuclear replacement (SCNR) – 'therapeutic cloning') should be permitted: a very permissive approach when compared to other EU countries. National cultural differences now had a specific target issue and, with the FP6 awaiting approval and contingent upon Parliamentary support, a powerful institutional vehicle for registering conflicting cultural values. (Decisions on Framework Programmes have to be made by co-decision between the Council and Parliament.)

The subsequent EU debate about hESC research and FP6 constituted a struggle for control of the political narrative and thus of the policy agenda. It can be analysed in terms of a framework based on salient ethical components within the narrative derived from the value and status conferred on the human embryo by a particular political culture. They are:

- embryo source (donated, supernumary, cloned)
- date of embryo creation
- age of embryo
- ESC source

- ESC date of creation
- ESC research purpose

These components emerge both singly and in combination. Political actors would declare themselves in support of, or opposition to, the research criteria implicit within each ethical component. Figure 1 outlines some (but not all) of the main combinations and provides an indication of the ways in which the trading of cultural values through the medium of ethical components may be refined and conducted. Each ethical cell in the matrices can be regarded as potential agenda setting territory and thus as a political resource that may be exchanged for, or coupled with, other cells as trading takes place within the political narrative.

At one end of the continuum of political cultures, the UK's Human Fertilisation and Embryology (Research Purposes) Regulation 2001 extends the Human Fertilisation and Embryology Act 1990 to permit the use of embryos, regardless of source, in research to increase knowledge about serious diseases and their treatment (Figure 1, all cells). At the other, the Irish constitution of 1937 (as amended in 1983) provides that 'the State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as practicable, by its laws to defend and vindicate that right' (European Commission, 2003b: 42. Literally interpreted: Figure 1, no cells). As Table 1 shows, in between there lie a variety of Member State positions and non-positions constructed by states seeking to reconcile conflicting cultural pressures from civil society, science and industry. For example, in an attempt to remove the human embryo from the political equation (and/or to distance themselves from the act of embryo destruction necessary for ESC creation), Germany, Austria and Denmark have allowed the importation of ESC lines whilst internally prohibiting their procurement from human embryos. In addition, Germany's Stem Cell Act 2002 requires that the ESCs were derived from supernumerary embryos before 1 January 2002 in the country of origin (European Commission, 2003b: 40. Figure 1, cells 7-8). (The date of ESC line creation is, of course, the same criterion as that used by President Bush when he announced his decision to allow Federal funds to be used for research on existing – ie pre 9<sup>th</sup> August 2001 – human ESC lines: an example, perhaps, of transnational policy learning.)

Commenting on the ethical contortions involved in the policy of ESC lines importation, the EGE noted ‘a tendency to accept double morality where there is no coherence between different positions adopted by country’. It continued: ‘one could expect that to consider research on human embryos to derive stem cells as unethical, might imply the prohibition of the import for research of embryonic stem cells derived from human embryos as well as of the use of potential therapeutic applications resulting from such research, which is not always the case.’ (EGE, 2002: para 1.21). In the difficult world of human embryo politics, ‘double morality’ may well be the ethical price that has to be paid for a political compromise.

**Figure 1**  
**Major ethical components of the political narrative**

<b>ESC Conditional date of creation</b>	<b>Embryo Conditional date of creation</b>	
	<b>No</b>	<b>Yes</b>
	<i>Donated embryo</i>	
<b>No</b>	1	2
<b>Yes</b>	3	4
	<i>Supernumerary embryo</i>	
<b>No</b>	5	6
<b>Yes</b>	7	8
	<i>Aborted embryo</i>	
<b>No</b>	9	10
<b>Yes</b>	11	12
	<i>Cloned embryo</i>	
<b>No</b>	13	14
<b>Yes</b>	15	16

### **The institutional struggle for control of the FP6 agenda**

Given the diversity of Member State political cultures on the human embryo, it was to be expected that the UK's report advocating greater freedoms for ESC research would prove provocative and ethically challenging. Responding to that report, on 7<sup>th</sup> September 2000 the European Parliament passed a resolution opposed to both reproductive and therapeutic cloning. Therapeutic cloning (Figure 1, cells 13-16) was seen as 'irreversibly crossing a boundary in research norms' and as contrary to public policy as adopted by the European Union (European Parliament, 2000). Much of the debate was couched in emotive and categorical terms with little suggestion from the opponents of ESC research that negotiation was either possible or proper. In its report *Ethical aspects of human stem cell research and use* published two months later, the EGE took a more sophisticated view and began the process of establishing an ethical continuum of types of human embryo and ESC research, using the kinds of criteria employed in Figure 1, and suggesting that some criteria are more acceptable than others (EGE, 2000). While it regarded spare (supernumerary) embryos as an appropriate source for stem cell research, in an interesting conditional formulation it deemed 'the creation of embryos with gametes donated for the purpose of stem cell procurement [as] ethically unacceptable, when spare embryos represent a ready alternative' (EGE, 2000: para 2.7. Figure 1, cells 5-8 plus a conditional acceptance of cells 1-4). Meanwhile, 'the creation of embryos by somatic cell nuclear transfer for research on stem cell therapy would be *premature*' since there are alternative sources (EGE, 2000: para 2.7, stress added. Figure 1, cells 13-16). Embedded in this discourse are notions, firstly, of embryo status contingent upon source and, secondly, of ethics as a developmental process that moves from 'premature' to, presumably, mature.

The EGE report signalled a move by some actors involved in the construction of the political narrative to attempt to change the debate from one characterised by static and opposing ethical positions to one where successive refinements of position were normal and negotiation possible. As time drew nearer for Parliament to consider the Commission's Framework Programme Six proposal, and as the critics of human embryo research made it clear that they would use this as an opportunity for expressing their opposition, so the objective need for negotiating room increased. Although the subsequent Parliamentary debate on the First Reading of the proposal in



November 2001 suggests that little had changed, and that categorical statements of broad ethical positions were still the norm, the amendments incorporated into the proposal prove otherwise. The amendments meant that FP6 would not fund ‘research activity aiming at human cloning for reproductive purposes’ or ‘the creation of embryos for research purposes including somatic cell nuclear transfer’ (therapeutic cloning – Figure 1, cells 13-16). However, it would fund (and here is the compromise) ‘research on “supernumerary” early-stage (ie up to 14 days) human embryos (embryos genuinely created for the treatment of infertility so as to increase the success rate of IVF but no longer needed for that purpose and when destined for destruction)’ (European Parliament, 2001b: Article 3. Figure 1, cells 5-8)

The success of these amendments indicates that there is in the situation a sub-text of covert political negotiation around the ethical components of embryo source and embryo age (up to 14 days). (The latter is of course elsewhere described as the ‘pre-embryo’, an important political category in the long running UK embryo debate – Mulkay, 1997: 30-2; Spallone, 1999). Under pressure from the conflicting political constituencies of the Framework Six Programme, the transnational narrative was beginning to evolve and to suggest that some types of embryos are ethically more important than others. In an attempt to facilitate this evolution and as part of the search for a way through the thickets of the ethical debate, in December 2001 the European Parliament set up the Temporary Committee on Human Genetics and Other New Technologies of Modern Medicine to report on the ethical, legal, economic and social implications of human genetics. In the event, its activities served to stimulate the involvement of new civil society policy networks in the discussion and legitimise the inclusion of fresh ethical dimensions. As the debate on its final report on 29<sup>th</sup> November 2001 demonstrates, ethical collisions in the Parliamentary arena were at this stage more achievable than were compromise positions (European Parliament, 2001c).

In contrast to this, in the separate arena of the EGE the expert agenda of human embryo research was experiencing a further process of ethical refinement in response to scientific and industrial demands for greater regulatory protection of their hESC investments. By 2002, there had been 500 patent applications worldwide referring to embryonic stem cells - of which one quarter had been granted – but the EU’s position

on whether patents on human embryonic stem cells should or could be granted under the conditions of its 1998 Patent Directive remained unresolved (EGE, 2002: para 1.16). The Directive was clear that industrial and commercial exploitation of human embryos is excluded from patenting but unclear about the patentability of cells obtained from embryos, regardless of embryo source (EGE, 2002: para 1.21). Reflecting on this issue, the Group stated its opinion that ‘patenting of inventions allowing the transformation of unmodified stem cells from human embryonic origin into genetically modified stem cell lines or specific differentiated stem cell lines for specific therapeutic or other uses, is ethically acceptable as long as the inventions fulfil the criteria of patentability’ (EGE, 2002: para 2.5). However, this liberalisation of the ethics of patenting was balanced by the EGE’s view on therapeutic cloning where, drawing on its earlier Opinion *Ethical aspects of human stem cell research and use*, it called for ‘a cautious approach, excluding the patentability of the process of creation of a human embryo by cloning for stem cells’ (EGE, 2002: para 2.5).

It is clear that at this stage the search for practical ethical solutions to cultural conflict around hESCs was progressing much more swiftly in the expert arena of the bioethicists than in the Parliamentary and Council arenas of the politicians. Nonetheless, it was in the latter two arenas that a way forward had to be found if FP6 was to be funded. Institutional struggle was about to begin in earnest. In an interesting and, in the view of the opponents of human embryo research, challenging manoeuvre, at the Second Reading of the FP6 proposal in June 2002 Parliament voted through the overarching Framework Programme and transferred the issue of the criteria for embryo and human ESC research to the process for approval of the relevant Specific Research Programme (European Parliament, 2002). This meant that the Parliament was not directly involved in the decision making because under EU procedures the Specific Programme details are a ‘technical issue’ and can be decided upon by Council without the agreement of Parliament. However, the advantage gained by this institutional move appeared to have been shortlived when in the September of the same year, under pressure from Austria, Italy, Germany and Ireland, the Council decided on a package of measures in response to the opposition concerns. This reiterated the ban on therapeutic cloning research and, furthermore, stipulated that there should be: a moratorium on the EU funding of human embryo and human ESC research until December 2003; a report on human embryonic stem cell research

as the basis for an inter-institutional seminar on bioethics; and, taking into account the seminar's outcome, further guidelines on the principles that should guide Community funding of such research to be produced by December 2003 (European Council, 2002). (In an interesting concession to the UK's pro-ESC research stance, the moratorium explicitly did not include 'banked or isolated human human embryonic stem cells in culture'.)

The increasing salience of novel modes of organised ethical engagement (Temporary Committee on Human Genetics, EGE Opinions, inter-institutional seminar, development of ethical funding guidelines, ethical review of projects) are indicators of the intensifying search for practical mechanisms for including cultural factors in the EU's transnational governance of the life sciences. In its March 2003 progress report on *Life sciences and biotechnology – a strategy for Europe*, the Commission observed that

Public authorities at large have to take into consideration concerns about the conditions under which fundamental choices are made in this field [of life sciences]. For its part the Commission is committed to ensuring that the ethical, legal, social and wider cultural aspects, as well as the different underlying ways of thinking, are taken into account at the earliest possible stage in Community-funded research. In particular, the issues of *human cloning and human embryonic stem cell research* have provoked intense public and political debate. Ethical and social debate must continue to be a natural part of the research and development process involving society as much as possible. (European Commission, 2003a: 3. Commission stress.)

However, the widespread recognition that cultural values are a legitimate component of the transnational governance of the life sciences did not readily lead to a parallel acceptance of the new mechanisms for the resolution of cultural conflict. Following the Commission's exhaustive report on human embryonic stem cell research and the inter-institutional seminar drawing on its findings in April 2003 (European Commission 2003b and 2003c), the terms and constituency of the debate were undoubtedly enhanced – but so also was the difficulty of finding a sustainable compromise position.

Driven to a search for the lowest common ethical denominator, in June 2003 the Commission proposed a set of ethical guidelines that included the selection of embryos for research on the basis of the criteria of embryo source and date of embryo creation. Community funding was to be restricted to the derivation of human embryonic stem cell lines ‘from human embryos created as a result of medically-assisted in vitro fertilisation designed to induce pregnancy and were no longer to be used for that purpose’ (supernumary embryos) and created before 27 June 2002, the date of approval of the overarching Framework Programme 6 (Figure 1, cells 6 and 8) (European Commission, 2003: 4-5). Unsurprisingly, international scientists objected strongly to the date of embryo creation criterion being applied because of what they saw as its impact on the freedom and quality of their research (Research Europe, 2003). Under the terms of the consultation procedure, the European Parliament debated the Commission’s proposal in November 2003 and, agreeing with the scientific view, not only removed the 27 June 2002 restriction but also enlarged the embryo source criterion to include those produced by spontaneous or therapeutic abortion (Figure 1, cells 9-12) as well as supernumerary embryos from IVF treatment (European Parliament, 2003a). This amendment in turn proved unacceptable to the Council with the result that on 31 December 2003 the moratorium on human ESC research expired with no agreement on the principles that should guide Community funding of that research. By default, therefore, the criteria contained in the European Parliament and Council Decision of 27 June 2002 and the Council Decision of 30 September 2002 in respect of the Specific Research Programme remained in place. Human embryonic stem cell research using therapeutic cloning (Figure 1, cells 13-16) could not be funded, that based on supernumary embryos (Figure 1, cells 5-8) could, and the position of research using donated and aborted embryos (Figure 1, cells 1-4 and 9-12) as the source remained unresolved.

The volatility of the continuing cultural politics of human embryonic stem cell research and FP6 is manifest both in the constantly shifting mosaic of ethical components in the political narrative and in the absence of any pattern in the institutional struggles between Commission, Council and Parliament. As different configurations of Figure 1’s ethical components came to the fore at different times, so the institutions would change their positions. A further destabilising influence was

the engagement between the political chemistry, networks and forces at work in the policy domain of FP6 and that of the neighbouring policy field of human tissues where a directive was being considered. The proposal for a directive setting quality and safety standards in relation to human tissues and cells began its progress through the EU's legislative machinery on 19<sup>th</sup> June 2002 (eight days before the approval of the FP6) and immediately became the focus of a conflict not about ethics as such (though this formed part of the debate) but, more importantly, about what ethics could legitimately be included in the discussion and what excluded. In this respect it became a test case for determining what role ethics should have in this policy making domain.

The opponents of human embryo research saw the directive as the means for implementing a pre-emptive strike against the pro-ESC lobby. If the ethical components of Figure 1 could be inserted into the directive as a block on human embryonic stem cell research, Member States would be obliged to implement it at the national level. The activities of their scientists would thus be curtailed regardless of the outcome of the conflict in the FP6 policy domain. However, the idea that difficult ethical issues should be incorporated into the directive did not resonate well with the culture of the sponsoring Commission Directorate Health and Consumer Protection which saw the business of setting standards for the donation, procurement, testing, processing, storage and distribution of human tissues and cells as a largely technical exercise with ethics making a facilitative rather than a challenging contribution to the implementation of an existing policy agenda. The European Group on Ethics had earlier in 1998 produced its report *Ethical aspects of human banking* dealing with ethical issues such as the protection of health, the integrity of the human body, informed consent and the protection of identity and these were happily incorporated into the first draft of the proposal for a directive (EGE, 1998; European Commission, 2002). In an aside, the proposal noted that 'germ cells, foetal cells/tissues and embryonic stem cells pose particular ethical problems', that 'there is no consensus among Member States upon which basic harmonised decisions at EU level can be taken with regard to their use or prohibition', and that 'the proposal does not interfere with decisions made by Member States concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells' (European Commission, 2002: 5-6).

This hands off approach was abruptly challenged by the Committee on the Environment, Public Health and Consumer Policy in its report to the Parliament as background to the First Reading of the proposal. (It is no coincidence that the rapporteur for the Committee was Peter Liese: a Catholic Christian Democrat MEP who was also active in the hESC and FP6 arena.) Here it was proposed that Member States should at least prohibit research on human cloning for reproductive purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei; that no tissues or cells derived from human embryos should be used for transplantation; and that cloned human embryos and human/animal hybrid embryos produced by cloning should be excluded as sources of material for transplant (European Parliament 2003b: amendments 14, 30 and 51). The subsequent acceptance of these amendments by Parliament shifted the focus of the ethical debate from utilitarian values concerned with the details of directive implementation to fundamental values that questioned parts of the science on which the directive was, or might be, based. To counter this, in revising the proposal, the Commission used the interesting tactic of defining some ethics as appropriate to the directive and others not. Thus whilst it was able to accept ethical provisions related to the anonymity of donors and non-profit procurement it argued that other provisions (notably those concerned with human embryos) fell ‘outside the scope of Article 152 of the Treaty, which provides for public health protection and *not for the implementation of ethical objectives*’ (European Parliament, 2003c: 7, stress added).

In the Second Reading by Parliament of the directive this selective approach to the role of ethics was sustained and the opponents of human embryonic stem cell research were obliged to accept a compromise amendment that protected the rights of Member States to ban or restrict the use of ESCs and stipulated that, where used, they should be subject to the directive’s provisions for the protection of public health (European Parliament and European Council, 2004). However, as with FP6 and the preparations for FP7, the debate and the political manoeuvring continue. A second directive (or regulation) is being prepared that would harmonise the regulatory framework on human tissue engineered products – the arena in which any therapeutic applications of human ESC research would naturally reside. No doubt the opponents of hESC research are already preparing their positions.

## **Conclusions – trading values in transnational governance**

The therapeutic promise of human embryonic stem cell research has generated a global competition for the control of its social, scientific and industrial future that is increasing in intensity. Countries are investing in the basic research necessary to develop the field, re-examining their regulatory arrangements, and seeking to attract transnational life sciences companies. But they do not operate in a cultural vacuum. Elements in their civil societies may draw upon a variety of political cultures to support or oppose what is officially regarded as being in the national scientific or industrial interest. To the extent that these cultural pressures are problematic, a need exists for a national or regional governance response. To be politically effective, that response will need to incorporate a mechanism for the trading of cultural values in order that negotiations can take place and compromises achieved.

In the case of the EU, these pressures are localised through the interaction of, on the one hand, the political cultures of the Member States and, on the other, the EU's institutions and methods of transnational governance. Member State cultures as revealed in legislative form are not static but are themselves responsive to the international context. Thus, for example, in July 2004 the French parliament banned reproductive human cloning as a 'crime against the human species' but postponed its ban on the use of supernumerary embryos for embryo research thus allowing certain types of hESC research to continue (Channelnewsasia, 2004). With less equivocation, in September 2004 the new Spanish socialist government announced that it would permit human embryonic stem cell research and viewed therapeutic cloning as 'an open matter' (Yahoo!news, 2004; The Scientist, 2004). As Member States change their positions so the matrix of forces at work in the Commission, Council and Parliament also shifts to create a continuing volatility in the balance between the ethical components of the political narrative.

However, some parts of that narrative are more volatile than others. Whereas the public debates of the European Parliament on human ESCs and FP6 were usually characterised by the stark presentation of conflicting cultural positions, in the expert arena of bioethics the search for compromise ethical equations has generated a quite

different political style characterised by reason, flexibility and adaptation. While in the former, the cultural politics were raw and challenging, in the latter the explicit search for political utility has necessitated the development of the rules and procedures that can contribute to a practical outcome. Cultural politics in the EU is therefore operating at two levels in order to accommodate the otherwise incompatible requirements of (a) the unchanging legitimacy of particular value positions and (b) the need for those positions to be negotiable. As the application of the ethical components of Figure 1 to the political narrative of both levels has illustrated, there now exists a range of finely graded value positions on human ESC research that constitute the currency for political trading. Although at the public level this trade would be denied, the evidence of the political narrative is that such trading indeed occurs, though as yet inefficiently. To the extent that this process can deal with the cultural demands, it can be regarded as a novel form of transnational governance.

For the future, and as the therapeutic applications of human ESC research become more evident, the prospect is one of a continuing engagement between the policy domains of hESC science and human tissues. This will be overlaid with a continuing cultural struggle for control of the EU's emergent new methods for the transnational governance of science. There will then be an objective need for the clarification of the role of ethics in the political narrative and of what Gottweis terms 'the ethics infrastructure' (Gottweis, 2003). National and transnational cultural groupings are becoming increasingly sophisticated in the formation and presentation of ethical arguments in this field and will require a parallel improvement in the way in which ethics is used as a form of political currency and exchange. Attempts to exclude ethical issues from the process of transnational governance as occurred in the case of the human tissue directive are likely to prove counter productive because they ignore the established and growing pressures of cultural politics on the policy making apparatus of the EU. In particular, the reliance of the technocratic approach to regulation on scientific expertise alone is likely to be succeeded by an inclusive style of ethical debate or risk producing politically unsustainable policies.

This analysis suggests that institutionalised modes of ethics engagement will become a permanent feature of the new cultural politics as mechanisms are sought that will enable the refining, manipulating, resolving and legitimating of cultural differences



through the trading of values in an authoritative language and setting. Such modes are likely to continue to operate in parallel to the formal procedures of Commission, Council and Parliament in an attempt to offset the ponderous limits of these institutions to deal with cultural politics. This paper has noted the politically functional contribution of the European Group on Ethics not only to the lubrication of the ethical interaction through its elaboration of fresh ethical distinctions and perspectives but also to the facilitation of decision making through the judicious use of its claim to impartiality. Bioethicists are emerging as a new epistemic power group levels and their inclusion in the transnational governance of the EU is part of a global process (Salter and Jones, 2004). As the EU case has shown, in the human embryonic stem cell field they can enable the interrogation of ethical options, and thus the refinement of the political currency, through the investment of ethical significance in such characteristics as the source, date of creation, age and research purpose of the embryo or ESC. Over time, and if functionally successful, we may find that the command of ethical as opposed to scientific expertise elevates bioethicists to the status of what may be termed 'the new technocrats' of transnational scientific governance. capable of brokering difficult cultural deals at both the national and international

**7971 words**

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