GLOBAL BIOPOLITICS

RESEARCH GROUP

Working Paper No. 21 . July 2007

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GBRG WORKING PAPERS

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Introduction

It is estimated that when all of the EU's Framework Programme 6 (2002-06) projects have come to an end, about €21 million will have been spent on human embryonic stem cell research. This figure constitutes 0.85 per cent of the €2.45 billion Health Research Programme budget within FP6 and 0.10 per cent of the total €17.5 billion budget (Europa 2007). If the financial commitment of the EU to hESC science can thus be shown to be very small, the EU's moral commitment has nonetheless been very large. For at least a decade, debates have raged throughout the institutions of the EU about the values that should inform the funding of this field. Indeed, such have been the divisions on the issue that they threatened to prevent the approval of FP5 (1998-2002), FP6 and its successor FP7 (2007-13).

The inverse relationship between the size of the hESC research budget and the political effort expended in agreeing its approval within the Framework Programme is a product of the intense cultural politics surrounding this new science in the several arenas of the EU. The reliance of human ESC research on the destruction of the blastocyst for the production of stem cells provokes a collision at national and international levels between the demands of science and cultural values that ascribe a high moral status to the early human embryo. The political negotiation of this collision is frequently difficult but, when viewed on a global scale, can be seen to be facilitated by the use of bioethics as a form of expert governance. Precisely how effective bioethics can be in this political role is dependent on both its authority and the nature of its linkage with institutional decision making. States vary in their use of bioethics as a formal aid to government and in the extent of its integration with the state bureaucracy.

This paper analyses the cultural conflict over the funding of hESC science in the Framework Programmes as reflected in the documents and debates of the European Commission, the Council of Ministers, the European Parliament and numerous committees. It shows how bioethics has facilitated the emergence of the 'moral economy' where values may be traded and cultural disputes routinised, though not necessarily resolved. Its approach is as follows. Firstly, it discusses the formal consolidation of the position of bioethics in the EU in terms of the rise of the European Group on Ethics in Science and New Technologies (EGE) and its contribution to the resolution of the difficulties over hESC research in FP5. Secondly, it explores in detail the bioethical discourse of FP6, the institutional manoeuvring around whether hESC research should be funded or not and if so on what ethical conditions. Thirdly, it examines the bureaucratisation of bioethics and its incorporation as an integral part of decision making on project applications for Framework Programme funding. Finally, the paper reflects on how far the recent FP7 debates over hESC science reveal a stabilisation of the cultural conflict within particular dimensions.

Cultural conflict and the European Group on Ethics

Cultural conflict in the EU over the moral status of the human embryo is not new. 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). Meanwhile, in response to these and other cultural concerns about the implications of scientific advance for the status of the human body, the European Group on Ethics in Science and New Technologies (EGE) was developing a role as a body with the authority to make ethical pronouncements on such issues. Originally established in 1991 as the Group of Advisers to the European Commission on the Ethical Implications of Biotechnology, the EGE currently comprises fifteen members who advise the President of the Commission on how the ethical values of European society can be taken into consideration in the scientific and technological development promoted by Community policies.

Its advice is contained in 'Opinions' on particular topics produced by the EGE, usually in response to a request from the President, but on occasions on its own initiative. Thus as an illustration of the range of its ethical concerns, the EGE has produced Opinions on gene therapy (1994), prenatal genetic diagnosis (1995), the patenting of inventions involving elements of human origin (1996), the genetic modification of animals (1996), cloning (1997), human tissue banking (1998), and patenting inventions involving human stem cells (2002), among others (Group of Advisers on the Ethical Implications of Biotechnology 1994, 1995, 1996a, 1996b, 1997; EGE 1998a, 2002). Its procedure is to draw upon international and European legal instruments and the work of national ethics committees, and then to outline its own view. In so doing, the EGE sees itself as establishing fundamental ethical principles in response to the fact that 'in spite of powers having remained mainly at national level in matters of ethics, the free European market is not sufficient to satisfy the requirements of European society. It thus falls to the Community authorities to take account of the public's ethical concerns, even if they are at variance with certain economic and financial interests underlying the functioning of the market' (EGE 2001: 10.

In effect, the Group sees itself as the guardian of the rights of civil society by enabling '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.' (EGE 2001: 12). In this role, probably its most significant contribution to the political culture of the EU has been its drafting, at the request of the President of the European Commission, the European Charter of Fundamental Rights for European Citizens, which was adopted in December 2000 by the EU Summit of Heads of State and Government (EGE 2000b).

In 1998, the EGE moved beyond being an external and occasional (if influential) consultant to the Commission to a more substantial role of political broker in the EU when the Commission's Research Directorate faced difficulties in formulating an agenda on health biotechnology for the Fifth Framework Programme (FP5). On the one hand, science and industry wanted more support for Europe's health

biotechnology sector. On the other, the bruising political experience over GM foods and crops had shown the European Parliament, in particular, that investment in biotechnology was an issue to which it should be sensitive. To help resolve this dilemma, the EGE was asked to produce an Opinion on the ethical aspects of human embryo research – on which stem cell research depends (EGE 1998b).

Undoubtedly influenced by that Opinion, the FP5 1998-2002 research agenda was defined to exclude 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). At the same time, and again on the recommendation of the EGE Opinion that FP5 should introduce the principle of ethical review, Article 7 of the Decision concerning 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, 2001c: 85). The EGE had become a policy broker.

The success of the EGE in its use of formal ethical debate as a vehicle for facilitating policy decisions in areas of cultural conflict over science and the status of the human body was also apparent in the contentious policy domain of patenting. What parts of the body can or cannot be owned and why? Here the eventual emergence of Directive 98/44/EC on the legal protection of biotechnological inventions was dependent on a number of interventions by the EGE and its insistence that ethical considerations form part of the legislation itself (Salter 2006). As a consequence of its 1996 Opinion *The patenting of inventions involving elements of human origin* the then Group of Advisers on the Ethical Implications of Biotechnology not only won a formal place for ethics in the Directive but also succeeded in stipulating that the following areas were to be excluded on the basis of ordre public and morality (Group of Advisers 1996a):

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identify of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from this process.

The role of the EGE (created in November 1997 as successor to the Group of Advisers in November 1997) was formally incorporated into the Directive as both recital and article. Thus Recital 19 notes that account has been take of Opinion No 8 of the Group of Advisers and Recital 44 and Article 7 state that the EGE 'evaluates all aspects of biotechnology….including where it is consulted on patent law' (European Parliament and Council of Ministers, 1998).

National pressures and ethical boundaries

The agreement on the biotechnology Directive consolidated and legitimised the position of the EGE as a bioethical mechanism for the treatment of difficult cultural issues surrounding the status of the human body. To that extent the EGE became an important player in the evolution of the moral economy of the EU. The moral

economy of hESC science can be analysed in terms of components derived from the building blocks of the science itself that are simultaneously scientific and ethical objects (Figure 1).

Figure 1

The components of cultural trading

- embryo source
  - aborted
  - IVF supernumary
  - non-IVF donated
  - cloned
- embryo creation date
- embryo age
- HESC line origin
- HESC line creation date
- HESC line research purpose

These components provide the basis for cultural trading between political authorities and the search for a workable compromise. In the case of the EU, Member States bring national positions to the EU-level negotiations over the moral economy of hESC science: positions that have been defined at the MS level through ethical debate and then enshrined in national legislation. In 2003, A European Commission survey of the then 15 Member State policies at the time of the debate about hESCs and FP6 revealed five major regulatory positions when expressed in terms of the above components, positions from which we can assume their cultural bargaining would begin (Table 1):

1. prohibition of procurement of HESCs from human embryos
2. prohibition of procurement of HESCs but allowing importation
3. allowing procurement of HESCs from supernumerary human embryos
4. prohibition of creation of human embryos for research purposes including cloning
5. Allowing the creation of human embryos for research purposes including cloning

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	Luxembou	Netherland	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).

At one end of the continuum of regulatory positions, the UK's Human Fertilisation and Embryology (Research Purposes) Regulation 2001 extended 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. At the other, the Irish constitution of 1937 (as amended in 1983) provided 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). As Table 1 shows, in between there lay 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 required that the ESCs were derived from supernumerary embryos before 1 January 2002 in the country of origin (European Commission, 2003b: 40). (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 9th 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.

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 cultural tensions inherent in this range of Member State policy positions became manifest. As we have seen, the political atmosphere was already well heated, particularly in the European Parliament. In this context, the publication on 16th 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 discourse and thus of the policy agenda. Within the debate emerged a range of more detailed positions, again constructed from the units of cultural trading listed in Figure 1 and using combinations outlined in Figure 2. Each ethical cell in the matrices can be regarded as potential agenda setting territory and thus as a political resource that through the operation of the moral economy may be exchanged for, or coupled with, other cells as trading takes place within the political discourse.

Figure 2
Combinations of ethical units in the moral economy of HESC science

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

Institutional struggle and political discourse

Given the diversity of Member State policy positions on the moral status of 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 7th September 2000 the European Parliament passed a resolution opposed to both reproductive and therapeutic cloning. Therapeutic cloning (Figure 2, 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 2, 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 2, 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 2, 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: in other words, it sought to establish the basic requirements of a moral economy. 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 2, 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, 2001a: Article 3. Figure 2, cells 5-8)

The success of these amendments indicates that there is in the situation a sub-text of covert political negotiation and cultural trading 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 political discourse 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 29th November 2001 demonstrates, ethical collisions in the Parliamentary arena were at this stage more achievable than were compromise positions (European Parliament, 2001b).

In contrast to this, in the separate arena of the EGE a moral economy was clearly at work: 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 and thus the activation of the moral economy 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 means that would enable a moral economy to work and thus promote the inclusion of 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. Cultural trading was taking place but no agreement could yet be reached.

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 2, 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 2, 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. Under the EU's Comitology rules, if Council fails to make a decision on a Commission proposal, the Commission can implement it. 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 2, cells 13-16) could not be funded, that based on supernumary embryos (Figure 2, cells 5-8) could, and the position of research using donated and aborted embryos (Figure 2, cells 1-4 and 9-12) as the source remained unresolved. FP6 went ahead on this basis and commenced on 1st January 2004. The politics of hESC science had taken the EU right up to the wire.

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 discourse and in the absence of any pattern in the

institutional struggles between Commission, Council and Parliament. A stable moral economy had yet to emerge. As different configurations of Figure 2'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 19th 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 and thus whether it was legitimate for a moral economy to exist at all in certain policy fields.

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 2 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 tissue 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 other words, it argued that only a very restricted kind of moral economy was appropriate to this issue.

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). The human tissues Directive 2003/23/EC was agreed and the attempt to use it as a vehicle for blocking hESC research was foiled.

Stabilising cultural conflict: FP7 and the bureaucratisation of ethics

The instability of the cultural conflict over FP6 and hESC science left the Commission in an exposed position where particular decisions on the funding of FP6 hESC projects might be challenged by Parliament. To deal with this situation the Commission introduced a new bureaucratic device, the *Procedural modalities for research activities involving banked or isolate human embryonic stem cells in culture to be funded under Council Decision 2002/834/EC* (European Commission 2003d), to form part of the Ethical Review of 'sensitive' FP6 applications. Under this procedure, all hESC projects were obliged to have an Ethical Review and then to be approved on a case by case basis by a special Regulatory Committee composed of Member States. The Ethical Review was also to ensure compliance by the project with the legislation of the nation wherein its research was to be conducted. Although FP6 rules did not exclude hESC derivation from supernumerary embryos, or other research on such embryos, in practice only proposals using existing hESC lines were submitted and funded – an implicit recognition of what was politically acceptable.

The implementation of the Procedural Modalities on hESC science under FP6 succeeded in stabilising the cultural conflict so far as that particular funding programme was concerned within a bureaucratic procedure that was regarded as acceptable by the main players. (18 proposals involving hESCs were reviewed out of a total 855 projects that underwent Ethical Review in FP6 (Fitzgerald 2006).) However, the interesting political question was whether that bureaucratic device would be a sustainable instrument of governance over time. The enlargement of the EU and the addition of ten new MS on 1st May 2004 changed the pattern of the cultural domain. By 2005 the national positions of the Member States on hESC

science and the human embryo, and therefore the cultural values they were likely to seek to pursue with regard to EU policies in that field, were as follows (Figure 3).

Regulations in EU Member States regarding human embryonic stem cell research (2005)

Belgium, UK and Sweden allow therapeutic cloning
Denmark, Finland, France, Greece Spain, Netherlands allow the derivation of new hESC lines from supernumerary IVF embryos
Estonia, Hungary, Latvia and Slovenia have no specific regulations on hESC, but allow some research on supernumerary IVF embryos
Germany and Italy have regulations which restrict hESC research: scientists cannot drive new hESC, but can import them. In Germany, these cells have to have been derived before 1st January 2002.
Ireland and Slovakia prohibit procurement of hESCs from human embryos.
Austria, Lithuania and Poland have legislation prohibiting hESC research.
Portugal, Luxembourg, Malta, Cyprus have no specific legislation

The issue of the moral status of the human embryo was not about to go away. On 10 March 2005, the European Parliament demonstrated its continuing interest in the treatment of embryos when it adopted a resolution calling for a ban on the trade in human egg cells. Embedded within the resolution was the call for research on embryonic stem cell research to be funded for national budgets and for EU funding to be used for alternatives like somatic stem cell and umbilical cord stem cell research (European Parliament 2005). Five months later, Parliamentary opposition to the prospect of hESC funding in FP7 emerged in the form of a letter from a group of 73 MEPs to the European Commission President, Manuel Barroso, calling on the Commission to respect the principle of subsidiarity in the matter: MS should decided if they want to fund research in the human embryo or not (EurActiv.com 2005).

However, although the early signs were that there was to be a repeat of the complex manoeuvrings over FP6, underpinned by a range of opposing value positions, this did not happen. At the First Reading of the proposed FP7 programme on 15 June 2005, Parliament reiterated the *de facto* position arrived at following the lengthy FP6 debates regarding the fields of research should not be financed: human cloning for reproductive purposes, research intended to modify the genetic heritage of human beings which could make such changes heritable, and research intended to create human embryos solely for the purpose of research or for stem cell procurement, including by means of somatic cell nuclear transfer ('therapeutic cloning'). MEPs also agreed that research on the use of human stem cell, both adult and embryonic, may be financed 'depending on the contents of the scientific proposal and the legal framework of the Member State(s) involved' (European Parliament 2006). Thereafter, the debate never broadened out to include the wide range of ethical units contained in Figure 2 (type of embryo, date of creation) that had characterised the FP6 discussions. (The exception to this was an amendment demanding that financing of research should be limited to embryonic stem cell lines created before 31 December 2003 – rejected by Parliament at the First Reading.) Effectively, the previous pragmatic consensus, reinforced by its incorporation in a bureaucratic form that was

seen to have worked, held firm. Problems were experienced at the Council with opposition from Austria, Germany and Italy plus the new entrants Lithuania, Malta, Poland and Slovakia. However, Germany and Italy were won over by the following political/ethical compromise:

> 'The European Commission will continue with the current practice and will not submit to the Regulatory Committee proposals for projects which include research activities intended to destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells.' (Research Fortnight 2006)

With this compromise, FP7 was agreed.

Conclusions

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 cultural values 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 cultural politics is generated characterised by a moral economy where the trading of values facilitates negotiation and compromise.

In the case of the EU, these pressures are localised through the interaction of Member State positions in the context of the EU's institutions and procedures. Member State cultures as revealed in legislative form are not static but 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 moral economy.

However, some parts of that economy 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 2 to the political discourse of both levels has illustrated, there existed a range of finely graded value positions on human ESC research that constitute the currency for biopolitical trading. Although at the public level this trade would be denied, the evidence of the political discourse is that such trading indeed occured.

The bureaucratic incorporation of the results of that trading in the 'Procedural modalities' governing the application of hESC projects for Framework Programme funding, has succeeded in stabilising the moral economy at a particular juncture (at least for the time being. Despite attempts by the opponents of hESC research to open up the issue during the discussions over FP7, this never really took off. On the other hand, neither have the supporters of hESC research made any further gains. Any research that involves the destruction of the human embryo will not be funded: so FP7 will only fund the 'subsequent steps' in the hESC research process – i.e. research on stem cell lines created by projects funded by other agencies.

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 discourse 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 in the moral economy. Attempts to exclude ethical issues from the EU's politics as occurred in the case of the human tissue directive are likely to prove counter productive because they ignore the established and growing cultural pressures on the policy making apparatus of the EU.

This analysis suggests that institutionalised modes of ethics engagement will become a political technology that constitutes 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 capable of brokering difficult cultural deals at both the national and international levels and their inclusion in the transnational governance of the EU is part of a global process (Salter and Jones, 2005). 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 of the moral economy, 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.

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