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**PAN-EUROPEAN AND INDIVIDUAL NATIONAL PERSPECTIVES:  
DEVELOPING A UNIFIED EUROPEAN REGULATORY APPROACH?**

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**Summary:**

This paper explores the possibility of a pan-European regulation of stem cell research. After identifying the range of current legal and regulatory positions across Europe, and drawing on a social science risk governance framework, the paper shows how distinct political cultures shape the SC agenda within Europe. It is suggested that regulatory consensus is difficult to achieve and is more likely in regard to technical standards and instruments than normative principles. The former involves consensus over standards (both in regard to the quality and the production (and storage etc) of the lines themselves). It is more difficult, indeed probably impossible, to secure a pan-European political consensus over the regulation of what might be regarded as the ethical boundaries of the field.

**Introduction**

Stem cell research has been pursued for over forty years through the use of *adult* stem cells in 'regenerative medicine', research that has already been translated into clinical practice. The significance of stem cells relates to the perceived negative and positive potential of stem cell technology. It has been the more recent research in *embryonic* stem cells (ESC) that has generated major political, ethical and regulatory debate and spawned new regulatory structures and legal provisions about the proper boundaries of bioscience research and experimentation. Ongoing ethical debates around the use of human embryonic stem cells and about the possibility of human cloning, figure prominently in public, media and policy domains. These debates have been highly polarised, and remain unresolved, within Europe, the US and elsewhere. It is evident that all countries are trying to find a way through this complex social, economic and ethical terrain towards a position which can be seen to be legitimate and work with the grain of public sentiment.

Regulation is a key tool through which political governance is expressed and mobilised to manage contentious areas of science and technology. As one such area, stem cell science is disruptive of social relations and conventional expectations surrounding reproduction, the body, identity, and human rights. Developing forms of governance that are socially resilient and thereby engender long-term political legitimacy in this area is not simply about the development of 'better' forms of risk governance, even if this is desirable. It is also about tying such governance into deeper norms and values relating to social reciprocity, authenticity and accountability. Securing such forms of resilience is, however, made more problematic today not simply by virtue of more complex, disruptive technologies. It also reflects wider cultural changes, notably the challenge to and dilution of traditional forms of social trust (based for example on familial, occupational, or welfare cultures), authority and expertise associated with the onset of 'liquid modernity' (Bauman, 2001) and the move from social relations based on mutual reciprocity to those based on 'contract' (and the attendant social pathologies of excessive litigation, audit and so on.).

Any analysis of a new field of science needs then to explore the intersection of culture, governance and specific forms of regulation. As such, it should expect to find significant differences between different countries as they try to develop regulatory frameworks that carry broad social consensus. This has been recently documented in detail by Jasanoff (2005) in her

analysis of the contrasting political cultures between the US and Europe and how these have shaped the regulatory response to 'red' (human) and 'green' (agricultural) biotechnology. While the former has been broadly less contentious in Europe than the US, the reverse is the case in regard to the latter. Political cultures also reflect and help reproduce quite distinct legal cultures, which are important determinants of the ways in which the implications of new technosciences, such as ESC, are to be interpreted. For example, there is a contrast between the system of adversarial law making and justice in the US compared with the inquisitorial justice of mainland Europe: in the second, it is the judge who decides what evidence is to be allowed, and whom is to be regarded as expert in providing it, rather than this being primarily determined by the rhetorical skills of the attorney. This difference has played an important role in the ways in which DNA evidence has been deployed in courts on either side of the Atlantic. Elsewhere, Abraham and Reed (2004) have shown how the divergent decisions made between the US and Europe with respect to the licensing of new drugs must be explained through reference to the role of politically active patient groups and their role in the regulatory cultures either side of the Atlantic.

These divergences in regard to the social management of new technosciences are reflected in the existence of heterogeneous regulatory institutions within and between countries charged with the task of handling contemporary innovation in bioscience (and other fields such as pharmacogenomics [Webster et al, 2004]). Hybrid institutions appear that are triggered by the need to manage an increasingly hybridised science, where combinations of materials, tissues, and experimental procedures are transforming conventional biological boundaries and practices. For example, research on chimera, where animal and human tissue/cells are combined, is a case in point, and has required regulatory agencies to think afresh about how to cope with what were once seen as discrete objects of inquiry, enjoying different identities and rights. Brown and Michael (2004), in their study of xenotransplantation, make a similar point when they say:

Novel natures have inspired the creation of equally novel regulatory institutions. Xenotransplantation, an inherently hybrid transpecies innovation, cuts across traditional institutional boundaries, crisscrossing the regulation of animal procedures, mechanical devices, medicines, research on human subjects, toxins and environmental health. And it is the formation of these new institutional regulatory hybrids that we are concerned with here (p. 208).

The regulatory diversity we see at present reflects divergent perceptions of nature and how it might be re-engineered or reconfigured. It also in part reflects what Pierre (2000) has also identified as a shift from what he describes as 'centripetal' to 'centrifugal' governance: that is the deregulation and devolution of responsibility to local policy networks.

In light of these opening remarks, there are a range of questions that social science might ask about regulatory cultures and the management of stem or tissue cultures:

- How might quality control be secured in a research field that is global in its sourcing of material yet diverse in the regulatory regimes from which and into which such material is derived and despatched? The provenance of stem cells, the way this might reflect distinct standards, and the movement of cells out of banks to be used elsewhere raise questions about the social management of the field that have, ethical, social and bioscience importance.
- How might regulatory bodies in different countries interact and learn from each other in managing the new field?
- What do regulations mean 'on the ground', across different countries?
- How are the requirements and provisions of the new SC banks – as a key part of the infrastructure for SC scientific research and innovation - making new demands on scientists that may in some contexts discourage full engagement with the field?
- To what extent will countries modify their regulatory approaches in the future if human stem cell research starts to provide breakthrough therapies?

This paper does not seek to answer all of these questions, but instead provides a basis on which we might begin to address them. It does so by discussing the relationship between stem cell research and political culture since it is an understanding of this relationship on which any answers should be based. Let us first review the current pattern of regulatory diversity within Europe.

### Current Regulatory Diversity

In light of the controversial nature of stem cell research described above, it is not surprising that there is little international consensus on regulation. In the United States, federal law restricts the use of public funds for embryo research. However, there are no regulations governing such research in the private sector, and there is considerable diversity across individual states (such as California's recent legislation Proposition 21 that raised a hypothecated tax for ESC research). No laws commenting on (or banning) human cloning have been passed by the Senate. Despite some discussions, there is no international legal framework in this area either.

In Europe, there is considerable variation across countries with respect to a number of discrete but linked issues: whether it is permissible to procure human embryonic stem cells from supernumerary embryos, where this is prohibited the import and use of human embryonic stem cell lines under certain conditions, and whether it is permissible to create human embryos for stem cell procurement. A recent overview of this (though clearly in need of some updating) is provided by the European Commission (2003). Table 1 provides an overview of key regulatory/legal positions for most EU states as of early 2005.

Table 1: Regulatory position on Stem Cell Research in European countries

Country	Reproductive cloning Prevented by national law	Research authorised by national law on		
		Stem cells	Human embryos	Aborted foetuses
Austria	Yes	No law	No	No law
Belgium	No	Yes	Yes	No law
Czech Republic	No	No law	No law	No law
Denmark	Yes	Yes	Yes	Yes
Finland	Yes	Yes	Yes	Yes
France	Yes	Yes	No	Yes
Germany	Yes	No	No	Yes
Greece	No	Yes	Yes	No law
Hungary	In preparation	No	No	No
Ireland	No	No	No	No law
Italy	Yes	No	No	No law
The Netherlands	In preparation	Yes	yes	Yes
Norway	Yes	No law	No law	No law
Poland	No	No law	No law	No law
Portugal	No	No	No	No law
Slovenia	Yes	No law	No law	No law
Spain	Yes	Yes	Yes	Yes
Sweden	No	No	Yes (14d)	No
Switzerland	Yes	No	Yes	Yes
Turkey	No	No law	No law	No law
United Kingdom	Yes	Yes	Yes (14d)	Yes

While there are areas of convergence there remain some significant points of divergence, and the prospect for a consensus-based EU-wide legislation directly relating to embryonic stem cell research is unlikely. Knowles (2004) has provided a useful classification of member-states that falls into three broad groups. Ireland, Germany, Austria, Italy and France represent countries in which no ESC derivation is permitted, although France is in the process of revising its regulations to allow stem cell researchers to work on excess embryos from IVF clinics. Netherlands, Sweden, Denmark, Finland, Spain and Greece approve embryonic stem cell derivation from spare embryos but do not permit the production of embryos for research purposes. In the UK and Belgium the creation of embryos for research purposes, via fertilization or cell nuclear replacement (CNR), is permitted (as it is outside the EU such as in Israel and Singapore). UK legislations derives from the 1990 HFE Act which permitted experimentation on supernumerary human embryos up to 14 days after fertilisation, upon which the so-called ‘primitive streak’ (forbear of the CNS) appears and thereby pain ‘felt’. The Warnock Inquiry which led to the Act recognised that the 14 days was a compromise between scientific demands for and religio-ethical objections against such research, but was an effective regulatory position that was politically feasible or workable (see Parry, 2002). The subsequent HFE (Research Purposes) Act of 2001 allowed research for therapeutic purposes on human embryos up to the 14 day limit.

An especially useful contribution to the framing of the diversity across nation states in regard to stem cells regulation has been made by Salter (2005). He identifies five main regulatory ‘options’ that states might adopt, each of which gives more, or less, moral status to the embryonic stem cell (in regard to its having (potential) human identity and rights). These are summarised in Table 2 below.

**Table 2: Policy options for regulating stem cells**

<i>Option 1</i>	<i>Option 2</i>	<i>Option 3</i>	<i>Option 4</i>	<i>Option 5</i>
Prohibition of procurement of ESCs from human embryos	Prohibition of procurement but allowing importation	Allowing procurement of ESCs from supernumerary human embryos	Prohibition of creation of human embryos for research purposes including cloning	Allowing creation of human embryos for research purposes including cloning

Source: Based on Salter, 2005.

In general most EU states cluster around options 3 and 4, with, at present, only the UK and Belgium adopting option 5.

### **Explaining the Differences**

What dynamics shape regulatory policy and help to explain these differences? As is evident from the above, there are powerful religio-ethical factors that play a part in creating the broadly hostile reception therapeutic cloning has received from catholic/southern European countries. And these may be deepened by the recent inauguration of the very conservative Pope Benedict. However, the pattern of response cannot be explained solely in these terms, for Spain, for example, does permit derivation of stem cells from embryos, and indeed within Spain (Andalusia) regional plans are under way to establish a stem cell bank and allow therapeutic cloning. France too is reconsidering its position. As Jasanoff (2005) argues, we need to attend to the ways in which existing normative discourses about science are embedded in wider political cultures and practices, and how, thereby, science and politics are engaged in ongoing exchange and mutual stabilization. This echoes a similar argument I made over a decade ago (Webster, 1991) when I suggested that we can understand how policymaking responds to new technologies and their perceived costs and benefits, risks and uncertainties, if we locate science policy within the wider political arena. Then I drew a distinction between the structures and processes of decision-

making, contrasting structures that are rights-driven, pluralistic/devolved and non-hierarchical with those that tend to be more bureaucratic and top-down, and decision-making processes that are more or less open and contested, more or less expert-led. Together this produces a four fold matrix. Chart 1 below shows the matrix populated with illustrative countries.

Chart 1 Political cultures and S&T policy-making

	Pluralistic/devolved	State-led
Open and contested	USA/Spain/Sweden/Australia	Netherlands Germany Austria
Closed with low public scrutiny	UK/Belgium	Accession states <sup>?</sup> /France Japan/South Korea

As suggested above, some countries may have a loose, pluralistic structure through which the planning process for science is developed. Others may adopt a much more centralised, directive style, the corporatist approach found in Germany. Or again, the adversarial science politics of the US contrast with the expert-led committee system in place in the UK (see also Jasanoff, 2005). Overtime, there may be movement across the matrix, as political cultures respond to new challenges and demands made of them. This can lead to social experimentation in policy-making, as was seen in the UK government’s ‘GM Nation’ exercise between 2002-4, which in practice opened up the policy debate to wide lay participation. Such experiments are always dependent on how far government sees them as acting *within existing* institutional structures or providing the basis for the development of new ones. The British government adopted the former line from the start, such that the outcomes of the debate were always likely to be limited, as has been seen (Pidgeon et al., 2004).

Stem cell research is shaped by the different structures and processes within European policymaking. The UK culture allows for incremental and expert-led policy, while the Spanish regional government structures and devolved power allows for alternative positions to be adopted locally, which then feedback on the state at a national level. More open cultures that combine strong bureaucratic regimes tend toward conservatism in policy-making, as is illustrated by Germany and Austria.

The matrix is offered simply as a heuristic device inasmuch as there are likely to be occasions when countries do not neatly fall within one category. But it does suggest how different political cultures may be more or less likely to adopt more or less ambitious policies about the boundaries of stem cells research. The iterative, expert-led policy in the UK has been built on the political consensus surrounding the earlier Warnock Inquiry, and has produced an extensive body of regulatory and advisory codes of practice that far from constraining science give it the room to develop in a gradualist way. Elsewhere, boundaries are defined through more formalised, public debate that lead to explicit national policy decisions that must appeal to a wider constituency of interests, as in the Netherlands or Sweden. However, where devolved decision-making is possible – as in the US and Spain – legitimacy can be more locally crafted and framed, as in California and more recently in Massachusetts and Andalusia.

While we can see then that different European (and other) states have tendencies towards quite distinct political cultures that will shape their regulatory policy, we should not only not presume that these will remain static over time, we should not presume that the national boundaries of a country define its technological boundaries. As Barry (2001) has argued,

The state...has been conceived of as a geographical territory; but it has also been imagined and formed as a kind of technological zone, the ends of which may coincide with its territorial borders, or be extended beyond them' (p 43).

Against this, Barry argues that 'national' technological zones 'cut across each other' (p49) – through intellectual property, standards, corporate innovation and so on. In stem cells research, we can see leakage of policy across different technology and regulatory zones: for example, German scientists can import stem cell lines derived from embryonic cloning even though the latter is restricted locally.

In light of this, we find that scientists (and corporations) will themselves – through their collaborations and informal networks – occupy more than one political culture at the same time and/or may deliberately move to a particular culture they find most conducive to their research. EU funding also facilitates this, of course, through supporting research networks on stem cells whose members come from countries with conflicting national codes of research: for example, the Commission has recently allocated €12billion to a pan-European stem cell research collaboration involving groups in the UK, Sweden, Germany, Italy, France and Finland to investigate the therapeutic potential of human embryonic stem cells.

Just as scientists might occupy and mobilise different governance regimes to secure research funds, so activist groups may mobilise different levels of governance to secure their own interests. As Salter and Jones (2003) have argued,

One of the consequences of the policy structures of the European Union has been the creation of more linkages between domestic groups and the EU level and incentives for domestic groups to form international linkages with similar groups to enhance their political position.... For example, in human embryo research, groups with faith-based ethical concerns which had experienced exclusion from consultation processes at the national level found access at the EU level easier to achieve.

There are then a diversity of regulatory regimes and political cultures within Europe, a series of overlapping technological 'zones', movement across and mobilisation of different regimes by actors pursuing different interests, and the co-occupancy of conflicting regimes in (public and private) scientific networks. This situation does not lend itself to convergence around a pan-European regulatory regime that secures support in the European Parliament and members states.

### **Convergence?**

Despite this, it is possible to see moves towards certain forms of regulatory convergence. But rather than these being related to the broad legal and ethical landscape described above, they are more to do with the technical instruments and standards that lie at the heart of the field itself. These are what make the field possible *as a field* through the work that scientists must undertake to achieve this. Fujimura (1992; 1996) has described this as the social process of 'crafting science' that involves both *production* and *articulation* work to stabilise and secure the scientific and innovation potential of a new field.

One of the most important tasks involved in crafting the SC field have been the (albeit slow) moves towards agreement of those markers that can be used to establish the (biological) quality of stem cells lines. These are key to all future experimentation since they will establish the basis on which results can be judged and shared by other scientists.

The UK Medical Research Council identifies the following tasks as key to the future development of the field:

- Developing completely defined culture conditions for stem cell derivation, propagation and differentiation

That is, to decide and standardise environments, techniques and material for how cells are sourced, grown and manipulated, and furthermore,

- Defining appropriate cell markers that distinguish stem cell types from one another, and that characterise stem cells, progenitor cells and differentiated cell types

That is, to set a standard taxonomy for what is to count as a 'true' stem cell. The international stem cell initiative co-ordinated by the MRC is the principal forum through which these two sets of tasks are being undertaken.

Beyond these questions about the (biological) *identity* of stem cells, there is a second range of tasks related to what we can call the *husbandry* of cells: the production, stability, storage and monitoring of lines to be used by third parties. This is a task that requires capital investment in 'clean rooms' up to GMP standard to ensure the safety and efficacy of lines and thereby enable some determination of their clinical utility and cost effectiveness (Faulkner, 2003). Stem Cell Banks are the primary sites for this type of 'production work' (Glasner, 2005).

Both these identity and husbandry tasks are typically dealt with outside of the orbit of political debate and 'obscured from public view...conducted between technical specialists, bureaucrats and industrial lobbyists' (Barry, 2005). These have played an important role in helping to provide a platform for European innovation; 'standardised technical devices' have, as Barry again says '...provided part of the solution to the difficulties of establishing common European institutions' (p 211). The current moves towards a harmonised regulatory framework for human tissue engineered products (such as skin, bone and cartilage) has been primarily framed as a technical matter requiring agreement among scientific, legal and commercial interests, driven by the need to provide a stable business model for European investment in the area, to enable the free circulation of TE products throughout the EU. The final agreement on this is expected in late 2005. Waldby and Mitchell (2006) have emphasised the importance of this production work to the European and indeed global 'tissue economy', and corporations such as Geron, Advanced Stem Cell Technology, Stem Cells Sciences Ltd and so on (see also Waldby, 2002). We should bear in mind, however, that while harmonised technical standards and instruments may be agreed, there will always remain a degree of contingency in the way in which labs on the ground are guided and steered by these standards.

One area of debate that has both identity and husbandry dimensions to it yet touches on wider ethical and normative issues, concerns the relative merits of adult and embryonic stem cell research. Many research scientists and private firms argue that adult stem cells (or somatic cells) do not carry the ethical weight of those derived from embryos, since they do not involve the 'destruction' of tissue that is attributed to have human potential. Companies have actively positioned themselves to deal only in adult lines because of fears of a public backlash against them if products were found to have been based on ESC. Recent claims have been made by 'adult' scientists that they can reproduce some of the pluripotency of ESCs. On the other hand, ESC scientists point out that adult cells are difficult to multiply in the lab and often die before they are of use. Such biological claims and counterclaims have served to widen the gap between the two subfields of research. The regulatory regimes summarised above can also be distinguished with regard to the relative support they give to either side of this divide.

## Conclusion

In light of the above, what does pan-European regulation mean? It has been suggested that regulatory consensus is difficult to achieve given the diversity of political cultures prevailing across Europe. It has been argued that convergence and consensus is more likely in regard to

technical standards and instruments than it is in relation to normative principles. It is probably impossible to secure a pan-European political consensus over the regulation of what might be regarded as the ethical boundaries of the field.

But Europe is no exception in this regard: the same applies to the US where we can see huge political divergences between the Federal and state-based restrictions on stem cell research. The regulatory issue is not simply technical and cannot be seen to be determined on the basis of incontrovertible 'evidence' upon which a convergence could be built.

As Jasanoff (2005) has argued,

Instead of fostering convergence, as determinist theories would have us expect, biotechnology has served as a site for the (re)performance of political culture'

In light of this, it seems that the European Commission will make most headway if it continues to devote its attention to the provision of technical standards that harmonise 'identity' criteria and 'husbandry' practices. The creation of new hybrid regulatory agencies is likely to be most important here in order to manage the biological hybridity that characterises the field. In contrast, a pan-European regulatory regime will be difficult to achieve, and indeed makes little sense unless it has global purchase and recognition and to this extent our focus should shift away from Europe *per se* to developments happening at a global level. The arrival of new accession countries will make Europe even more difficult a political site on which to build harmonised regulation, especially in regard to ESC.

From the embryonic stem cell scientist's perspective, it appears that the sort of political culture found in countries such as Belgium and the UK may be more likely to provide the broadest opportunities for research, whether at national or devolved levels.

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