Regulating stem cell research in Europe by the back door

S Holm

Regulation of stem cell research in Europe should not take place without public and scholarly input

The European Union (EU) has, at present, no jurisdiction over research carried out in the member states, or concerning the “ethics” of member states. This does not, however, mean that decisions made by the European institutions cannot influence such matters greatly.

There has recently been a lot of focus on the decision not to fund embryonic stem cell research during the first year of the 6th framework programme (mainly due to opposition to funding from the German government), but behind the scenes a much more important and wide ranging set of regulations are being prepared.

The European Commission has prepared a draft directive on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells. The purpose of this directive was originally to “ensure the quality and safety of human tissues and cells for clinical use” in the EU. This is clearly a laudable objective, fully in line with the EU’s jurisdiction in consumer protection and public health.

During the intricate processes of political decision making in Brussels something has however happened to the draft directive that makes it appropriate for the bioethics community to devote some critical attention to it.

In April of this year the European parliament considered the draft directive and proposed major amendments. The first major amendment dramatically increased the scope of the directive from human cells and tissues for application to the human body (in therapy and clinical trials), to human cells and tissues used in therapy and all kinds of research (including in vitro research and animal models) (see reference 2, amendment 7).

The second major amendment prohibits the creation of human embryos solely for research or for the creation of stem cells, including their creation by means of cell nuclear transfer, as well as any form of research aimed at reproductive cloning (see reference 2, amendment 30). In combination with another amendment, it also prohibits the import of cells created in this way into the EU (see reference 2, amendment 34).

The text that the European parliament wants for the directive is therefore in direct contradiction to current UK legislation and the legislation of a number of other member states that either allow the production of such cells (the UK) or their import (Denmark, Sweden, The Netherlands). This is in itself an issue worthy of analysis, but it is not the major problem concerning this draft directive.

The major problem with the draft directive in its current form is the way wide ranging regulations of ethically contentious areas are being drafted, discussed, and decided without public or scholarly input and discussion.

The ethical status of human embryonic stem cells is contentious, as is the issue of reproductive cloning. They are not issues that we can hope to reach an agreement on any time soon, partly because they touch on our basic beliefs about what a human being is and what it is that makes life valuable and worth living (for an overview of the debates see my paper, Going to the roots of the stem cell controversy). It is therefore important that discussion about these issues is not closed prematurely before everybody has had a chance to think about them, make up their own mind, and decide whether they want to participate in the discussion. Even after full discussion we will probably not agree, but everyone will at least have had the opportunity to test their arguments in a free and frank exchange of views. At that point in time our elected representatives can then decide, after having listened attentively to us, the citizens who have elected them.

If the directive was enacted in its present form it would have bypassed this stage of public reflection completely.

The draft directive is now back at the commission, and it is predictable that not all of the amendments proposed by the parliament will make it through to the next draft. For some this is a reason for relief, but unless the commission initiates a public discussion of these issues, the democratic process will not be much

Appendix

Comparison of commission and parliament texts

<table>
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<tr>
<th>Commission text</th>
<th>Parliament text</th>
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<tbody>
<tr>
<td><strong>Amendment 7</strong></td>
<td>This Directive also covers research using human tissues and cells such as when used for purposes other than application to the human body—that is, in vitro research or in animal models. Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this Directive.</td>
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<tr>
<td><strong>Amendment 30</strong></td>
<td>Member states shall at least prohibit: research on human cloning for reproductive purposes; research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei</td>
</tr>
<tr>
<td><strong>Amendment 34 (only first part)</strong></td>
<td>Member States shall take all necessary measure to ensure that all imports of human tissues or cells from third countries are approved by the competent authority.</td>
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This Directive also covers research using human tissues and cells such as when used for purposes other than application to the human body—for example, in vitro research or in animal models, as far as donation and procurement are concerned.

Member states shall at least prohibit:

- research on human cloning for reproductive purposes;
- research designed to create human embryos solely for research purposes or to supply stem cells, including by means of the transfer of somatic cell nuclei.
furthered, and the legitimacy of the final directive not much improved.

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