Regenerative Medicine in Europe: The REMEDIIE project

Project outline
May 7 2009
Principal goals of REMEDiE

- A detailed examination of the political economy of globalised regenerative medicine, applying this to highly significant policy and public issues within Europe
- An integrated series of projects organised around three inter-related streams of research – markets, politics, bioethics
- The use of new techniques to interrogate data using macro-econometric modelling and geometric mapping of data items secured by different projects in the three areas
Main argument:

Global markets, politics and bioethics (governance) depends on the meaning of the ‘bio-object’ being mobilised in the RM universe, and degree to which this can be stabilised to create biovalue.
Political economy of regen med: appropriation

IP: biology is being shaped so it fits better into ownership regimes – eg synthetic biology
But…indeterminate IP associated with hybrid objects

Standardisation of biomarkers
But…variability creates problems for scale-up

Arrival of big pharma – GSK/Pfizer during 2008 – (eg Pfizer’s new Regen Med Research Unit in Cambridge UK/Mass)
But…hybrid and potentially weak business model
Differing business models and hybrid model of cell-based products

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<thead>
<tr>
<th>Pharmaceuticals</th>
<th>Cell based products</th>
<th>Medical devices</th>
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<tbody>
<tr>
<td>High up front costs</td>
<td>High up-front costs</td>
<td>Lower up-front costs</td>
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<td>Long dev times</td>
<td>Long dev times</td>
<td>Short dev times</td>
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<td>High gross margins</td>
<td>Low gross margins</td>
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<td>Large markets</td>
<td>Focused markets</td>
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Political economy of regen med: regulatory state

Providing legal and regulatory space for commercial and clinical development – e.g. 2008 HFEA legislation in UK and ATMP Directive 2008 in EU – providing some determinacy

Fostering public engagement – eg Stem Cell Dialogue in UK

Setting limits on the meaning of legitimate regen med – eg ban on reproductive cloning
Regulation of Healthcare Products in the EU

From indeterminacy to Zones of determinacy?

Dir 93/42/EEC
Reg (EC) 1394/2007
Dir 2003/63/EC
Reg (EC) 726/2004
Dir 2001/83/EC

EU Legislation

Science

Medical Devices Tissue Engineering Cell Therapy Gene Therapy Biotech (e.g. insulin) Chemical Medicines (e.g. aspirin)

Advanced Therapy Medicinal Products
But indeterminacies…

• No EU-wide legal definition of the embryo
• Heterogeneous banking procedures internationally
• Regulatory flexibility – Geron case – how far can it go?
• Need for new clinical trials provisions?
• Regulatory avoidance: the black economy for tissue
Political economy of regen med: governance and bioethics

Form, extent and implementation of governance and bioethics depends on the perceived meaning of the ‘bio-object’ that is subject to oversight.

What’s in a name?

Chimera – embryos from two different species

Hybrid – DNA from two species – two parents of different species

Cybrid… admixed embryo
But indeterminacies

Global diversity in political/moral status given to the embryo – relation between civil society and the state

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<th>Option 1</th>
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<tr>
<td>Prohibition of procurement of ESCs from human embryos</td>
<td>Prohibition of procurement but allowing importation</td>
<td>Allowing procurement of ESCs from supernumerary human embryos</td>
<td>Prohibition of creation of human embryos for research purposes including cloning</td>
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<td>e.g. Austria</td>
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<td>e.g. UK/Belgium</td>
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Moral status of embryo declines
Conclusion
Some key questions:

What’s specific to RM within wider biotech context?

How far are indeterminacies being closed down while new ones opened up?

...and how does this occur spatially – both geographically and through policy networks (hybrid public/private)?

How to compare the UK/EU/global