Regenerative Medicine in the 21st Century: Managing Uncertainty at the Global Level

Introduction
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The Pyle Center,
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REMEDiE Regenerative Medicine in Europe

Emerging Needs and Challenges in a Global Context

Introduction

The globalisation of regenerative medicine is gathering pace yet has not been examined with respect to its medium and long-term implications for European regulators, the corporate and clinical sectors or patients located within different member states. Over the coming years it is hypothesised that the global pace of change in this field will be extensive, though uneven, and this needs to be both tracked and assessed to provide basic empirical and analytical research results to be made available to healthcare systems across Europe. It is a field that is characterized by complex dynamics across a range of scientific, clinical and industrial sectors, highly unstable, yet developing rapidly. Regenerative Medicine (RM) is also important to Europe given the emerging competition from Asia/Pacific and North America regions that are making health biotech development a priority and investing in what they perceive to be an industry of the future. April 24th 2007 saw the EU Parliament adopt the ‘Advanced Therapies Regulation’ to harmonise guidelines that will, if approved by the Council, create a centralised process for approving new tissue and cell engineering therapies. This is an important basis for stabilising the RM market and research in Europe: this project examines the current and emerging socio-economic, political and bioethical issues that will need to be addressed in Europe as work in the RM field accelerates.

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Principal objectives 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 development of a global database to identify global (inter-related) trends and to develop visualisation techniques to map these
Political economy of regen med

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
1. Political economy of regen med: commercialisation

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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<th>Pharmaceuticals</th>
<th>Cell based products</th>
<th>Medical devices</th>
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2. 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 – e.g. Stem Cell Dialogue in UK

Setting limits on the meaning of legitimate regen med – e.g. 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

Advanced Therapy Medicinal Products

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

- No EU-wide legal definition of the embryo
- Does the EU pharma model underpinning ATMP ‘work’ for regen med?
- Regulatory flexibility – Geron case – how far can it go?
- Is there a need for new clinical trials provisions?
3. Political economy of regen med: governance and bioethics

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

- 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 – this reflects relation between civil society and the state

Cross border stem cell tourism – skirting around boundaries

Regulatory avoidance: the black economy for tissue and the commercialisation of the oocyte
The debate ahead…

Some key questions for the Conference:
- What’s specific to RM within wider biotech context across three domains?
- How far are indeterminacies being closed down while new ones opened up?
- How far can existing regulation encompass RM innovation?
- How to compare the UK/EU/US/and wider global developments