Regenerative Medicine in Europe: The REMEDiE project

Project outline

May 7 2009

SEVENTH FRAMEWORK PROGRAMME

REMEDiE Regenerative Medicine in Europe

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

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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

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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 Pfizers new Regen Med Research Unit in Cambridge UK/Mass)
But…hybrid and potentially weak business model

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Differing business models and hybrid model of cell-based products

Pharmaceuticals	**Cell based products**	**Medical devices**
High up front costs	High up-front costs	Lower up-front costs
Long dev times	Long dev times	Short dev times
High gross margins	Low gross margins	Low gross margins
Large markets	Focused markets	Focused markets

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

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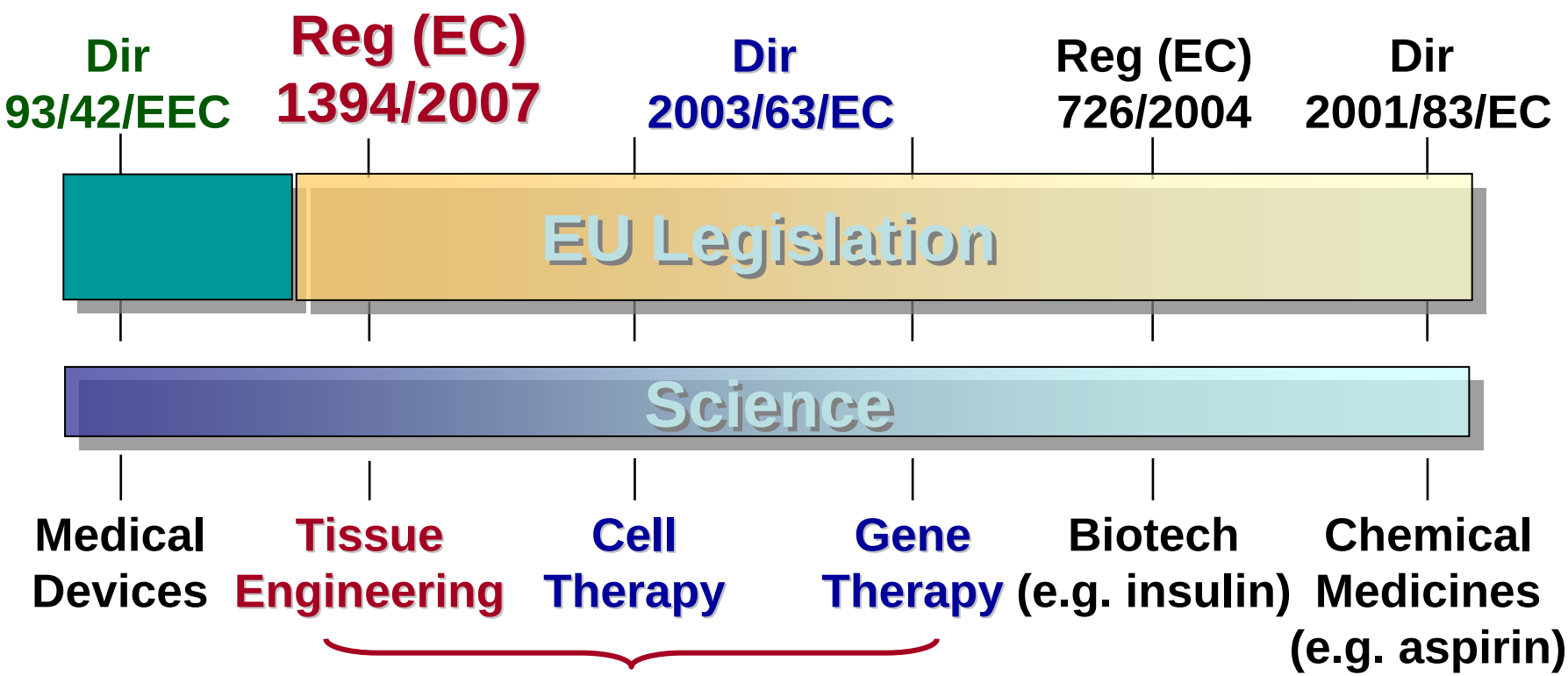
Regulation of Healthcare Products in the EU

From indeterminacy to Zones of determinacy?



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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

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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

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But indeterminacies

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

Option 1 Prohibition of procurement of ESCs from human embryos e.g Austria	***Option 2*** Prohibition of procurement but allowing importation	***Option 3*** Allowing procurement of ESCs from supernumerary human embryos e.g. NL	***Option 4*** Prohibition of creation of human embryos for research purposes including cloning	***Option 5*** Allowing creation of human embryos for research purposes including cloning e.g UK/Belgium

Moral status of embryo declines →

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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

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