



Global policy and state governance

Brian Salter
Centre for Biomedicine and Society
King's College London

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Obama overturns stem cell ban

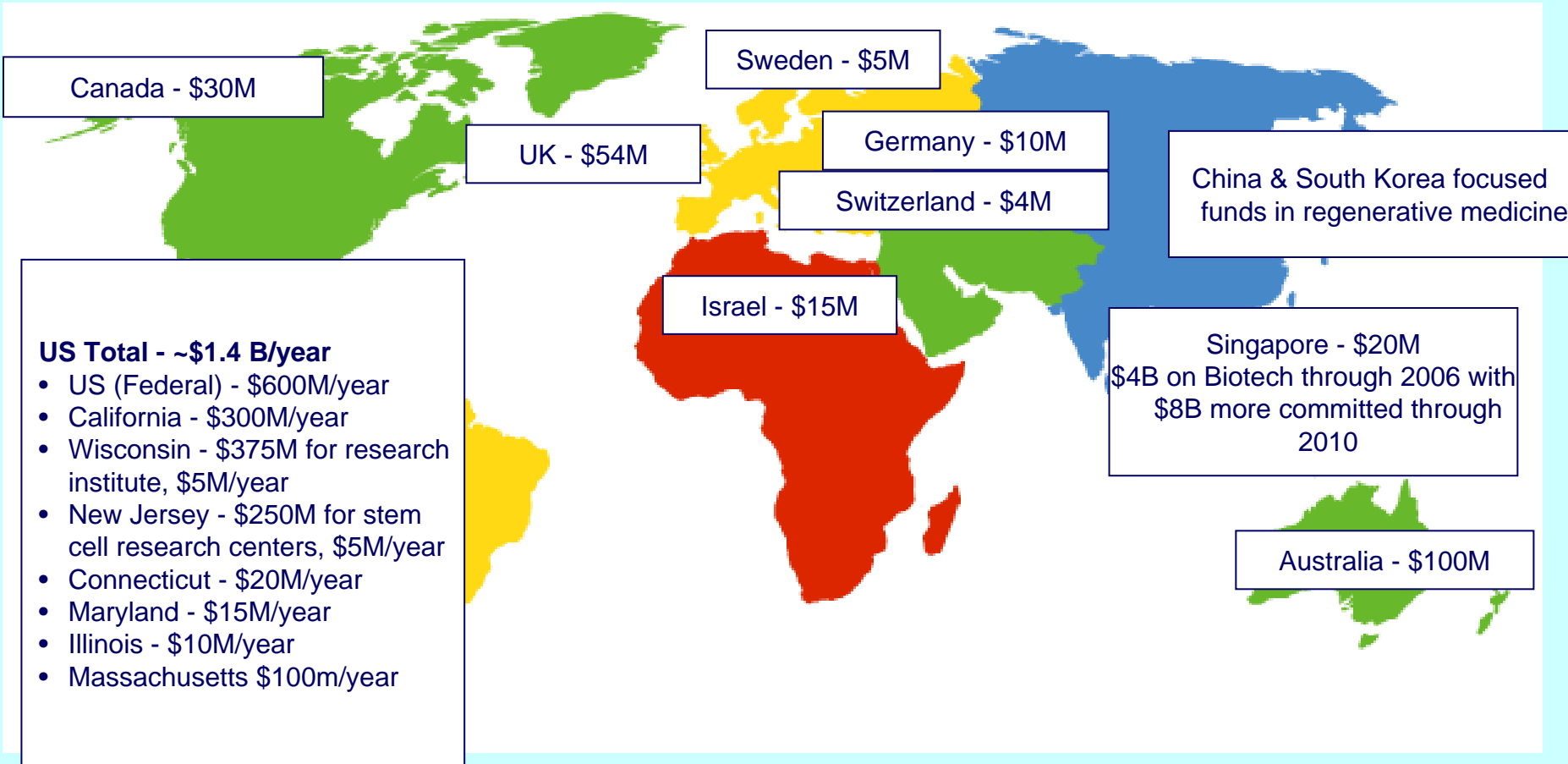


“Today, with the Executive Order I am about to sign, we will bring the change that so many scientists and researchers, doctors and innovators, patient and loved ones have hoped for, and fought for, these past eight years: we will lift the ban on federal funding for promising embryonic stem cell research. We will vigorously support scientists who pursue this research. **And we will aim for American to lead the world in the discoveries it one day may yield.**”

“Some of our best scientists leave for other countries that will sponsor their work. **And those countries may surge ahead of ours in the advances that transform our lives.**”

“By doing this, we will ensure America’s continued global leadership in scientific discoveries and technological breakthroughs. That is essential not only for our economic prosperity, but for the progress of all humanity.”

State investment in stem cell science



Outline of presentation

- Inter-state competition in a globalised knowledge bioeconomy
- The rise of East Asia to challenge US hegemony
- Policy implications for transnational public and private governance
- Policy questions

States competing within a *global* knowledge bioeconomy characterised by

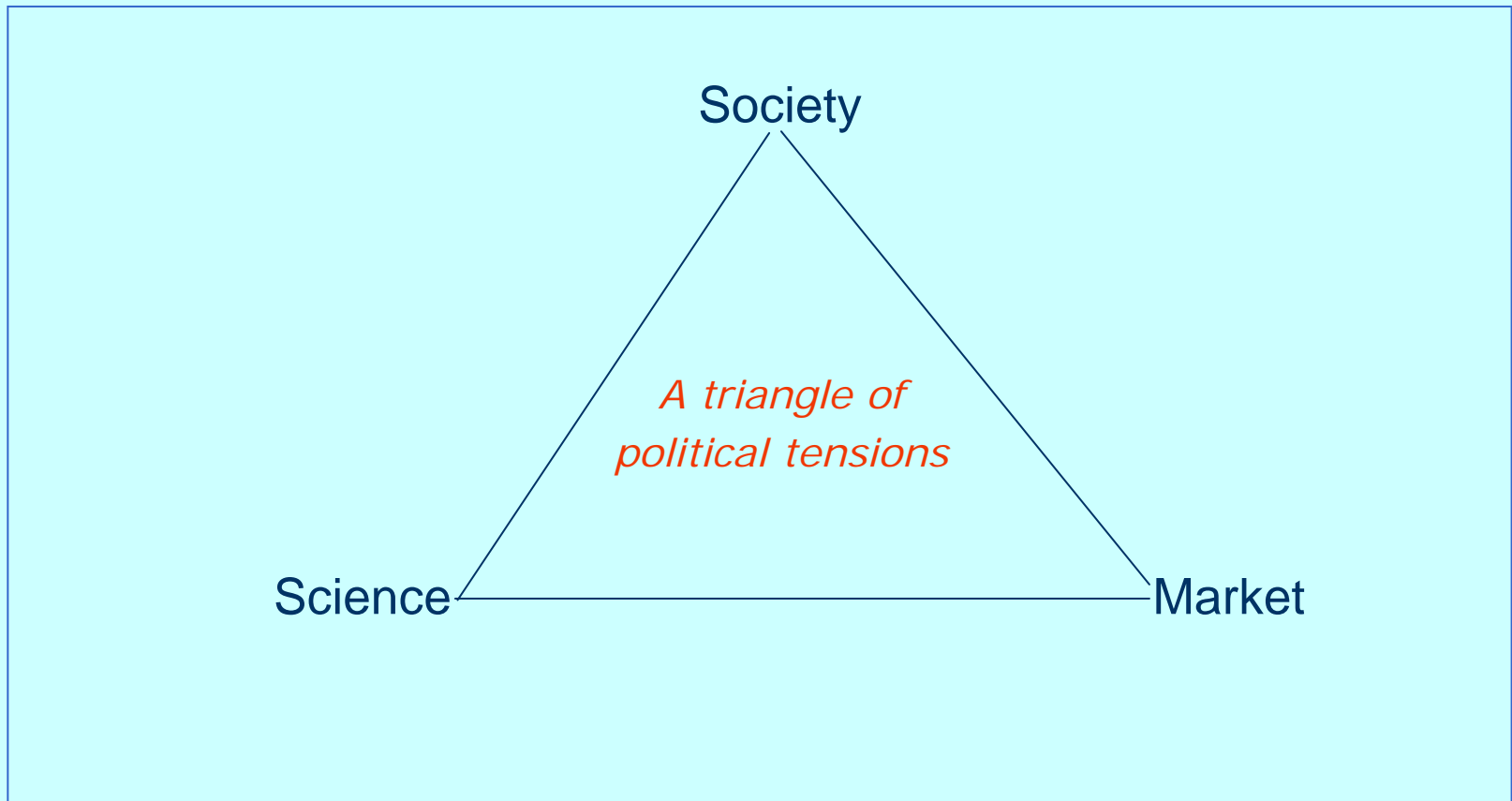
- Global scientific labour market and project collaboration
- Global trading of research materials such as human tissue
- Global clinical labour market through outsourcing of clinical trials
- Global venture capital markets
- Global commodification of biological material through bioprospecting
- Global intellectual property market
- Global moral economy for the trading of values through bioethical arbitration

How do states compete for advantage?

Policy choices by states in governing stem cell knowledge production

- Science
- Market
- Society

Science, society and the market: Co-producing governance to support innovation



Tensions in the science, society, market relationship can occur in any of these global domains

This means that the production of new governance knowledge may be required at:

- National level
- Regional level
- International level

Governing science: resources

- R and D investment – basic and translational science
- Organisation of science
- Supply of materials
- Supply of skilled scientific labour – training, retention, returnees

Governing science: regulatory infrastructure

- Procurement - supply/market of materials, storage and availability (including Good Cell Culture Practice - CCP)
- Basic science – confirmed proof of product and process (including Good Laboratory Practice - GLP)
- Pre-clinical trials (GLP)
- Clinical trials - including Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP)
- Manufacture - including Good Tissue Practice (GTP) and (GMP)

Necessary for international scientific collaboration

Governing the market

- Ownership – IP, culture and morality
- Public-private partnerships
- Venture capital – taxation, control of profits
- Small biotechs
- Large pharma

Governing society: Public trust and consumer confidence

- Need in democracies for engagement with cultural values across all stages of the innovation process from the basic science to the therapeutic product
- Political need for procedures to access and respond to social values (eg HGC, HFEA consultation)
- The contribution of bioethics: role of expert/advisory committees

These policy interventions allow a state to position itself within the global competition for advantage in stem cell science

The global distribution of state positions on hESC regulation

	<i>n</i> of countries
1. Prohibition of procurement of ESCs from human embryos	7
2. Prohibition of procurement but allowing importation	2
3. Allowing procurement of ESCs from supernumerary human embryos	18
4. Prohibition of creation of human embryos for research purposes including cloning	26
5. Allowing creation of human embryos for research purposes including cloning	7

The two ends of the policy continuum

Option 1. Prohibition of procurement of ESCs from human embryos

Austria, Germany, Ireland, Italy, Lithuania, Poland, Slovakia

Option 5. Allowing creation of human embryos for research purposes including cloning

Belgium, India, Israel, Singapore, South Korea, UK, Japan

The direction of ethical and policy change

- A uniform shift from more restrictive to less restrictive policies (away from Policy Option 1 and towards Policy Option 5), apart from Italy
- Examples in the last 3 years are: Australia, Belgium, Denmark, France, Germany, Greece, Japan, the Netherlands, Singapore, South Korea, Spain, and the United Kingdom.
- No examples of a shift in the other direction
- But further moves to Option 5 may be curtailed by the commitment of many countries to Option 4.

A different story

Emerging economies of East Asia

- Reject Obama's premise
- Do not necessarily accept the developed world's approach to innovation governance
- In any case lack the historic resources to implement this approach (eg basic science, venture capital expertise)
- Need to find novel forms of governance to short circuit stem cell innovation

Rationale— Emerging Economies

- General push to prioritize high-value biomedical and pharma research
- Strategy of taking advantage of FDI and joint ventures with overseas companies to develop domestic capacities for R&D
- Potential for shared IP or other contractual arrangements
- Strategy of taking advantage of WTO IP regulations rather than countering them

Rationale - Advanced Economies and Transnational Pharma

- Perception of declining profits in first world markets due to rising costs of clinical trial recruitment, “burdens” of regulation, growing pressure to relieve high drug costs in the US
- India and China – large hospital and medical systems, large number of available patients, treatment naive, many of them with limited access to drugs or limited health insurance cover.
- The possibility of entering domestic markets, particularly in China, with small urban elite representing a large market share in absolute terms.

For Example, Offshore Outsourcing

- The subcontracting of essential services to private providers, who may in turn relocate their services to developing countries
- The trend has been most widely commented upon in IT and software services, but is increasingly impacting on biomedical science
- Affects two main areas of pharmaceutical and biomedical R&D – scientific labour and clinical trials/human subject experimentation

Impact on stem cell science

The offshore outsourcing of clinical trials through CROs (clinical research organizations) is beginning to have an impact on the translational stage of stem cell research, with Western scientists engaged in joint ventures allowing them to push ahead with clinical trials in China or India.

Result

Push towards:

- 'Open' global innovation in stem cell science
 - Non-linear
 - Open to global inputs
- Fluidity of exchange and barter regarding innovation components in inter-governmental deals

Governance implications

- How does the East Asian dynamic relate to regional and global forms of governance?
- How adequate are these forms of governance when faced by
 - the demands of open innovation and
 - The challenge to US hegemony in stem cell innovation

Within regional governance (EU)

- Clinical Trials Directive 2001/20/EC
- Human Tissue Directive 2004/23/EC
- Regulation 1394/2007 on Advanced Therapy Medicinal Products amending Directive 2002/83/EC
- Modalities (ethical rules) for FP6 and FP7
- European Patent Office decision on patenting of hESCs

Within international economic governance

- Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)
- Agreement on Trade-related Investment Measures (TRIMS) – Bans requirements related to local content, trade balancing, export requirements, and requirements on public agencies to procure goods from local suppliers
- General Agreement on Trade in Services (GATS) - Extension of WTO rules from trade in products to trade in services including investment and FDI. Governments should not interfere in service trade between countries or regulate MNCs operating in their country.

Private governance and the international search for global harmonisation of standards

Standards may be:

- Matters of fact (eg criteria for agreed measures, protocols, classificatory systems and technical benchmarks)
- Ethical (eg criteria for the sourcing of human embryos)
- Both (eg UK Stem Cell Bank)

Private transnational governance: International Stem Cell Forum

- International Stem Cell Initiative
- International Stem Cell Banking Initiative
- Intellectual Property Rights Working Group
- Ethics Working Group

Private transnational governance: International Society for Stem Cell Research

- Guidelines for the Conduct of Human Embryonic Stem Cell Research
- Guidelines for the Clinical Translation of Stem Cell Research

Transnational bioethical governance and the facilitation of the global moral economy

- Public
 - UNESCOs International Bioethics Committee
 - World Health Organisation
 - European Group on Ethics in Science and New Technologies
- Private
 - International Association of Bioethics
 - Asian Bioethics Association

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With the added impetus of the East Asia dynamic

Policy implications: the state

- An innovation model characterised by
 - a global division of innovation effort
 - continuing fluidity in the global markets of scientific labour, VC investment, IP and value exchange
- The 'adaptive' state
 - Facilitation of cross-departmental working
 - Single bureaucratic focus (UK Office for Life Sciences led by Minister for Science and Innovation)
 - Network governance

Policy implications: regional and transnational

- Does the policy making apparatus of the EU have the capacity to respond to this dynamic given the constraints of the science-society-market triangle of political tensions in Europe?
- Will the states of East Asia challenge the dominance of the developed countries in the private transnational governance of science and bioethics?
- Will they find willing allies?
- Is transnational private governance sufficiently robust to deal with the political tensions of open innovation? Does it need public institutional support?
- What are the transnational governance implications of the dominance of the US – eg global role of FDA (sharing of expertise, policy transfer)?

Thank you team

ESRC SCI project

The global politics of human embryonic stem cell science

Professor Herbert Gottweis

Professor Catherine Waldby

Dr Melinda Cooper

Dr Olivia Harvey

Amanda Dickins

Outputs

- 3 books
- 32 articles in social science journals
- 6 articles in science journals
- 80 conference presentations

Thank you



THE GLOBAL POLITICS OF HUMAN EMBRYONIC STEM CELL SCIENCE

Regenerative Medicine in Transition

HERBERT GOTTWEIS, BRIAN SALTER
AND CATHERINE WALDBY

Health, Technology and Society Series
Series Editors: Andrew Webster and Sally Wyatt

