Global comparisons

- Permissive policy: various ES cell derivation techniques allowed, including SCNT
- Flexible policy: stem cells may be derived from human embryos donated by fertility clinics only
- Restrictive policy or no established policy (which may mean any research is permitted)

Source: William Hoffman, MBBNet
http://mbbnet.umn.edu/scmap.html
United States

Federal restrictions on funding with ES cells
  • Has limited stem cell research
  • Recent indications that situation may begin to change

Range of State initiatives
  • California: Proposition 71, $3 bn fund for stem cell research
  • NJ, MA, CT, WI & others also supporting research
  • Minority of States have tightened restrictions

Active Companies
  • E.g., Geron, ACT, Stem Cells, Inc., SERO/MIL and increasingly, others
  • Significant resources and investment for commercialization
Europe

Diversity of ESC work and support
- Banned: Italy, Austria, Ireland
- Restrictions: Fr, Ger, Greece, Netherlands
- Permitted: UK, Belgium, Spain, Czech

Some highly-regarded adult SC research

UK highly focused and committed to leadership and commercial success (e.g., Stem Cell Sciences Plc.)

Active efforts to establish acceptable guidelines
Scandinavia

- Strong research, recognized expertise
- Government support
- Favorable legislation
- Clear routes for commercialization

Similar competitive strength of UK, especially in Sweden and Denmark
EuroStemCell Partners

European consortium with mission to build the scientific foundation required to take stem cell technology successfully to the clinic.

Promoting collaboration and technology transfer

Members: 27 research groups across 11 academic centers and 3 companies in 8 European countries
   England, Scotland, France, Germany, Denmark, Sweden, Italy, Switzerland
   NeuroNova (Sweden), NsGene A/S (Denmark), Stem Cell Sciences (Scotland)

www.eurostemcell.org
Asia

- Seen as a priority area
- Significant government investment, supportive regulations, impressive infrastructure, world-class expertise

Main Focus

China clinical translation
Singapore commercial emphasis

.....Significant Competitive Threat!!
Other Significant Players

• Australia
  – Leading center of excellence
  – Uncertain regulatory framework
  – Appears to be losing strong position

• Canada
  – Canadian Stem Cell Network particularly strong
  – Research with surplus embryos allowed but therapeutic cloning banned

• Israel
  – Strong academic expertise
  – Therapeutic cloning permitted
  – Active spin-out companies
Commercial Opportunities

Research Applications
• Disease Models
• Drug Screening
• Toxicity Testing

Enabling Technologies
• Research Consumable Cell Banking
• Manufacturing Clinical Trials
• Licensing Cell Lines Training

Therapeutics
• Growth Factors
• Cell Therapies
Stem cell markets

- **Academic research**
  - expected >$6BN new investment next 10 years in USA

- **Drug discovery / development**
  - US$750M (2004) for cell based screening
  - growing 20% year on year

- **Cell therapies**
  - reported US$2.7BN (2001)
  - estimated US$10BN (2013)
Translation of stem cell research into commercial products

Stages:
- Basic Research
- Applied Development
- Clinical Therapies

Infrastructure:
- Universities, Research Institutes
- Biotech SMEs
- Pharma
- Clinicians

Stakeholders:
- Government / regulatory agencies

Funding:
- Research Councils
- Charities
- Commercial funding
- VC, pharma

Funding Gap
The SCS twin business model

- Core competency
- Two businesses
- Business model

Growing revenue stream

Supporting R&D for SCS cell therapeutics

Research products & drug discovery

Novel cell-based therapeutics

Stem cells

- heart
- nerves
- skin
- white blood cells
- red blood cells
Stem Cell Therapy

Human neural stem cells

- Epilepsy
- Anticipated second indication
- Duchenne Muscular Dystrophy (hMADS)

Timeline:
- 2006 to 2015
- Basic Research
- Pre-clinical
- Clinical
- NDA
- Approval
- Launch
- POC
- Repeat POC with GMP lots
Challenges

• IP: lack of clarity

• Lack of significant venture capital investment

• Caution from Big Pharma

• Need for translational funding
Acknowledgements

- http://mbbnet.umn.edu/scmap.html
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