Outlook for Stem Cell Research: Emerging Legal Issues

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Session Objectives

- Provide background context to legal discussion
- Understand major legal issues in stem cell research, with focus on human embryonic stem cell research (hESCR)
- Recognize how law influences and is influenced by science, ethics, policy (politics)
Law + Science, Ethics, Policy

SCIENCE
- What technically can we do?

ETHICS
- What should we do?

LAW
- What can (should?) we do?

POLICY
- What will we do in light of competing values, political climate?
LEGAL CIRCLES OF INFLUENCE

INTERNATIONAL

FEDERAL

STATE

INSTITUTION
hESCR

EVOLUTION OF LEGAL ISSUES
Trajectory of Legal Issues

- **Permissibility**: Is it ok or not ok? (hESCR / “derivation” or “use”)
- If ok, how **Fund**
- If ok, how **Regulate**
- Concern shifts to ownership rights and (limits on) transfer of ownership
  - Personal “property” (commodification)
  - Intellectual property (commercialization)
  - Physical property (commercialization)
Recurring Themes in Discussion of Legal Issues

- Revisit circles of influence
- State – Federal – International patchwork of regulations
- “Bio-federalism” of US
Initial Legal Focus: Permissibility / Funding

- Federal
  - Dickey-Wicker Amendment (1996-)
  - Pres. Obama’s Executive Order (March 2009)
- State
- International
Traditional Legal Response: Regulation

- Federal
  - NIH/OHRP (NIH draft guidelines, 4/09)
  - FDA
  - NAS
  - Legislature

- States

- International
  - ISSCR
  - Hinxton Group
Emerging Legal Focus: The 3 Cs

- Commodification
  - Personal property of gametes, embryos

- Commercialization
  - Intellectual property – patents
  - Physical property – materials (licensing)

- Collaboration
  - Dealing with the patchwork of regulations
hESCR

EMERGING LEGAL DEVELOPMENTS: THE 3 C’S
First C: Commodification

Donation Issues

• Informed consent
• Compensation

*Close connection to ethics
Second C: Commercialization

The Commercialization Chain: Derivation of SC line – Use of SCs – Preclinical trial – Clinical use

- Uncertainty of regulation: barrier to scientific development
- Conflicting ethical views: barrier to investment
- Level of Regulation
  - Less regulation ~ more progress
  - Clear regulation ~ more progress
Commercialization cont’d

Intellectual Property (Patents) and Physical Property (Licenses)

• Can (Should) we Patent?

• Regulating Commercialization
  ◦ Limits on Patent Scope
  ◦ Dealing with Existing Patents and Licensing Schemes

*Close connection to economics/business; some to ethics
Third C: Collaboration

The Patchwork and Thicket Issue

- **Commodification:**
  - Collaboration with other state, nation researchers who differ in view on “requisite” (who, what, when) consent and “appropriate” compensation

- **Commercialization:**
  - Collaboration with other state, nation researchers who differ in view of permissibility, patent scope, licensing regimes
WHAT NEXT?

hESCR & the Law
“The Law” needs to ...

- Analyze scope/substance of:
  - Obama E.O.
  - NIH regulations
  - Federal legislative action
  - State activity
  - Int’l activity

- Chart out/clarify boundaries and areas of overlap/conflict among above
“The Law” needs to ...

• Develop public repository for:
  ◦ Regulations, ethical guidance, consent forms, info for donors, etc.

• Develop model guidance, law, etc.

• Develop commercialization chain clearinghouse
  ◦ To Inform, Guide, Monitor
“The Law” needs to ...

- Promote collaboration via open, multi-level discussion
  - Funding, Guidelines/Regulation (re: consent, compensation, IP and P law)
- Reflect/be in iterative discourse with science and ethics
Selected References

• Donation:

• Regulation – Federal guidance:
Selected References cont’d

- **Regulation – Int’l guidance:**

- **Regulation – Other Articles:**
Useful websites

**State**

- National Conference of State Legislatures: [http://www.ncsl.org/programs/health/genetics/embfet.htm](http://www.ncsl.org/programs/health/genetics/embfet.htm) (overview of state legislation @ SCR; can also search for pending legislation)
- CIRM: [http://www.cirm.ca.gov/](http://www.cirm.ca.gov/) (regs, other info)

**Federal**


**International**

- ISSCR: [http://www.isscr.org/guidelines/index.htm](http://www.isscr.org/guidelines/index.htm) (guidelines; sample informed consent and licensing materials; other resources)
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