Stem Cells: Impact on Law, Ethics, and Policy

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Stem Cells: Timeline

- **1996**: Dickey-Wicker Amendment
- **1998**: Bush ban on federal funding of hESC
- **2000**: New Jersey and California fund stem cell research
- **2002**: 1st derivation of hESC line
- **2004**: Connecticut funds stem cell research
- **2006**: 1st derivation of IPSCs
- **2008**: Obama EO 13505
- **2010**: New York funds stem cell research
- **2012**: Sherley v. Sebelius (2010-13)
- **2014**: Feminists Choosing Life v. ESSCB (2009-11)
- **2014**: State “Right to try” laws passed
- **U.S. v. Regenerative Sciences**
Stem Cells: Impact on Law, Ethics, and Policy

• Use of human embryos for hESC research
  • Destruction of embryos
  • Creating embryos solely for research purposes

• SCNT and therapeutic cloning

• Human-animal chimeras

• Oocyte donor compensation

http://hesc.stanford.edu/research/programs/scnt.html
Stem Cells: Impact on Law, Ethics, and Policy (cont.)

• Patentability

• Participants in/donors to hESC research = “human subjects”?

• Informed consent to:
  • Donation
  • Future research
  • Storage, banking, and sharing

• Withdrawal of donated materials from research

1. Regulating Human Embryonic Stem Cell Research: An Overview of Federal and New York State Policies

2. “Right to Try” Unapproved Stem Cell Therapies

H9 human embryonic stem cells stained for the stem cell marker Tra-1-60 (red) and nuclei (green). (Snigda Chatterjee)
Regulating Human Embryonic Stem Cell Research: An Overview of Federal and New York State Policies
Dickey-Wicker Amendment

1st derivation of hESC line

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Dickey-Wicker Amendment

“(a) None of the funds made available in this Act may be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero…”

• Attached as rider to yearly HHS appropriations
1996

Dickey-Wicker Amendment

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Sherley v. Sebelius (2010-13)
Sherley v. Sebelius (2010-2013)

Plaintiffs sought to enjoin application of and funding pursuant to the NIH Guidelines based on allegations that the Guidelines:

(1) Violate the Dickey-Wicker Amendment

Primary questions:

(a) Is the Dickey-Wicker amendment ambiguous?
(b) If so, did NIH reasonably interpret the Dickey-Wicker amendment?

(2) Were issued in violation of the Administrative Procedures Act
State Laws

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New York Empire State Stem Cell Board (ESSCB)

- $600 Million in New York State funds over 11 Years

- Mission: To foster a strong stem cell research community in New York State and to accelerate the growth of scientific knowledge about stem cell biology and the development of therapies and diagnostic methods under the highest ethical, scientific, and medical standards for the purpose of alleviating disease and improving human health.

- Vote to allow compensation of oocyte donors for hESC research purposes
Feminists Choosing Life v. ESSCB (2009-2011)

• Civil lawsuit instituted in New York State Court

• Plaintiffs’ primary allegation: ESSCB policy allowing compensation of oocyte donors for hESC research purposes violates PHL 265-a:

“[N]o grants made available in the fund from any source shall be directly or indirectly utilized for research involving human reproductive cloning.”
“Right to Try” Unapproved Stem Cell Therapies
Unproven Stem Cell Therapies

State “Right to try” laws passed


U.S. v. Regenerative Sciences
Unproven Stem Cell Therapies

- Clinical use of unproven medical interventions that do not have sufficient previous research or demonstrable evidence that the procedures are safe and effective in the target population

- (versus scientific research and medical innovation)
U.S. v. Regenerative Sciences, LLC (2014)

- Key issue: Should autologous cells be regulated as drugs (subject to FDA oversight) or treated as part of medical practice?
- Regenerative Sciences argued that the agency did not have oversight over its human-cell-based products
- D.C. Circuit upheld the FDA’s authority over autologous stem cell therapies, sustaining the agency’s ability to regulate products based on human cells and tissues
State “Right to Try” Laws

- State laws that allow terminally-ill patients to try experimental, unapproved medical interventions that have completed an FDA Phase 1 clinical trial

- Conflict directly with FDA jurisdiction
State “Right to Try” Laws

• So what about non-FDA approved stem cell therapies?

• “the rallying cry of the free-to-choose movement”

• June 5, 2014: Neuralstem announced it would offer human neural stem cell therapy for treatment of ALS in Colorado