Stem Cell Policies: Legal rules

US275 Scientific Ethics
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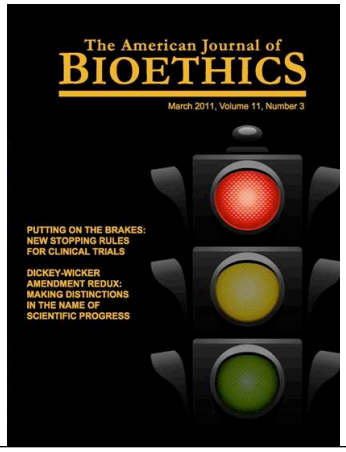
The Dickey-Wicker Amendment bans federal funding for creating or destroying human embryos for research

- Appropriations rider which amends the U.S. Department of Health and Human Services budget
  - Originally signed by President Clinton
  - Amended to each budget since then
- In Sherley vs Sebelius appeal, court ruled that amendment does not prohibit research on stem cell lines.



Presidents have used Executive Orders to permit federal funding for human embryonic stem cell research

- George W. Bush (2001 – 2009)
  - allowed funding for research using 21 stem cell lines created prior to 2001
- Barack Obama (2009 – present)
  - allows funding for stem cell lines created after 2001

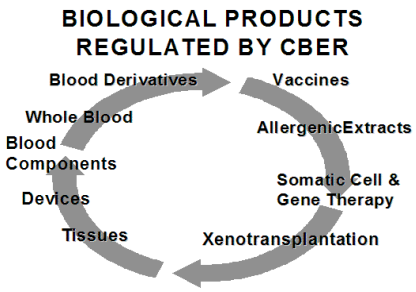
National Institutes of Health guidelines allow the use of funds on embryonic stem cells lines

- Created for reproductive purposes using nonfederal funds
- Donated freely with proper informed consent
- Does not allow funding for
  - creation of or research on embryonic stem cells lines from embryo other than those no longer needed for in vitro fertilization (IVF).

Francis Collins
Director of the
National Institutes of Health

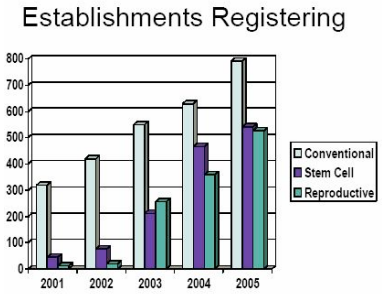
FDA oversees Vaccines, Blood & Biologics

- Cellular and gene therapy produces
- Tissue and tissue products
- Does not approve surgical or medical procedures



FDA regulates human cells, tissues, and cellular and tissue-based products

- Originally in place to prevent spread of HIV in transplanted human tissues
  - Now includes risks of Hepatitis B and C, etc.
  - Current Good Tissue Practices
- Regulated by the center for Biological Evaluation and Research (CBER)
  - Includes cultured cells, gene therapy products, and human cloning products

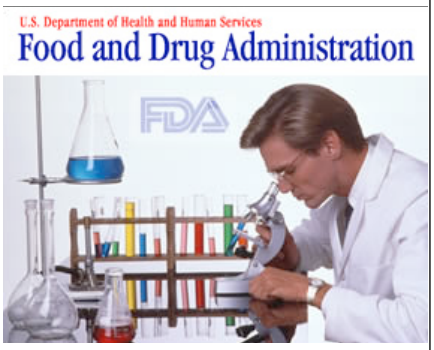


FDA registered Good Tissue Practice Establishments (2001 - 2005)
http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/RegulationofTissues/ucm150485.htm

Some human tissues, cells, and cellular and tissue-based products are ***exempt*** from FDA regulation, but still have to show good tissue practices

If they are:

- Minimally manipulated
- Not combined with another agent or samples from another source
- Are for autologous use, close (1st or 2nd degree relative), or reproductive use



Good Tissue Practices prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps

- donor screening and donor testing requirements
  - ensure that the HCT/Ps do not contain communicable disease agents
- do not become contaminated during manufacturing.

http://health.state.tn.us/ceds/index.htm

Current Good Manufacturing Practices (cGMPs) regulations are enforced by the FDA to ensure quality standards for human pharmaceuticals

- assures the identity, strength, quality, and purity of drug products
- Quality control
  - Quality raw materials,
  - calibrated equipment,
  - good procedures
- Quality assurance
  - Testing of samples

Section 351 of the Public Health Safety Act regulates the licensing of biologic products including most stem-cell based products.

- Covers cells or tissues that
  - "are highly processed,
  - are used for other than their normal function,
  - are combined with non-tissue components, or
  - are used for metabolic purposes"
- Requires Investigational New Drug Application before human studies begin

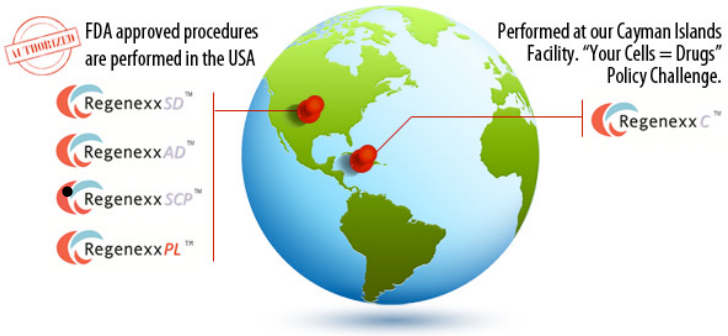
Regenexx is a U.S. company that uses a patient's own stem cells for treatment.

- bone marrow biopsy combined with blood
- cells are processed
- injected into the region of the body needing repair.
  - joints, bone, tendon, ligaments

The FDA "Your Cells = Drugs" Policy prohibits the culturing of a patients stem cells prior to implantation

- Regenex position
  - your cells
- FDA position
  - regulate chemical drugs
  - altered cells and chemicals they produce are subject to regulation

The challenged procedure is only conducted at the Cayman Islands Facility.



Assignment

FDA - Watch dog or Pitbull?

The Food and Drug Administrations primary role in monitoring and regulating drugs is to protect the public health from unsafe and/or unproven treatments. The FDA is in a precarious position between the developers of innovative treatments and physicians and patients seeking the most effective cures. The FDA is viewed as to lax when safety concerns develop with a previously approved medication, but too stringent when the need for additional safety and effectiveness data that is being slowly collected in clinical studies results in the delay in approval of a new drug. The knowledge of stem cell science and claims of miraculous stem cell cures race ahead of data from clinical trials, leaving the FDA to navigate through conflicting interests.

In your discussion group:
Review the articles on the court challenge between Regenexx and the FDA and the discuss with your small group, what criteria should the FDA use in determining whether or not to approve stem cell therapies.

Readings

Halme D.G., Kessler, D.A. (2006). FDA Regulation of Stem-Cell-Based Therapies. New England Journal of Medicine, 354:1730-1735.
http://www.nejm.org/doi/full/10.1056/NEJMhpr063086

Stem Cells and the Lawsuit That May Shape Our Medical Future
http://www.forbes.com/sites/gerganakoleva/2012/02/10/stem-cells-and-the-lawsuit-that-may-shape-our-medical-future/

Stem Cells, FDA, and the Edge of Science: Three Expert Viewpoints
http://www.forbes.com/sites/gerganakoleva/2012/02/19/stem-cells-fda-and-the-edge-of-science-three-expert-viewpoints/

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Any Questions?

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http://www.vippitbullkennels.com/images/animated-question-mark.gif