Assuring the Future of Federally-Funded Embryonic Stem Cell Research

Gregory Saggio, D.O.
Health Policy Fellow 2012-2013
Framing The Issue

President Obama issued **Removing Barriers to Responsible Scientific Research Involving Human Stem Cells in March 2009** (Executive Order 13505)

- Changes the way National Institutes of Health (NIH) can support and conduct human embryonic stem cell research by **lifting the federal ban on funding**

- This immediately put the legal, scientific, and religious communities on a collision course

Sherley vs. Sebelius

- Dr. Sherley and associates - Massachusetts scientists doing research using adult stem cells

-Filed a law suit based on the Dickey-Wicker Amendment in response to the President’s executive order

-Argued that approving additional federal funding for human embryonic stem cell research would unfairly limit their own access to federal funds for adult stem cell research
Dickey-Wicker Amendment

• Since 1996, the Dickey-Wicker Amendment restricts the use of federal funds for creating, destroying, or knowingly injuring human embryos.

• This Amendment has been included in annual appropriations legislation with largely the same language and purpose and remains in effect to the present day.
  - attached to the appropriations bills for the Departments of Health and Human Services, Labor, and Education.

Background: Timeline

1970s: In Vitro Fertilization: Test Tube Baby

Jimmy Carter created the Ethics Advisory Board to create guidelines on human embryonic stem cell research

1980s: The Ethics Advisory Board’s charter expired- created a moratorium on federal funding under Reagan and Bush 1

1993: Federal funding for research using tissue from miscarried/aborted fetuses donated with mother’s consent and embryos created by IVF

1995: In direct response, under Republican control of the House and the Senate, the Dickey-Wicker Amendment was passed

2001: President George W Bush made federal funds available to support research using already existing stem cell lines.


Anderson, J. B. Stem Cells: A Political History. First Things. 11/2008

Since President Obama’s executive order and the Sherley vs Sebelius suit, there have been three years of legal battles and appeals.

Current law allows the federal government to fund research using embryonic stem cells derived from leftover embryos from In-vitro fertilization (IVF) procedures and embryonic stem cell lines already approved. It does, however, preclude the creation of embryos for the purpose of research.
Types of Stem Cells

- Adult Stem Cells (ASC) - Already differentiated into specific cell types
  - Marrow transplant

- Embryonic Stem Cells (ESC) - Pluripotent – can turn into any type of tissue but there are ethical dilemmas

- Induced Pluripotent Stem Cells (iPSC) - use Adult cells genetically engineered to become pluripotent
  - Avoids ethical dilemma

Why Does it Matter?

- United States- clear leader in scientific research worldwide due to governmental funding

- 1999 to 2008 ~ three million, or 31.8% of the 9.4 million scientific journal articles originated from researchers based in the United States (as indexed by Thomson Reuters)

- U.S. economy- more than $400 billion spent on scientific research and development in the 2010 - Federal Gov’t contributed more than $147 billion

- The NIH spends more than $30.7 billion and supports more than 50,000 grants

- NIH plans to provide $562 million for human embryonic stem cell research during the years of the Obama administration (large percentage being spent over last 3-4 years)

Diseases Potentially Treatable or Curable Using hESC

- Diabetes
- Heart Disease / Heart Failure
- Alzheimer's Disease/ Dementia
- Lung Disease
- Kidney Disease
- Neurological Diseases/ Spinal Cord Injuries
- Hematological Diseases
- Cancers
Cost of Disease to U.S. Healthcare

- **$245 billion**: American Diabetes Association (2012)
- **$444 billion**: American Heart Association/CDC (2010)
  - Heart Failure – $244 per year for every taxpayer by 2030
  - $70 billion by 2030
- **$200 billion**: Alz.org- Alzheimer’s/dementia (2012)
- **$35-$40 billion**: National Institutes of Health on End Stage Renal Disease

## Stakeholders

<table>
<thead>
<tr>
<th>Proponents</th>
<th>Opponents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Michael J. Fox Foundation</td>
<td>• Catholic Church</td>
</tr>
<tr>
<td>• American Medical Association</td>
<td>• National Right To Life</td>
</tr>
<tr>
<td>• American Osteopathic Association</td>
<td>• Heritage Foundation</td>
</tr>
<tr>
<td>• American Diabetes Association</td>
<td>• Do No Harm</td>
</tr>
<tr>
<td>• American Hospital Association</td>
<td>• Americans Unite for Life</td>
</tr>
<tr>
<td>• Alzheimer’s Society</td>
<td></td>
</tr>
<tr>
<td>• American Cancer Society</td>
<td></td>
</tr>
</tbody>
</table>
Ethics

- Need to destroy embryo to obtain cells?
- Should an embryo be granted personhood?
- Embryo (and even the fetus) as a ‘non-person’ – real but relatively low moral value?
- Informed consent procedures
- Intellectual property rights
- Compensation for cell donation

Conclusion

- Early 2013 SCOTUS decided not to hear the Sherley appeal.

- Regardless, the Dickey-Wicker amendment should be repealed to assure the legal ambiguity surrounding this topic is removed.

- Repealing the amendment could prevent any future legal actions and federally-supported scientific research could proceed unabated.
Conclusion

• Make funding decisions based on strong scientific evidence while respecting views based on values and ethical concerns so that researchers can pursue future treatments and cures for devastating diseases
Thank You