Stem cell research
Evolving policy for a new science

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November 17, 2010

A Tale of Two Women

Louise Brown
Photo: Daily Mail

Baroness Mary Warnock
Photo: The Telegraph

Warnock Report

- **1978** Louise Brown, the world's first "test-tube baby," is born in England, thanks to Robert Edwards and Patrick Steptoe.
- **1985** "The Report of the Committee of Inquiry into human fertilisation and embryology" (Warnock Report) is published in Great Britain. Explores the implications of human reproductive technologies such as IVF.
- **1990** The Warnock Report leads to Parliament establishing the Human Fertilisation and Embryology Authority (HFEA), a body accountable to the Department of Health that regulates all UK clinics providing reproductive technology services.
- **2002** The HFEA issues first licenses for human embryonic stem cell research in Britain using surplus embryos from IVF treatments.

Fertility Treatment in the U.S.

- **1981** Elizabeth Jordan Carr, America's first "test-tube baby," is born.
- Because of Congressional concerns over Roe v. Wade, IVF and infertility research in the U.S. have taken place in the largely unregulated private sector.
- **2003** The SART-RAND study estimates 400,000 surplus embryos in U.S. fertility clinics.
- **2004** The President's Council on Bioethics issues a report calling for tighter regulation of assisted reproduction.

The Clinton Years

- **1993** HHS Secretary Donna Shalala lifts the moratorium on federal funding of human embryo research in accordance with President Bill Clinton's executive order.
- **1994** A National Institutes of Health human embryo research panel supports the research but thousands of letters urge President Clinton to reverse his earlier decision. He agrees. Federal funding of embryo research is stopped.

Source: Center for American Progress

The Clinton Years
Dickey-Wicker Amendment

- **1995** Congress bans the federal funding for research on embryos through the Dickey-Wicker Amendment.

The amendment prohibits the use of federal funds for "the creation of a human embryo or embryos for research purposes; or 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*…."

Source: Center for American Progress

The Clinton Years

- **1998** University of Wisconsin scientist James Thomson isolates human embryonic stem cells and shows their remarkable potential to rejuvenate and to specialize into tissues.
- **1999-2000** The NIH develops guidelines for funding human embryonic stem cell research, but presidential candidate George W. Bush declares his opposition to the research in a campaign speech so NIH remains cautious about entertaining funding proposals until after the presidential election.

Source: Center for American Progress

The Bush Years

- **August 2001** President George W. Bush prohibits the federal funding of any research using stem cell lines derived after August 9, 2001. The president claims that more than 60 stem cell lines are available for funding.
- **November 2001** President Bush issues an executive order creating the President's Council on Bioethics and appoints conservative Leon Kass to lead it.
- **2006 & 2007** President Bush vetoes the Stem Cell Research Enhancement Act passed by Congress. The proposed legislation would have allowed research on more human embryonic stem cell lines to be eligible for federal funding.

Source: Center for American Progress

Obama Changes the Policy

- **March 2009** President Obama issues an executive order lifting the Bush administration's strict limits on human embryonic stem cell research, charging the NIH with issuing new research guidelines in 120 days.
- **July 2009** The NIH issues guidelines expanding the number of stem cell lines eligible for federal funding, specifically lines created privately from unused embryos donated by fertility clinics with consent of the donors.

Suddenly, Last Summer

- **August 2010** Federal District Court Judge Royce Lamberth issues an injunction blocking President Obama's Executive Order arguing that it violates the Dickey-Wicker Amendment. [Sherley v. Sebelius]
- **September 2010** The U.S. Court of Appeals for the District of Columbia grants a temporary override of Judge Lamberth's injunction while it reviews his decision.

Global Policy in 2003

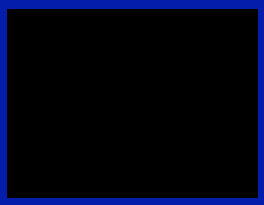
Global Policy in 2007

Map used on the Senate floor by Senator Jeff Bingaman (D -NM) during debate over the Stem Cell Research Enhancement Act, April 2007

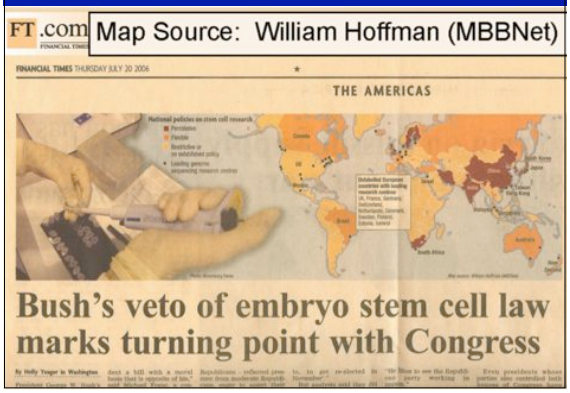
Global Policy in 2007

Senator Jeff Bingaman (D -NM) during debate over the Stem Cell Research Enhancement Act, April 2007

U.S. Senate
April 11, 2007

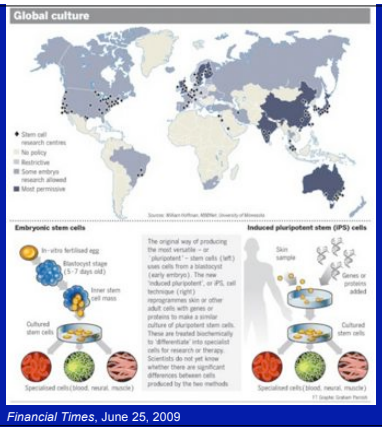


Human Embryonic Stem Cell Policy: *Financial Times*



Global Policy in 2009

Map reflects changes in U.S. policy as a result of President Obama's Executive Order and new NIH guidelines



Financial Times, June 25, 2009

Global Policy in 2009

- Countries with a permissive policy permit research on stem cell lines derived from human embryos donated from fertility (IVF) clinics plus other techniques for deriving stem cells (eg. nuclear transfer / research cloning).
- Countries with a flexible policy permit research on stem cell lines derived from human embryos donated from fertility (IVF) clinics.
- In countries with a restrictive policy human embryonic stem cell research is either prohibited, not explicitly permitted with existing stem cell lines, or permitted with existing lines but not through the derivation of new lines.

Global Policy in 2009

Permissive	Flexible	Restrictive
Australia	Brazil, Canada,	Austria
Belgium	Czech Republic,	Germany
China	Denmark, Estonia,	Ireland
Finland	France, Greece,	Italy
India	Hungary, Iceland,	Lithuania
Israel	Iran, Latvia,	Norway
Japan	Netherlands,	Poland
Singapore	New Zealand,	Slovakia
South Korea	Portugal, Russia,	
Sweden	Slovenia,	
United Kingdom	South Africa, Spain,	
	Switzerland,	
	Taiwan, Thailand,	
	Turkey, Ukraine,	
	United States	

United Nations

- 2005 The UN adopts a Declaration on Human Cloning by which member states were called on to adopt all measures necessary to "prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."

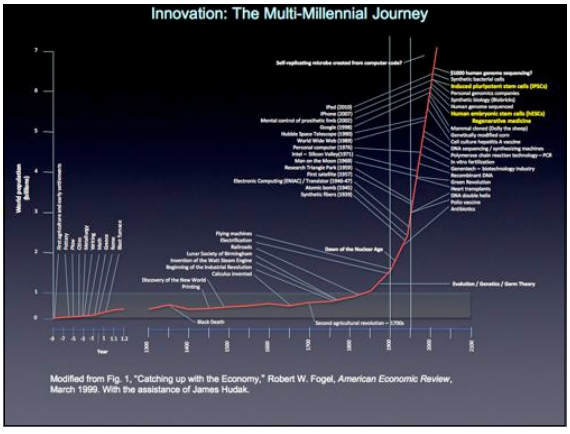
Several member countries including China, Belgium, South Korea and the UK said they would abide by the prohibition of human reproductive cloning but not therapeutic or research cloning.

Clinical Studies
Human Embryonic Stem Cells

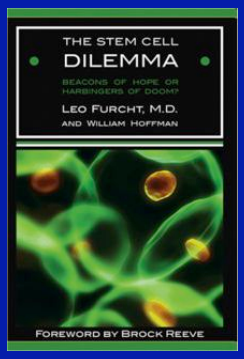
- January 2009 Geron Corp. receives FDA clearance to begin world's first human clinical trial of human embryonic stem cell-based therapy.
- August 2009 Geron's IND for spinal cord injury placed on hold by the FDA because of a high frequency of tiny nonproliferative cysts found at the injury site in animal studies.
- July 2010 FDA lifts hold on Geron trial.
- October 2010 Geron enrolls first patient.
- November 2010 In UK ReNeuron launches trial for stroke.
- Soon Researchers at UCL / USC preparing to test hESC-based treatment for age-related macular degeneration.

Geron's David Earp
Stem Cells Asia 2010

- Manufacturing – flask-based process ~ 10^{10} cell / lot
- Cells removed from mouse feeders in 1999
- Remyelination capacity of GNOPC1 established in 2002
- 10^6 – 10^9 cells / dose needed for therapies
- Engineering path to 10^{14} underway
- 2100 rodents (1100 injected with GNOPC1)
- 6 x 10^9 GNOPC1 cells used in rodent studies
- Partnerships with Corning (Synthemax) and GE Healthcare (cardiomyocyte product)
- Shift of emphasis from biology to manufacturing



Books



Arcade Publishing, 2008; 2nd ed. 2011