

Beyond Bioethics:  
A Proposal for Modernizing  
the Regulation of Human Biotechnologies

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March 2, 2007

# The Human Biotechnology Governance Project: Overview

- ❖ Washington, DC-based study group
  - ◆ 39 Members
  - ◆ 11 Presentations
  - ◆ Representatives of BIO, ASRM, FASEB, AAAS, President's Council on Bioethics, etc.
- ❖ Study group members not asked to endorse the final proposal
- ❖ Final report available at <http://www.biotechgov.org/FnLrPrT.php>

# Briefing Outline

## ❖ Overview

- ◆ Making the case
- ◆ Recent developments
- ◆ Domain of inquiry
- ◆ Regulation: general considerations

## ❖ Guiding principles

## ❖ What a new institution might look like

- ◆ Independent agency
- ◆ New mechanisms for public consultation

# Making the Case

“I was born with a grave congenital malformation. I was very lucky though, I had extremely supportive and loving parents. They did everything in their power to give me a fair chance at a good life.

Some advocates for the disabled claim that to support preimplantation genetic diagnosis (PGD) is to show contempt for their condition.

I believe it is exactly the opposite. It is precisely because some of these diseases are so burdensome and so debilitating, and because being affected by these diseases is such a terrible accident, that parents should carefully consider, in particularly debilitating cases, the possibility of not having children.”

## Making the Case - cont.

I am certainly not denying that PGD entails eugenic risks. These risks are grave. They demand that all necessary precautions be taken. But I beg you, in the name of all the children that, like myself, would have preferred, if they had the choice, not to have been born rather than entering life with a heavily debilitating condition, to lift the ban on preimplantation genetic diagnosis.

Luc Recordon, member of the Swiss Parliament, June 2005

# Recent Developments

## ❖ Embryo screening

- ◆ “Better Than Sex. The growing practice of embryo eugenics” (Slate 16/9/2006)
- ◆ UK parents seeking perfect babies (London Telegraph 21/5/2006; London Sunday Times 28/5/2006)

## ❖ Sex selection

- ◆ “Increasingly, couples use embryo screening” (The Washington Post 21/9/2006)
- ◆ “9% of clinics choosing baby's sex” (Chicago Sun-Times 21/9/2006)

## ❖ Screening for disabilities

- ◆ Some disabled parents use IVF to create disabled children (BioEdge 12/12/2006)

# Recent Developments - cont.

## ❖ Trade of human embryos:

- ◆ “The Embryo Factory. The business logic of made-to-order babies” (Slate 15/1/2007)
- ◆ “Ethical row over the first ‘made-to-order’ embryos” (Daily Mail 4/8/2006)

## ❖ Commercialization of reproductive tissues:

- ◆ Payment to egg donors ‘justified’ (London Times 10/8/2006)
- ◆ “Ethicists and biologists ponder the price of eggs” (Nature News 9/8/2006)
- ◆ “Women will be paid to donate eggs for science” (The Observer 18/2/2006)
- ◆ “Woman sells her eggs on net to pay off £15,000 credit card debts” (Daily Mail 2/11/2006)

## Recent Developments - cont.

### ❖ Sperm production:

- ◆ “Mice born from stem-cell sperm” (Nature News 13/7/2006)
- ◆ “Stem cells turned into sperm” (New Scientist 11/7/2006)
- ◆ “ ‘Lab-made sperm’ fertility hope” (BBC News Online 10/7/2006)

### ❖ Human-animal hybrids:

- ◆ “Stem cell experts seek license to create human-rabbit embryo” (The Guardian 5/10/2006)
- ◆ “Debate rages over animal-human chimeras” (New Scientist 11/8/2006)
- ◆ “Scientists to create ‘frankenbunny’ in big research leap” (The Evening Standard 5/10/2006)

# Domain of Inquiry

- ❖ Assisted Reproductive Technologies (ART)
  - ◆ Standard reproductive procedures, e.g. IVF
  - ◆ Innovative reproductive treatments (ooplasm transfer, co-culture)
  - ◆ Technologies of reproductive customization (sex-selection technologies such as MicroSort, PGD)
- ❖ Research involving human reproductive tissues (human embryos, oocytes, sperm)
  - ◆ fertility research, developmental biology
  - ◆ Embryonic stem cells research

# Embryo Politics

- ❖ All regulatory efforts complicated by embryo/abortion politics in US
- ❖ Our beginning point: intermediate moral status of embryos
  - ◆ Implies that embryo and stem cell research are legitimate
  - ◆ But regulation is required

# Regulation: General Considerations

- ❖ Cautious approach to regulation
  - ◆ Whatever you regulate, you get less of
  - ◆ Do not want to stifle innovation and growth
  - ◆ Burden of proof ought to be on those calling for new regulation
- ❖ Regulation as facilitator of innovation
  - ◆ Example of British HFEA
- ❖ Analogy: ICC, trucking, railroads, and airlines

# Regulation: General Considerations - cont.

## ❖ Pros:

- ◆ New regulatory powers necessary to deal with future issues
- ◆ Regulatory agency has both resources and expertise to properly address new ethical dilemmas
- ◆ Stable and predictable regulatory environment

## ❖ Cons:

- ◆ Additional administrative costs
- ◆ Opportunity costs to ART sector and research enterprise
- ◆ Precedent for federal regulation of a practice of medicine

# Regulatory Architecture

- ❖ Regulation must be based on a view of the ends that biomedicine should serve
- ❖ Regulatory interventions guided by ethical principles
- ❖ Activities to be prohibited
- ❖ Activities to be regulated

# Ethical Principles

- ❖ Regulation should promote:
  - ◆ Well-being and health of children
  - ◆ Equal access to ART on the part of infertile couples
  - ◆ Well-being and health of women
  - ◆ Therapeutic over enhancement uses of biomedicine
- ❖ Free and informed consent
- ❖ Regulation should limit the commercialization of human reproductive tissues

# Targets of Prohibition

- ❖ Practices potentially banned:
  - ◆ Reproductive cloning
  - ◆ Creation of certain forms of human-animal chimeras and hybrids
  - ◆ Germ-line modification
  - ◆ New reproductive possibilities that alter the biological relationship of parents and children
  - ◆ Patenting of human embryos

# Targets of Regulation

- ❖ Practices potentially regulated:
  - ◆ Somatic cell nuclear transfer (“research cloning”)
  - ◆ Pre-implantation genetic diagnosis
  - ◆ Sex selection technologies
  - ◆ Stem cell research
  - ◆ Commercialization of elements of human reproduction
- ❖ More generally:
  - ◆ Innovative reproductive procedures
  - ◆ Technologies of reproductive customization
  - ◆ Biomedical research involving reproductive tissues

# Design Considerations

- ❖ Inspired by British/Canadian approach, but
  - ◆ Specific provisions to avoid agency capture/polarization
    - ◇ By industry insiders
    - ◇ single-issue interest groups
- ❖ The Public is ambivalent about many scientific developments
  - ◆ Not nearly as divided as interest groups
  - ◆ By engaging general public broadly acceptable political solutions likely to emerge
- ❖ Our Approach
  - ◆ Regulatory authority given to an independent agency
  - ◆ Independent agency run by a commission
  - ◆ Commission depends on permanent expert panel for advice
  - ◆ Agency draws on novel mechanisms for public consultation

# Public Attitudes towards hESC Research and Research Cloning

## ❖ hESC Research:

- ◆ User of supernumerary embryos acceptable
- ◆ Creation of human embryos for research purposes unacceptable

## ❖ Research Cloning:

- ◆ “Neutral” formulations: 2 to 1 opposition
- ◆ If question mentions only benefits: support increases, but public remains divided
- ◆ If question mentions only destruction of the embryo: 80% opposed
- ◆ If question mentions both benefits and destruction of the embryo: rejection by a 2 to 1 margin

# Public Attitudes - hESC Research

“Should supernumerary embryos be used in medical research?”

<i>2001</i>	<i>Support</i>	<i>Oppose</i>	<i>Q#</i>	<i>Intensity</i>
Harris Poll 1	61	21	81	++
Harris Poll 2	72	21	82	++
CNN/USA Today/Gallup Poll 1	55	40	83	+
Ipsos-Reid	75	20	84	++
CNN/USA Today/Gallup Poll 2	55	39	86	+
Washington Post/ABC News	63	33	87	++
Gallup Poll	77	18	88	++

<i>2004</i>	<i>Support</i>	<i>Oppose</i>	<i>Q#</i>	<i>Intensity</i>
Harris 1	72	13	58	++
Opinion Research Corporation	73	24	59	++
Harris 2	73	11	96	++
Juvenile Diabetes Foundation 1	44	46	90	~
Juvenile Diabetes Foundation 2	56	36	89	+

# Research Cloning

<i>Neutral formulation:</i>	<i>Favor</i>	<i>Oppose</i>	<i>Intensity</i>
NBC News, 1999, N=2011 (37)	48	47	~
Portrait of America, August 23 2000, N=1000 (38)	24	64	- -
<i>Research benefits:</i>			
Los Angeles Times, October 20 2002, N=1854 (35)	24	63	- -
Roy Morgan Research, July 24 2001 (36)	40	41	~
Portrait of America, August 23 2000, N=1000 (40)	33	48	-
Virginia Commonwealth Univ., Sep. 2003, N=1003 (44)	49	48	~
Virginia Commonwealth Univ., Sep. 2002, N=1000 (45)	45	51	~
<i>Research benefits &amp; Destruction of embryos:</i>			
Gallup Poll, August 2001, N=1017 (30)	28	66	- -

# Making Agencies Independent, Ensuring Legitimacy

- ❖ Independent agencies
  - ◆ Independent commissioners
  - ◆ Appointment terms and voting rules
- ❖ Mechanisms for public consultation
  - ◆ Notice-and-comment
  - ◆ Public hearings
  - ◆ Consensus conferences, citizens panels
- ❖ Precedents at a federal level

# Problem of Interest Group Capture and Polarization

- ❖ Need public consultation as antidote against interest group distortions
- ❖ Who should be consulted?
  - ◆ Representative random sample of the general public
- ❖ Informed public opinion
- ❖ Is scientific literacy a problem?
- ❖ Deliberation: vehicle of consensus or catalyst of polarization?

# A Proposal for a New Agency

- ❖ Structured as Independent Agency
  - ◆ Appointment rules require political balance
  - ◆ Independent commissioners
- ❖ Public consultation mechanisms
  - ◆ Deliberative Panels (face-to-face deliberation)
  - ◆ Consultative College (online based system)
- ❖ Feasibility
  - ◆ Precedents exist
  - ◆ Inexpensive, if costs of litigation, legal uncertainty and delays are considered