

Beyond Bioethics: New Approaches to the Governance of Human Biotechnology

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The Human Biotechnology Governance Project: Overview

- Formed Washington, DC-based study group
 - 39 Members
 - 11 Presentations
 - Representatives of BIO, ASRM, FASEB, AAAS, Presidents Council on Bioethics, more
- Study group members not asked to endorse final proposal

Briefing Outline I

- Overview
 - Domain of inquiry
 - Regulation: General Considerations
- Sources of concern and guiding principles
- The current legislative and regulatory framework
- Regulation in other developed countries

Briefing Outline II

- Pros and Cons of Alternative Approaches
- What a new institution might look like
 - Independent agency
 - New mechanisms for public participation
- Constitutional constraints
- International considerations

Domain of Inquiry

- Technologies and medical practices related to human reproduction
- Practice of medicine
 - Artificial reproductive technologies
- Research
 - Stem cells, research cloning
- Includes:
 - PGD, reproductive & research cloning, germ-line, novel forms of reproduction

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 should be done under regulatory framework

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

Sources of Concern

- Regulation must be based on a view of the ends that biomedicine should serve
- Statement of principles
- Activities to be prohibited
- Activities to be regulated

General 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
 - Free and informed consent
 - Limits to commercialization
 - Therapeutic over enhancement uses of biomedicine

Targets of Prohibition

- Practices potentially banned:
 - Reproductive cloning
 - Creation of 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:
 - Research cloning
 - Pre-natal genetic screening and selection of embryos
 - Biomedical research involving early-stage embryos/blastocysts
 - Sex selection
 - Commercialization of elements of human reproduction

The Current US Legislative and Regulatory Framework

- Federal regulators
 - Food and Drug Administration
 - National Institutes of Health
 - CDC
- State regulators
- Self-regulation
- Direct legislative intervention

Federal Regulators

- Food and Drug Administration
 - Gold standard for pharmaceutical regulation
 - Regulates only drugs, medical devices & biologics
 - Regulation only on basis of safety and efficacy
 - Does not regulate the practice of medicine
 - Does not control the off-label uses of drugs
- National Institutes of Health
 - Can include ethical considerations as basis for funding
 - Can regulate only through funding decisions

Federal Legislation Relevant to Assisted Reproduction

- Regulation of Reproductive Medicine
 - The Fertility Clinic Success Rate & Certification Act 1992 (FCSRCA)
 - Establishes model program for inspection and certification of labs, as yet unimplemented
- Regulation of Research
 - IRBs and human subject protection
 - Common rule not broad enough in definition of risks
 - Regulation via control of federal funding of embryo research prevented by Dickey-Wicker amendment

Regulation by States

- States are primary regulators of the practice of medicine
 - Includes licensure of physicians, facilities, hospital credentialing, board certification, DEA registration, etc.
 - Rules not specific to ART
- Cloning bills
 - Arkansas, Iowa, North Dakota, South Dakota and Michigan ban both types of cloning
 - California and New Jersey explicitly permit research cloning
 - Former model legislation overturned by Proposition 71
 - All are very narrowly written

Direct legislative intervention

- 40+ cloning bills introduced after 2001
- Senate Bill S303
 - Prohibits reproductive cloning, permits research cloning
 - Silent on other issues (PGD, germ-line, hybrids, etc.)
 - Inadequate controls via IRBs
 - Implies vastly less oversight than British HFEA

Self-Regulation

- Associations promulgating guidelines
 - American Society for Reproductive Medicine (ASRM)
 - Society for Assisted Reproductive Technologies (SART)
- Regulation largely hortatory
 - Limited ability to monitor and enforce compliance with rule

ART Regulation – UK

- Human Fertilisation and Embryology Act, 1990
- HFEA:
 - Established the Human Fertilisation and Embryology Authority (HFEA)
 - Scope: private and public clinics and laboratories
 - Licensing scheme for treatment services, storage of gametes and embryos, embryo research
 - Violation of Act is a criminal offense

The HFE Authority

- 17 members
- Term of 3 years (renewable once)
- Must be women and men
- Expert and “lay” – lay must be the majority
- Must be predominantly non-scientists and non-clinicians
- Positions advertised – civil servants select
- Appointed by Minister for Health
- Accountable to Parliament through Minister for Health

ART Regulation – Canada

- Assisted Human Reproduction Act of 2004 (AHRA)
- AHRA:
 - Establishes the AHR Agency
 - Includes guiding principles
 - Prohibits unacceptable practices (i.e. reproductive cloning)
 - Regulates treatment, storage and research on human embryos through licensing
 - Regulates public and private research
 - Regulates trade of human gametes & surrogacy

Britain vs. Canada

- Britain:
 - HFE Authority
 - Reproductive cloning prohibited
 - Research cloning allowed (regulated)
 - hESC regulated
- Canada:
 - AHR Agency
 - Reproductive cloning prohibited
 - Research Cloning prohibited
 - hESC regulated

Other Legislative Initiatives

	<i>New Regulatory Authority</i>	<i>Reproductive Cloning</i>	<i>Research Cloning</i>	<i>PGD</i>
Canada	Yes	Prohib.	Prohib.	Legisl.
Australia	Yes	Prohib.	3 y. morat.	Prohib.
Germany	No	Prohib.	Prohib.	Prohib.
UK	Yes	Prohib.	Regulated	Leg/reg.
France	Yes	Prohib.	Prohib.	Leg/Reg.
Italy	No	Prohib.	Prohib.	Prohib.
Spain	No	Prohib.	Prohib.	Legisl./Reg.
Sweden	No	Prohib.	Legal	Legisl.
Japan	No	Prohib.	Legal	Unreg.
China	No	Prohib.	Legal	Legisl.
Singapore	No	Prohib.	Legal	Unreg.
S. Korea	No	Prohib.	Legal	Legis./reg.
US	No	No (de facto)	Unreg.	Unreg.

Pros and Cons of Alternative Approaches

- Maintaining/augmenting the status quo
- Direct legislative intervention
- Self-regulation
- Creating a new regulatory authority

Using Existing Statutory Powers

- Pros:
 - Avoids direct and indirect costs of regulation
 - Existing statutes can be modified to address concerns
- Cons:
 - Major gaps in existing regulatory powers
 - Novel uses of powers subject to court challenges
 - Inadequate public participation
 - Hard to change bureaucratic culture

Direct Legislative Intervention

- Pros:
 - Congress can speak most authoritatively
 - The most important ethical choices cannot be delegated
 - E.g., questions regarding moral status of embryos
- Cons:
 - Congress does not have time or knowledge to legislate on most issues
 - Specific legislation lacks flexibility
 - S 303 doesn't have adequate provisions for regulatory oversight of hESC research
 - Prop 71 is even worse

Self-Regulation

- Pros:
 - ART practice has elaborate system of self-regulation in place
 - Self-regulation is inherently flexible
 - Record to date is unclear; inadequate data
- Cons:
 - Self-regulation often fails for lack of incentives
 - Limited monitoring capabilities
 - Limited enforcement capabilities
 - Self-regulation most effective in conjunction with formal regulation

Creating a New Regulatory Authority

- Pros:
 - New powers necessary to deal with future issues
 - New approach needed to avoid interest group capture/deadlock
- Cons:
 - Potential costs, both direct and indirect
 - Precedent for regulating a practice of medicine

A New Institution: General Design Considerations

- Modeled on British/Canadian authorities
- Need to avoid agency capture/polarization
 - By industry insiders or single-issue interest groups
- Rationale: Public not as divided as interest groups
 - Need to engage general public not represented by interest groups
- Our Approach
 - Statutory powers given to an independent agency
 - Commission draws on new mechanisms for public participation

Interest Group Capture and Deadlock

- Current impasse over cloning represents a political failure
 - Public not nearly as polarized as active interest groups
- Public Attitudes – 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 excess 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	+

Making Agencies Independent and Representative

- Independent agencies
 - Appointment terms and voting rules
 - Use of independent commissioners
- 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 participation as buffer against interest group polarization
- Who should be consulted?
 - Stakeholders and interest groups
- The problem of scientific literacy
- 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 participation mechanisms
 - Deliberative Panels (+surveys)
 - Consultative College

Constitutional Constraints

- No rulings specifically on procreative rights
- Several rulings related to procreative capacity, use of contraceptives, abortion, marriage, right to rear and educate children.
- Court likely to recognize a right to “traditional” forms of procreation
- Court likely to rule on narrow grounds.
- The more “innovative” the case, the less likely is the Court to “discover” a new fundamental right.

International Considerations

- U.N. treaty is a blunt and inflexible tool
- Criminalization of certain practices is an excessive measure
- Incremental approach through strengthening of international bodies such – possibly – the International Association of Stem Cell Research and other groups.
- Harmonization of domestic legislation not yet necessary.

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 & Destruction of embryos:</i>			
Gallup Poll, August 2001, N=1017 (30)	28	66	--