Beyond Bioethics: New Approaches to the Governance of Human Biotechnology

Francis Fukuyama and Franco Furger
Johns Hopkins University
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

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

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

<table>
<thead>
<tr>
<th>2004</th>
<th>Support</th>
<th>Oppose</th>
<th>Q#</th>
<th>Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harris 1</td>
<td>72</td>
<td>13</td>
<td>58</td>
<td>++</td>
</tr>
<tr>
<td>Opinion Research Corporation</td>
<td>73</td>
<td>24</td>
<td>59</td>
<td>++</td>
</tr>
<tr>
<td>Harris 2</td>
<td>73</td>
<td>11</td>
<td>96</td>
<td>++</td>
</tr>
<tr>
<td>Juvenile Diabetes Foundation 1</td>
<td>44</td>
<td>46</td>
<td>90</td>
<td>~</td>
</tr>
<tr>
<td>Juvenile Diabetes Foundation 2</td>
<td>56</td>
<td>36</td>
<td>89</td>
<td>+</td>
</tr>
</tbody>
</table>
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 as possibly the International Association of Stem Cell Research and other groups.
- Harmonization of domestic legislation not yet necessary.
## Research Cloning

<table>
<thead>
<tr>
<th>Neutral formulation:</th>
<th>Favor</th>
<th>Oppose</th>
<th>Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>NBC News, 1999, N=2011 (37)</td>
<td>48</td>
<td>47</td>
<td>~</td>
</tr>
<tr>
<td>Portrait of America, August 23 2000, N=1000 (38)</td>
<td>24</td>
<td>64</td>
<td>- -</td>
</tr>
</tbody>
</table>

Research benefits:

<table>
<thead>
<tr>
<th>Research benefits:</th>
<th>Favor</th>
<th>Oppose</th>
<th>Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Los Angeles Times, October 20 2002, N=1854 (35)</td>
<td>24</td>
<td>63</td>
<td>- -</td>
</tr>
<tr>
<td>Roy Morgan Research, July 24 2001 (36)</td>
<td>40</td>
<td>41</td>
<td>~</td>
</tr>
<tr>
<td>Portrait of America, August 23 2000, N=1000 (40)</td>
<td>33</td>
<td>48</td>
<td>- -</td>
</tr>
<tr>
<td>Virginia Commonwealth Univ., Sep. 2003, N=1003 (44)</td>
<td>49</td>
<td>48</td>
<td>~</td>
</tr>
<tr>
<td>Virginia Commonwealth Univ., Sep. 2002, N=1000 (45)</td>
<td>45</td>
<td>51</td>
<td>~</td>
</tr>
</tbody>
</table>

Research benefits & Destruction of embryos:

<table>
<thead>
<tr>
<th>Research benefits &amp; Destruction of embryos:</th>
<th>Favor</th>
<th>Oppose</th>
<th>Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gallup Poll, August 2001, N=1017 (30)</td>
<td>28</td>
<td>66</td>
<td>- -</td>
</tr>
</tbody>
</table>