# WWS 586a Biotechnology Policy

Professor Lee M. Silver

Spring Semester, 2004

Class Time: Mondays 7:30-10:30 pm

Class Location: Forbes College Seminar Room (03)

Complete Syllabus with hyperlinked references available at:

**https://web.princeton.edu/sites/lsilver/biotech**

## Topics

1. **Biotechnology** and Society: Overview and History
2. **Microorganisms,** Recombinant DNA and Genomics. Patents
3. **Plants:** Genetic modification of plants -- GMOs and politics
4. **Animals:** Transgenic animals and Xenotransplantation
5. **Somatic cell genetic engineering** (in vivo, ex vivo, enhancement)
6. **Human reproduction** commercialization (surrogacy, gamete selling, IVF, ICSI)
7. **Human embryos**: stems cells and embryo cloning
8. **Reproductive cloning**
9. **Genetic testing** of individual adults or children
10. **Embryo selection** for genetic traits (PGD)
11. **Germline genetic engineering**: therapy and enhancement

## Analysis of individual biotechnologies

(1) What is the science & technology?

(2) What are the commercial application

(3) Who are the suppliers and consumers

(4) What are the potential consequences, both positive and negative

(individual health, societal, ecological, economic, political)

(5) What are the issues under debate and who is debating them (the players)?

(6) What is an appropriate risk-benefit analysis

(7) How should public policy be formulated?

## Policy Considerations

### What are the goals of public policy?

Protection of citizens

Protection of society

Protection of environment

Protection of economic interests

### What factors inform the political debate?

How is biotechnology different than other technologies?

Values, ethics, religion

Risk vs. benefit vs. cost

Individual liberty versus societal values

### Who are the players?

Government, scientists, industry,

Patient groups, animal rights groups

Other NGOs (Jeremy Rifkin et al., Greenpeace)

### Approaches to public policy

Lassiez-faire

Government regulation (laws, funding regulations, discouragement)

Government facilitation (funding, encouragement, provision of access)

### Differences among societies

USA, Europe, Japan,China

# Overview of Biotechnology

**Biotech industry Sites**

- Council for Biotechnology Information
- Checkbiotech (updated news)
- Framing the questions for policy analysis

Public perception of life and biotechnology

- What is biotech (from the industry trade site)
- History of Biotechnology
- Who regulates biotech?

## Conflicting World views

- Process vs. Product in moral arguments
- Greek philosophy and biotechnology
- The Natural Law view: a values-based perspective
- Accidental Release of GM crops: Two views
  - Council for Responsible Genetics
  - Biotechnology
- The Africa situation
- Biotech disaster (tissue transplantation)

## Regulation

- Regulation: Case studies
- How does business call it

## Risk analysis

- The Precautionary Principle
- Another view of the precautionary principle
- ACSH Holiday Dinner

## Supplemental Reading (not required)

- The precautionary principle: economic analysis

## 2. Plants: GMOs and politics.

- Pre-transgenic plant biotechnology
  - The Green Revolution
- Pro-Biotech sites
  - Council for Biotechnology Information (for a general scan only)
  - Statement from the biotech trade organization
  - Greenpeace founder switches sides

- The opposition to GMOs
  - Jeremy Rifkin: The framework for the opposition to GMOs
  - Detailed harms and the claim of no benefits
  - Another anti-GMO Treatise

- Ecological Impacts
  - Richard Lewontin -- a scientist confronts anti-biotech
  - Ecological risk assessment
  - Contamination of Mexican corn (media report)
    - Original scientific paper
  - Doubts about contamination claims
  - Monarch Butterflies (ad campaign)
  - USDA report on Monarch Butterflies and BT crops

- Health impact
  - Starlink and allergies (NY Times report)

- **Plant Biotechnology and the Poor**

- CASE STUDIES
  - Transgenic introgression into Mexican Corn
  - Allergies and Starlink
  - Ecological Effects (Monarch Butterflies)
  - Field Contamination
  - Zambia
- How Americans feel about GMOs
- Politics
  - European policy critique
  - China embraces GMOs
  - Overview of Monsanto's problems
  - Response to overview

- Regulation
  - U.S. regulatory process
  - Country-by-country comparison

- Labeling
  - Health impact: substantial equivalence
  - Anti-biotech labeling advertisement

## 3. Transgenic Animals

### Pharming: using animals as factories

- An overview of the technology (focus on the transgenic animal

section)

- A short analysis of regulatory requirements
- An Example: Cows producing human blood (for reading by scientists, all can skim)

### Modification to increase yield: transgenic fish

- Report from the Pew Foundation
- In context: transgenic fish and traditional aquaculture

### Modification for environmental protection

- Environmentally friendly pigs

### Modification for enriched food

- Designer Milk
- Objections to making cow's milk more human
- Another objection

## Xenotransplantation

- **Science**
  - The virus question: an overview
  - Risk assessment
- **Regulation (Most Important)**
  - Regulatory Framework **(skim)**
  - New U.S. committee

  - International analysis **(skim)**
- **Disputing the precautionary principle**
  - Questioning precaution: A moderate viewQuestioning precaution: A libertarian critique

## Further information (not required reading)

- Scientific American Overview
- Federal guidelines for xenotransplantation
- Analysis of FDA guidelines
- Opposition to xenotransplantation
- Testing for transmission of pig viruses
- Pigs engineered to be less antigenic

## 5. Somatic cell Genetic Engineering = Gene Therapy

- Definitions and UNESCO ethical analysis
- The state of the field as of 2000:
- The first success
- The setback
- Current status of gene therapy in the U.S.
- The strongest stance against gene therapy
- A balanced look at risks and benefits
- Genetic enhancement
- Public opinion

**Further Reading (for your enjoyment only)**

- Promises and Problems
- A call for international regulations
- FDA explanation of gene therapy
- The hemophilia effort and vectors in general

## 6. Commercialization of Human Reproduction

- Remaking Eden chapters provide overview of Assisted Reproductive Technologies (ART)
- Book chapter from Lori Andrews provides a differen perspective
- Editorial on recent articles suggesting that IVF causes a high rate of birth defects

- (For reference only: the original articles (one and two)
- From somatic cells to sperm and eggs (news brief)
- TOPICS TO CONSIDER

1. Should IVF be regulated separately from other medical practices? (It is in the U.K., but not the U.S.)
2. Who should decide what risks are acceptable(the doctor, governmental regulations, or the patients)? Should it be limited to certain types of patients (married, heterosexual, age limit, )?
3. Should commercial surrogacy be regulated, banned, allowed to thrive in the free market?
4. Should human egg selling be regulated, banned, allowed to thrive in the free market (see ad below)? Should it be treated differently than sperm selling?
5. Should unusual reproductive technologies (like ICSI or double-mother children) be banned or treated like other reproductive technologies?

# 7. Human embryos: stems cells and embryo cloning

- The Clinton Bioethics Commission
  - Executive summary report on embryonic stem cells
  - What the polls said
  - **For reference only**:
    - The whole NBAC report (in case you want to see it)
    - NIH discussion & guidelines (year 2000)
- The August 9, 2001 Bush speech on stem cells
  - President's Bush speech on embryonic stem cells
- The Bush Bioethics Commission
  - Executive Summary of report on human embryo cloning
  - A dissenting opinion - Dr. Michael S. Gazzaniga
  - In opposition from the left - Arthur Caplan

- The assent from the left

- The current political scene in Congress
- The cloning prohibition act that includes embryos
- The cloning probibition act that does not include embryos

For Your Reference and Edification Only

- The scientific background
- An excellent NIH Stem cell primer (for those who need it)
- **For further reference only**
  - What are embryonic stem cells?
  - What is the point of therapeutic cloning?
  - Another stem cell primer

- **Political Advocacy Sites**

- Religious Advocacy Site (against stem cells and cloning)
- Coalition for the Advancement of Medicine (for stem cells and cloning)
- Family Research Council (against stem cells and cloning)
- National Right to Life political action request
- Liberals and conservatives united against embryo cloning
- Progressives for embryo cloning
- More from the left in opposition to embryo cloning

- Recent Findings
- Recent stem cell reports

- Other References
- Media musings before the Bush speech

- An analysis of the Bush speech and its ramifications
- The neoconservative view ( The Weekly Standard)

# 7. Reproductive cloning

## Presidential Bioethics Commissions

- The Clinton Bioethics Commission (NBAC) executive summary
- The Bush Bioethics Commmision executive summary section on reproductive cloning

## Current Attempts to make policy

- FDA letter asserting authority to regulate cloning (pdf file)
- FDA commentary on its jurisdiction over cloning
- Brownback bill to outlaw therapeutic and reproductive cloning
- Hatch-Kennedy bill to outlaw reproductive cloning but to allow and encourage therapeutic cloning

## Ethics and Values

- Glenn McGee: A primer
- The Wisdom of Repugnance (by Leon Kass)
- 21 arguments and their counter

## What are the real safety risks today?

- The Health Profie of Cloned animals (pdf)

## Cloning Companies & Individuals

- Clonaid
- Severino Antinori
- Clones-R-Us

## The Scientific Evidence (for molecular biologists)

- Cloning can cause developmental problems (pdf)

- Cloned cattle can be healthy and normal (pdf)
- Imprinting in cloned mice is normal (pdf)

**Additional Information** (for reference only)

- Complete report & transcripts from the Bush Bioethics Commission
- The complete report from the Clinton (NBAC) bioethics commission
- National Academy of Sciences Executive Summary (pdf file)
- A pro-cloning advocacy site
    - A UK survey and cultural analysis of cloning perceptions (pdf file)

## 8. Genetic analysis of individual adults or children

- **Secretary's Advisory Committee on Genetic Testing (SACGT)**
    - Introduction and Summary of Final Report
    - For reference only: the whole report (html file or pdf file)
    - For reference only: more science overview
- The political response to SACGT
- An interesting web site
- Genetic screening by insurance companies (dilemma of adverse selection)
- Genetic testing and pharmacogenomics
- Individual versus community: population database participation
    - DNA fingerprinting: more information than meets the eye

## 9. Embryo selection for genetic traits:

### Preimplantation Genetic Diagnosis (PGD)

- **Overview from Remaking Eden**

- **In favor of parental choice**
  - Pareto analysis
  - Analysis from plurality and liberty
- **In Opposition to PGD**
  - A eugenic objection to PGD
  - A feminist concern with prenatal testing
  - Objections from the Disability Community
  - An argument against consumerism
- **Questions for discussion concerning potential lines of regulation**

1. Should FDA approval be required before a clinic is allowed to use a particular diagnostic protocol on embryos? Alternatively, there could be a requirement for local approval by an Institutional Review Board. A third alternative would leave the decision entirely in the hands of the clinic or physicians.

2. Should approval be based on evidence that a particular genotype will lead to disease in the child or adult-to-be? Should approval be limited to the avoidance of diseases having a certain level of penetrance or a early age of onset? (Huntington Disease and Breast Cancer are normally late onset dieases).

3. Should parents (and their physician proxies) be allowed to select embryos based on characteristics that do not necessarily benefit the child-to-be (e.g. a blood type match for an older sibling)?

4. Should parents be allowed to select for traits that are generally viewed as enhancements?

5. Should parents be allowed to select for traits that are generally viewed by society as diminishments (e.g. deafness)?

6. How might society be affected by liberal access to embryo selection?

# 10. Germline Genetic Engineering

- Highlights from a detailed committee report for the AAAS
  - For reference only - the full report
- Overview of the science & the problem (from your professor's point

of view)

- To see the scientific details of how genetic engineering could be made feasible, click here.

- A pro-GE viewpoint from James Watson
- An anti-GE viewpoint
  - For reference only - another anti-GE treatise
- A different set of policy recommendations
- What does the future hold?
- {For reference only: a comprehensive pro-GE web site with views from both well-known advocates and those who oppose human germline genetic engineering}