

DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria

DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

HC70A Winter 2008
Genetic Engineering in Medicine,
Agriculture, and Law
Professor Bob Goldberg

Lecture 8 (Revised)
Science & The
Constitution:Regulating Science &
Genetic Engineering

TEXT READING

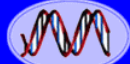
Chapters 12 & 13

SELECTED REFERENCES

1. *Cloning & The Constitution*, By I.H. Carmen (1985)
2. *A Practical Companion To The Constitution*, By J.K. Lieberman (1999)
3. *The Recombinant DNA Controversy: A Memoir*, By D. S. Fredrickson (2001)
4. *Genetics: Ethics, Law, and Policy*, By Lori B. Andrews et al. (2002)
5. *Patent, Copyright, & Trademark*, By S. Elias & R. Stim (2005)
6. *Stem Cell Century*, By Russell Korobkin (2007)
7. *Biotechnology and The Law*, By H.B. Wellons et al. (2007)

THEMES

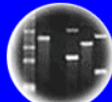
1. Historical Attempts to Regulate Science-The Genetic Engineering Controversy
2. Government of the United States
3. What is in the Constitution About Science-Directly & Indirectly?
4. Can Scientific Inquiry and Research Be Regulated?
5. Can Experimentation Be Regulated Directly?
6. Case Studies in Regulating Science Directly
7. Can Science Be Regulated Indirectly?
8. Regulating Science-A Summary



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



Bonus Point Assignment **Inherit The Wind**

**In One 400 Word Paragraph (12 pt Font,
Single Space)**

**What, Your Opinion, Is the "Take-Home"
Message of "Inherit The Wind" and How Does
It Relate To Science?**

10,000 Bonus Points (Hand In Today)

I Viewed "Inherit The Wind" In Its Entirety

Signature_____

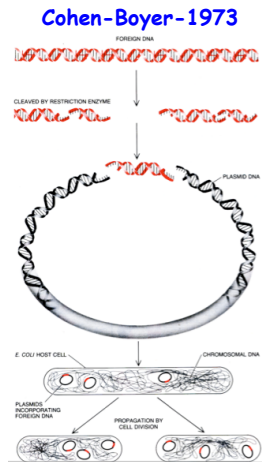
The Genetic Engineering Controversy: 1974-1986

Attempts to Regulate Genetic Engineering at the Local, State, & Federal Levels

The Recombinant-DNA Debate

The four-year-old controversy over the potential biohazards presented by the gene-splicing method and the effectiveness of plans for their containment is viewed in a broader context

by Clifford Grobstein **Berg Letter (1974), Asilomar (1975), NIH Guidelines (1976)**



		PHYSICAL CONTAINMENT (FOR E. COLI HOST SYSTEMS ONLY)	
		EK2	EK3
PHYSICAL CONTAINMENT	1	DNA from nonpathogenic prokaryotes that naturally exchange genes with <i>E. coli</i>	
	2	Plasmid or bacteriophage DNA from host cells that naturally exchange genes with <i>E. coli</i> (if plasmid or bacteriophage DNA contains harmful genes or if DNA fragment is less than 50 percent pure and characterized, higher levels of containment are required.)	
	3	DNA from embryonic or germ-line cells of cold-blooded vertebrates	DNA from nonembryonic cold-blooded vertebrates
	4	DNA from other cold-blooded animals and lower eukaryotes (except insects maintained in the laboratory for fewer than 10 generations)	DNA from moderate-risk pathogenic prokaryotes that naturally exchange genes with <i>E. coli</i>
BIOLOGICAL CONTAINMENT	5	DNA from plants (except plants containing known pathogens or producing known toxins)	DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i>
	6	DNA from low-risk pathogenic prokaryotes that naturally exchange genes with <i>E. coli</i>	DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i>
	7	Organic DNA from nonprimate eukaryotes. (For organic DNA that is less than 99 percent pure, higher levels of containment are required.)	DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i>
	8	Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with <i>E. coli</i> (if there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.)	DNA from moderate-risk pathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i>
GENETIC CONTAINMENT	9	DNA from embryonic primate-tissue or germ-line cells	DNA from nonembryonic primate tissue (DNA from animal viruses (if cloned DNA contains harmful genes))
	10	DNA from other mammalian cells	DNA from animal viruses (if cloned DNA contains harmful genes)
CONTAINMENT OF CLONED DNA	11	DNA from vertebrate or germ-line vertebrate cells (if vertebrate produces a toxin)	DNA from animal viruses (if cloned DNA does not contain harmful genes)
	12	DNA from moderate-risk pathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i>	DNA from nonembryonic primate tissue (DNA from animal viruses (if cloned DNA contains harmful genes))

Scientists Report Using Bacteria To Produce the Gene for Insulin

5/24/77

Rat Insulin Genes:

Construction of Plasmids Containing the Coding Sequences

Abstract. Recombinant bacterial plasmids have been constructed that contain complementary DNA prepared from rat ileitis of Langerhans messenger RNA. Three plasmids contain cloned sequences representing the complete coding region of rat proinsulin I, part of the preproinsulin I prepeptide, and the untranslated 3' terminal region of the mRNA. A fourth plasmid contains sequences derived from the A chain region of rat preproinsulin II.

AXEL ULLRICH, JOHN SHINE
JOHN CHIRGWIN, RAYMOND PICTET
EDMUND TSICHER, WILLIAM J. RUTTER
HOWARD M. GOODMAN
*Department of Biochemistry and
Biophysics, University of California,
San Francisco, 94143*

SCIENCE, VOL. 196

17 JUNE 1977

Scientists Fear Bid to Regulate Genetic Studies

By **HAROLD M. SCHMECK Jr.**
Special to The New York Times

2/20/77

GENE-SPLICING CONCERN IN BOSTON

SPECIAL TO THE NEW YORK TIMES
Published: May 31, 1981

HARVARD AND TOWN DEBATE GENE STUDY

Cambridge Council to Hear a Report
Urging Tight Controls—Some Fear
Tests Could Create New Disease

By **JOHN KIFNER**
Special to The New York Times

*"Threats of diseases and monsters that could be brought
about by recombinant DNA....gene splicing should be banned
within the city limits."*

1/17/77

CALIFORNIA WEIGHING CURBS ON GENE STUDY

Proposed Safeguards in Research
on Genetic Hybrids Would Be
First Imposed by a State

Special to The New York Times

2/7/77

**Congress Is Likely to Delay Until at Least Next Year
DNA Research Regulations Once Thought Critical**

10/25/77

**Cambridge Council Allows
Harvard DNA Research**

CAMBRIDGE, Mass., Feb. 7 (UPI)—The

Allows Research Following NIH Guidelines

2/8/77

**PRINCETON RESEARCH
ON DNA IS PERMITTED**

**Moderate-Risk Project Is Approved
by Borough Council, 6 to 1**

Allows P1, P2, & P3 Research Following NIH Guidelines

Special to The New York Times

1/12/78

June 21, 1986

U.S. UNVEILS RULES ON BIOTECHNOLOGY

By KEITH SCHNEIDER, SPECIAL TO THE NEW YORK TIMES

Biotech Companies

6/21/86

**What About Recent Attempts to Regulate
Science at the Local, State, & Federal Levels?**

September 23, 2002

California Law Permits Stem Cell Research

Gov. Gray Davis today signed a law that explicitly allows research on stem cells from fetal and embryonic tissue.

April 12, 2007

Stem Cell Bill Clears Senate, and Bush Promises a Veto

By [MICHAEL LUO](#)

March 6, 1997

G.O.P. Lawmaker Proposes Bill to Ban Human Cloning

By KATHARINE Q. SEELYE

December 4, 2003

National Briefing | West: California: No-Glow Zone

State regulators refused to allow sales of the first bio-engineered household pet, a zebra fish that fluoresces. The so-called GloFish are expected to go on sale elsewhere next month. California is the only state with a ban on genetically engineered species.

What About Other Legal Issues Dealing With Genetic Engineering?

Life Is Patentable

**SCIENCE MAY PATENT
NEW FORMS OF LIFE,
JUSTICES RULE, 5 TO 4**

1980
The Supreme Court rules that Ananda Chakrabarty's bacterium is not a "product of nature" and so can be patented; other living things "made by man" are declared patentable as well



Ananda Chakrabarty



1988
Harvard University gets a patent for the OncoMouse, a rodent with a gene inserted that predisposes it to cancer

6/17/1980

A Brief History of Patenting "Life"

PATENTING LIFE: A CHRONOLOGY

The patent system—both courts and patent examiners—has always wrestled with the question of what is truly an invention (and therefore deserving of a patent) and what constitutes a mere attempt to expropriate in unaltered form a physical law or material from the natural world, a reason for rejecting an application.

1889

The commissioner of patents determines that plants, even artificially bred ones, are "products of nature," and therefore ineligible for patenting. The applicant in this case—*Ex parte Lotimer*—had tried to patent fibers separated from the plant and was turned down.



Iris

1930

The U.S. Congress passes the Plant Patent Act, which allows the patenting of new plant varieties that reproduce asexually.

1948

A Supreme Court ruling held that simply combining bacteria does not count as an invention (*Funk Brothers Seed Company v. Kalo Inoculant Company*).

1971

Cetus, the first biotechnology company, opens its doors.

1980

The Supreme Court rules that Ananda Chakrabarty's bacterium is not a "product of nature" and so can be patented; other living things "made by man" are declared patentable as well.



Ananda Chakrabarty

Congress passes the Bayh-Dole Act (the Patent and Trademark Laws Amendment), which allows universities to enter into exclusive licensing for their intellectual property.

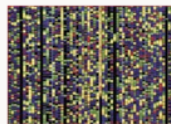
1988

Harvard University gets a patent for the *OncoMouse*, a rodent with a gene inserted that predisposes it to cancer.



Human chromosomes

1990
The Human Genome Project is launched.



DNA sequencing

1996

Both public- and private-sector scientists from all over the world involved in DNA sequencing pass a resolution—the Bermuda Rules—that states that "all human genomic sequence information, generated by centers funded for large-scale human sequencing, should be freely available and in the public domain."

START infopacn

Everybody Wants a Piece of You

One-fifth of your DNA is now owned (as in patented) by someone else.

How is it possible to patent PC parts, but human parts? Organizations are now patenting sequences of nucleotides so they can license the rights to other companies that use the sequences to develop drugs or diagnostic tests. In a sense, the institutions that hold these patents own the intellectual property rights to you—in fact, a new study from researchers at MIT shows that 4,270 US patents have been issued for 4,382 individual human genes—almost 20 percent of the entire genome. "Patents appear to be concentrated in areas relevant to human disease and biological pathways," says Fiona Murray, a professor

A LOOK AT CHROMOSOME 12

274 total patents (sections highlighted in black)

Gene: A2M
Significance: Linked to Alzheimer's disease and emphysema
Patent holders: General Hospital Corporation, Incyte

Gene: ADCY6
Significance: Associated with an enzyme found in heart and brain tissues
Patent holder: Millennium Pharmaceuticals

Gene: CACNB3
Significance: Involved in the release of neurotransmitters and hormones
Patent holders: American Home Products*, Bayer, Merck, SIBIA Neurosciences*

Gene: RINB
Significance: Related to night blindness
Patent holders: Ludwig Institute for Cancer Research, PE Corporation*

Gene: CD1
Significance: Linked to Lupus and a form of white blood cell deficiency
Patent holders: Columbia University, General Hospital Corporation, Incyte, United States of America, University of Pennsylvania, Wistar Institute

Gene: DINI
Significance: Plays a role in regulating development of reproductive organs and the nervous system
Patent holders: Burger*, Cetus

Gene: IL22
Significance: Involved in inflammatory bowel disease and Crohn's disease
Patent holders: Genentech, Ludwig Institute for Cancer Research

Gene: PRK7
Significance: Linked to chronic lymphatic leukemia
Patent holders: Glaxo*, Incyte

Top 10 Holders of Gene Patents

PATENT HOLDER	NO. OF GENES PATENTED
1. Incyte	about 2,000
2. Millennium Pharmaceuticals	142
3. Human Genome Sciences	140
4. Ludwig Institute for Cancer Research	96
5. The Regents of the University of California	89
6. SmithKline Beecham*	79
7. Agilent	58
8. Isis Pharmaceuticals	58
9. Genentech Institute*	53
10. Lexicon Genetics	48

* Company has since merged, been acquired, or changed its name.
Source: Kate Jonson and Fiona Murray, MIT National Center for Biotechnology Information

646-012006-WORLD Issue 14 01

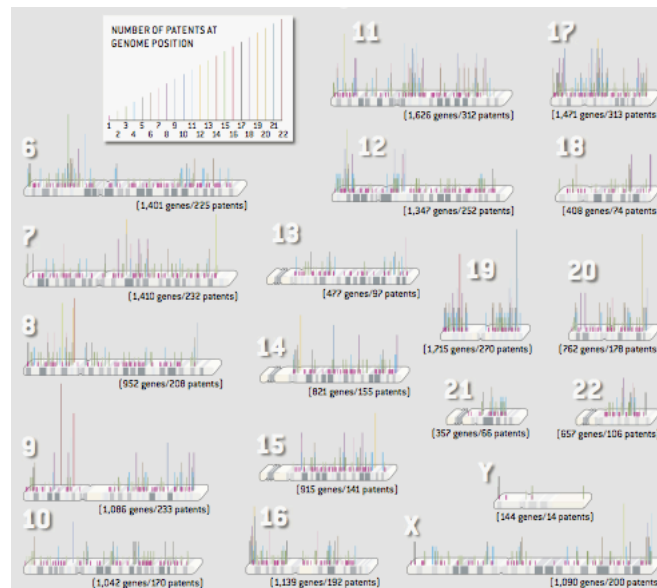
One-Fifth of Human Genes Have Been Patented, Study Reveals

Stefan Lovgren
for National Geographic News
October 13, 2005

A new study shows that 20 percent of human genes have been patented in the United States, primarily by private firms and universities.

Jensen & Murray (2005) *Science* 310,239-240 (October 14, 2005)

Who Owns Your Genes: Human Gene Patents



Scientific American, February 2006

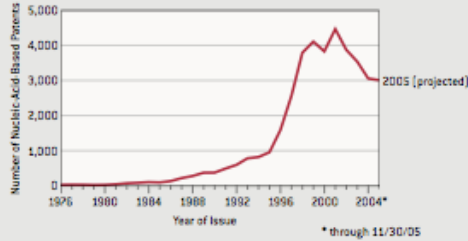
20% of Human Genes Have Been Patented (2006)

Who Has Patents on Your Genes?

WHO OWNS THE PATENTS?

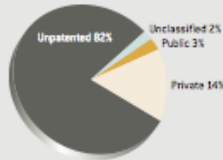
YEARLY U.S. PATENTS RELATED TO DNA OR RNA

The granting of patents involving nucleic acids, including from nonhumans, peaked in 2001 and then declined (graph), probably because of tightening requirements. The holders of many of the patents are listed in the table (right).



PATENTS ON HUMAN GENES

As the pie chart shows, private interests in the U.S. were the largest holders of patents on the 23,688 human genes in the National Center for Biotechnology Information database in April 2005.

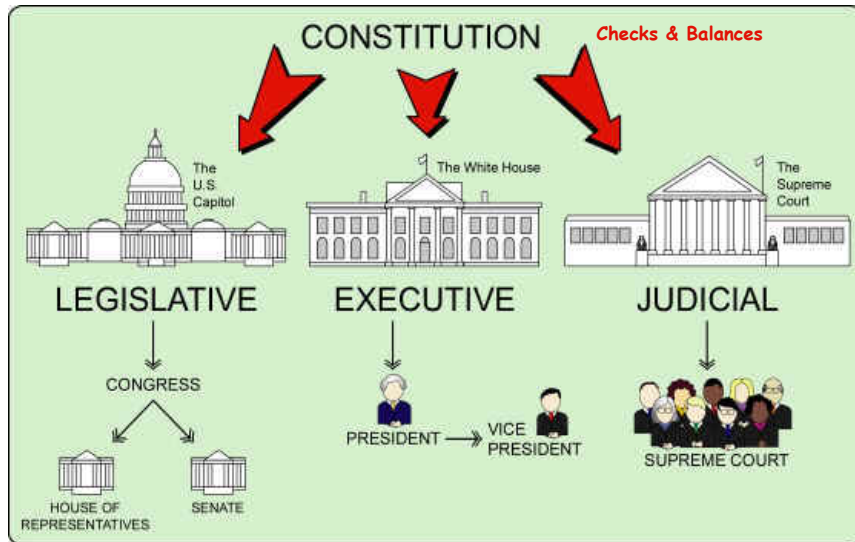


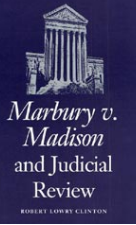
LARGEST PATENT HOLDERS	NUMBER OF PATENTS*
University of California	1,018
U.S. government	928
Sanoofi-Aventis	587
GlaxoSmithKline	580
Incyte	517
Bayer	426
Chiron	420
Genentech	401
Amgen	396
Human Genome Sciences	388
Wyeth	371
Merck	365
Applera	360
University of Texas	358
Novartis	347
Johns Hopkins University	331
Pfizer	288
Massachusetts General Hospital	287
Nova Nordisk	257
Harvard University	255
Stanford University	231
Lilly	217
Affymetrix	207
Cornell University	202
Salk Institute	192
Columbia University	186
University of Wisconsin	185
Massachusetts Institute of Technology	184

Scientific American, February 2006

Organization of the United States Government

NO Precedent For This Form of Government in 1789—"Invented" From Scratch!





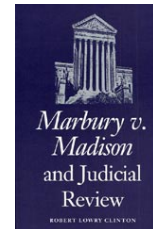
Marbury v. Madison-1803

The critical importance of Marbury is the assumption of several powers by the Supreme Court. One was the authority to declare acts of Congress, and by implication acts of the president, unconstitutional if they exceeded the powers granted by the Constitution. But even more important, the Court became the arbiter of the Constitution, the final authority on what the document meant. As such, the Supreme Court became in fact as well as in theory an equal partner in government, and it has played that role ever since.

Chief Justice John Marshall

Activist Judges?

Voting Rights, Civil Rights, Age & Gender Discrimination
Affirmative Action, etc,



How Does the Constitution Affect Science Directly or Indirectly?

Article or Amendment	What Is Application?
Article I, Section 8.1	Promote the General Welfare
Article I, Section 8.8	Patents & Copyrights
Article I, Section 8.18	Make All Laws to Execute (Police Powers)
Amendment I	Freedom of Speech
Amendment IV	Searches & Seizures
Amendment V	Due Process-Privacy-Federal
Amendment X	Powers Reserved to the States (Police Powers)
Amendment XIII	Slavery
Amendment XIV	Due Process-Privacy-State
Preamble	Promote the General Welfare

What Does the Constitution Say
Directly About Science?

Is the Word "Science" in the Constitution?

1. Article I - Section 8.8

The Congress shall have the Power:

[8] "To Promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their Writings and Discoveries"

Keyword: Inventors not Science.
Wanted to Promote Economic Development & Promote a National Economics Policy Grounded in Property Rights.
That is, Entrepreneurship!

PATENTS!!

2. Article I - Section 8.18

The Congress shall have the Power:

[18] **"To make all Laws which shall be necessary and proper for carrying into Execution the forgoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department of Officer thereof.**

Key Concept: Congress Established Patent and Trademark Office (USPTO) and Intellectual Property laws

**How Does the Constitution Deal
Indirectly With Science?**

**Without Using the Word Science or
Mentioning the Progress of Science and
Discoveries?**

1. Preamble

“We the People of the United States, in order to form a more perfect Union, establish justice, insure domestic tranquility, provide for the common defense, promote the General Welfare.....”

Key Concept: General Welfare-Which Can Apply to Almost Everything Dealing With Science, Health, Medicine, Agriculture, and Safety!

2. Article I - Section 8.1

The Congress shall have the Power:

[1] “To lay and collect Taxes, Duties, Imposts, and Excises, to pay the Debts and provide for the common Defense and general Welfare of the United States; but all Duties, Imposts, and Excises shall be uniform throughout the United States”

Key Concept: Provide For the General Welfare-Which Can Apply to Almost Everything Dealing With Science, Health, Medicine, Agriculture, and Safety!

2. Article I - Section 8.1

Congress Established Under This Article:

- Smithsonian Institute (1846)
- National Academy of Sciences (1863)
- National Bureau of Standards (1901)
- Public Health Service (1912)
- National Institutes of Health (1930)
- National Science Foundation (1946)
- USDA, EPA, FDA, CDC, NASA, etc., etc

Key Concept: All Vested Under Constitutional Grant to Congress to Promote the General Welfare-All Involved in Science, Medicine, Agriculture, & Technology Activities

3. Amendment I

Freedom of Speech and Expression:

“Congress shall make no Law respecting an establishment of religion, prohibiting the free exercise thereof; or abridging freedom of speech, or of the press, of the right of the people peacefully to assemble, and to petition the Government for a redress of grievances.”

Key Concepts: Freedom to Think About Science, Publish, and Discuss Science in Meetings and Laboratories

4. Amendment IV

Searches and Seizures:

"The right of the people to secure their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched and the persons or things to be seized"

Key Concepts: Right Against Unreasonable Searches to Your Own "Body Parts," Science Writings, and Experimental Materials

4. Amendment V

Due Process:

"No Person shall be held to answer for a capital, or otherwise infamous crime, unless on presentment or indictment of a Grand jury, except in cases arising in the land or navel forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be a subject for the same offense to be twice put in jeopardy of life and limb, nor shall be compelled in any criminal case to be a witness against himself. Nor be deprived of Life, liberty, or property, without due process of law; nor shall any property be taken for public use without just compensation."

Key Concepts: Right to Life & Liberty=Privacy=Reproductive Rights
Medical Treatment (Refusal/Acceptance)

5. Amendment XIII

Involuntary Servitude:

Section 1: "Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist with the United States, or any place subject to their jurisdiction."

Section 2: "Congress shall have the power to enforce this article by appropriate legislation"

Key Concept: No Slavery or Involuntary Servitude-Clones or Patenting Humans

6. Amendment XIV

State Due Process:

Section 1: "All persons born or naturalized in the United States and subject to the jurisdiction thereof, are citizens of the United States and the State where they reside. No State shall enforce any law which shall abridge the privileges and immunities of the United States; nor shall any State deprive a person of life, liberty, or property without due process of law; nor deny any person within its jurisdiction the equal protection of the laws."

Sections 2, 3, and 4: (2) Proportional reduction of representatives by number of males who participated in rebellion; (3) exclusion of previous members of congress, judiciary, etc. who participated in rebellion from holding public office, (4) pay no debt related to rebellion or owning slaves

Key Concept: Right to Life & Liberty=Privacy=Reproductive Rights Medical Treatment (Refusal/Acceptance) at State Level

6. Amendment X

Powers Not Delegated to the United States:

"The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

- Gibbons vs. Ogden (1824) - Justice John Marshall - "that immense mass of legislation which embraces everything within a territory or state...."
- Brown vs. Maryland (1827) - Justice John Marshall - defined the totality of state legislative power the "police powers."
- Barnes vs. Glen Theatre, Inc. (1991) - Justice William Rehnquist - "the traditional police powers of the states is defined as the authority to provide for the public health, safety, and morals"

Key Concept: State Promotion of General Welfare=Police Powers

How Do These Articles and Amendments Apply to Science?

Article I - Section 8.1

Promote the General Welfare: Federal "Police" Powers

- **Fund** Science Research & Exploration
- **Regulate** Health (e.g., disease outbreaks)
- **Regulate** Medical Testing Devices/Services (DNA Testing)
- **Regulate** Drugs
- **Regulate** Food Additives
- **Regulate** Releases Into the Environment (GMOs)
- **Regulate** Lab Conditions
- **Regulate** Private DNA Testing/Sequencing Services
- **Establish** DNA Databases

Article I - Section 8.8

Intellectual Property

- **Regulate** Patents (genes, genetic engineering, cells)
- **Regulate** Copyrights (software)
- **Regulate** Trademarks (biotech companies, drugs)

What IS Patentable & What Are the Rules (e.g., 20 y)?

Article I - Section 8.18

Make Laws to Execute Powers

- Intellectual Property Laws & USPTO
- Agencies to Promote and Regulate Science (NSF, NIH, CDC)
- Public Health Laws
- Laws Regarding Science Funding
- CODIS (FBI)-DNA Database
- OSHA-Lab Safety
- FDA, CDC, etc.

Amendment X

Police Powers to States & Localities

State Funding and Regulation of:

- Science Research & Exploration
- Health (e.g., disease outbreaks)
- Medical Testing Devices/Services (DNA Testing)
- Drugs (as long as not interstate commerce)
- Food Additives
- Releases Into the Environment (GMOs)
- Etc.

Amendment IV

Searches and Seizures

- Body Parts (e.g., hair)
- Saliva (DNA testing)
- Blood (DNA testing)

Must Have Probable Cause

∴ No DNA Sampling "Sweeps"-For Example
an Entire An Entire Neighborhood

Amendments V and XIV

Federal Due Process (Right to Privacy)

State Due Process (Right to Privacy)

Right to Life (Medical Treatment)

- Procreative Choice-Terminate Pregnancy (genetic testing: PGD, amniocentesis, chorionic villi sampling)
- In Vitro Fertilization
- Stem Cells
- Birth Control
- Cloning
- Medical Treatment (life)

Amendment XIII

Slavery and Involuntary Servitude

- Patenting Humans
- Owning Human Clones

**Can Scientific Inquiry and
Research Be Regulated?**

HAVE AN ABSOLUTE RIGHT TO CARRY OUT SCIENTIFIC INQUIRY AND RESEARCH

1. **Freedom of Speech Includes Right to Scientific Inquiry** - Have the Right to Think About Nature, Ponder Hypotheses, and How Nature Works. Have the Right to do Research and Advance the State of Knowledge
2. **Freedom of the Press Includes Right to Publish** - Have Right to Publish Scientific Theories, Hypotheses, and Results. BUT NOT ABSOLUTE (Freedom of Speech is not absolute). Therefore, could be outweighed by PUBLIC INTEREST (e.g., publishing how to make bioweapons or a nuclear bomb).
3. **Freedom to Assemble Peacefully** - Have Right to Come Together in a Meeting, Conference, and/or Laboratory to Do Research and Communicate Research Results and Exchange Ideas, Seek Truth, and/or Learn About Science and Nature

YES-HAVE AN ABSOLUTE RIGHT TO THINK,
IMAGINE, FORM GROUPS, ARGUE IDEAS,
AND DO RESEARCH

**BUT WHAT ABOUT ACTUALLY CARRYING OUT
EXPERIMENTS IN A LABORATORY OR IN A
HOME, OR BUSINESS?**

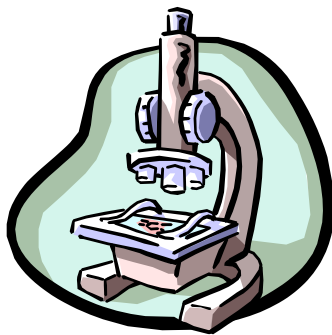
**CAN EXPERIMENTATION (e.g, recombinant dna,
stem cells) BE REGULATED?**

THERE IS NO FUNDAMENTAL RIGHT OF SCIENTIFIC INQUIRY TO CARRY OUT EXPERIMENTS!

1. When Moving From Reflection, Theory, Hypothesis, and Thought to TESTING AND EXPERIMENTATION - Move From World of Speech (talking, publishing) to WORLD OF ACTION AND CONDUCT.
2. Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That Which is Not Hazardous (e.g., testing bombs in your house; recombinant DNA).
3. Experimentation Triggers Public Welfare Considerations
4. Freedom to Pursue Knowledge is Distinguishable From Right to Choose Method For Achieving That Knowledge (e.g., experimentation methods and approaches).

Experimentation CAN BE Regulated Directly By Law and/or Indirectly By Funding!

How Can Experimentation Such As Genetic Engineering Be Regulated Directly?



Police Powers of Federal, State, and
Local Governments-To Promote the
General Welfare-Can Regulate
Experimentation.

**"If Inherently Hazardous to Protect
the Welfare of the Public and/or
an Individual"**

**Case #1-Recombinant DNA
Cambridge, MA. City Council-1977**

- **Facts:** Cambridge City Council Tried to Ban All Recombinant DNA Experiments in the City of Cambridge, Including Harvard University. *"Threats of diseases and monsters that could be brought about by recombinant DNA....gene splicing should be banned within the city limits."*
- **Outcome:** After a Heated Debate, the Cambridge Experimental Review Board (CERB) Recommended Going Forward With recombinant DNA Under NIH Guidelines. *"A citizen's jury (CERB) of lay people and scientists came to a sensible conclusion, and that was the ordinance that passed."*



Case #2-Sale of Genetically Engineered GloFish in CA-2003



- **Facts:** Fish and Game Commission of CA Was Asked to Renew License to Do Research on Genetically Modified Fish
- **Outcome:** Citing ethical concerns, state regulators Wednesday refused to allow sales of the first bio-engineered household pet, a zebra fish that glows fluorescent. The 3-1 vote came moments after commissioners approved the state's 14th license for research into genetically modified fish. But commissioners drew the line on permitting widespread sales of a biotech fish for pure visual pleasure.

Background: California adopted its regulations for fear genetically modified farmed fish, such as salmon, could get loose and devastate the state's wild populations. "Welcome to the future. Here we are, playing around with the genetic bases of life," Schumchat said. "At the end of the day, I just don't think it's right to produce a new organism just to be a pet. To me, this seems like an abuse of the power we have over life, and I'm not prepared to go there today."



Case #3-Release of Transgenic Rice Containing Human Proteins in KS-2007



- **Facts:** Ventria, Inc. Applied For a Permit to Grow Rice With Human "Pharmaceutical" Proteins in Kansas
- **Outcome:** SUPPLEMENTAL PERMIT CONDITIONS For Release of Rice Containing Genes for Lactoferrin, Lysozyme or Serum Albumin. USDA-APHIS-BRS Permits 06-278-01r, 06-278-02r and 06-285-02r.

Background: Farmers Worry About Genetically Modified Rice Approval WASHINGTON, DC, May 21, 2007 (ENS) - The National Farmers Union expressed "great concern" over today's approval by the U.S. Department of Agriculture's Animal Plant and Health Inspection Service, APHIS, to allow Ventria Bioscience to plant rice that is genetically modified to produce pharmaceuticals in Kansas. "This is as an important development for Kansas farmers, who stand to benefit from the additional income." Polansky said. "They also have the satisfaction of knowing they are helping provide affordable healthcare products to children who desperately need it."

Principle: Potential Hazard to Environment and/or Food Supply

Case #4 Bioterrorism: Congressional Legislation to Improve Public Health Preparedness and Response Capacity-2002

- **Facts:** To Protect Nation From Bioterrorism Attacks After 9/11 and Anthrax "Attacks" on Congress

- **Outcome:** Bioterrorism Preparedness Act of 2002

Background: Funds For Research on Pathogens To Uncover Knowledge Required to Counteract Bioweapons' Attacks (e.g., antibiotics, vaccines). Registration of all human pathogens and pathogen research in US Laboratories.

Principle: Public Safety/Welfare Risk

Case #5 Human Cloning Laws-2008

- **Facts:** To Regulate Cloning of Human Beings
- **Outcome:** Varies By State. **California** Business And Professions: 16004-5 Health & Safety, 24185, 24187, 24189, 12115-7. **Prohibits reproductive cloning. Allows therapeutic cloning.** Permits cloning for research; provides for the revocation of licenses issued to businesses for violations relating to human cloning; prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; establishes civil penalties.
- **Principle:** Cannot Be 100% Certain That Health and Welfare of a Cloned Child Will be "Normal." Might be challenged on "right to privacy-procreative choice issues"

See: <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm> for state by state list

Case #6 Human Vitro Fertilization Laws-2008

- **Facts:** To Regulate Egg Donors For Stem Cell Research
- **Outcome:** The Governor of California Arnold Schwarzenegger has signed into law a bill that prevents both private and state-funded laboratories from paying women to donate eggs for human embryonic stem (ES) cell research. The Reproductive Health and Research Bill (SB1260), sponsored by state Senators Deborah Ortiz and George Runner, will limit compensation to reimbursement for direct expenses incurred by egg donors. It also says that women who are considering donating eggs must be fully informed of the potential risks, and that they must provide both written and oral consent before undergoing the procedure.
- **Principle:** Protect Health and Welfare of Donor and Society

Can Think But Can't Always Act!

How Can Experimentation Be Regulated Indirectly?

Regulate Through Power of Funding and Research \$

1. No Constitutional Right to Obtain Funding For Research at Federal, State, and Local Levels
 - a. Federal Embryonic Stem Cell Research Restricted
 - b. Must Apply For Grants Which Are Merit-Based and Peer-Reviewed
2. Must Abide By Conditions of Funding Agencies to Obtain Research \$
 - a. Recombinant DNA Guidelines
 - b. Human Institutional Review Boards (IRBs)
 - c. Release of GMOs Into the Environment

Direct and Indirect Regulation of Science, Research, and Experimentation: Summary

1. Recombinant DNA-Gene Splicing Experiments
 - a. **Directly** By Regulation at Federal, State, and Local Levels By Police Powers To Protect the General Welfare
 - b. **Indirectly** by Funding Agencies
2. Transgenic Microbes, Animals, and Plants
 - a. Release Into The Environment, Altered Food Composition, Use as "Pesticides."
 - b. **Directly** By Police Powers and **Indirectly** By Funding Requirements
3. In Vitro Fertilization and Stem Cells
 - a. Medical Licensing, Instrumentation, Tests, Use of Embryos For Research.
 - b. **Directly** By Police Powers and **Indirectly** By Funding Requirements (Bush's Executive Order on Funding For Human Stem Cells)
4. Human Reproductive and Therapeutic Cloning
 - a. **Directly** By Police Powers and **Indirectly** By Funding Requirements
 - b. **But....Little Case Law**

Human Reproductive and Therapeutic Cloning

1. **Griswold vs. Connecticut-Ban On Contraceptives-Right To Privacy-Justice Douglas-1965 (Activist Judges??!)**
 - a. "If the Fourth and Fifth Amendments were described as protections against governmentintrusions of the sanctity of a man's home and the privacies of life."
 - b. We deal with a right to privacy older than the Bill of Rights"
 - c. Use of contraception "concerns a zone of privacy created by several constitutional guarantees--which is an aspect of the liberty protected by the due process clauses of the Fourteenth and Fifth Amendments."
 - d. "If a law against a totalitarian limit on family size is a complete variance with our constitutional concepts, then a law outlawing birth controls is at variance."
 - e. "If the right to privacy means anything, it is the right of an individual, married or single, to be free from unwarranted government intrusion into matters affecting a person as to whether to have a child."
 - f. Personal autonomy over one's body and liberty to act in certain ways.
2. **Roe Vs. Wade-1973**
 - a. Right of a woman to terminate pregnancy in first two trimesters
3. **Lifchez vs. Hartigan-Illinois Ban on IVF, PGD, Prenatal Procedures-1990**
 - a. Unconstitutional-Right to use procedures to bring about pregnancy
4. **Stenberg vs. Carhart-Nebraska Ban on Partial Birth Abortions-2000**
 - a. Unconstitutional if necessary to preserve health and welfare of mother

Compelling State Interest To Protect Health and Welfare of Child (Be "Normal") and Mother (Medical Treatment!!)

See Stem Cell Century, by Russell Korobkin (2008)