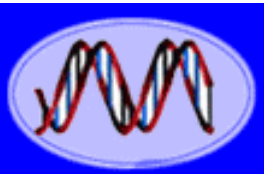
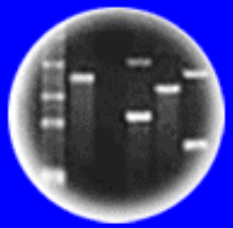


DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

HC70A & SAS70A Winter 2010
Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg & John Harada

Lecture 9

Science & The Constitution: Regulating Science & Genetic Engineering

UCLA

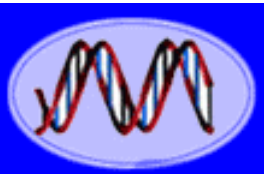
UCDAVIS
UNIVERSITY OF CALIFORNIA

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)
8. *A Guide to Biotechnology Law & Business*, By Robert A. Bohrer (2007)
9. *The Role of Science in The Law*, By Robin Feldman (2009)



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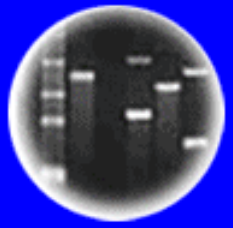


DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

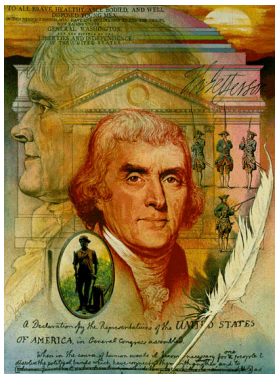
Plants of Tomorrow

THEMES

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

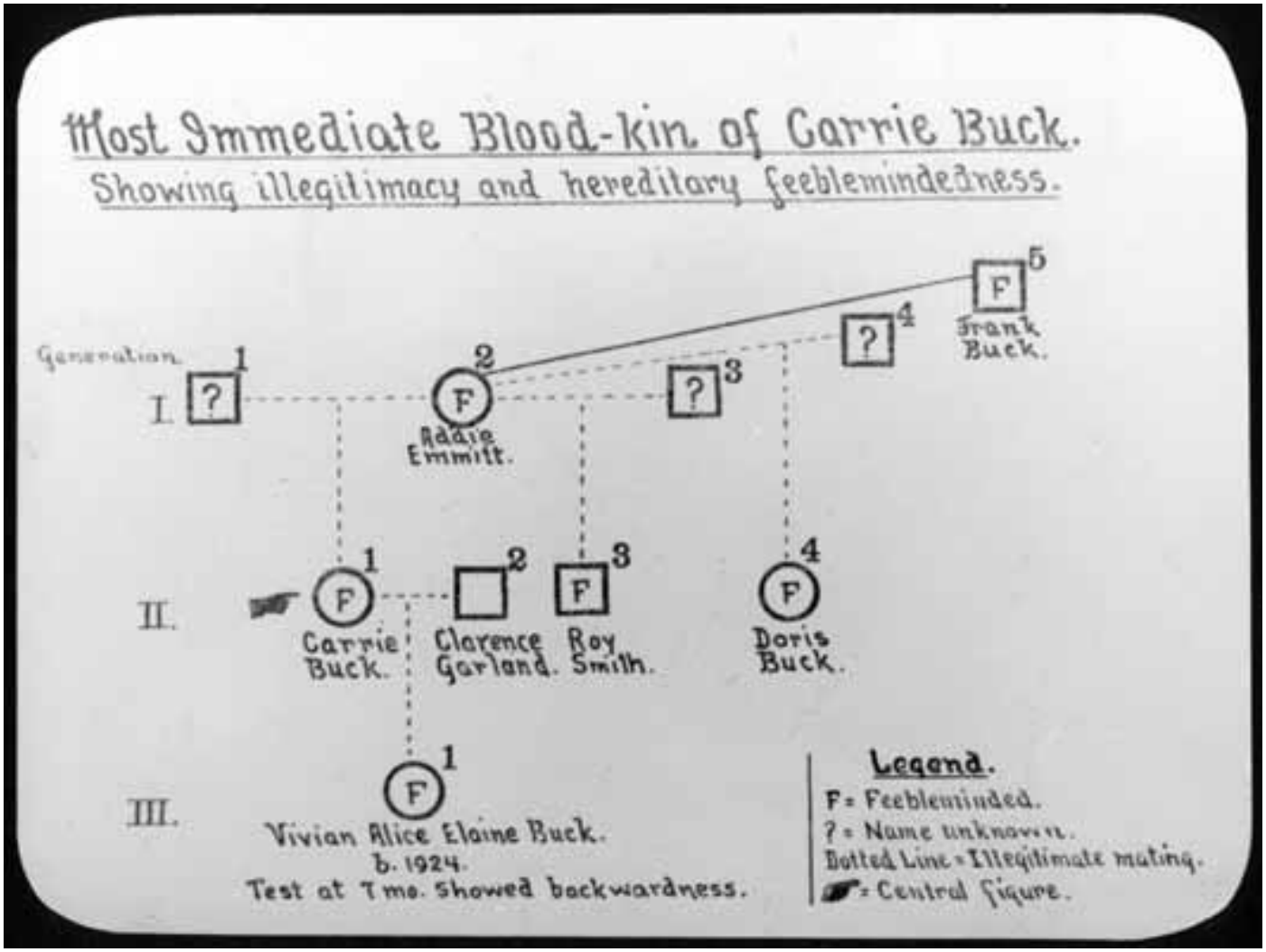
"Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and keep pace with the times."

Thomas Jefferson, July 12, 1810



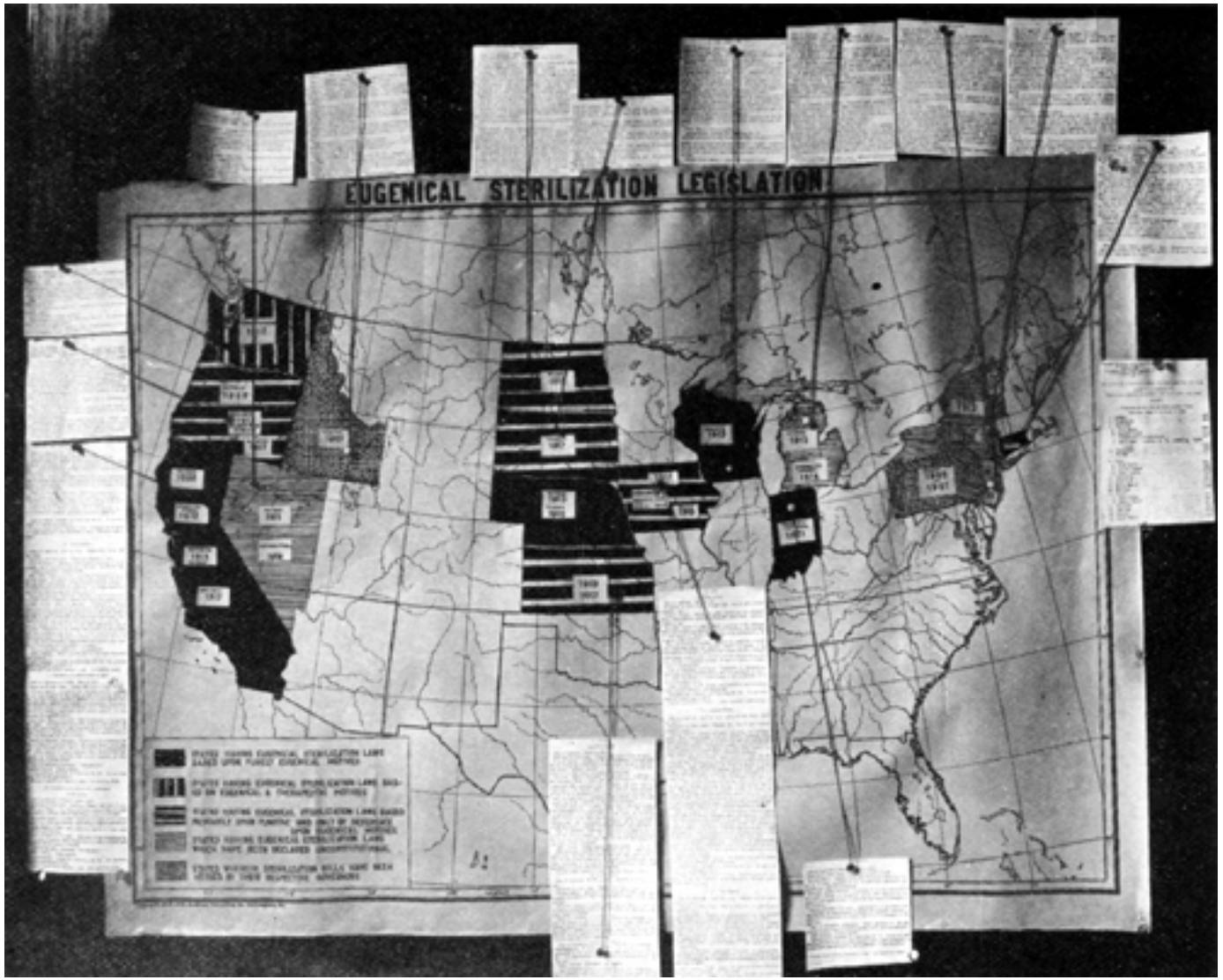
What is the History of The Relationship Between Genetics & the Law in the United States?

"Pedigree" of Carrie Buck

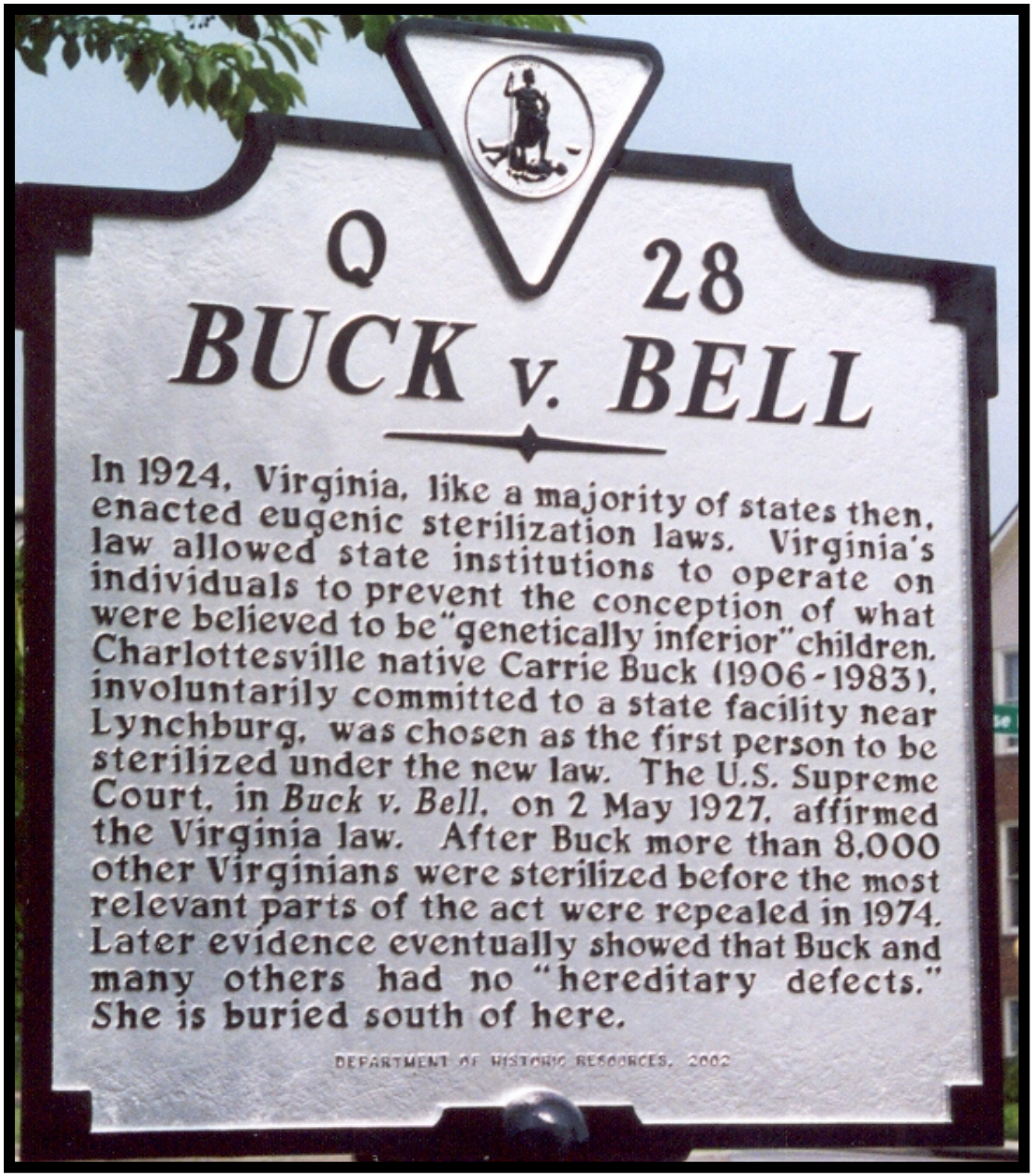


State of Virginia Colony For Epileptics & Feebleminded- 1924

State Sterilization Laws 1921



64,000 Forced Sterilizations in US - Last one in Oregon in 1981


Q 28
BUCK v. BELL
In 1924, Virginia, like a majority of states then, enacted eugenic sterilization laws. Virginia's law allowed state institutions to operate on individuals to prevent the conception of what were believed to be "genetically inferior" children. Charlottesville native Carrie Buck (1906-1983), involuntarily committed to a state facility near Lynchburg, was chosen as the first person to be sterilized under the new law. The U.S. Supreme Court, in *Buck v. Bell*, on 2 May 1927, affirmed the Virginia law. After Buck more than 8,000 other Virginians were sterilized before the most relevant parts of the act were repealed in 1974. Later evidence eventually showed that Buck and many others had no "hereditary defects." She is buried south of here.
DEPARTMENT OF HISTORIC RESOURCES, 2002

BUCK v. BELL

The ruling was written by Justice Oliver Wendell Holmes. In support of his argument that the interest of the states in a "pure" gene pool outweighed the interest of individuals in their bodily integrity, he argued in 1927:

"We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices, often not felt to be such by those concerned, in order to prevent our being swamped with incompetence. It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. *The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes."*

Holmes concluded his argument with the infamous phrase *"Three generations of imbeciles are enough."*

The Law Impacts Science in Many Ways……

Attempts to Regulate Science Are Not New!

Trial of Galileo - 1633

Lysenko and Genetics in Soviet Union 1930-1950s

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

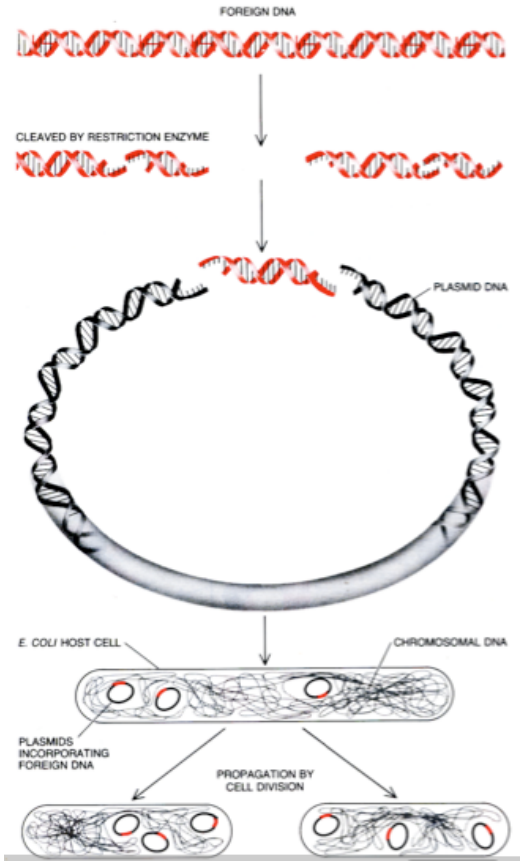
The Genetic Engineering Controversy: 1974-1986

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

Cohen-Boyer-1973



Berg Letter (1974), Asilomar (1975), NIH Guidelines & Recombinant DNA Advisory Committee (RAC) (1976)

PHYSICAL CONTAINMENT	BIOLOGICAL CONTAINMENT (FOR *E. COLI* HOST SYSTEMS ONLY) EK1	EK2	EK3
P1	DNA from nonpathogenic prokaryotes that naturally exchange genes with *E. coli* Plasmid or bacteriophage DNA from host cells that naturally exchange genes with *E. coli*. (If plasmid or bacteriophage genome contains harmful genes or if DNA segment is less than 99 percent pure and characterized, higher levels of containment are required.)		
P2	DNA from embryonic or germ-line cells of cold-blooded vertebrates DNA from other cold-blooded animals and lower eukaryotes (except insects maintained in the laboratory for fewer than 10 generations) DNA from plants (except plants containing known pathogens or producing known toxins) DNA from low-risk pathogenic prokaryotes that naturally exchange genes with *E. coli* Organelle DNA from nonprimate eukaryotes. (For organelle DNA that is less than 99 percent pure higher levels of containment are required.)	DNA from nonembryonic cold-blooded vertebrates DNA from moderate-risk pathogenic prokaryotes that naturally exchange genes with *E. coli* DNA from nonpathogenic prokaryotes that do not naturally exchange genes with *E. coli* DNA from plant viruses Organelle DNA from primates. (For organelle DNA that is less than 99 percent pure higher levels of containment are required.) Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with *E. coli*. (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.)	
P3	DNA from nonpathogenic prokaryotes that do not naturally exchange genes with *E. coli* DNA from plant viruses Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with *E. coli*. (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.),	DNA from embryonic primate-tissue or germ-line cells DNA from other mammalian cells DNA from birds DNA from embryonic, nonembryonic or germ-line vertebrate cells (if vertebrate produces a toxin) DNA from moderate-risk pathogenic prokaryotes that do not naturally exchange genes with *E. coli* DNA from animal viruses (if cloned DNA does not contain harmful genes)	DNA from nonembryonic primate tissue DNA from animal viruses (if cloned DNA contains harmful genes)
P4		DNA from nonembryonic primate tissue DNA from animal viruses (if cloned DNA contains harmful genes)	

The Berg Letter: Science, July, 1974
The Catalyst For the Asilomar Conference & NIH Recombinant DNA Guidelines

Potential Biohazards of Recombinant DNA Molecules

Paul Berg; David Baltimore; Herbert W. Boyer; Stanley N. Cohen; Ronald W. Davis; David S. Hogness; Daniel Nathans; Richard Roblin; James D. Watson; Sherman Weissman; Norton D. Zinder

Science, New Series, Vol. 185, No. 4148 (Jul. 26, 1974), 303.

LETTERS

Potential Biohazards of Recombinant DNA Molecules

Recent advances in techniques for the isolation and rejoining of segments of DNA now permit construction of biologically active recombinant DNA molecules in vitro. For example, DNA restriction endonucleases, which generate DNA fragments containing cohesive ends especially suitable for rejoining, have been used to create new types of biologically functional bacterial plasmids carrying antibiotic resistance markers (*1*) and to link *Xenopus laevis* ribosomal DNA to DNA from a bacterial plasmid. This latter recombinant plasmid has been shown to replicate stably in *Escherichia coli* where it synthesizes RNA that is complementary to *X. laevis* ribsomal DNA (*2*). Similarly, segments of *Drosophila* chromosomal DNA have been incorporated into both plasmid and bacteriophage DNA's to yield hybrid molecules that can infect and replicate in *E. coli* (*3*).

The above recommendations are made with the realization (i) that our concern is based on judgments of potential rather than demonstrated risk since there are few available experimental data on the hazards of such DNA molecules and (ii) that adherence to our major recommendations will entail postponement or possibly abandonment of certain types of scientifically worthwhile experiments. Moreover, we are aware of many theoretical and practical difficulties involved in evaluating the human hazards of such recombinant DNA molecules. Nonetheless, our concern for the possible unfortunate consequences of indiscriminate application of these techniques motivates us to urge all scientists working in this area to join us in agreeing not to initiate experiments of types 1 and 2 above until attempts have been made to evaluate the hazards and some resolution of the outstanding questions has been achieved.

UCLA Biohazard Committee Approvals

1978

UNIVERSITY OF CALIFORNIA, LOS ANGELES
BIOHAZARDS COMMITTEE

Approval Notice

PRINCIPAL INVESTIGATOR OF MAIN GRANT: Robert B. Goldberg

TITLE OF MAIN GRANT: Isolation of Seed Storage Protein Genes for the Soybean Plant

PRINCIPAL INVESTIGATOR OF PROTOCOL: Same as above

DEPARTMENT: Biology

DIVISION: ----------

TITLE OF PROJECT: Organization and Expression of Seed Storage Protein Genes in Soybean Development

FUNDING AGENCY: NIH

CONTRACT OR GRANT NO. (If known): ----------

DATES FOR WHICH REVIEWED: FROM: 4-1-79 TO: 3-31-80

DATE FOR RE-SUBMISSION: 2-28-80

DATE APPROVED: 5-18-78

ACTUAL STARTING DATE OF PROTOCOL: 4-1-79

The Biohazards Committee has reviewed the proposed use of recombinant DNA molecules in the project identified above and assures that:

The applicable facilities and procedures have been reviewed by the Biohazards Committee and judged to be both adequate and consistent with the requirements of the NIH guidelines.

The Biohazards Committee will monitor the facilities and procedures throughout the duration of the project.

P2-EK1

Date: May 18, 1978

Signature: David D. Pratt.
Chairman, Biohazards Committee

Original to: National Institutes of Health
cc to: Director, Office of Contract and Grant Administration
Principal Investigator

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

1. As principal investigator I am familiar with the NIH Guidelines for Research Involving Recombinant DNA Molecules (issued June 23, 1976 and published in the Federal Register, July 7, 1976). I agree to abide by their provisions.

Signed Robert B. Goldberg
Robert B. Goldberg
Assistant Professor of Biology

2. Experiments which involve recombinant DNA molecules.

A. Background. "Organization and Expression of Seed Storage Protein Genes in Soybean Development"

3. An assessment of the levels of physical and biological containment required by the current NIH Guidelines for these experiments.

The formation of hybrids between plant DNA and bacterial plasmids is given a P2-EK1 classification provided that the plant does not harbor a pathogenic agent nor produce a product toxic to other species (NIH Guidelines, III-18). Plant varieties to be used in experiments with plasmid DNAs do not harbor known plant viruses or pathogenic bacteria, nor do they produce any toxic product. As such I assess a P2-EK1 level of containment as appropriate for these experiments.

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 islets 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 TISCHER, 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

**Congress Has Never Passed a Law Regulating Genetic Engineering-
State, City, and County Laws Do Exist, However (e.g., Mendicino)**

Cambridge Council Allows Harvard DNA Research

CAMBRIDGE, Mass., Feb. 7 (UPI)—The

Allows Research Following NIH Guidelines

2/8/77

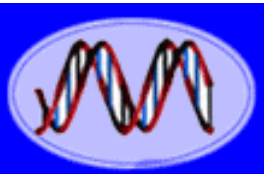
PRINCETON RESEARCH ON DNA IS PERMITTED

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



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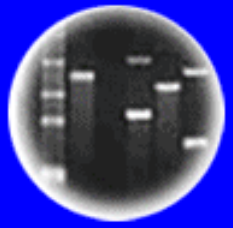

DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

Should There Be Laws Regulating Science?

a. Yes
b. No

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

Laws Exist That Regulate Science at the Federal Level

genome.gov
National Human Genome Research Institute
National Institutes of Health

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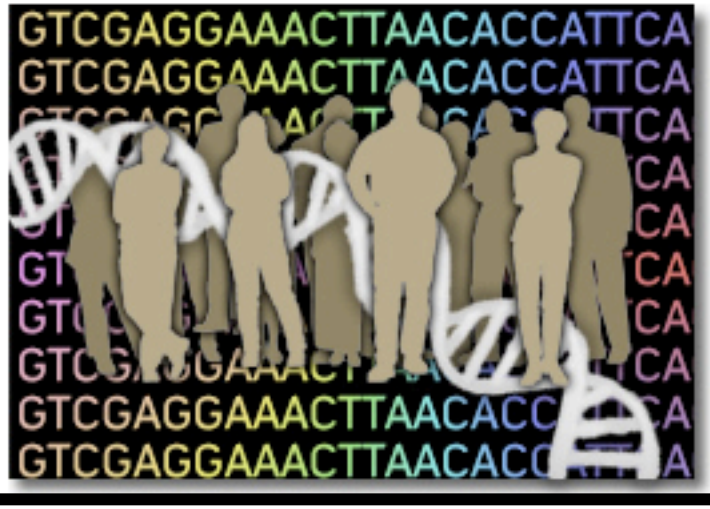
Genetic Information Nondiscrimination Act of 2008 (GINA)



Federal Law on Genetic Discrimination

Genetic Information Nondiscrimination Act of 2008

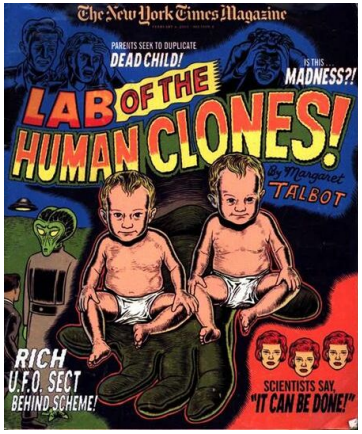
What will GINA do?
GINA generally will prohibit discrimination in health coverage and employment on the basis of genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment.

The statute defines 'genetic information' as information about:

- an individual's genetic tests (including genetic tests done as part of a research study);
- genetic tests of the individual's family members (defined as dependents and up to and including 4th degree relatives);
- genetic tests of any fetus of an individual or family member who is a pregnant woman, and genetic tests of any embryo legally held by an individual or family member utilizing assisted reproductive technology;
- the manifestation of a disease or disorder in family members (family history);
- any request for, or receipt of, genetic services or participation in clinical research that includes genetic services (genetic testing, counseling, or education) by an individual or family member.

Genetic information does not include information about the sex or age of any individual.

The statute defines 'genetic test' as an analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes. The results of routine tests that do not measure DNA, RNA, or chromosomal changes, such as complete blood counts, cholesterol tests, and liver-function tests, are not protected under GINA. Also, under GINA, genetic tests do not include analyses of proteins or metabolites that are directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.



March 6, 1997

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

By KATHARINE Q. SEELYE

There is No Federal Human Cloning Law

April 12, 2007

Stem Cell Bill Clears Senate, and Bush Promises a Veto

By MICHAEL LUO

There is No Federal Stem Cell Research Law
One is Being Considered in Current Congress

Part IV

The President

Executive Order 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells

Memorandum of March 9, 2009—Presidential Signing Statements

Memorandum of March 9, 2009—Scientific Integrity

Executive Order 13505 of March 9, 2009

Removing Barriers to Responsible Scientific Research Involving Human Stem Cells

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

Sec. 2. *Research.* The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

CNSNews.com

Obama Signs Law Banning Federal Embryo Research Two Days After Signing Executive Order to OK It

Friday, March 13, 2009

By Terence P. Jeffrey, Editor-in-Chief

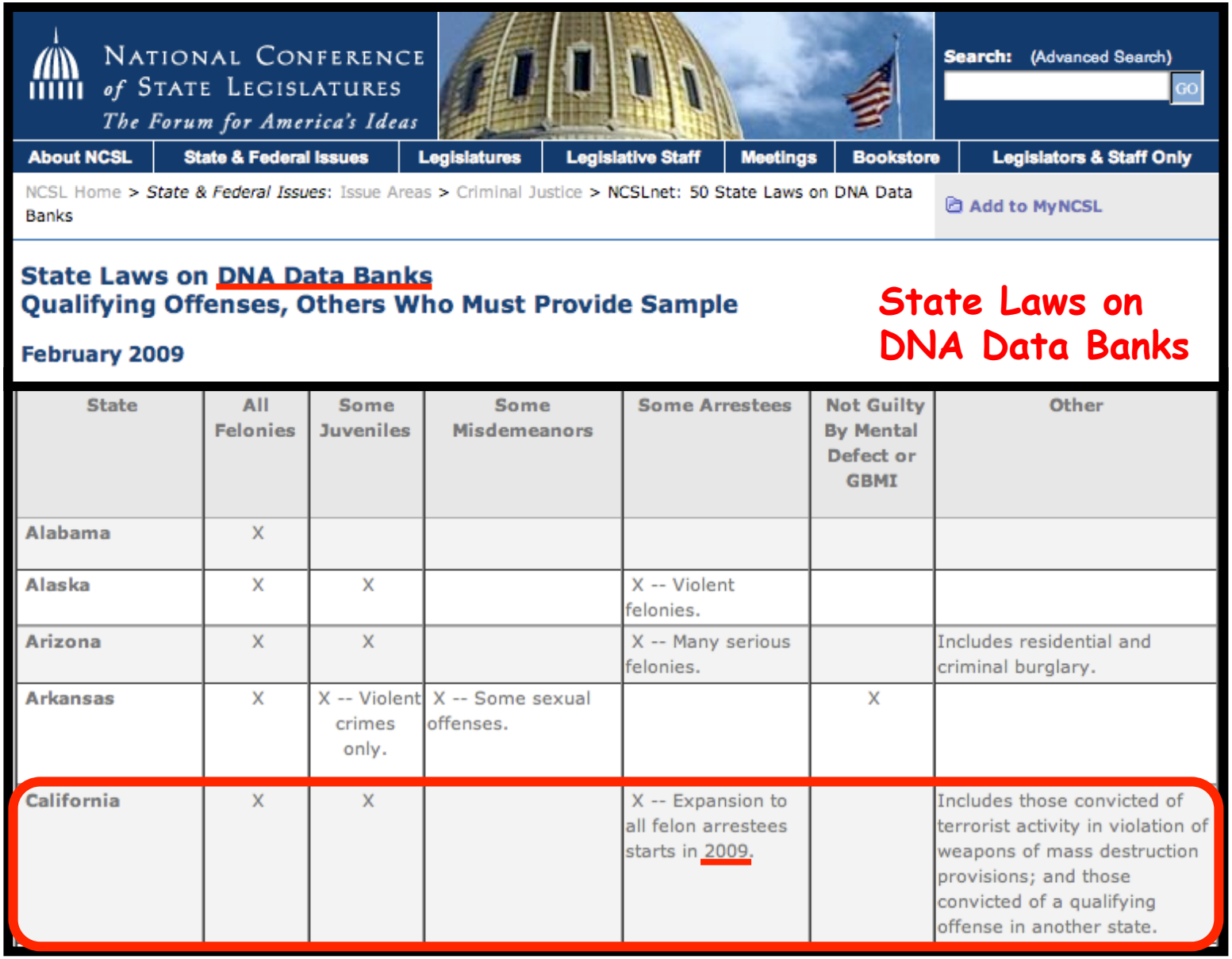
Dickey-Wiker Amendment

(CNSNews.com) - On Wednesday, only two days after he lifted President Bush's executive order banning federal funding of stem cell research that requires the destruction of human embryos, President Barack Obama signed a law that explicilty bans federal funding of any "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death."

The text of Section 509 of the Omnibus Appropriations Act, 2009, reads as follows:

SEC. 509. (a) None of the funds made available in this Act may be used for—(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Laws Exist That Regulate Science at the State Level



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State Laws on DNA Data Banks
Qualifying Offenses, Others Who Must Provide Sample

February 2009

State Laws on DNA Data Banks

State	All Felonies	Some Juveniles	Some Misdemeanors	Some Arrestees	Not Guilty By Mental Defect or GBMI	Other
Alabama	X					
Alaska	X	X		X -- Violent felonies.		
Arizona	X	X		X -- Many serious felonies.		Includes residential and criminal burglary.
Arkansas	X	X -- Violent crimes only.	X -- Some sexual offenses.		X	
California	X	X		X -- Expansion to all felon arrestees starts in 2009.		Includes those convicted of terrorist activity in violation of weapons of mass destruction provisions; and those convicted of a qualifying offense in another state.

California	Cal. Food & Agricultural Code §§ 491 to 492 (2007)	**State Oversight.** Legislative findings that with the burgeoning field of biotechnology comes a need for the public to be informed about the benefits and potential risks of the technology. Establishes the Food Biotechnology Task Force.
California	Cal. Food & Agricultural Code § 2272 (2007)	**State Oversight.** Allows for the County Agricultural Commissioner to include supplemental information on biotechnology in the annual report on the condition of agriculture.
California	Cal. Food & Agricultural Code § 12798 (2007)	**State Funding.** Establishes competitive grant programs to fund pest management research, including biotechnological research.
California	Cal. Food & Agricultural Code § 52300 to 52306 (2007)	**State Oversight.** Legislature to clarify the role and responsibility of the Department of Food and Agriculture in the oversight of regulated agricultural biotechnology.
California	Cal. Food & Agricultural Code § 52100 (2007)	**Destruction.** Any person who intentionally destroys test or research crop is liable for up to twice the market value of the crops.
California	Cal. Unemployment and Ins. Code § 9700 - 9702 (2007)	**State Support.** Sets forth legislative findings and declarations that the San Diego biotechnology industry increasingly needs more biotechnology professionals of all levels that are familiar with industry-like conditions for basic, applied, and transitional research, training, and production; states legislative findings that the San Diego Multiuse Biotechnology Training Center is being created to serve as an anchor for the growth of biotechnology enterprise.
California	Cal.Penal Code § 11417 (2002)	**Destruction.** Considers acts against agricultural biotechnology an act of terrorism.
California	Cal. Fish and Game Code § 15007 (2007)	**Regulation.** Makes it illegal to spawn, cultivate, or incubate any transgenic fish in the state controled waters of the Pacific Ocean.

GloFish Fluorescing With Different Colors!!

Genetics and Life, Disability and Long-term Care Insurance

Updated January 2008

State Laws on Insurance Genetic Discrimination

State and Statutes	Restricts Discrimination Based on Genetic Information in Life Insurance	Restricts Discrimination Based on Genetic Information in Disability Insurance	Restricts Discrimination Based on Genetic Information in Long-term Care Insurance	Requires Actuarial Justification to Use Genetic Information in Life Insurance	Requires Informed Consent to Use Genetic Information
Alabama					
Alaska					
Arizona §20-448	v	v		v	v
Arkansas					
California Insurance §§10146 to 10149.1	v	v	v		v[1]

Genetics and Health Insurance State Anti-Discrimination Laws

State Laws on Health Insurance Genetic Discrimination

Updated January 2008

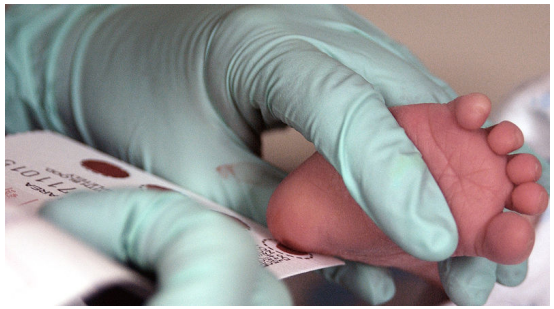
Genetic Information: Legal Issues Relating to Discrimination and Privacy
Congressional Research Service, March 2008

The table below provides a current summary of state laws pertaining to the use of genetic information in health insurance. Restrictions on the use of genetic information in health insurance may address the use of genetic information in individual insurance, group insurance or both. These laws may restrict health insurers from engaging in certain activities, including using genetic information to determine eligibility or set premiums, requiring genetic testing of applicants, or disclosing genetic information without consent. The laws listed below do not govern the use of genetic information in employer-sponsored health benefit plans, which are under the purview of the federal government, and certain exceptions may apply. The states with genetics and health insurance laws listed below also may have laws related to other genetics policy issues, such as genetic privacy or genetic discrimination in other settings. The legislature may have addressed these issues in conjunction with or separately from genetics and health insurance.

NCSL members can access further information on this topic in the article "Plunging into the Gene Pool" from the March 2007 issue of State Legislatures. A series of publicly available GeneticsBriefs also provide background information on the subject.

State	Citation	Type of Insurance Policy	May not Establish Rules for Eligibility based on Genetic Information	May not Require Genetic Tests/Genetic Information	May not Use Genetic Information for Risk Selection or Risk Classification Purposes	May not Disclose Information Without Informed Consent
California	Insurance Code: §§742.405, 7, 10140, 3, 6 to 9, 9.1	Individual and Group	X	X	X	X

Mandatory Newborn Screening For Genetic Disorders



California Department of Public Health
Genetic Disease Screening Program
Newborn Screening Program

Disorders Detectable by NBS Program as of December 15, 2009

I. Cystic Fibrosis

II. Endocrine Disorders
- primary congenital hypothyroidism
- variant hypothyroidism
- congenital adrenal hyperplasia-salt wasting (21-hydroxylase deficiency)
- congenital adrenal hyperplasia-simple virilizing (21-hydroxylase deficiency)

III. Metabolic Disorders (via tandem mass spectrometry (MS/MS) Screening)

A. Amino Acid Disorders
- classical phenylketonuria (PKU)
- variant PKU
- guanosine triphosphate cyclohydrolase 1 (GTPCH) deficiency (biopterin deficiency)
- 6-pyruvoyl-tetrahydropterin synthase (PTPS) deficiency (biopterin deficiency)
- dihydropteridine reductase (DHPR) deficiency (biopterin deficiency)
- pterin-4a-carbinolamine dehydratase (PCD) deficiency (biopterin deficiency)
- argininemia/arginase deficiency
- argininosuccinic acid lyase deficiency (ASAL deficiency)
- citrullinemia, Type I/argininosuccinic acid synthetase deficiency (ASAS deficiency)
- citrullinemia, Type II (citrin deficiency)
- gyrate atrophy of the choroid and retina
- homocitrullinuria, hyperornithinemia, hyperammonemia – HHH
- homocystinuria/cystathionine beta-synthase deficiency (CBS deficiency)
- methionine adenosyltransferase deficiency (MAT deficiency)
- maple syrup urine disease – (MSUD)
- prolinemia
- tyrosinemia, Type I, II, III, and transient

B. Organic Acid Disorders
- 2-methyl-3-hydroxybutyryl-CoA dehydrogenase deficiency
- 2-methylbutyryl-CoA dehydrogenase deficiency
- 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMGCoA lyase deficiency)
- 3-methylcrotonyl-CoA carboxylase deficiency (3MCC deficiency)
- 3-methylglutaconic aciduria (MGA), Type I (3-methylglutaconyl-CoA hydratase deficiency)
- beta-ketothiolase deficiency (BKT)
- ethylmalonic encephalopathy (EE)
- glutaric acidemia type-1 (GA-1)
- isobutyryl-CoA dehydrogenase deficiency
- isovaleric acidemia (IVA)
- malonic aciduria
- methylmalonic acidemia, mut –
- methylmalonic acidemia, mut 0
- methylmalonic acidemia (Cbl A, B)
- methylmalonic acidemia (Cbl C, D)
- multiple carboxylase deficiency (MCD)
- propionic acidemia (PA)

C. Fatty Acid Oxidation Disorders
- carnitine transporter deficiency
- carnitine-acylcarnitine translocase deficiency (CAT deficiency)
- carnitine palmitoyl transferase deficiency-type 1 (CPT-1 deficiency)
- carnitine palmitoyl transferase deficiency-type 2 (CPT-2 deficiency)
- long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency)
- medium chain acyl-CoA dehydrogenase deficiency (MCAD deficiency)
- medium/short chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (M/SCHAD deficiency)
- multiple acyl-CoA dehydrogenase deficiency (MAD deficiency)/glutaric acidemia type-2 (GA-2)
- short chain acyl-CoA dehydrogenase deficiency (SCAD deficiency)
- trifunctional protein deficiency (TFP deficiency)
- very long chain acyl-CoA dehydrogenase deficiency (VLCAD deficiency)

IV. Other Metabolic Disorders
A. classical galactosemia
B. biotinidase deficiency

V. Hemoglobin Disorders
- sickle cell anemia (Hb S/S disease)
- sickle C disease (Hb S/C disease)
- sickle D disease (Hb S/D disease)
- sickle E disease (Hb S/E disease)
- Hb S/ hereditary persistence of fetal hemoglobin (Hb S/HPFH)
- sickle cell disease variant (other sickle cell disease, Hb S/V)
- Hb S/ Beta^0 thalassemia
- Hb S/Beta$^+$ thalassemia
- Hb C disease (Hb CC)
- Hb D disease (Hb DD)
- alpha thalassemia major
- Hb H disease
- Hb H/ Constant Spring disease
- beta thalassemia major
- Hb E/ Beta^0 thalassemia
- Hb E/Beta$^+$ thalassemia
- Hb E/ Delta Beta thalassemia
- Hb C/ Beta^{0}thalassemia
- Hb C/Beta$^+$ thalassemia
- Hb D/ Beta^0 thalassemia
- Hb D/Beta$^+$ thalassemia
- Hb Variant/ Beta^{0}thalassemia
- Hb Variant/Beta$^+$ thalassemia
- other hemoglobinopathies (Hb variants)

Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the Newborn Screening Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk to justify a diagnostic work-up, a negative screening result does not rule out the possibility of a disorder. Health care providers should remain watchful for any sign or symptoms of these disorders in their patients. A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider.

(Updated 12/15/2009)

National Newborn Screening and Genetics Resource Center

NNSGRC

National Newborn Screening Status Report

Updated 03/01/10

The U.S. National Screening Status Report lists the status of newborn screening in the United States.

Dot "●" indicates that screening for the condition is universally required by Law or Rule and fully implemented
A = universally offered but not yet required, **B** = offered to select populations, or by request, **C** = testing required but not yet implemented
D = likely to be detected (and reported) as a by-product of MRM screening (MS/MS) targeted by Law or Rule

STATE	Core[1] Conditions										Additional Conditions Included in Screening Panel (universally required unless otherwise indicated)
	Hearing	Endocrine		Hemoglobin			Other				
	HEAR	CH	CAH	Hb S/S	Hb S/A	Hb S/C	BIO	GALT	CF	SCID	
Alabama	●	●	●	●	●	●	●	●	●		
Alaska	●	●	●	●	●	●	●	●	●		
Arizona	A	●	●	●	●	●	●	●	●		
Arkansas	●	●	●	●	●	●	●	●	●		
California	B	●	●	●	●	●	●	●	●		HHH; PRO; EMA

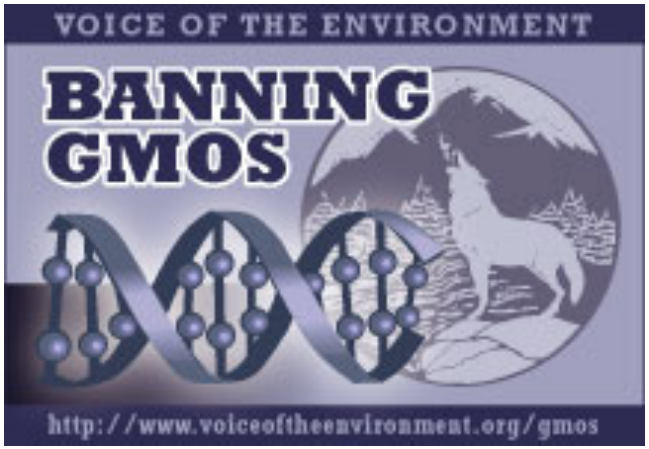
STATE	Core[1] Conditions - Metabolic																			
	Fatty Acid Disorders					Organic Acid Disorders									Amino Acid Disorders					
	CUD	LCHAD	MCAD	TFP	VLCAD	GA-I	HMG	IVA	3-MCC	Cbl-A,B	BKT	MUT	PROP	MCD	ASA	CIT	HCY	MSUD	PKU	TYR-1
Alabama	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Alaska	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Arizona	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Arkansas	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
California	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

STATE	Secondary Target[1] Conditions																								
	Fatty Acid Disorders								Organic Acid Disorders						Amino Acid Disorders								Other Metabolic		Hbg
	CACT	CPT-Ia	CPT- II	DE-RED.	GA-II	MCKAT	M/SCHAD	SC AD	2M3HBA	2MBG	3MGA	Cbl-C,D	IBG	MAL	ARG	BIOPT-BS	BIOPT-RG	CIT-II	H-PHE	MET	TYR- II	TYR- III	GALE	GALK	Variant Hbg's
Alabama	●		●		●				●	●	●	●				●	●	●	●	●	●	●			●
Alaska	●	●	●		●			●	●	●	●	●	●	●	●	B	B	●	●	●	●		B	B	●
Arizona	D	D	D		D				D		D	D						D	D		D	D			D
Arkansas																			●						●
California	●	●	●		●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●				●

Mandatory Screening For >50 Genetic Disorders

California GMO Bans

Counties	Cities
Mendocino Marin, Santa Cruz Trinity	Arcata Point Arena.



State Laws on Stem Cell Research

State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/ embryo	Consent provisions to conduct research on fetus/embryo[3]	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Arizona §§36-2302, 2303	No	Yes, prohibits research on aborted living/non-living embryo or fetus	No	Yes, prohibits the use of public monies for cloning for research	No
Arkansas §§20-17-802, 20-16-1001 to 1004	No	Yes, prohibits research on aborted live fetus	Yes, consent to conduct research on aborted fetus born dead	Yes, prohibits research on cloned embryos	Yes, prohibits sale of fetus/fetal tissue
California Health & Safety 2004 Proposition 71 §§ 123440, 24185, 12115-7, 125300-320	Yes, permits research on adult and embryonic stem cells from any source	Yes, prohibits research on aborted live fetus	Yes, consent to donate IVF embryo to research	Prohibits sale of embryos and oocytes; prohibits payment in excess of the amount of reimbursement of expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research	Yes, prohibits sale for the purpose of reproductive cloning or for stem cell research

State Laws on Human Cloning

State	Statute Citation	Summary	Prohibits Reproductive Cloning	Prohibits Therapeutic Cloning	Expiration
Arizona	HB 2221 (2005)	Bans the use of public monies for reproductive or therapeutic cloning.	Prohibits use of public monies	Prohibits use of public monies	
Arkansas	§20-16-1001 to 1004	Prohibits therapeutic and reproductive cloning; may not ship transfer or receive the product of human cloning; human cloning is punishable as a Class C felony and by a fine of not less than $250,000 or twice the amount of pecuniary gain that is received by the person or entity, which ever is greater	yes	yes	
California	Business And Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7	Prohibits reproductive 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	yes	no	

Constitutional?

Stem Cell Research

State Laws on Stem Cells

Updated January 2008

Many state statutes that have an impact stem cell research were enacted to address other issues such as abortion and in vitro fertilization over the last few decades. There are four primary sources for embryonic stem cells: existing stem cell lines, aborted or miscarried embryos, unused in vitro fertilized embryos, and cloned embryos. Research on only one, multiple, or all sources may be subject to state law. Current federal policy limits federally funded research to research conducted on embryonic stem cell lines created before August 2001. Federal funding of research involving cloning for the purpose of reproduction or research is prohibited. However, there is no federal law banning human cloning altogether. The Food and Drug Administration has claimed authority over the regulation of human cloning technology as an investigational new drug (IND) and stated that at this time, they would not approve any projects involving human cloning for safety reasons, but Congress has not passed legislation confirming the FDA's authority to prohibit cloning.

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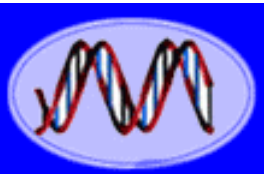
What About Other Legal Issues Dealing With Genetic Engineering?

Life Is Patentable

(Diamond vs. Chakrabarty)

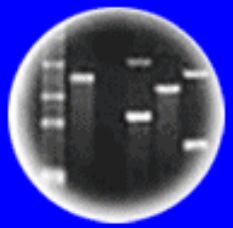
SCIENCE MAY PATENT NEW FORMS OF LIFE, JUSTICES RULE, 5 TO 4

6/17/1980



DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

Should Patenting a Genetically Engineered Mouse Be Permitted?

a. Yes
b. No

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 Latimer*—had tried to patent fibers separated from the plant and was turned down


Iris

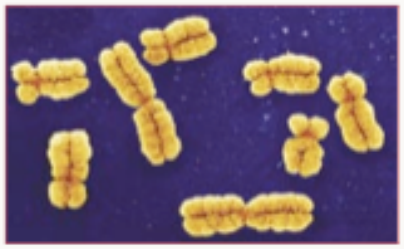
1930
The U.S. Congress passes the Plant Patent Act, which allows the patenting of new plant varieties that reproduce asexually

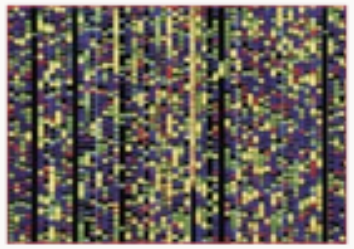
1948
A Supreme Court ruling held that simply combining bacteria does not count as an invention (*Funk Brothers Seed Company v. Kalo Inoculant Company*)

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


Human chromosomes


DNA sequencing

1980
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

1990
The Human Genome Project is launched

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 infoporn

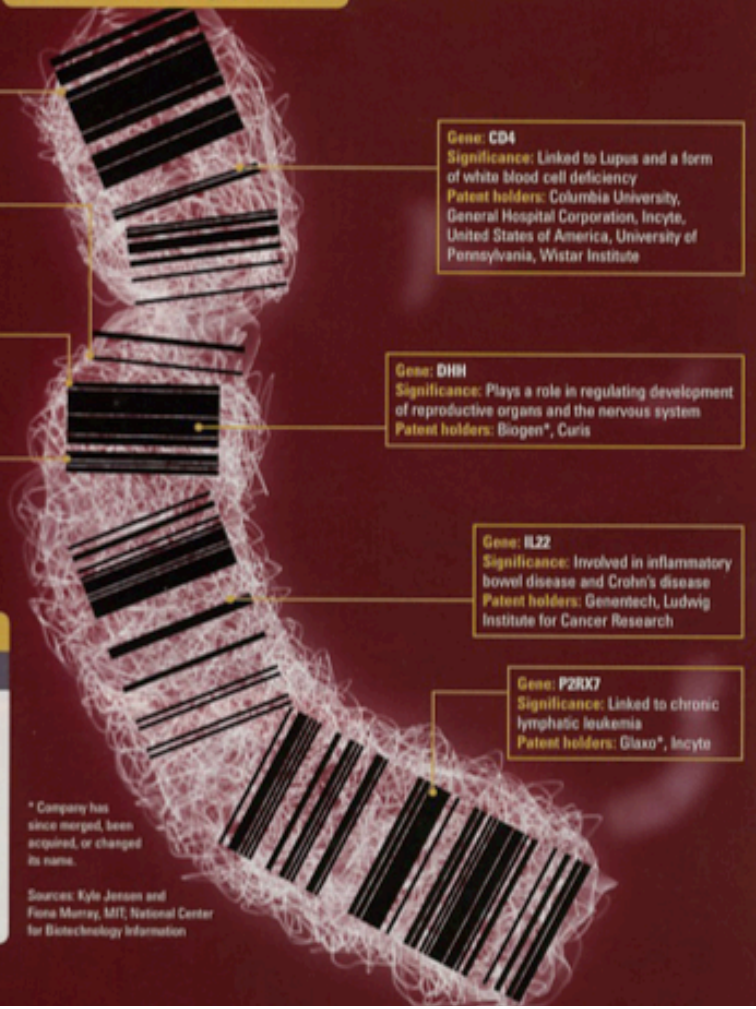
Everybody Wants a Piece of You

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

You've heard of patenting 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 – nearly a fifth of 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

374 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 thyroid 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: RDH5
Significance: Related to night blindness
Patent holders: Ludwig Institute for Cancer Research, PE Corporation*

Gene: CD4
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: DHH
Significance: Plays a role in regulating development of reproductive organs and the nervous system
Patent holders: Biogen*, Curis

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

Gene: P2RX7
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	90
5	The Regents of the University of California	89
6	SmithKline Beecham*	79
7	Applera	59
8	Isis Pharmaceuticals	58
9	Genetics Institute*	53
10	Lexicon Genetics	48

* Company has since merged, been acquired, or changed its name.

Sources: Kyle Jensen and Fiona Murray, MIT; National Center for Biotechnology Information

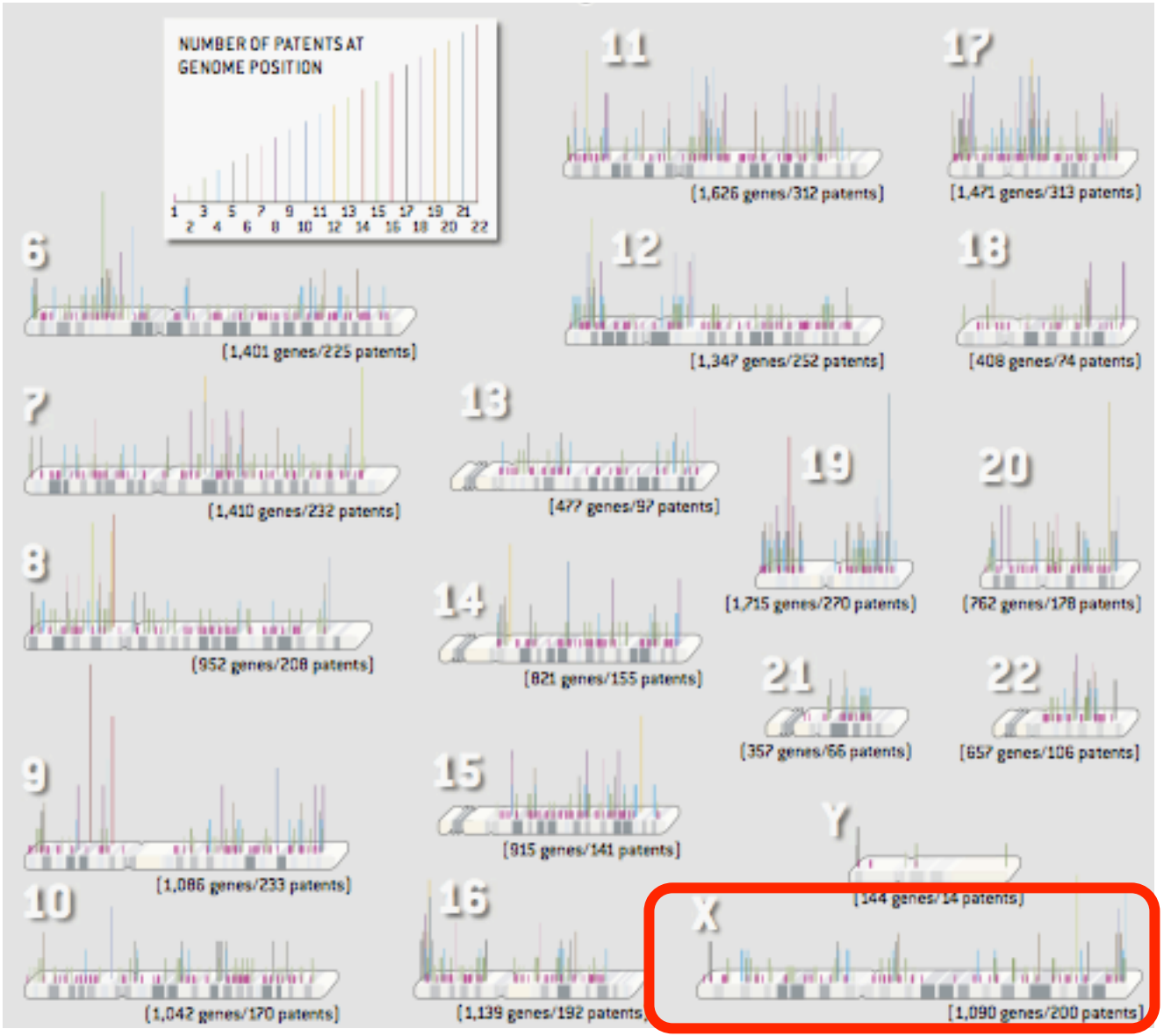
One-Fifth of Human Genes Have Been Patented, Study Reveals

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

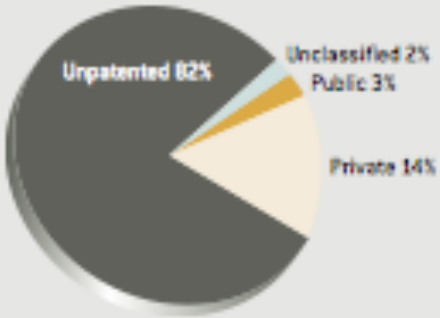
The granting of patents involving nucleic acids, including from nonhumans, peaked in 2001 and then declined [*graph*], probably because of tightening requirements. The holders of many of the patents are listed in the table [*right*].

LARGEST PATENT HOLDERS	NUMBER OF PATENTS†
University of California	1,018
U.S. government	926
Sanofi 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	289
Massachusetts General Hospital	287
Novo 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

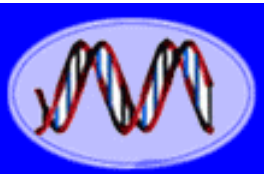
† as of 9-14-05

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.



Scientific American, February 2006



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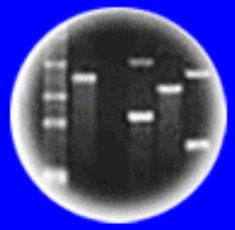


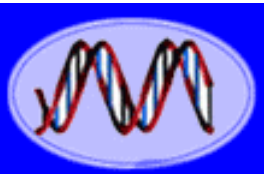
DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

The Genes in Your Chromosomes Can Be Patented?

a. Yes
b. No



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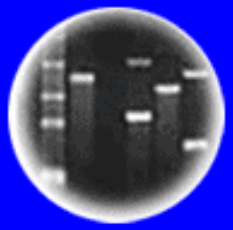

DNA Fingerprinting

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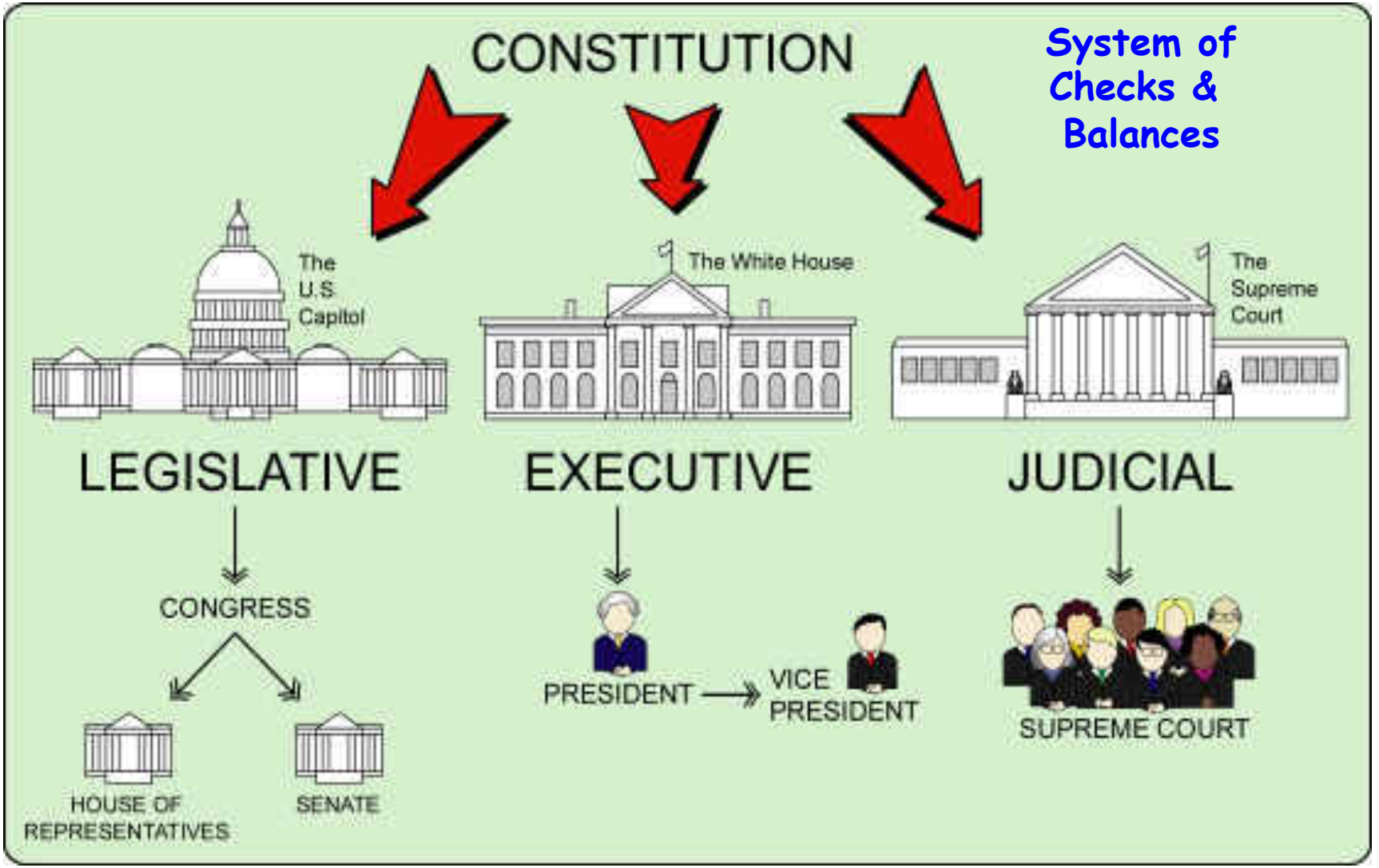
Genes Can Be Patented?

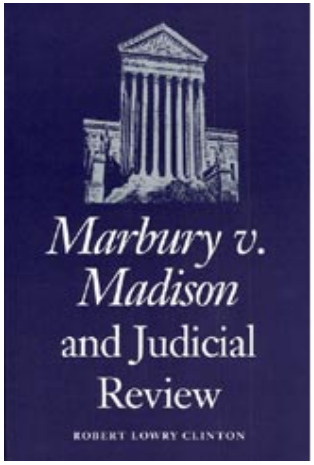
a. Yes
b. No

Organization of the United States Government

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



1776, David McCullough *John Adams*, David McCullough *Founding Brothers*, Joseph Ellis



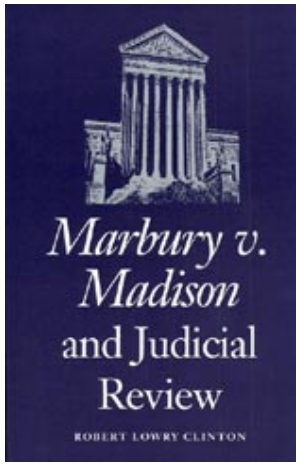
Marbury v. Madison-1803

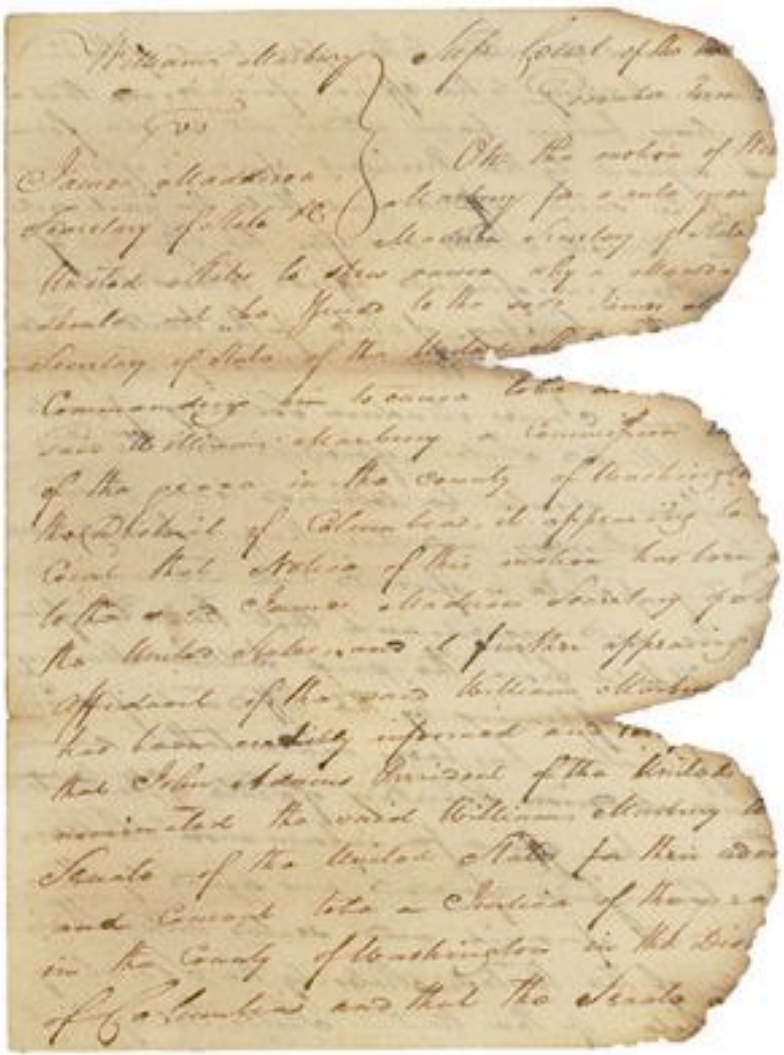
The critical importance of Marbury is the assumption of several powers by the Supreme Court. One was the a uthority to declare acts of Congress, and by implication acts of the president, unconstitutional if they exceeded the powers granted by the Constitution. But even more i mportant, the Court became the arbiter of the Constitution, the f inal 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,





National Archives

Marshall Law: Remnants of a court order served to Madison in 1802, from the National Archives

JUSTICE

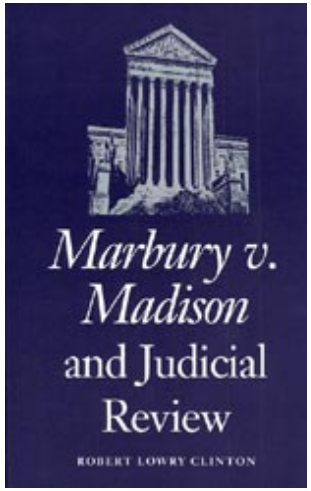
Why Marbury V. Madison Still Matters

More than 200 years after the high court ruled, the decision in that landmark case continues to resonate.

By Cliff Sloan and David McKean | NEWSWEEK

Published Feb 21, 2009

From the magazine issue dated Mar 2, 2009



How Does the Constitution Affect Science Directly or Indirectly?

Article or Amendment	What Is Application?
Preamble	Promote the General Welfare
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

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, provde 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)

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

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

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 (Combined DNA Index System)
- OSHA-Lab Safety
- FDA, CDC, etc.

Amendment IV

Searches and Seizures

- Body Parts (e.g., hair)
- Saliva (DNA testing)
- Blood (DNA testing)
- Cheek Swab (DNA testing)
- Lab Notebooks, Records

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: PGS, amniocentisis, chorionic villi sampling)
- In Vitro Fertilization
- Stem Cells
- Birth Control
- Cloning (therapeutic)
- Medical Treatment (life)

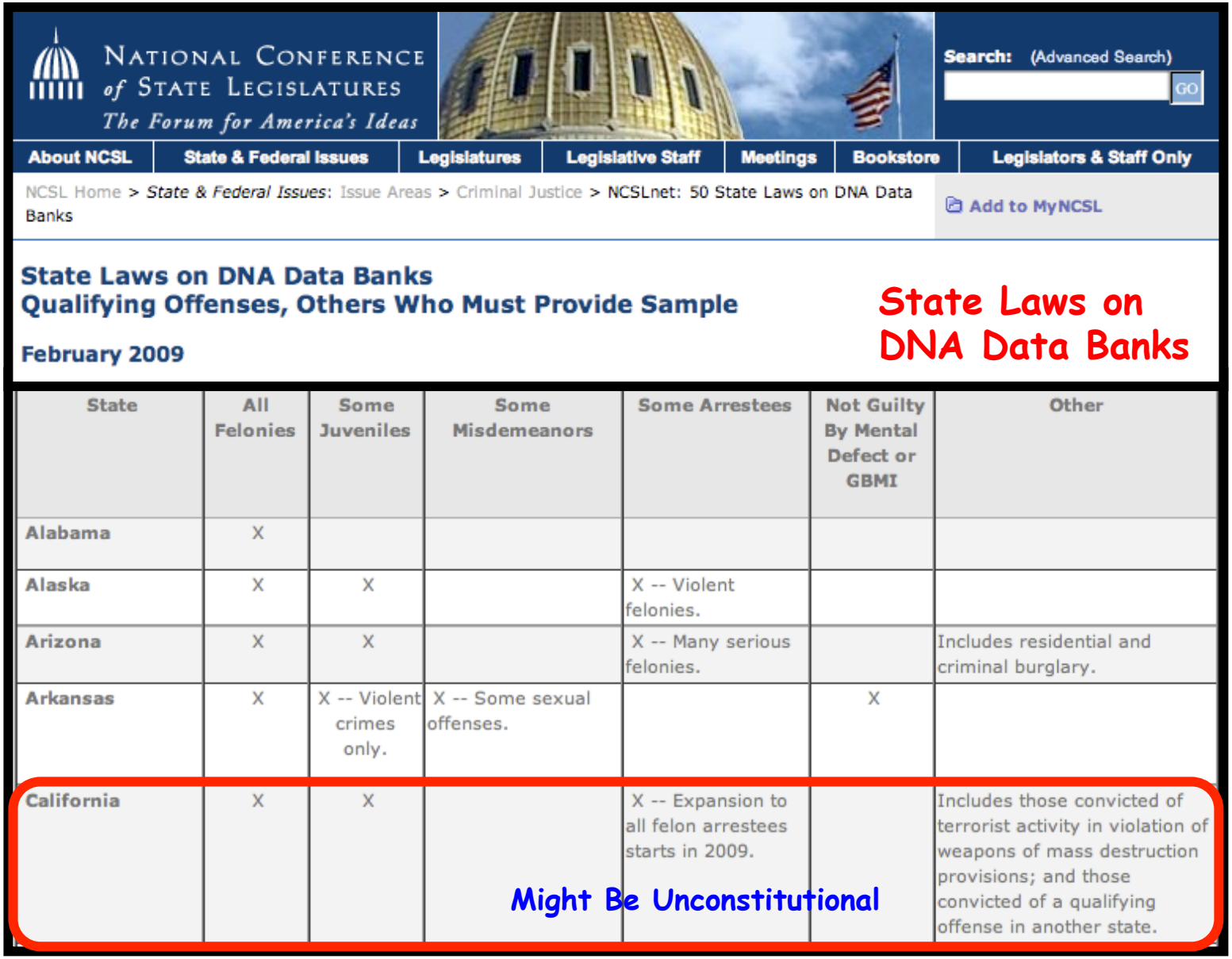
Amendment X

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)
- DNA Data Bases, etc.

Laws Exist That Regulate Science at the State Level



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Qualifying Offenses, Others Who Must Provide Sample

February 2009

State Laws on DNA Data Banks

State	All Felonies	Some Juveniles	Some Misdemeanors	Some Arrestees	Not Guilty By Mental Defect or GBMI	Other
Alabama	X					
Alaska	X	X		X -- Violent felonies.		
Arizona	X	X		X -- Many serious felonies.		Includes residential and criminal burglary.
Arkansas	X	X -- Violent crimes only.	X -- Some sexual offenses.		X	
California	X	X		X -- Expansion to all felon arrestees starts in 2009.		Includes those convicted of terrorist activity in violation of weapons of mass destruction provisions; and those convicted of a qualifying offense in another state.

Might Be Unconstitutional

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?

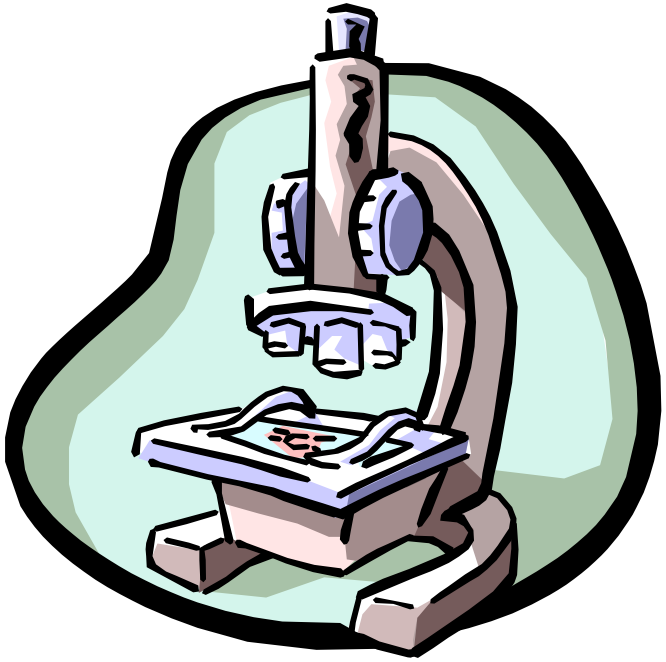
CAN EXPERIMENTATION (e.g, recombinant dna, stem cells) BE REGULATED?

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 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."*

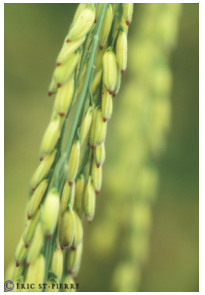
Case #2-Sale of Genetically Engineered GloFish in CA-2003

- **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., anitbiotics, vaccines). Registration of all human pathogens and pathogen researcch in US Laboratories.

Principle: Public Safety/Welfare Risk

Can Think But Can't Always Act!

How Can Genetic Engineering 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 (EPA)

UCLA Biohazard Committee Approvals

1978

UNIVERSITY OF CALIFORNIA, LOS ANGELES
BIOHAZARDS COMMITTEE

Approval Notice

PRINCIPAL INVESTIGATOR OF MAIN GRANT: Robert B. Goldberg

TITLE OF MAIN GRANT: Isolation of Seed Storage Protein Genes for the Soybean Plant

PRINCIPAL INVESTIGATOR OF PROTOCOL: Same as above

DEPARTMENT: Biology

DIVISION: ----------

TITLE OF PROJECT: Organization and Expression of Seed Storage Protein Genes in Soybean Development

FUNDING AGENCY: NIH

CONTRACT OR GRANT NO. (If known): ----------

DATES FOR WHICH REVIEWED: FROM: 4-1-79 TO: 3-31-80

DATE FOR RE-SUBMISSION: 2-28-80

DATE APPROVED: 5-18-78

ACTUAL STARTING DATE OF PROTOCOL: 4-1-79

The Biohazards Committee has reviewed the proposed use of recombinant DNA molecules in the project identified above and assures that:

The applicable facilities and procedures have been reviewed by the Biohazards Committee and judged to be both adequate and consistent with the requirements of the NIH guidelines.

The Biohazards Committee will monitor the facilities and procedures throughout the duration of the project.

P2-EK1

Date: May 18, 1978

Signature: David D. Pratt.
Chairman, Biohazards Committee

Original to: National Institutes of Health
cc to: Director, Office of Contract and Grant Administration
Principal Investigator

MEMORANDUM OF UNDERSTANDING AND AGREEMENT

1. As principal investigator I am familiar with the NIH Guidelines for Research Involving Recombinant DNA Molecules (issued June 23, 1976 and published in the Federal Register, July 7, 1976). I agree to abide by their provisions.

Signed Robert B. Goldberg
Robert B. Goldberg
Assistant Professor of Biology

2. Experiments which involve recombinant DNA molecules.

A. Background. "Organization and Expression of Seed Storage Protein Genes in Soybean Development"

3. An assessment of the levels of physical and biological containment required by the current NIH Guidelines for these experiments.

The formation of hybrids between plant DNA and bacterial plasmids is given a P2-EK1 classification provided that the plant does not harbor a pathogenic agent nor produce a product toxic to other species (NIH Guidelines, III-18). Plant varieties to be used in experiments with plasmid DNAs do not harbor known plant viruses or pathogenic bacteria, nor do they produce any toxic product. As such I assess a P2-EK1 level of containment as appropriate for these experiments.

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