

# HC70A & SAS70A Winter 2014 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg, Channapatna Prakash & John Harada

Lecture 9

Science & The Constitution: Regulating Science & Genetic Engineering











# TEXT READING

Chapter 9 (Biotechnology Regulations) & Chapter 10 (Ethics & Biotechnology)

Biotechnology Agencies, Laws, & Patents







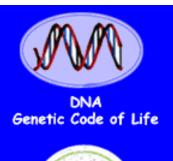


### SELECTED REFERENCES

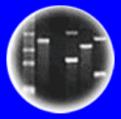
- 1. Cloning & The Constitution, By I.H. Carmen (1985)
- 2. A Practical Companion To The Constitution, By J.K. Lieberman (1999)
- 3. The Recombinant DNA Controversy: A Memoir, By D. S. Fredrickson (2001)
- 4. Genetics: Ethics, Law, and Policy, By Lori B. Andrews et al. (2002)
- 5. Stem Cell Century, By Russell Korobkin (2007)
- 6. Biotechnology and The Law, By H.B. Wellons et al. (2007)
- 7. A Guide to Biotechnology Law & Business, By Robert A. Bohrer (2007)
- 8. The Role of Science in The Law, By Robin Feldman (2009)
- 9. Patent, Copyright, & Trademark, By R. Stim (2012)
- 10.Patents in Genomics and Human Genetics, By Robert Cook-Deegan & Christopher Heaney, Annu. Rev. Human Genetics, 11, 383-425 (2010)
- 11. Maryland vs. King, US Supreme Court, June, 2013











**DNA Fingerprinting** 



Cloning: Ethical Issues and Future Consequences



Plants of Tomorrow

## **THEMES**

- 1. History of Genetics & Law in the US
- 2. Inborn Errors & Eugenics
- 3. Evolution and the Law
- 4. Historical Attempts to Regulate Science-The Genetic Engineering & Stem Cell Controversies
- 5. Examples of Regulating Science at the Federal and State Levels
- 6. Patenting Your Genes
- 7. Government of the United States
- 8. What is in the Constitution About Science-Directly & Indirectly?
- 9. Can Scientific Inquiry and Research Be Regulated?
- 10. Can Experimentation Be Regulated Directly?
- 11. Case Studies in Regulating Science Directly
- 12. Can Science Be Regulated Indirectly?
- 13. Regulating Science-A Summary

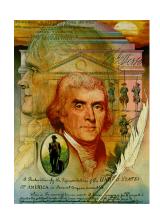
"Laws and institutions must go hand in hand with the progress of the human mind. As that becomes more developed, more enlightened, as new discoveries are made, new truths disclosed, and manners and opinions change with the change of circumstances, institutions must advance also, and keep pace with the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

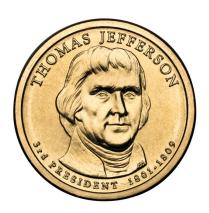
Thomas Jefferson, July 12, 1810

## Is 1810 Science the same 2014 Science?

### What Was Known About Biology in 1810?

- The Cell (1665)
- Scientific Method (1637)
- Living From Living (1668)
- Microscope and Microorganisms (1674)
- Modern Organism Classification System (1735)
- Smallpox Vaccination (1796)
- Lamarckian Evolution (1809)







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



# Garrod Discovered That Some Human Metabolic Diseases Have a Genetic Basis And Follow Mendelian Rules of Inheritance

# INBORN ERRORS OF METABOLISM

The Croonian Lectures delivered before the Royal College of Physicians of London, in June, 1908

## ARCHIBALD E. GARROD

D.M., M.A. OXON.

Fellow of the Royal College of Physicians,
Assistant Physician to, and Lecturer on Chemical Pathology
at St. Bartholomew's Hospital,
Physician to the Hospital for Sick Children,
Great Ormond Street



LONDON

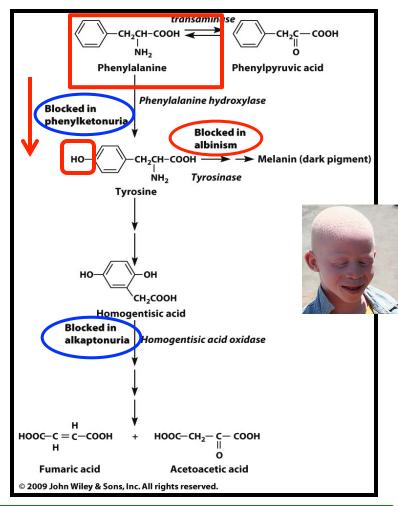
HENRY FROWDE HODDER & STOUGHTON
OXFORD UNIVERSITY PRESS 20, WARWICK SQUARE, E.C.

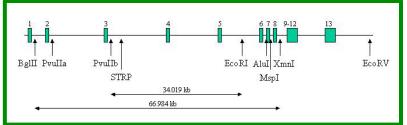
1909

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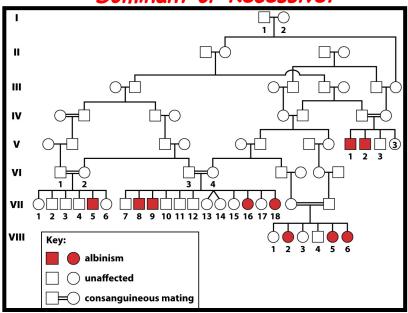
It appears to me that the strongest argument which can be adduced in favour of this view that alkaptonuria is a Mendelian recessive character is afforded by the fact that albinism, which so closely resembles it in its mode of incidence in man, behaves as a recessive character in the experimental breeding of animals.<sup>32</sup> Nor do the figures quoted by Bateson or relating to the proportion of albino members in human families show any more close conformity to the requirements of Mendel's law than do those above quoted for alkaptonuric families.

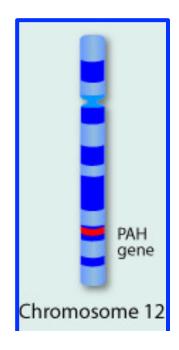
## Inborn Errors of Metabolism - Defects in Phenylalanine Breakdown

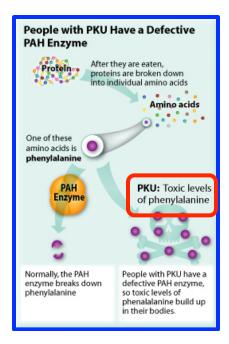




#### Dominant or Recessive?









## PHENYLKETONURIA (1/15,000 US Children)



#### **SYMPTOMS**

 Phenylalanine plays a role in the body's production of melanin, the pigment responsible for skin and hair color. Therefore, infants with the condition often have lighter skin, hair, and eyes than brothers or sisters without

the disease.

- Delayed mental and social skills
- Head size significantly below normal
- Hyperactivity
- Jerking movements of the arms or legs
- Intellectual disability
- Seizures
- Skin rashes
- Tremors
- Unusual positioning of hands

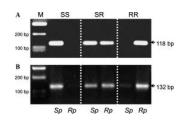
#### **TESTS**

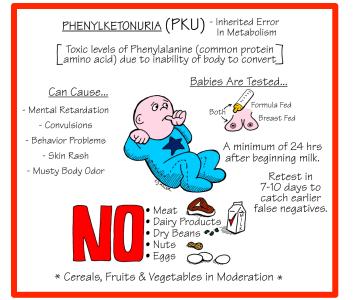
PKU can be easily detected with a <u>simple blood test</u>. All states in the US require a PKU screening test for all newborns as part of the newborn screening panel. The test is generally done by taking a few drops of blood from the baby before the baby leaves the hospital.

DNA Testing

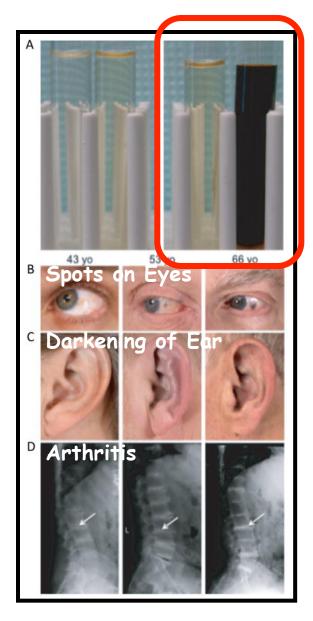








# Inborn Errors in the Homogentisic Acid Oxidase (HGD) Gene Leading to Alkaptonuria



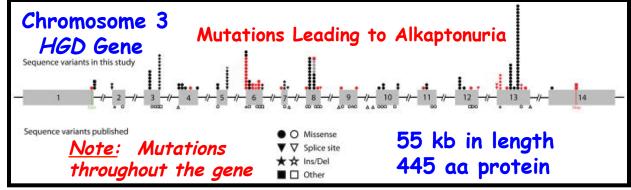


Hum Mutat. Author manuscript; available in PMC 2010 December 1.

Published in final edited form as:

Hum Mutat. 2009 December; 30(12): 1611-1619. doi:10.1002/humu.21120.

Mutation spectrum of homogentisic acid oxidase (*HGD*) in alkaptonuria



#### Summary of identified HGD variants

Note: Different Types of Mutations

	Missense	Splice site	Indel a	Other b	Total
NIH Study (Novel)	36 (14)	7 (3)	6 (3)	3 (2)	52 (22)
Other published	26	6	4	3	39
Total	62	13	10	6	91

alndel: includes insertions, deletions and insertion-deletions

DOther: Includes nonsense and no-stop mutations

## Francis Galton Invented the Term Eugenics



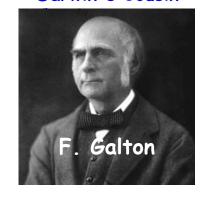
- · Regression Line
- · Standard Deviation
- · Correlation
- Fingerprint Patterns

## **EUGENICS**

"IS THE STUDY OF THE AGENCIES UNDER SOCIAL CONTROL, THAT IMPROVE OR IMPAIR THE RACIAL QUALITIES OF FUTURE GENERATIONS EITHER PHYSICALLY OR MENTALLY."

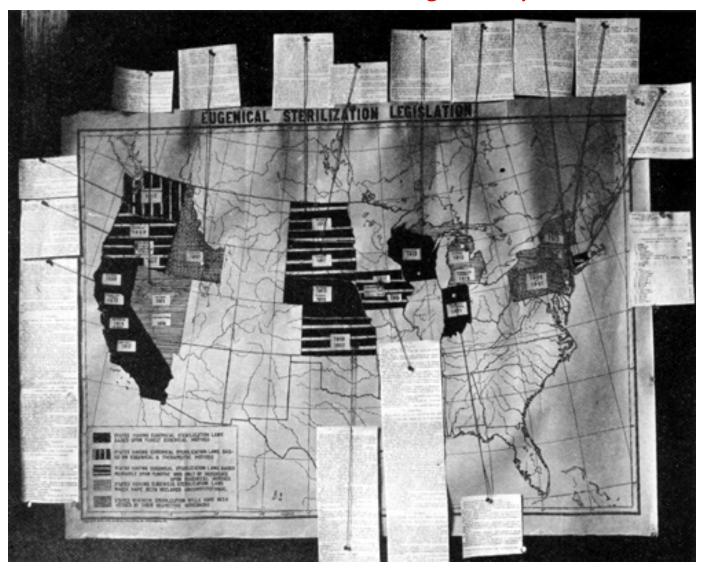
SIR FRANCIS GALTON.

#### Darwin's Cousin



# State Sterilization Laws 1921

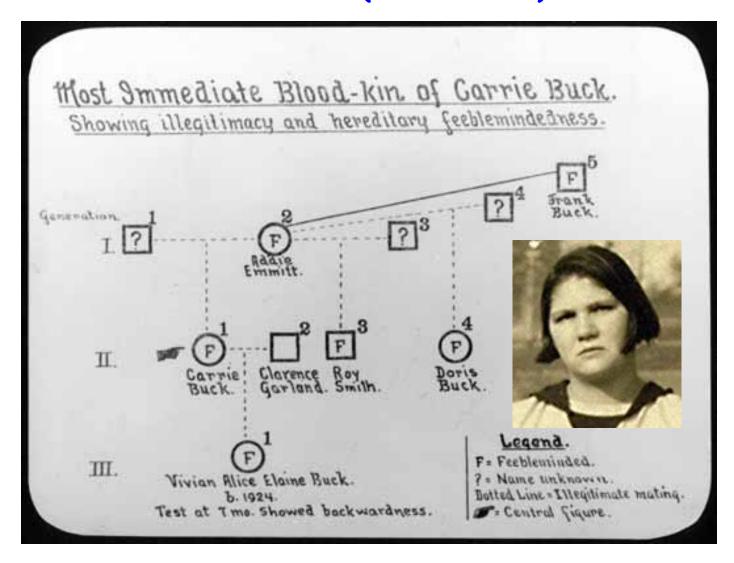
Government Intervention to Promote Biological Improvement of Humans



64,000 Forced Sterilizations in US - Last one in Oregon in 1981 (Tubal Ligations & Vasectomies)



# One of the Most Famous Sterilization Cases in US Legal History Carrie Buck (Buck vs. Bell)



State of Virginia Colony For Epileptics & Feebleminded - 1924

# O 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.

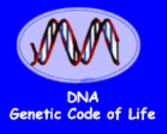
# BUCK v. BELL

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 <u>"Three</u> generations of imbeciles are enough."

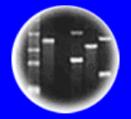




# Laws Impacting the Teaching of Science......



Entire Genetic Code of a Bacteria



**DNA Fingerprinting** 

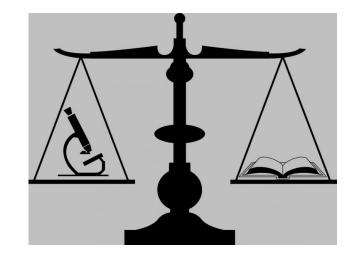


Cloning: Ethical Issues and Future Consequences



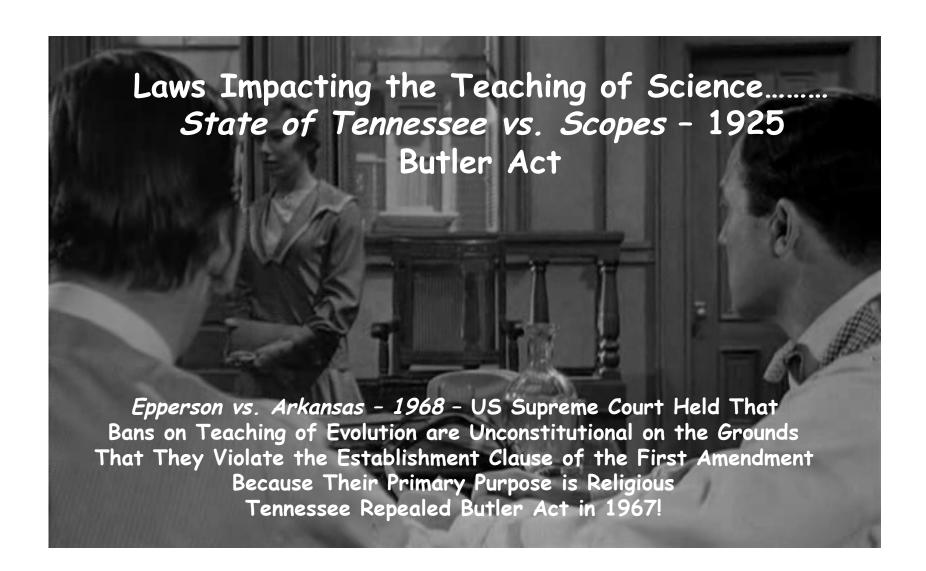








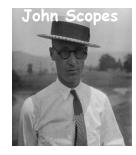




# The Scopes Strategy: Creationists Try New Tactics to Promote Anti-Evolutionary Teaching in Public Schools

Under the guise of "academic freedom" creationists are co-opting some old heroes of the fight to teach evolution in the classroom for their anti-science campaign

By Lauri Lebo | Monday, February 28, 2011 | ₹ 23



# Ten Major Court Cases about Evolution and Creationism

- In 1968, in Epperson v. Arkansas, the United States Supreme Court invalidated an Arkansas statute that prohibited the teaching of evolution. The Court held the statute unconstitutional on the grounds that the First Amendment to the U.S. Constitution does not permit a state to require that teaching and learning must be tailored to the principles or prohibitions of any particular religious sect or doctrine. (Epperson v. Arkansas (1968) 393 U.S. 97, 37 U.S. Law Week 4017, 89 S. Ct. 266, 21 L. Ed 228)
- 4. In 1987, in Edwards v. Aguillard, the U.S. Supreme Court held unconstitutional Louisiana's "Creationism Act". This statute prohibited the teaching of evolution in public schools, except when it was accompanied by instruction in "creation science". The Court found that, by advancing the religious belief that a supernatural being created humankind, which is embraced by the term creation science, the act impermissibly endorses religion. In addition, the Court found that the provision of a comprehensive science education is undermined when it is forbidden to teach evolution except when creation science is also taught. (Edwards v. Aguillard (1987) 482 U.S. 578)
- 10. On December 20, 2005, in Kitzmiller et al. v. Dover, U.S. District Court Judge John E. Jones III ordered the Dover Area School Board to refrain from maintaining an Intelligent Design Policy in any school within the Dover Area School District. The ID policy included a statement in the science curriculum that "students will be made aware of gaps/problems in Darwin's Theory and other theories of evolution including, but not limited to, intelligent design." Teachers were also required to announce to their biology classes that "Intelligent Design is an explanation of the origin of life that differs from Darwin's view. The reference book Of Pandas and People is available for students to see if they would like to explore this view in an effort to gain an understanding of what Intelligent Design actually involves As is true with any theory students are encouraged to keep an open mind". In his 139-page ruling, Judge Jones wrote it was "abundantly clear that the Board's ID Policy violates the Establishment Clause". Furthermore, Judge Jones ruled that "ID cannot uncouple itself from its creationist, and thus religious, antecedents". In reference to whether Intelligent Design is science Judge Jones wrote ID "is not science and cannot be adjudged a valid, accepted scientific theory as it has failed to publish in peer-reviewed journals, engage in research and testing, and gain acceptance in the scientific community". This was the first challenge to the constitutionality of teaching "intelligent design" in the public school science classroom. (Tammy Kitzmiller, et al. v. Dover Area School District, et al., Case No. 04cv2688)



# BOROUGH OF

The ruling concluded that intelligent design is not science, and permanently barred the board from "maintaining the ID Policy in any school within the Dover Area School District, from requiring teachers to denigrate or disparage the scientific theory of evolution, and from requiring teachers to refer to a religious, alternative theory known as ID."



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

# The Genetic Engineering Controversy: 1974-1986

The Recombinant DNA Controversy: A Memoir, By D.S. Fredrickson (2001)

# 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

Berg Letter (1974), Asilomar

by Clifford Grobstein

(1975), NIH Guidelines & Recombinant DNA Advisory
Committee (RAC) (1976)

Cohen-Boyer-1973 DECEMBER OF THE OFFICE MONING TO BE E. COLI HOST CELL PROPAGATION BY

	EK1	CONTAINMENT (FOR E. COLI HOST SYST	EMS ONLY)
P1	DNA from nonpathogenic prokaryotes that naturally exchange genes with £. coli.  Plasmid or bacteriophage DNA from host cells that naturally exchange genes with £. 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.)	ENE	ens .
P2	DNA from embryonic or germ-line cells of cold-blooded wertebrates  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 £. coll  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 £. coli  DNA from nonpathogenic prokaryotes that do not naturally exchange genes with £. coli  DNA from plant viruses  Organelic DNA from primates. (For organelic DNA from primates. (For organelic DNA from primates.)  Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with £. col. (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 £. coli DNA from plant viruses Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with £. 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 £. cof  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)	

Nobel Prize
For
Inventing
Genetic
Engineering

# 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 St	orage Protein Genes for the Soybean Plant				
PRINCIPAL INVESTIGATOR OF PROTOCOL:	FUNDING AGENCY: NIH				
Same as above	CONTRACT OR GRANT NO. (If known):				
DIVISION: Biology	DATES FOR WHICH REVIEWED: FROM: 4-1-79 TO: 3-31-80				
TITLE OF PROJECT: Organization and Expression of Seed Storage Protein Genes in	RE-SUBMISSION: 2-28-80				
Soybean Development	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: V. J. M. J. 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 Assistant Professor of Biology

2. Experiments which involve recombinant DNA molecules.

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

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

#### 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

# HARVARD AND TOWN DEBATE GENE STUDY

1/17/77

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

# CALIFORNIA WEIGHING CURBS ON GENE STUDY

2/7/77

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





# Attempts to Regulate Human Cloning and Stem Cell Research at the Local, State, & Federal Levels?

## The Stem Cell Funding "Wars" - 1995 to Present

- · President Clinton's NIH Advisory Panel Recommended That Federal Funds Be Used For Research on Human Embryos Discarded From In Vitro Fertilization -1995
- · Dickey-Wicker Amendment Prohibited Federal Funding For Research in Which Human Embryos Are Destroyed 1995
- · Human Embryonic Stem Cells Discovered (hESC) -1998
- President Bush Announced That Federal Funds Could Be Used For the First Time on Existing hESC Lines, but Not on Newly Established hESC lines - 2001
- President Bush Vetoes a Bill Passed by Congress Allowing Federal Funding of hESC
   Research 2006
- · Present Obama Announced That Federal Funds Could Be Used for hESC Research Consistent with the Dickey-Wicker Amendement 2009
- · US District Court Halts Federally Funded hESC research Under Obama Guidelines -2010
- US Appeals Court Allows Federally Funded hESC Research. Upheld by Supreme Court 2010, 2011, 2012, 2013

Bush vetoes embryonic stem-cell bill

Supreme Court rejects challenge to Obama stem cell policy







There is No Federal Human Cloning Law. HR6623, 2012 (Pending), Prohibition Against Human Cloning.

```
6 "(a) In General.—It shall be unlawful for any per-
7 son or entity, public or private, in or affecting interstate
8 commerce—
9 "(1) to perform or attempt to perform human
10 cloning;
11 "(2) to participate in an attempt to perform
12 human cloning; or
13 "(3) to ship or receive the product of human
14 cloning for any purpose.
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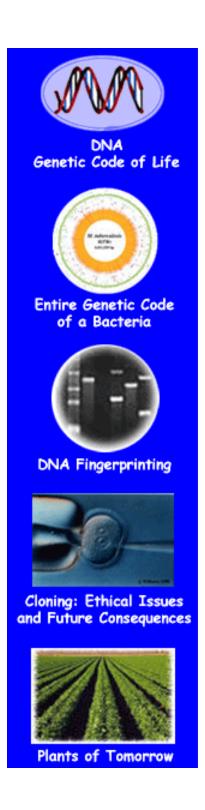
Fifteen States, Including California, Have Laws Dealing With Human Cloning -- From Banning Both Reproductive and Therapeutic Cloning to only Reproductive Cloning (e.g., California).



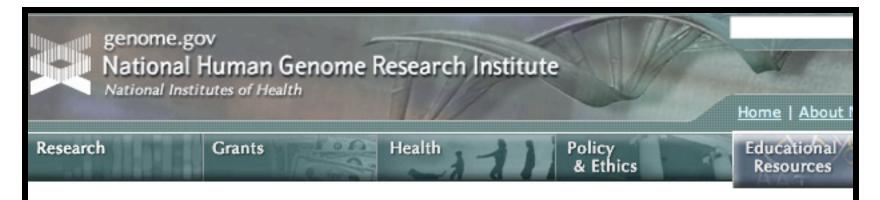
# Should There Be Laws That Prohibit Human Cloning?

a. Yes

b. No

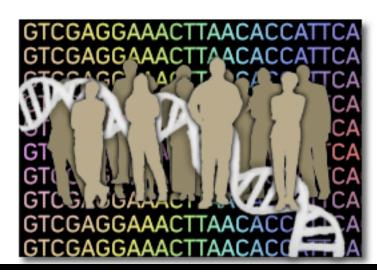


# Many Laws Exist That Regulate Science at the Federal Level Some Examples



Home > Educational Resources > Fact Sheets → Genetic Discrimination Fact Sheet

### Genetic Information Nondiscrimination Act of 2008 (GINA)



Federal Law on Genetic Discrimination

### Genetic Information Nondiscrimination Act of 2008

#### What will GINA do?

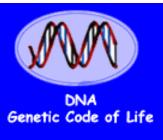
GINA generally will prohibit discrimination in health coverage and employment on the basis of genetic information. GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators 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 4<sup>th</sup> 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.

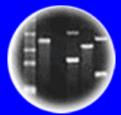
Genetic information does not include information about the sex or age of any individual.

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.





Entire Genetic Code of a Bacteria



**DNA Fingerprinting** 



Cloning: Ethical Issues and Future Consequences



Plants of Tomorrow

# DNA Identification Act of 1994

# One Hundred Third Congress of the United States of America

#### AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the twenty-fifth day of January, one thousand nine hundred and ninety-four

#### Subtitle C—DNA Identification

Sec. 210301. Short title.

Sec. 210302. Funding to improve the quality and availability of DNA analyses for

law enforcement identification purposes.

Sec. 210303. Quality assurance and proficiency testing standards.

Sec. 210304. Index to facilitate law enforcement exchange of DNA identification in-

formation.

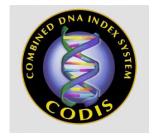
Sec. 210305. Federal Bureau of Investigation. Sec. 210306. Authorization of appropriations.

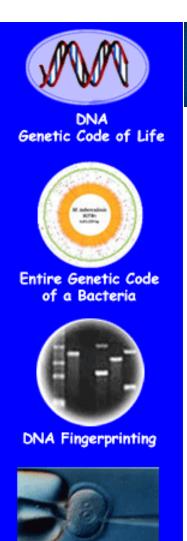
#### A BILL

To establish scientific standards and protocols across forensic disciplines, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE: TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Forensic Science and Standards Act of 2014".







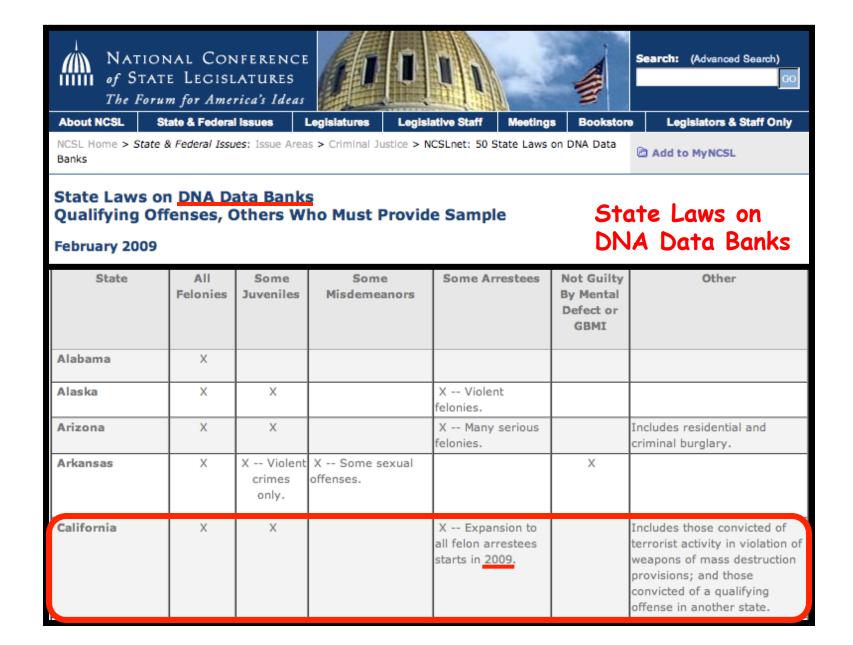
Cloning: Ethical Issues and Future Consequences

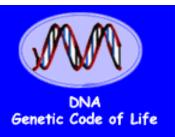
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# Laws Exist That Regulate Science at the State Level Some Examples

#### Laws Exist That Regulate Science at the State Level

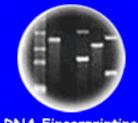
















Cloning: Ethical Issues and Future Consequences



#### SUPREME COURT OF THE UNITED STATES

Syllabus

MARYLAND v. KING

CERTIORARI TO THE COURT OF APPEALS OF MARYLAND

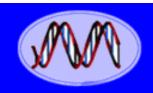
No. 12–207. Argued February 26, 2013—Decided June 3, 2013





#### California Genetic Laws

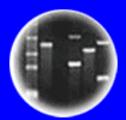
- · Newborn Genetic Screening
- · Genetic Non Discrimination in Insurance
- Human Cloning Laws
- · Genetic Employment Laws
- · Genetic Counselor Licensing Laws
- · Embryonic and Fetal Research Laws
- · Embryo and Gamete Disposition Laws
- Genetic Privacy Laws



Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues and Future Consequences



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### California Passes Law Prohibiting Discrimination Based on Genetic Information

POSTED ON OCTOBER 24, 2011 BY HUNTON & WILLIAMS LLP

As reported in the Hunton Employment & Labor Perspectives Blog:

California Governor Jerry Brown recently signed into law Senate Bill No. 559 (SB 559), which prohibits discrimination based on an individual's genetic information. While SB 559 significantly expands the protections from genetic discrimination provided under the federal Genetic Information Nondiscrimination Act of 2008 (GINA), at this time, its impact on most California employers is thought to be limited to the potential for greater damages to be awarded under it than under its federal counterpart.

#### What This Means for California Employers

GINA already prohibits discrimination on the basis of genetic information in the areas of employment and health insurance. Title II of GINA, which governs employers, prohibits the use of genetic information in hiring, termination, or making decisions related to compensation, terms, conditions, or privileges of employment. Title II also restricts employers from requesting, requiring, or purchasing genetic information, with certain limited exceptions, and limits the disclosure of genetic information. (A detailed discussion of the U.S. Equal Employment Opportunity Commission's final regulations interpreting Title II of GINA can be found here.) However, GINA's scope is limited to employers who employ 15 or more employees.

SB 559 extends the prohibition on discrimination based on genetic information to employers employing five or more persons. SB 559 also expands on the protections available under the federal law by prohibiting discrimination based on genetic information in the additional areas of housing, mortgage lending, public accommodations, emergency medical services, licensing exams, and programs administered or funded by the state. In the employment context, SB 559 amends the California Fair Employment and Housing Act (FEHA), which already protects the right and opportunity of all persons to seek, obtain and hold employment without discrimination on account of race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, marital status, sex, age, or sexual orientation, to also include genetic information as a prohibited basis for discrimination.



#### **National Newborn Screening Status Report**

#### Updated 01/06/13 Mandatory Screening For >50 Genetic Disorders

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

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California	•	•	•		•		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•				•



## California Genetic Privacy Laws

State and Statute	Personal		Consent Required to			Define as Persona	al Property	Specific Penalties
	Access to Genetic Infor- mation Required	Perform/ Require Genetic Test	Obtain/ Access Genetic Infor- mation	Retain Genetic Infor- mation	Disclose Genetic Infor- mation	Genetic Infor- mation	DNA Samples	for Genetic Privacy Violations
Alabama								
Alaska §18.13.010-100		×	х	x	×	x	х	х
Arizona		×			×			
§20-448.02								
Arkansas §20-35-101 to 103					х			
California					х			х
Insurance §10149.1								



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Issues & Research » Health » Genetic Nondiscrimination Laws in Life, Disability

Go 14283

#### 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	٧
Arkansas					
California Insurance §§10146 to 10149.1	v	v	v		v <sup>1</sup>





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Issues & Research » Health » Genetic Nondiscrimination in Health Insurance Laws

Go 14374

#### 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	Х	х	х	х





#### State Laws on Stem Cell Research

#### State Laws on Human Cloning

State/Jurisdiction Statute Section	permits research on fetus/embryo	on aborted fetus/ embryo	Consent provisions to conduct research on fetus/embryo <sup>3</sup>	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
Arizona §§ <u>36-2302</u> , <u>2303</u>	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	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 &	Yes, permits research	Ves prohibits	Yes, consent to	Prohibits sale of	Yes, prohibits sale
Proposition 71 §§	on adult and embryonic stem cells from any source		donate IVF embryo to research	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	for the purpose of reproductive cloning or for stem cell research

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		Constit	utional?
California	Professions <u>§16004</u> <u>5</u> Health & Safety <u>§24185, §24187,</u> <u>§24189, §12115-7</u>	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 renalties	ves	no	



## GloFish Fluorescing With Different Colors!!





### California GMO Bans

Counties

Mendocino
Marin,
Santa Cruz
Trinity

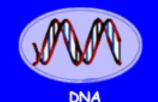
<u>Cities</u> Arcata Point Arena.

## California GMO Labeling Initiative

What About Federal Preemption?









Entire Genetic Code of a Bacteria



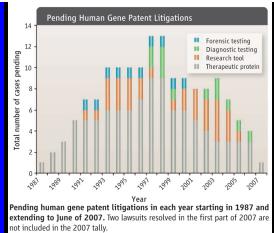
**DNA** Fingerprinting



Cloning: Ethical Issues and Future Consequences

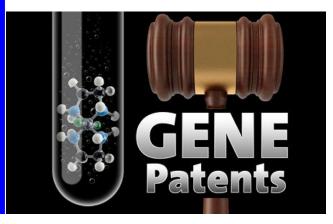


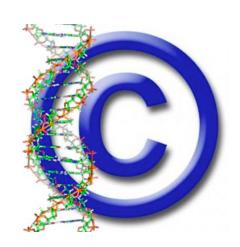
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## What About Other Legal Issues and Laws Dealing With Genes and Genetic Engineering?



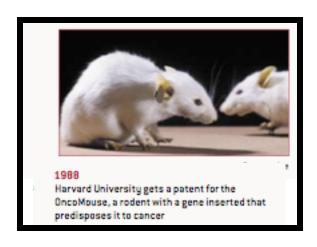


## Life Is Patentable

(Diamond vs. Chakrabarty)

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





#### **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 Altheimer'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: RDHS

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

#### Top 10 Holders of Gene Patents

PATENT HOLDER	NO. OF GENES	PATE	HI	ı
1 Incyte		about	2,00	×

1 Incyse	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

#### Gener CD4

Significance: Linked to Lupus and a form of white blood cell deficiency Patent helders: Columbia University, General Hospital Corporation, Incyte, United States of America, University of Ponasylvania, 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

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

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





March 29, 2010

#### **Judge Invalidates Human Gene Patent**

By JOHN SCHWARTZ and ANDREW POLLACK

A federal judge on Monday struck down patents on two genes linked to breast and ovarian cancer. The decision, if upheld, could throw into doubt the patents covering thousands of human genes and reshape the law of intellectual property

United States District Court Judge Robert W. Sweet issued the 152-page decision, which invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutations have been associated with cancer.

The American Civil Liberties Union and the Public Patent Foundation at the Benjamin N. Cardozo School of Law in New York joined with individual patients and medical organizations to challenge the patents last May: they argued that genes, products of nature, fall outside of the realm of things that can be patented. The patents, they argued, stifle research and innovation and limit testing options.

November 30, 2012

### Supreme Court to Look at a Gene Issue

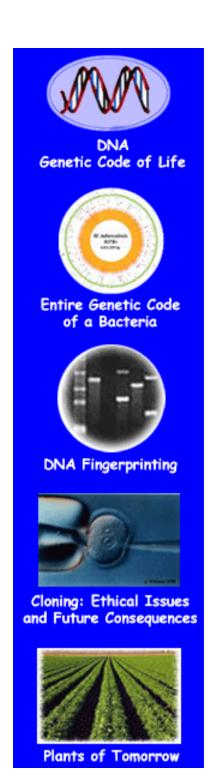
By ADAM LIPTAK





Rights to Human Gene Patents Go on Trial

Do patents on breast, ovarian cancer genes, retard new research?

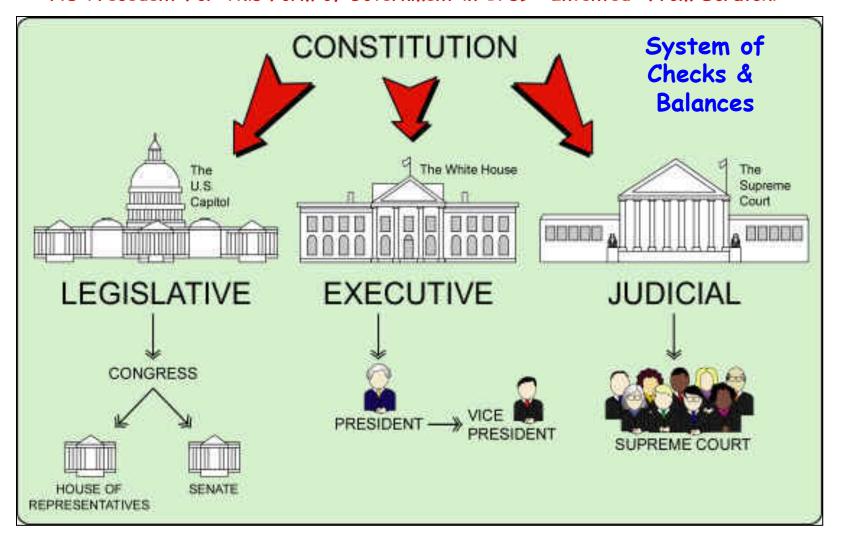


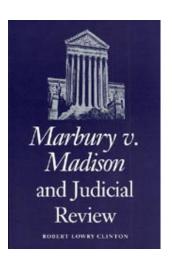
## What Enables the Federal Government & States To Enact Laws Regarding Science?

- Constitution-Article I Section 8.8
   Promote the General Welfare
  - Amendments-Bill of Rights
- Amendment X-Powers Reserved to States
  - Federal Criminal Statutes
    - State Constitutions
  - State Tort & Criminal Statutes

#### Organization of the United States Government

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



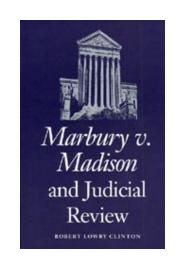


### Marbury v. Madison-1803

The critical importance of Marbury is the assumption of several powers by the Supreme Court. One was the 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 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,

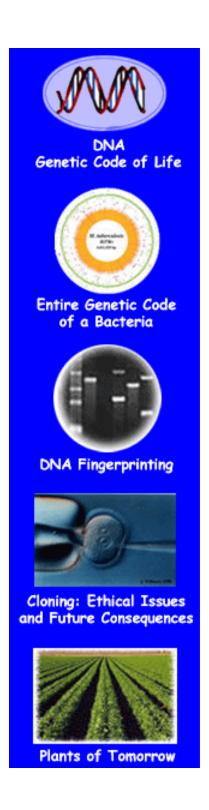


#### How Does the Constitution Affect Science Directly or Indirectly?

Article or Amendment	What Is Application?
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
Amendment I	Freedom of Speech
Amendment IV	Searches & Seizures
Amendment V	Due Process-Privacy-Federal
Amendment VI	Federal Supremacy Clause
Amendment X	Powers Reserved to the States (Police Powers)
Amendment XIII	Slavery
Amendment XIV	Due Process-Privacy-State



# And How Do These Articles and Amendments Apply to Science?



## What Does the Constitution Say Directly About Science?

Is the Word "Science" in the Constitution?

## The Congress shall have the Power:

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

<u>Keyword</u>: Inventors not Science.

Wanted to Promote Economic Development & Promote a <u>National</u> Economics Policy Grounded in Property Rights.

That is, Entrepreneurship!

#### PATENTS!!

## 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., 20y)?

## 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 or Officer thereof.

<u>Key Concept</u>: 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?

## 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....."

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

## 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"

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

# Promote the General Welfare: Federal Powers

- Fund Science Research & Exploration (NIH, NSF, NASA)
- · Regulate Health (e.g., disease outbreaks) (CDC)
- · Regulate Medical Testing Devices/Services (DNA Testing)
- · Regulate Drugs (FDA)
- · Regulate Food Additives (FDA)
- · Regulate Releases Into the Environment (GMOs)
- · Regulate Lab Conditions
- · Regulate Private DNA Testing/Sequencing Services (23&Me)
- · Regulate Human Cloning and Stem Cell Funding
- · Establish DNA Databases (CODIS)
- · Establish Criminal Codes/Laws

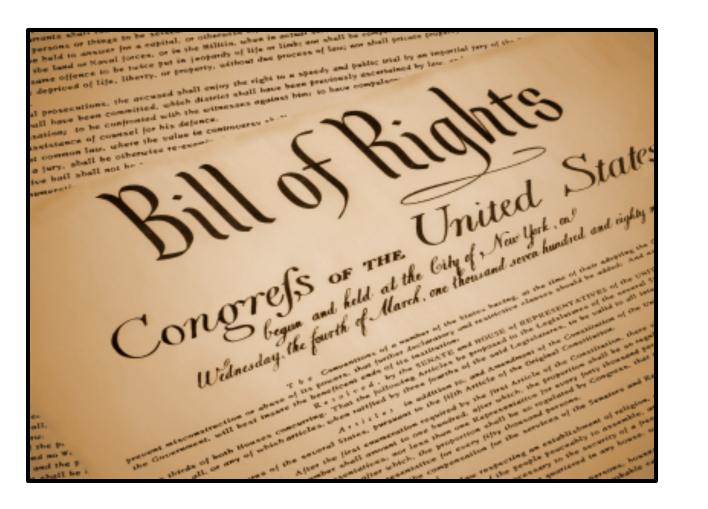
### Congress Established Under This Article:

- 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, OSHA, CODIS, USPTO, NOAA, etc., etc.

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



# What Does the Bill of Rights Say Indirectly About Regulating Science?



## Amendment I

## Freedom of Speech and Expression:

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

<u>Key Concepts</u>: Freedom to Think About Science, Publish, and Discuss Science in Meetings and Laboratories

## 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

# Can Scientific Inquiry and Research Be Regulated?

#### 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 BE REGULATED (e.g. Recombinant DNA)?



DNA



Can Think But Can't Always Act!

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

- 1. When Moving From Reflection, Theory, Hypothesis, and Thought to <u>TESTING AND EXPERIMENTATION</u> Move From World of Speech (talking, publishing) to <u>WORLD OF ACTION AND CONDUCT.</u>
- 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!

# 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"

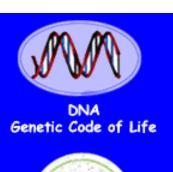
<u>Key Concepts</u>: Right Against Unreasonable Searches to Your Own "Body Parts," Science Writings, and Experimental Materials

# Amendment IV

### Searches and Seizures

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

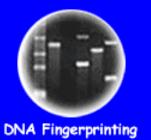
No DNA Sampling "Sweeps"-For Example an Entire An Entire Neighborhood





## Maryland Vs. King Ruling: US Supreme Court Decides DNA Swabs During Arrests Are Constitutional In 5-4 Decision

# Entire Genetic Code of a Bacteria





Cloning: Ethical Issues and Future Consequences



#### SUPREME COURT OF THE UNITED STATES

Syllabus

MARYLAND v. KING

CERTIORARI TO THE COURT OF APPEALS OF MARYLAND

No. 12-207. Argued February 26, 2013-Decided June 3, 2013

California Proposition 69 Requiring DNA
Samples to be Taken of All Felony Arrestees
is Constitutional



#### MARYLAND v. KING

- Taking and analyzing a cheek swab of the arrestee's DNA is, like fingerprinting and photographing, a legitimate police booking procedure that is reasonable under the Fourth Amendment.
- The officer collected a DNA sample using the common "buccal swab" procedure, which is quick and painless, requires no "surgical intrusion beneath the skin, and poses no threat to the arrestee's "health or safety".
- Using a buccal swab inside a person's cheek to obtain a DNA sample is a search under the Fourth Amendment. And the fact that the intrusion is negligible is of central relevance to determining whether the search is reasonable, "the ultimate measure of the constitutionality of a governmental search,
- In this balance of reasonableness, great weight is given to both the significant government interest at stake in the identification of arrestees and DNA identification's unmatched potential to serve that interest.
- By comparison to the substantial government interest and the unique effectiveness of DNA identification, the intrusion of a cheek swab to obtain a DNA sample is minimal.
- The processing of respondent's DNA sample's CODIS loci also did not intrude on his privacy in a way that would make his DNA identification unconstitutional. Those loci came from noncoding DNA parts that do not reveal an arrestee's genetic traits and are unlikely to reveal any private medical information.



Do You Agree With the Supreme Court's Decision in Maryland Vs. King?

- a. Yes
- b. No

# 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."

<u>Key Concepts</u>: Right to Life & Liberty=Privacy=Reproductive Rights

Medical Treatment (Refusal/Acceptance)

## 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, reprodctive?)
- · Medical Treatment (life)

# Amendments V and XIV

#### Planned Parenthood vs. Casey (1992)

At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life."

#### Griswold v. Connecticut (1965)

Involved a Connecticut law (1879) that prohibited the use of any drug, medicinals article or instrument for the purpose of preventing conception

"Would we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The [381 U.S. 479, 486] The very idea is repulsive to the notions of privacy surrounding the marriage relationship."

Justice William O. Douglas

# Amendment VI

The Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under authority of the United Sates, shall be the supreme law of the land; and the judges in every State shall be bound thereby, anything in the Constitution, or laws of any State to the contrary notwithstanding

State Laws That Conflict With Federal Law Are "Without Effect"

A Federal Law That Conflicts With State Law Will "Preempt" State Law

Altria Group vs. Good, 2008; Maryland vs. Louisiana, 1981

# California GMO Labeling Initiative

NO<sub>on</sub>37

STOP THE DECEPTIVE FOOD LABELING SCHEME

What About Federal Preemption?



# 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

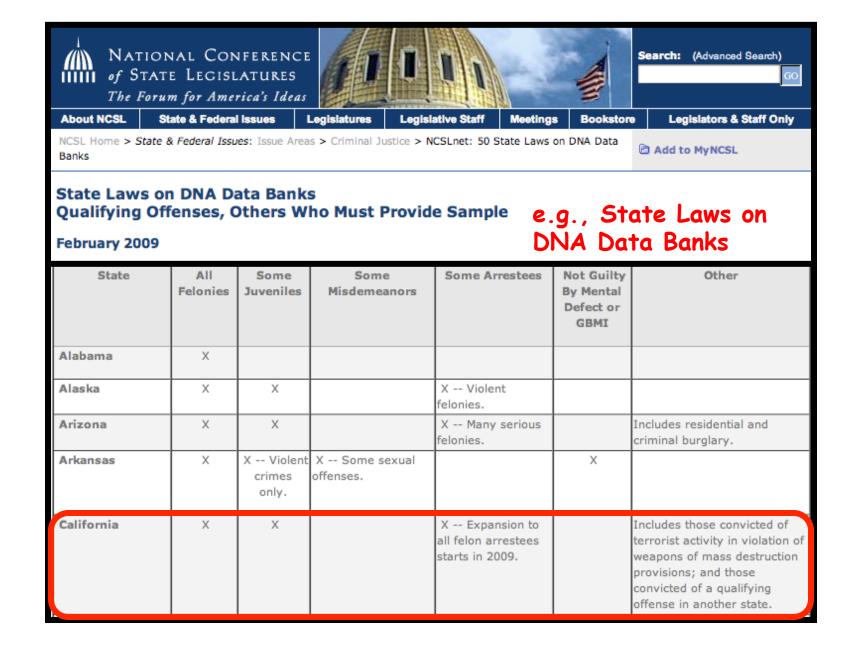
# Amendment X

### 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



# Amendment XIII

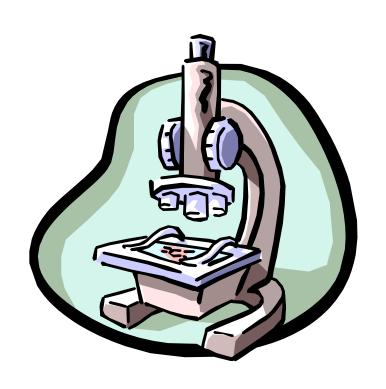
#### Involuntary Servitude:

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

<u>Key Concept</u>: No Slavery or Involuntary Servitude-Clones or Patenting Humans

# 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"

# Recombinant DNA — Cambridge, MA. City Council — 1977

- <u>Facts</u>: 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."



### Sale of Genetically Engineered GloFish in CA — 2003



- <u>Facts</u>: 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."

California Fish and Game Code - 2007 - Outright Ban on Release of Transgenic Fish

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

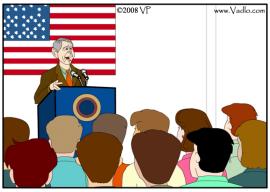
• <u>Facts</u>: To Protect Nation From Bioterrorism Attacks After 9/11 and Anthrax "Attacks" on Congress

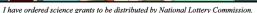
• Outcome: Bioterrorism Preparedness Act of 2002

<u>Background</u>: Funds For Research on Pathogens To Uncover Knowledge Required to Counteract Bioweapons' Attacks (e.g., anitbiotics, vaccines). Requires registration of all human pathogens and pathogen research in US Laboratories.



Principle: Public Safety/Welfare Risk









# How Can Genetic Engineering and Science 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. <u>Must Abide By Conditions</u> of Funding Agencies to Obtain Research \$
  - a. Recombinant DNA Guidelines
  - b. Human Institutional Review Boards (IRBs)
  - c. Release of GMOs Into the Environment (EPA)
  - d. Destruction of Human Embryos

# 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 Sovbean Development	FUNDING AGENCY: NIH  CONTRACT OR GRANT NO. (If known):  DATES FOR WHICH REVIEWED: FROM: 4-1-79 TO: 3-31-80
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.	
Date:    May 18, 1978   Signature: Chairman, Biohazards Committee	

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 Assistant Professor of Biology

2. Experiments which involve recombinant DNA molecules.

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

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

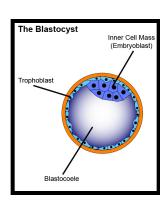
The formation of hybrids between plant DNA and bacterial plasmids is given a P2-EK1 classification provided that the plant does not harbor a pathogenic agent nor produce a product toxic to other species (NIH Guidelines, III-18). Plant varieties to be used in experiments with plasmid DNAs do not harbor 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.







#### Federal Stem Cell Research Funding



#### 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

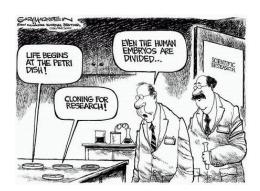
Removing Barriers to Responsible Scientific Research Involving Human Stem Cells

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.





# Direct and Indirect Regulation of *Genetic Engineering*: Summary

- 1. Recombinant DNA-Gene Splicing Experiments
  - a. <u>Directly</u> 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. <u>Directly</u> By Federal Agencies & State Police Powers, and <u>Indirectly</u> By Funding Requirements