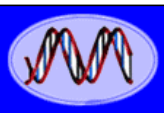
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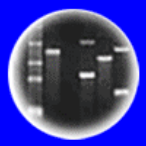
Genetic Code of Life


Entire Genetic Code of a Bacteria


DNA Fingerprinting


Cloning: Ethical Issues and Future Consequences


Plants of Tomorrow

HC70A & SAS70A Spring 2017
Genetic Engineering in Medicine, Agriculture, and Law

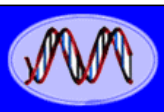
Professors Bob Goldberg & John Harada

Lecture 9

Science & The Constitution: Regulating Science & Genetic Engineering

UCLA

UCDAVIS
UNIVERSITY OF CALIFORNIA



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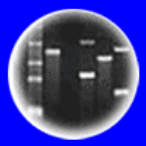

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THEMES

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

TEXT READING

Chapter 9 (Biotechnology Regulations) & Chapter10 (Ethics & Biotechnology)

Biotechnology Agencies, Laws, & Patents

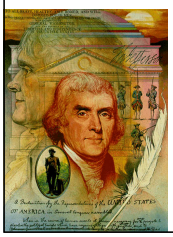
SELECTED REFERENCES

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. *Maryland vs. King, US Supreme Court*, June, (2013)
10. *The History of Patenting Genetic Material*, By Jacob E. Cherkow & Henry T. Greely , *Annu. Rev. Genetics*, 49, 161-182 (2015)
11. *Diagnostics Need Not Apply*, By Rebecca S. Eisenberg, *J. Science & Technology Law*, 21.2 (2015)
12. *Patent, Copyright, & Trademark*, By R. Stim (2016)
13. Imbeciles; The Supreme Court, American Eugenics, & the Sterization of Carrie Buck, By Adam Cohen (2016)

"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*."

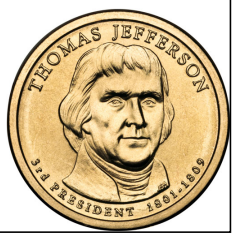
Thomas Jefferson, July 12, 1810

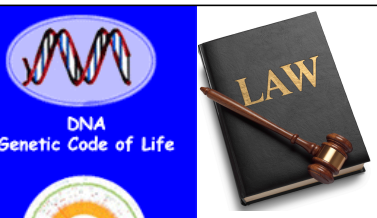
Is 1810 Science the same 2017 Science?



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 The Relationship Between Genetics and The Law in the United States?

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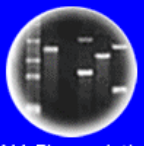

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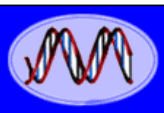

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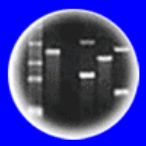

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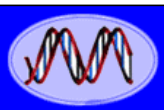
Mendel's Laws of Genetics Were Rediscovered in 1900!

Three Botanists – Hugo DeVries, Carl Correns, and Erich von Tschermak – Independently Rediscovered Mendel's Work* in 1900

[*from the Proceedings of the Natural History Society of Brünn in 1866]

The word gene was invented to describe the physical properties of inheritance in 1905 by the botanist Wilhelm Johannsen, and Thomas Hunt Morgan showed that genes are on chromosomes in 1910!



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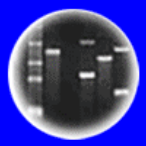

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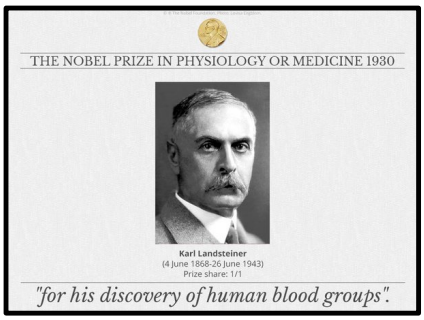
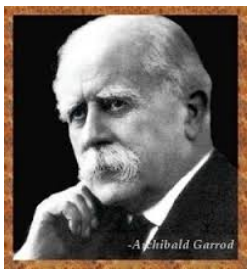
Human Genetics Was Born in 1900

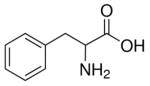
The ABO Blood Types Were the First Human Traits Discovered That Followed Mendelian Inheritance (1900)



Alkaptonuria (Black Urine/Bone Disease) Was the First Human Disease Shown to Follow Mendelian Inheritance (1902)



Defect in Amino Acid Phenylalanine Metabolism



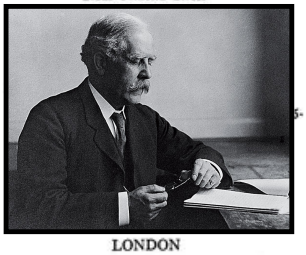
Garrod Discovered That Human Metabolic Diseases Have a Genetic Basis and Follow Mendelian Rules of Inheritance. He Hypothesized That Genetic Diseases Were Due to a Missing Steps in a Body's Chemical Reactions

INBORN ERRORS OF METABOLISM

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

By

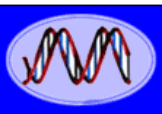
ARCHIBALD E. GARROD
D.M., M.A. OXON.
Fellow of the Royal College of Physicians.
Assistant Physician to, and Lecturer on Chemical Pathology at St. Bartholomew's Hospital.
Physician to the Hospital for Sick Children, Great Ormond Street



LONDON
HENRY FROWDE HODDER & STOUGHTON
OXFORD UNIVERSITY PRESS 20, WARWICK SQUARE, E.C.
1909

Contents

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.[32] Nor do the figures quoted by Bateson[33] 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.



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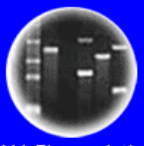

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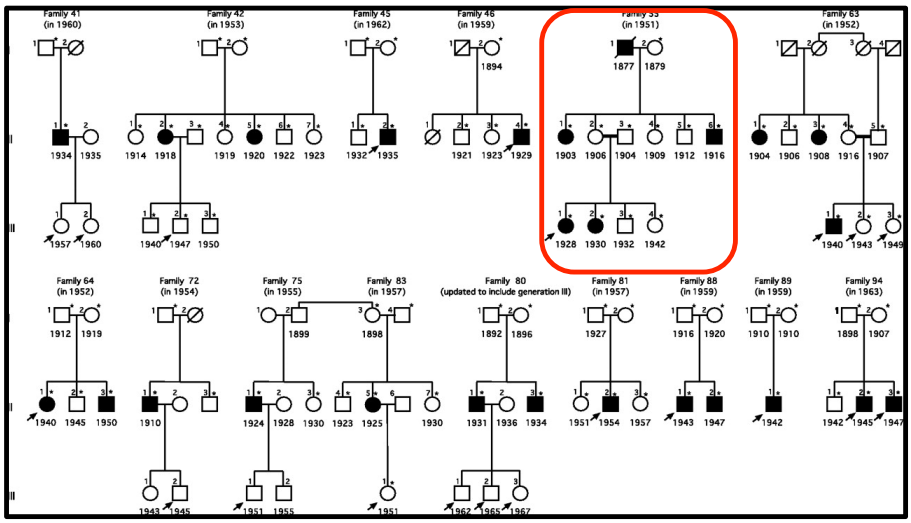
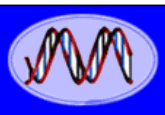
Garrod's Discovery of Human Disease Gene Inheritance Using Pedigrees

(Alkaponuria, Albinism, Cystinuria, & Pentosuria)



Garrod's Families Were Studied Until the 1960s!



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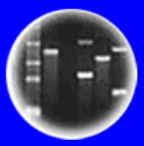

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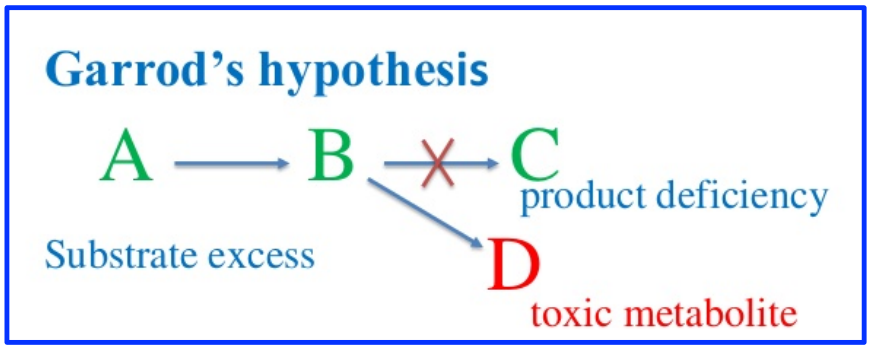
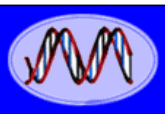
Garrod Hypothesized That Inherited Defects in Metabolic Pathways Lead To Toxic Compound Accumulation That Cause the Disease



Garrod Was the First to Propose a Relationship Between Genes and Enzymes and Metabolic Defects



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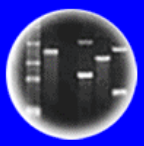

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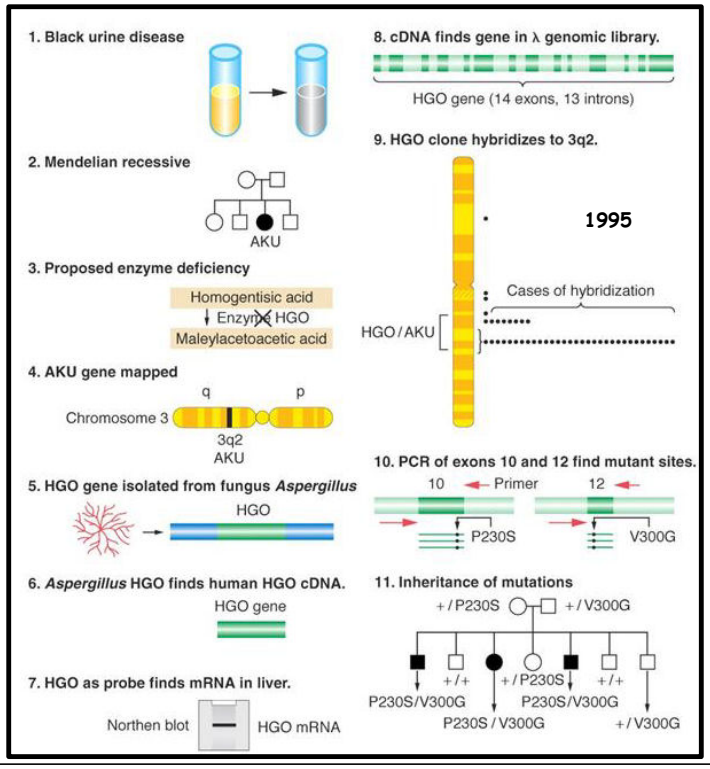
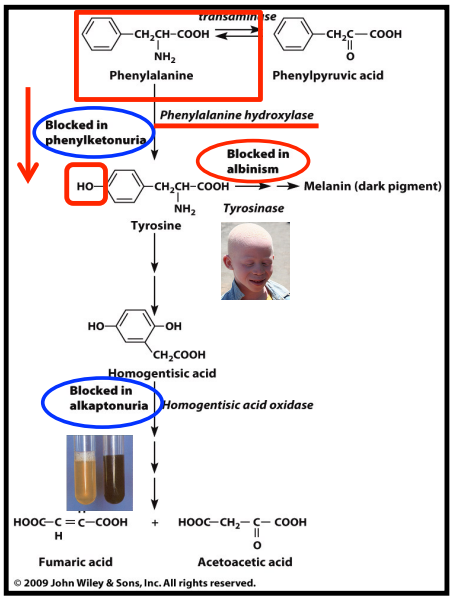
Isolation of Garrod's Alkaptonuria Gene

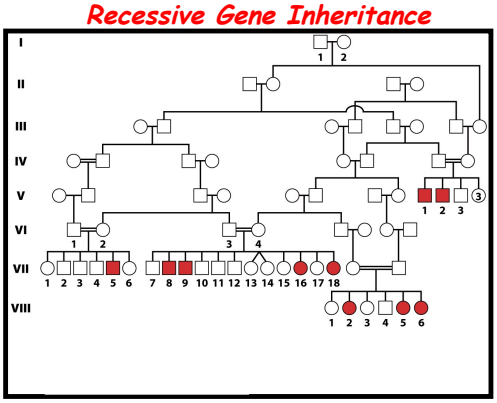
Homogentisic Acid Hydrolase

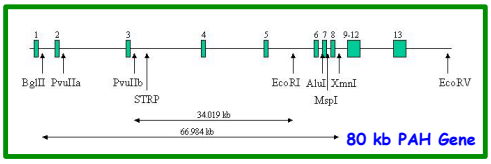


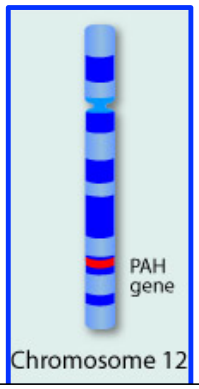
Inborn Errors of Metabolism – Phenylketonuria (Asbjørn Følling: Norway, 1934)

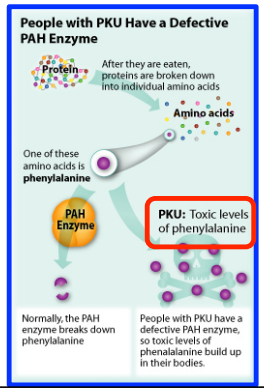


Recessive Gene Inheritance





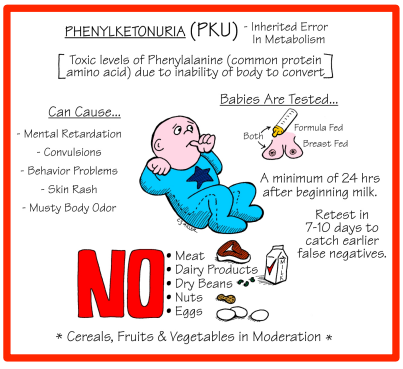




PHENYLKETONURIA (1/15,000 US Children)

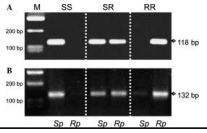
SYMPTOMS

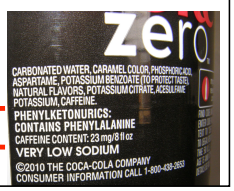
- Phenylalanine plays a role in the body's production of melanin, the pigment responsible for skin and hair color. Therefore, infants with the condition often have lighter skin, hair, and eyes than brothers or sisters without the disease.
- Delayed mental and social skills
- Head size significantly below 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 *simple blood test*. 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





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CALIFORNIA NEWBORN SCREENING PROGRAM

50 YEARS OF NEWBORN SCREENING

baby's first test

Did you know...

Children should be **SCREENED SHORTLY AFTER 24 HOURS** of being born

MOST STATES SCREEN FOR **29** out of **31** RECOMMENDED HEALTH CONDITIONS

More than **1 IN 300 NEWBORNS** have a condition detectable through Newborn Screening

Most babies with serious but treatable conditions caught by Newborn Screening **GROW UP HEALTHY** with expected development

In **1963** Newborn Screening begins with a **HEEL STICK**

In **1999** **HEARING SCREENING** is recommended for newborns

In **2012** the **PULSE OXIMETRY** test becomes a part of Newborn Screening

In **2013** Newborn Screening celebrates its **50TH** Anniversary

Source: BabysFirstTest.org

This project is funded by the Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA), Grant No. U5MHC16109

Newborn screening tests for over 75 disorders.
The types of disorders include:

- **Metabolic Disorders** such as Phenylketonuria
- **Endocrine Disorders** such as Primary Congenital Hypothyroidism
- **Hemoglobin Disorders** such as Sickle Cell Disease
- **Cystic Fibrosis**
- **Severe Combined Immunodeficiency (SCID)**

WHO?

California state law requires that hospitals and midwives collect a newborn screen on every baby born in the State.

California Department of Public Health
Newborn Screening Branch
WWW.CDPH.CA.GOV/NBS

Only Exemption Is For Religious Beliefs

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CALIFORNIA NEWBORN SCREENING PROGRAM

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phenylketonuria Highlight

HEALTH AND SAFETY CODE - HSC
DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT) [123100 - 125850] *(Division 106 added by Stats. 1995, Ch. 415, Sec. 8.)*
PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS [124975 - 125292.10] *(Part 5 added by Stats. 1995, Ch. 415, Sec. 8.)*
CHAPTER 1. Genetic Prevention Services [124975 - 125119.5] *(Chapter 1 added by Stats. 1995, Ch. 415, Sec. 8.)*

ARTICLE 2. Newborn Screening [125000 - 125002] *(Article 2 added by Stats. 1995, Ch. 415, Sec. 8.)*

125000. (a) It is the policy of the State of California to make every effort to detect, as early as possible, **phenylketonuria** and other preventable heritable or congenital disorders leading to intellectual disability or physical defects.

The department shall establish a genetic disease unit, that shall coordinate all programs of the department in the area of genetic disease. The unit shall promote a statewide program of information, testing, and counseling services and shall have the responsibility of designating tests and regulations to be used in executing this program.

The information, tests, and counseling for children shall be in accordance with accepted medical practices and shall be administered to each child born in California once the department has established appropriate regulations and testing methods. The information, tests, and counseling for pregnant women shall be in accordance with accepted medical practices and shall be offered to each pregnant woman in California once the department has established appropriate regulations and testing methods. These regulations shall follow the standards and principles specified in Section 124980. The department may provide laboratory testing facilities or contract with any laboratory that it deems qualified to conduct tests required under this section. However, notwithstanding former Section 125005, provision of laboratory testing facilities by the department shall be contingent upon the provision of funding therefor by specific appropriation to the Genetic Disease Testing Fund enacted by the Legislature. If moneys appropriated for purposes of this section are not authorized for expenditure to provide laboratory facilities, the department may nevertheless contract to provide laboratory testing services pursuant to this section and shall perform laboratory services, including, but not limited to, quality control, confirmatory, and emergency testing, necessary to ensure the objectives of this program.

(b) The department shall charge a fee for any tests performed pursuant to this section. The amount of the fee shall be established and periodically adjusted by the director in order to meet the costs of this section.

(c) The department shall inform all hospitals or physicians and surgeons, or both, of required regulations and tests and may alter or withdraw any of these requirements whenever sound medical practice so indicates. To the extent practicable, the department shall provide notice to hospitals and other payers in advance of an increase in the fees charged for the program.

(d) This section shall not apply if a parent or guardian of the newborn child objects to a test on the ground that the test conflicts with his or her religious beliefs or practices.

(e) The genetic disease unit is authorized to make grants or contracts or payments to vendors approved by the department for all of the following:

(1) Testing and counseling services.

(2) Demonstration projects to determine the desirability and feasibility of additional tests or new genetic services.

(3) To initiate the development of genetic services in areas of need.

(4) To purchase or provide genetic services from any sums as are appropriated for this purpose.

(f) The genetic disease unit shall evaluate and prepare recommendations on the implementation of tests for the detection of hereditary and congenital diseases, including, but not limited to, biotinidase deficiency and cystic fibrosis. The genetic disease unit shall also evaluate and prepare recommendations on the availability and effectiveness of preventative followup interventions, including the use of specialized medically necessary dietary products.

It is the intent of the Legislature that funds for the support of the evaluations and recommendations required pursuant to this subdivision, and for the activities authorized pursuant to subdivision (e), shall be provided in the annual Budget Act appropriation from the Genetic Disease Testing Fund.

(g) Health care providers that contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership, may provide, without contracting with the department, any or all of the testing and counseling services required to be provided under this section or the regulations adopted pursuant thereto, if the services meet the quality standards and adhere to the regulations established by the department and the plan pays that portion of a fee established under this section that is directly attributable to the department's cost of administering the testing or counseling service and to any required testing or counseling services provided by the state for plan members. The payment by the plan, as provided in this subdivision, shall be deemed to fulfill any obligation the provider or the provider's patient may have to the department to pay a fee in connection with the testing or counseling service.

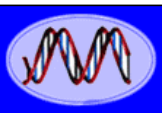
(h) The department may appoint experts in the area of genetic screening, including, but not limited to, cytogenetics, molecular biology, prenatal, specimen collection, and ultrasound to provide expert advice and opinion on the interpretation and enforcement of regulations adopted pursuant to this section. These experts shall be designated agents of the state with respect to their assignments. These experts shall receive no salary, but shall be reimbursed for expenses associated with the purposes of this section. All expenses of the experts for the purposes of this section shall be paid from the Genetic Disease Testing Fund.

(Amended by Stats. 2012, Ch. 457, Sec. 33. Effective January 1, 2013.)

HEALTH AND SAFETY CODE - HSC
DIVISION 106. PERSONAL HEALTH CARE (INCLUDING MATERNAL, CHILD, AND ADOLESCENT) [123100 - 125850] *(Division 106 added by Stats. 1995, Ch. 415, Sec. 8.)*
PART 5. HEREDITARY DISEASES/CONGENITAL DEFECTS [124975 - 125292.10] *(Part 5 added by Stats. 1995, Ch. 415, Sec. 8.)*
CHAPTER 1. Genetic Prevention Services [124975 - 125119.5] *(Chapter 1 added by Stats. 1995, Ch. 415, Sec. 8.)*

ARTICLE 2. Newborn Screening [125000 - 125002] *(Article 2 added by Stats. 1995, Ch. 415, Sec. 8.)*

Genetics and the Law!!!



DNA
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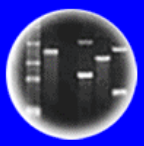
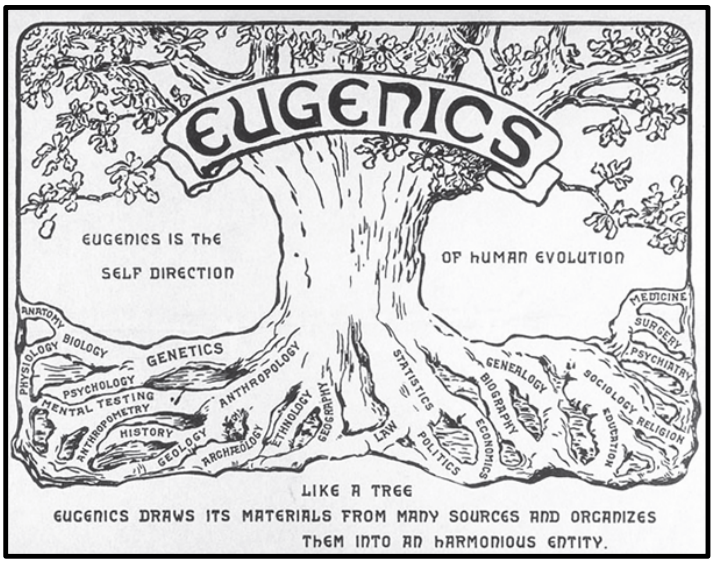
Entire Genetic Code of a Bacteria

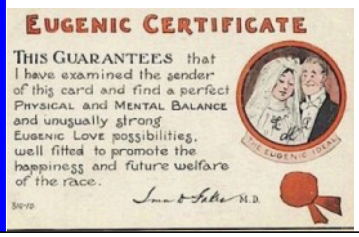


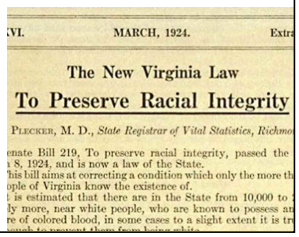
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow







Francis Galton Invented the Term Eugenics

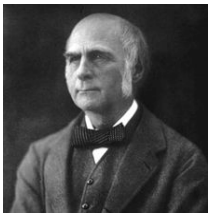
- Regression Line
- Standard Deviation
- Correlation
- Fingerprint Patterns

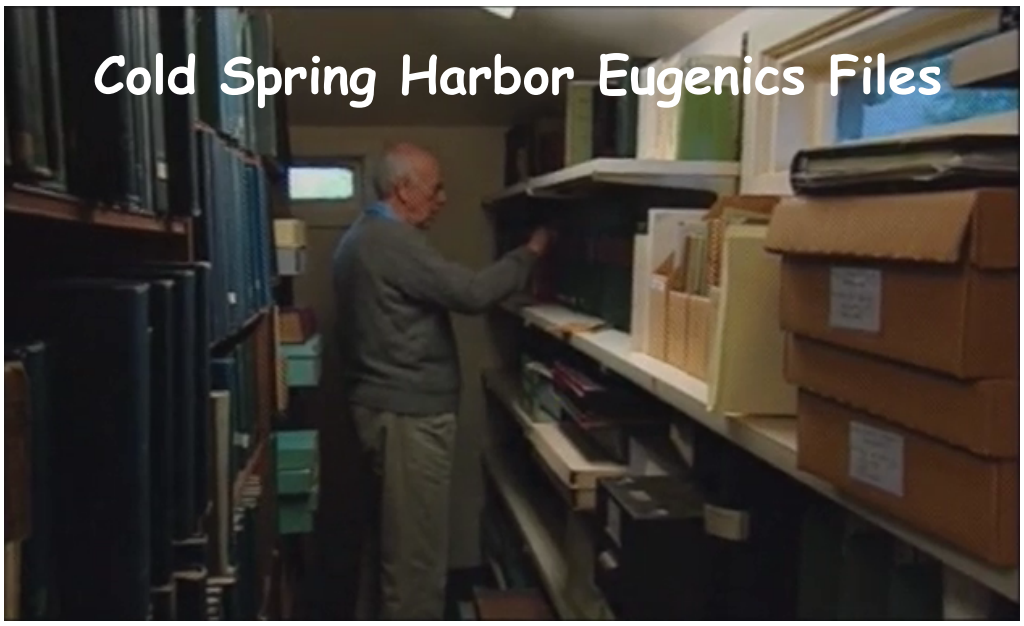
EUGENICS

"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 Half Cousin





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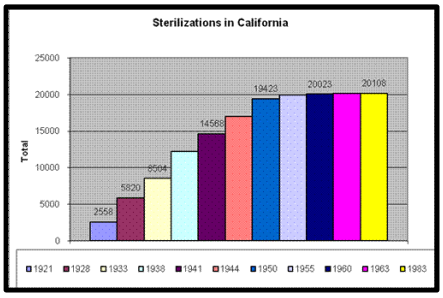
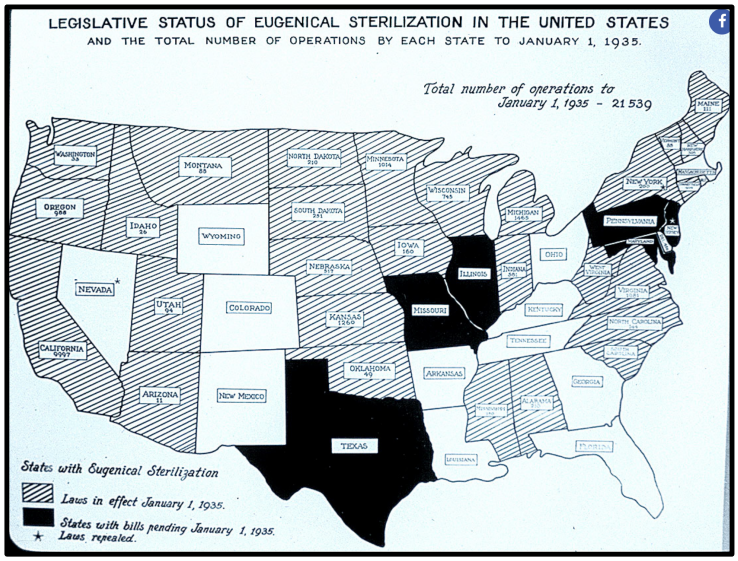


Groups identified in the Law

The 1909 law was aimed specifically at those in prisons and with mental disabilities that caused them to be institutionalized. Of those with mental disabilities, the law targeted patients in state hospitals and institutions of the feeble-minded. In terms of the prisoners, the law targeted those who were inmates for life, showing "sex or moral perversions", or were certain repeat offenders. The 1913 law expanded to target all inmates in state hospitals or homes for the feeble-minded (except voluntary patients in state hospitals), as well as all repeat offenders in state. The 1917 amendments greatly expanded the groups targeted even further to include those who had hereditary mental diseases, "those suffering from perversion or marked departures from normal mentality", and those with sexually-transmitted diseases. These two later laws expanded to include virtually any individual deemed unfit. Out of those sterilized, 70% were labeled as mentally ill.

State Sterilization Laws 1921

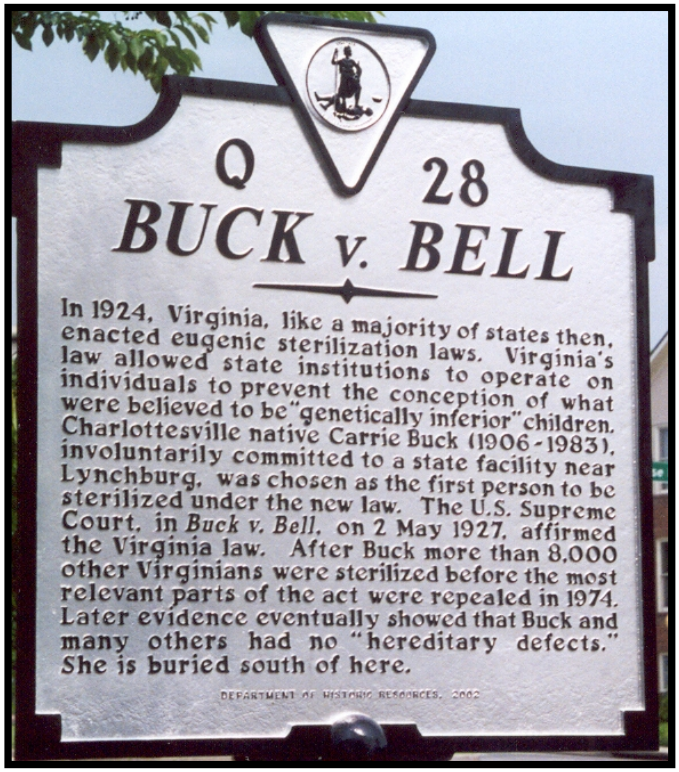
Government Intervention to Promote Biological Improvement of Humans



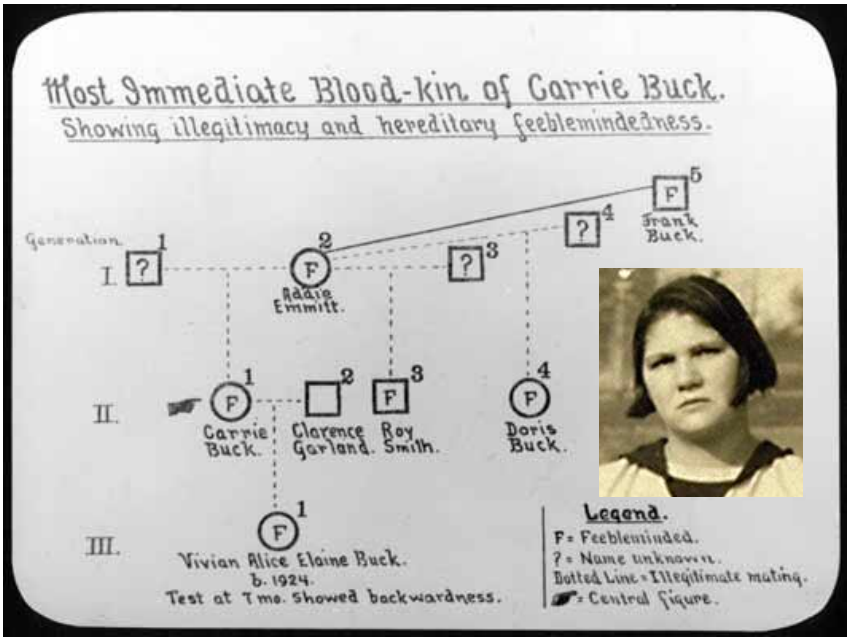
64,000 Forced Sterilizations in US - Last one in Oregon in 1981

(Tubal Ligations & Vasectomies)

Two States Have Offered Reparations For Forced Sterilization
North Carolina ($50,000) & Virginia ($25,000)



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

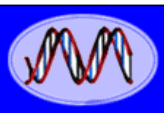


State of Virginia Colony For Epileptics & Feebleminded- 1924

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."***



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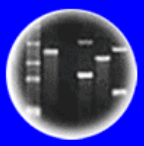

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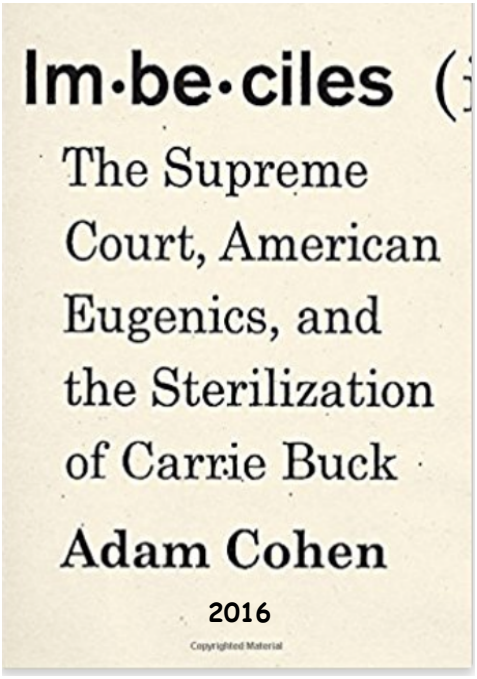

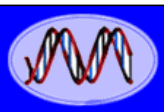

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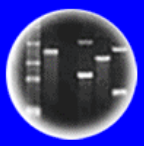

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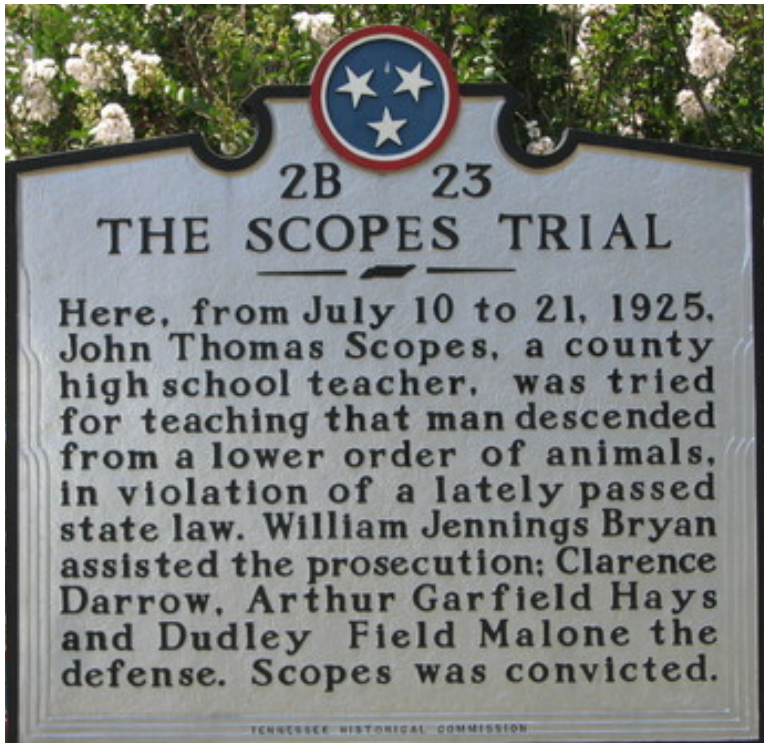


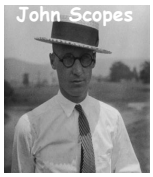
Permanent Address: http://www.scientificamerican.com/article.cfm?id=scopes-creationism-education

Scientific American, February, 2011

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

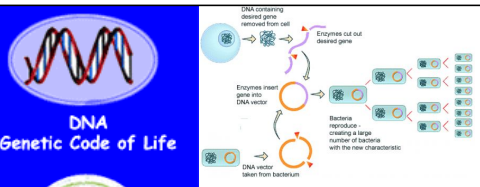
1. In 1968, in ***Epperson v. Arkansas***, the United States Supreme Court invalidated an Arkansas statute that prohibited the teaching of evolution. The Court held the statute unconstitutional on the grounds that the First Amendment to the U.S. Constitution does not permit a state to require that teaching 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)

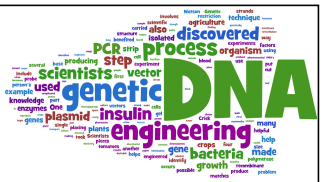
4. In 1987, in ***Edwards v. Aguillard***, the U.S. Supreme Court held unconstitutional Louisiana's "Creationism Act". This statute prohibited the teaching of evolution in public schools, except when it was accompanied by instruction in "creation science". The Court found that, by advancing the religious 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 educatio 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)

Tammy Kitzmiller vs. Dover Area School District - 2005

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.





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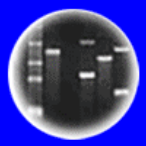

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Regulating Genetic Engineering at the Local, State, & Federal Levels

The Past

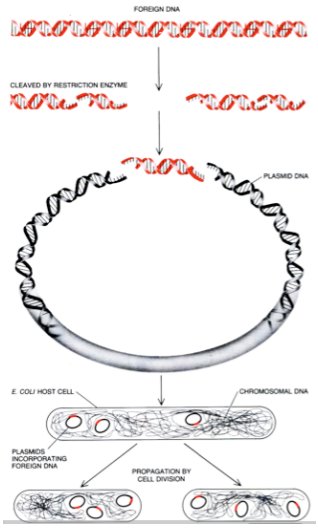
***The Recombinant DNA Controversy: A Memoir*, By D.S. Fredrickson (2001)**

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

by Clifford Grobstein

Cohen-Boyer-1973



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

BIOLOGICAL CONTAINMENT (FOR *E. COLI* HOST SYSTEMS ONLY)

PHYSICAL CONTAINMENT

	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)	

Nobel Prize For Inventing Genetic Engineering

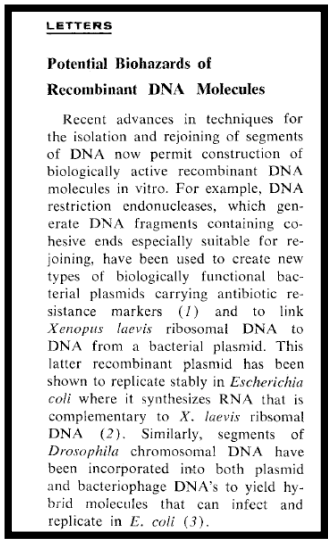
The Berg Letter: Science, July, 1974

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

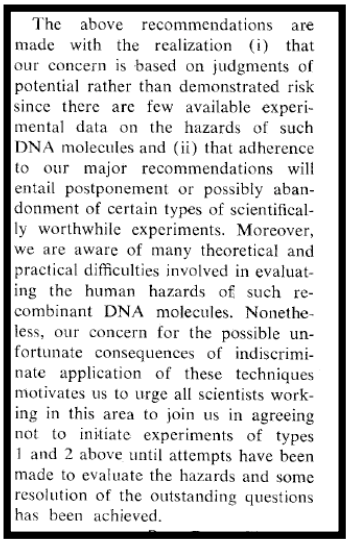
Science, New Series, Vol. 185, No. 4148 (Jul. 26, 1974), 303.



LETTERS

Potential Biohazards of Recombinant DNA Molecules

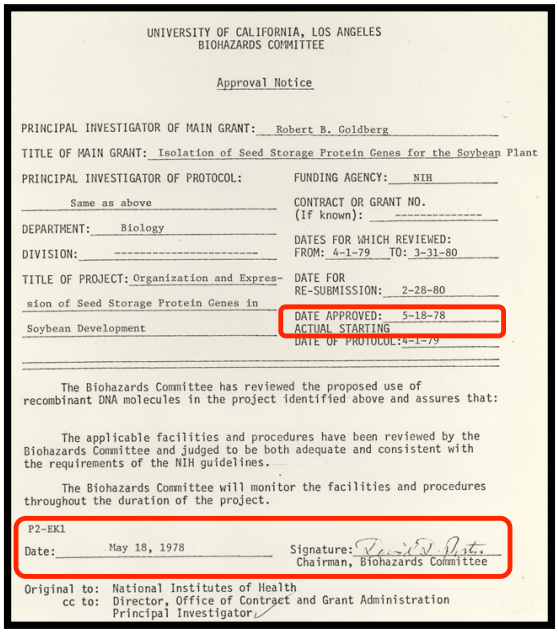
Recent advances in techniques for the isolation and rejoining of segments of DNA now permit construction of biologically active recombinant DNA molecules in vitro. For example, DNA restriction endonucleases, which generate DNA fragments containing cohesive ends especially suitable for rejoining, have 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 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.

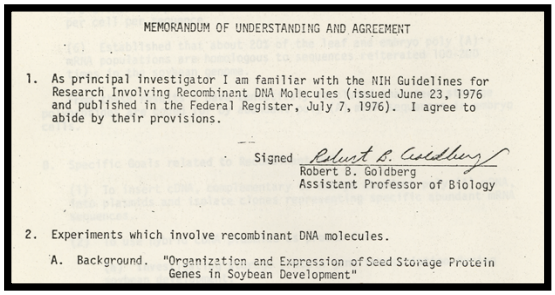
The Biohazards Committee will monitor the facilities and procedures throughout the duration of the project.

P2-EK1

Date: May 18, 1978

Signature: [signature]
Chairman, Biohazards Committee

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



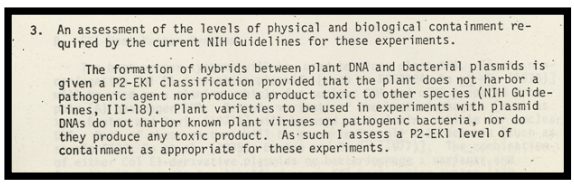
MEMORANDUM OF UNDERSTANDING AND AGREEMENT

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 [signature]
Robert B. Goldberg
Assistant Professor of Biology

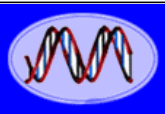
2. Experiments which involve recombinant DNA molecules.

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.



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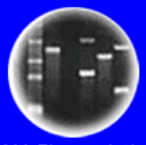

DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

1/12/78

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

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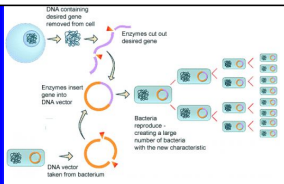

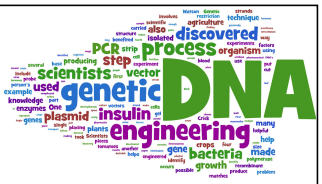

Regulating Genetic Engineering at the Local, State, & Federal Levels

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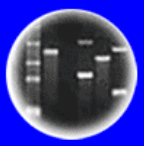

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The Only Federal Law Dealing With a Genetic Engineering Procedure

PUBLIC LAW 114–113—DEC. 18, 2015

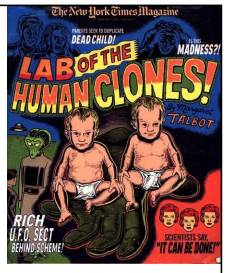
2017 Congressional Budget (Expires 9/30/17)

- **FDA Cannot Spend Any Money to Review Applications For Clinical Trials That Involve Human Embryos With Heritable Genetic Modifications**

Dickey-Wiker Amendment-1995

Federal Funds Cannot Be Used To:

- **Create Human Embryos For Research Purposes**
- **Fund Research in Which a Human Embryo Will Be Destroyed, Discarded, or Knowingly Subjected to Risk or Injury of Death**



There is No Federal Human Cloning Law

HR3498, 2015 (Not Passed), Prohibition Against Human Cloning

"§ 302. Prohibition on human cloning

"(a) IN GENERAL.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce—

"(1) to perform or attempt to perform human cloning;

"(2) to participate in an attempt to perform human cloning; or

"(3) to ship or receive the product of human cloning for any purpose.

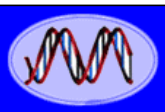
Fifteen States, Including California, Have Laws Dealing With Human Cloning -- From Banning Both Reproductive and Therapeutic Cloning to only Reproductive Cloning (e.g., California).

Regulating Human Cloning and Stem Cell Research at the Local, State, & Federal Levels?

The Stem Cell Funding "Wars" - 1995 to Present
Can't Make "Them" But Can Study "Them"

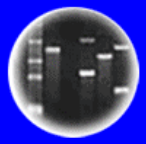
- President Clinton's NIH Advisory Panel Recommended That Federal Funds Be Used For Research on Human Embryos Discarded From In Vitro Fertilization -1995
- Dickey-Wicker Amendment Prohibited Federal Funding For Research in Which Human Embryos Are Destroyed - 1995
- Human Embryonic Stem Cells Discovered (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 Amendment - 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**



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria



DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Federal Law on Labeling Genetically Modified Foods
2016

Public Law 114–216
114th Congress

An Act

To reauthorize and amend the National Sea Grant College Program Act, and for other purposes.

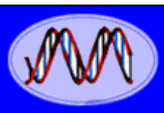
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) is amended by adding at the end the following:

"Subtitle E—National Bioengineered Food Disclosure Standard

This is the Only Federal Law That Directly Regulates a Genetically Engineered Product Other Than a Drug



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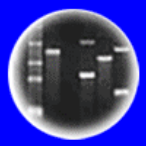


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

But…….Congressional Road Blocks For GMO Salmon

GMO Salmon

FDA won't be able to allow the sale of genetically modified salmon until it has a plan for labeling the fish. And out of FDA's budget "not less than $150,000 shall be used to develop labeling guidelines and implement a program to disclose to consumers whether salmon offered for sale to consumers is a genetically engineered variety." When FDA approved GM salmon last month it said companies didn't have to label it, provoking the fury of anti-GMO groups.

FOOD POLITICS

POLICY

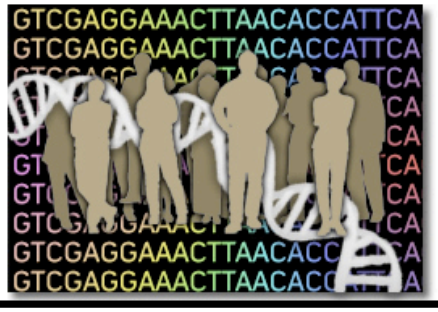
Fish flip-flop Despite the decision last November by the US Food and Drug Administration (FDA) to approve genetically modified salmon for human consumption, Americans will not be eating the fish any time soon. On 29 January, the FDA banned imports of fast-growing salmon produced in Panama and Canada by AquaBounty Technologies of Maynard, Massachusetts. The move is in response to the US budget bill passed last December, which bans sales of the fish until the FDA decides whether it should be labelled as genetically modified. The agency may take several years to finalize this rule.

Paul Darrow/NYT/Redux/eyevine

GINA GENETIC INFORMATION NONDISCRIMINATION ACT

About | Contact

Genetic Information Nondiscrimination Act of 2008



Federal Law on Genetic Discrimination

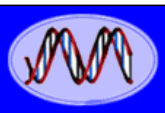
What is GINA?

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects people from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

This means it is illegal for your health insurer to use family health history and genetic test results as a reason to deny you health insurance, or decide how much you pay for your health insurance.

This means it is illegal for your employer to use family health history and genetic test results in making decisions about your employment.

GINA GENETIC INFORMATION NONDISCRIMINATION ACT



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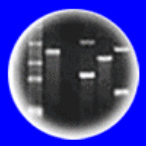


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

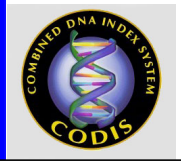
DNA Identification Act of 1994

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



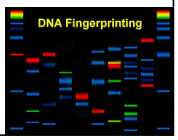
A BILL

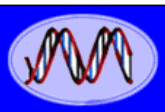
To establish scientific standards and protocols across forensic disciplines, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Forensic Science and Standards Act of 2014".





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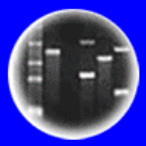


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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

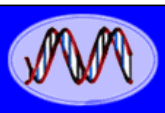
SUPREME COURT OF THE UNITED STATES

Syllabus

MARYLAND *v.* KING

CERTIORARI TO THE COURT OF APPEALS OF MARYLAND

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



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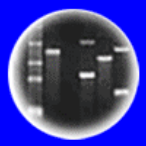
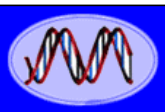


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Genetic Engineering is Regulated but Primarily by Federal Agencies and Not By Direct Some Examples



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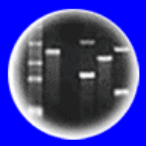


DNA Fingerprinting

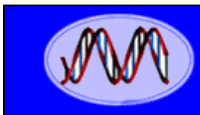
Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Federal Agencies Involved in the Coordinated Framework For the Regulation of Biotechnology

TABLE 12.1 PRIMARY FEDERAL REGULATORY AGENCIES IN THE UNITED STATES

Regulatory Oversight of Biotechnology Products Agency	Product Regulated
U.S. Department of Agriculture	Plants, plant pests (including microorganisms), animal vaccines
Environmental Protection Agency	Microbial/plant pesticides, other toxic substances, microorganisms, animals producing toxic substances
U.S. Food and Drug Administration	Food, animal feeds, food additives, human and animal drugs, human vaccines, medical devices, transgenic animals, cosmetics
Major Laws that Empower Federal Agencies to Regulate Biotechnology	
Law	**Agency**
The Plant Protection Act	USDA
The Meat Inspection Act	USDA
The Poultry Products Inspection Act	USDA
The Eggs Products Inspection Act	USDA
The Virus Serum Toxin Act	USDA
The Federal Insecticide, Fungicide, and Rodenticide Act	EPA
The Toxic Substances Control Act	EPA
The Food, Drug, and Cosmetics Act	FDA, EPA
The Public Health Service Act	FDA
The Dietary Supplement Health and Education Act	FDA
The National Environmental Protection Act	USDA, EPA, FDA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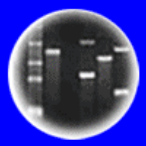
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Cloning: Ethical Issues and Future Consequences


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Office of Science and Technology Policy

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

AGENCY: Executive Office of the President, Office of Science and Technology Policy.
51 FR 23302
June 26, 1986

Coordinated Framework for Regulation of Biotechnology

ACTION: Announcement of policy; notice for public comment.

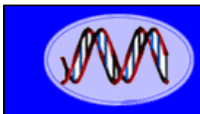
SUMMARY: This Federal Register notice announces the policy of the federal agencies involved with the review of biotechnology research and products. As certain concepts are new to this policy, and will be the subject of rulemaking, the public is invited to comment on these aspects which are specifically identified herein.

Federal Register / Vol. 80, No. 193 / Tuesday, October 6, 2015 / Notices

SCIENCE AND TECHNOLOGY POLICY OFFICE

Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology

AGENCY: National Science and Technology Council, Science and Technology Policy Office.
ACTION: Notice of request for information.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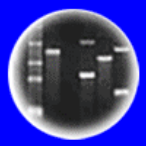

DNA Fingerprinting

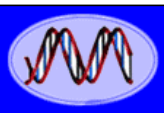

Cloning: Ethical Issues and Future Consequences


Plants of Tomorrow

Regulation of Transgenic Animals & Plants

TABLE 12.2 EXAMPLES OF SHARED RESPONSIBILITIES BY FEDERAL REGULATORY AGENCIES

New Trait/ Organism	Regulatory Review Conducted by	Reviewed for
Viral resistance in food crop	USDA	Safe to grow
	EPA	Safe for the environment
	FDA	Safe to eat
Herbicide tolerance in food crop	USDA	Safe to grow
	EPA	New use of companion herbicide
	FDA	Safe to eat
Herbicide tolerance in ornamental crop	USDA	Safe to grow
	EPA	New use of companion herbicide
Modified oil content in food crop	USDA	Safe to grow
	FDA	Safe to eat
Modified flower color in ornamental crop	USDA	Safe to grow
Modified soil bacteria that degrade pollutants	EPA	Safe for the environment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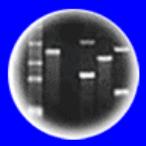
DNA Fingerprinting


Cloning: Ethical Issues
and Future Consequences


Plants of Tomorrow

What About Human Somatic Cell Gene Therapy & Editing?

FDA

NIH National Institutes of Health
Turning Discovery Into Health

Biomedical Technology Assessment

Oversight of Human Gene Transfer Research

Biomedical Technology Assessment

Recombinant DNA Advisory Committee

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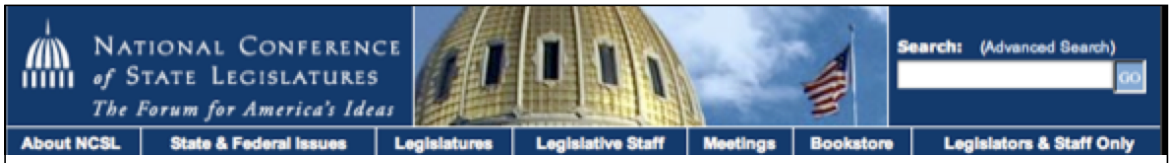
Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

NCSL
National Conference of State Legislatures
Strengthening States for 40 Years

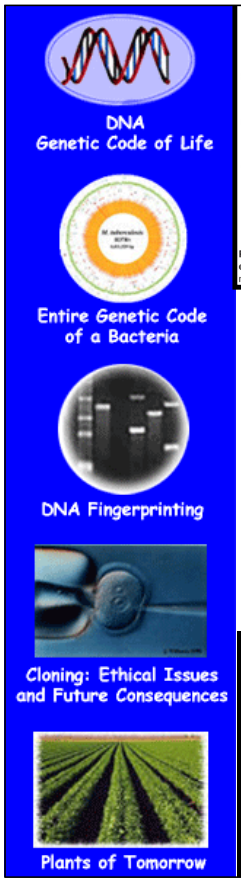
Laws Exist That Regulate Science at the State & Local Levels
Some Examples

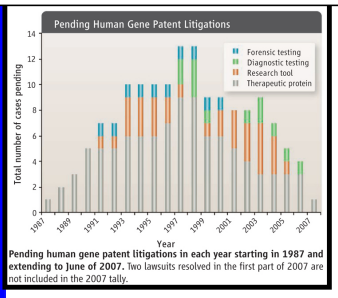
STATE LAWS



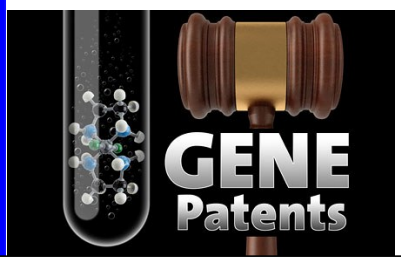
California Genetic Laws

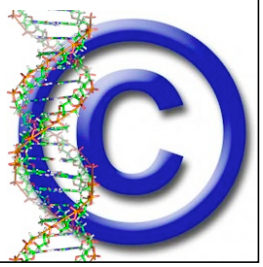
- Newborn Genetic Screening
- Genetic Non Discrimination in Insurance
- Human Cloning Laws
- Genetic Employment Laws
- Genetic Counselor Licensing Laws
- Embryonic and Fetal Research Laws
- Embryo and Gamete Disposition Laws
- Genetic Privacy Laws





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

6/17/1980

Justices, 9-0, Bar Patenting Human Genes

By **ADAM LIPTAK** JUNE 13, 2013

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

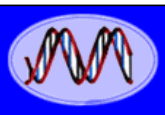
United States District Court Judge Robert W. Sweet issued the 152-page decision, which invalidated seven patents related to the genes BRCA1 and BRCA2, whose mutations have been associated with cancer.

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.

MYRIAD
GENE PATENT LITIGATION

Rights to Human Gene Patents Go on Trial

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



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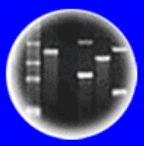


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

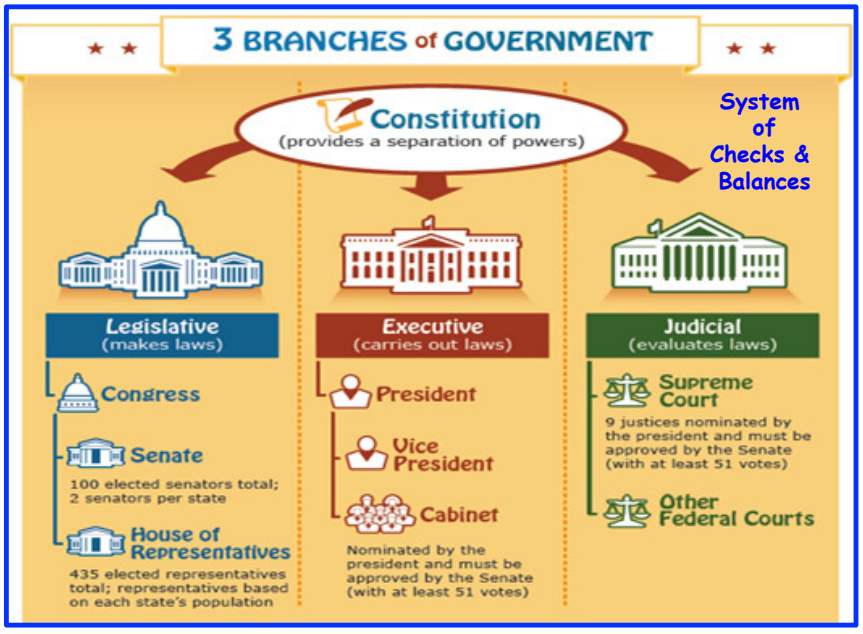
Plants of Tomorrow

What Enables the Government To Enact Laws Regarding Genetic Engineering and Science

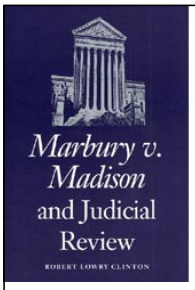
- Constitution-Article I Section 8.8 Promote the General Welfare
- Amendments-Bill of Rights
- Amendment X-Powers Reserved to States
- Federal Criminal Statutes
- State Constitutions
- State Tort & Criminal Statutes

Organization of the United States Government

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



1776, David McCullough *John Adams*, David McCullough *Founding Brothers & Revolutionary Summer* Joseph Ellis



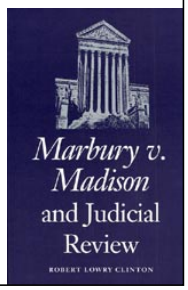
Marbury v. Madison-1803

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

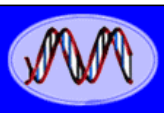
Activist Judges?

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



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
Article VI	Federal Supremacy Clause
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



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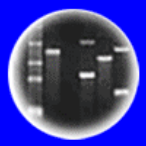

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Plants of Tomorrow

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!!

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., 20y)?

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 or 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?

Preamble

"We the People of the United States, in order to form a more perfect Union, establish justice, insure domestic tranquility, proved 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!

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!

Article I - Section 8.1

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

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 or Officer thereof.

Key Concept: Congress Established Agencies Such as NIH, NSF, and USDA

Article 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

Public Law 114–216
114th Congress

An Act

To reauthorize and amend the National Sea Grant College Program Act, and for other purposes.

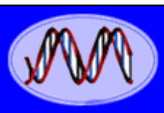
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) is amended by adding at the end the following:

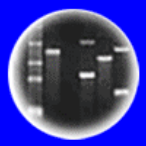
"Subtitle E—National Bioengineered Food Disclosure Standard

Vermont GMO Labeling Law Is Invalid!!



DNA
Genetic Code of Life

Entire Genetic Code of a Bacteria

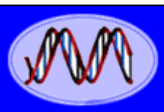


DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

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



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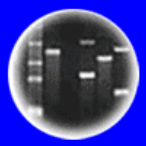

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Plants of Tomorrow

Can Scientific Inquiry and Research Be Regulated?

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

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)?

ASILOMAR CONFERENCE GROUNDS

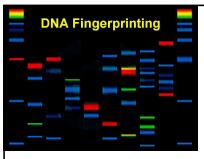
Asilomar Conference on Recombinant DNA

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

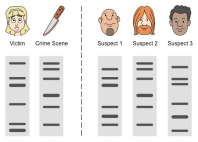
1. When Moving From Reflection, Theory, Hypothesis, and Thought to *TESTING AND EXPERIMENTATION* - Move From World of Speech (talking, publishing) to *WORLD OF ACTION AND CONDUCT.*
2. Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That Which is Not Hazardous (e.g., testing 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).

Can Think But Can't Always Act!

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



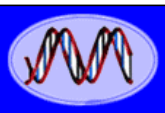
Amendment IV



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"

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



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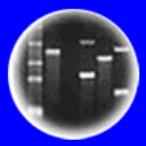

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Plants of Tomorrow

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

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

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)

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,amniocentesis, chorionic villi sampling)
- In Vitro Fertilization
- Stem Cells
- Cloning (therapeutic, reproductive?)
- Birth Control
- Medical Treatment (end of life??)
- Germline Gene Editing?

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."

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.

Amendment XIII

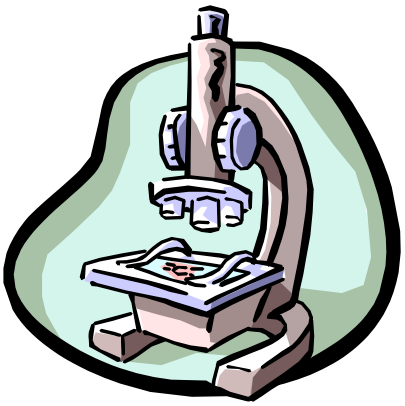
Involuntary Servitude:

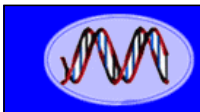
Section 1: "Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist with the United States, or any place subject to their jurisdiction."

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

How Can Genetic Engineering Be Regulated Directly?





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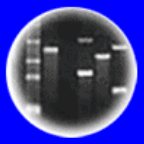


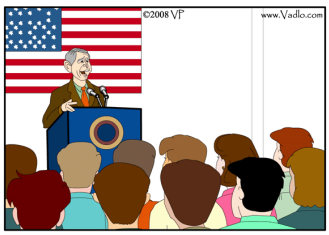
DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

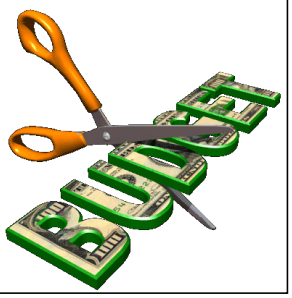
Police Powers of Federal, State, and Local Governments-To Promote the General Welfare-Can Regulate Experimentation.

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

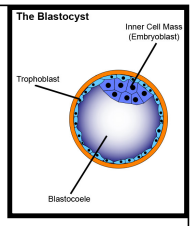


I have ordered science grants to be distributed by National Lottery Commission.

How Can Genetic Engineering and Science Be Regulated Indirectly?



Example - Federal Stem Cell Research Funding (2017)



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

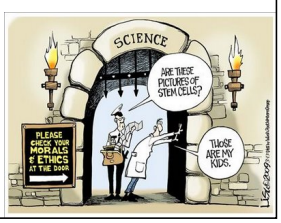
By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

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.

No Federal Funds Can Be Used To Support the Destruction of a Human Embryo (i.e, to obtaining embryonic stem cells



UCLA Biohazard Committee Approvals Required To Obtain Funding (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: [signature]
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 [signature]
Robert B. Goldberg
Assistant Professor of Biology

2. Experiments which involve recombinant DNA molecules.

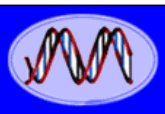
A. Background. "Organization and Expression of Seed Storage Protein Genes in Soybean Development"

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.

NSF

Genetic Engineering



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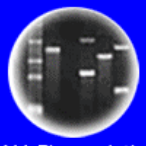

DNA Fingerprinting

Cloning: Ethical Issues and Future Consequences

Plants of Tomorrow

Regulate Science Through Power of Funding and Research $

1. <u>No Constitutional Right to Obtain Funding</u> 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