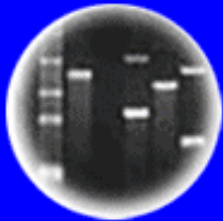


DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

HC70A, SAS70A, & PLSS059 Winter 2019 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg, John Harada,
& Channapatna Prakash

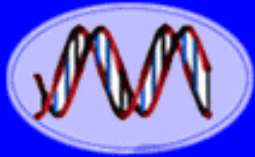
Lecture 9

Science & The Constitution: Regulating Science & Genetic Engineering

UCLA

TUSKEGEE
UNIVERSITY

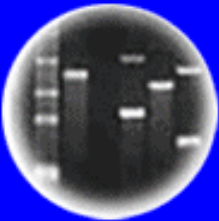
UC DAVIS
UNIVERSITY OF CALIFORNIA



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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 - Then & Now
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 12 (Biotechnology Regulations) & Chapter 13 (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. *Constitutional Law*, By Erwin Chemerinsky (2015)
13. *Patent, Copyright, & Trademark*, By R. Stim (2016)
14. *Imbeciles; The Supreme Court, American Eugenics, & The Sterilization of Carrie Buck*, By Adam Cohen (2016)
15. *A Crack in the Creation*, By Jennifer Doudna and Samuel Sternberg (2017)



“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.”

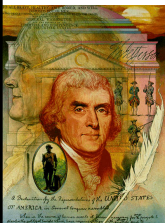
Thomas Jefferson, July 12, 1810

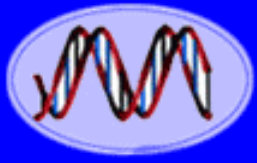
Was 1810 Science the same 2018 Science?

What Was Known About Biology in 1810?

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

No - Darwin, Genetics, Molecular Biology, Biochemistry, Genetic Engineering!!

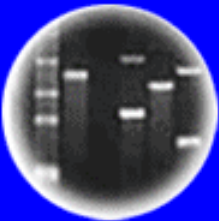




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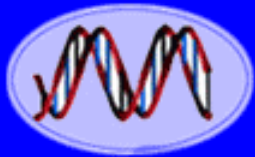


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What is the The Relationship Between **Genetics** and **The Law** in the United States?

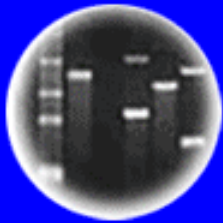




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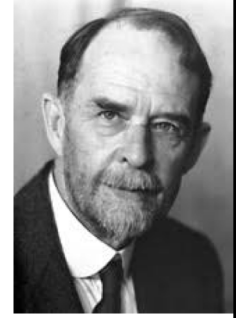
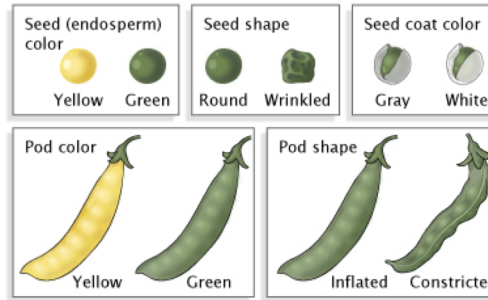
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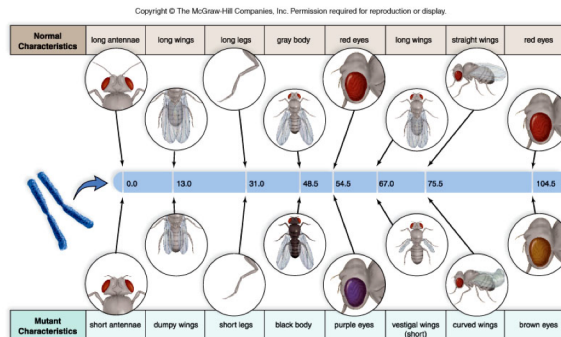
Gregor Mendel



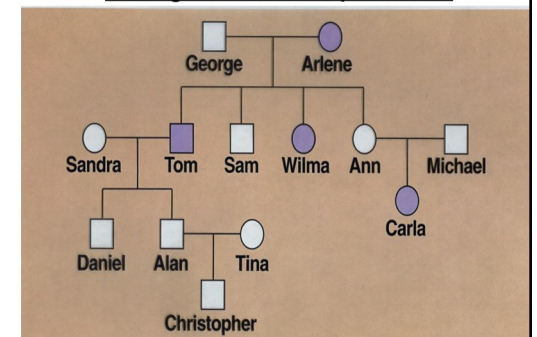
Thomas H. Morgan

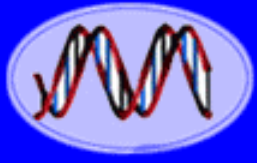
The Beginning of the 20th Century Was Similar to the Beginning of the 21st Century - New Discoveries in Genetics Led to Many New Ethical and Societal Issues

Discovery of Genetics vs. Sequencing the Human Genome



Pedigree of Alkaptonuria

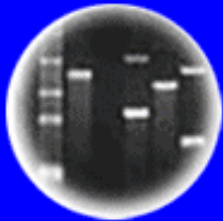




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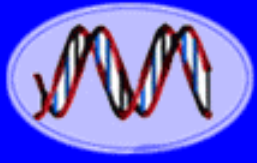
Mendel's Laws of Genetics Were Rediscovered in 1900!

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]



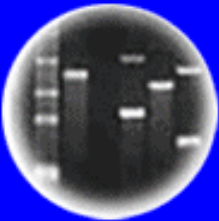
The word **gene** was invented to describe the physical properties of inheritance in 1909 by the botanist **Wilhelm Johannsen**, and **Thomas Hunt Morgan** showed that **genes are on chromosomes** in 1910! **William Bateson** first used the word **genetics** (from Greek *gennō*, γεννώ; "to give birth") to describe the study of inheritance in 1905



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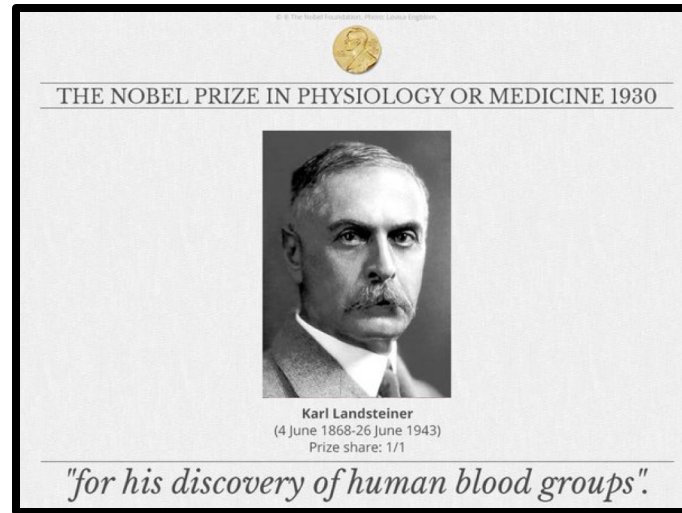
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and Future Consequences



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Human Genetics Was Born in 1900

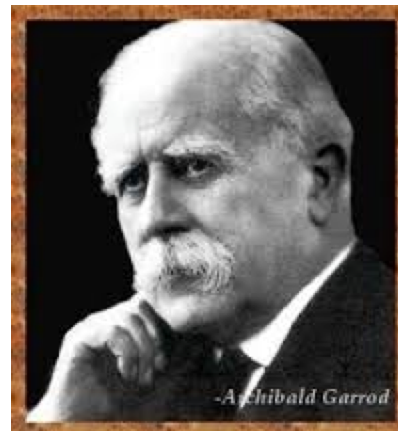
The ABO Blood Types Were the First Human Traits
Discovered That Followed Mendelian Inheritance (1900)



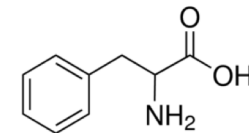
Landsteiner

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

Garrod
(with help from
Bateson)



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*

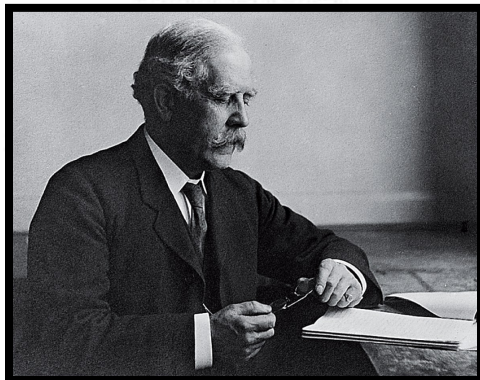
INBORN ERRORS OF METABOLISM

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

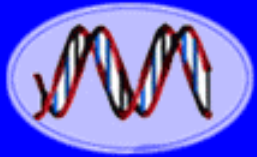
OXFORD UNIVERSITY PRESS 20, WARWICK SQUARE, E.C.

1909

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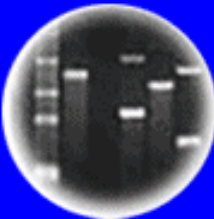
It appears to me that the strongest argument which can be adduced in favour of this view that alkaptonuria is a Mendelian recessive character is afforded by the fact that albinism, which so closely resembles it in its mode of incidence in man, behaves as a recessive character in the experimental breeding of animals.³² Nor do the figures quoted by Bateson³⁰ 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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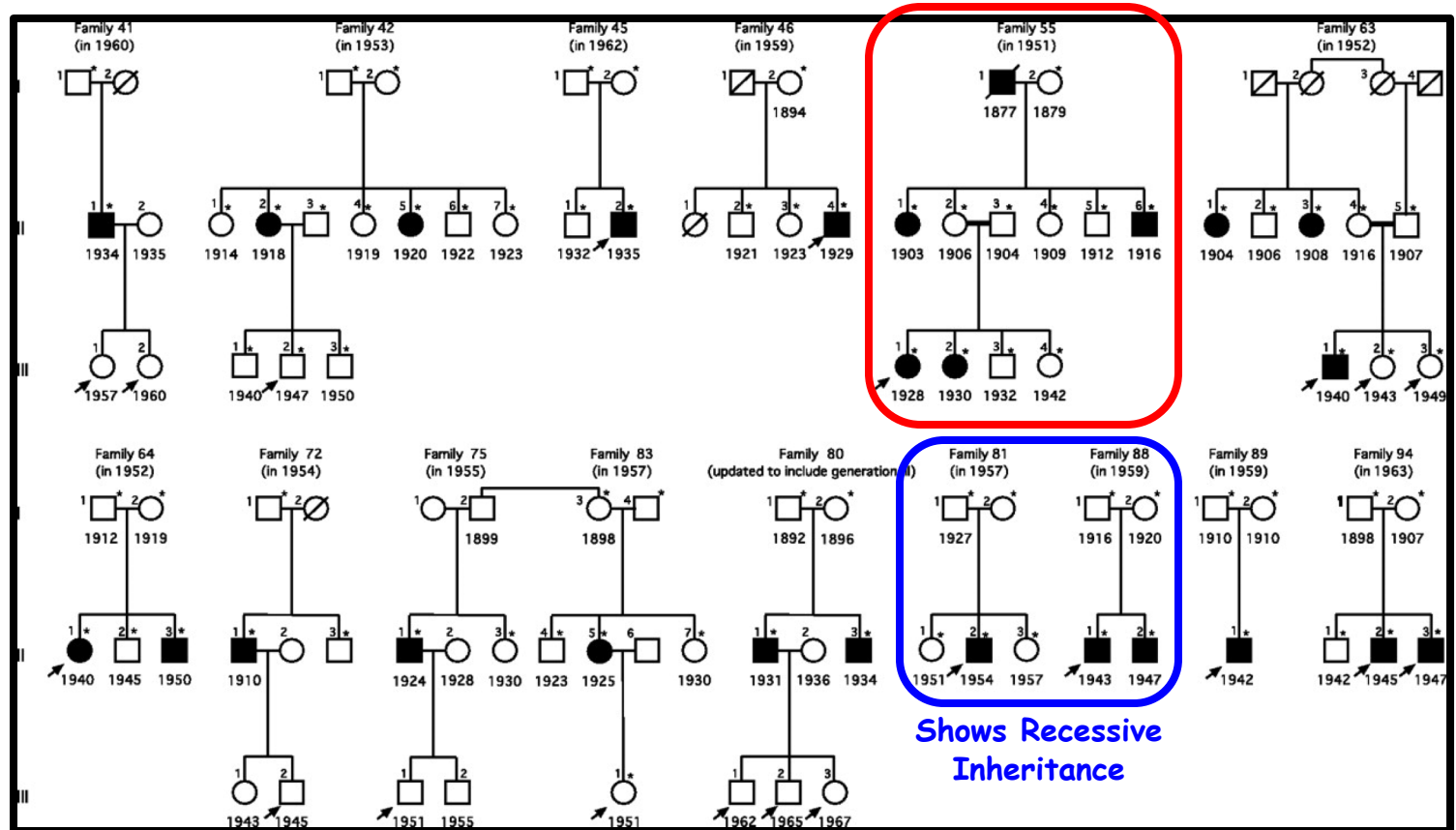


Cloning: Ethical Issues
and Future Consequences

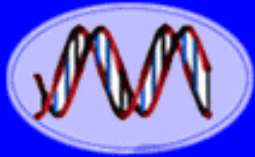


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Garrod's Discovery of Human Disease Gene Inheritance Using Pedigrees (Alkaptonuria, Albinism, Cystinuria, & Pentosuria)



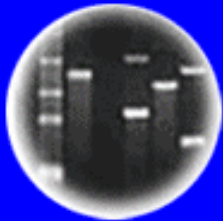
Garrod's Families Were Studied Until the 1960s!



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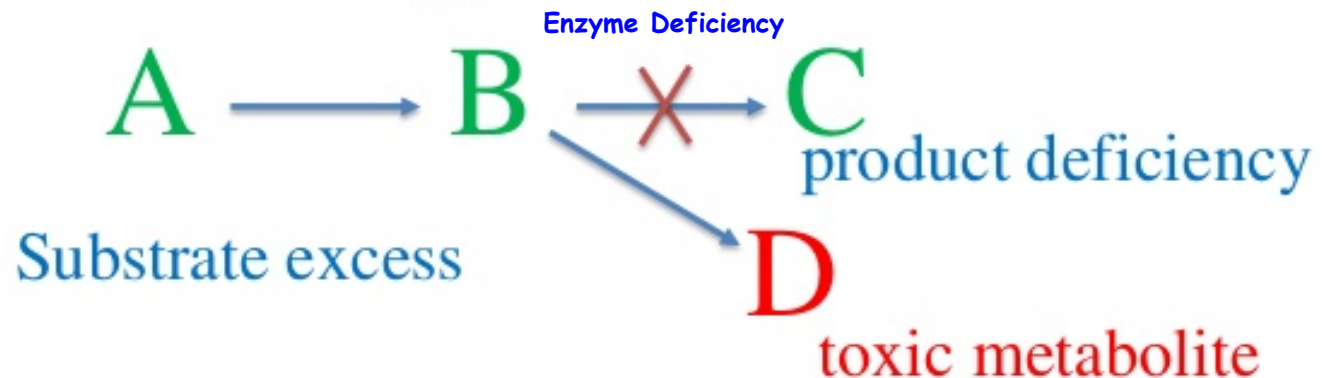
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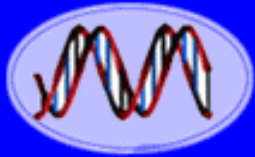
Garrod Hypothesized That Inherited Defects in Metabolic Pathways Lead To Toxic Compound Accumulation That Cause the Disease

Garrod's hypothesis



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

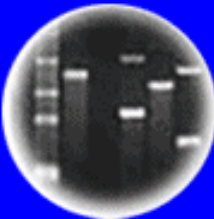
20 Years Later Griffith Discovered the "Transforming Principle" in Pneumonia Bacteria



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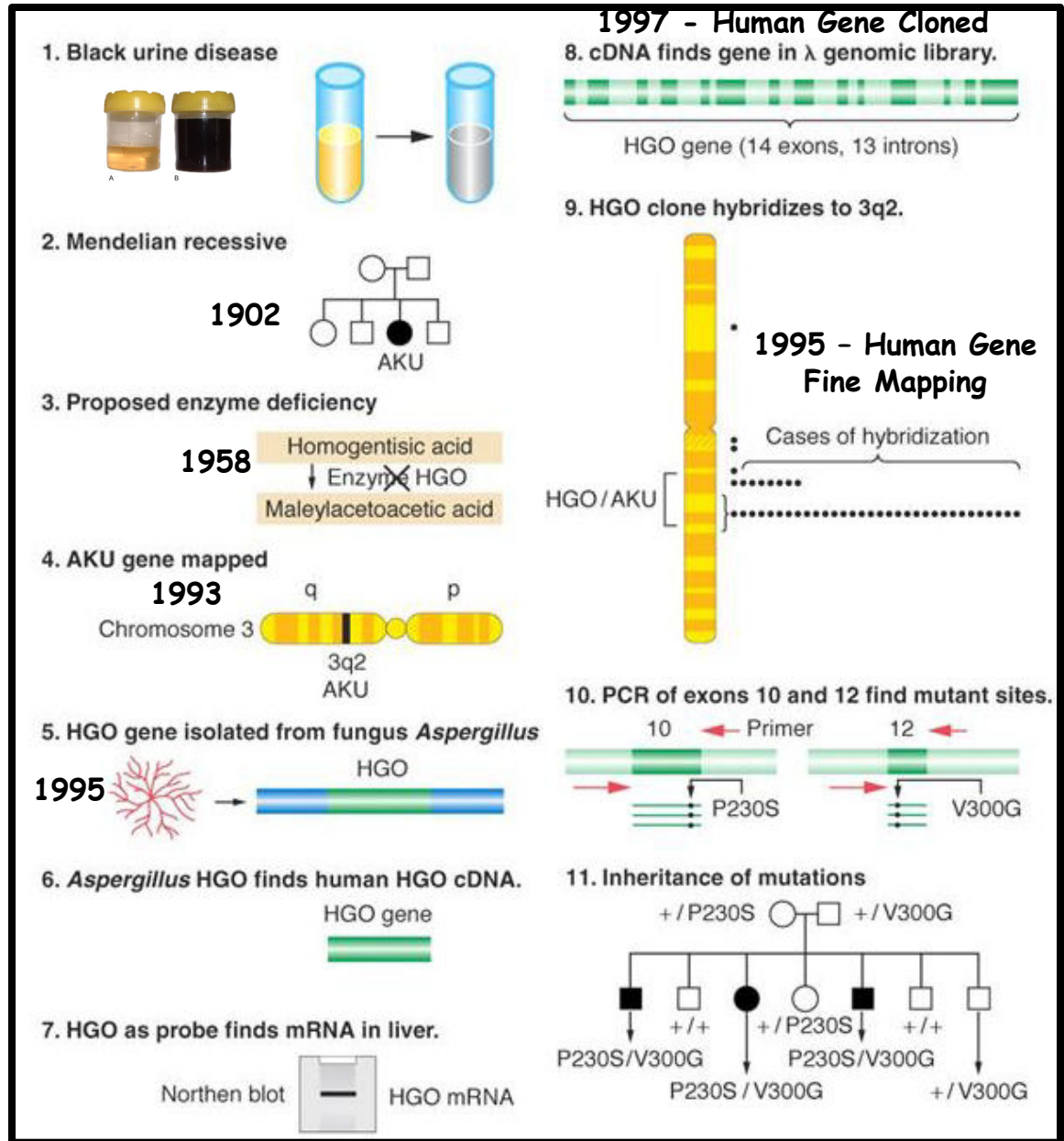


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Isolation of Garrod's Alkaptonuria Gene

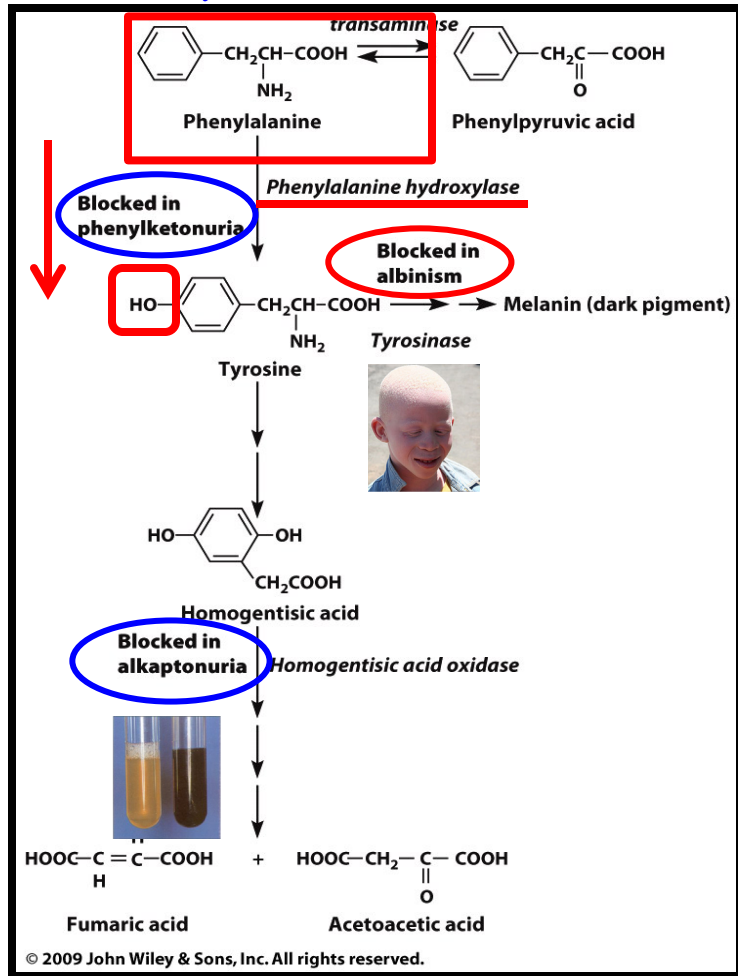
Homogentisic Acid Oxidase (HGO)

Alkaptonuria does not cause developmental delays or cognitive impairment and does not appear to affect life span. However, chronic pain and mobility issues can develop due to homogentisic acid accumulating in joints.

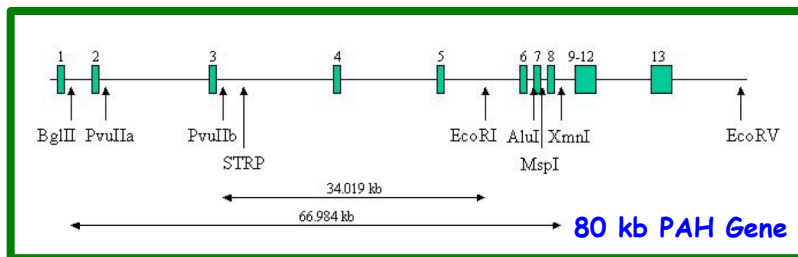
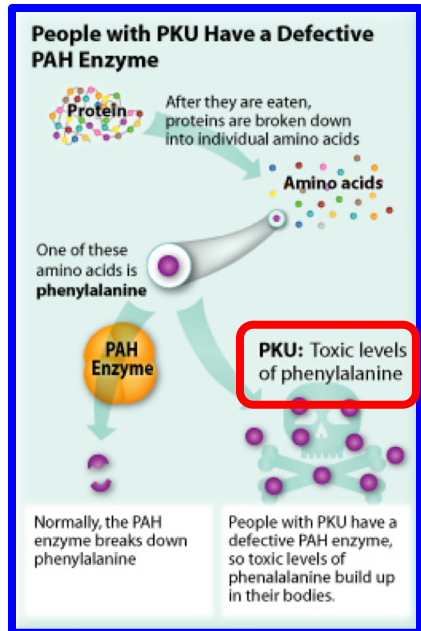
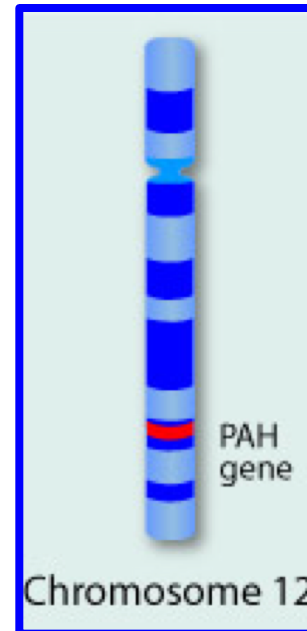
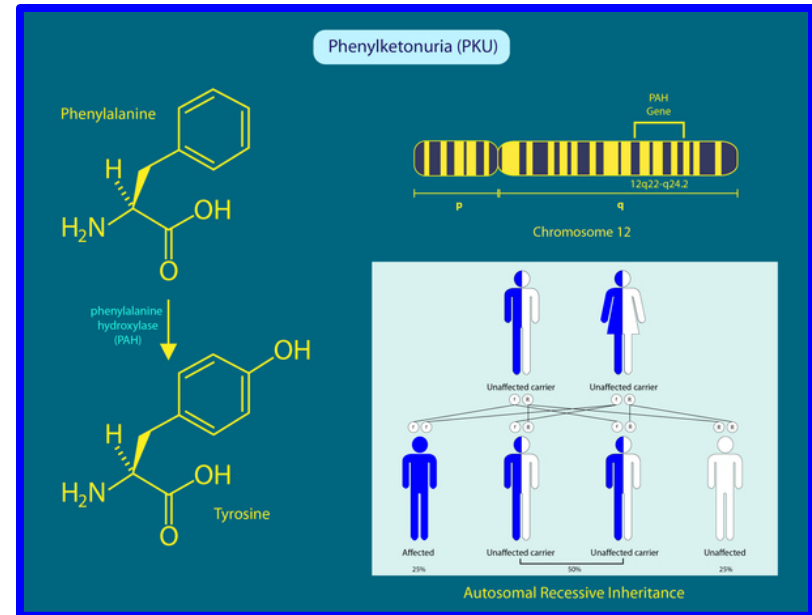


Inborn Errors of Metabolism - Phenylketonuria (Asbjørn Følling: Norway, 1934)

Phenylalanine Metabolism



Recessive Gene Inheritance



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**

PHENYLKETONURIA (PKU) - Inherited Error In Metabolism

[Toxic levels of Phenylalanine (common protein amino acid) due to inability of body to convert]

Can Cause...

- Mental Retardation
- Convulsions
- Behavior Problems
- Skin Rash
- Musty Body Odor

Babies Are Tested...

Both Formula Fed and Breast Fed

A minimum of 24 hrs after beginning milk.

Retest in 7-10 days to catch earlier false negatives.

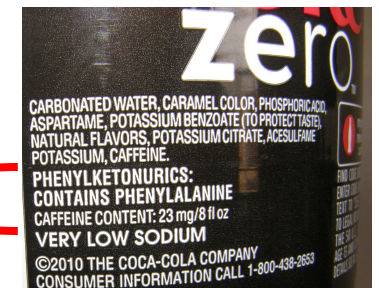
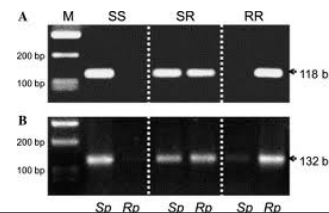
NO

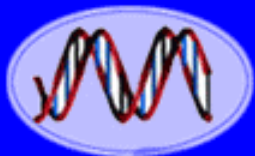
- Meat
- Dairy Products
- Dry Beans
- Nuts
- Eggs

* Cereals, Fruits & Vegetables in Moderation *

TESTS (Preventing PKU)

- 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

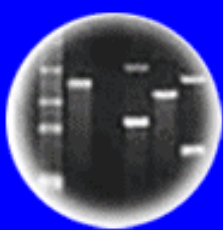




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Cloning: Ethical Issues and Future Consequences



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CALIFORNIA NEWBORN SCREENING PROGRAM

50 YEARS OF NEWBORN SCREENING



Did you know...

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



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



MOST STATES SCREEN FOR **29** out of **31**

RECOMMENDED HEALTH CONDITIONS

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

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

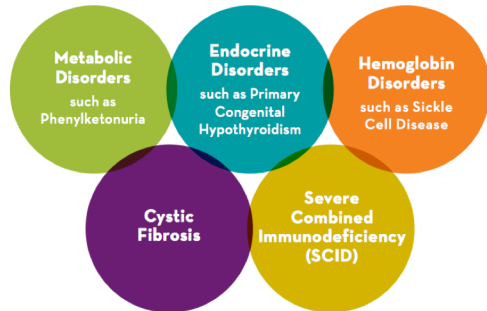
In **1999** **HEARING SCREENING** is recommended for newborns

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. U54MC16509

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



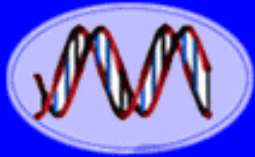
WHO?

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

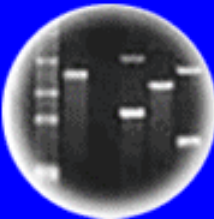
Only Exemption Is For



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CALIFORNIA NEWBORN SCREENING PROGRAM

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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.

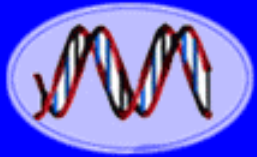
(Amended by Stats. 2012, Ch. 457, Sec. 33. Effective January 1, 2013.)

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!!!

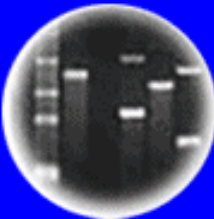




DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting

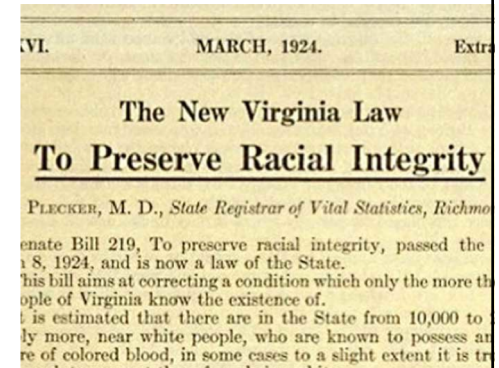
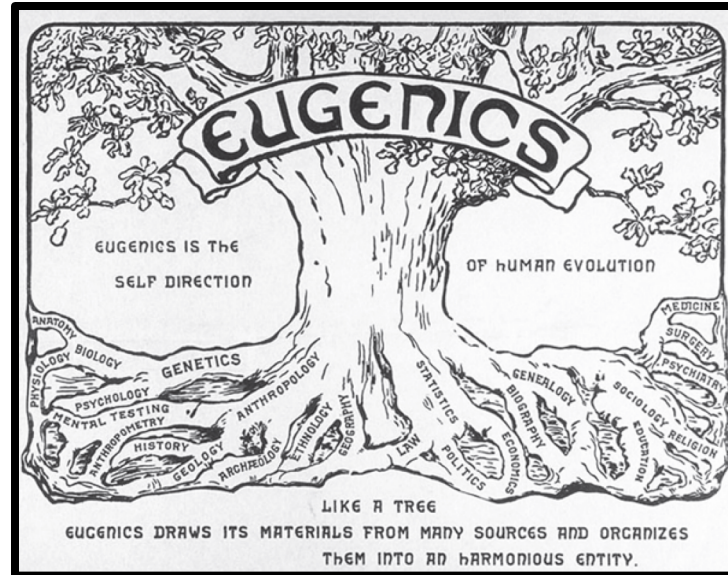
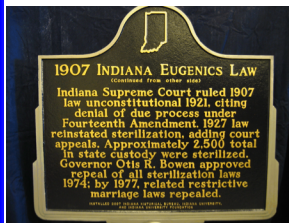


Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

The Eugenics Movement in Early 20th Century Led to the Idea that Genetics Could be Used For the Improvement of Humanity *Of Course - Whose Improvement and What "Traits" Should Be Improved! And Who Should Decide!*



Francis Galton Invented the Term Eugenics

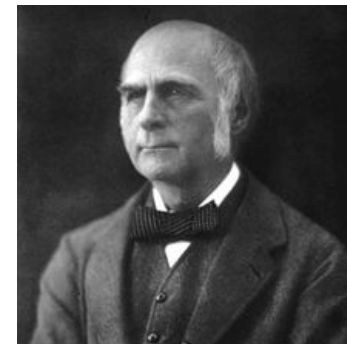


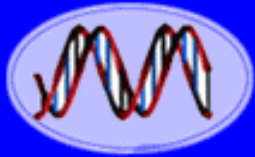
- Regression Line
- Standard Deviation
- Correlation
- Fingerprint Patterns

Darwin's Half
Cousin

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.

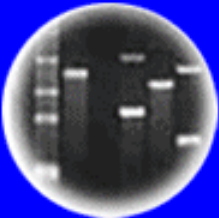




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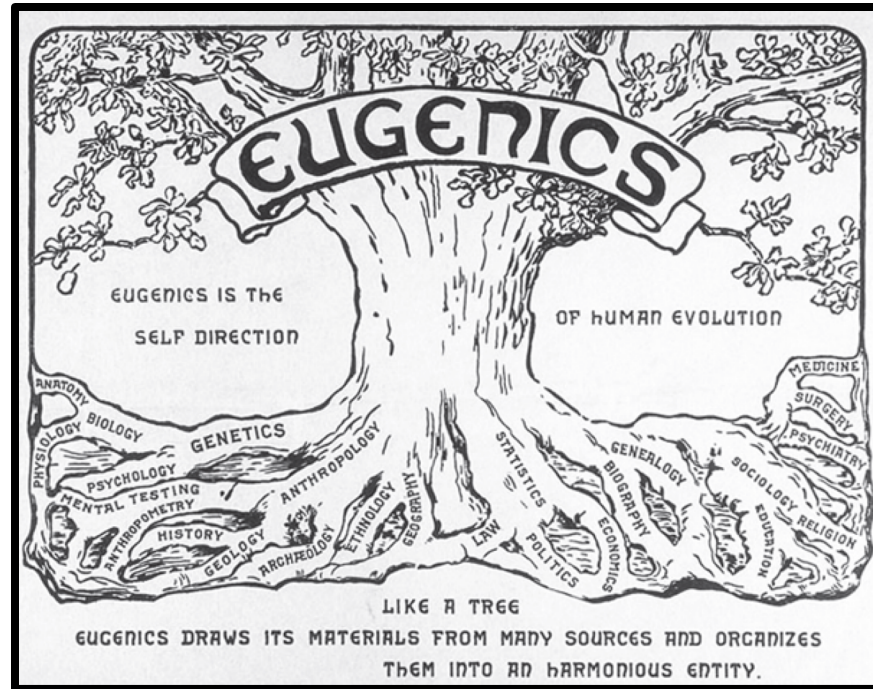
DNA Fingerprinting



Cloning: Ethical Issues
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Negative Eugenics

Eliminating "Undesirable Traits" From Human Populations

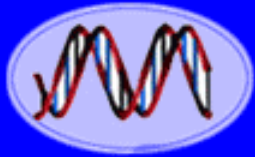
Positive Eugenics

Enhancement or Increasing "Desired" Human Traits

**By "Discouraging" or "Encouraging"
Reproduction Between Individuals**

*This Idea Ultimately Lead to Horrible Human
Tragedies - From Discrimination in Immigration
and Society to Sterilization to Genocide!*

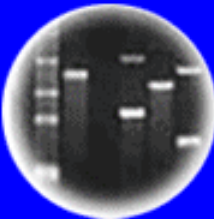
The Biological Fallacy of Eugenics



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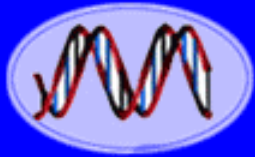
Plants of Tomorrow

Negative Eugenics Eliminating "Undesirable Traits" From Human Populations

Example - Phenylketonuria (PKU)

- frequency of homozygous recessive individuals
 q^2 (aa) = 1 in 10,000 = 0.0001
- frequency of recessive allele (q):
 $q = \sqrt{0.0001} = \underline{0.01}$
- frequency of dominant allele (p):
 p (A) = $1 - 0.01 = \underline{0.99}$
- frequency of carriers, heterozygotes:
 $2pq = 2 \times (0.99 \times 0.01) = \underline{0.0198} = \sim 2\%$
- $\sim 2\%$ of the US population carries the PKU allele
 $300,000,000 \times .02 = 6,000,000$ people

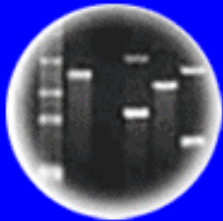
- Most of deleterious PKU alleles are in heterozygotes
- **How will these individuals be identified?**
- How prevent 6,000,000 individuals from passing the PKU allele to their offspring?
- Each of us carries 50 to 100 variants in known disease genes - should we prevent everyone from reproducing?
- Approximately 30 human genes are mutated every generation.
- **Therefore, deleterious alleles will reappear in human populations! Including dominant genes!**



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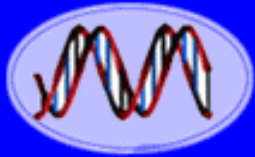
Immigration Act of 1924 - Johnson-Reed Act

- The Immigration Act of 1924 limited the number of immigrants allowed entry into the United States through a national origins quota.
- The basic purpose of the 1924 Immigration Act was to preserve the ideal of U.S. homogeneity.
- The Act of 1924 established that even Asians not previously prevented from immigrating - the Japanese in particular - would no longer be admitted to the United States.
- The Act of 1924 effectively excluded from entry anyone born in a geographically defined "Asiatic Barred Zone" which was defined in the Immigration Act of 1917.
- The percentage of visas available to individuals from the British Isles and Western Europe increased, but newer immigration from other areas like Southern and Eastern Europe was very limited.



Korematsu vs. United States, 1944

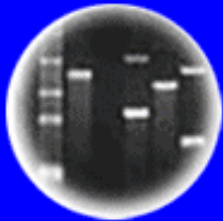




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California's Eugenic Laws

1909: California passes an act "to permit asexualization of inmates of the state hospitals and the California Home for the Care and Training of Feeble-Minded Children and of convicts in the state prisons"

1917: California passes an amendment to the 1913 law to include the sterilization of "sexual degenerates, perverts, and those suffering from diseases of a syphilitic nature."

1927: *Buck v Bell* passes the US Supreme Court, ruling mandatory sterilization of the "unfit and retarded for the protection of the state" to be constitutional.

1949-1952: Involuntary sterilizations dramatically decline in California as fewer medical superintendents prioritize the procedure

1979: California repeals all non-consensual sterilization laws

2000-2006: California prisons illegally sterilize 148 unwilling female prisoners

1913: California passes an act "to provide for the asexualization of the inmates of state hospitals for the insane, ... of convicts in state prisons, and of idiots."

1923: California passes an amendment to the 1913 law to include the sterilization of prisoners who had committed sexual abuse on girls under the age of 10.

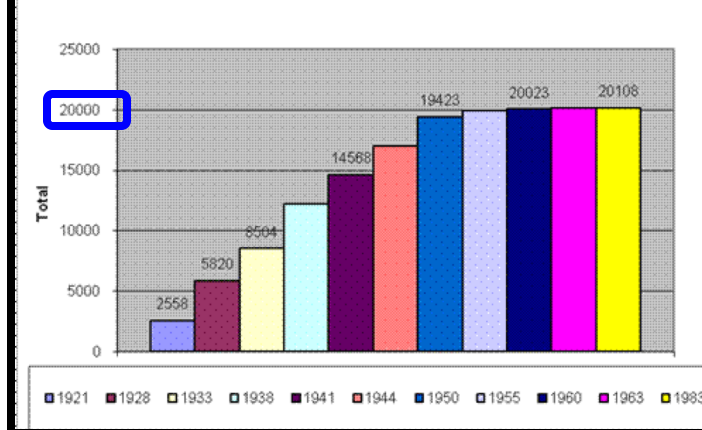
1937: Proposed legislation to establish a "State Eugenics Board" fails to become law in California

1951: California passes an amendment "eliminating sex perversion of syphilitic disease as the basis for sterilization of persons in mental institutions and allowing sterilization for mental illness or mental deficiency only."

2003: California issues a formal apology to the victims of the sterilization laws

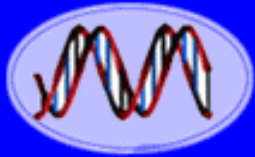
Graphic created by the Population Research Institute: pop.org

Sterilizations in California



Groups Identified in the Law

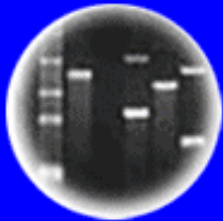
The 1909 law was aimed specifically at those in prisons and with mental disabilities that caused them to be institutionalized. Of those with mental disabilities, the law targeted patients in state hospitals and institutions of the feeble-minded. In terms of the prisoners, the law targeted those who were 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.



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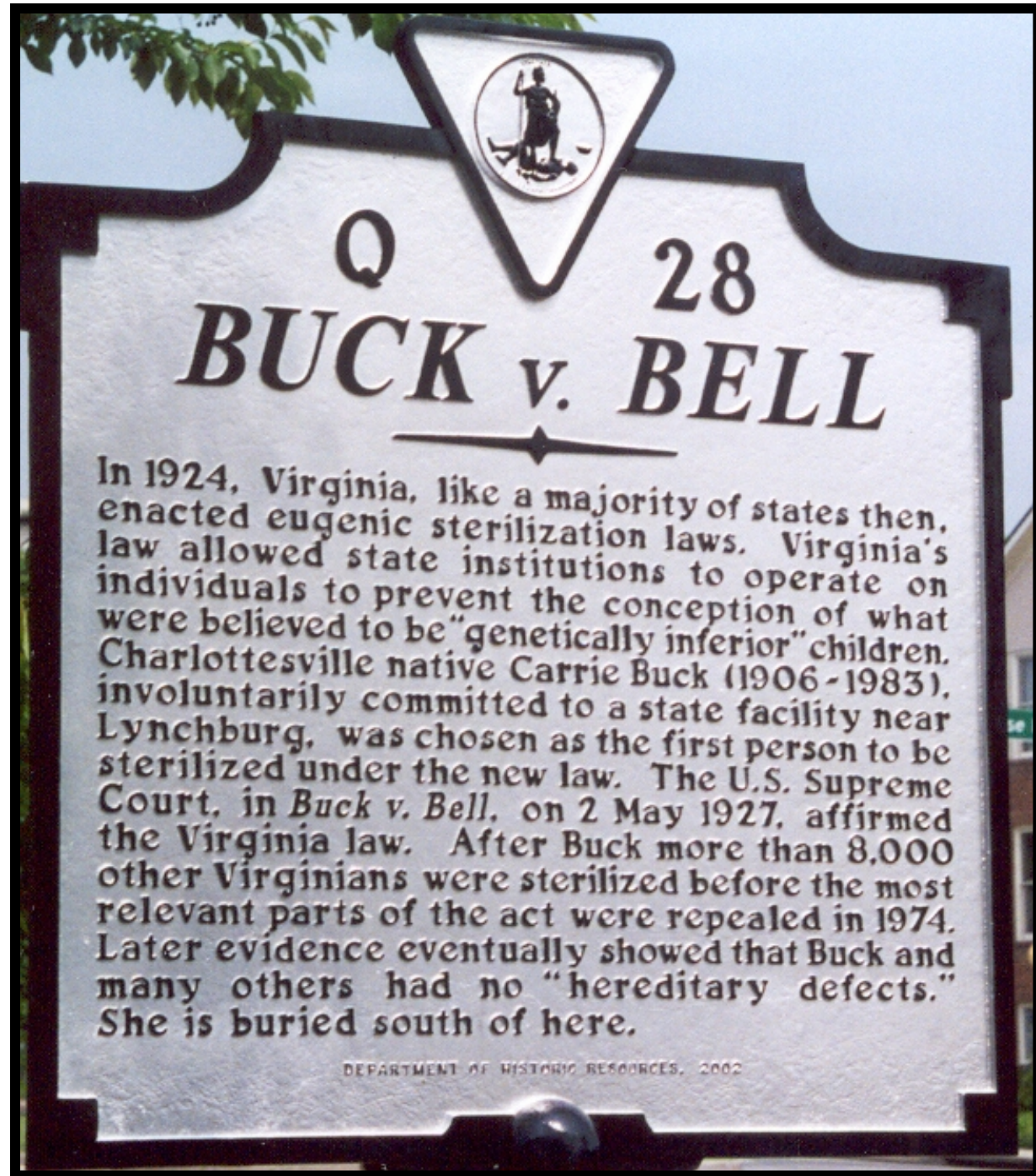
DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences

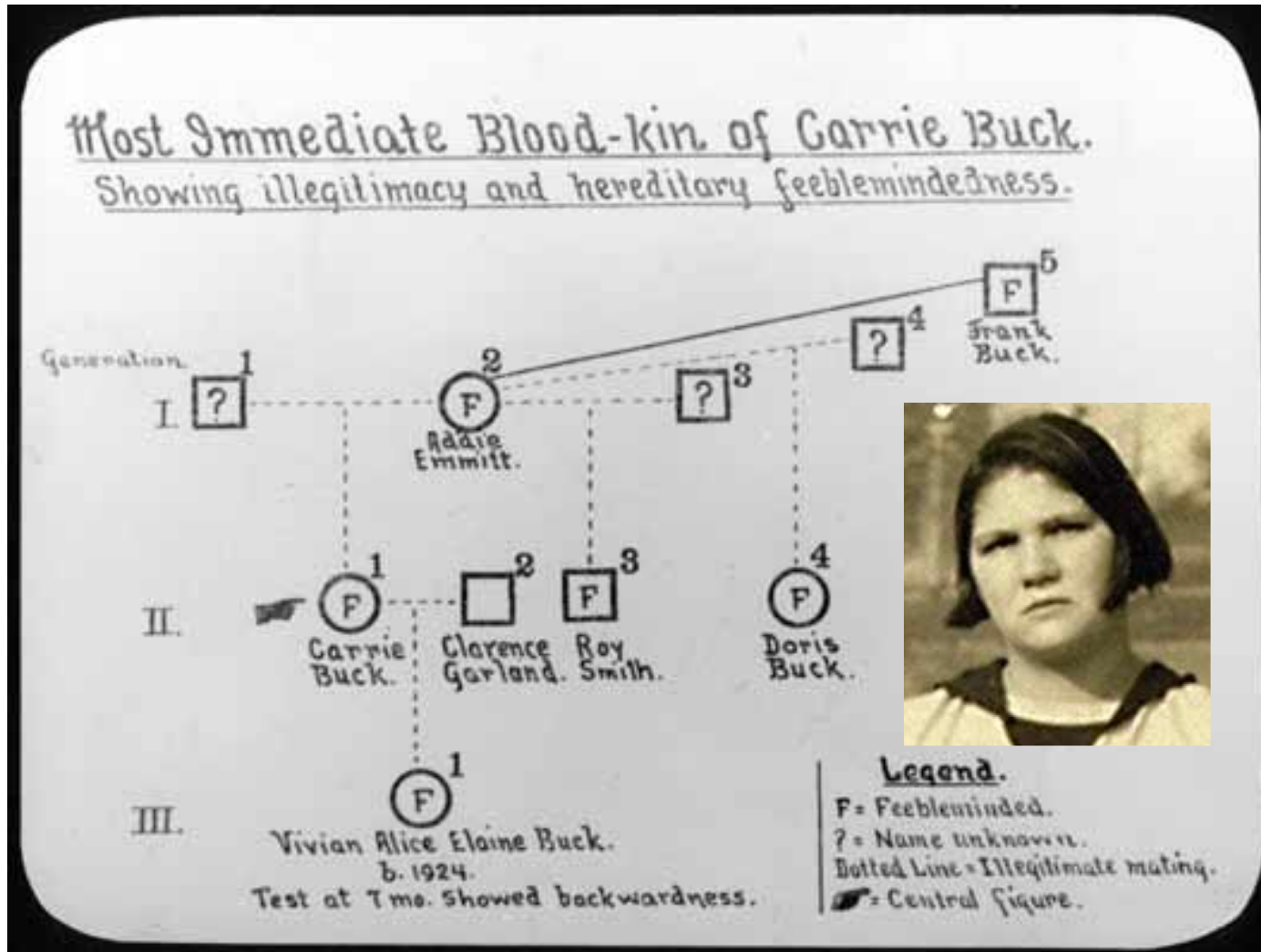


Plants of Tomorrow



DEPARTMENT OF HISTORIC RESOURCES, 2002

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



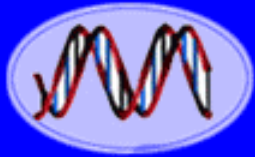
State of Virginia Colony For Epileptics & Feeble-minded- 1924

BUCK v. BELL

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

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

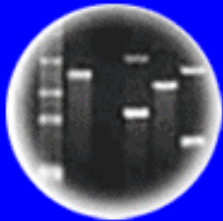
Holmes concluded his argument with the infamous phrase *"Three generations of imbeciles are enough."*



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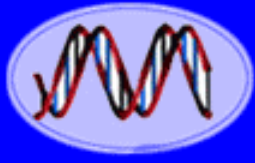
Im·be·ciles (I)

The Supreme
Court, American
Eugenics, and
the Sterilization
of Carrie Buck

Adam Cohen

2016

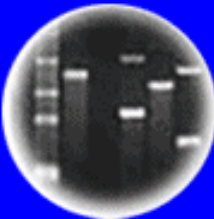
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Plants of Tomorrow

Skinner vs. Oklahoma

Oklahoma's Habitual Criminal Sterilization Act of 1935

- State could impose a compulsory sterilization sentence against individuals who had been convicted three or more times of "felonies amounting to Moral Turpitude."
- Skinner had been convicted once for chicken-stealing and twice for armed robbery.
- White collar crimes were excluded.
- **Court held unanimously that the Act violated the equal protection clause of the 14th Amendment.**
- **Justice William O. Douglas concluded:** *"Oklahoma makes no attempt to say that he who commits larceny by trespass or trick or fraud has biologically inheritable traits which he who commits embezzlement lacks. We have not the slightest basis for inferring that line has any significance in eugenics, nor that the inheritability of criminal traits follows the neat legal distinctions which the law has marked between those two offenses. In terms of fines and imprisonment, the crimes of larceny and embezzlement rate the same under the Oklahoma code. Only when it comes to sterilization are the pains and penalties of the law different. The equal protection clause would indeed be a formula of empty words if such conspicuously artificial lines could be drawn."*
- **Although not striking down Buck vs. Bell, Justice Douglas stated:** *The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands it can cause races or types which are inimical to the dominant group to wither and disappear. There is no redemption for the individual whom the law touches. Any experiment which the State conducts is to his irreparable injury. He is forever deprived of a basic liberty. We mention these matters not to reexamine the scope of the police power of the States. We advert to them merely in emphasis of our view that strict scrutiny of the classification which a State makes in a sterilization law is essential, lest unwittingly, or otherwise, invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws.*

Thus - Buck vs. Bell was not explicitly overturned and state sterilizations continued until 1980!

Nazi Forced Sterilization Law of 1933 For the "Prevention of Hereditarily Diseased Offspring" Was Modeled After California Sterilization Laws

The basic provisions of the 1933 law stated that:

- (1) Any person suffering from a hereditary disease may be rendered incapable of procreation by means of a surgical operation (sterilization), if the experience of medical science shows that it is highly probable that his descendants would suffer from some serious physical or mental hereditary defect.
- (2) For the purposes of this law, any person will be considered as hereditarily diseased who is suffering from any one of the following diseases: -
 - (1) Congenital Mental Deficiency,
 - (2) Schizophrenia,
 - (3) Manic-Depressive Insanity,
 - (4) Hereditary Epilepsy,
 - (5) Hereditary Chorea (Huntington's),
 - (6) Hereditary Blindness,
 - (7) Hereditary Deafness,
 - (8) Any severe hereditary deformity.
- (3) Any person suffering from severe alcoholism may be also rendered incapable of procreation.[2]

The law applied to anyone in the general population, making its scope significantly larger than the compulsory sterilization laws in the United States, which generally were only applicable on people in psychiatric hospitals or prisons.

Reichsgesetzblatt

Teil I

1933 Ausgegeben zu Berlin, den 25. Juli 1933 Nr. 86

Inhalt: Befehl zur Verhütung erbkranken Nachwuchses. Vom 14. Juli 1933.....	§. 529
Urfache Verordnung zur Durchführung der Verordnung über die Deilfenscheinpflichtung. Vom 20. Juli 1933.....	§. 531
Verordnung über die Errichtung einer vorläufigen Billtkammer. Vom 22. Juli 1933.....	§. 531
Verordnung über Zolländerungen und Ausfuhrsteine. Vom 24. Juli 1933.....	§. 533
Verordnung zur Durchführung des Gesetzes über die Aufhebung der im Kampf für die nationale Erhebung erteilten Dienststrafen und sonstigen Maßregelungen. Vom 25. Juli 1933.....	§. 535

Befehl zur Verhütung erbkranken Nachwuchses.
Vom 14. Juli 1933.

Die Reichsregierung hat das folgende Gesetz beschlossen, das hiermit verkündet wird:

§ 1

(1) Wer erbkrank ist, kann durch chirurgischen Eingriff unfruchtbar gemacht (sterilisiert) werden, wenn nach den Erfahrungs der ärztlichen Wissenschaft mit großer Wahrscheinlichkeit zu erwarten ist, daß seine Nachkommen an schweren körperlichen oder geistigen Erbshäden leiden werden.

(2) Erbkrank im Sinne dieses Gesetzes ist, wer an einer der folgenden Krankheiten leidet:

1. angeborenem Schwachsinn,
2. Schizophrenie,
3. zirkularem (manisch-depressivem) Irresein,
4. erblicher Halluzin,
5. erblichem Weiktanz (Huntington'sche Chorea),
6. erblicher Blindheit,
7. erblicher Taubheit,
8. schwerer erblicher körperlicher Mißbildung.

(3) Ferner kann unfruchtbar gemacht werden, wer an schwerem Alkoholismus leidet.

§ 2

(1) Antragsberechtigt ist derjenige, der unfruchtbar gemacht werden soll. Ist dieser geschäftsunfähig oder wegen Weisteschwäche entmündigt oder hat er das achtzehnte Lebensjahr noch nicht vollendet, so ist der gesetzliche Vertreter antragsberechtigt; er bedarf dazu der Genehmigung des Vormundschaftsgerichts. In den übrigen Fällen beschränkter Geschäftsfähigkeit bedarf der Antrag der Zustimmung des gesetzlichen Vertreters. Hat ein Volljähriger einen Pfleger für seine Person erhalten, so ist dessen Zustimmung erforderlich.

(a) Dem Antrag ist eine Bescheinigung eines für das Deutsche Reich approbierten Arztes beizufügen, daß der Unfruchtbarzumachende über das Wesen und die Folgen der Unfruchtbarmachung aufgeklärt worden ist.

(b) Der Antrag kann zurückgenommen werden.

§ 3

Die Unfruchtbarmachung können auch beantragen

1. der beamtete Arzt,
2. für die Inassen einer Kranken-, Heil- oder Pflegeanstalt oder einer Strafanstalt der Anstaltsleiter.

§ 4

Der Antrag ist schriftlich oder zur Niederschrift der Geschäftsstelle des Erbgesundheitsgerichts zu stellen. Die dem Antrag zu Grunde liegenden Tatsachen sind durch ein ärztliches Gutachten oder auf andere Weise glaubhaft zu machen. Die Geschäftsstelle hat dem beamteten Arzt von dem Antrag Kenntnis zu geben.

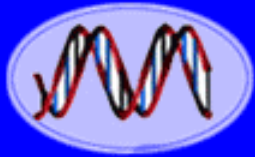
§ 5

Zuständig für die Entscheidung ist das Erbgesundheitsgericht, in dessen Bezirk der Unfruchtbarzumachende seinen allgemeinen Gerichtsstand hat.

§ 6

(1) Das Erbgesundheitsgericht ist einem Amtsgericht anzugliedern. Es besteht aus einem Amtsrichter als Vorsitzenden, einem beamteten Arzt und einem weiteren für das Deutsche Reich approbierten Arzt, der mit der Erbgesundheitsgerichte besonders vertraut ist. Für jedes Mitglied ist ein Vertreter zu bestellen.

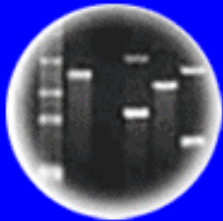
(2) Als Vorsitzender ist ausgeschlossen, wer über einen Antrag auf vormundschaftsgerichtliche Genehmigung nach § 2 Abs. 1 entlassen hat. Hat ein beamteter Arzt den Antrag gestellt, so kann er bei der Entscheidung nicht mitwirken.



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Cloning: Ethical Issues
and Future Consequences

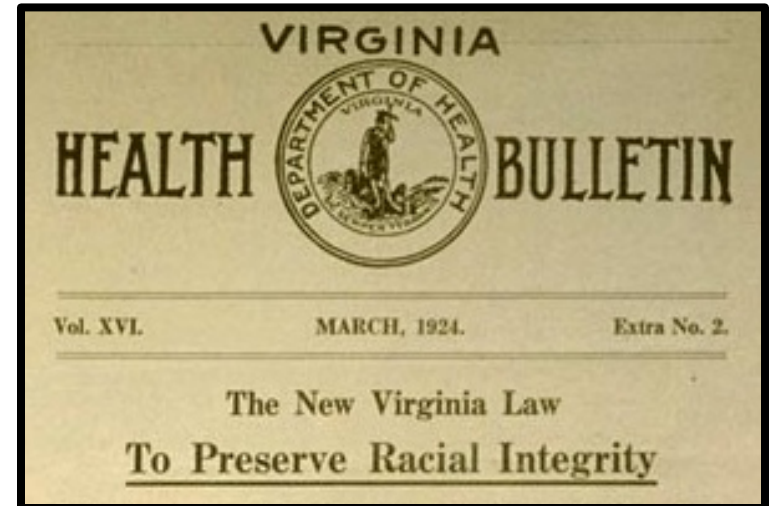
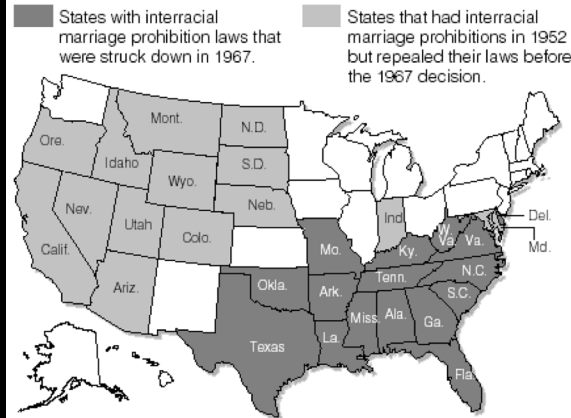


Plants of Tomorrow

Miscegenation Laws

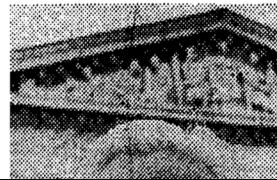
Banning Interracial Marriage

In 1967, the United States Supreme Court struck down laws in 16 states prohibiting interracial marriages. Fifteen years earlier, 14 other states had also banned interracial marriage but repealed their laws before the 1967 decision.



Justices Upset All Bans On Interracial Marriage

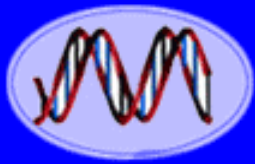
9-to-0 Decision Rules Out
Virginia Law—15 Other
States Are Affected



Equal Protection Question - Is the government's classification justified by a sufficient purpose? Can the government identify an important objective for discrimination? Not Racial discrimination!

Loving vs. Virginia (1967)

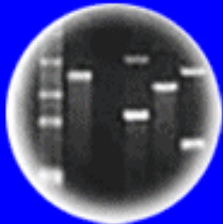
- Law Denied Equal Protection
- Law Deprived Constitutionally Protected Liberty Without Due Process - *"the freedom to marry has long been recognized as one of the vital personal rights essential to the orderly pursuit of happiness by free men. Marriage is one of the basic civil rights on man, fundamental to our very existence and survival. The law surely deprives all of the State's citizens of liberty without due process"*
- Set a Precedent For Obergefell vs. Hodges Which Ruled That Same Sex Marriages Are Constitutional (2015)!!



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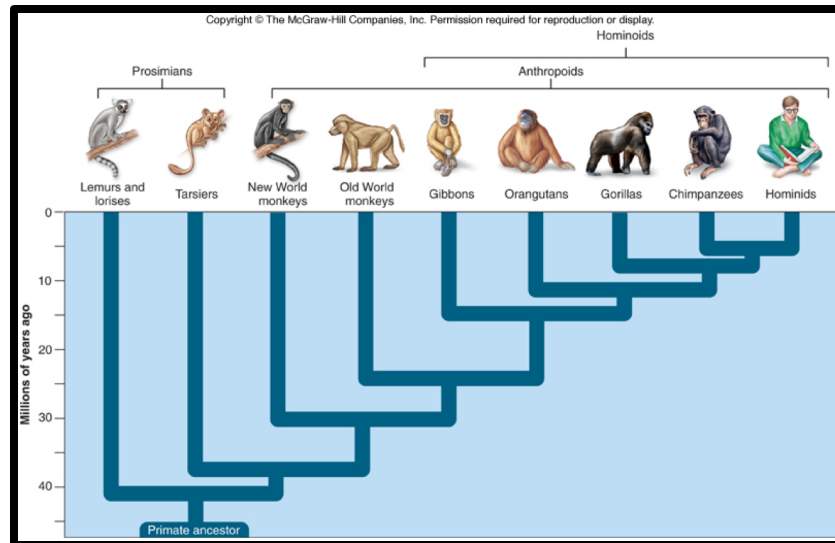
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HUMAN EVOLUTION

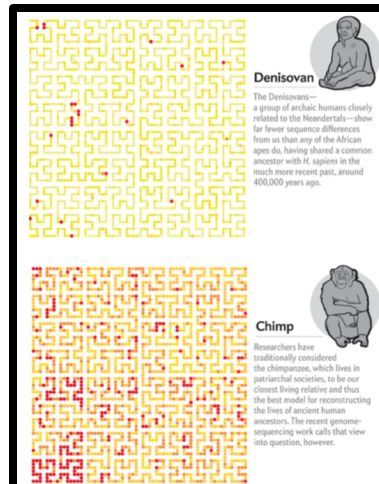
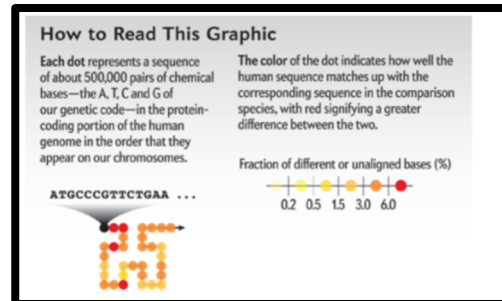
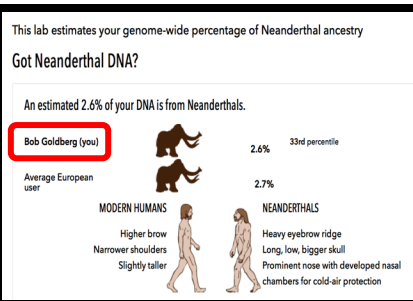
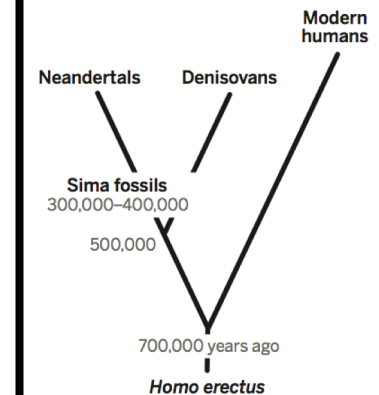
Humanity's long, lonely road

Oldest ancient nuclear DNA suggests humans and Neandertals parted ways early

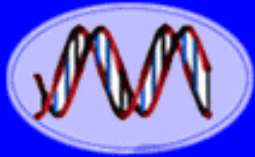


Deeper branches

Putting the Sima fossils on the Neandertal lineage implies an earlier split between modern and some archaic humans.



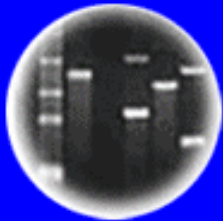
Science, Evolution, & The Law



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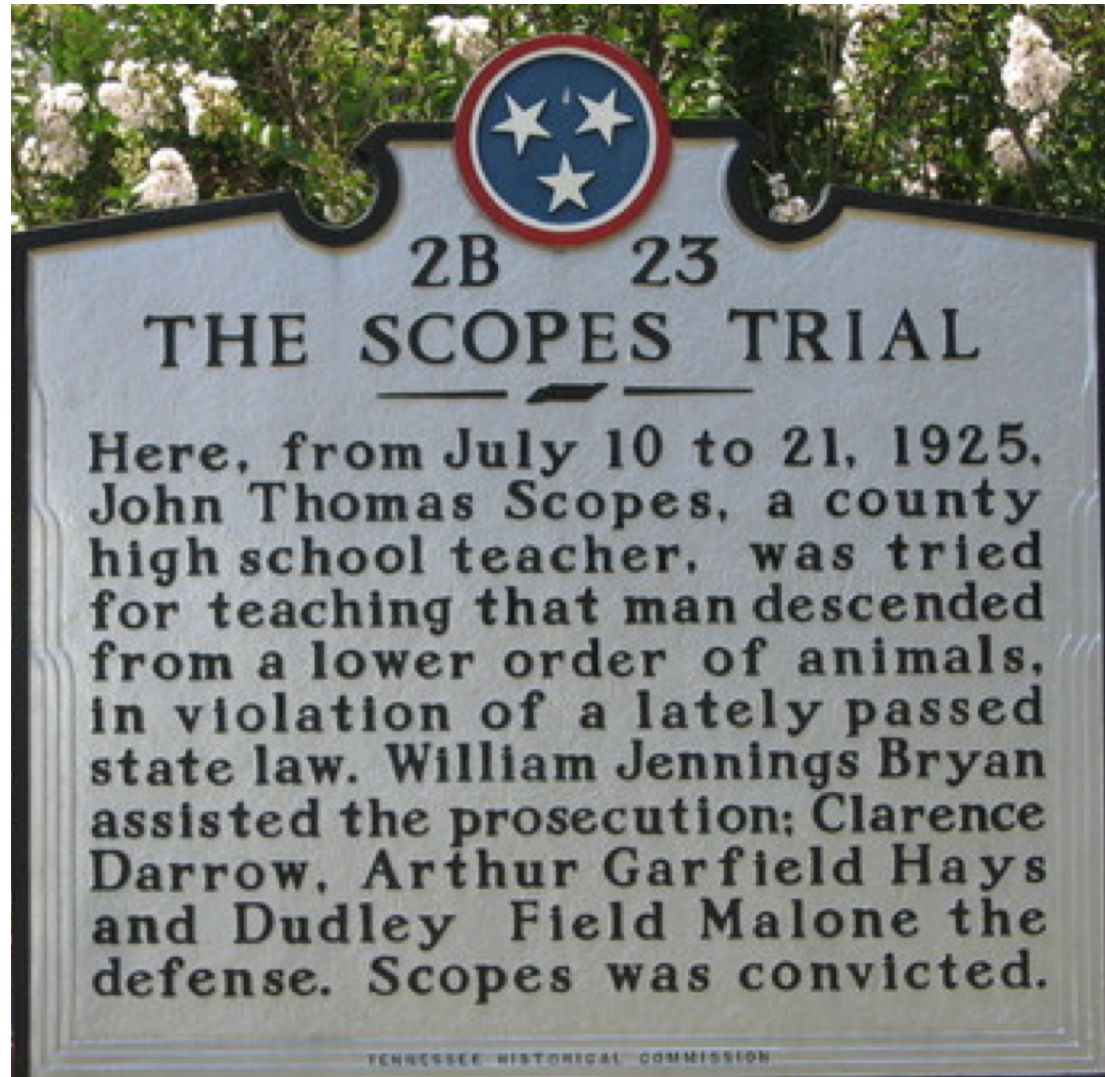
DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

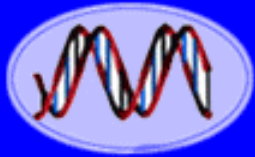


21 March 1925

Butler Act prohibiting teaching of human evolution enacted.



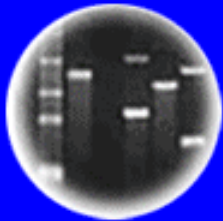
Teaching Evolution Laws



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Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow



Epperson vs. Arkansas - 1968

Justice Abe Fortas stated that the law had been based solely on the beliefs of fundamentalist Christians, who felt that evolutionary theories directly contradicted the biblical account of Creation. This use of state power to prohibit the teaching of material objectionable to a particular sect amounted to an unconstitutional establishment of religion.

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

John Scopes



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 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)

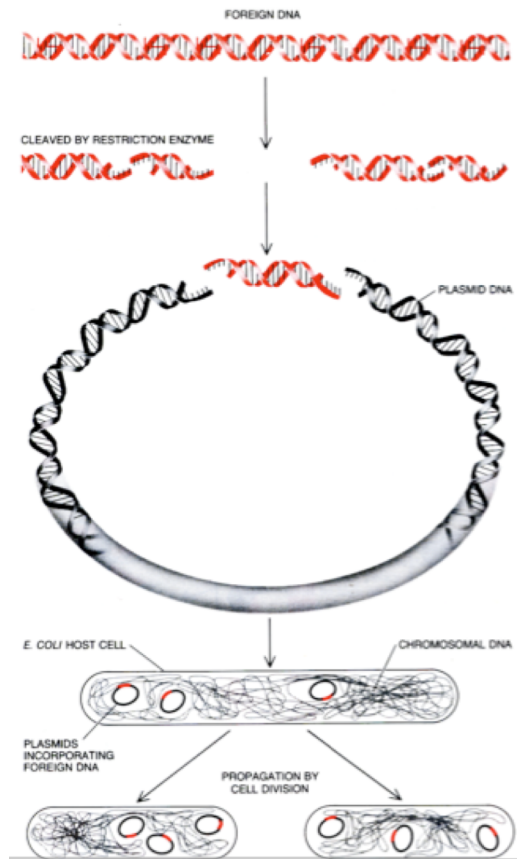
The Recombinant-DNA Debate

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

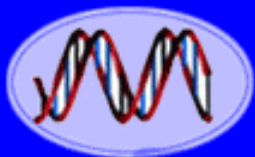
Berg Letter (1974), Asilomar (1975), NIH Guidelines & Recombinant DNA Advisory Committee (RAC) (1976)

by Clifford Grobstein

Cohen-Boyer-1973



		BIOLOGICAL CONTAINMENT (FOR E. COLI HOST SYSTEMS ONLY)		
		EK1	EK2	EK3
PHYSICAL CONTAINMENT	P1	DNA from nonpathogenic prokaryotes that naturally exchange genes with <i>E. coli</i> Plasmid or bacteriophage DNA from host cells that naturally exchange genes with <i>E. coli</i> . (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 <i>E. coli</i> 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 <i>E. coli</i> DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i> 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 <i>E. coli</i> . (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.)	
	P3	DNA from nonpathogenic prokaryotes that do not naturally exchange genes with <i>E. coli</i> DNA from plant viruses Plasmid or bacteriophage DNA from host cells that do not naturally exchange genes with <i>E. coli</i> . (If there is a risk that recombinant will increase pathogenicity or ecological potential of host, higher levels of containment are required.).	DNA from 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 <i>E. coli</i> 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)	



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



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

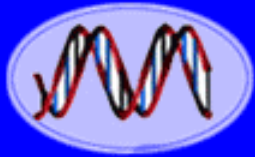
PRINCETON RESEARCH ON DNA IS PERMITTED

1/12/78

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

Allows P1, P2, & P3 Research Following NIH Guidelines

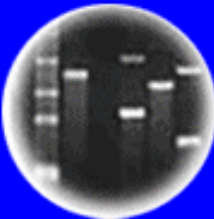
Special to The New York Times



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The Only Federal Law Dealing With a **Genetic Engineering** Procedure



Germline Gene Therapy

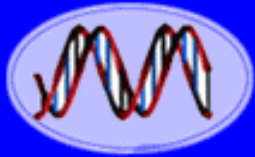
2019 Congressional Budget (Expires 9/30/19)

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

Dickey-Wicker Amendment-1995

Federal Funds Cannot Be Used To:

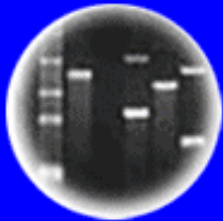
- Create Human Embryos For Research Purposes
- Fund Research in Which a Human Embryo Will Be Destroyed, Discarded, or **Knowingly Subjected to Risk** or Injury of Death



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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.

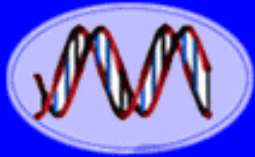
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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

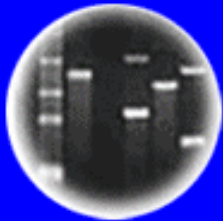
This is the Only Federal Law That Directly Regulates a Genetically Engineered Product Other Than a Drug



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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

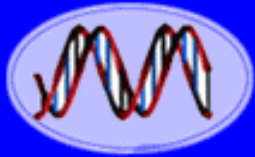
POLICY

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



Paul Darrow/NYT/Redux/eyevine

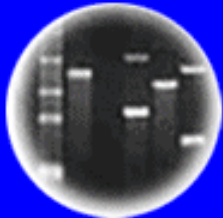
budget bill passed last December, which bans sales of the fish until the FDA decides whether it should be labelled as genetically modified. The agency may take several years to finalize this rule.



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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*

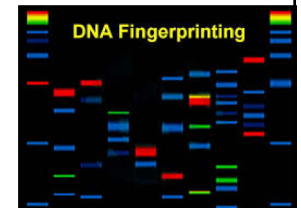
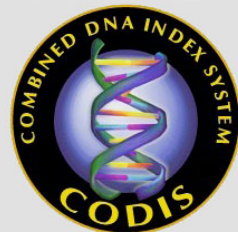
Subtitle C—DNA Identification

- 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 information.
- 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”.



Genetic Information Nondiscrimination Act of 2008



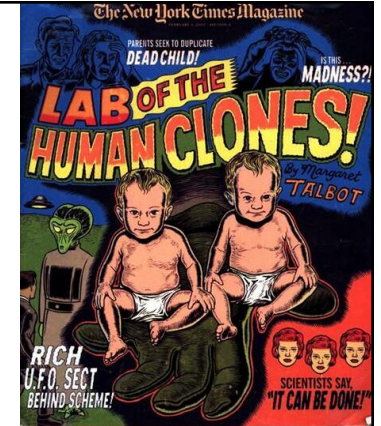
Federal Law on Genetic Discrimination

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.



There is No Federal Human Cloning Law HR3498, 2015 (Not Passed), Prohibition Against Human Cloning

5 “§ 302. Prohibition on 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;

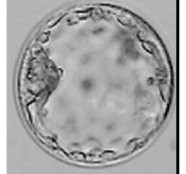
11 “(2) to participate in an attempt to perform
12 human cloning; or

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

**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"

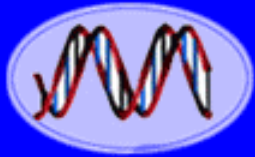
- President Clinton's NIH Advisory Panel Recommended That Federal Funds Be Used For Research on Human Embryos Discarded From In Vitro Fertilization -1995
- Dickey-Wicker Amendment Prohibited Federal Funding For Research in Which Human Embryos Are Destroyed - 1995
- Human Embryonic Stem Cells Discovered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

Bush vetoes embryonic stem-cell bill

Supreme Court rejects challenge to Obama stem cell policy



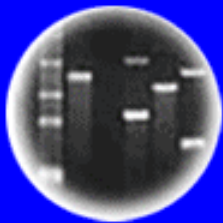
Genetic Engineering is Regulated but Primarily by Federal Agencies and Not By Direct Some Examples



DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting

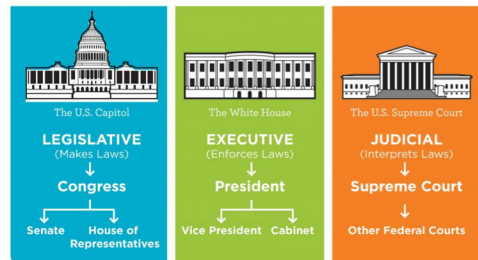


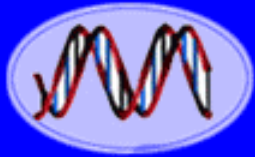
Cloning: Ethical Issues
and Future Consequences



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Three Branches of Government FEDERAL LEVEL

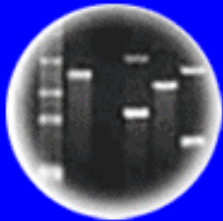




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Office of Science and Technology Policy

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
The Daily Journal of the United States Government

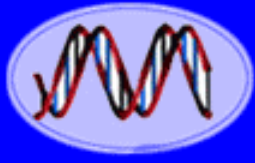
Federal Register / Vol. 80, No. 193 / Tuesday, October 6, 2015 / Notices

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.

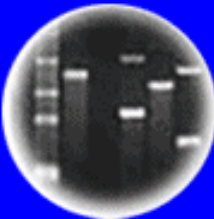
ACTION: Notice of request for information.



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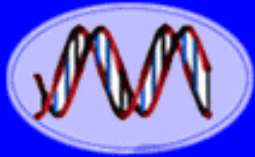
Federal Agencies Involved in the Coordinated Framework For the Regulation of Biotechnology

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, <u>transgenic animals</u> , 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

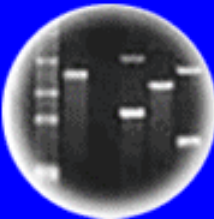
**Gene Editing Has
Non-Regulated
Status For Crops
But Not For
Animals**



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DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences

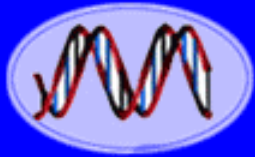


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Regulation of Transgenic Animals & Plants

TABLE 12.2 EXAMPLES OF SHARED RESPONSIBILITIES
BY FEDERAL REGULATORY AGENCIES

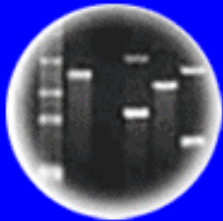
New Trait/ Organism	Regulatory Review Conducted by	Reviewed for
Viral resistance in food crop	USDA	Safe to grow
	EPA	Safe for the environment
	FDA	Safe to eat
Herbicide toler- ance in food crop	USDA	Safe to grow
	EPA	New use of com- panion herbicide
	FDA	Safe to eat
Herbicide tolerance in ornamental crop	USDA	Safe to grow
	EPA	New use of com- panion herbicide
	FDA	Safe to eat
Modified oil con- tent in food crop	USDA	Safe to grow
	FDA	Safe to eat
Modified flower color in ornamental crop	USDA	Safe to grow
	EPA	Safe for the environment



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DNA Fingerprinting



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What About Human Somatic Cell Gene Therapy & Editing?



National Institutes of Health
Turning Discovery Into Health

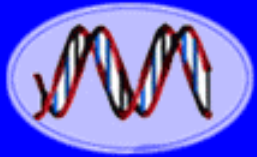


Biomedical Technology Assessment

Oversight of Human Gene Transfer Research

Biomedical Technology Assessment

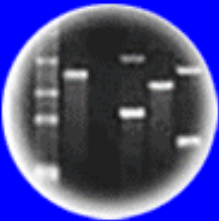
Recombinant DNA Advisory Committee



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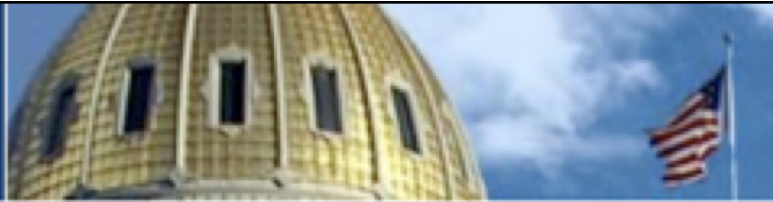


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Laws Exist That Regulate Science at the State & Local Levels Some Examples

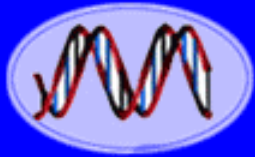
STATE LAWS





California Genetic Laws

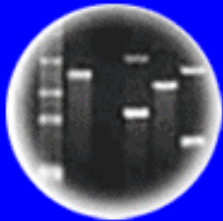
- Newborn Genetic Screening
- Genetic Non Discrimination in Insurance
- Human Cloning Laws
- Genetic Employment Laws
- Genetic Counselor Licensing Laws
- Embryonic and Fetal Research Laws
- Embryo and Gamete Disposition Laws
- Genetic Privacy Laws



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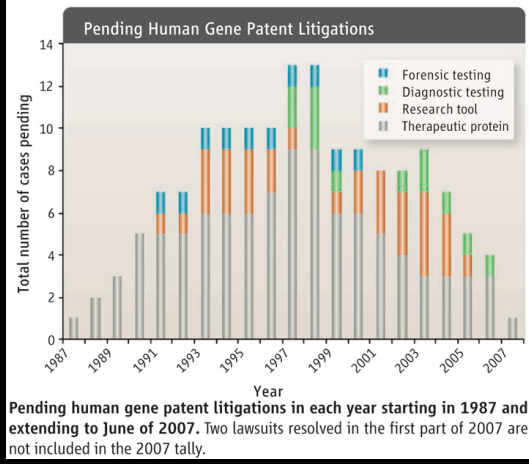
DNA Fingerprinting



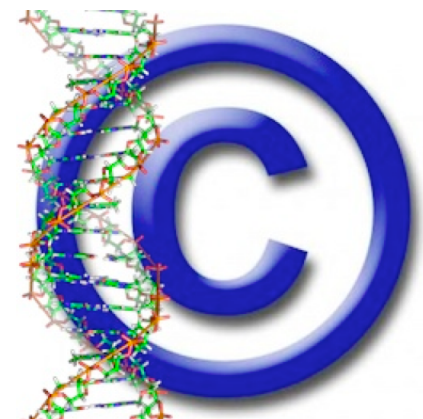
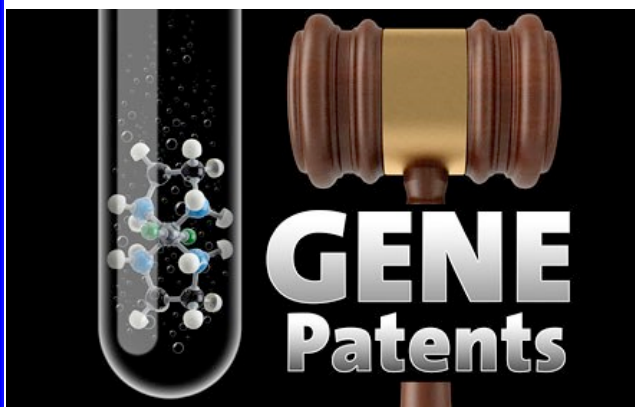
Cloning: Ethical Issues
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What About Other Legal Issues and Laws Dealing With Genes and Genetic Engineering?



Life Is Patentable

(Diamond vs. Chakrabarty)

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

1980

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



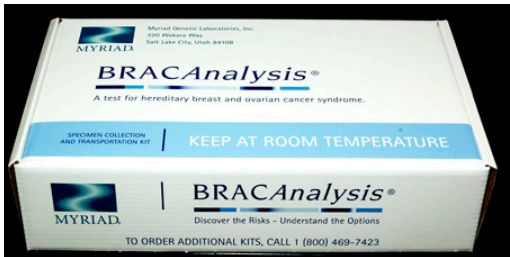
Ananda Chakrabarty



1988

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

6/17/1980



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.

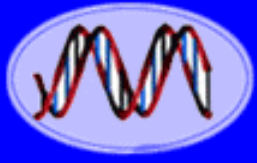
The American Civil Liberties Union and the Public Patent Foundation at the Benjamin N. Cardozo School of Law in New York joined with individual patients and medical organizations to challenge the patents last May: they argued that genes, products of nature, fall outside of the realm of things that can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

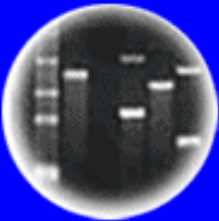
Do patents on breast, ovarian cancer genes, retard new research?



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and Future Consequences



Plants of Tomorrow

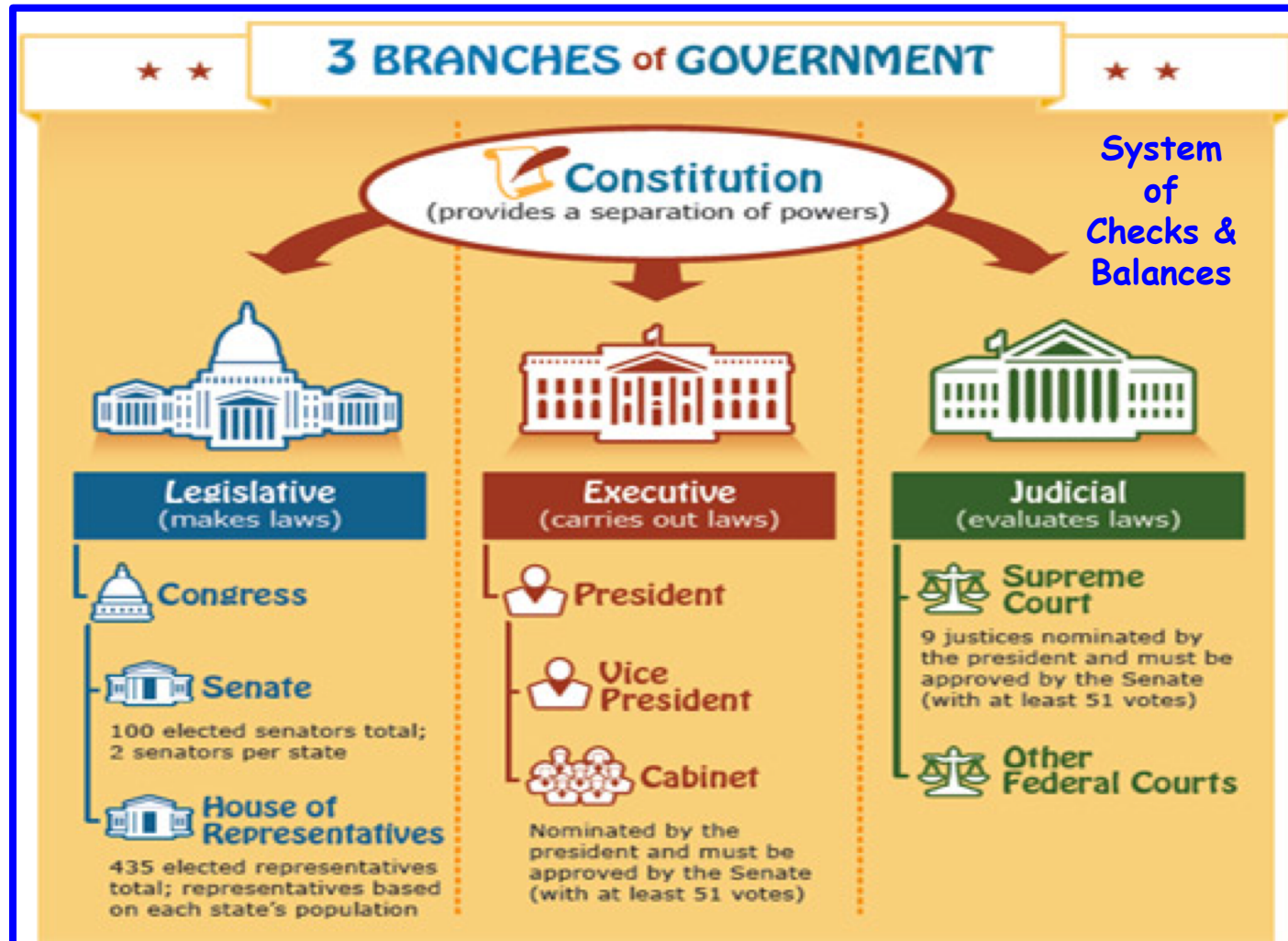
What Enables the Government To Enact Laws Regarding Genetic Engineering and Science?

- **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*
and Judicial
Review

ROBERT LOWRY CLINTON

Marbury v. Madison-1803

stop

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

Chief Justice John Marshall

Activist Judges?

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



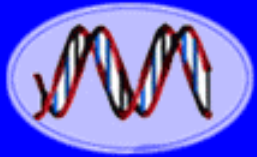
*Marbury v.
Madison*
and Judicial
Review

ROBERT LOWRY CLINTON

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

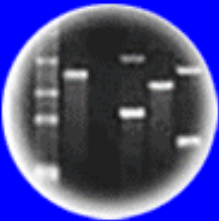




DNA
Genetic Code of Life



Entire Genetic Code
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

What Does the 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, provide for the common defense, promote the General Welfare.....”

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

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 States, shall be the supreme law of the land; and the judges in every State shall be bound thereby”

**State Laws That Conflict With Federal Law Are “Without Effect”
A Federal Law That Conflicts With State Law Will “Preempt” State Law
A State Court Cannot Issue Rulings That Contradict Decisions of a Federal Court
Altria Group vs. Good, 2008; Maryland vs. Louisiana, 1981
Abelman vs. Booth, 1859,**

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,

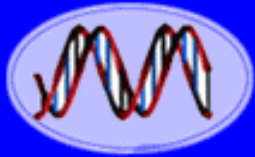
SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.

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



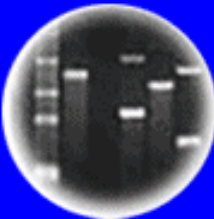
**Vermont GMO Labeling Law
Is Invalid!!**



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DNA Fingerprinting



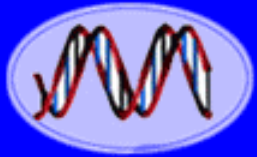
Cloning: Ethical Issues
and Future Consequences



Plants of Tomorrow

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

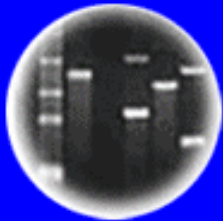




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Plants of Tomorrow

Can Scientific Inquiry and Research Be Regulated?



HitToon.com #1208537

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)?**



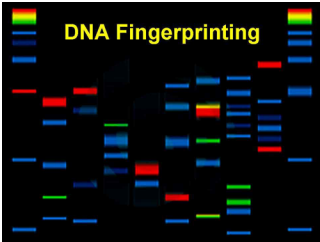
Asilomar Conference
on Recombinant
DNA

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

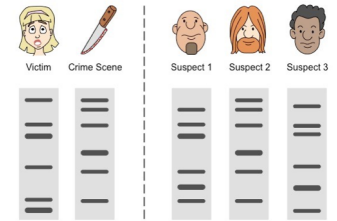
1. When Moving From Reflection, Theory, Hypothesis, and Thought to TESTING AND EXPERIMENTATION - Move From World of Speech (talking, publishing) to WORLD OF ACTION AND CONDUCT.
2. **Can Think But Can't Always Act!** Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That 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!



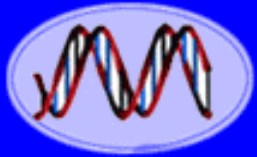
Amendment IV



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”

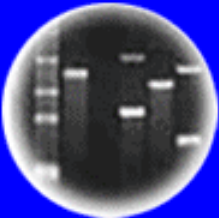
Key Concepts: Right Against Unreasonable Searches to Your Own “Body Parts,” Science Writings, and Experimental Materials



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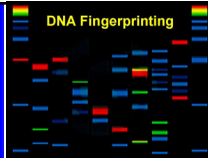
DNA Fingerprinting



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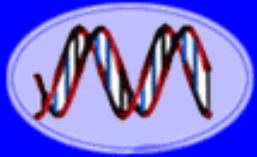
Searches and Seizures Clauses of US and CA Constitutions Are Virtually Identical!

US Constitution - Fourth Amendment

The right of the people to be secure in 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.

California Constitution SEC. 13.

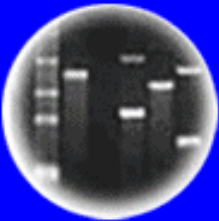
The right of the people to be secure in their persons, houses, papers, and effects against unreasonable seizures and searches may not be violated; and a warrant may not issue except on probable cause, supported by oath or affirmation, particularly describing the place to be searched and the persons and things to be seized.



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Plants of Tomorrow



<https://www.oyez.org/cases/2012/12-207>



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

Question

Does the Fourth Amendment allow states to collect and analyze DNA from people arrested, but not convicted, of serious crimes?

YES. Justice Anthony M. Kennedy delivered the opinion of the 5-4 majority. The Court held that conducting a DNA swab test as a part of the arrest procedure does not violate the Fourth Amendment because the test serves a legitimate state interest and is not so invasive so as to require a warrant.

"For these reasons and others set forth in the opinion published today, the Court concludes that DNA identification of arrestees is a reasonable search that can be considered part of a routine booking procedure."

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.”

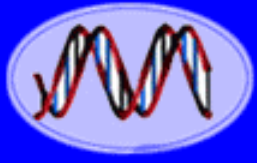
Key Concept: State Promotion of General Welfare=Police Powers

Amendment X

Police Powers to States & Localities

State Funding and Regulation of:

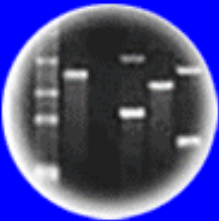
- Science Research & Exploration
- Health (e.g., disease outbreaks)
- Medical Testing Devices/Services (DNA Testing)
- Drugs (as long as not interstate commerce)
- Food Additives
- Releases Into the Environment (GMOs)
- DNA Data Bases, etc.



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Can GloFish Can Be Sold In California?

- Cal. Depart. of Fish and Game Code § 15007 (2007)

Regulation Makes it illegal to spawn, cultivate, or incubate any transgenic fish in the state controlled waters of the Pacific Ocean.

- Cal. Depart. of Fish and Game Code Ruling (2015)
The Dept. of Fish and Game will propose the addition of an exception to Section 1.92 that would allow the sale of transgenic tropical aquarium fish that the Dept. has determined pose no foreseeable risk or harm to native fish or wildlife.

Genetic Engineering & The Law!!



Amendment XIII

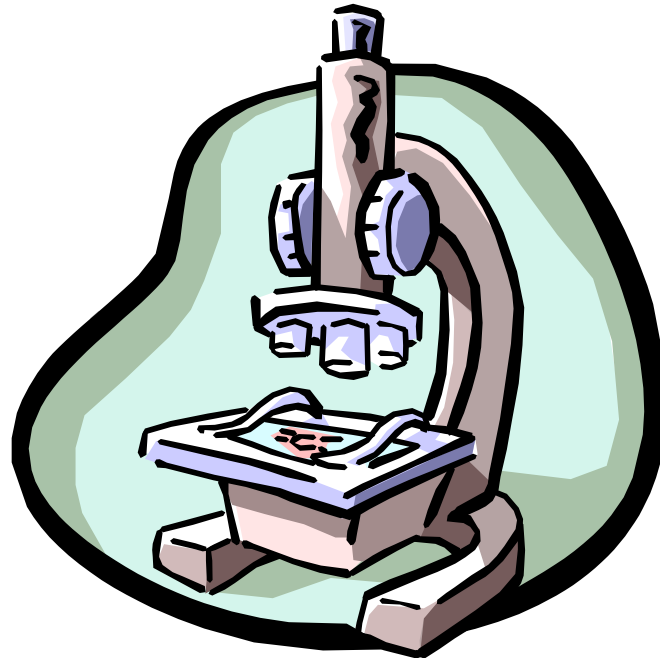
Involuntary Servitude:

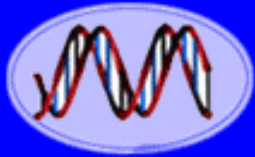
Section 1: “Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist with the United States, or any place subject to their jurisdiction.”

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?

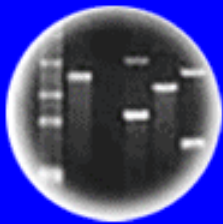




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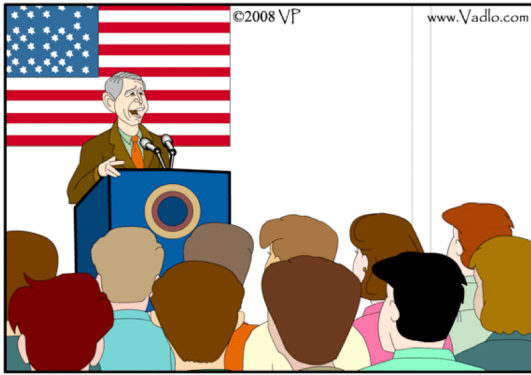


Plants of Tomorrow



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”**



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www.Vadlo.com

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



How Can Genetic Engineering and Science Be Regulated Indirectly?



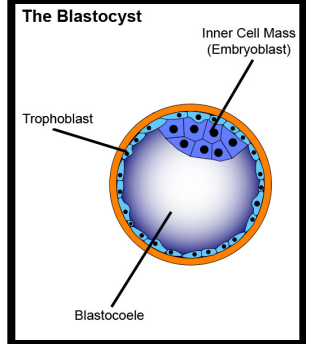
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Randy McIlwaine





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.

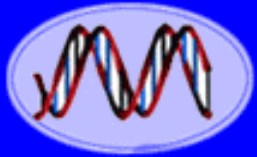
For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific 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)

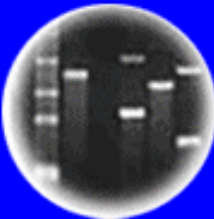




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The Only Federal Laws Dealing With **FUNDING** Genetic Engineering Procedures



PUBLIC LAW 114-113—DEC. 18, 2015

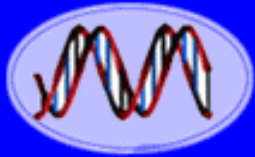
2019 Congressional Budget (Expires 9/30/19)

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

Dickey-Wicker Amendment-1995

Federal Funds Cannot Be Used To:

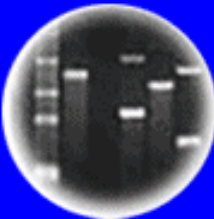
- **Create Human Embryos For Research Purposes**
- **Fund Research in Which a Human Embryo Will Be Destroyed, Discarded, or **Knowingly Subjected to Risk** or Injury of Death**



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Plants of Tomorrow

Regulate Science Through Power of Funding and Research \$



1. No Constitutional Right to Obtain Funding For Research at Federal, State, and Local Levels
 - a. **Federal Embryonic Stem Cell Research Restricted**
 - b. **Must Apply For Grants Which Are Merit-Based and Peer-Reviewed**

2. Must Abide By Conditions of Funding Agencies to Obtain Research \$
 - a. **Recombinant DNA Guidelines**
 - b. **Human Institutional Review Boards (IRBs)**
 - c. **Release of GMOs Into the Environment (EPA)**
 - d. **Destruction of Human Embryos**