



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

# HC70A & PLSS059 Winter 2020 Genetic Engineering in Medicine, Agriculture, and Law

Professors Bob Goldberg &  
Channapatna Prakash

## Lecture 9

### Science & The Constitution: Regulating Science & Genetic Engineering

UCLA

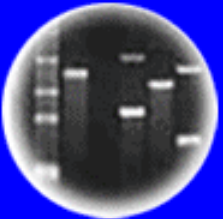
TUSKEGEE  
UNIVERSITY



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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)

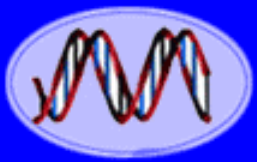
### Biotechnology Agencies, Laws, & Patents



## 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. *Biotechnology and The Law*, By H.B. Wellons et al. (2007)
6. *A Guide to Biotechnology Law & Business*, By Robert A. Bohrer (2007)
7. *The Role of Science in The Law*, By Robin Feldman (2009)
8. *Maryland vs. King, US Supreme Court*, June, (2013)
9. *The History of Patenting Genetic Material*, By Jacob E. Cherkow & Henry T. Greely , *Annu. Rev. Genetics*, 49, 161-182 (2015)
10. *Diagnostics Need Not Apply*, By Rebecca S. Eisenberg, *J. Science & Technology Law*, 21.2 (2015)
11. *Constitutional Law*, By Erwin Chemerinsky (2015)
12. *Patent, Copyright, & Trademark*, By R. Stim (2016)
13. *Imbeciles; The Supreme Court, American Eugenics, & The Sterilization of Carrie Buck*, By Adam Cohen (2016)
14. *A Crack in the Creation*, By Jennifer Doudna and Samuel Sternberg (2017)

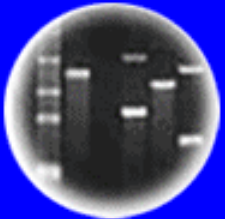




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*"When Ideology 'Infects' Science,  
It Always Leads to a Disaster"*

*Bob Goldberg*

*"I Beseech You in the Bowels of Christ,  
Think It Possible You May Be Mistaken"*

*Oliver Cromwell Quoted by J. Bronowski*



“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.”

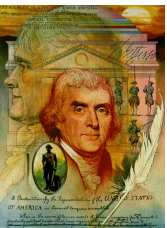
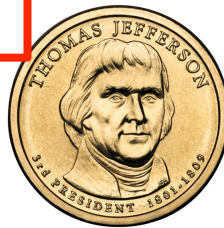
Thomas Jefferson, July 12, 1810

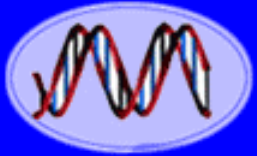
## Was 1820 Science the Same as 2020 Science?

### What Was Known About Biology in 1820?

- 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!!

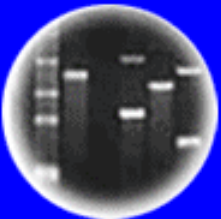




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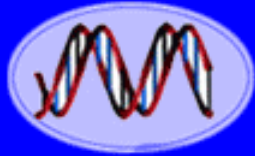


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# What is the The Relationship Between **Genetics** and **The Law** in the United States?

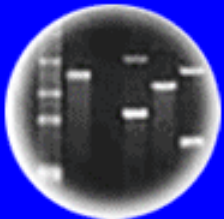




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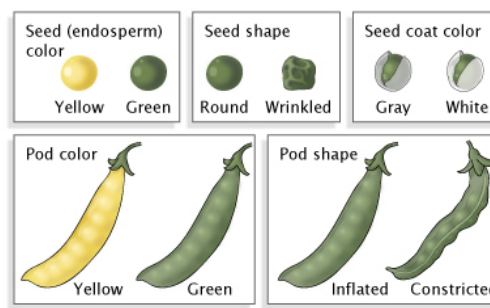
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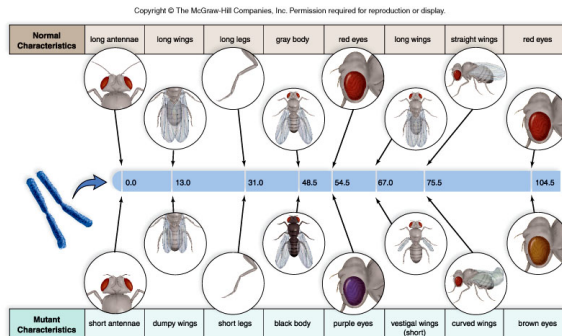
Gregor Mendel



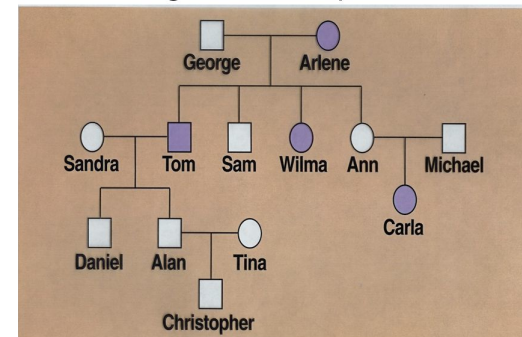
Thomas H. Morgan

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

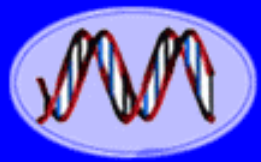
*Discovery of Genetics vs. Sequencing the Human Genome*



Pedigree of Alkaptonuria



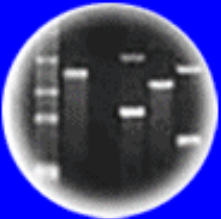




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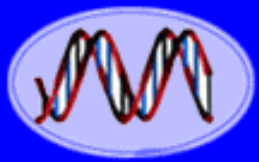
# Mendel's Laws of Genetics Were Rediscovered in 1900!

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]



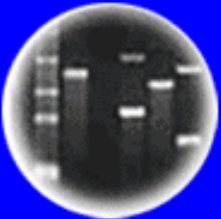
The Word **Gene** Was Invented to Describe the Physical Properties of Inheritance in 1909 by the Botanist **Wilhelm Johannsen**. And **Thomas Hunt Morgan** Showed That **Genes Are On Chromosomes** In 1910! **William Bateson** First Used the Word **Genetics** (From Greek Gennō, Γεννώ; "To Give Birth") to Describe the Study of Inheritance In 1905.



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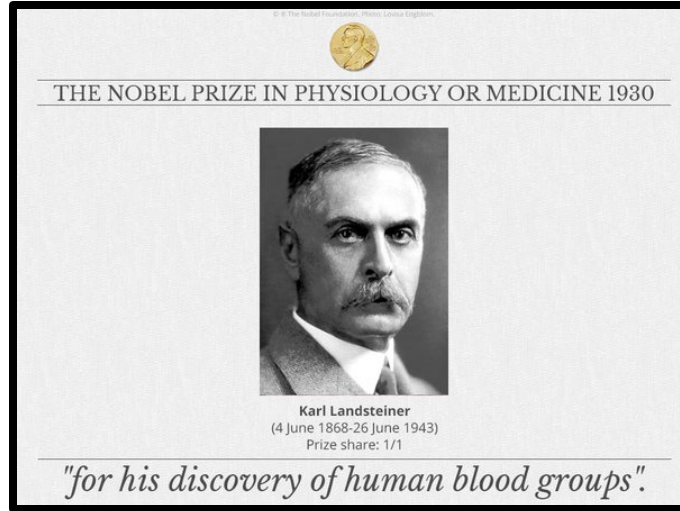
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# Human Genetics Was Born in 1900

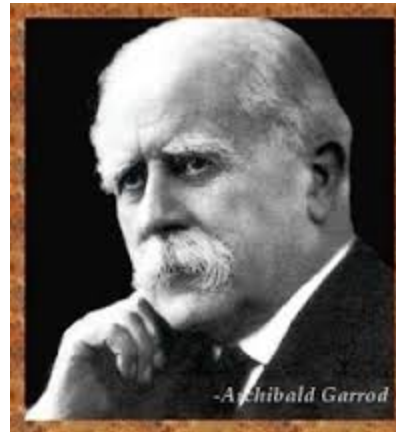
The ABO Blood Types Were the First Human Traits  
Discovered That Followed Mendelian Inheritance (1900)



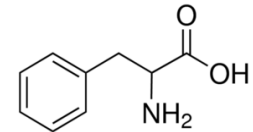
Landsteiner

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



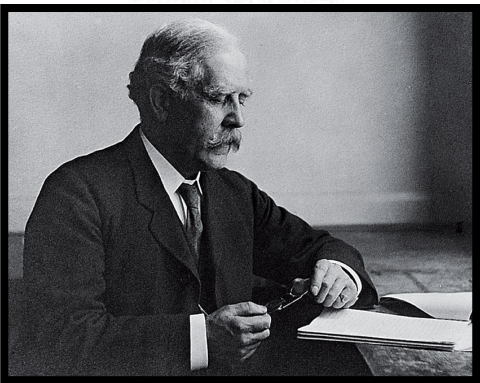
**Garrod Discovered That Human Metabolic Diseases Have a Genetic Basis and Follow Mendelian Rules of Inheritance. He Hypothesized That Genetic Diseases Were Due to a Missing Steps in a Body's Chemical Reactions**

**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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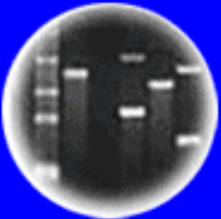
It appears to me that the strongest argument which can be adduced in favour of this view that alkaptonuria is a Mendelian recessive character is afforded by the fact that albinism, which so closely resembles it in its mode of incidence in man, behaves as a recessive character in the experimental breeding of animals.<sup>32</sup> Nor do the figures quoted by Bateson<sup>30</sup> relating to the proportion of albino members in human families show any more close conformity to the requirements of Mendel's law than do those above quoted for alkaptonuric families.



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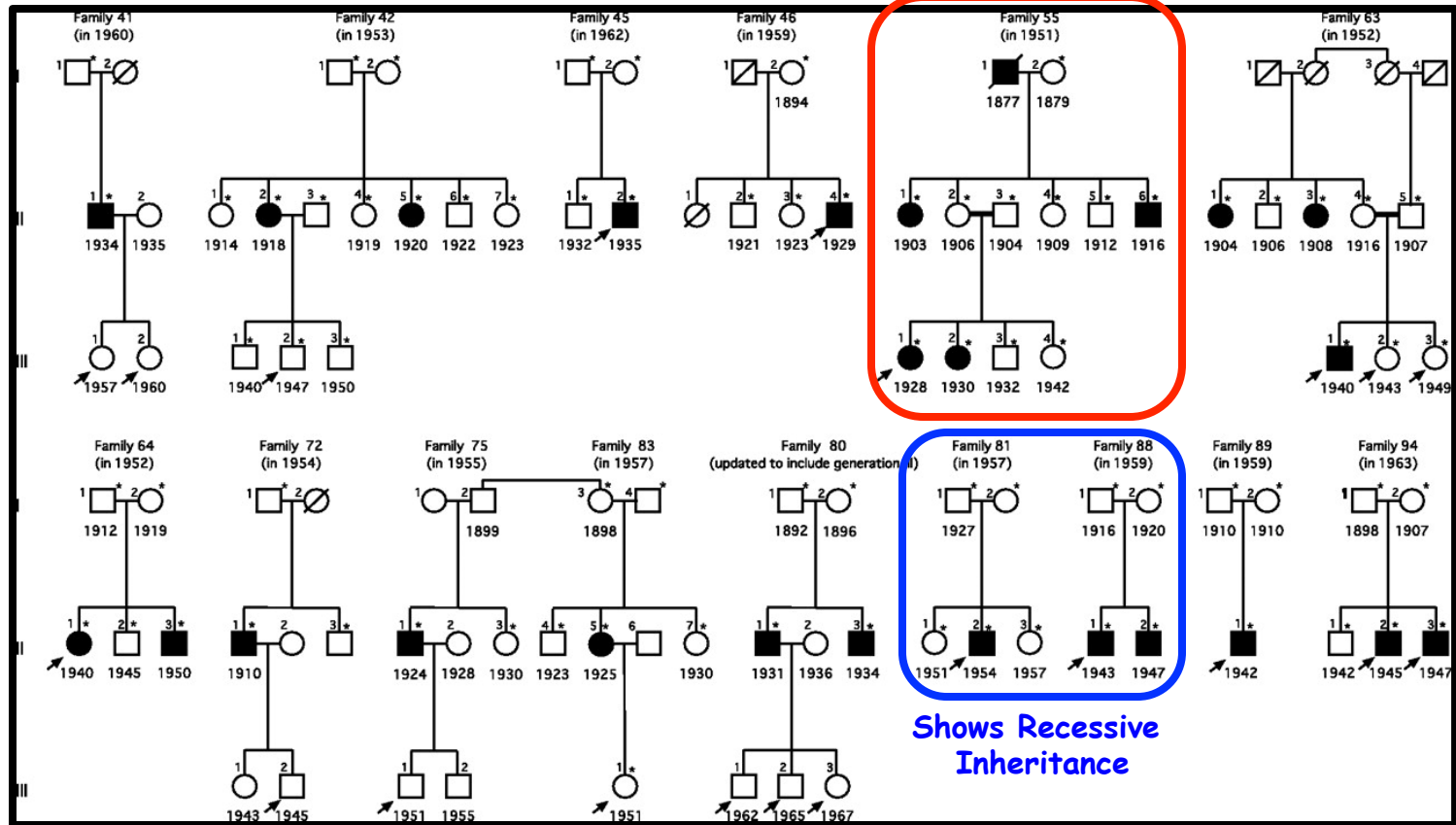


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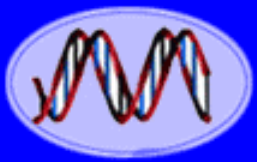


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# Garrod's Discovery of Human Disease Gene Inheritance Using Pedigrees (Alkaponuria, Albinism, Cystinuria, & Pentosuria)



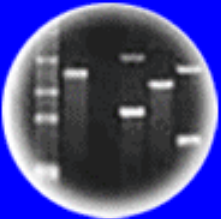
*Garrod's Families Were Studied Until the 1960s!*



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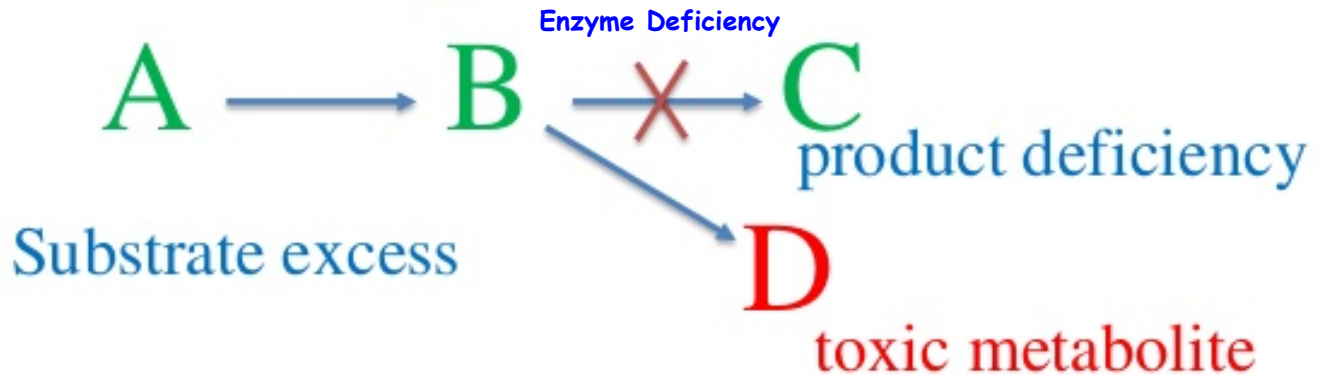
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Garrod Hypothesized That Inherited Defects in Metabolic Pathways Lead To **Toxic Compound Accumulation** That Cause the Disease

## Garrod's hypothesis

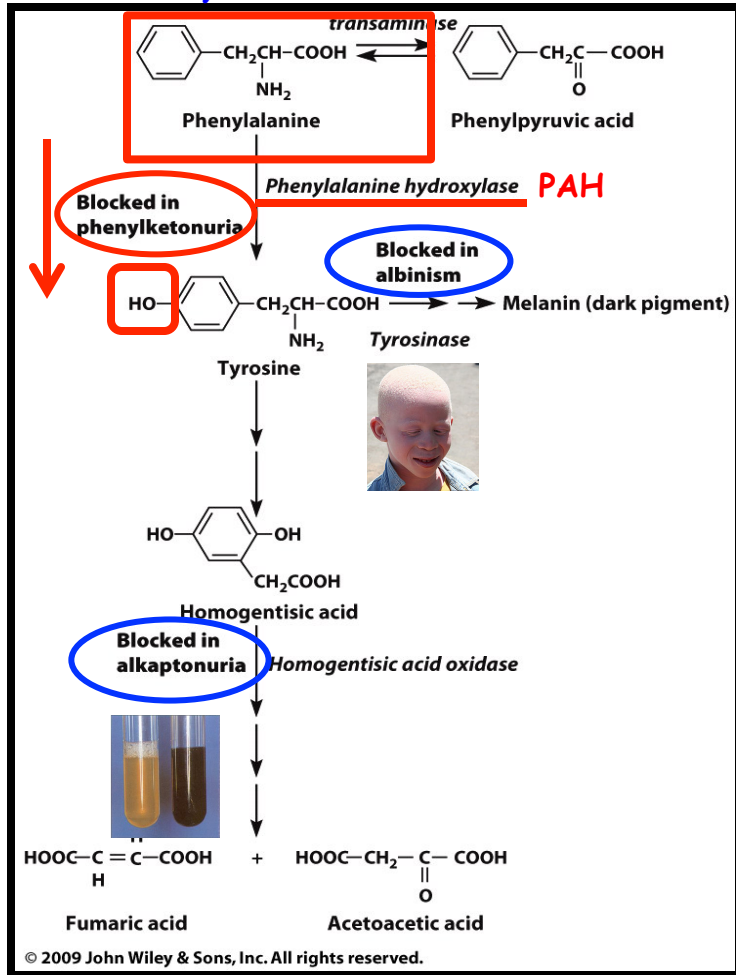


*Garrod Was the First to Propose a Relationship Between Genes and Enzymes and Metabolic Defects*

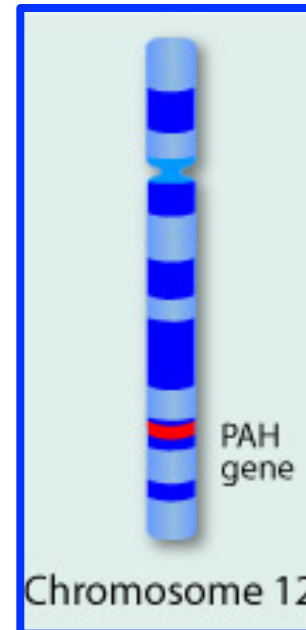
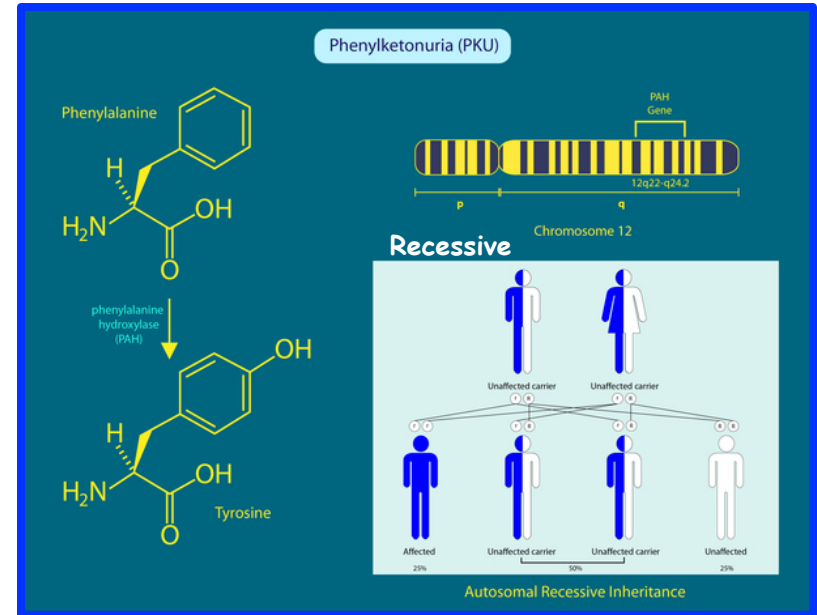
*20 Years Later Griffith Discovered the "Transforming Principle" in Pneumonia Bacteria*

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

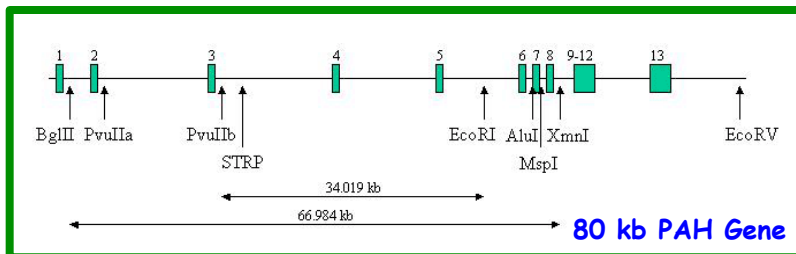
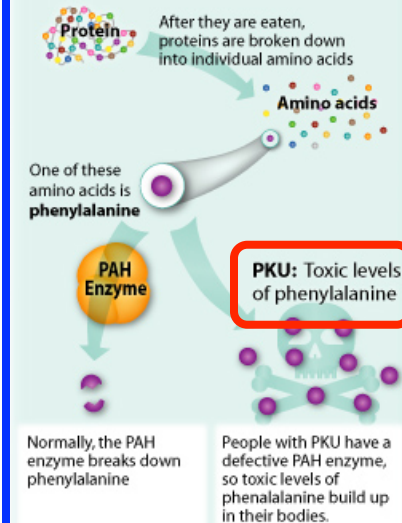
## Phenylalanine Metabolism



## Recessive Gene Inheritance



## People with PKU Have a Defective PAH Enzyme



## 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.

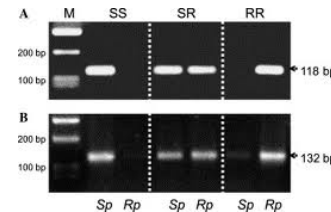
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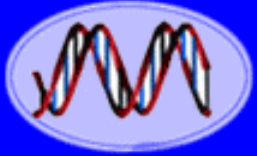
- Meat
- Dairy Products
- Dry Beans
- Nuts
- Eggs

\* 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

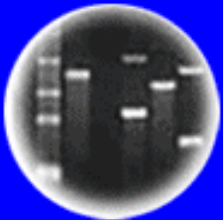




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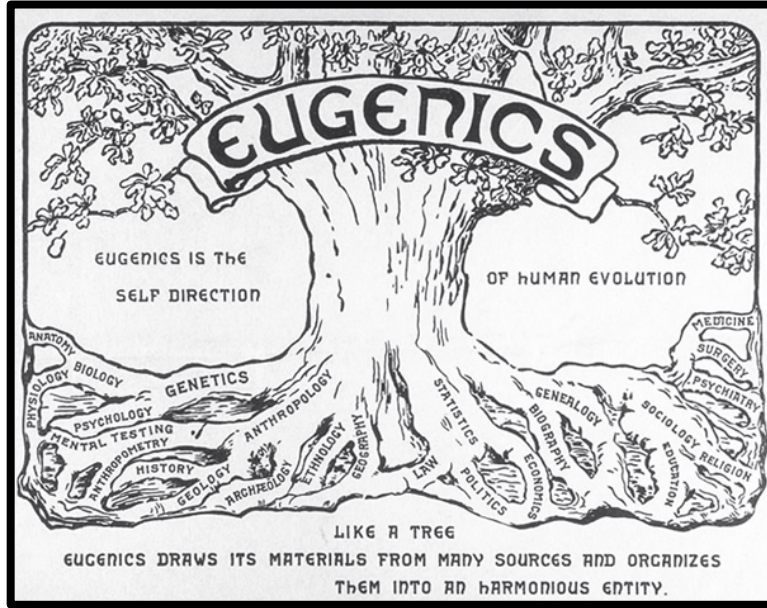


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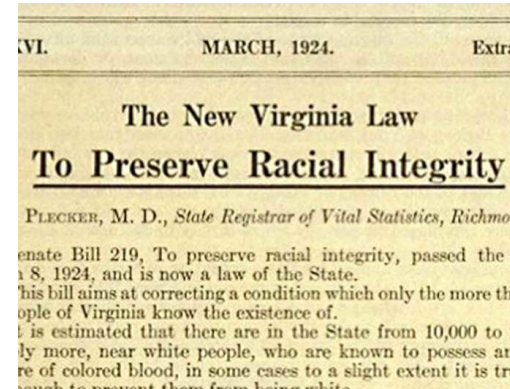
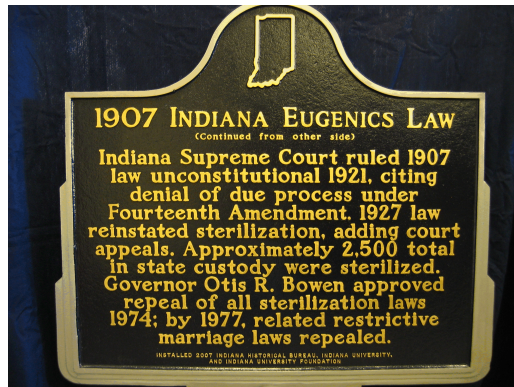
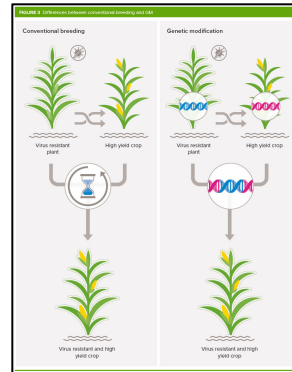


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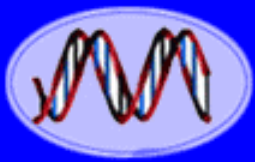
# The Eugenics Movement in Early 20<sup>th</sup> Century Led to the Idea that Genetics Could be Used For the Improvement of Humanity *Of Course - Whose Improvement and What "Traits" Should Be Improved! And Who Should Decide!*



## Selective Breeding



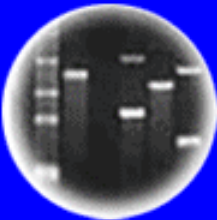




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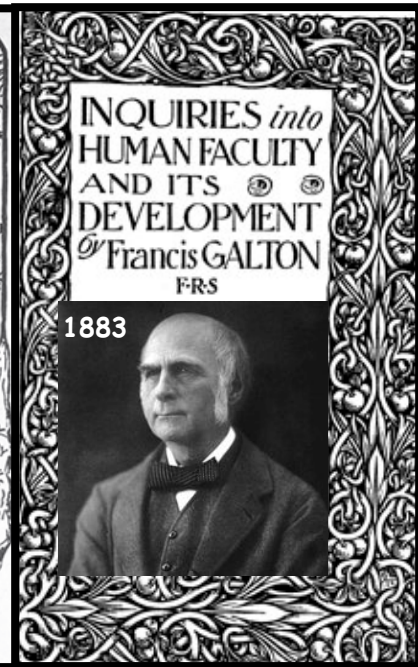
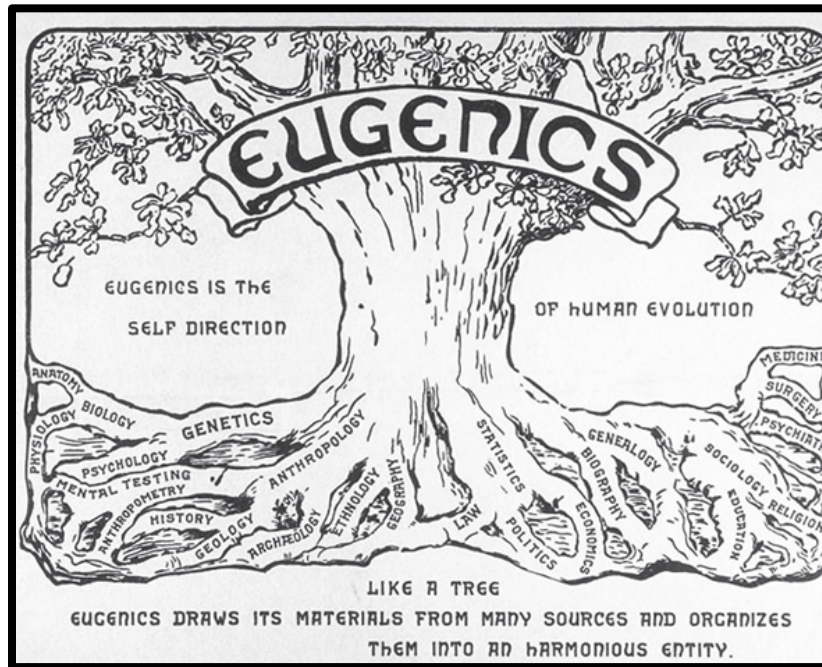
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## Negative Eugenics

Eliminating "Undesirable Traits" From Human Populations

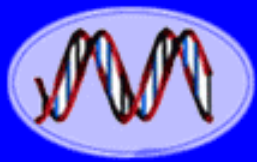
## Positive Eugenics

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!*

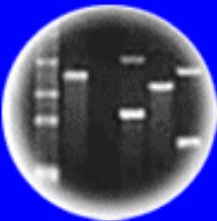
# The Biological Fallacy of Eugenics



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## 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

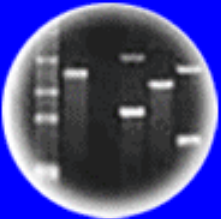
- Most of deleterious PKU alleles are in heterozygotes
- **How will these individuals be identified?**
- How prevent 6,000,000 individuals from passing the PKU allele to their offspring?
- **Each of us carries 50 to 100 variants in known disease genes - should we prevent everyone from reproducing?**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



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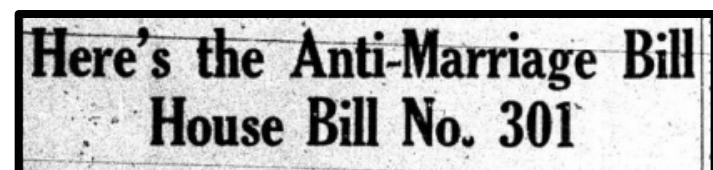
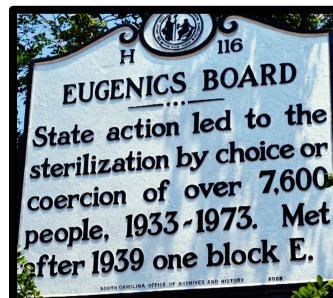
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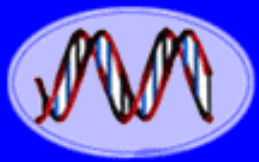


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# Other Consequences of the Eugenics Movement in the US

- Immigration Laws
- Sterilization Laws
- Miscegenation Laws

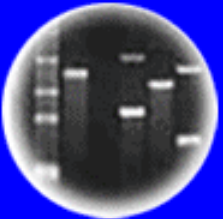




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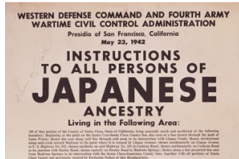
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# Immigration Act of 1924 - Johnson-Reed Act

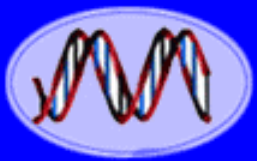
- The Immigration Act of 1924 limited the number of immigrants allowed entry into the United States through a national origins quota.
- The basic purpose of the 1924 Immigration Act was to preserve the ideal of U.S. homogeneity.
- The Act of 1924 established that even Asians not previously prevented 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 (Italians, Poles, Hungarians, Jews, etc.).



Korematsu vs. United States, 1944



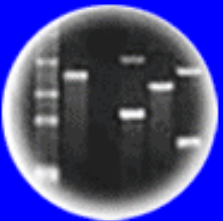




DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



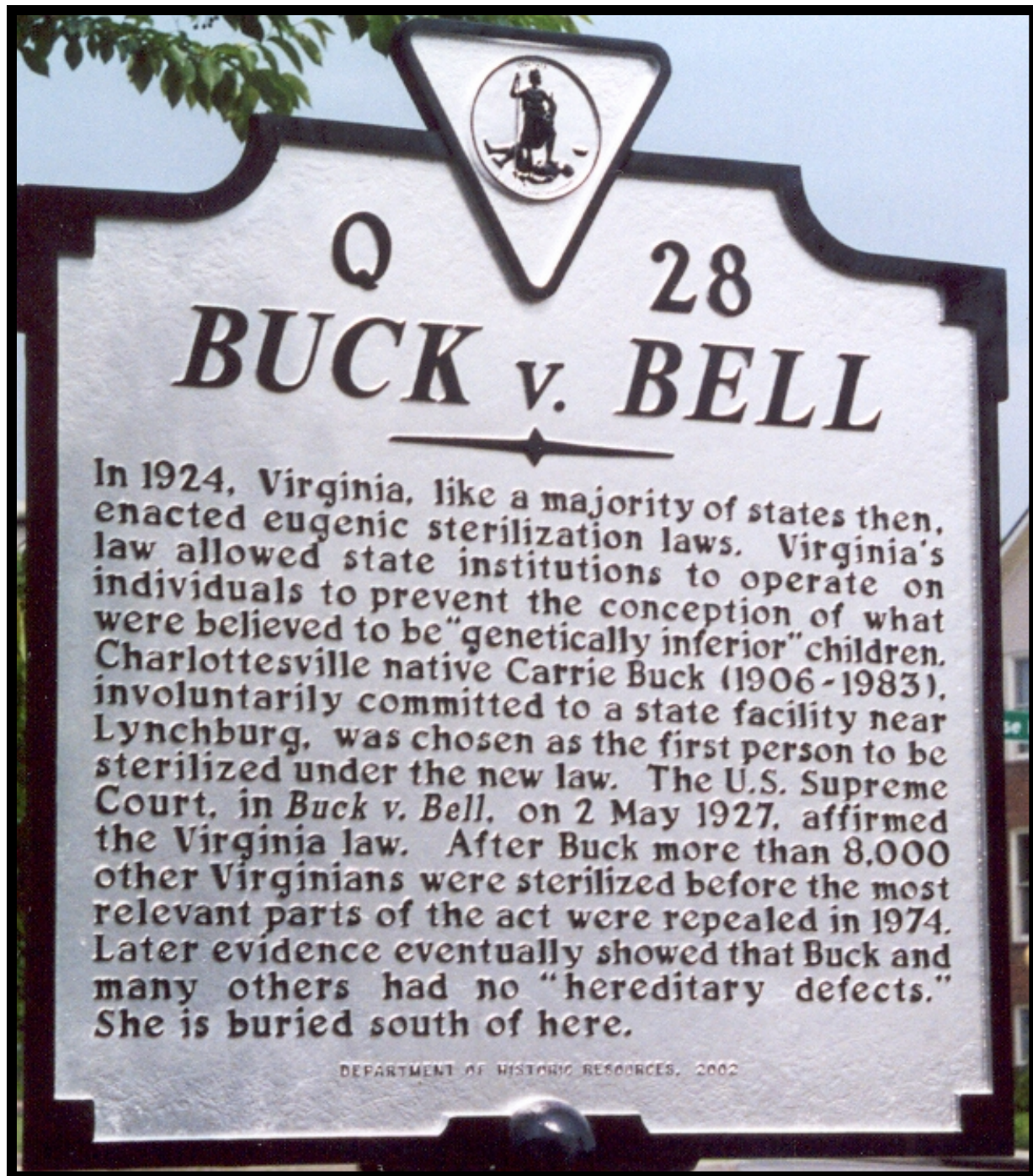
DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

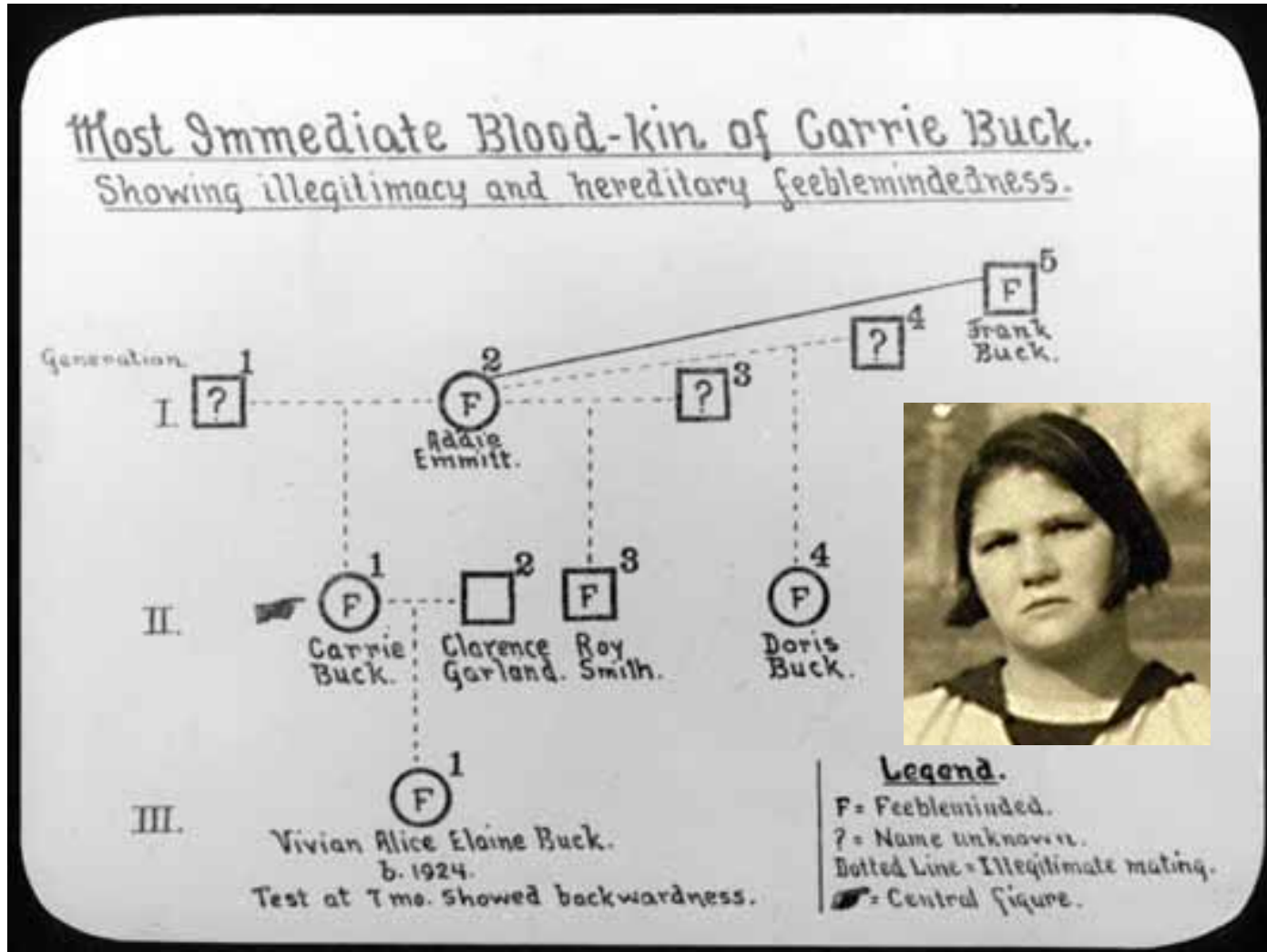


Q 28  
**BUCK v. BELL**

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

DEPARTMENT OF HISTORIC RESOURCES, 2002

# 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.**”

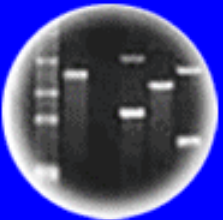




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# Im·be·ciles (I)

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

Adam Cohen

2016

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

## Reichsgesetzblatt

Teil I

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

Inhalt: Gesetz zur Verhütung erbkranken Nachwuchses. Vom 14. Juli 1933.....	§. 529
Höfste Verordnung zur Durchführung der Verordnung über die Deutschenemittelfabrikation. Vom 20. Juli 1933.....	§. 531
Verordnung über die Errichtung einer vorläufigen Billtkammer. Vom 22. Juli 1933.....	§. 531
Verordnung über Zolländerungen und Ausführungsine. 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

**Gesetz 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 Erfahrungen 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 Fallsucht,
5. erblichem Weikranz (Suntingtonische 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 Weisheitschwäche 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 Strafanzstalt 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 entfallen hat. Hat ein beamteter Arzt den Antrag gestellt, so kann er bei der Entscheidung nicht mitwirken.

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.

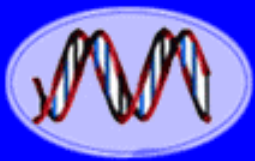
(2) For the purposes of this law, any person will be considered as hereditarily diseased who is suffering from any one of the following diseases: -

- (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.*

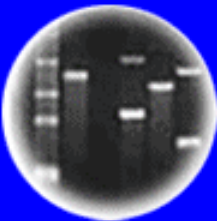
# Miscegenation Laws



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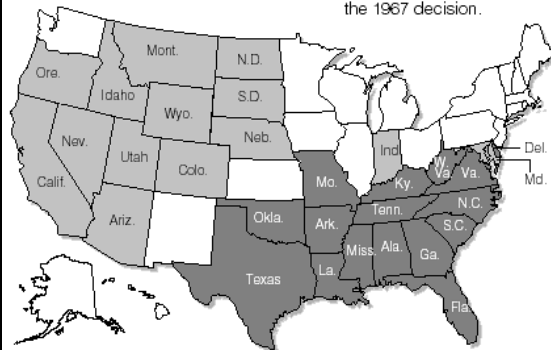


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## Banning Interracial Marriage

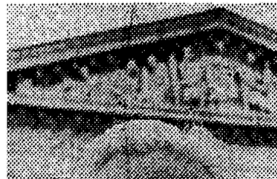
In 1967, the United States Supreme Court struck down laws in 16 states prohibiting interracial marriages. Fifteen years earlier, 14 other states had also banned interracial marriage but repealed their laws before the 1967 decision.

States with interracial marriage prohibition laws that were struck down in 1967. States that had interracial marriage prohibitions in 1952 but repealed their laws before the 1967 decision.

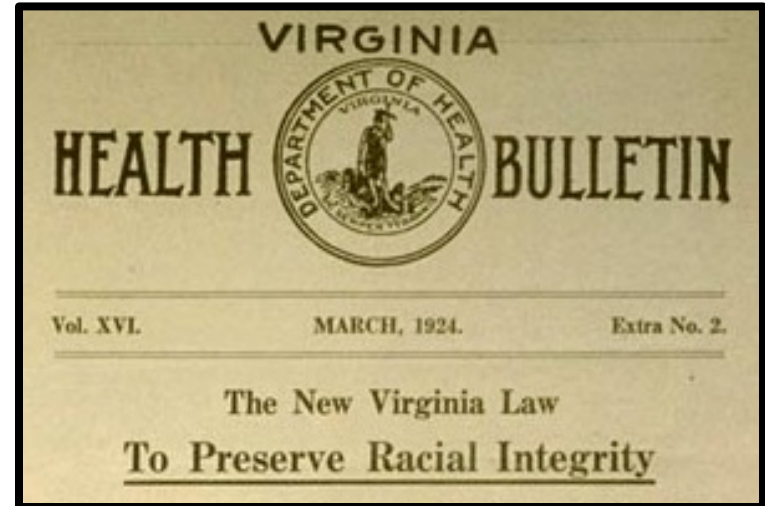


## Justices Upset All Bans On Interracial Marriage

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)

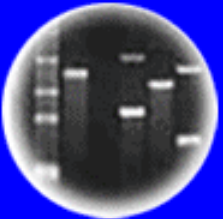
- Law Denied Equal Protection
- Law Deprived Constitutionally Protected Liberty Without Due Process - *"the freedom to marry has long been recognized as one of the vital personal rights essential to the orderly pursuit of happiness by free men. Marriage is one of the basic civil rights on man, fundamental 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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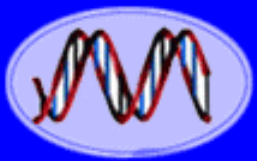
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# Teaching Evolution & The Law



**Biology Into the Courtroom**

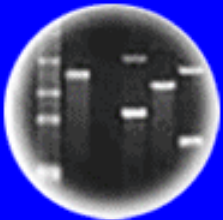
# The Scopes "Monkey" Trial



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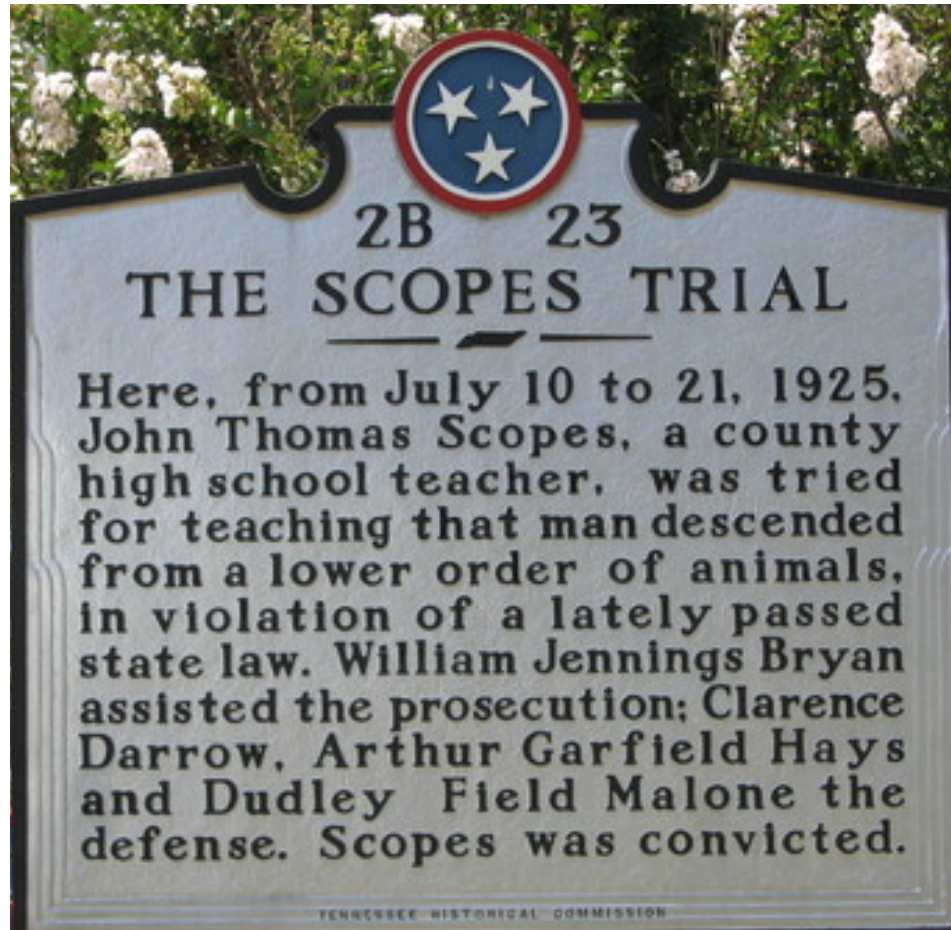
DNA Fingerprinting



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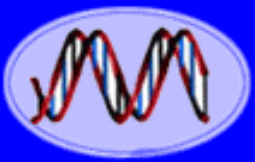


21 March 1925

Butler Act prohibiting teaching of  
human evolution enacted.



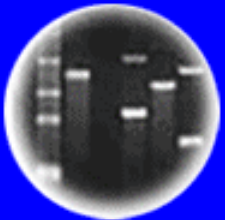
# Teaching Evolution Court Battles



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Arkansas Prohibited Teaching of Human  
Evolution in Schools -1928

Was Declared Unconstitutional in 1968

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 (1<sup>st</sup> Amendment)**



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

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

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

## Ten Major Court Cases about Evolution and Creationism

Creationism + Evolution Laws  
Intelligent Design + Evolution Laws  
Unconstitutional

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)





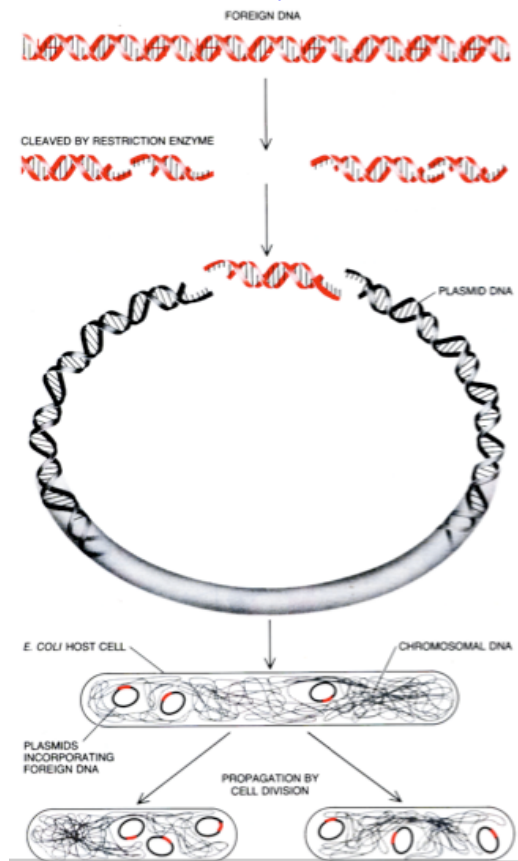
# The Recombinant-DNA Debate

*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*

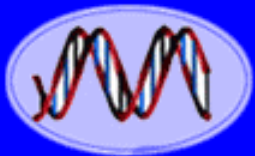
by Clifford Grobstein

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

## Cohen-Boyer-1973



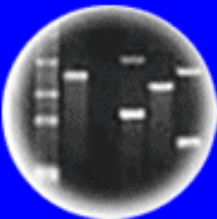
		BIOLOGICAL CONTAINMENT (FOR E. COLI HOST SYSTEMS ONLY)		
		EK1	EK2	EK3
PHYSICAL CONTAINMENT	P1	DNA from nonpathogenic prokaryotes that naturally exchange genes with <i>E. coli</i>  Plasmid or bacteriophage DNA from host cells that naturally exchange genes with <i>E. coli</i> . (If plasmid or bacteriophage 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)	



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Cloning: Ethical Issues  
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In 1977, Cambridge became the first city in the world to regulate the manipulation of genetic material. The Cambridge Recombinant DNA Technology Ordinance establishes strict oversight of university and commercial laboratories that engage in recombinant DNA research. The requirements set forth in the city ordinance are based on the widely employed National Institutes of Health (NIH) Guidelines for Research Involving DNA Molecules. TO DATE THERE IS NO NATIONAL LAW.

Enforcement of the city's Recombinant DNA Technology Ordinance is carried out by the Cambridge Biosafety Committee. The committee is comprised of Cambridge residents with no ties to the industry and it is staffed by the Cambridge Public Health Department. The committee strives to quickly guide Cambridge laboratories through the regulatory process.

2/8/77

# Cambridge Council Allows Harvard DNA Research

CAMBRIDGE, Mass., Feb. 7 (UPI)—The

*Allows Research Following NIH Guidelines*

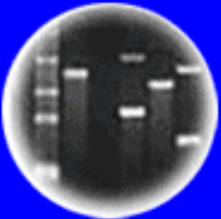




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# The Only Federal Law Dealing With a Genetic Engineering Procedure



## Germline Gene Therapy

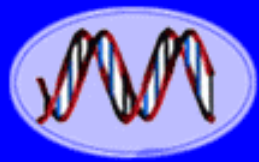
2019-2020 Congressional Budget (Expires 9/30/20)

- 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:

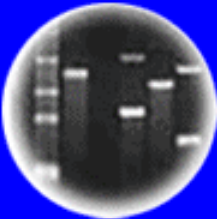
- Create Human Embryos For Research Purposes
- Fund Research in Which a Human Embryo Will Be Destroyed, Discarded, or Knowingly Subjected to Risk or Injury of Death



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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,*

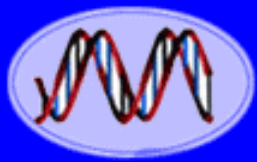
## **SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.**

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**

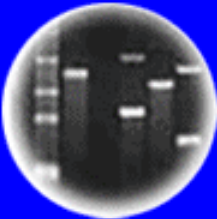




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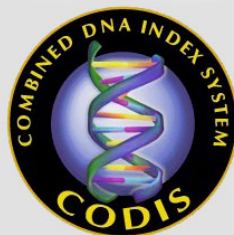
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# DNA Identification Act of 1994

## 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*

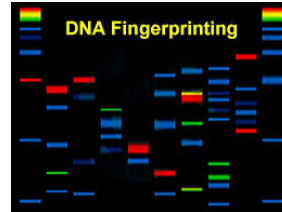
### Subtitle C—DNA Identification

- 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.

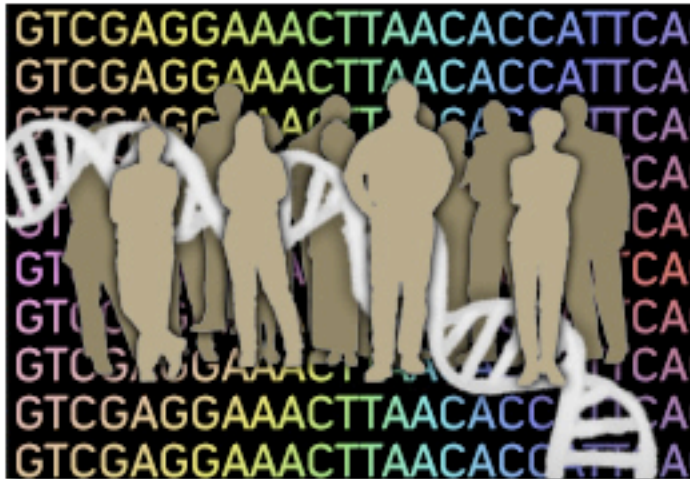
### A BILL

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

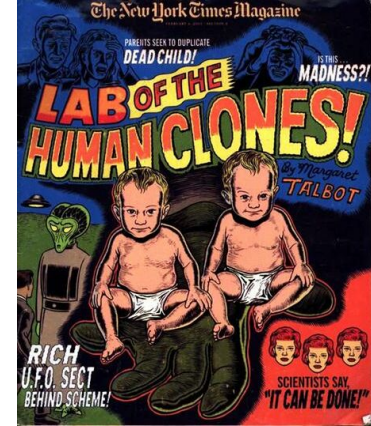
#### What is GINA?

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

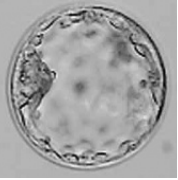
6 “(a) IN GENERAL.—It shall be unlawful for any per-  
7 son or entity, public or private, in or affecting interstate  
8 commerce—

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 (2012) Upheld by Supreme Court in 2013 by Refusal to Review. *Sherley vs. Sebelius*

Bush vetoes embryonic stem-cell bill

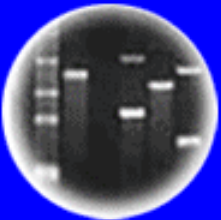
Supreme Court rejects challenge to Obama stem cell policy



DNA  
Genetic Code of Life



Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



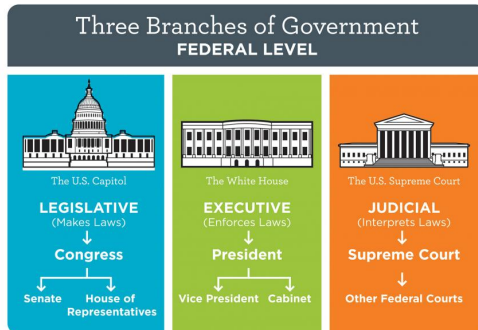
Cloning: Ethical Issues  
and Future Consequences

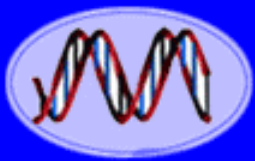


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# Genetic Engineering is Regulated but Primarily by Federal Agencies and Not By Direct Some Examples

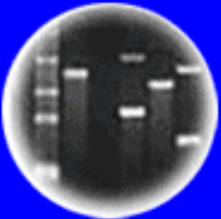




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# Office of Science and Technology Policy

## 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

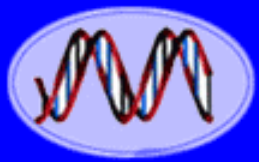
Updated in 2017

### 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.

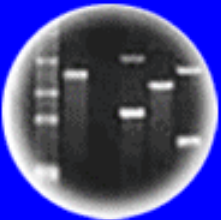
ACTION: Notice of request for information.



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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

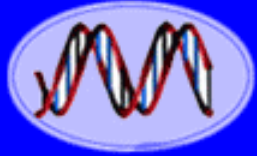
Regulatory Oversight of Biotechnology Products Agency	Product Regulated
U.S. Department of Agriculture	Plants, plant pests (including microorganisms), animal vaccines
Environmental Protection Agency	Microbial/plant pesticides, other toxic substances, microorganisms, animals producing toxic substances
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**

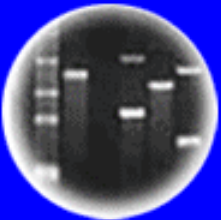
# What About Human Somatic Cell Gene Therapy & Editing?



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National Institutes of Health  
*Turning Discovery Into Health*



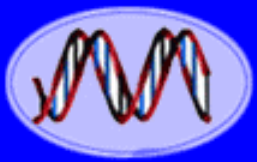
**Biomedical Technology Assessment**

**Oversight of Human Gene Transfer Research**

**Biomedical Technology Assessment**

**Recombinant DNA Advisory Committee**

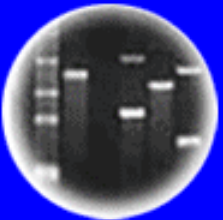




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NCSL

NATIONAL CONFERENCE of STATE LEGISLATURES

*Strengthening States for 40 Years*

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

STATE LAWS

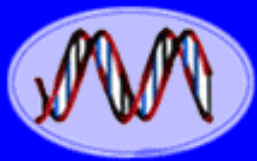




## California Genetic Laws

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

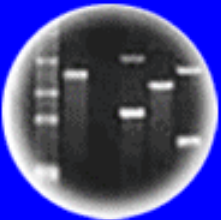




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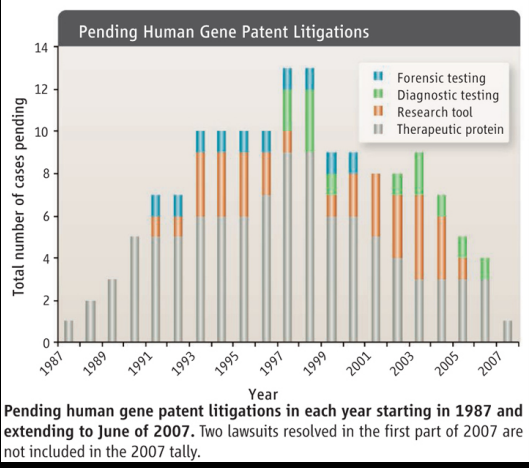
DNA Fingerprinting



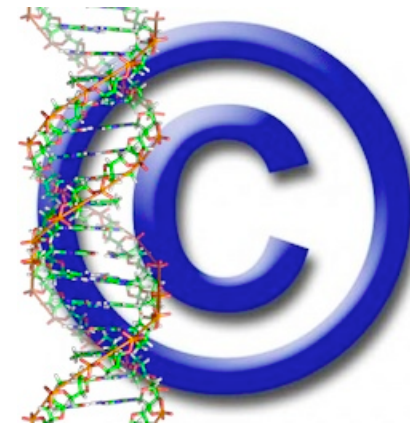
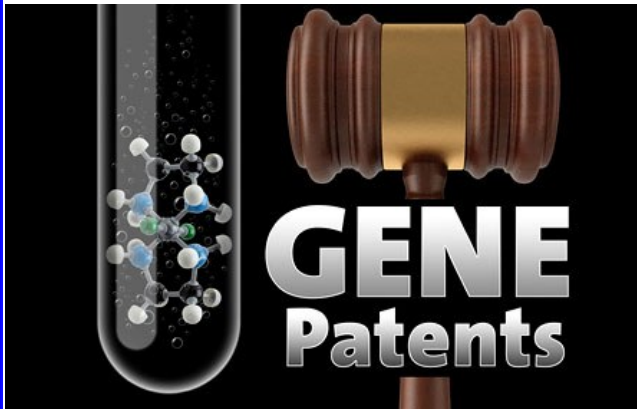
Cloning: Ethical Issues  
and Future Consequences



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



# Life **Is** Patentable

(Diamond vs. Chakrabarty)

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

**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

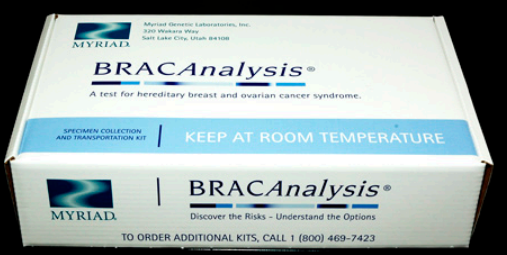


Ananda Chakrabarty



**1988**

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



# *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.



**Rights to Human Gene Patents Go on Trial**

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

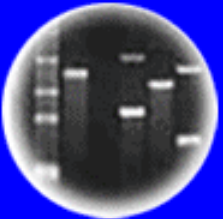
**MYRIAD**  
GENE PATENT LITIGATION



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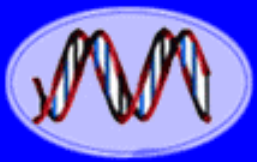
# What Enables the Government To Enact Laws Regarding Genetic Engineering and Science?

- **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**

# How Does the Constitution Affect Science Directly or Indirectly?

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

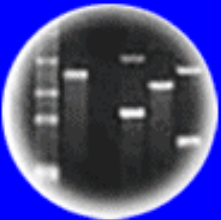




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What Does the Constitution  
Say Directly About Science?

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)?



# 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 8.18

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 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 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,*

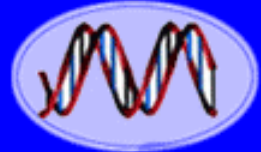
**SECTION 1. NATIONAL BIOENGINEERED FOOD DISCLOSURE STANDARD.**

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**



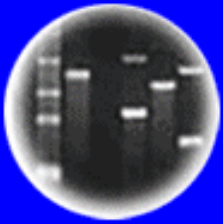
**Vermont GMO Labeling Law  
Is Invalid!!**



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DNA Fingerprinting



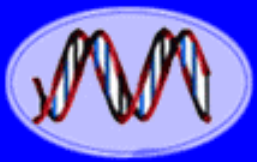
Cloning: Ethical Issues  
and Future Consequences



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

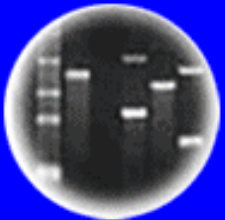




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# Can Scientific Inquiry and Research Be Regulated?





# Amendment I



## Freedom of Speech and Expression:

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

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

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

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

**CAN EXPERIMENTATION BE REGULATED (e.g.,  
Recombinant DNA)?**



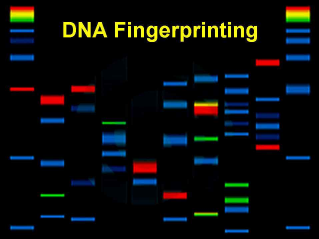
Asilomar Conference  
on Recombinant  
DNA

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

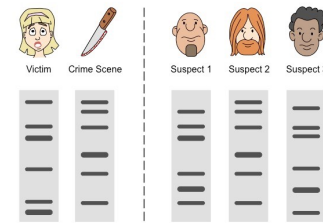
1. When Moving From Reflection, Theory, Hypothesis, and Thought to TESTING AND EXPERIMENTATION - Move From World of Speech (talking, publishing) to WORLD OF ACTION AND CONDUCT.
2. **Can Think But Can't Always Act!** Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That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





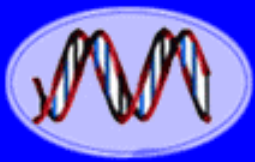
# Amendment IV



## 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”

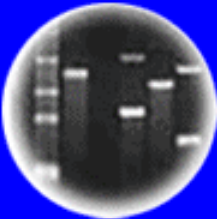
Key Concepts: Right Against Unreasonable Searches to Your Own “Body Parts,” Science Writings, and Experimental Materials



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<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 - *Roe vs. Wade* (1973)
- Genetic testing: PGD, amniocentesis, chorionic villi, etc.
- In Vitro Fertilization
- Stem Cells
- Cloning (therapeutic, reproductive?)
- Birth Control *Griswold vs. Connecticut* (1967); *Carey vs. Population Services* (1977)
- Medical Treatment (end of life) CA End of Life Option Act (2016)
- 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:

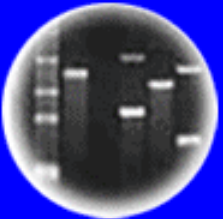
- Science Research & Exploration
- Health (e.g., disease outbreaks)
- Medical Testing Devices/Services (DNA Testing)
- Drugs (as long as not interstate commerce)
- Food Additives
- Releases Into the Environment (GMOs)
- DNA Data Bases, etc.



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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

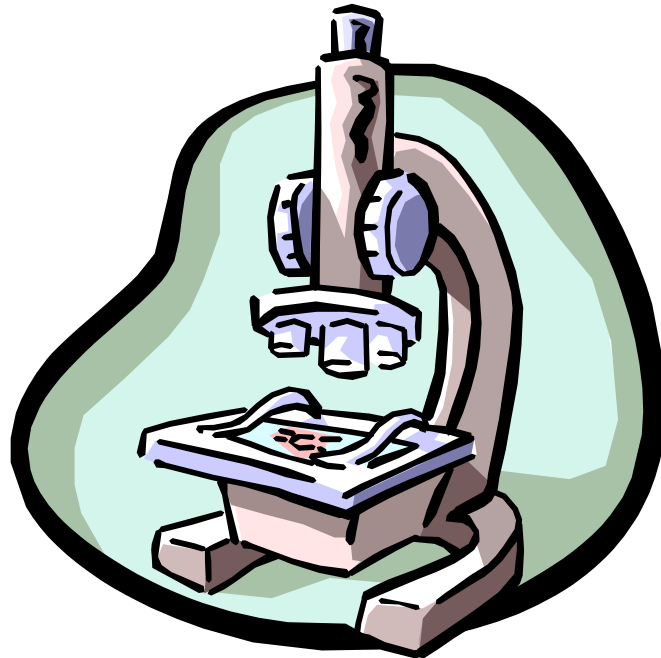
## Involuntary Servitude:

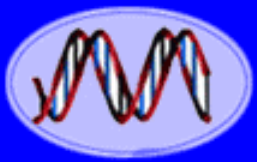
Section 1: “Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist with the United States, or any place subject to their jurisdiction.”

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?

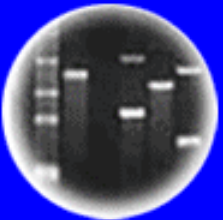




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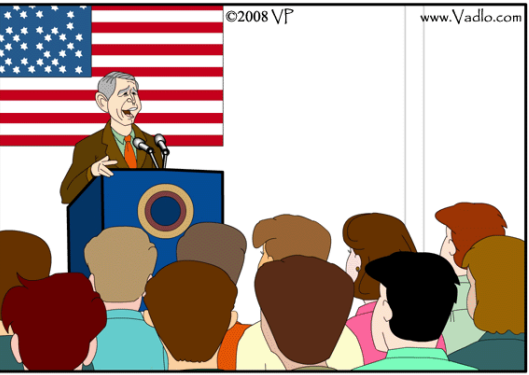


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# Police Powers of Federal, State, and Local Governments-To Promote the General Welfare-Can Regulate Experimentation.

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



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

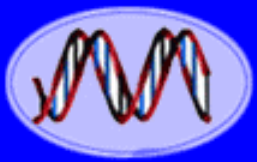


# How Can Genetic Engineering and Science Be Regulated Indirectly?



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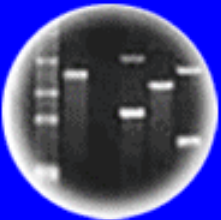




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# Regulate Science Through Power of Funding and Research \$



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**

