






DNA  
Genetic Code of Life




Entire Genetic Code  
of a Bacteria



DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



Plants of Tomorrow

**HC70A**  
**Spring 2021**  
**Genetic Engineering in Medicine,  
Agriculture, and Law**

**Professor Bob Goldberg**  
**Lecture 9**

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

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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

2



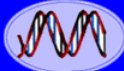
## TEXT READING

Chapter 12 (Biotechnology Regulations) &  
Chapter 13 (Ethics & Biotechnology)

Biotechnology Agencies, Laws, & Patents



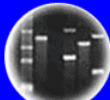
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*"When Ideology 'Infects' Science,  
It Always Leads to a Disaster"*

*Bob Goldberg*

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

*Oliver Cromwell Quoted by J. Bronowski*



4

**“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.*”**

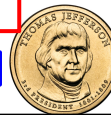
Thomas Jefferson, July 12, 1810

### Was 1821 Science the Same as 2021 Science?

#### What Was Known About Biology in 1821?

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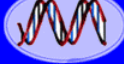
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## What is the The Relationship Between **Genetics** and **The Law** in the United States?



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Gregor Mendel

Seed (endosperm) color Yellow Green	Seed shape Round Wrinkled	Seed coat color Gray White
Pod color Yellow Green	Pod shape Inflated Constricted	



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*

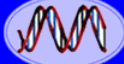


Copyright © The McGraw-Hill Companies, Inc. Chromosomes: organization of genes


Pedigree of Alkaptonuria



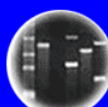
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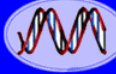
## Mendel's Laws of Genetics Were Rediscovered in 1900!

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.

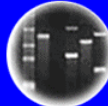
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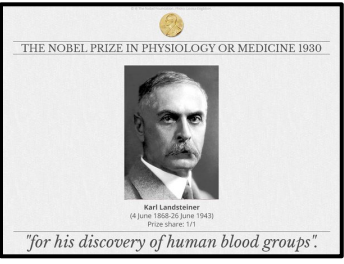
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## Human Genetics Was Born in 1900

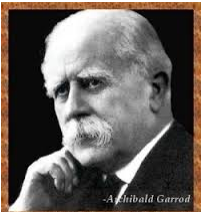
The ABO Blood Types Were the First Human Traits  
Discovered That Followed Mendelian Inheritance (1900)



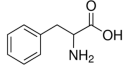
Landsteiner

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



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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 in, 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.

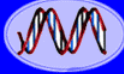
1909

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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\* 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.

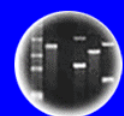
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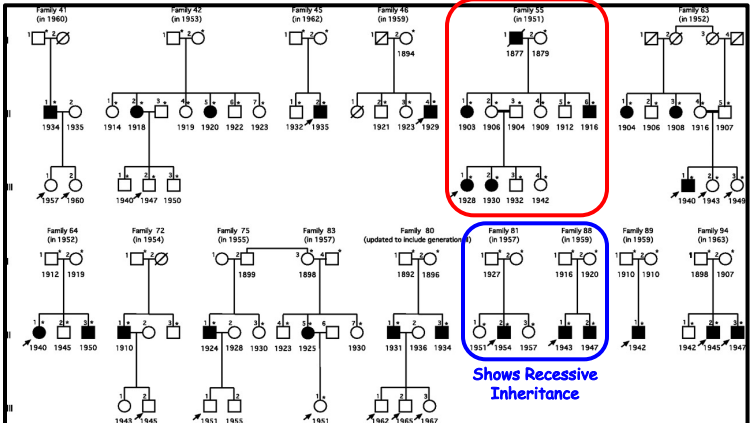
Cloning: Ethical Issues and Future Consequences



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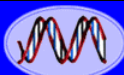
## Garrod's Discovery of Human Disease Gene Inheritance Using Pedigrees

(Alkaptonuria, Albinism, Cystinuria, & Pentosuria)




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

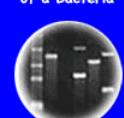
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## Garrod Hypothesized That Inherited Defects in Metabolic Pathways Lead To Toxic Compound Accumulation That Cause the Disease

**Garrod's hypothesis**

$$A \xrightarrow{\text{Enzyme Deficiency}} B \xrightarrow{\times} C$$
product deficiency

Substrate excess
D
toxic metabolite

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

### Phenylalanine Metabolism

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### Recessive Gene Inheritance

Phenylketonuria (PKU)

Chromosome 12

Recessive

Autosomal Recessive Inheritance

80 kb PAH Gene

### People with PKU Have a Defective PAH Enzyme

PKU: Toxic level of phenylalanine

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

### SYMPTOMS

- Phenylalanine plays a role in the body's production of melanin, the pigment responsible for skin and hair color. Therefore, infants with the condition often have lighter skin, hair, and eyes than brothers or sisters without the disease.
- Delayed mental and social skills
- Head size significantly below normal
- Hyperactivity
- Jerking movements of the arms or legs
- Intellectual disability

**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...**

Formula Fed  
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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## 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!*



**EUGENICS**  
EUGENICS IS THE SELF DIRECTION OF HUMAN EVOLUTION  
LIKE A TREE  
EUGENICS DRAWS ITS MATERIALS FROM MANY SOURCES AND ORGANIZES THEM INTO AN HARMONIOUS ENTITY.



ONLY HEALTHY SEED MUST BE SOWN!  
CHECK THE SEEDS OF HEREDITARY DISEASE AND UNFITNESS BY EUGENICS



**1907 INDIANA EUGENICS LAW**  
Indiana Supreme Court ruled 1907 law unconstitutional 1921, citing denial of the process under Fourteenth Amendment. 1927 law reinstated sterilization, adding court appeals. Approximately 2,500 total in state custody were sterilized. Governor Ohio W. Bowen approved repeal of all sterilization laws, 1974; by 1977, related restrictive marriage laws repealed.

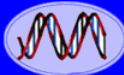
**Selective Breeding**






**The New Virginia Law To Preserve Racial Integrity**  
PLECKER, M. D., State Registrar of Vital Statistics, Richmond  
enate Bill 219, To preserve racial integrity, passed the 18, 1924, and is now a law of the State. This bill aims at correcting a condition which only the more thoughtful of Virginia know the existence of. It is estimated that there are in the State from 10,000 to 15,000 more, near white people, who are known to possess an admixture of colored blood, in some cases to a slight extent it is true.

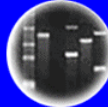
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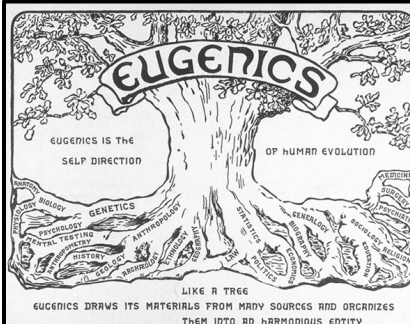
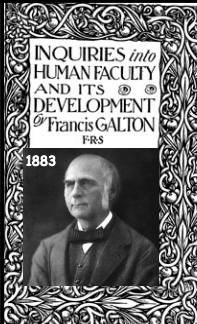
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**Negative Eugenics**

Eliminating "Undesirable Traits" From Human Populations

**Positive Eugenics**

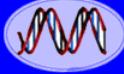
Enhancement or Increasing "Desired" Human Traits

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!

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## The Biological Fallacy of Eugenics

### 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 = 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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## Consequences of the Eugenics Movement in the US

- **Immigration Laws**
- **Sterilization Laws**
- **Miscegenation Laws**

SHALL WE HAVE

# CHINESE

NO! NO! NO!

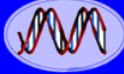
EUGENICS BOARD

State action led to the sterilization by choice or coercion of over 7600 people, 1933-1973. Met after 1939 one block E.

Here's the Anti-Marriage Bill

## House Bill No. 301

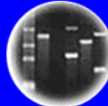
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## Immigration Act of 1924 - Johnson-Reed Act

- 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



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## Eugenics Influence on 1920s Immigration Acts

The reason for their concern? Emerging ideas about race science and genetics that were driving the development of the field of "eugenics." Newly arriving immigrants from Southern and Eastern Europe were considered suspect because of questions of ethnicity and race. On the Senate floor in 1896, Sen. Henry Cabot Lodge (R-Mass.) spoke out against "a great and perilous change in the very fabric of our race."

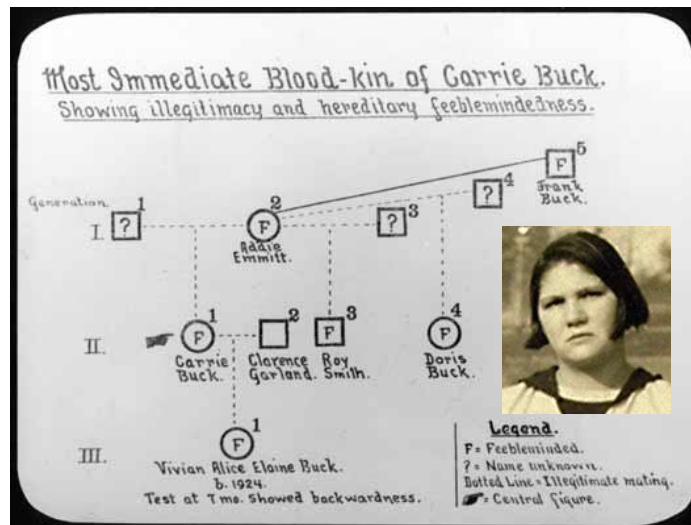
Scholars developed pseudoscientific theories of a racial hierarchy with the "Nordic race" at the top, high above Southern and Eastern Europeans, and followed by non-White people from the rest of the world. In his 1916 book "The Passing of the Great Race," Madison Grant compared the Nordic race, whom he referred to as "the white man, par excellence," to an endangered species that needed to be preserved. For Grant, the only way to do that was to create a protected area through immigration restrictions.

In the aftermath of World War I, people displaced by the widespread destruction in Europe set their sights on migrating to the United States to rebuild their lives. As Congress debated increasing immigration restrictions in April 1921, Secretary of State Charles Evans Hughes submitted a report from U.S. diplomats in Europe on who was planning to migrate. The report warned of "Jews of an undesirable type" and "Armenians, Jews, Persians, and Russians" who "cannot be regarded as desirable populations for any country." It concluded that "our restriction on immigration should be so rigid that it would be impossible for most of those people to enter the United States."

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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

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# BUCK v. BELL

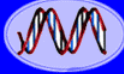
The ruling was written by Justice Oliver Wendell Holmes. In support of his argument that the interest of the states in a "pure" gene pool outweighed the interest of individuals in their bodily integrity, he argued in 1927:

"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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## 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.

States with interracial marriage prohibition laws that were struck down in 1967.
States that had interracial marriage prohibitions in 1950 but repealed their laws before the 1967 decision.



VIRGINIA  
DEPARTMENT OF HEALTH  
HEALTH BULLETIN

Vol. XVI      MARCH, 1924      Extra No. 2.


The New Virginia Law  
To Preserve Racial Integrity

**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)!!

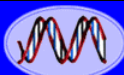
**Justices Upset All Bans  
On Interracial Marriage**

**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

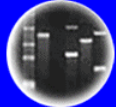
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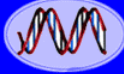
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## Teaching Evolution & The Law




Biology Into the Courtroom


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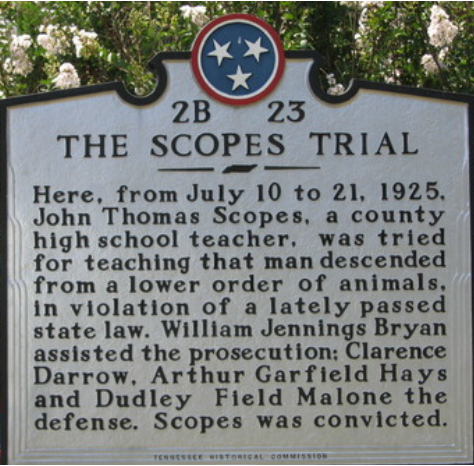


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## The Scopes "Monkey" Trial




2B 23  
**THE SCOPES TRIAL**  
Here, from July 10 to 21, 1925, John Thomas Scopes, a county high school teacher, was tried for teaching that man descended from a lower order of animals, in violation of a lately passed state law. William Jennings Bryan assisted the prosecution; Clarence Darrow, Arthur Garfield Hays and Dudley Field Malone the defense. Scopes was convicted.




21 March 1925

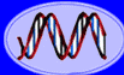
Butler Act prohibiting teaching of human evolution enacted.




**Scopes Fined \$100 - Overturned**  
**On Appeal - Butler Act Repealed in 1967**



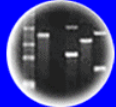
29




DNA  
Genetic Code of Life




Entire Genetic Code  
of a Bacteria



DNA Fingerprinting




Cloning: Ethical Issues  
and Future Consequences



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## Teaching Evolution Court Battles



**Arkansas Prohibited Teaching of Human Evolution in Schools -1928**  
**Was Declared Unconstitutional in 1968**

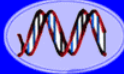
### Epperson vs. Arkansas - 1968

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 (1st Amendment)


30



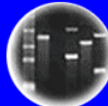





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In 1977, Cambridge became the first city in the world to regulate the manipulation of genetic material. The Cambridge Recombinant DNA Technology Ordinance establishes strict oversight of university and commercial laboratories that engage in recombinant 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.

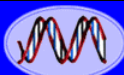
2/8/77

## Cambridge Council Allows Harvard DNA Research


—CAMBRIDGE, Mass., Feb. 7 (UPI)—The

Allows Research Following NIH Guidelines

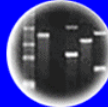
33




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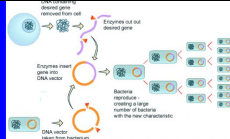
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and Future Consequences



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## Regulating Genetic Engineering at the Local, State, & Federal Levels The Present

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



### Germline Gene Therapy

2019-2021 Congressional Budget (Expires 9/30/21)

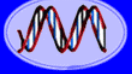
- **FDA Cannot Spend Any Money to Review Applications For Clinical Trials That Involve Human Embryos With Heritable Genetic Modifications**

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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Cloning: Ethical Issues  
and Future Consequences



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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

36

## Laws Regulating the Use of DNA and Genetic Information at the Local, State, & Federal Levels The Present

37

## 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.

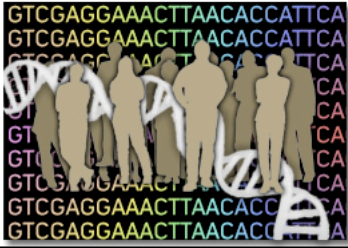
1 *Be it enacted by the Senate and House of Representatives*  
 2 *of the United States of America in Congress assembled,*  
 3 **SECTION 1. SHORT TITLE. TABLE OF CONTENTS.**  
 4 (a) **SHORT TITLE.**—This Act may be cited as the  
 5 "Forensic Science and Standards Act of 2014".

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**GINA** GENETIC INFORMATION NONDISCRIMINATION ACT About | Contact

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**Genetic Information Nondiscrimination Act of 2008**



**Federal Law on Genetic Discrimination**



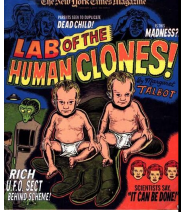
**What is GINA?**  
 The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects people from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information.

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

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

**GINA**  
GENETIC INFORMATION NONDISCRIMINATION ACT

39

**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).**

40

**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**

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**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 Directly by Congress**

**Some Examples**

LEGISLATIVE  
(Phases: Law)

Congress  
House of Representatives

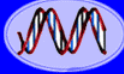
EXECUTIVE  
(Phases: Law)

President  
or President's Cabinet


JUDICIAL  
(Phases: Law)

Supreme Court  
Other Federal Courts

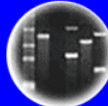
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## Office of Science and Technology Policy

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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

**SCIENCE AND TECHNOLOGY POLICY OFFICE**

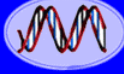
**Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology**

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


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

Updated in 2017

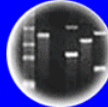
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## Federal Agencies Involved in the Coordinated Framework For the Regulation of Biotechnology

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**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	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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**What About Human Somatic Cell Gene Therapy & Editing?**

**DNA Genetic Code of Life**

**Entire Genetic Code of a Bacteria**

**DNA Fingerprinting**

**Cloning: Ethical Issues and Future Consequences**

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**NIH** National Institutes of Health  
*Turning Discovery Into Health*

**Biomedical Technology Assessment**  
Oversight of Human Gene Transfer Research

**Biomedical Technology Assessment**  
Recombinant DNA Advisory Committee

45

**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**

**PROPOSED LOCAL LAWS**

**DNA Genetic Code of Life**

**Entire Genetic Code of a Bacteria**

**DNA Fingerprinting**

**Cloning: Ethical Issues and Future Consequences**

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## 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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Pending Human Gene Patent Litigations

Total number of cases pending

Year

Legend: Forensic testing, Diagnostic testing, Research tool, Therapeutic protein

Pending human gene patent litigations in each year starting in 1987 and extending to June of 2007; two lawsuits resolved in the first part of 2007 are not included in the 2007 tally.



They're our breast cancer genes — we identified them.

It's kind of you to let us have the disease for free.

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



**GENE Patents**



48



# Life Is Patentable

(Diamond vs. Chakrabarty)

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

6/17/1980



49



## Justices, 9-0, Bar Patenting Human Genes

By ADAM LIPTAK JUNE 13, 2013

March 20, 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?

50

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

Article or Amendment	What Is Application?
Preamble	Promote the <i>General Welfare</i>
Article I, Section 8.1	Promote the <i>General Welfare</i>
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?

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## 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!!**

53

## 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)?**

54

## How Does the Constitution Deal Indirectly With Science?

Without Using the Word Science or  
Mentioning the Progress of Science and  
Discoveries?

55

### 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!

56

## 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!

57

## 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

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## 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

59

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



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## Can Scientific Inquiry and Research Be Regulated?

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## 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

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**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

64



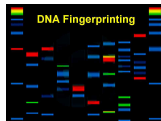
## THERE IS NO FUNDAMENTAL RIGHT OF SCIENTIFIC INQUIRY TO CARRY OUT EXPERIMENTS!

1. When Moving From Reflection, Theory, Hypothesis, and Thought to TESTING AND EXPERIMENTATION - Move From World of Speech (talking, publishing) to WORLD OF ACTION AND CONDUCT.
2. Can Distinguish Between Research That is Hazardous or Potentially Hazardous and That Which is Not Hazardous (e.g., testing bombs in your house; recombinant DNA).
3. Experimentation Triggers Public Welfare Considerations
4. Freedom to Pursue Knowledge is Distinguishable From Right to Choose Method For Achieving That Knowledge (e.g., experimentation methods and approaches).



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

65



## 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."*



67

## 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)

68

## 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?

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## 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

70

# 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. Dept. 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. Dept. 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!



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## Amendment XIII

### **Involuntary Servitude:**

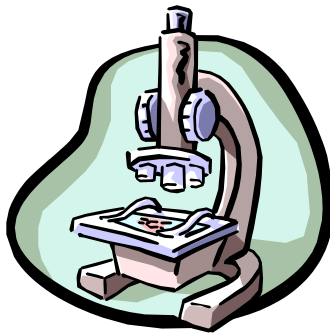
Section 1: “Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist with the United States, or any place subject to their jurisdiction.”

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**

73

## How Can Genetic Engineering Be Regulated Directly?



74

DEPARTMENT OF COMMERCE

REGULATE BY

FORFEIT FOR THE REGULATION OF CLONING

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

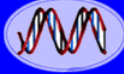
## How Can Genetic Engineering and Science Be Regulated Indirectly?

Dr. E BANKS DIRECTOR OF GENETIC RESEARCH


So... cutting my funding, eh? Well, I've got a pair of mutant fists that say otherwise!

USDA United States Department of Agriculture


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DNA  
Genetic Code of Life




Entire Genetic Code  
of a Bacteria






DNA Fingerprinting



Cloning: Ethical Issues  
and Future Consequences



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**