HC70A Winter 2006

Professor Bob Goldberg

Lecture #6

Genetics and the Law

Themes/Concepts

1. What is Genetic Information Used for?
2. Human disease Genes & Detection Methods
3. Methods Used for forensic testing Individuals
4. What is the history of Genetics Laws in the US?
5. Eugenics/Back to Bell — DNA interactive Clips
6. Current Eugenics Laws Worldwide — stop 3/7/06
7. Issues with Genetic testing?
8. Federal Genetic Non-Discrimination Laws
9. State Laws Dealing with Genetics/Issues
10. State Cloning/Embryo Laws
11. State Prenatal Screening Laws
12. State Insurance Laws Dealing with Genetics
13. State Employment Laws Dealing with Genetics
14. State Laws Regarding DNA Databases & Crime — stop 3/9/06

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(1) "Genetic Privacy"
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(2) "Genetics: Ethics, Law, & Policy"
Lori B. Andrews et al.
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(3) "Genetics & Society"
P.S. Harper & A.J. Clarke
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(4) "The Evaluation of Forensic DNA"
Evidence
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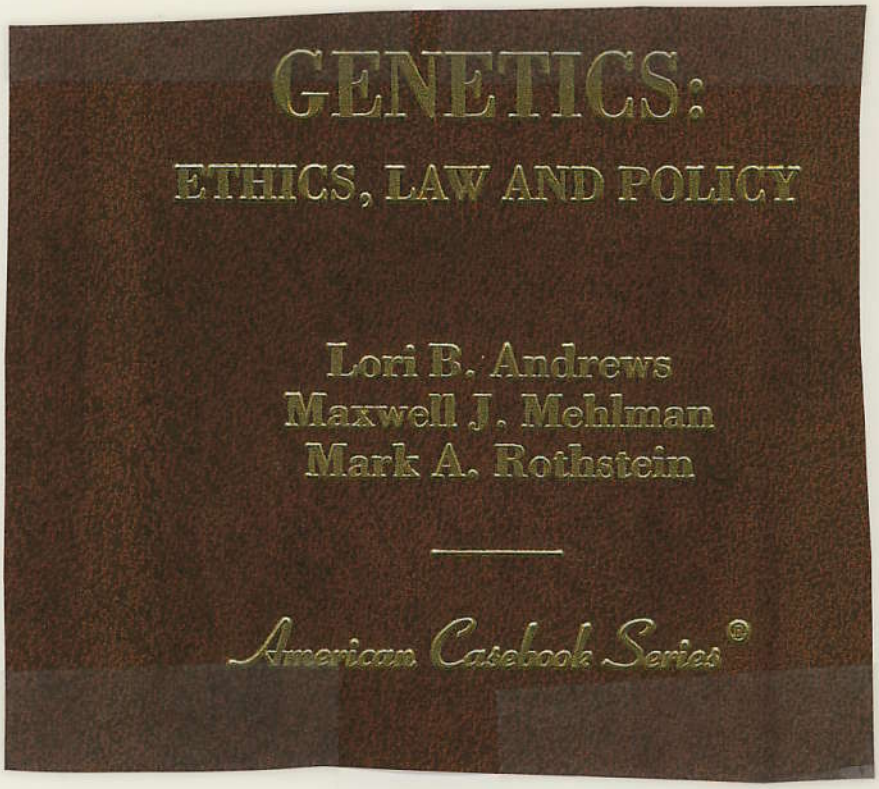


Genetic Privacy

A Challenge to Medico-Legal Norms

Graeme Laurie

WHAT is Genetic Information Used for?

(1) Medical Uses

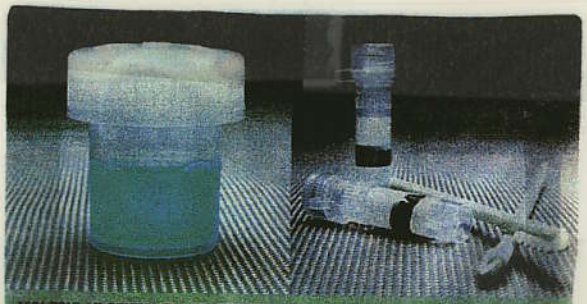
a. Carrier screening
b. pre-natal diagnostic testing
c. new born screening
d. presymptomatic testing for predicting adult-onset disorders such as Huntington's disease
e. presymptomatic testing for estimating risk of developing adult-onset cancers & Alzheimer's disease
f. Confirmational diagnosis of a symptomatic person

future:
g. pharmacogenetics / drug sensitivity
h. preventive medicine – potential to develop heart disease, obesity, etc.
i. population SNPs to associate group with high incidence of genetic disease with Gene!

(2) Non-Medical Uses

a. Insurance (Life/Health)
b. Employment (Workplace Hazard susceptibility)
c. paternity / kinship / Estate Settlement
d. Forensics / Identification
e. Criminal Law (Innocence / Guilt)
f. Immigration (kinship)
g. Schools (Identification) – Children

DNA Testing Comes Home



MOLECULAR GENEALOGY RESEARCH PROJECT Uses mouthwash. **FREE.** molecular-genealogy.byu.edu

FAMILY TREE DNA No blood—just swab your cheek. $149 **AND UP.** dnafamilytree.com

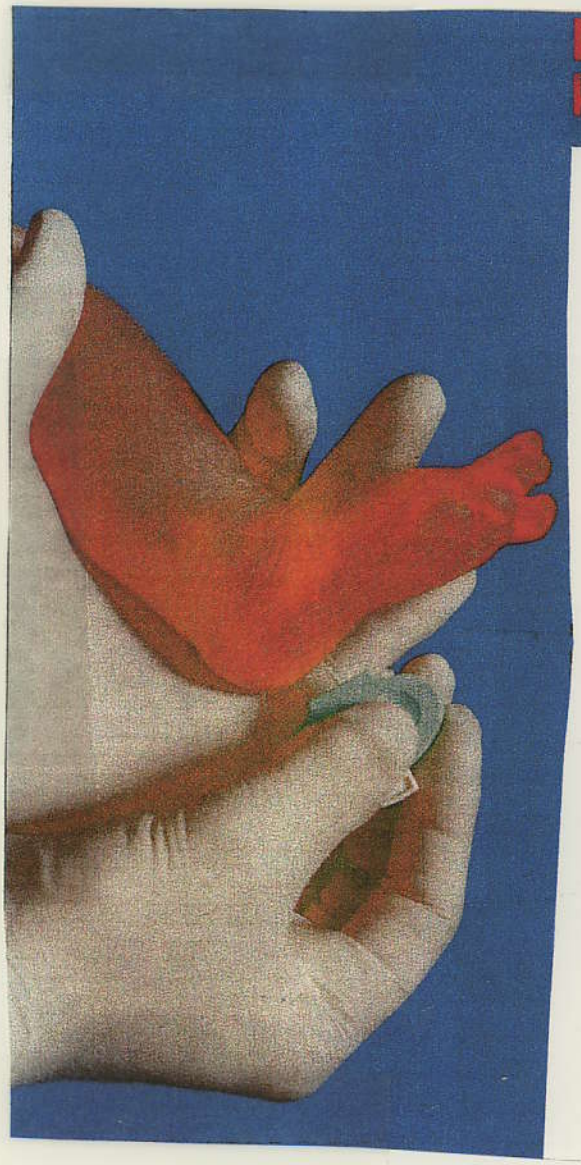
SCIENCE

DO-IT-YOURSELF DNA

If you've tried and tried but your family tree is still just a seedling, mail-order DNA testing may be for you. Comparing your genetic profile with those of other genealogy buffs—and potential relatives—can provide new leads. For $149 and up, Family Tree DNA will give you a list of 25 markers (or genetic traits) you carry, based on a swab from the inside of your cheek. For a bit more—$220 and up—Oxford Ancestors (oxfordancestors.com) will check 10 markers and tell you which "Seven Daughters of Eve" clan you belong to. If that's too steep, the Molecular Genealogy Research Project will test 250 markers for free. Run by Brigham Young University, it hopes to create a worldwide database. The catch: the data must be kept anonymous. In other words, the project will create a map of ancestry lines—not an individual report for you.

—MATTHEW MACROBERTS

FOR GENEOLOGY / FAMILY TREE
HUMAN ORIGINS

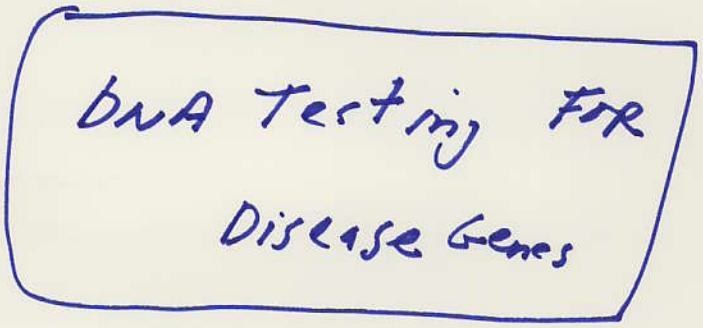


Do you want to know your future?

Every state in the country requires that infants be tested for a list of obscure diseases. Before long, some states could move on to DNA testing of all newborns. Now is the time to decide a critical question: How much do we want to know and when do we want to know it?

By Jeff Wheelwright
Photography by Catherine Ledner

Infant Testing - Newborn screening programs (FUTURE?)


DNA Testing FOR
Disease Genes

Human Disease Genes
INBORN ERRORS OF Metabolism

Table 10.2 Selected Human Genetic Disorders with Demonstrated Enzyme Deficiencies

Genetic Defect	Locus	Enzyme Deficiency (Mom Rons)	OMIM Entry
Acid phosphatase deficiency		Acid phosphatase	20090
Alkaptonuria	3q21–q23	Homogentisic acid oxidase	203500
Ataxia, intermittent[a]		Pyruvate decarboxylase	208800
Cystic fibrosis	7q31.2	Cystic fibrosis transmembrane conductance regulator (CFTR)	602421
Cataract	17q24	Galactokinase	230200
Citrullinemia[a]	9q34	Argininosuccinate synthetase	215700
Disaccharide intolerance I	3q25–q26	Invertase	222900
Fructose intolerance	9q22.3	Fructose-1-phosphate aldolase	229600
Galactosemia[a]	9p13	Galactose-1-phosphate uridyl transferase	230400
Gaucher disease[a]	1q21	Glucocerebrosidase	230800
G6PD deficiency (favism)[a]	Xq28	Glucose-6-phosphate dehydrogenase	305900
Glycogen storage disease I	17q21	Glucose-6-phosphatase	232200
Glycogen storage disease II[a]	17q25.2–q25.3	α-1,4-Glucosidase	232300
Glycogen storage disease III[a]	1p21	Amylo-1,β-glucosidase	232400
Glycogen storage disease IV[a]	3p12	Glycogen branching enzyme	232500
Hemolytic anemia[a]	3p21.1, 8p21.1, 20q11.2, 1q21	Glutathione peroxidase or glutathione reductase or glutathione synthetase or hexokinase or pyruvate kinase	138320, 138300, 231900, 266200
Hypoglycemia and acidosis	9q22.2–q22.3	Fructose-1,6-diphosphatase	229700
Immunodeficiency	1p32	Uridine monophosphate kinase	191710
Intestinal lactase deficiency (adult)		Lactase	223000
Ketoacidosis[a]	5p13	Succinyl CoA: 3-ketoacid CoA-transferase	245050
Kidney tubular acidosis with deafness	2cen–q13	Carbonic anhydrase B	267300
Leigh's necrotizing encephalopathy[a]	11q13.4–q13.5	Pyruvate carboxylase	266150
Lesch-Nyhan syndrome[a]	Xq26–q27.2	Hypoxanthine-guanine phosphoribosyltransferase	308000
Lysine intolerance		Lysine: NAD-oxidoreductase	247900
Male pseudohermaphroditism		Testicular 17,20-desmolase	309150
Maple sugar urine disease, type IA[a]	19q13.1–q13.2	Keto acid decarboxylase	248600
Muscular dystrophy, Duchenne and Becker types	Xp21.2	Dystrophin absent or defective; serum acetylcholinesterase or acetylcholine transferase or creatine phosphokinase elevated	310200
Niemann-Pick disease[a]	11p15.4–p15.1	Sphingomyelin hydrolase	257200
Orotic aciduria I[a]	3q13	Orotidylic decarboxylase and orotidylic pyrophosphorylase	258900
Phenylketonuria[a]	12q24.1	Phenylalanine hydroxylase	261600
Porphyria, acute intermittent[a]	11q23.3	Uroporphyrinogen III synthetase	176000
Porphyria, congenital erythropoietic[a]	10q25.2–q26.3	Uroporphyrinogen III synthase	263700
Pulmonary emphysema	14q32.1	α-l-Antitrypsin	107400
Pyridoxine dependency with seizures	2q31	Glutamic acid decarboxylase	266100
Ricketts, vitamin D–dependent		25-Hydroxycholecalciferol 1-hydroxylase	277420
Tay-Sachs disease[a]	15q23–q24	*N*-acetylhexosaminidase A	272800
Thyroid hormone synthesis, defect in	2p25	Iodide peroxidase or deiodinase	274500
Tyrosinemia, type III	12q24–qter	*p*-Hydroxyphenylpyruvate oxidase	276710

[a]Prenatal diagnosis possible.

INBORN ERRORS OF Metabolism

Protein Degradation

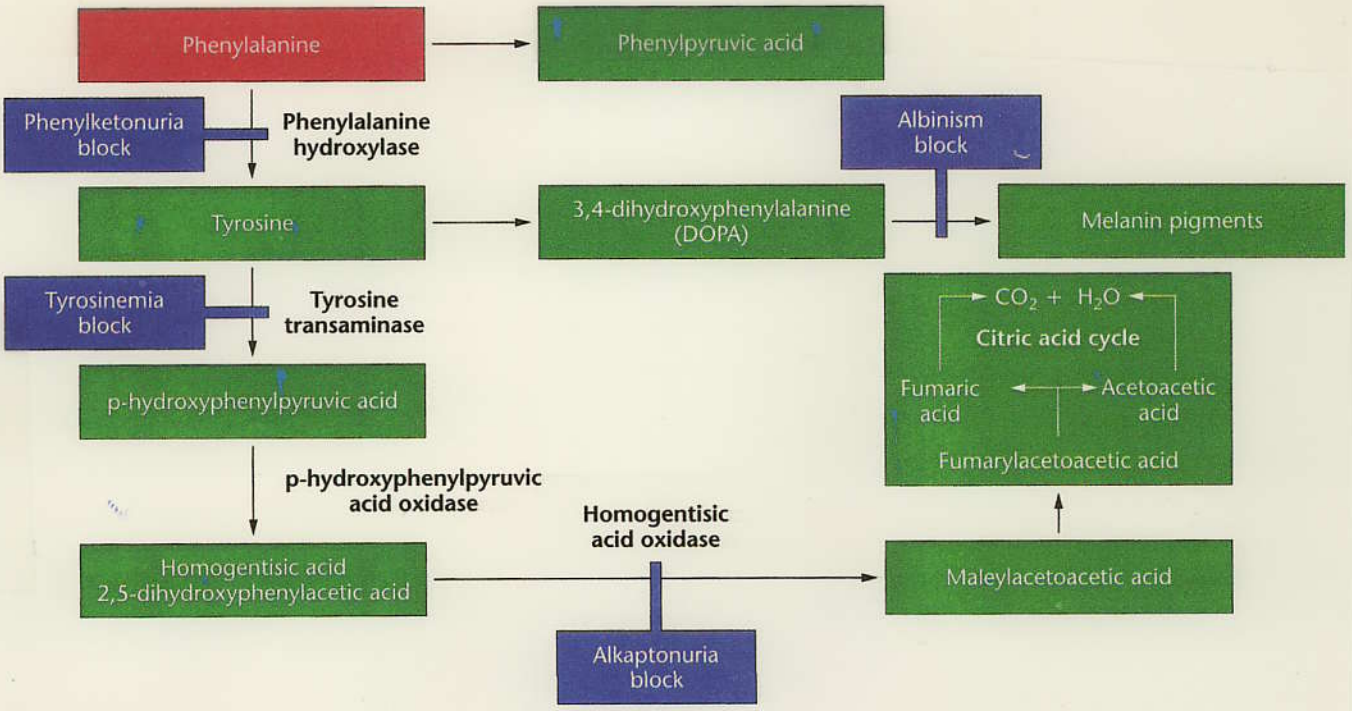
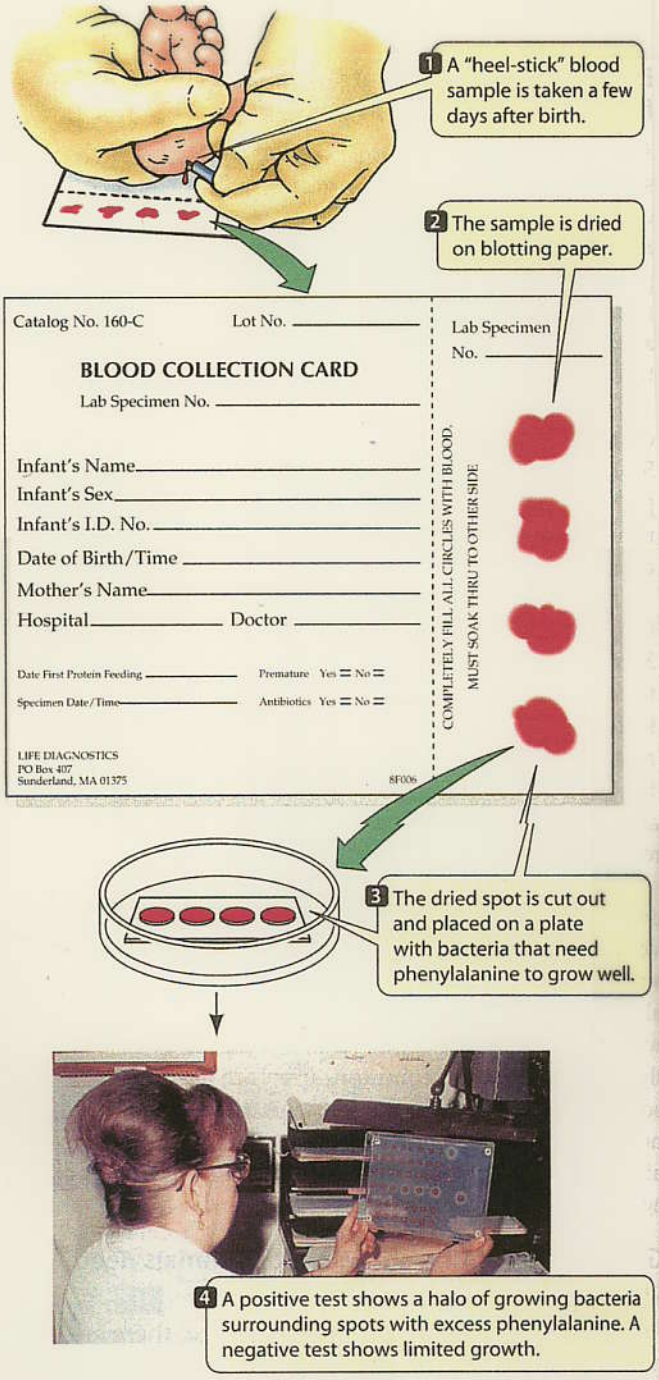


FIGURE 14.10 Metabolic pathway involving phenylalanine and tyrosine. Various metabolic blocks resulting from mutations lead to the disorders phenylketonuria, alkaptonuria, albinism, and tyrosinemia.

Newborn screens for compounds that accumulate before block in metabolic pathway

Screening Newborn Infants For Disease Genes



18.10 Genetic Screening of Newborns for Phenylketonuria
A simple test devised by Robert Guthrie in 1963 is used today to screen newborns for phenylketonuria. Early detection means that the symptoms of the condition can be prevented by following a therapeutic diet.

PKU

GUTHRIE test

FIRST Newborn Screening Program!

Old way!

POST-NATAL / CHILD + ADULT TESTING

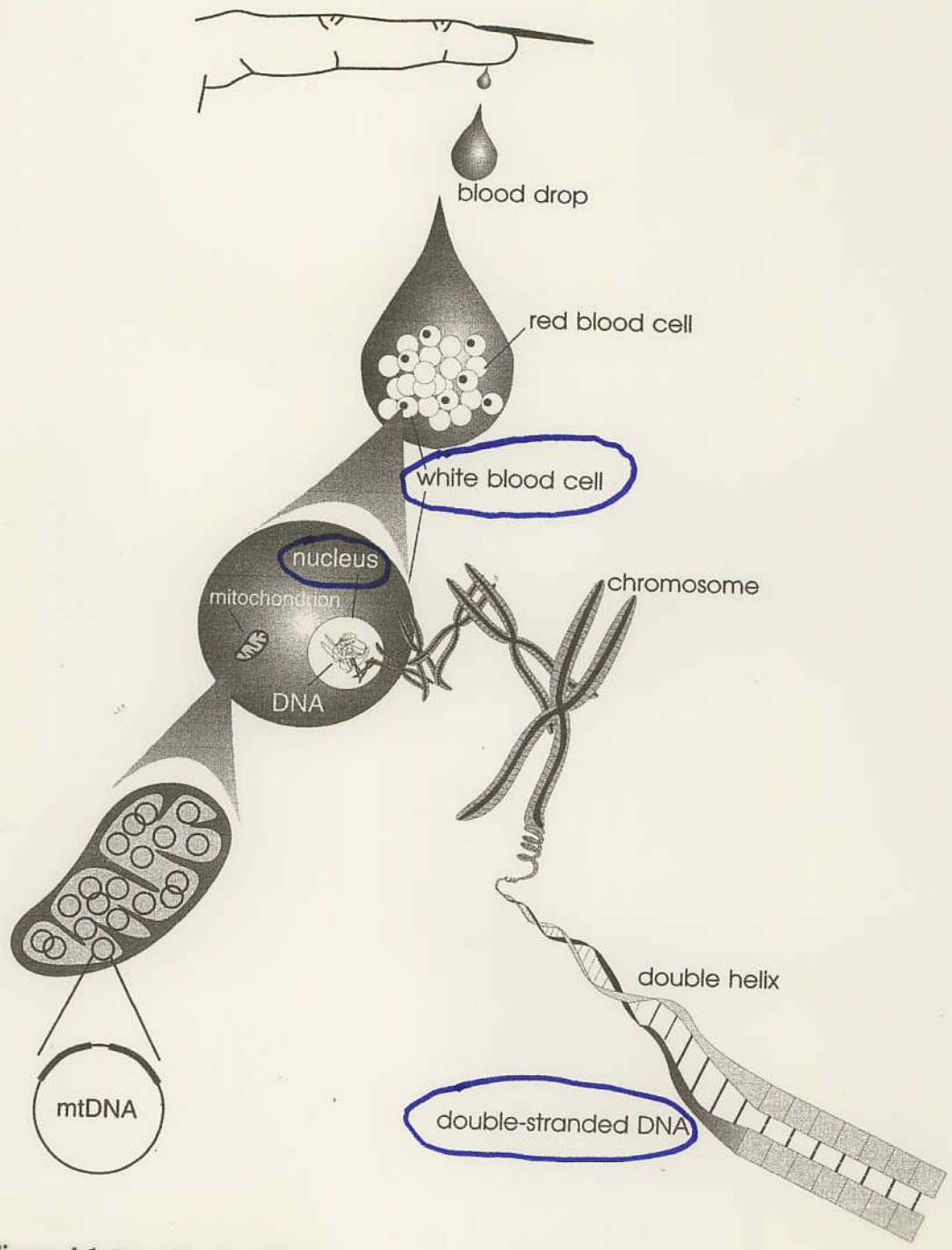


Figure 4.1 From blood to DNA.

DNA Testing - The Original Old Fashioned Way

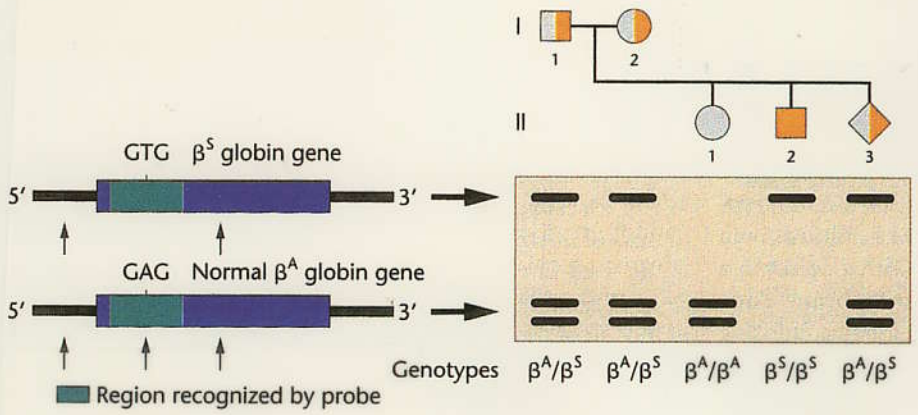
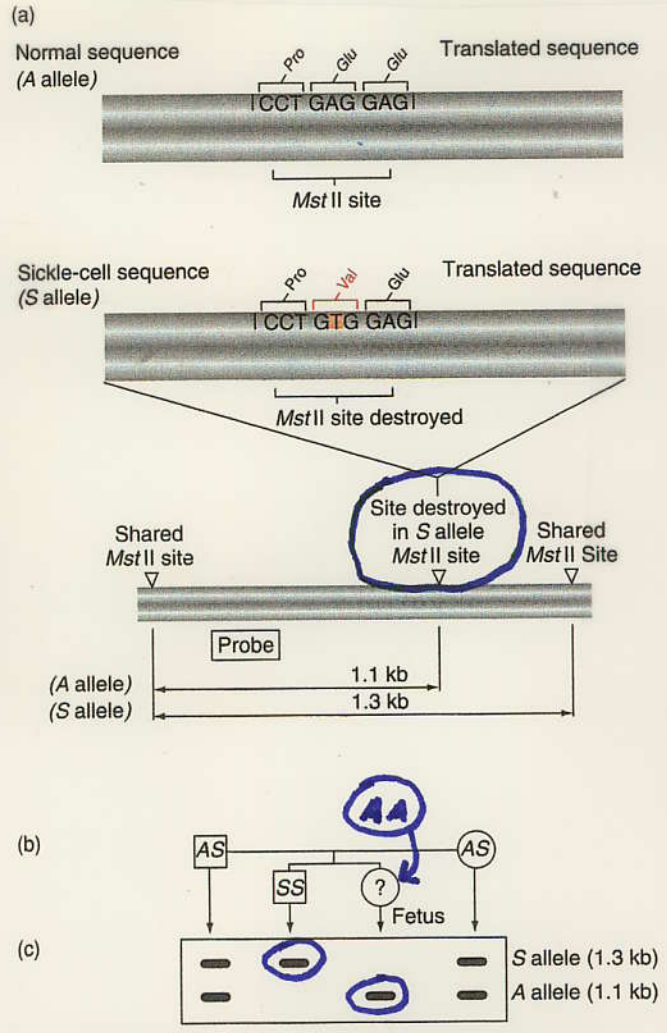


FIGURE 21.8 Southern blot diagnosis of sickle-cell anemia. Arrows represent the location of restriction enzyme cutting sites. In the mutant (β^S) globin gene, a point mutation (GAG → GTG) has destroyed a restriction enzyme cutting site, resulting in a single large fragment on a Southern blot. In the pedigree, the family has one unaffected homozygous normal daughter (II-1), an affected son (II-2), and an unaffected fetus (II-3). The genotype of each family member can be read directly from the blot, and these are shown below the blot.



RFLP due to base-pair change in βA Globin Gene

Figure 9.16 Direct detection of the sickle-cell genotype.
(a) The sickle-cell mutation destroys a recognition site for the *Mst*II restriction enzyme. Consequently, a probe that hybridizes to the left of this site recognizes a 1.1 kbp *Mst*II restriction fragment from the wild-type allele and a 1.3 kbp restriction fragment from the sickle-cell allele.
(b) A family pedigree in which both parents are carriers, a first child has sickle-cell disease, and a fetus is of unknown genotype.
(c) Southern blot analysis shows the RFLP genotype associated with each genotype at the sickle-cell locus. The fetus is homozygous for the wild-type allele.

12

DNA Testing using PCR & RFLP's – A Faster Way

Principle the same!!

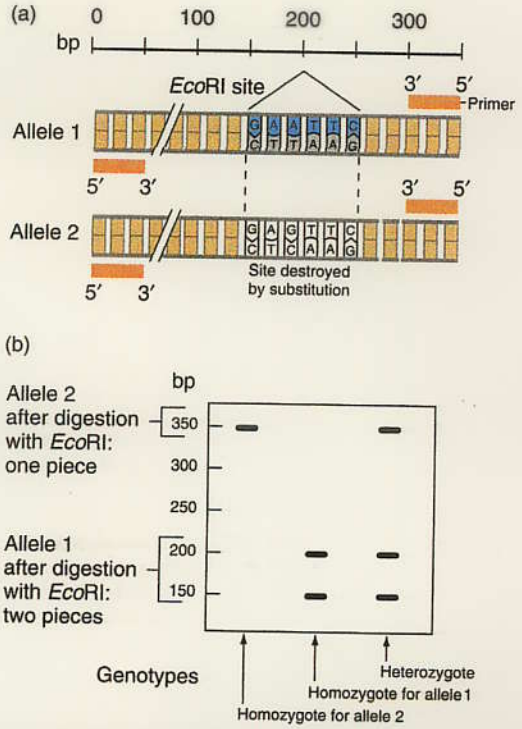
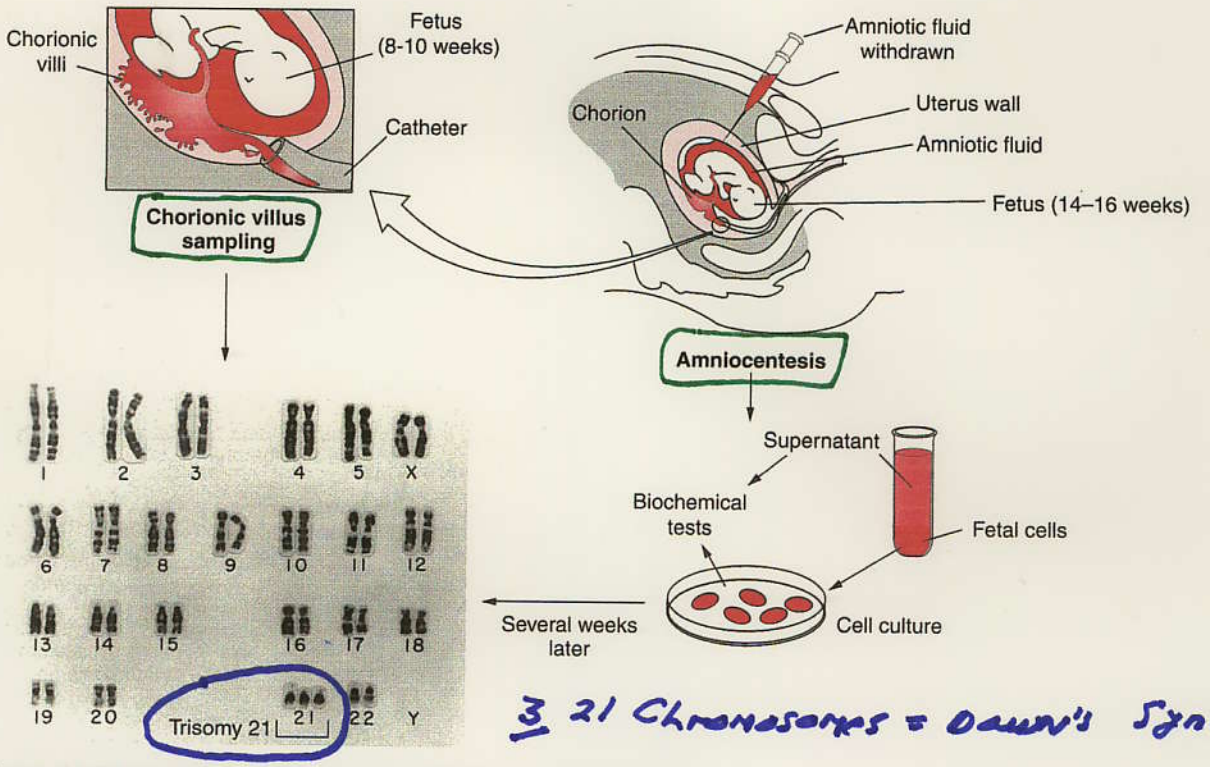


Figure 9.7 Restriction site polymorphisms can be detected most efficiently with PCR-based protocols. (a) PCR amplification of two alleles of a DNA locus with a restriction site polymorphism. Allele 1 has an *Eco*RI site that is eliminated in allele 2. The PCR products amplified from both alleles are identical in size. (b) Exposure of these PCR products to *Eco*RI causes cleavage of the allele 1 product but not the allele 2 product. Gel electrophoresis and ethidium bromide staining distinguish the three genotypes possible with the two alleles at this locus.

Advantage – Small amount of DNA needed

Pre-Natal Testing



3 21 Chromosomes = Down's Syndrome

Figure 11.2 Amniocentesis and Chorionic Villus Sampling Fetal testing for chromosomal abnormalities is most commonly achieved through either amniocentesis or chorionic villus sampling. This karyotype from a person with Down syndrome shows three copies of chromosome 21 (Trisomy 21).

FOR Gene & Chromosomal Defects

DNA Testing Using PCR + ASO's - A Simple Method!

Fast Forward

The Direct Analysis of Human Genotype

Part of Mendel's genius was the ability to infer a *hidden* genotype from the phenotype expressed by not just one individual but by that individual's relatives as well. Human pedigrees follow this tradition, revealing genotypes on the basis of phenotypic information observed over several generations of a family. But despite the information they reveal, pedigrees do not always provide enough data for prediction. Phenotypically normal prospective parents, for example, may not know, even from an extensive family history, whether they both carry an allele for a deleterious recessive trait; they are thus unable to assess their chances of producing an afflicted child. Today, however, geneticists can go beyond deduction and inference and analyze genotype directly. With techniques developed in the mid-1970s, it is possible to tell exactly what a particular gene "looks like," pick out specific gene pieces, and assess comparable pieces for their differences or similarities. Such comparisons may reveal the presence or absence of disease-causing alleles, such as the dominant allele underlying Huntington disease or the recessive alleles giving rise to cystic fibrosis and sickle-cell anemia. For the prospective parents alluded to above, if just one of them does *not* carry a disease-causing recessive allele, the couple does not have to worry about conceiving an afflicted child.

The power of the new technology arises from its resolution and sensitivity. The resolution, or ability to detect differences between two similar substances, is as high as it can get. A combination of procedures allows detection of differences at the level of single nucleotides, the elementary building blocks of genes (see Chapters 5, 8, and 9). The sensitivity of the new technology is also as great as it can be. Today researchers can detect and analyze the one copy of each gene present in a single sperm cell.

In one application of the new technology, identification of the beta-globin (β-globin) genotype provides the basis for diagnosing sickle-cell anemia, a recessive genetic disease that afflicts roughly 1 in 600 African-Americans. Figure A shows the potential results of a test for the normal and sickle-cell alleles of the β-globin gene. The protein determined by this gene is one component of the oxygen-carrying hemoglobin molecule. In the generation of disease, the normal β-globin allele (*HbβA*, abbreviated *A*) is dominant, and the abnormal allele (*HbβS*, or simply *S*) is recessive. Because the normal *A* allele leads to the production of fully functional hemoglobin, people possessing at least one copy of this allele are healthy under most conditions. By contrast, because the abnormal *S* allele leads to the formation of defective hemoglobin molecules, people with two copies of the *S* allele suffer from sickle-cell anemia. With no normal hemoglobin, these *SS* homozygotes have a decrease in oxygen supply, tire easily, and often develop heart failure from stress on the circulatory system. The test whose possible results are depicted in Fig. A was based on the polymerase chain reaction (PCR) which can replicate a single gene, or parts thereof, many times over (see Chapter 8 for details). Geneticists can find out what alleles are present in the replicated material through probes that show whether or not a particular allele is present. For example, with two allele-specific probes for the β-globin gene—one for *A*, the other for *S*—they can distinguish a normal *AA* homozygote from a healthy heterozygous *AS* carrier, and both of these from a homozygous *SS* individual afflicted with sickle-cell anemia.

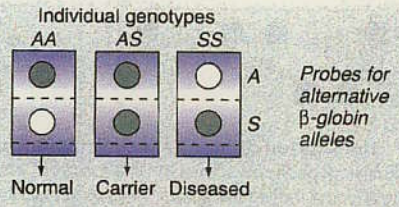


Figure A A direct look at the β-globin genotype. Two probes, one specific for the normal *A* allele, the other specific for the abnormal sickle-cell *S* allele, are necessary to determine the genotype of a sample of DNA amplified by the polymerase chain reaction. The presence of a particular allele is indicated by reaction of the corresponding probe with the DNA sample to produce a darkened signal visible on X-ray film. In this diagram of a β-globin genotype analysis, the green circles show that a probe reacted with a specific allele, the white circles indicate no reaction. Note that only the carrier with both *A* and *S* alleles has two green circles.

Like the mutant alleles for the β-globin gene, the mutant alleles that determine Huntington disease (HD) and cystic fibrosis (CF) are distinguishable in powerful molecular tests. With HD, both heterozygotes and homozygotes for the mutant allele will eventually show symptoms of the disease. With CF, heterozygotes will be carriers that do not show symptoms, while homozygotes for the mutant allele will have the disease.

The ability to analyze genotype directly has profound social implications. This is particularly true because geneticists can use PCR and other modern techniques on fetal cells obtained from a pregnant woman, and thereby diagnose the genotype of the fetus even before it is born. The Genetics and Society box on pp. 30–31 takes a look at some of the issues related to potential uses of the new technology.

Advantage - Small amount of DNA needed & No Restriction Enzymes

ASO - Allele-specific Oligonucleotide

SHORT SPECIFIC NUCLEIC ACIDS MADE synthetically

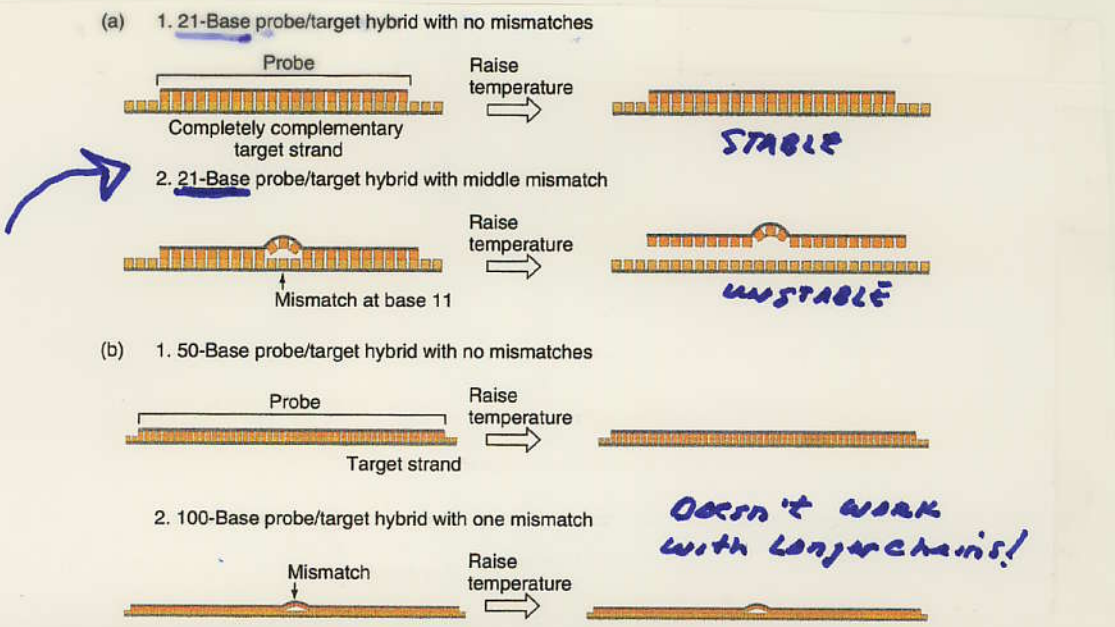


Figure 9.8 Short hybridization probes can distinguish single-base mismatches, longer probes cannot. (a) Researchers allow hybridization to occur between a short 21-base probe and two different target sequences. (1) A perfect match between probe and target extends across all 21 bases. When the temperature rises, this hybrid has enough hydrogen bonds to remain intact. (2) With a single-base mismatch in the middle of the probe, the effective length of the probe-target hybrid is only 10 bases. When the temperature rises, this hybrid does not have enough hydrogen bonds to remain intact, and it falls apart. (b) Researchers allow hybridization to occur with probes of 50 bases and 100 bases. (1) A perfect match between a 50-base probe and its target bases achieves a maximum of stability such that any extension in the length of the match would not have a significant effect on the temperature at which the hybrid falls apart. (2) Thus, it is not easy to distinguish a 100-bp hybrid with one mismatched base from a 100-bp hybrid with a perfect match.

(1) ASOs FORM a Hybrid with NO Mismatches at high temperature

(2) ASOs are unstable & do not FORM Hybrids at high temperatures with <u>one or more</u> Mismatches!

∴ CAN Distinguish Sequences with only 1 base pair difference!

Using ASOs to Detect Specific Alleles that Differ by One Nucleotide

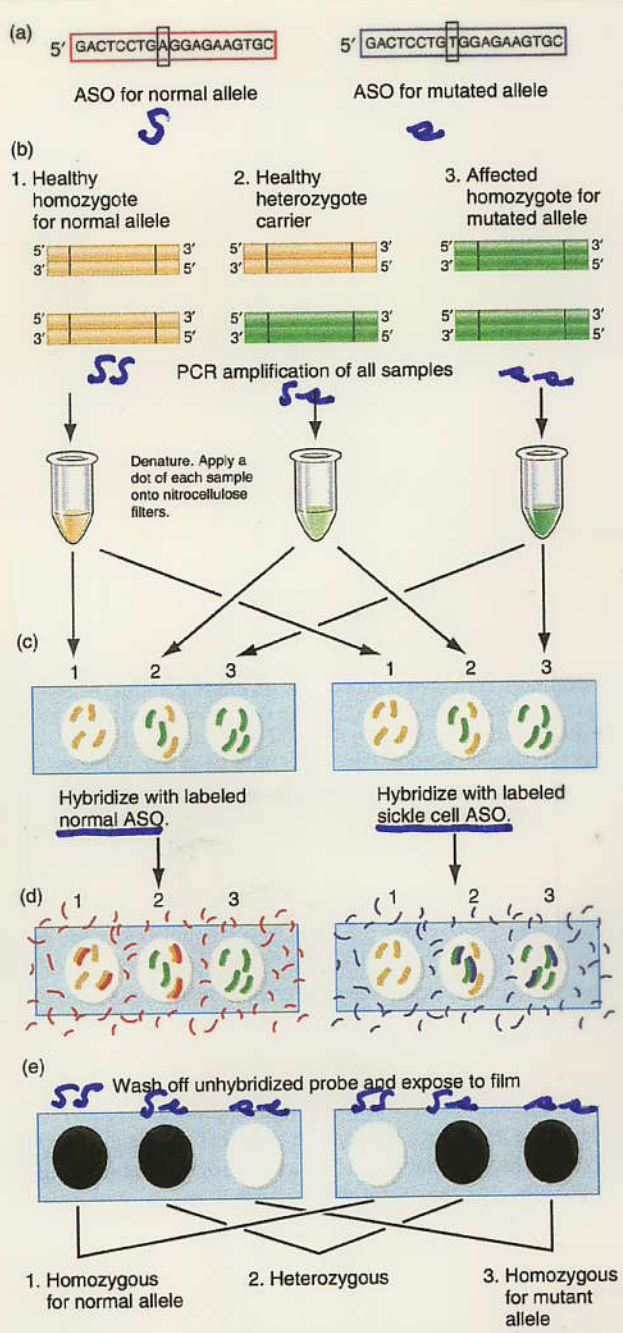
Testing For Sickle-Cell Allele

(1) Extract DNA

(2) Amplify Globin Alleles with PCR

(3) Hybridize Each DNA with Healthy + Mutant ASO @ High temperature

(4) Score Results Using Color Assay



Duplicate Hybridizations One to Normal ASO & One to Mutant ASO

Figure 9.9 Using PCR with ASOs to determine genotype at the β-globin locus. (a) Before performing the genotyping protocol, it is necessary to synthesize two oligonucleotides that differ at only a single base; one of these oligonucleotides is complementary to the wild-type β-globin allele, the other is complementary to the sickle-cell allele. These two synthetic DNA molecules serve as the ASOs for the sickle-cell genotype assay. (b) Genomic DNA samples obtained from individual people are subjected to PCR amplification with primers complementary to nonpolymorphic sequences that flank the base that mutates to cause sickle-cell anemia. (c) The amplified sample from each individual is divided into two aliquots that are blotted directly to filter paper. (d) One aliquot from each sample is hybridized to the wild-type ASO; the other aliquot is hybridized to the sickle-cell ASO. (e) Autoradiography indicates the β-globin genotype of each individual.

USING ASOs to Detect the Cystic Fibrosis Gene

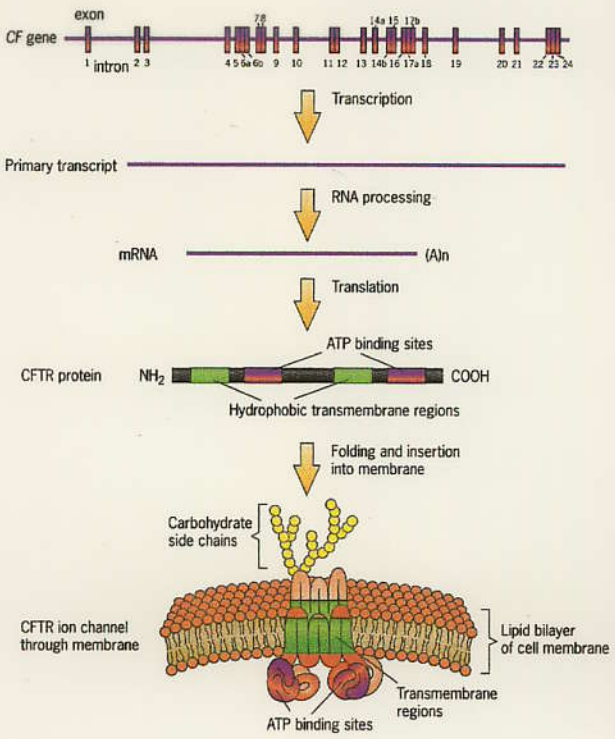


Figure 22.5 The structure of the *CF* gene and its product, the CFTR protein. The CFTR protein forms ion channels through the membranes of epithelial cells of the lungs, intestine, pancreas, sweat glands, and some other organs.

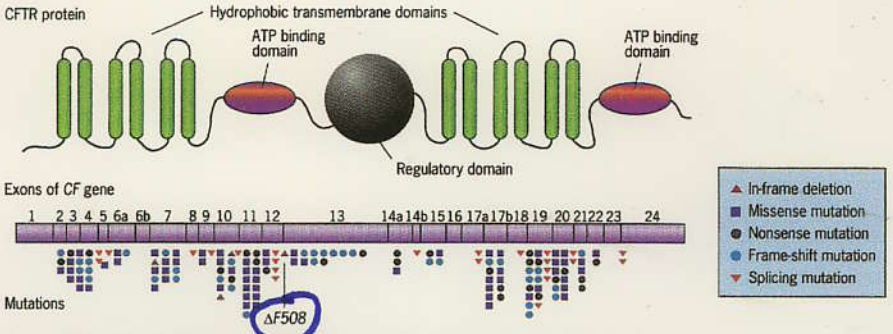


Figure 22.6 The distribution and classification of the mutations that cause cystic fibrosis are shown below the exons of the *CF* gene. A schematic diagram of the CFTR protein is shown above the exon map to illustrate the domains of the protein that are altered by the mutations. About 70 percent of all cases of CF result from mutation *ΔF508*, which deletes the phenylalanine present at position 508 of the normal CFTR protein.

USING ASOs to Detect CF Gene / Screening for CF

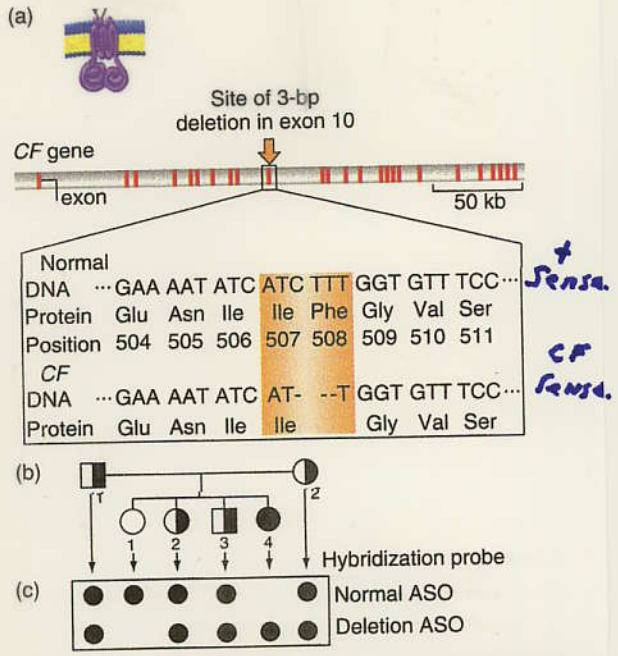


Figure 9.17 Direct detection of the most common cystic *fibrosis mutation.* *The CF gene extends across 250,000 base pairs* and is organized in 27 exons. It encodes a protein with 1480 amino acids. (a) The most common disease-causing mutation in the *CF* gene is a deletion of three bases in exon 10. It is possible to amplify the region containing the site of the most common mutation by PCR and divide the PCR products into two aliquots. You then blot the aliquots onto filter paper and probe with ASOs for the wild-type and mutant alleles. The ASO for the mutant allele differs by the absence of three bases from the ASO for the wild-type allele. (b) Pedigree of a family in which one daughter (child 4) has cystic fibrosis. (c) Analysis of the results of an ASO hybridization test provide direct information on the *CF* genotype of all family members.

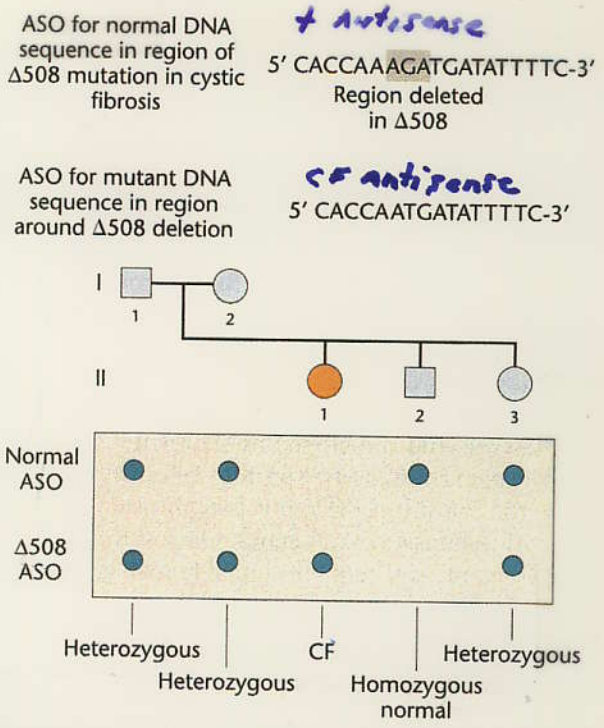


FIGURE 21.10 Screening for cystic fibrosis (CF) by allele-specific oligonucleotides (ASOs). ASOs for the region spanning the most common mutation in CF, a three-nucleotide deletion (Δ508), are prepared from normal CF genes and Δ508 CF genes. In screening, the CF gene is amplified by PCR using DNA extracted from blood samples and spotted on a DNA-binding membrane. The membrane is hybridized to a mixture of the two ASOs. The genotype of each family member can be read directly from the filter. DNA from I-1 and I-2 hybridizes to both ASOs, indicating that they carry a normal allele and a mutant allele and are therefore, heterozygous. The DNA from II-1 hybridizes only to the Δ508 ASO, indicating that she is homozygous for the mutation and has cystic fibrosis. The DNA from II-2 hybridizes only to the normal ASO, indicating that he carries two normal alleles. II-3 has two hybridization spots and is heterozygous.

USING ASO & PGD to Screen FOR CF Alleles in Embryos Produced By IVF

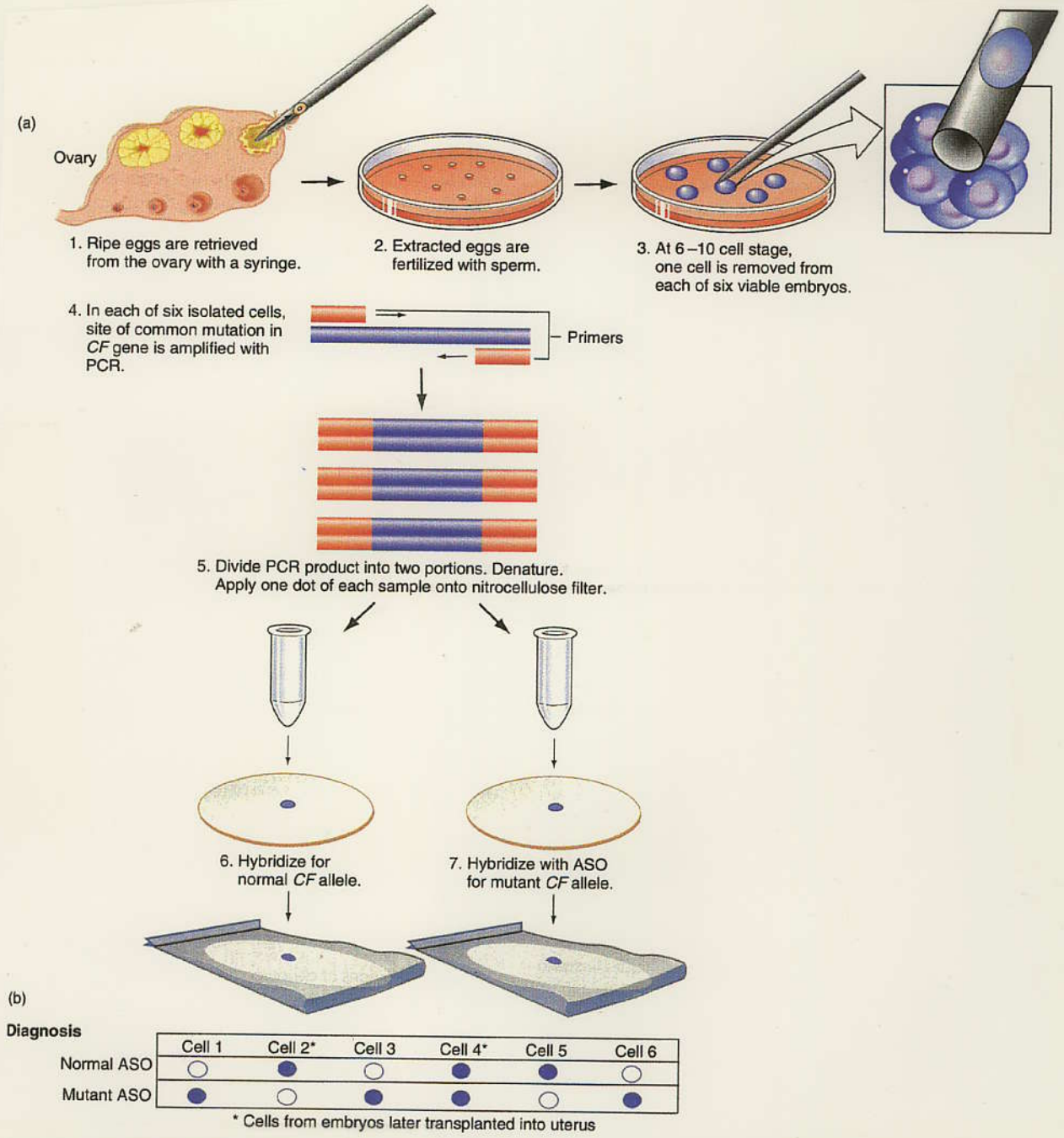


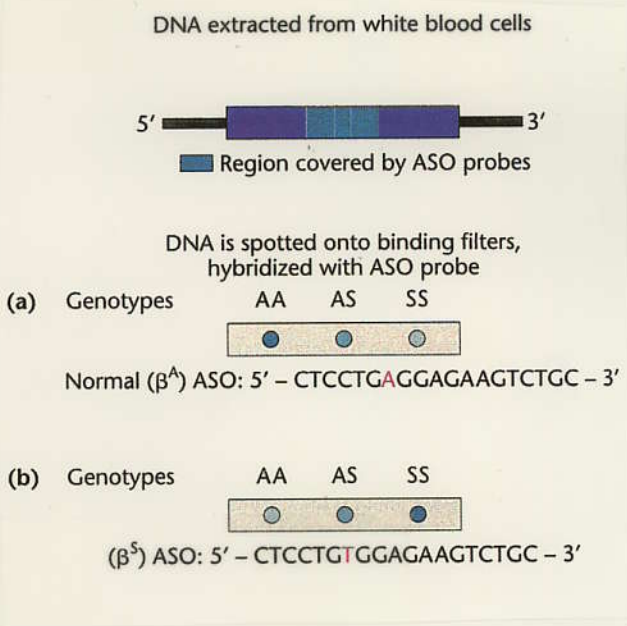
Figure 9.1 Detecting the cystic fibrosis genotype of embryonic cells. (a) *In vitro* fertilization and preimplantation diagnosis. (b) Cell 2 is homozygous for the normal allele; cell 4 is heterozygous for the *CF* mutation.

DNA/GENE SCREENING - The old way & the new way!

SICKLE-CELL SCREENING

Figure 22.7 Detection of the sickle-cell hemoglobin mutation by Southern blot analysis of genomic DNAs cut with restriction enzyme *Mst*II.

(1) RFLP



(2) ASO

FIGURE 21.9 Genotype determinations using allele-specific oligonucleotides (ASOs). In this technique, the β-globin gene is amplified by PCR using DNA extracted from blood cells. The amplified DNA is denatured and spotted onto strips of DNA-binding filters. Each strip is hybridized to a specific ASO and visualized on X-ray film after hybridization and exposure. If all three genotypes are hybridized to an ASO from the normal β-globin gene, the pattern in (a) would be observed: AA-homozygous individuals have normal hemoglobin that has two copies of the normal β-globin gene and would show heavy hybridization; AS-heterozygous individuals carry one normal β-globin gene and one mutant gene and would show weaker hybridization; SS homozygous sickle-cell individuals carry no normal copy of the β-globin gene and would show no hybridization to the ASO probe for the normal β-globin gene. (b) The same genotypes hybridized to the probe for the sickle-cell β-globin gene would show the reverse pattern: no hybridization by the AA genotype, weak hybridization by the heterozygote (AS), and strong hybridization by the homozygous sickle-cell genotype (SS).

Disease Genes in the Human Genome

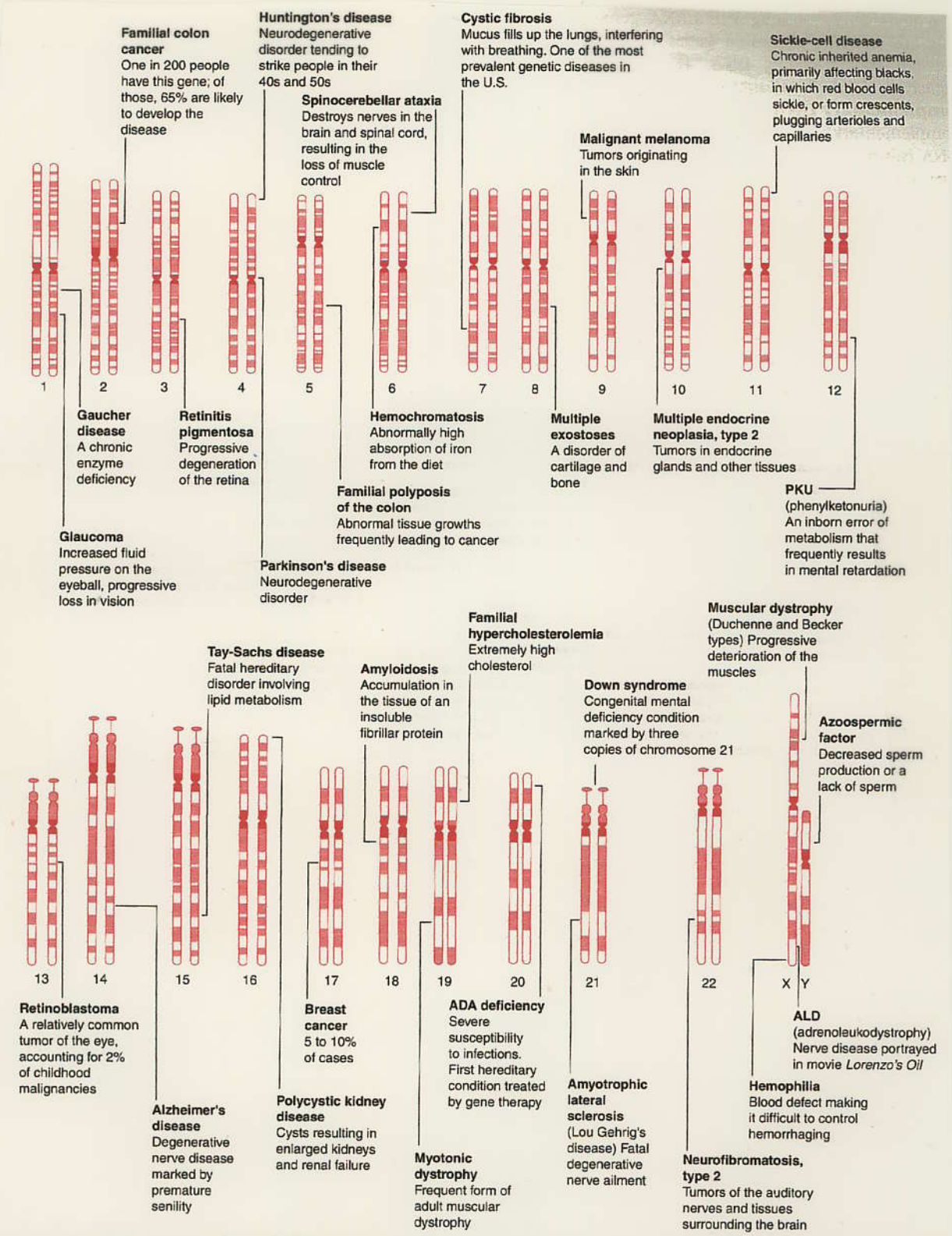
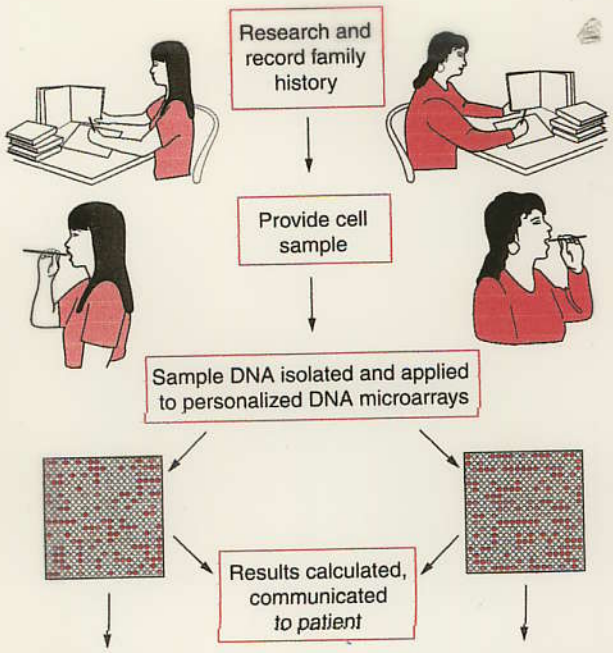


Figure 11.22 Disease Gene Maps of Human Chromosomes Maps show one or two genes on each human chromosome that are involved in a genetic condition. Many more genes than are shown in this figure are located on each chromosome. Note: Chromosomes are not drawn to scale.

USING MICROARRAYS to SCREEN FOR MANY Different Genes at the SAME TIME



Susan's Genetic Profile

Trait	Risk
Addictive behavior	: Greater than general population
Lung cancer	: Greater than general population
Colon cancer	: Less than general population
Alzheimer's disease	: Less than general population

Lisa's Genetic Profile

Trait	Risk
Cystic fibrosis	: 100% diagnosis
Type II diabetes mellitus	: Less than general population
Cardiovascular disease	: Greater than general population

Figure 11.6 Using Gene Microarrays to Create a Genetic Profile

The Future!

USING MICROARRAYS FOR GENE SCREENING

THE MAGIC OF MICROARRAYS

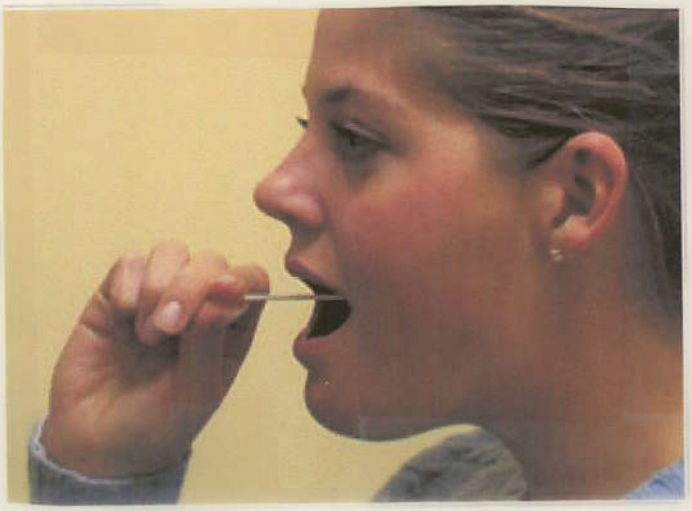
Research tools known as DNA microarrays are already clarifying the molecular roots of health and disease and speeding drug discovery. They could also hasten the day when custom-tailored treatment plans replace a one-size-fits-all approach to health care

BY STEPHEN H. FRIEND AND ROLAND B. STOUGHTON

DOT PATTERNS EMERGE when DNA microarrays analyze tissue samples. Individual differences in those patterns could one day help doctors match treatments to the unique needs of each patient.

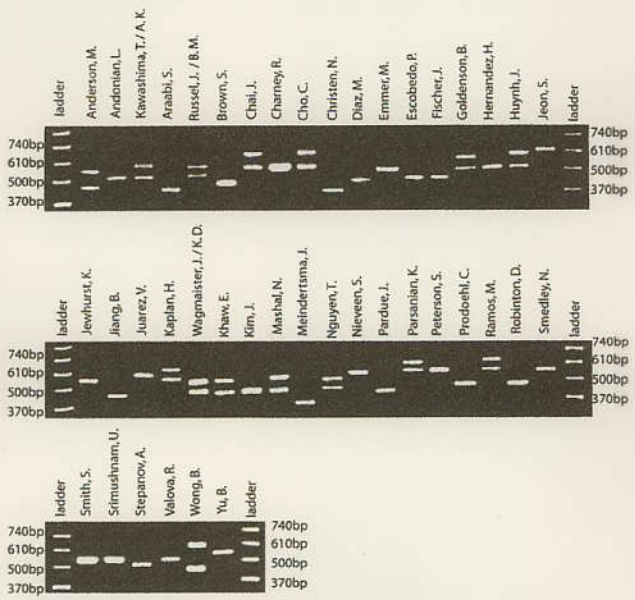
DNA Testing for
Individual Identity
&
forensics

SCREENING / TESTING FOR Individual Genotypes

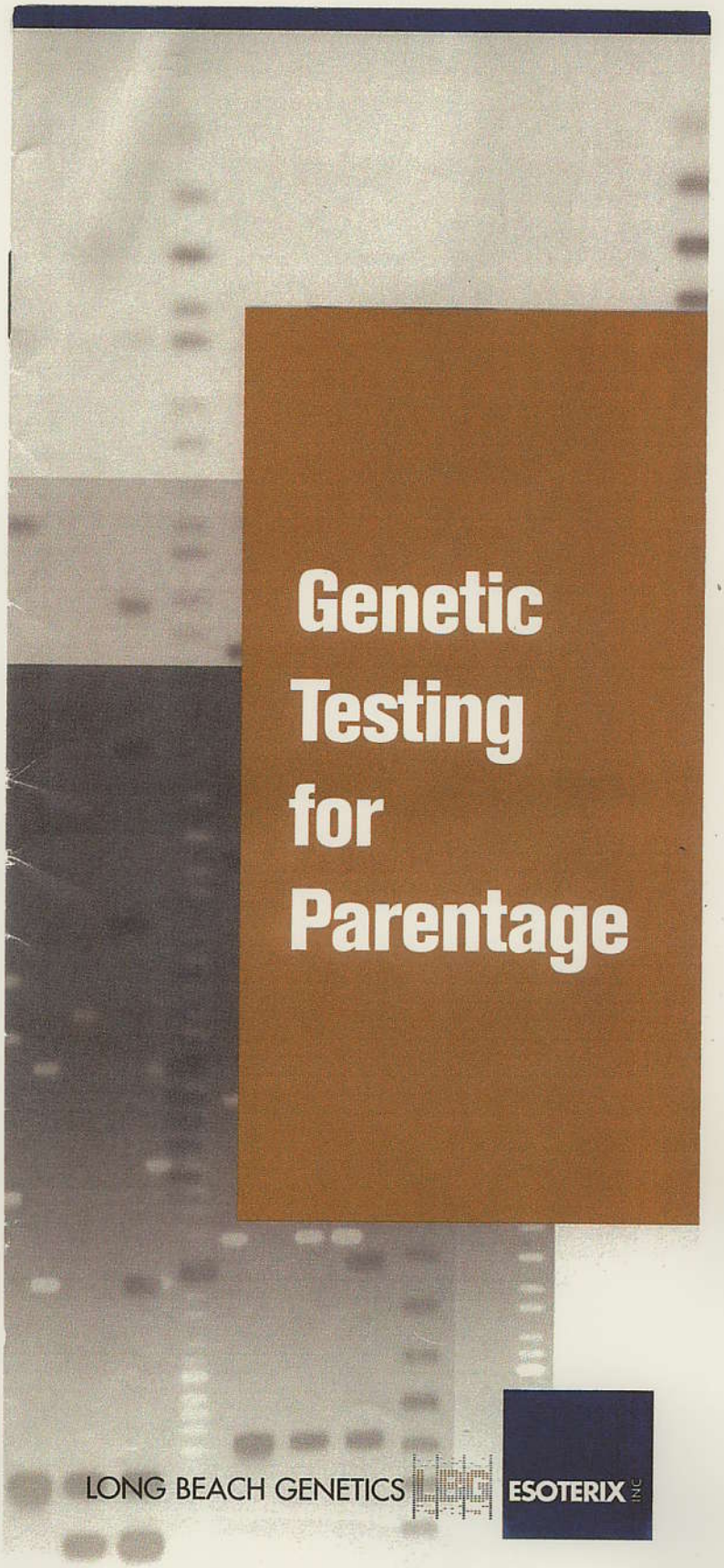


PCR-BASED VNTR Strategy

Figure 1. *D1S80* **Alleles in the Winter, 2006 HC70A UCLA Class Population.**



Note: Three of you were absent from class the day we did the DNA fingerprinting. Your initials are marked next to the DNA fingerprints of Tomo Kawashima, Jon Russell, and Javier Wagmaister. Assume that these DNA fingerprints are yours and answer the questions accordingly.


Genetic
Testing
for
Parentage
LONG BEACH GENETICS
ESOTERIX INC

(72)

USING DNA Testing to Screen for Parentage

Principles of Parentage Testing

For each test, genetic markers occur in pairs:

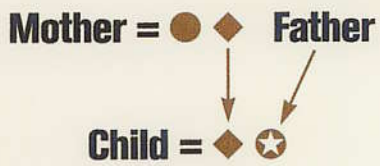
Child = ◆ ✪

Test 1

Child = ◆ ✪

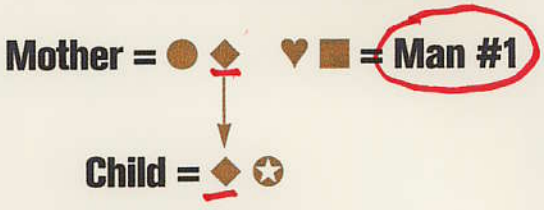
For test #1, this child's genetic markers are "diamond" and "star".

For each pair of the child's markers, one comes from the mother, and the other comes from the father:



This child has inherited "diamond" from its mother. Therefore, the child has inherited "star" from its father.

If the tested man is missing the marker(s) contributed by the father, this constitutes "exclusion":



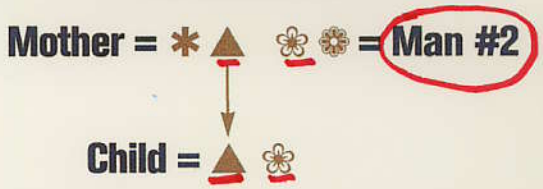
Tested man #1, having markers "square" and "heart", would not contribute "star" to his offspring and thus would be "excluded" by Test " #1.

A non-excluded man (i.e. who possesses the paternal marker) is implicated as the father to the extent that the paternal marker is uncommon:

Tested man #2, as he has marker "star", matches the child of this mother in Test #1. If only 10% of men have "star", 90% lack it and would be excluded. A non-excluded man is either the father or one man in 10.

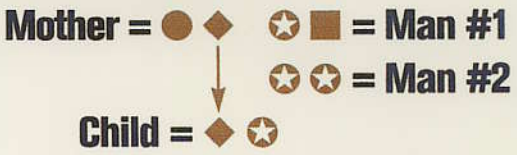
Test 2

Results from independent tests may be combined by the "product rule":



Tested man #2 is also not excluded by the second test. If only 10% of men have "flower", the tested man is either the father, or one man in 10. Considering both tests, the man is either the father, or one man in 100 (10 x10).

Some non-excluded men match better than others:



Tested man #1 and #2 both have "star" and thus are not excluded. Man #1 would pass "star" to half of his offspring and "square" to the other half. Man #2 would pass "star" to all of his offspring. If man #1 is either the father or one man in 10, man #2 is either the father or like one man in 20. The statistic that incorporates both non-exclusion and "goodness of fit" is called "paternity index"

Using DNA Testing in Forensics

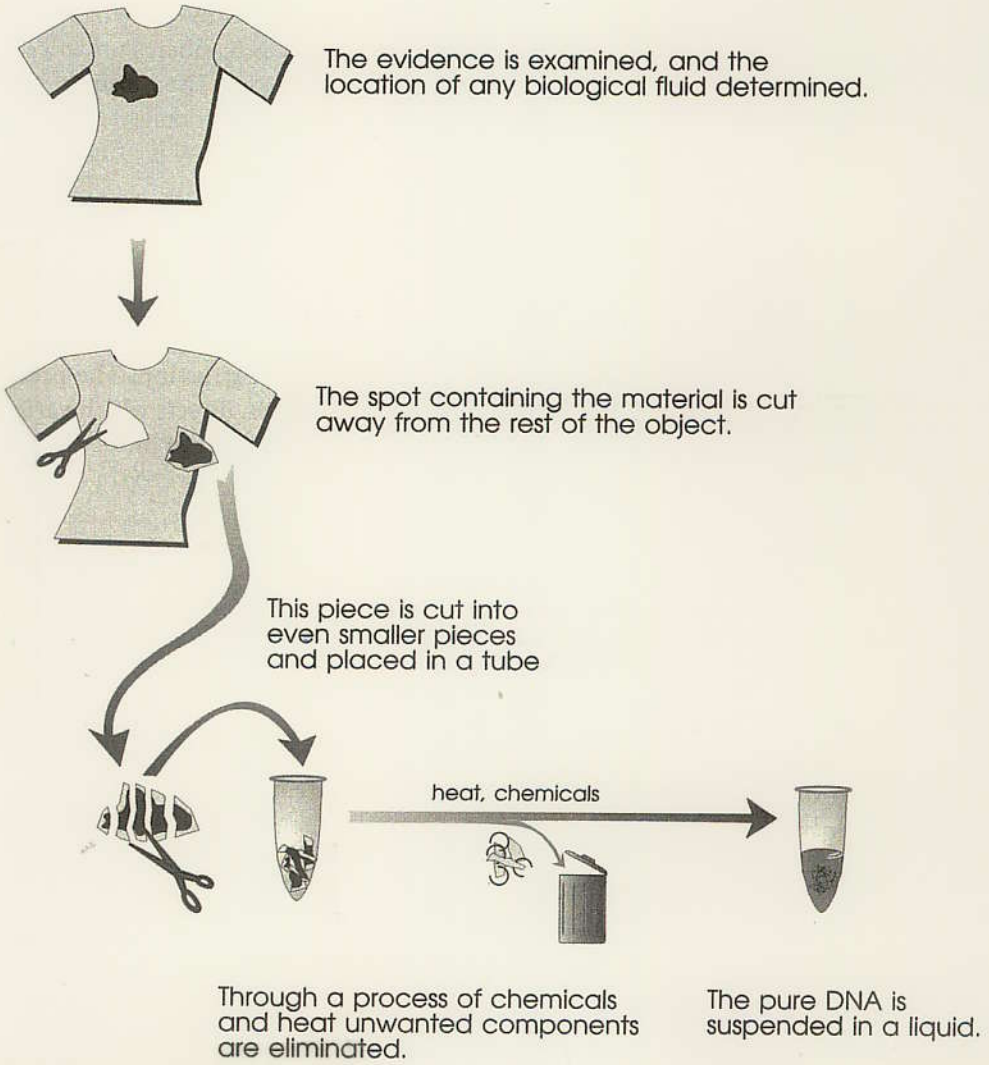


Figure 6.2 *Flowchart for organic extraction of DNA.*

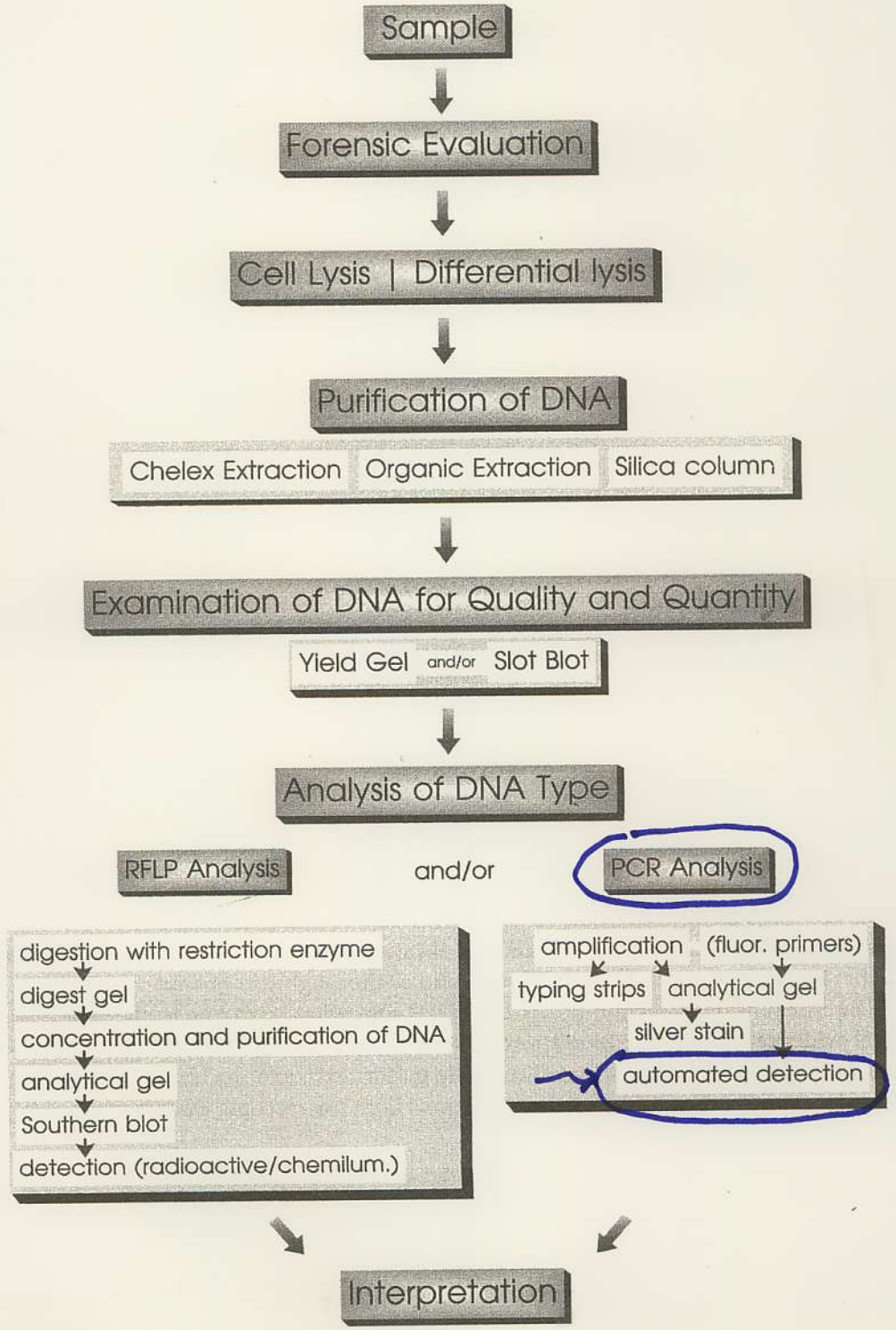


Figure 6.1 Flowchart for forensic DNA typing.

Determining Genotypes / The old Fashioned DNA Blot way!

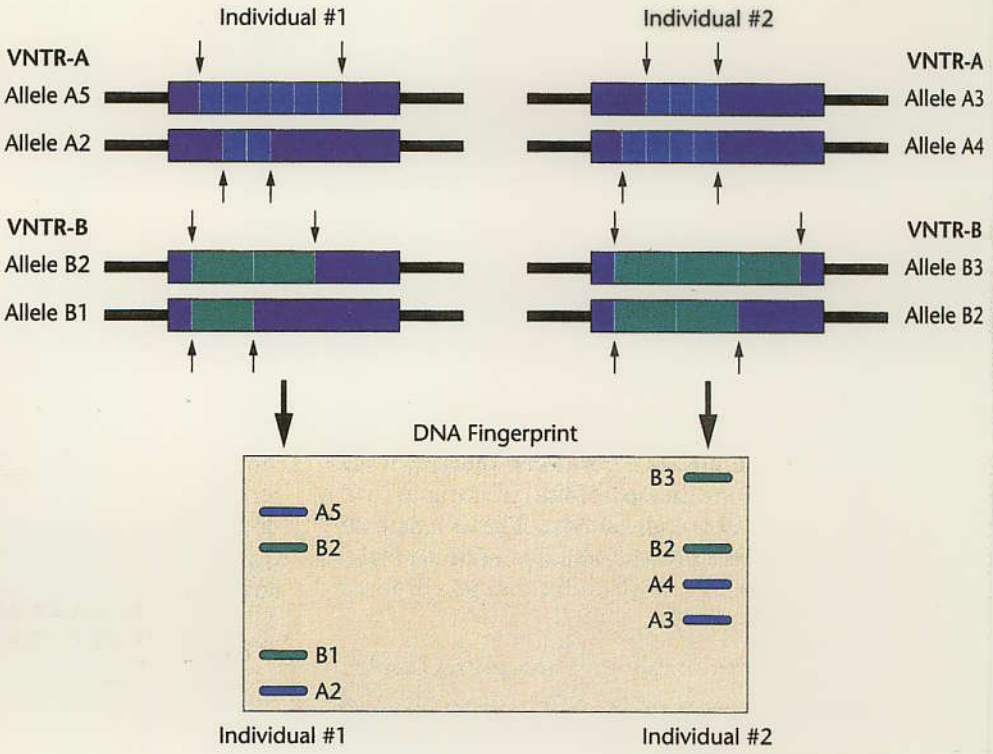


FIGURE 21.15 VNTR loci and DNA fingerprints. VNTR alleles at two loci (A and B) are shown for each individual. Arrows mark restriction cutting sites flanking the VNTRs. Restriction digestion produces a series of fragments that can be detected as bands on a Southern blot (below). Because of differences in the number of repeats at each locus, the overall pattern of bands is distinct for each individual, even though one band is shared (the band representing the B2 allele). Such a pattern is known as a DNA fingerprint. GenCDX

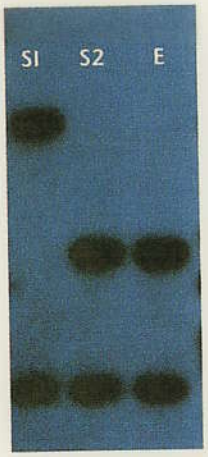


FIGURE 21.16 DNA fingerprinting in a forensic case. The DNA profile of suspect 2 (S2) matches that of the blood sample obtained as evidence E.

Meiosis + Generation of Allelic Variability

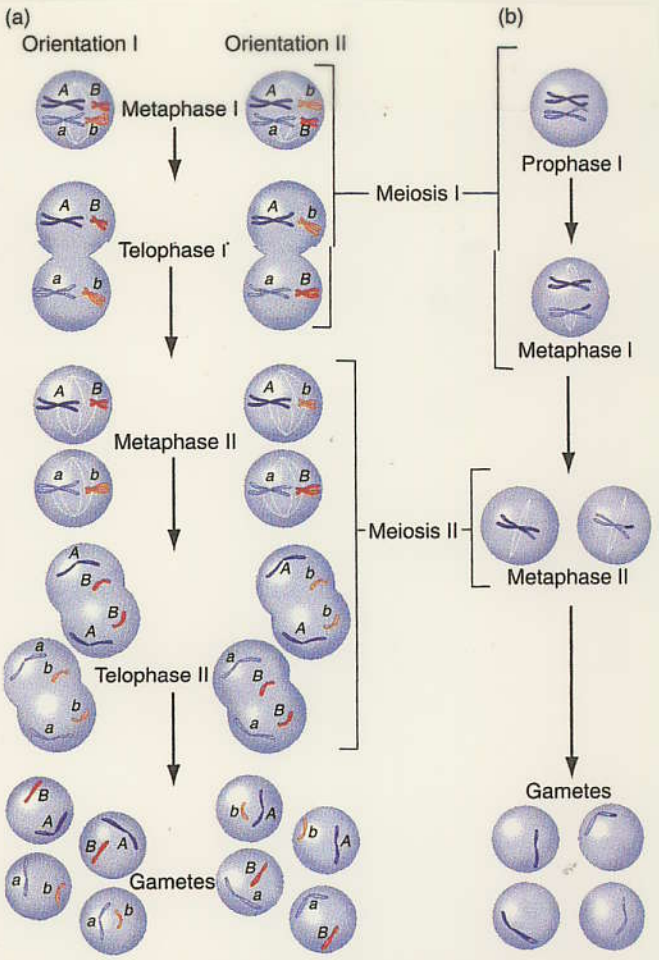
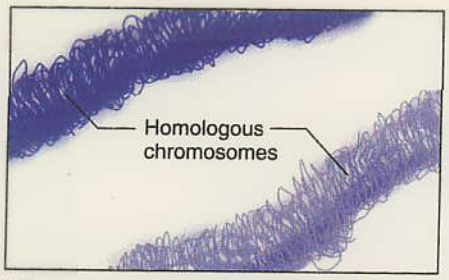
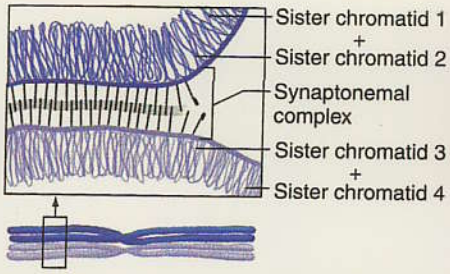


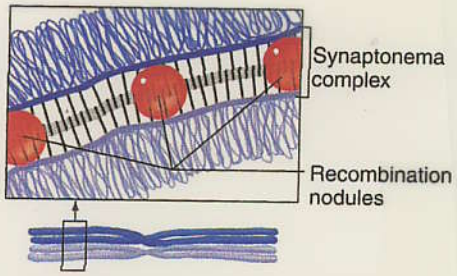
Figure 3.17 How meiosis contributes to genetic diversity. (a) The independent assortment of different pairs of homologous chromosomes. The variation resulting from independent assortment increases with the number of chromosomes in the genome. (b) Crossing-over between homologous chromosomes ensures that each gamete produced by any individual will be unique.



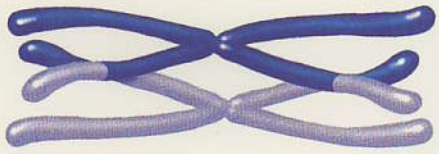
(a) Leptotene: Threadlike chromosomes begin to condense and thicken, becoming visible as discrete structures. Although the chromosomes have duplicated, the sister chromatids of each chromosome are not yet visible in the microscope.



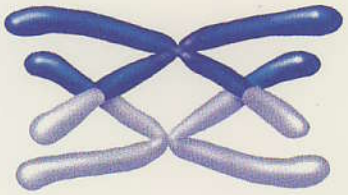
(b) Zygotene: Chromosomes are clearly visible, and begin active pairing with homologous chromosomes along the synaptonemal complex to form a bivalent, or tetrad.



(c) Pachytene: Full synapsis of homologues. Recombination nodules appear along the synaptonemal complex.



(d) Diplotene: Bivalent appears to pull apart slightly, but remains connected at crossover sites, called chiasmata.



(e) Diakinesis: Further condensation of chromatids. Nonsister chromatids that have exchanged parts by crossing-over remain closely associated at chiasmata.

GENERATING Allelic Diversity at VNTR Loci by unequal crossing over

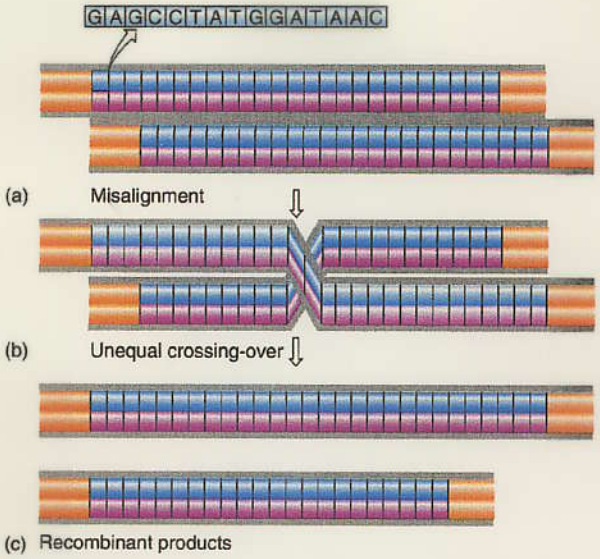


Figure 9.4 Minisatellites are highly polymorphic because of their potential for misalignment and unequal crossing-over. Minisatellites are composed of relatively long tandem repeating units of identical sequence. (a) Misalignment and (b) unequal crossing-over produce (c) recombinant products that contain different numbers of repeating units than either parental locus; each new recombinant product is a new allele.

ASSAYING FOR VNTR ALLELES USING RESTRICTION ENZYMES + DNA BLOTS

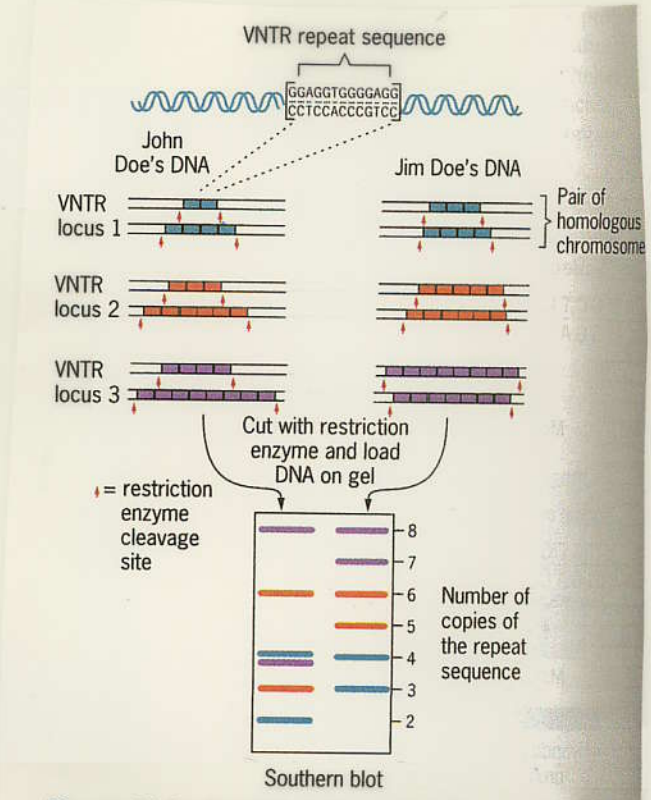
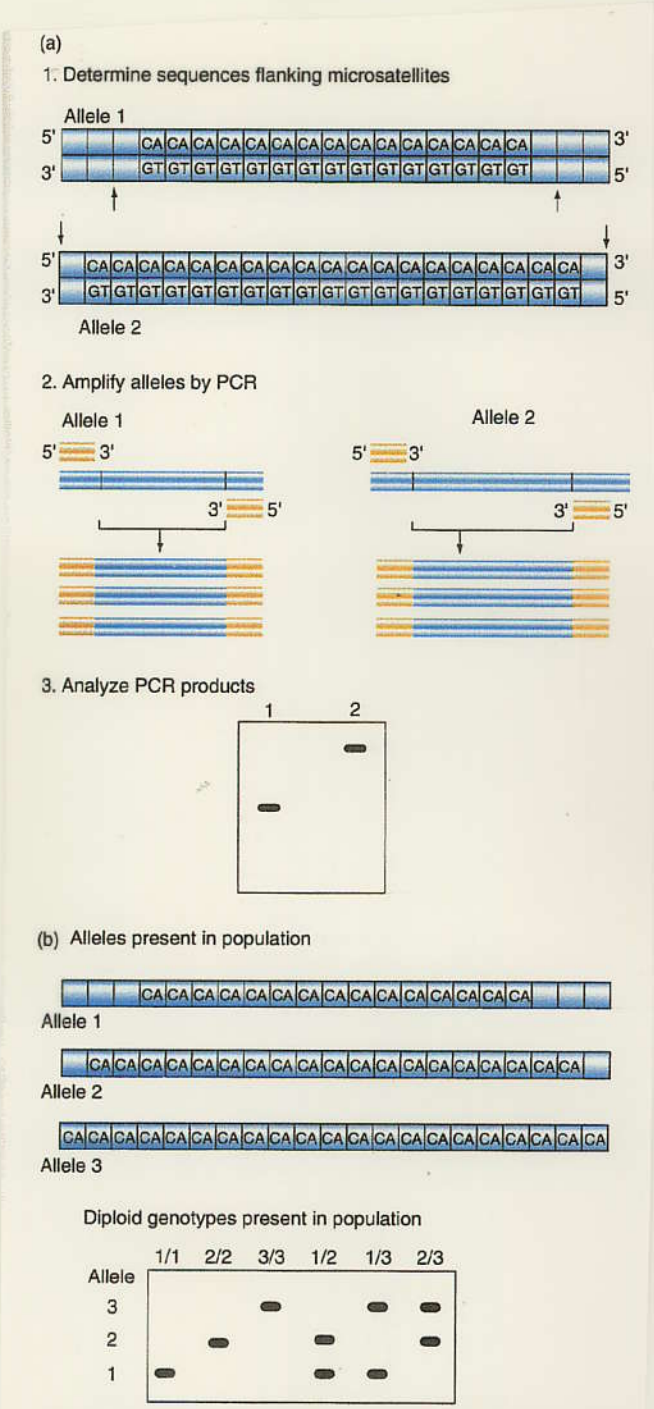


Figure 22.8 Simplified diagram of the use of variable number tandem repeats in preparing DNA fingerprints.

Assaying for VNTR Alleles Directly

Using PCR + Gels!



Primers specific for each Loci

Repeats cause a size change

Detected on Gel

Figure 9.12 Detection of microsatellite polymorphisms by PCR and gel electrophoresis. (a.1) Microsatellite alleles differ from one another in length. (2) Sequence determination from both sides of a microsatellite enables the construction of primers that can be used to amplify the microsatellite by PCR. (3) Gel electrophoresis and ethidium bromide staining distinguish the alleles from each other.
(b) Microsatellites are often highly polymorphic with many different alleles present in a population. With just three alleles, there are six possible genotypes. With N (any number of) alleles, there will be $\frac{N}{2}(N + 1)$ genotypes.

AUTOMATED UNTR (STR) Allele Analysis Using Currently FOR FORENSICS

1. Extract DNA
2. Amplify using fluorescent primers
3. Specific color FOR EACH LOCUS + Set of Alleles FROM That LOCUS
4. Detect on sequencing machine

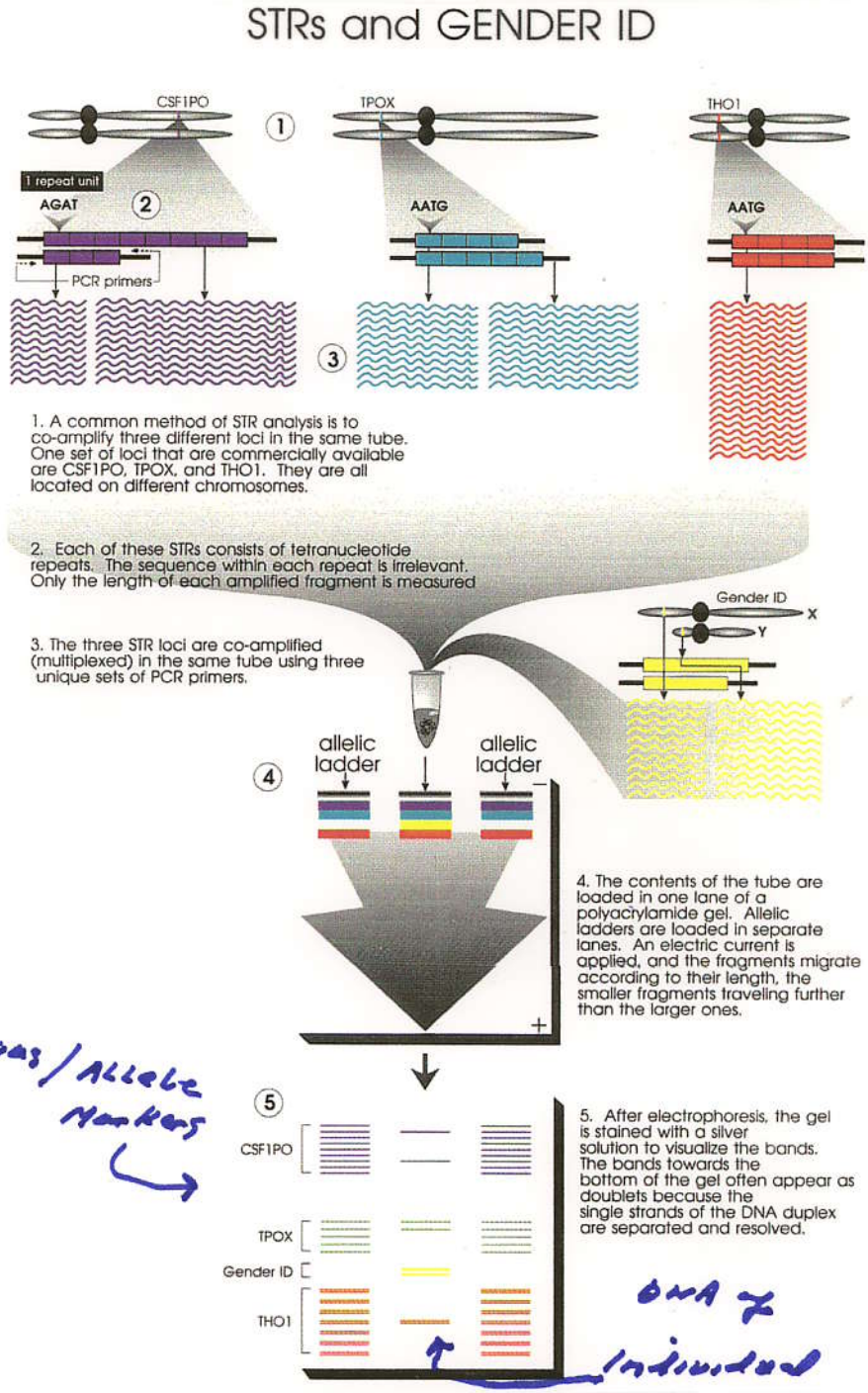
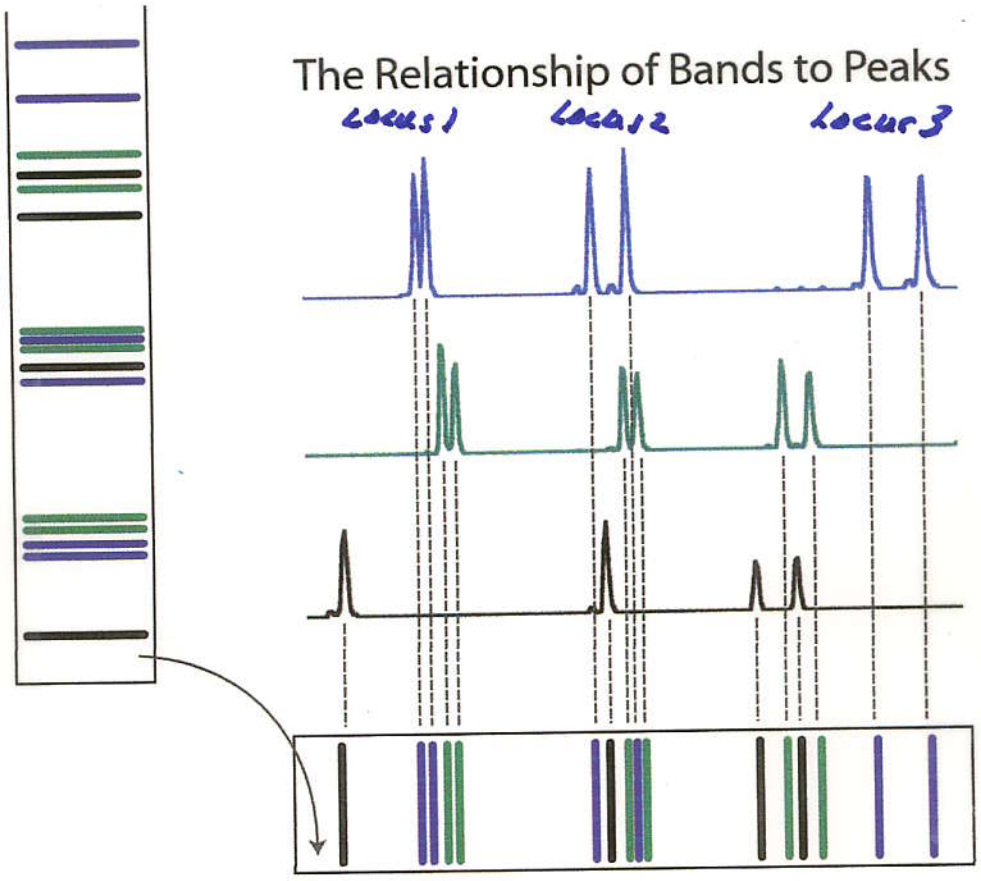


Plate 8 STR analysis. The diagram depicts PCR amplification, gel electrophoresis, and manual detection by silver staining of an STR triplex plus Amelogenin (gender ID). The same general process can be used for any amplified fragment length polymorphism.

SEQUENCING MACHINE detects FLUORESCENCE with a LASER

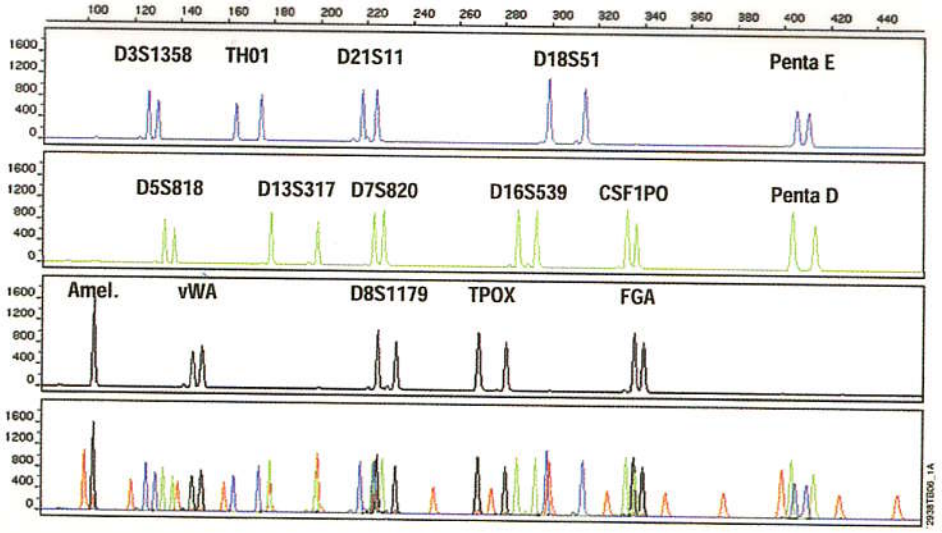


Note – 2 alleles per Locus

DNA Fingerprint of individual at 9 Loci

Plate 9 The relationship of bands to peaks. Analysts are most familiar with reading bands on gels after electrophoretic separation of DNA, but STR kits using fluorescently tagged primers require different visualization techniques. Using recent hardware and software innovations, electrophoretically separated DNA fragments are represented as peaks emerging from the instrument over time. Here, a typical band pattern of an electrophoretic separation is represented on the left. Imagine taking the top of this band pattern and rotating it clockwise down to the right corner of the illustration. The band pattern is now horizontal rather than vertical, and each band is represented by a peak above the band. The three colors representing the different fluorescent dye primer tags are each printed on a separated horizontal panel.

AUTOMated DNA Finger Printing at 16 loci at once!!



5 loci

6 loci

5 loci

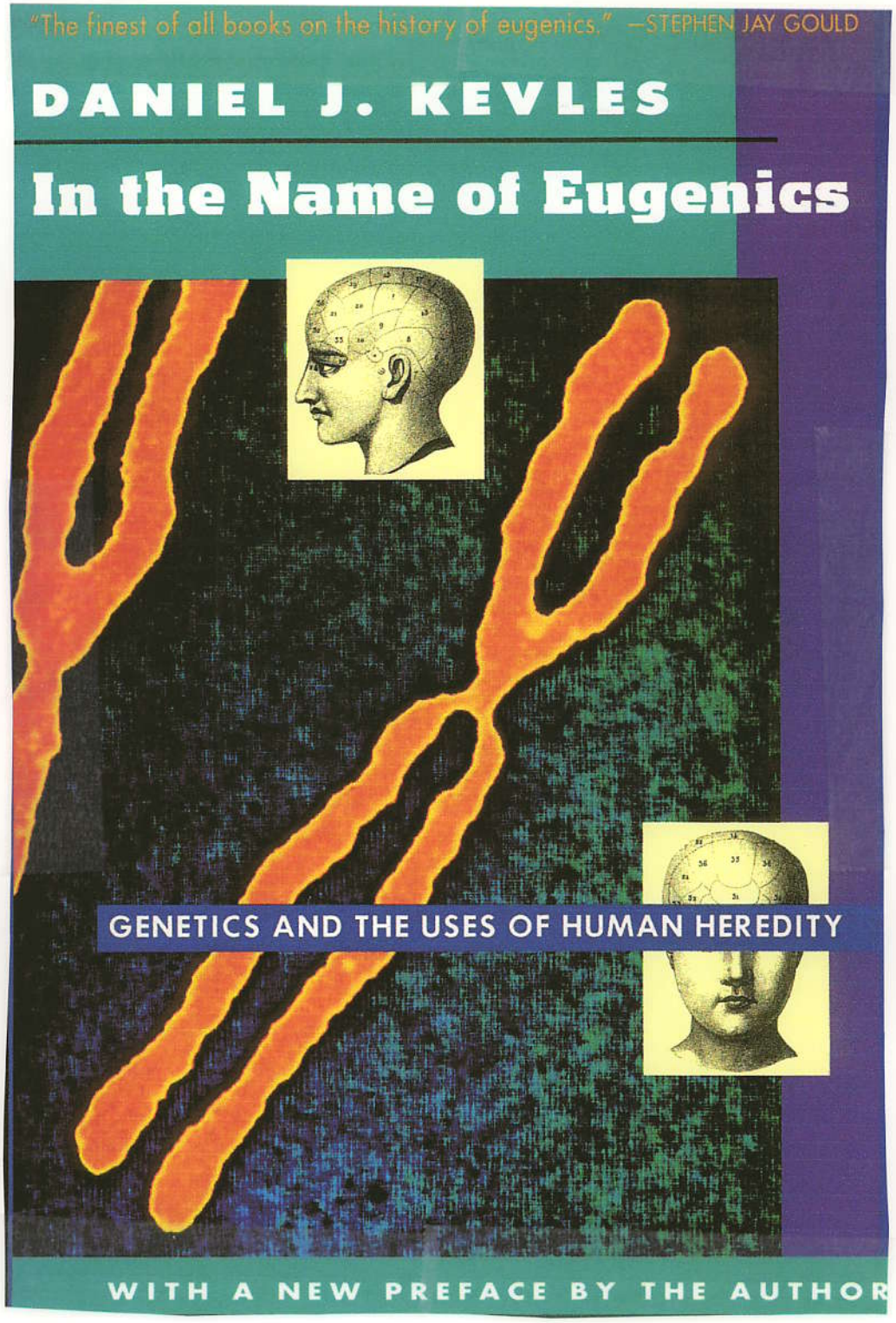
16 loci

32 alleles!

Plate 13 PowerPlex®16. The DNA profile from a single individual at 16 different loci using three fluorescent dyes. The profile is represented in two ways. Each of the top three panels shows alleles for specific loci in the different dye colors; the bottom panel is a composite of the top three panels, as well as the internal lane standard in a fourth color (red). (Courtesy of Promega Corporation.)

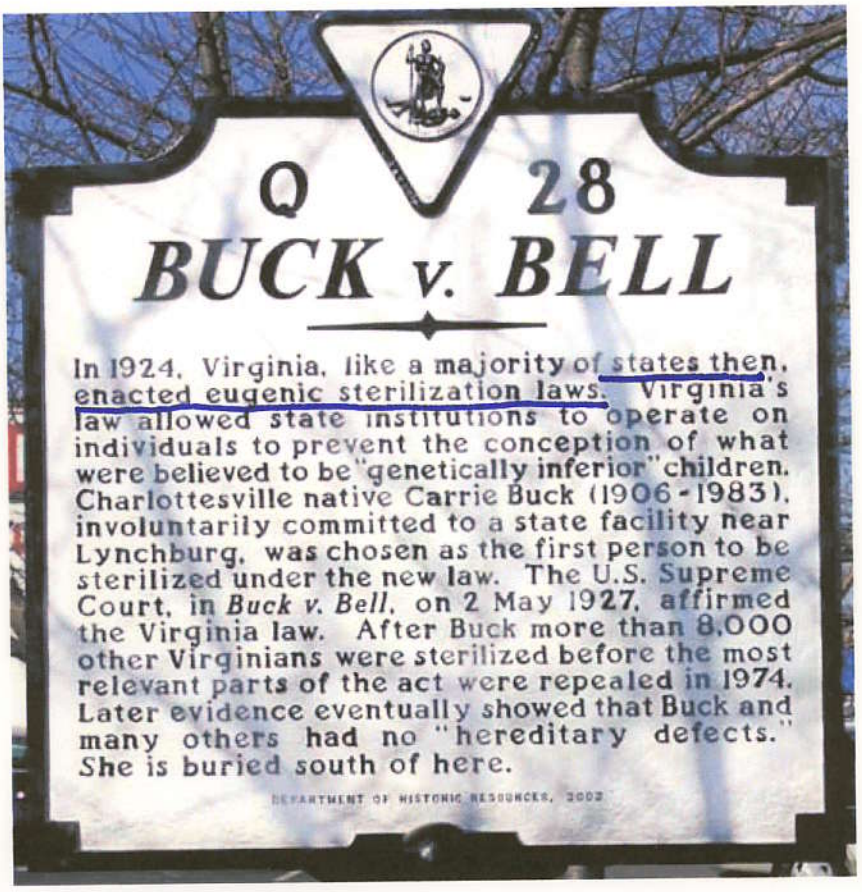
PCR-BASED
FAST
SIMPLE
Highly Accurate!
Cheap!

What is the History of "Gene" Laws in the US?



Eugenics

Exhibit 5.4: Historical Marker



Historical marker erected on May 2, 2002.

photo credit: Courtesy of Historical Collections, Claude Moore Health Sciences Library, University of Virginia.

better "left behind in the cast-off junk of ignorant efforts, with which the past is filled."[41]

By the outbreak of the First World War, sterilization laws were in such dispute as to have been de facto suspended in their operation in a number of states. The courts had also declared unconstitutional not only the stringent Iowa statute but less sweeping measures in six other states. Advocates of eugenic sterilization, frustrated at the legal impasse, wanted to take the issue to the Supreme Court. In Virginia, eugenicists helped draw up a sterilization statute, passed by the legislature in March 1924, that was designed to meet the constitutional objections. The opportunity to press a test case arose that June, when a seventeen-year-old girl named Carrie Buck, who seemed definable as a "moral imbecile," was committed to the Virginia Colony for Epileptics and Feebleminded, in Lynchburg.[42]

Carrie's mother, Emma, had lived at the Colony since 1920 and was also certified to be feebleminded. Carrie herself had conceived a child out of wedlock, and shortly before her commitment, she gave birth to a daughter, Vivian. Carrie was given the Stanford revision of the Binet-Simon I.Q. test and was found to have a mental age of nine years, well within Henry Goddard's definition of "moron." Carrie's mother was found to have a mental age of slightly under eight years. Thus, according to these results, there was mental deficiency in two successive generations. If Vivian could be shown to be feebleminded too, Carrie would be a perfect subject for a test of the Virginia sterilization statute. In September 1924, the Colony's board of directors ordered Carrie Buck sterilized, and a court-appointed guardian initiated legal proceedings by appealing the order in a suit on Carrie's behalf against the superintendent of the Colony, Albert S. Priddy.[43]

In preparing their case, Virginia officials consulted Harry Laughlin at the Eugenics Record Office. Laughlin examined the pedigrees of Carrie, her mother, and her daughter, and information about them given him by Colony officials, and—without ever having seen them in person—provided an expert deposition that Carrie's alleged feeblemindedness was primarily hereditary. Carrie and her forebears, Laughlin submitted, "belong to the shiftless, ignorant, and worthless class of anti-social whites of the South." At the time of Laughlin's deposition, however, there was no evidence at all that Vivian was mentally deficient. To clarify the matter, Caroline E. Wilhelm, a Red Cross worker who had placed Vivian in a foster home, was prevailed upon to examine her there. At the initial hearing, in the Circuit Court of Amherst County, she testified that there was "a look" about Vivian (who at the time of the visit was seven months old) which was "not quite normal." Evidence also came from Arthur Estabrook of the Eugenics Record Office, who had subjected Vivian to a mental test for an infant and concluded that she was below average for a child her age. In the court

proceeding, Estabrook testified that the feeblemindedness in the Buck line conformed to the Mendelian laws of inheritance, and the judge upheld the sterilization order.[44]

The case—now known as *Buck* v. *Bell*, because Priddy had in the meantime died and been replaced as the defendant by the Colony's new superintendent, John H. Bell—was carried to the Virginia Supreme Court of Appeals in 1925, and the sterilization order was again upheld. In April 1927 it was argued before the United States Supreme Court. Carrie's defense counsel, I. P. Whitehead, a onetime member of the board of directors of the Colony, attacked the sterilization statute, warning that under this type of law a "reign of doctors will be inaugurated and in the name of science new classes will be added, even races may be brought within the scope of such a regulation and the worst forms of tyranny practiced." Nevertheless, the Court was persuaded not only that Carrie Buck and her mother were "feebleminded" but also—because Vivian was, too (or so all the experts said)—that the feeblemindedness was heritable. The Court, whose membership ranged in political conviction from William Howard Taft to Louis D. Brandeis, upheld the Virginia statute by a vote of eight to one. The sole dissenter was Justice Pierce Butler, a conservative, and he kept his minority opinion to himself. The decision declared that sterilization on eugenic grounds was within the police power of the state, that it provided due process of law, and that it did not constitute cruel or unusual punishment.[45]

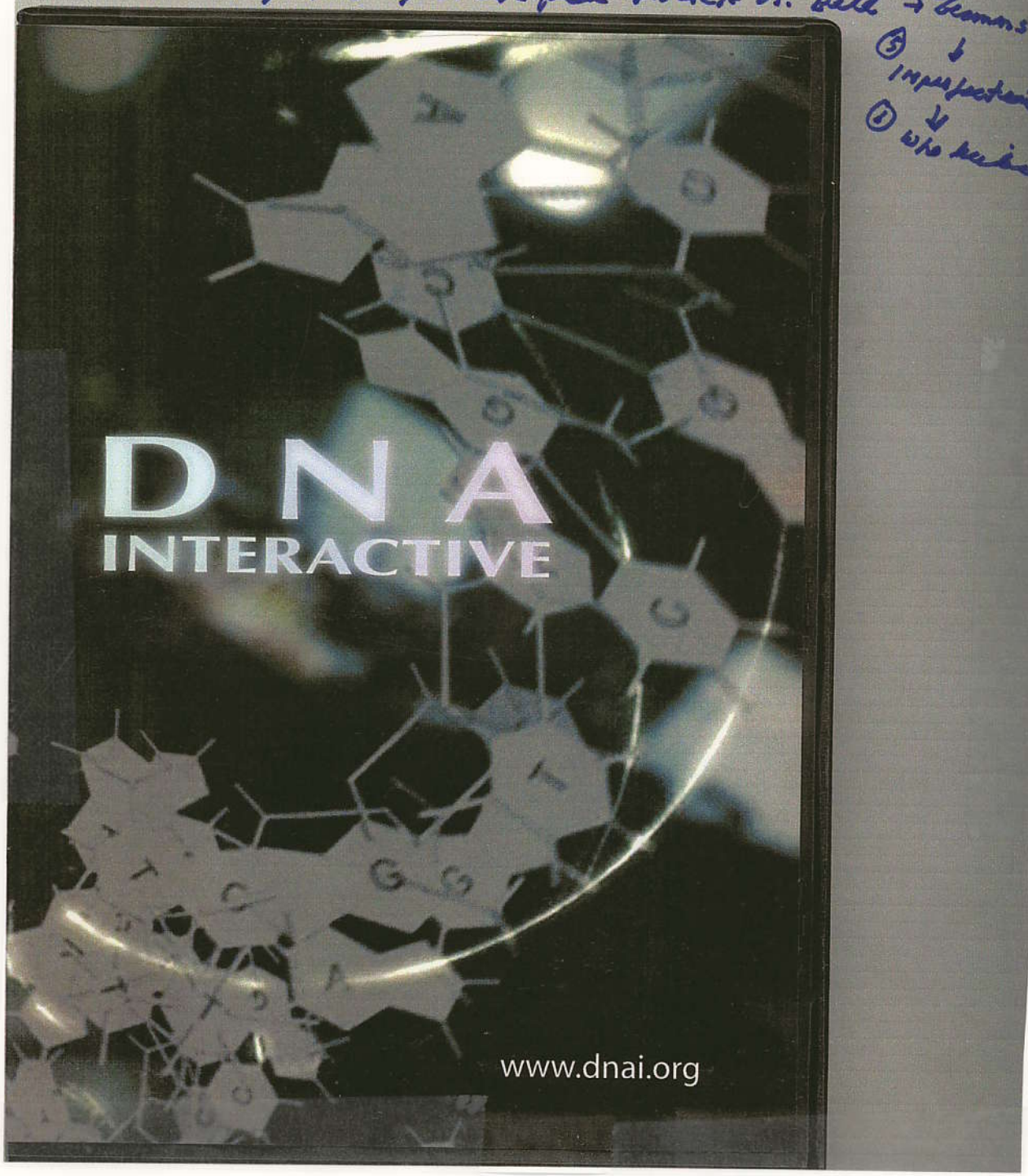
The Court's opinion was written by Justice Oliver Wendell Holmes, an enthusiast of science as a guide to social action, who managed to find a link between eugenics and patriotism: "We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices . . . in order to prevent our being swamped with incompetence. . . . The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes." With deliberate punch Holmes asserted: "Three generations of imbeciles are enough."[46]

Eugenicists naturally rejoiced at *Buck* v. *Bell*. For some years prior to the decision, the American Eugenics Society had promoted what it thought might be a constitutional revision of the faulty sterilization statutes. Apart from procedural and technical changes, the revisions centered on making the laws eugenic rather than punitive in intent. After *Buck* v. *Bell*, what was constitutional was clear. By the end of the nineteen-twenties, sterilization laws were on the books of twenty-four states, with the South no longer a regional exception. (Though now severely restricted by federal regulation, they are still on the books of twenty-two states today.) The laws were not uniformly enforced, but Carrie Buck was sterilized soon after the Court's

decision, and officials at the Virginia Colony subjected other inmates to the procedure—a total of about a thousand in the next ten years. By the mid-thirties, some twenty thousand sterilizations had been legally performed in the United States.[47]

Buck v. *Bell* generally stimulated either favorable, cautious, or—most commonly—no editorial comment. Few if any newspapers took notice of the impact of the decision on civil liberties in the United States. The I.Q. tests used in the Buck case have long since been discredited as indicators purely of general intelligence. With regard to the allegedly hereditary nature of mental defect in the Buck line, it is of interest that Carrie's daughter Vivian went through the second grade before she died of an intestinal disorder in 1932. Her teachers reportedly considered her very bright.[48]

Themes → Ethics & Implications ③ → Eugenics
① American perspective → ② Sterilization → Buck vs. Bell → ④ Genomes & Imperfections ↓ ⑤ Who benefits?



Eugenic Laws currently in Place!

CHINA'S GENETIC LAW

P.S. Harper

INTRODUCTION

On 1 June 1995, the People's Republic of China brought into force the first clearly eugenic law that the world has seen since modern genetics began to have impact on medical practice. Innocuously entitled the law on "Maternal and Infant Health Care", it contains, among other more general and uncontroversial proposals, clauses that are of profound significance for the application and perception of genetics far beyond the boundaries of China itself. Whether this law will lead to what would generally be considered the abuse of genetics remains to be seen, but the rulings would certainly legitimize, in the strict sense of the word, practice that would be unacceptable to the medical genetics community in most of the world.

Because of these wider implications, and because China itself contains one-third of the world's population, it is worth looking closely at this development; having myself been peripherally involved over a long period, and having found that many professionals in genetics are entirely unaware of the whole topic, I give here some background material that may help to put it into perspective.

First, it is relevant to quote (from the official Chinese translation) [1] some of the clauses in the law that specifically involve genetic disorders.

LAW OF THE PEOPLE'S REPUBLIC OF CHINA IN MATERNAL AND INFANT HEALTH CARE

Adopted at the 10th Meeting of the Standing Committee of the Eighth National People's Congress on 27 October 1994, promulgated by Order No. 33 of the President of the People's Republic of China on 27 October 1994, and effective as of 1 June 1995.

Article 8 The pre-marital physical check-up shall include the examination of the following diseases:

(i) genetic diseases of a serious nature;
(ii) target infectious diseases; and
(iii) relevant mental disease.

The *medical and health institution shall* issue a certificate of pre-marital medical check-up thereafter.

Article 10 Physicians shall, after performing the pre-marital physical check-up, explain and give medical advice to both the male and the female who have been diagnosed with certain genetic disease of a serious nature which is considered to be inappropriate for child-bearing from a medical point of view; the two may be married only if both sides agree to take long-term contraceptive measures or to take ligation operation for sterility. However, the marriage that is forbidden as stipulated by the provisions of the Marriage Law of the People's Republic of China is not included herein.

Article 16 If a physician detects or suspects that a married couple in their child-bearing age suffer from genetic disease of a serious nature, the physician shall give medical advice to the couple, and the couple in their child-bearing age shall take measures in accordance with the physician's medical advice.

Article 18 The Physician shall explain to the married couple and give them medical advice for a termination of pregnancy if one of the following cases is detected in the prenatal diagnosis:

(i) the fetus is suffering from genetic disease of a serious nature;
(ii) the fetus is with defect of a serious nature; and
(iii) continued pregnancy may threaten the life and safety of the pregnant woman or seriously impair her health due to the *serious disease she suffers* from.

Supplementary provisions

'Genetic diseases of a serious nature' refer to diseases that are caused by genetic factors congenitally, that may totally or partially deprive the victim of the ability to live independently, that are highly possible to recur in generations to come, and that are medically considered inappropriate for reproduction;

'Relevant mental diseases', refer to schizophrenia, manic-depressive psychosis and other mental diseases of a serious nature.

It could of course be argued, (and has been within China) that these proposals are simply the practical way of a country with relatively undeveloped services trying to ensure that prenatal diagnosis of genetic disorders and comparable measures are actually made available to its population; also that with a 'one child policy', such as already exists in China, it is important to ensure that the child born does not have avoidable handicap. It is certainly true that the law stipulates that decisions are to be made by appropriately trained people (article 26), while fetal sexing on non-medical grounds is specifically prohibited (article 32).

It is impossible though to deny the directive, even coercive tenor of the genetic clauses in the law, while its linkage with infectious diseases and mental illness makes it clear that genetic disorders are being considered primarily as a public health issue.

Why should China have produced a law of this type at a time when virtually all other countries have moved away from restrictive or eugenic legislation for

genetic disorders? It is difficult for an outsider to be sure on this, but that broader political factors have been involved is clear from the following official commentary on the draft version of the law, produced a year before the final form [2].

HEALTH MINISTER PRESENTS EUGENICS LAW TO NPC STANDING COMMITTEE

(a) Xinhua new agency, Beijing in English 1114 Greenwich Mean Time (GMT), 20 Dec. 93.

Text of report

China is to use legal means to avoid new births of inferior quality and heighten the standards of the whole population. The measures include deferring the date of marriage, terminating pregnancies and sterilization, according to a draft law on eugenics and health protection which was presented to the current session of the Eighth National People's Congress (NPC) Standing Committee.

Explaining the law to participants at an NPC session that opened here today (Beijing, 20th December) Minister of Public Health, Chen Minzhang, said that the measures will help prevent infections and hereditary diseases and protect the health of mothers and children.

Under the draft law, those having such ailments as hepatitis, venereal disease or mental illness, which can be passed on through birth, will be banned from marrying while carrying the disease. Pregnant women who have been diagnosed as having certain infectious diseases or an abnormal foetus will be advised to halt the pregnancy. Couples in the category should have themselves sterilized, the draft says.

China is in urgent need of adopting such a law to put a stop to the prevalence of abnormal births. Minister Chen explained statistics show that China now has more than 10 million disabled persons who could have been prevented through better controls.

The draft also stipulates that organizations that are engaged in pre-marital checks, eugenics, pre-birth diagnosis or sterilizations should be approved by the authorities at the county level and above. Chen said, "Personnel involved in this area should be subjected to strict training".

The Minister of Public Health called on medical authorities at various levels to establish a comprehensive network for the implementation of the law.

The draft does not state whether China will adopt euthanasia to eliminate congenitally abnormal children, saying that the international community has not come to a conclusion on that issue. The draft also does not touch on the issues of artificial fertilization or test-tube babies because the effects of these techniques have caused some disputes and because it's too early to put any limitations into law.

note: use of interior quality!

Note: Cultural differences from us

Points of law

Is China's law eugenic?

China's approach to family planning has been attacked in the West as authoritarian and an infringement on individual rights. Below, Chinese Academician Qiu Renzong rejects claims that his country's Law on Maternal and Infant Health is eugenic. Overleaf, a German Sinologist challenges Qiu Renzong's position.

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1. 'A concern for collective good'

Qiu Renzong, Bioethics programme director, Chinese Academy of Social Sciences, Beijing.

China's Law on Maternal and Infant Health (see box opposite page) has attracted considerable criticism in the Western media and scientific circles. Some of the criticism is valid but some is based on misunderstandings caused by linguistic or cultural barriers. Much of the confusion revolves around the word yousheng, which repeatedly occurs in the legal text. A tricky word with dual meanings, it is commonly used to mean "healthy births" in association with child-rearing. However, yousheng can also be used to describe eugenic programmes such as that practised by the Nazis. Unfortunately, English translations of the law tend to reflect this latter meaning.

Is the Maternal and Infant Health Law eugenic? I would argue that for a policy to be eugenic it must first reject individual consent and second, be based on racism. Neither of these conditions applies to China's law. While doctors may advise two individuals at risk of passing on hereditary disease to refrain from marrying or to undergo sterilization, the ultimate decision is left to these adults. When prenatal testing reveals genetic disease, a doctor will offer advice—not a directive—concerning abortion.

If the twentieth part of the cost and pains were spent in measures for the improvement of the human race that is spent on the improvement of the breed of horses and cattle, what a galaxy of

The way to a higher domain

It is also crucial to recognize that the law is not motivated by racism but by a desire to reduce birth defects. Indeed, there is no racist tradition in China. The Chinese have been the victims of Western imperialism and Japanese militarism. They may have made grave

genius might we not create.

Francis Galton, British scientist, initiator of the study of eugenics (1822-1911)

mistakes, but they have never claimed superiority over another people, and their military actions have never been motivated by racism. Nor is racism part of China's internal policies. The Han, China's dominant ethnic group, do not claim superiority over China's minorities. Westerners are often shocked by Chinese attitudes to defective foetuses because they do not understand the cultural and economic factors involved. The great Confucianist Xun Zi (300-237 BC) said: "Birth is the beginning of a human being, and death is the end of a human being. A human being who has a good beginning and a good end fulfills the Tao [the Way to a higher spiritual domain]." Two major factors shaping genetic policy in China emerge from this Confucian view. First, abortion is morally and socially acceptable because life begins with birth. A foetus is not considered a human being. Second, congenital disease and deformity are considered a sign of sin committed by the parents or ancestors in their previous life. Given that a defective newborn child is traditionally called a "monster foetus", it is not surprising to find little in the way of familial or social support. One of the parents of a deformed baby will usually have to stop working, and the costs of caring for such a child can amount to a third of an average worker's salary.

Points of law

The following are key excerpts from the official translation of China's Maternal and Infant Health Care Law, which came into effect in 1995.

Article 8: The pre-marital physical check-up shall include the examination of the following diseases: (i) genetic diseases of a serious nature; (ii) target infectious diseases; and (iii) relevant mental disease.

Article 10: Physicians shall, after performing the pre-marital physical check-up, explain and give medical advice to both the male and the female who have been diagnosed with certain genetic disease of a serious nature which is considered to be inappropriate for child-bearing from a medical point of view; the two may be married only if both sides agree to take

Poverty

Changing these negative attitudes will take a great deal of time. There are now more than 50 million handicapped people, mostly living in poverty, and it is unreasonable to expect any major improvements in the treatment of handicapped children and their mothers in the near future. In this context, many feel that these children and their mothers would be better off if the handicapped had never been born. In fact, the Chinese Association of the Handicapped formally urged the government in 1989 to speed up legislation to prevent the birth of deformed babies, given their suffering and the burden they represent for society.

The concern for the collective good has at times led geneticists and others in China to infringe upon individual autonomy. They have confused what is technologically possible (genetic testing) with what is ethically permissible. However, I feel that the law is a positive step towards guaranteeing everyone access to genetic counselling and to prohibiting sex-selection. Chinese geneticists and bioethicists have criticized some articles of the law. Their suggestions include more explicit recognition of the principle of informed consent. Last year, the authorities consulted leading Chinese bioethicists and geneticists and will make the needed changes at an appropriate time. Meanwhile, I

CULTURAL differences!

(1) Note Birth Beginning of Life!

(2)

(3) Collective good!

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STATEMENT OF THE BOARD OF DIRECTORS OF THE AMERICAN SOCIETY OF HUMAN GENETICS:
Eugenics and The Misuse of Genetic Information to Restrict Reproductive Freedom

Approved by the ASHG Board of Directors, October 1998

Introduction

The global scientific community is making extraordinary advances in understanding the human genome. This knowledge has contributed many important medical benefits. Yet, concern about the possibility of misuse of genetic concepts and genetic information may be as great today as at any time since World War II. Many fear that as we learn more about how genes vary and function, some individuals or institutions may be tempted to ascribe an overly deterministic influence to their role in shaping human health and potential and pursue social policies that limit or constrain reproductive freedom.

Therefore, the Board of Directors of the American Society of Human Genetics reaffirms its commitment to the fundamental principle of reproductive freedom and unequivocally declares its opposition to coercion based on genetic information.

Statement

The American Society of Human Genetics recognizes that genetic variation can significantly influence risk for disease and the nature of an individual's future health and that many human capacities and talents are influenced by genes.

The American Society of Human Genetics deplores laws, governmental regulations and any other coercive effort intended to restrict reproductive freedom or constrain freedom of choice on the basis of known or presumed genetic characteristics of potential parents or the anticipated genetic characteristics, health or capacities of potential offspring.

The American Society of Human Genetics recognizes the need for international cooperation to protect reproductive freedom and stands ready to work with colleagues in and outside the field of human genetics to achieve this goal.

The American Society of Human Genetics believes that the best way to prevent genetic information from being used to restrict reproductive freedom is to educate the public (in particular those directly involved in setting public policy) about the scope and limitations of our understanding of genetics and genetic tests. It is especially important that individuals be educated about how to ask for and obtain appropriate genetic information and that health care providers be educated to assist them.

Background

A Note on Language

The drafting of this document was complicated by the substantial variations in meaning given to the word "eugenics". Ultimately, the drafters decided to de-emphasize that word. Yet, because on many occasions during this century scientifically unsound and socially harmful policies have been implemented in many nations in the name of eugenics, a comment on the term is warranted.

When Francis Galton (1883) coined the term eugenics, he took it from the Greek; eu means "good" and genic derives from the word for "born". Galton defined it as "the science of improvement of the human race germ plasm through better breeding." At the height of the eugenics movement in the 1920s, the Encyclopedia Britannica (1926) entry on eugenics emphasized that the term connoted a "plan" to influence human reproduction. A typical modern dictionary definition is "a science that deals with the improvement (as by control of human mating) of hereditary qualities of a race or breed" (Webster's 1983). Although it is not apparent from the dictionary definition, the word has a pejorative connotation, and is frequently used in reference to governmentally driven policies to limit reproductive freedom. Knowledge-based decisions made by individuals or couples to avoid the birth of a child with disease or disability, so long as they are not unduly influenced by coercive governmental, institutional, or other policies, are acceptable.

Many public health practices to improve the health of living or future people have been implemented to achieve laudable goals. Examples include newborn screening programs to identify infants with disorders for which early treatment is beneficial, the provision of prenatal diagnostic services, maternal vaccination for rubella, addition of folic acid to food to reduce the risk of certain birth defects, and warnings on alcohol or cigarette labels about the potential for damage to the fetus. The American Society of Human Genetics views prenatal screening and diagnostic programs, including those undertaken with the knowledge that an individual who chooses to be tested may seek selective termination of pregnancy, as acceptable so long as individuals are not coerced.

Historical Note

Many nations have a history of eugenic thought or practice based on perceived genetic risks. It is important to note that such practices were based on little or no scientifically defensible beliefs. Some have tried to keep gene pools separate by forbidding unions between members of different social groups. For example, the caste system in India may represent the largest such eugenic program ever, spanning almost 2500 years (Dobzhansky 1973). Anti-miscegenation laws in the United States, which appeared as early as 1630 in the colonies and existed until they were struck down as unconstitutional in 1967, were premised in part on the erroneous notion that interracial marriage produced children of reduced genetic quality.

Galton used the word eugenics to characterize efforts to produce children who would be well born. However, he did not merely desire that as many infants as possible be born healthy. His real goal was to insure that as large a fraction as possible of each generation be the offspring of what he considered the best "stock." By 1883 Galton, who then had been studying human heredity for almost 20 years, was convinced that the British upper classes were having too few children to maintain what he considered their crucially important contribution to the gene pool of Victorian England. He exhorted the upper classes to have more children. Over the next 30 years this idea garnered much interest. Among its most famous proponents in the United States was President Theodore Roosevelt, who warned that the failure of couples of Anglo-Saxon heritage to have large enough families would lead to "race suicide" (Reilly 1991). Roosevelt's support of eugenic ideals reflects the popular appeal of eugenics during the first half of this century. Adherents included liberals and conservatives, progressives and libertarians. In the early decades of this century the emphasis on encouraging reproduction among those assumed to possess a superior genetic endowment became known as "positive eugenics."

The term immediately suggests a contrasting policy, "negative eugenics", which emerged at about the same time. The goal of negative eugenics is the restriction of parenting by "undesirable" individuals, presumably because of a strong likelihood that their children would be "unfit". During the first half of the twentieth century, the United States, implemented two "negative eugenics" programs. The United States immigration policy that was erected in the 1920s and dismantled in 1968 favored immigrants from northern and western Europe over other peoples. It was rationalized during Congressional testimony by a self-described eugenics

Immigration Laws
Sterilization Laws – negative Eugenics

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expert who strongly favored the quota system that became the centerpiece of the law (Reilly 1991). The United States never enacted a federal sterilization statute, but about 30 states did, many after the Supreme Court upheld a Virginia law that permitted state officials to sterilize institutionalized retarded persons whom a physician determined likely to become the parent of children with similar deficits (Buck v. Bell 1927). Between 1907 and 1960 in the United States at least 60,000 people were sterilized without their consent pursuant to these state laws. During the 1930s, the heyday of these programs, about 5,000 persons were sterilized each year. The majority were young women for many of whom the evidence of genetically caused mental retardation was poor or non-existent (Reilly 1991). Geneticists were not active participants in these programs; with few exceptions, however, neither were they public critics.

England never enacted an involuntary sterilization law, nor launched a coercive private effort. In Canada, the Province of Alberta was strongly influenced by sterilization programs in the United States. Alberta had an active program from 1928 until 1960, pursuant to which several thousand people were sterilized (Caulfield and Robertson 1996). A class action lawsuit by many of the surviving individuals was recently settled with the government (Muir 1996).

Although arguments for maintaining racial purity abound in nineteenth century German literature, the Nazis were also influenced by events in the United States. The 1934 German racial hygiene law relied on a model bill written by the American eugenicist, Harry Hamilton Laughlin, who for three decades directed the Eugenics Record Office at Cold Spring Harbor. In its first full year of operation the Nazi program dramatically eclipsed activities in the United States, sterilizing about 80,000 persons without their consent. The much grander scope was achieved because the Nazi law applied to the entire population (rather than institutionalized persons), created a system of "hereditary health courts" designed exclusively to hear and process petitions for sterilization, and permitted petitions proposing that an individual should be sterilized to be filed by a broad range of citizens.

The German sterilization program quickly evolved to target and eliminate retarded and epileptic children, the mentally ill, and other groups. The program has been called a precursor to the gas chambers. During the early years (1934-38) the Nazi sterilization program was not primarily an attempt to improve the gene pool. It focused on eliminating "useless eaters" - persons who would consume resources without contributing to their production. One exception was persons with Huntington disease. It was a stated goal of the Nazis to sterilize as many persons at risk for this disorder as possible. The Nazi sterilization program owed part of its success to the efficiency with which the government maintained patient registries which made it comparatively easy to locate persons with various disorders (Burleigh 1994).

Often overlooked in discussions of Nazi eugenic practices are the sterilization programs that were implemented during the 1930s in other European countries (Adams, 1990) as well as in other nations around the globe. In smaller nations (for example, Sweden, which had an active eugenic sterilization program until the 1960s), the impact of the programs was proportionately larger than in the United States.

After World War II (1948) Japan passed a Eugenic Protection Law that permitted the sterilization of persons who had even distant relatives with any one of about 30 (presumably and, in most cases, erroneously) inherited conditions (Tsuchiya 1997). Japan's law was amended in 1996, in part to remove the term eugenic. We know of no firm evidence that it was applied coercively.

Over the last 20 years a few governmentally supported public health programs have focused on reducing the number of births of children with specific disorders. In some cases voluntary public response to these programs has led to a substantial reduction. Examples include the rapid decline in the United Kingdom in the number of children born with neural tube defects (Cuckle and Wald 1987) and the public health campaigns to reduce the

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number of children born with beta-thalassemia in Sardinia (Cao et al 1989) and Cyprus (Angostiniotis et al 1986).

ırrent Programs that May Restrict Reproductive Freedom

There are few public health programs operating in the world today that may be said to use genetic information to restrict reproductive freedom.

Singapore has implemented a policy of using economic incentives to encourage reproduction by educated women and to encourage sterilization among uneducated, poor women, but it does not rely on genetic information and is not mandatory (Chan 1985).

China's Maternal and Infant Health Care Law (1994) has aroused concern because it appears to require medical counseling before marriage for people whose families have a relative with one of a listed group of conditions (including mental illness, epilepsy, and mental retardation) that the law presumes (with little or no scientific basis) are hereditary. The law (the official translation of which involves nuances of language that complicate analysis) also has been construed to require sterilization or long-term contraception as a pre-condition of marriage if a person is determined by the doctor to be at risk for bearing an affected child. Another section of the Chinese law appears to require that couples at risk for certain disorders must undergo prenatal diagnosis and follow the directive of the attending physician.

However, the law includes no penalty for non-compliance and (to the best of our knowledge) is not enforced. It seems to represent a "standard of care," albeit highly directive, to which the government aspires rather than a rule of conduct that must be obeyed. The official English translation of the law uses the word "shall" in a ınner that connotes compulsion, but some Chinese bioethicists insist that it is meant to connote "ought", e.g. . ethical obligation, rather than a legal rule (Qiu 1998). China's human geneticists, recognizing the importance of even symbolic language that seems to embrace eugenics, have requested that the central government change the law to comply with international concern, and to acknowledge the centrality of voluntary choice in genetic testing and counseling (Yang 1998). Taiwan has had a similar law (Sung 1998). on its books for several years, which has neither been enforced nor drawn international criticism.

Many governments support programs in the interests of improving the odds that children will be healthy. Some are mandatory. In our view, none involve the misuse of genetic information. Examples include: 1) programs to encourage or discourage the number of births among the entire population, 2) laws that try to protect the fetus from environmental harm (e.g. warnings on cigarette packages about the risk of smoking during pregnancy), 3) laws that implement newborn genetic screening programs, 4) laws or regulations that fund genetic services, including genetic counseling, genetic testing, prenatal diagnosis, and the provision of special diets for newborns with certain inborn errors of metabolism (Cunningham 1998), and 5) laws forbidding first cousin marriages and other consanguineous unions.

Conclusion

Efforts to implement programs that restrict reproductive freedom based on genetic information are scientifically and ethically unacceptable and should be challenged. While it is sometimes possible to ascertain the risk of bearing a child with a genetic disorder, for the majority of pregnancies it is not possible to make predictions about a future child's health or other capacities. Misguided efforts to do so devalue humanity.

cknowledgments

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Key words: eugenics, genetics, reproductive freedom

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GENETIC TESTING ISSUES continued

YOU DECIDE

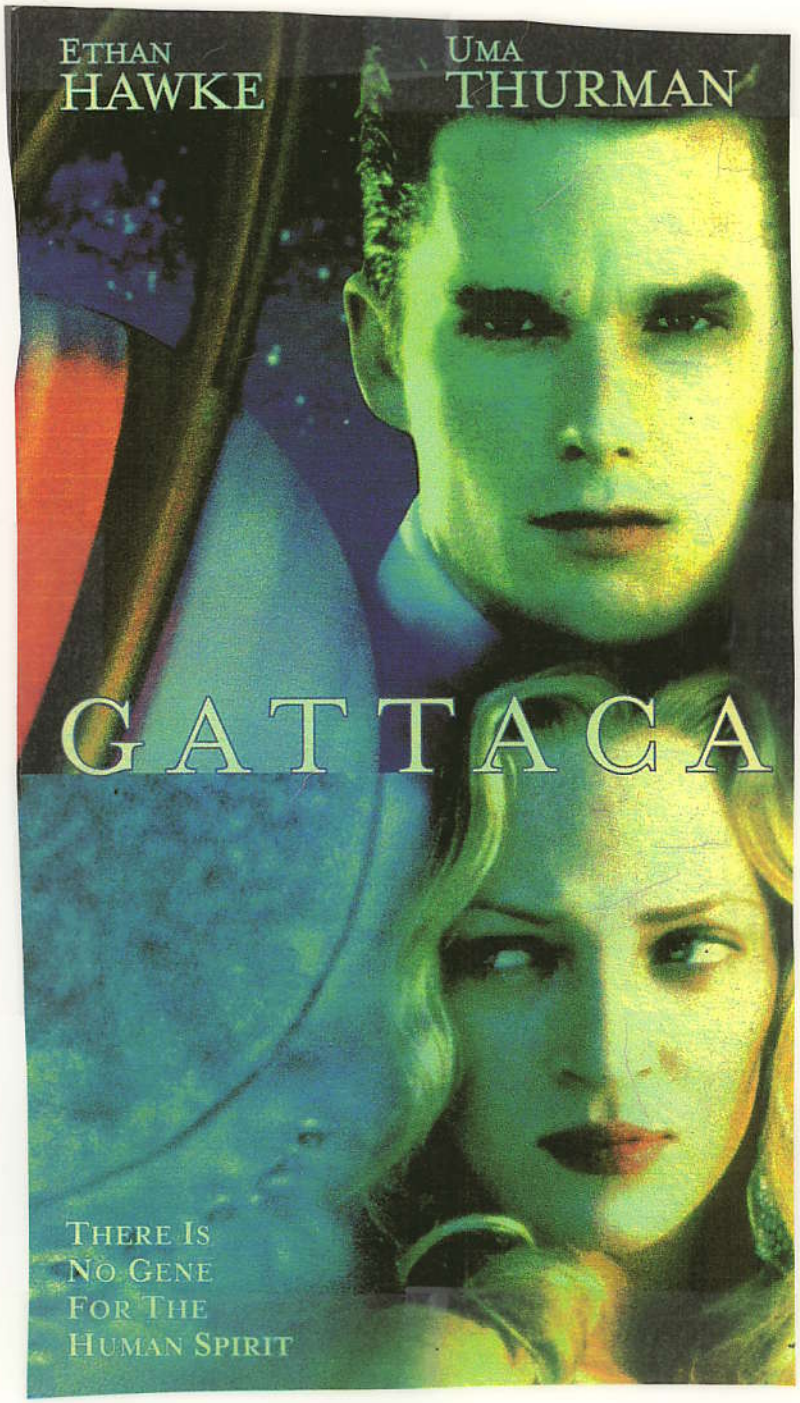
Genetic Testing: Issues to Consider

Since genetic testing became available, a number of concerns have been raised about how genetic information could be used and what it may be used for beyond personal and private decisions. Consider some of these issues:

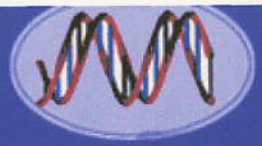
- Should we test unborn children or adults for genetic conditions for which there is currently no treatment or cure?
- What are acceptable consequences if parents learn that their unborn child has a genetic defect?
- What are the psychological effects of a false result, which may erroneously indicate that a healthy person has a disease gene, or a gene defect that goes undetected in a person with a genetic disorder?
- How do we ensure privacy and confidentiality of genetic information and avoid genetic discrimination? Who should have access to your genetic information? How could your genetic background be used to discriminate against you? How could your health or life insurance company's access to your genetic information affect your premiums? Could your premiums be raised based on "genetic" risk in the same way that premiums are raised based on other risks, such as how old you are and the car you drive?
- What are your obligations to inform others such as a potential spouse or employer of your knowledge about a possible genetic disorder?
- If genes are discovered for undesirable human behaviors, how would these genes be perceived in legal courts if accused criminals use genetics as their basis for a not guilty by reason of genetics plea?
- Would society implement mechanisms to prevent or dissuade individuals with genetic defects from having children?

As you can see, genetic testing is certainly not without its controversies and limitations, and there are few easy answers to these issues. Visit the "Your Genes, Your Choices" website listed at the end of this chapter for a thought-provoking series of ethical dilemmas created by genetic testing and genetic technology. What would you do if you had to face the scenarios presented at this site?

The Future??



Mandatory Adult Testing / Child Testing would violate 5th & 14th Amendments to Constitution



DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria

DNA Fingerprinting

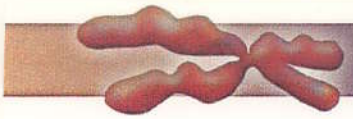
Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

Genetic Screening Issues

- Why Screen For Genes?
- When is a Test Accurate Enough?
- Mandatory or Voluntary Screening?
- Who Should Be Tested?
- Employer & Insurance Company Testing?
- Protection From Genotype Discrimination?
- Testing for Genetic Diseases With No Cures??
- How Ensure Privacy & Confidentiality?
- Obligations to Inform Others (Spouse/Sibling) of Genetic Disorder Knowledge?
- How Ensure Privacy & Confidentiality?
- Genetic Databases??

GENETIC SCREENING ISSUES



Developing Guidelines for Genetic Screening

In the early 1970s, the United States launched a national screening program for carriers of the sickle-cell trait based on a simple test of hemoglobin mobility; normal and "sickling" hemoglobins move at different rates in a gel. People who participated in the screening program could use the test results to make informed reproductive decisions. A healthy man, for example, who learned he was a carrier, would not have to worry about having affected children if his mate were a noncarrier. If, however, they were both carriers, they could choose either not to conceive or to conceive in spite of the 25% risk of bearing an afflicted child. In the 1980s, the possibility of direct prenatal diagnosis of the fetal genotype, as described in the Fast Forward box "The Direct Analysis of Human Genotype" on p. 28, provided additional options. Depending on their beliefs, a couple could decide to continue a pregnancy only if the fetus were not a homozygote for the *S* allele, or knowing that their child would have sickle-cell syndrome, they could learn how to deal with the symptoms of the condition.

The original sickle-cell screening program, based on detection of the abnormal hemoglobin protein, was unfortunately not an unqualified success, largely because of insufficient educational follow-through. Many who learned they were carriers mistakenly thought they had the disease, and because employers and insurance companies obtained access to the information without receiving sufficient instruction as to its meaning, some *AS* heterozygotes were denied jobs or health insurance for no acceptable reason. Problems of public relations and education thus made a reliable screening test into a source of dissent and alienation.

Today, with the ability to look directly at the genotype of individuals born or unborn, it is becoming feasible to screen families at risk not only for sickle-cell anemia but for a growing number of other genetic disorders as well. The need to establish guidelines for genetic screening thus becomes more and more pressing. Several related questions reveal the complexity of the issue.

1. *Why carry out genetic screening at all?* There are two basic reasons. The first is to obtain information that will benefit individuals. For example, if you learn at an early age that you have a genetic predisposition to heart disease, you can change your lifestyle to include more exercise and a low-fat diet, thereby improving your chances of staying healthy. Or, you can use the results from genetic screening to make informed reproductive decisions that reduce the probability of having children affected by a genetic disease. In Brooklyn, New York, for example, among a community of Hasidic Jews of Eastern European descent, there used to be a high incidence of a fatal neurodegenerative syndrome known as Tay-Sachs disease. In this traditional, Old World community, marriages are arranged by rabbis or matchmakers who, by encouraging testing for the abnormal allele, helped eradicate the disease. With confidential access to test results, a rabbi could counsel against marriages between two carriers. The second reason for genetic screening, which often conflicts with the first, is to benefit groups within society. Insurance companies and employers, for example, would like to be able to find out who is at risk for various genetic conditions.
2. *When is a test accurate and comprehensive enough to be used as the basis for screening?* The accuracy of standard genetic tests for cystic fibrosis is more than 90%. Because it is not 100%, a few people who test negative may actually be carriers. In contrast, the tests for Huntington disease and the sickle-cell trait pick up close to 100% of those who carry the abnormal allele. In addition to the problem of false negatives, all genetic tests occasionally produce a false positive. What all this means is that some people might decide not to have children on the basis of inaccurate information. While the accuracy of the tests continues to improve, the question remains: Do the benefits outweigh both the costs and the risks of inaccuracies?
3. *Once an accurate test becomes available at reasonable cost, should screening be required or optional?* This is partly a societal

(1) why?

(2) Accuracy?

(3) Required or optional?

TESTING ISSUES CONTINUED

decision because the public treasury bears a large part of the cost of caring for the sufferers of genetic diseases. But it is also a personal decision. For most inherited diseases there is as yet no cure. Since the psychological burden of anticipating a fatal disease for which there is no treatment can be devastating, some people might decide not to be tested. Other reasons people may not want to be tested include religious beliefs and concerns about confidentiality. On the other hand, timely information about the presence of an abnormal gene that causes a condition for which there is a therapy can save lives; an example is the genetic test for hemochromatosis, an inherited disorder affecting 1 of every 200 people in the United States. The disease deposits iron in the heart, liver, and other organs of the body, and by the fifth or sixth decade of life, those organs break down. The simple, ancient practice of bloodletting, if begun early in life, prevents the complications of hemochromatosis. Timely information may also affect childbearing decisions and thereby reduce the incidence of a disease in the population.

4. *If a screening program is established, who should be tested?* The answer depends on what the test is trying to accomplish as well as on the fact that genetic screening is expensive, a consideration that must be weighed against the usefulness of the data it provides. For the 1 in 200 people inheriting the hemochromatosis mutation, widespread testing could reduce health-care costs of affected individuals later in life. By contrast, to reduce the risk of a child being born with a rare inherited disease, a program might try to target groups with the highest incidence. In the United States, only one tenth as many African-Americans as Caucasians are affected by cystic fibrosis, and Asians almost never have the disease. Should all racial groups be tested or only Caucasians? Because of the expense, this kind of analysis has not yet been applied to large populations; instead, such direct testing has been reserved for couples or individuals whose family history puts them at risk for a severely debilitating disease.

5. *Should private employers and insurance companies be allowed to test their clients and employees?* Some employers advocate genetic screening to reduce the incidence of occupational disease, arguing that they can use data from genetic tests to make sure employees are not assigned to environments that might cause them harm. People with sickle-cell syndrome, for example, may be at increased risk for a life-threatening episode of severe sickling if exposed to carbon monoxide or trace amounts of cyanide. Critics of this position say that screening violates workers' rights, including the right to privacy, and increases racial and ethnic discrimination in the workplace. Many critics also oppose informing insurance companies of the results of genetic screening, as these companies may deny coverage to people with inherited medical problems or just the possibility of developing such problems. According to one medical ethicist, discrimination of this sort will grow unless countries pass laws, similar to one enacted in France, that ensure genetic information is confidential, to be given out only at the discretion of the tested individual. In 1998, the Clinton administration asked Congress to draft legislation that would prohibit the requirement of a genetic test as a condition of employment, and would bar employers from obtaining or disclosing genetic information about employees under most circumstances.

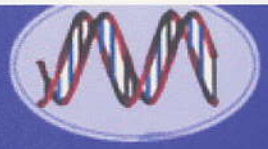
6. *Finally, how should people be educated about the meaning of test results?* In one small-community screening program, people identified as carriers of the recessive, life-threatening blood disorder known as β-thalassemia were ostracized and as a result, ended up marrying one another. This only made medical matters worse as it greatly increased the chances that their children would be born with two copies of the defective allele and thus the disease. By contrast, in Ferrara, Italy, where there used to be 30 new cases of β-thalassemia every year, extensive screening was so successfully combined with intensive education that the 1980s passed with no more than a few new cases of the disease.

Given all of these considerations, what kind of guidelines would you like to see established to ensure that genetic screening reaches the right people at the right time and that information gained from such screening is used for the right purposes?

(4) who?

(6) Education?

(5) Employers Insurance?



DNA
Genetic Code of Life

Entire Genetic Code
of a Bacteria

DNA Fingerprinting

Cloning: Ethical Issues
and Future Consequences

Plants of Tomorrow

Laws That Affect DNA Testing

- Constitution-Article I Section 8.8-Promote the General Welfare
- Constitution-Article I Section 8.18-To Make Laws Necessary to Execute Foregoing Powers
- Amendment IV-Searches & Seizures
- Amendments V/IV-Life, Liberty Due Process
- Amendment X-Powers Reserved to States
- Federal Criminal Statutes
- State Constitutions
- State Tort & Criminal Statutes

LAWS THAT APPLY to DNA TESTING

1. "Promote the Public Welfare" in Constitution – "police" powers
2. X Amendment – powers left to the States – Promote Public Welfare
3. IV Amendment – Searches & Seizures
4. II & IV Amendments – Right to PRIVACY (mandatory testing – Reproductive Rights)
5. Tort Liability
6. CRIMINAL LAWS (Promote public welfare)

Genetics Privacy and Legislation

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I. Federal Policy History

No federal legislation has been passed relating to *genetic discrimination in individual insurance coverage* or to *genetic discrimination in the workplace*. Several bills were introduced during the last decade. Some of these bills attempted to amend existing civil rights and labor laws, while others stood alone. The primary public concerns are that (1) insurers will use genetic information to deny, limit, or cancel insurance policies or (2) employers will use genetic information against existing workers or to screen potential employees. Because DNA samples can be held indefinitely, there is the added threat that samples will be used for purposes other than those for which they were gathered.

Executive Order Protecting Federal Employees

On February 8, 2000, U.S. President Clinton signed an *executive order* prohibiting every federal department and agency from using genetic information in any hiring or promotion action. This executive order, endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance

- *Prohibits* federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits. Employers cannot request or require employees to undergo genetic tests in order to evaluate an employee's ability to perform his or her job.
- *Prohibits* federal employers from using protected genetic information to classify employees in a manner that deprives them of advancement opportunities. Employers cannot deny employees promotions or overseas posts because of a genetic predisposition for certain illnesses.
- *Provides* strong privacy protections to any genetic information used for medical

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treatment and research. Under the EO, obtaining or disclosing genetic information about employees or potential employees is prohibited, except when it is necessary to provide medical treatment to employees, ensure workplace health and safety, or provide occupational and health researchers access to data. In every case where genetic information about employees is obtained, it will be subject to all Federal and state privacy protections.

Bills Introduced to Congress

The following bills have been read and referred to Congressional committees.

- H.R. 3636 - Genetic Privacy and Nondiscrimination Act of 2003. Introduced to the House of Representatives, November 21, 2003.
- S. 1053 - Genetic Information Nondiscrimination Act of 2003 - Introduced to the Senate, May 13, 2003.
- H.R. 1910 - To prohibit discrimination on the basis of genetic information with respect to health insurance. Introduced to the House of Representatives, May 1, 2003.
- S. 16 - Equal Rights and Equal Dignity for Americans Act of 2003 - To protect the civil rights of all Americans, and for other purposes. Introduced to the Senate, January 7, 2003.
- Previous Bills (No longer candidates for law)
  - S.1995 - Genetic Information Nondiscrimination Act of 2002.
  - S.318 - Genetic Nondiscrimination in Health Insurance and Employment Act 2001.
  - S. 382 - Genetic Information Nondiscrimination in Health Insurance Act of 2001
  - H.R. 602 - Genetic Nondiscrimination in Health Insurance and Employment Act 2001.

For more information on federal policy regarding genetic discrimination, see Policy and Legislation: Discrimination from the National Human Genome Research Institute.

Congressional Hearings

- Testimony of Bobby P. Jindal - Senate Committee on Health, Education, Labor and Pensions Hearing, February 13, 2002.
- Report: Protecting Against Genetic Discrimination: The Limits of Existing Law - Hearing before the Senate Committee on Health, Education, Labor and Pension, February 13, 2002.
- Genetic Non-Discrimination - Hearing Before the Senate Committee on Health, Education, Labor and Pension, July 25, 2001 - Hearing report from the Office of Legislative Policy and Analysis.
- Potential for Discrimination in Health Insurance Based on Predictive Genetic Tests, July 11, 2001 - Hearing before the US House of Representatives Committee on Energy and Commerce.

II. State Policy History

States have a patchwork of genetic-information nondiscrimination laws, none of them comprehensive. Existing state laws differ in coverage, protections afforded, and enforcement schemes. Some of the first state laws enacted to address this issue prohibited discrimination against individuals with specific genetic traits or disorders. Other state laws regulate both the use of genetic testing in employment decisions and the disclosure of genetic test results. These state laws generally prohibit employers from requiring workers and applicants to undergo genetic testing as a condition of employment. Some states permit genetic testing when it is requested by the worker or applicant for the purpose of investigating a compensation claim or determining the worker's susceptibility to potentially toxic chemicals in the workplace. These statutes often require the worker to provide informed written consent for such testing, contain specific restrictions governing disclosure, and prevent the employer from taking adverse action against the employee.

[See charts of state genetics laws and information on genetics legislative activity on the National Conference of State Legislatures Web site. See the NIH NHGRI Policy and Legislation Database of all genetics insurance discrimination legislation.]

State Genetics Reports

- North Carolina: North Carolina State Plan for Genomics and Public Health (PDF) - January 2004.
- Illinois: The Challenges of Human Cloning for Public Policy in Illinois (PDF) - February 2001.
- Oregon: Genetic Privacy and Research in Oregon
- Kentucky: Genetic Testing in Health, Life, and Disability Insurance in Kentucky (PDF) - January 2000.
- Michigan: Report of the Michigan Commission on Genetic Privacy and Progress (PDF) - February 1999.
- New York: Genetics Testing and Screening in the Age of Genomics Medicine - November 2000.
- Washington: Genetic Privacy, Discrimination, and Research in Washington State (PDF) - October 2002.
    - Washington State Genetics Education Plan (PDF) - 1997.
- Wisconsin: Genetic Services Plan for Wisconsin - 2001.

III. Existing Federal Anti-Discrimination Laws and How They Apply to Genetics

Although no specific federal genetic nondiscrimination legislation has been enacted, some believe that parts of existing nondiscrimination laws could be interpreted to include genetic discrimination. Here is a brief overview of these laws and how they apply to genetics.

Americans with Disabilities Act of 1990 (ADA)

The most likely current source of protection against genetic discrimination in the

workplace is provided by laws prohibiting discrimination based on disability. Title I of the Americans with Disabilities Act (ADA), enforced by the Equal Employment Opportunity Commission (EEOC), and similar disability-based antidiscrimination laws such as the Rehabilitation Act of 1973 do not explicitly address genetic information, but they provide some protections against disability-related genetic discrimination in the workplace.

- Prohibits discrimination against a person who is regarded as having a disability.
- Protects individuals with symptomatic genetic disabilities the same as individuals with other disabilities.
- Does not protect against discrimination based on unexpressed genetic conditions.
- Does not protect potential workers from requirements or requests to provide genetic information to their employers after a conditional offer of employment has been extended but before they begin work. (Note: this is a heightened concern because genetic samples can be stored.)
- Does not protect workers from requirements to provide medical information that is job related and consistent with business necessity.

In March 1995, the EEOC issued an interpretation of the ADA. The guidance, however, is limited in scope and legal effect. It is policy guidance that does not have the same legal binding effect on a court as a statute or regulation and has not been tested in court. According to the interpretation,

DOES NOT APPLY TO CARRIERS!

- Entities that discriminate on the basis of genetic predisposition are regarding the individuals as having impairments, and such individuals are covered by the ADA.
- Unaffected carriers of recessive and X-linked disorders, individuals with late-onset genetic disorders who may be identified through genetic testing or family history as being at high risk of developing the disease are not covered by the ADA

See the ADA Home Page for more information.

(3)

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) applies to *employer-based and commercially issued group health insurance only*. HIPAA is the only federal law that directly addresses the issue of genetic discrimination. There is no similar law applying to private individuals seeking health insurance in the individual market.

NOT INDIVIDUAL PLANS

- Prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting eligibility for coverage or for charging an individual more for coverage.
- Limits exclusions for preexisting conditions in group health plans to 12 months and prohibits such exclusions if the individual has been covered previously for that condition for 12 months or more.
- States explicitly that genetic information in the absence of a current diagnosis of illness shall not be considered a preexisting condition.
- Doesn't prohibit employers from refusing to offer health coverage as part of their benefits packages.

For more information see HIPAA information from US Department of Health and Human Services (HHS) or the HIPAAdvisory Web site.

(CO)

HIPAA National Standards to Protect Patients' Personal Medical Records, Dec. 2002

This regulation would protect medical records and other personal health information maintained by health care providers, hospitals, health plans and health insurers, and health care clearinghouses. The regulation was mandated when Congress failed to pass comprehensive privacy legislation (as required by HIPAA) by 1999. The new standards: limit the nonconsensual use and release of private health information; give patients new rights to access their medical records and to know who else has accessed them; restrict most disclosure of health information to the minimum needed for the intended purpose; establish new criminal and civil sanctions for improper use or disclosure; and establish new requirements for access to records by researchers and others. They are not specific to genetics, rather they are sweeping regulations governing all personal health information.

For more on the standards, see:

- Administration Simplification Under HIPAA: National Standards for Transactions, Security, and Privacy - A fact sheet from US Department of Health and Human Services (HHS) (March 2003).
- HHS Issues Privacy Rules for Use of Health Records - Freedom of Information Center article explains the latest rules for HIPAA, August, 2002.
- HHS Announces Final Regulation Establishing First-ever National Standards to Protect Patients' Personal Medical Records - HHS Press Release, (December 2000).
- Summary of the Final Regulation - HHS Fact Sheet (December 2000).

Title VII of the Civil Rights Act of 1964

An argument could be made that genetic discrimination based on racially or ethnically linked genetic disorders constitutes unlawful race or ethnicity discrimination.

- Protection is available only where an employer engages in discrimination based on a genetic trait that is substantially related to a particular race or ethnic group.
- A strong relationship between race or national origin has been established for only a few diseases.

IV. Recommendations for Future Legislation

Workplace Discrimination

Based on previous recommendations from the National Action Plan on Breast Cancer (NAPBC) and the NIH-DOE Working Group on the Ethical, Legal, and Social Implications (ELSI) of human genome research, in a 1998 report the Clinton Administration announced recommendations for future legislation to ensure that discoveries made possible by the Human Genome Project are used to improve health and not to discriminate against workers or their families. These recommendations are

- Employers should not require or request that employees or potential employees take a genetic test or provide genetic information as a condition of employment or benefits.
- Employers should not use genetic information to discriminate against, limit,

segregate, or classify employees in a way that would deprive them of employment opportunities.
- Employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.

Genetic testing and the use of genetic information by employers should be permitted in the following situations to ensure workplace safety and health and to preserve research opportunities. However, in all cases where genetic information about employees is obtained, the information should be maintained in medical files that are kept separate from personnel files, treated as confidential medical records, and protected by applicable state and federal laws.

- An employer should be permitted to monitor employees for the effects of a particular substance found in the workplace to which continued exposure could cause genetic damage under certain circumstances. Informed consent and assurance of confidentiality should be required. In addition, employers may use the results only to identify and control adverse conditions in the workplace and to take action necessary to prevent significant risk of substantial harm to the employee or others.
- The statutory authority of a federal agency or contractor to promulgate regulations, enforce workplace safety and health laws, or conduct occupational or other health research should not be limited.
- An employer should be able to disclose genetic information for research and other purposes with the written, informed consent of the individual.

These recommendations should apply to public and private-sector employers, unions, and labor-management groups that conduct joint apprenticeship and other training programs. Employment agencies and licensing agencies that issue licenses, certificates, and other credentials required to engage in various professions and occupations also should be covered.

Individuals who believe they have been subjected to workplace discrimination based on genetic information should be able to file a charge with the Equal Employment Opportunity Commission, Department of Labor, or other appropriate federal agency for investigation and resolution. The designated agency should be authorized to bring lawsuits in the federal courts to resolve issues that would not settle amicably. The courts should have the authority to halt the violations and order relief, such as hiring, promotion, back pay, and compensatory and punitive damages to the individual. Alternatively, an individual should be able to elect to bring a private lawsuit in federal or state court to obtain the same type of relief plus reasonable costs and attorney's fees. To enforce these protections, the designated enforcement agency must be given sufficient additional resources to investigate and prosecute allegations of discrimination.

Insurance Discrimination

In 1995, the NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) developed and published the following recommendations for state and federal policy makers to protect against genetic discrimination (*Science*, vol. 270, Oct. 20, 1995):

Definitions

- "Genetic information" is information about genes, gene products, or inherited characteristics that may derive from the individual or a family member.

- "Insurance provider" means an insurance company, employer, or any other entity providing a plan of health insurance or health benefits, including group and individual health plans whether fully insured or self-funded.

Recommendations

- Insurance providers should be prohibited from using genetic information or an individual's request for genetic services to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements.

- Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.

- Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without the individual's prior written authorization. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

A final report of the ELSI Working Group was released in 1996.

Sample Genetic Privacy Act and Commentary
A draft bill (Genetic Privacy Act) was written in 1995 by George Annas of the Boston University School of Public Health to assist legislators. This sample bill proposed that access to information in genetic data banks should be regulated during sample collection, storage, disclosure, and use. Several state lawmakers adapted language and concepts from the draft bill to write proposals for legislation in their own states.

V. Why Legislation Is Needed Now

(1) Based on genetic information, employers may try to avoid hiring workers they believe are likely to take sick leave, resign, or retire early for health reasons (creating extra costs in recruiting and training new staff), file for workers' compensation, or use healthcare benefits excessively.

(2) Some employers may seek to use genetic tests to discriminate against workers--even those who do not and may never show signs of disease--because the employers fear the cost consequences.

(3) The economic incentive to discriminate based on genetic information is likely to increase as genetic research advances and the costs of genetic testing decrease.

(4) Genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop disease or where the genetic condition has no effect on the ability to perform work

(5) Given the substantial gaps in state and federal protections against employment discrimination based on genetic information, comprehensive federal legislation is needed to ensure that advances in genetic technology and research are used to address the health needs of the nation--and not to deny individuals employment opportunities and benefits. Federal legislation would establish minimum protections that could be supplemented by state laws.

(6) Insurers can still use genetic information in the individual market in decisions about coverage, enrollment, and premiums.

(7) Insurers can still require individuals to take genetic tests.

(8) Individuals are not protected from the disclosure of genetic information to insurers, plan sponsors (employers), and medical information bureaus, without their consent.

(9) Penalties in HIPAA for discrimination and disclosure violations should be strengthened in order to ensure individuals of the protections afforded by the legislation.

VI. Cases of Genetic Discrimination

Although no genetic-employment discrimination case has been brought before U.S. federal or state courts, in 2001 the Equal Employment Opportunity Commission (EEOC) settled the first lawsuit alleging this type of discrimination.

EEOC filed a suit against the Burlington Northern Santa Fe (BNSF) Railroad for secretly testing its employees for a rare genetic condition that causes carpal tunnel syndrome as one of its many symptoms. BNSF claimed that the testing was a way of determining whether the high incidence of repetitive-stress injuries among its employees was work-related. Besides testing for this rare problem, company-paid doctors also were instructed to screen for several other medical conditions such as diabetes and alcoholism. BNSF employees examined by company doctors were not told that they were being genetically tested. One employee who refused testing was threatened with possible termination.

On behalf of BNSF employees, EEOC argued that the tests were unlawful under the Americans with Disabilities Act because they were not job-related, and any condition of employment based on such tests would be cause for illegal discrimination based on disability. The lawsuit was settled quickly with BNSF agreeing to everything sought by EEOC.

Besides the BNSF case, the Council for Responsible Genetics claims that hundreds of genetic-discrimination cases have been documented and describes select cases in its Genetic Discrimination Position Paper (PDF). In one case, genetic testing indicated that a young boy had Fragile X Syndrome, an inherited form of mental retardation. The insurance company for the boy's family dropped his health coverage, claiming the syndrome was a preexisting condition. In another case, a social worker lost her job

within a week of mentioning that her mother had died of Huntington's disease and that she had a 50% chance of developing it.

Despite claims of hundreds of genetic-discrimination incidents, an article from the January 2003 issue of the *European Journal of Human Genetics* reports a real need for a comprehensive investigation of these claims. The article warns that many studies rely on unverified, subjective accounts from individuals who believe they have been unfairly subjected to genetic discrimination by employers or insurance companies. Rarely are these subjective accounts assessed objectively to determine whether actions taken by employers and insurers were truly based on genetic factors or other legitimate concerns.

VII. More Information

Web Sites

- Policy & Ethics Current Topics: Privacy, Discrimination and Legal Issues - Links to policy and legislative information on genetic privacy, genetic discrimination, patenting genetic information, and DNA forensics. From the National Human Genome Research Institute.
- Resources from the National Conference of State Legislature (NCSL)
  - Genetic Technologies Project
  - Policy Briefs: Current Genetics Issues of the Day
  - Genetics Laws and Legislative Activity
  - NCSL Publication Order Form
- Genetic Education Materials (GEM) Database - Searchable listing of public health genetics policy documents and clinical genetics educational materials. From the National Newborn Screening and Genetics Resource Center (NNSGRC).
- DisabilityInfo.gov - Comprehensive Federal Web site of disability-related government resources.
- Workplace Rights: Genetic Discrimination - Information from the American Civil Liberties Union.
- How Private Is My Medical Information? - Fact sheet from the Privacy Rights Clearinghouse, October 2002.

Organizations

- Genetics & Public Policy Center
- Council for Responsible Genetics
- National Patient Advocate Foundation
- American Civil Liberties Union
- Health Privacy Project
- Privacy Rights Clearinghouse

Position Statements

- American Academy of Actuaries: National Conference of Insurance Legislators - Hearing on Proposed Genetic Discrimination Model Act
- American College of Medical Genetics (PDF) - Points to Consider in Preventing Unfair Discrimination Based on Genetic Disease Risk, December 2001.
- American Society of Human Genetics (ASHG) - Endorsement of Senate Bill 318,

the Genetic Nondiscrimination and Health Insurance and Employment Act, December 18, 2001.

- President Bush's Radio Address on Genetic Discrimination - June 23, 2001.
- CRG Genetic Discrimination Position Paper (PDF) - From the Council for Responsible Genetics, January 2001.
- Biotechnology Industry Organization (BIO) - Policy Statement Regarding the Prohibition of Discriminatory Use of Medical Information, March 1999.
- Universal Declaration on the Human Genome and Human Rights - From the United Nations Educational, Scientific, and Cultural Organization (UNESCO), November 1997.

Articles

- Medical Privacy Law Stirs Controversy - Article in the *Star-Telegram* Fort Worth News posted February 23, 2003.
- Analyzing Genetic Discrimination in the Workplace - Article from *Human Genome News*, February 2002.
- New Federal Privacy Rules Stump Researchers - *The Scientist* **15**: 33, September 17, 2001 - A new federal privacy rule in the Health Insurance Portability and Accountability Act of 1996 (HIPAA)--requires researchers who use the nation's tissue banks to obtain authorizations when they use patient-specific information, such as medical histories. As of April 2003, both criminal and civil penalties for violations can be applied.
- Pink Slip in Your Genes - *Scientific American*, January 2001 - Evidence builds that employers hire and fire based on genetic tests; meanwhile, protective legislation languishes.
- Does Genetic Research Threaten Our Civil Liberties? - Article from actionbioscience.org, August 2000. Mapping the human genome may lead to new medical breakthroughs; however, it may also lead to an individual's loss of privacy, discrimination by class or genetic profile, and genetic enhancement of select individuals or populations.

Books

- *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics* by Leon Kass. 313 pp., 2002.

Information on this page was taken from several sources, including the NIH NHGRI Legislation Office in the Office of Policy Coordination, Department of Labor, *Human Genome News*, National Action Plan on Breast Cancer, and U.S. Department of Energy–National Institutes of Health Working Group on Ethical, Legal, and Social Implications of Genome Research.

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Last modified: Friday, February 24, 2006

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S. 306, the Genetic Information Nondiscrimination Act of 2005

February 16, 2005

Summary

S. 306, the *Genetic Information Nondiscrimination Act*, would establish strong protections against discrimination based on genetic information both in health insurance and employment. **S. 306** would limit the access to and use of genetic information by health care insurers, employers (both private and public sector), employment agencies, labor organizations, and joint labor-management training programs. This bill would also ensure the confidentiality of genetic information and limit disclosure of genetic information.

Background

Scientists have recently completed the historic task of mapping the human genome, which will give physicians better tools to diagnose, prevent, and treat diseases. However, to fulfill the promise of this new knowledge, Americans need to be assured that their genetic information will not be used to discriminate against them. Surveys reveal the public's concern that insurers and employers have access to their genetic information and will use it in a discriminatory manner. Research also shows that people choose not to have genetic tests and do not participate in research involving genetic testing because of concern about discrimination. The Senate Health, Education, Labor and Pensions (HELP) Committee has heard compelling testimony from workers who were genetically tested without their knowledge or consent.

The existing patchwork of state and federal laws are confusing and inadequate to protect against genetic discrimination. Different versions of federal genetic nondiscrimination legislation have been introduced in Congress since the mid-1990s. After years of negotiations, a bipartisan agreement was reached in the Senate in

2003 to resolve the differences between competing genetic nondiscrimination legislation. While approved by the Senate, these protections were not enacted into law during the 108th Congress.

Major Provisions

Title I: Genetic Nondiscrimination in Health Insurance

In both the group and individual insurance markets, **S. 306** would prohibit health insurance companies from using genetic information - including information about genetic services - to deny insurance coverage or to adjust premium rates paid by the individual or the group to which that individual belongs. The bill would prohibit insurers in both the group and individual insurance markets from denying coverage

outright or pricing that coverage out of the reach of consumers based on their genetic information.

S. 306 also sets limits on requesting or requiring genetic tests. The bill would bar a health plan from requesting or requiring an individual, or a family member of that individual, to undergo a genetic test. The legislation also would prohibit a health care professional from requiring that an individual undertake a genetic test; however, health professionals are not prohibited from requesting that their patients have a genetic test, and a health care professional employed by or affiliated with a health plan is not prohibited from informing an individual about the availability of a genetic test if it is part of a bona fide wellness program. The bill seeks to strike a balance between protecting consumers from being compelled to take genetic tests as a requirement of treatment or coverage, while ensuring that medical professionals are not inhibited from giving their patients the full benefit of genetic tests.

In addition to the nondiscrimination provisions, **S. 306** addresses concerns about maintaining the privacy of genetic information. The health care privacy regulations issued by the Department of Health and Human Services generally allow the use and disclosure of medical information for enrollment, premium rating, or the creation, renewal, or replacement of an insurance plan, but **S. 306** would bar use or disclosure of genetic information for these purposes.

The time when health insurers are most likely to use genetic information for discriminatory purposes is during the period prior to a person's enrollment. This is the time when insurance companies decide whether to offer a person coverage and, if so, what premium to charge. To prevent insurance companies from factoring genetic information into these decisions, the bill would prohibit insurance companies from requesting, requiring, or purchasing genetic information about an individual prior to that individual's enrollment in coverage. The legislation would establish conditions for when the incidental collection of genetic information is not a violation of this prohibition, so as not to penalize companies who inadvertently receive genetic information. However, the bill would ban discriminatory uses of that information, even if the information has been acquired inadvertently.

Final regulations reflecting the provisions of this title are to be released within one year of enactment and would take effect 18 months after enactment. By building these protections against genetic discrimination into existing statutes (e.g., the *Employee Retirement Income Security Act*, the *Public Health Service Act*, the *Social Security Act*, and the Internal Revenue Code), Title 1 generally uses the same enforcement mechanisms as the underlying statutes. Provisions related to the privacy of genetic information would be covered by the same enforcement structure as apply to improper disclosures of individually identifiable health information under the *Health Insurance Portability and Accountability Act of 1996*.

Title II: Prohibiting Employment Discrimination on the Basis of Genetic Information

S. 306 would bar public and private sector employers (including state, federal, and Congressional employers), employment agencies, labor organizations, and joint labor-management training programs from making employment-related decisions based on genetic information of applicants and employees. It would be unlawful to refuse to hire or discharge an employee, or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because of genetic information. Employers would not be able to limit, segregate or classify employees in a way that would deprive them of employment opportunities or otherwise adversely affect

their status because of genetic information. Unions also would be barred from making membership decisions based on genetic information, and both unions and employment agencies could not make job referrals based on this information.

To enhance privacy protections, **S. 306** would disallow these entities from requesting, requiring, or purchasing genetic information except in limited circumstances. Even when a covered entity acquires genetic information under one of these exceptions, the bill would ensure that individuals remain protected regarding maintenance, disclosure, and use of the information. Under **S. 306**, individuals would be allowed to enforce these protections in accordance with the remedies and procedures allowed under current law.

Both titles of the bill define genetic information as information about an individual's genetic tests, genetic tests of members of the individual's family, and the occurrence of a disease or disorder in family members of the individual. Genetic information does not include information about the sex or age of the individual.

Legislative History

Legislation addressing genetic nondiscrimination was first considered in the 103rd Congress as part of the national health care reform debate. Genetic nondiscrimination protections, in stand-alone bills or in broader legislation, were introduced in the 104th Congress and in subsequent Congresses. Since 1996, the HELP Committee has examined the issue of genetic discrimination in health insurance and employment, including conducting five hearings on genetic discrimination as well as hearings on the related issue of medical privacy.

In 2003, a bipartisan agreement was reached among the Senate sponsors of competing genetic nondiscrimination legislation. The legislation, **S. 1053**, was unanimously passed by the HELP Committee and was approved by the Senate by a vote of 95 to 0. But the House did not take up similar legislation, and protections against genetic discrimination were not enacted into law.

In February 2005, Senator Snowe reintroduced the bipartisan bill, **S. 306**, with minor changes (e.g., change of dates), and the HELP Committee unanimously approved it on February 9. The legislation is expected to be brought to the Senate floor for a vote on February 16.

Statement of Administration Policy

At press time, the Administration had not issued a Statement of Administration Policy (SAP) on **S. 306**. But in 2003, the Administration issued a SAP in support of **S. 1053**, the bipartisan bill that was approved by the Senate during the 108th Congress.

STATE LAWS

NATIONAL CONFERENCE of STATE LEGISLATURES

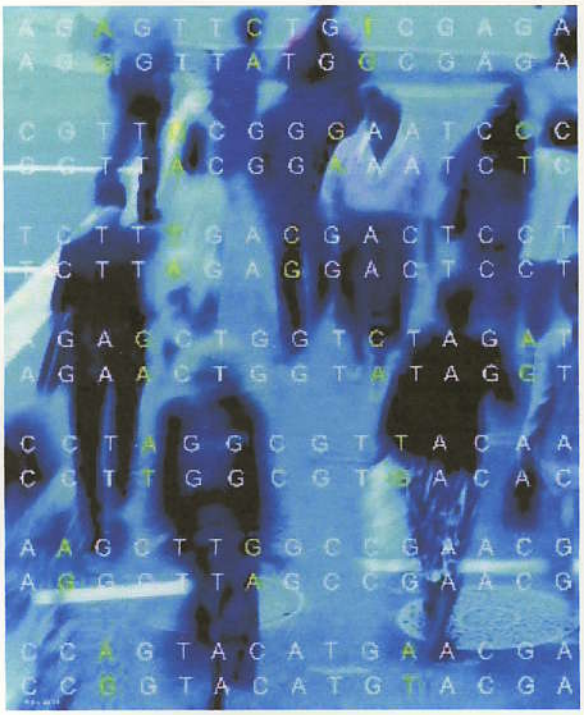
Genetic Technologies Project
Health Care Program

Genetics Laws and Legislative Activity

STATE GENETICS LAWS

I st Amendment

- Embryonic and Fetal Research
- Employment
- Frozen Embryos
- Genetic Counselor Licensing
- Genetic Privacy
- Health Insurance
- Health Insurance Enforcement
- Human Cloning
- Life, Disability and Long-Term Care Insurance
- Newborn Screening



Source: U.S. Department of Energy Human Genome Program, http://www.ornl.gov/hgmis

GENETICS LEGISLATION DATABASE

NCSL's Genetics Legislation Database contains information on bills considered in state legislatures in 2004 and 2005. Topics covered in the database include newborn screening, stem cell research, privacy, discrimination, and other issues. NCSL updates the database at least once a month.

Please contact Alissa Johnson at alissa.johnson@ncsl.org with questions or suggestions.

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Policy and Legislation Database

Current Issues:

- Privacy and Discrimination
- Genetics and the Law
- Health Issues
- Social, Cultural and Religious Issues in Genetic Research
- Biomedical Research Issues

Ethics Research

Online Bioethics Resources

In Other Sections:

Initiatives and Resources Related to Minorities and Special Populations

Budget and Financial Information

Home › Policy and Ethics › Search the Database › Search Results

Policy and Legislation Database Search

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Citation/Title (link to full text)	Content Type	Source	Date	Topic(s)
Assembl. Con. Res. 24, 2005 Reg. Sess., 2005 Cal. Stat. Res. ch. 111 • Summary	Federal and State statutes/laws	California	2005	Commercialization and Patenting, Stem Cell Research
Assembl. Con. Res. 1, 2005 Reg. Sess., 2005 Cal. Stat. Res. ch. 128 • Summary	Federal and State statutes/laws	California	2005	Commercialization and Patenting, Stem Cell Research
S.J. Res. 17, 2005 Reg. Sess., 2005 Cal. Stat. Res. ch. 109 • Summary	Federal and State statutes/laws	California	2005	Cloning, Stem Cell Research
Cal. Welf. & Inst. Code § 14132 (aa) • Summary	Federal and State statutes/laws	California	2005	Genetic Testing and Counseling
Stem Cell Research: Funding, Bonds, Initiative Constitutional Amendment and Statute • Summary	Federal and State statutes/laws	California	2004	Stem Cell Research
S.B. 142 • Summary	Federal and State statutes/laws	California	2004	Genetic Testing and Counseling, Newborn Screening
Cal Health & Safety Code §§ 125118-125119.5 • Summary	Federal and State statutes/laws	California	2004	Cloning
Cal Health & Safety Code §§ 125300-125320 • Summary	Federal and State statutes/laws	California	2004	Stem Cell Research
Cal Health & Safety Code §§ 24185-24187 • Summary	Federal and State statutes/laws	California	2004	Cloning
Cal. Bus. & Prof. Code § 16004	Federal and State	California	2004	Cloning

• Summary	statutes/laws			
Cal. Bus. & Prof. Code § 16105 • Summary	Federal and State statutes/laws	California	2004	Cloning
Cal. Bus. & Prof. Code § 2260.5 • Summary	Federal and State statutes/laws	California	2004	Cloning
Cal. Health & Safety Code §§ 124980 to 124981 • Summary	Federal and State statutes/laws	California	2004	Genetic Testing and Counseling
Cal. Civ. Code § 56.17 • Summary	Federal and State statutes/laws	California	2003	Privacy of Genetic Information
Cal. Gov't Code § 12926(h)(2) • Summary	Federal and State statutes/laws	California	2003	Employment/Insurance Discrimination
Cal. Ins. Code § 10233.1 • Summary	Federal and State statutes/laws	California	2003	Employment/Insurance Discrimination, Genetic Testing and Counseling
Cal. Gov't Code § 12940 • Summary	Federal and State statutes/laws	California	2002	Employment/Insurance Discrimination, Genetic Testing and Counseling
Cal. Health & Safety Code § 127660 • Summary	Federal and State statutes/laws	California	2002	Genetic Testing and Counseling
Cal. Civ. Code § 56.265 • Summary	Federal and State statutes/laws	California	2000	Privacy of Genetic Information
Cal. Fam. Code § 8909 • Summary	Federal and State statutes/laws	California	2000	Nonmedical Applications (Adoption)
Cal. Fam. Code § 9202.5 • Summary	Federal and State statutes/laws	California	2000	Nonmedical Applications (Adoption)
Cal. Health & Safety Code § 124980 • Summary	Federal and State statutes/laws	California	2000	Genetic Testing and Counseling, Informed Consent, Privacy of Genetic Information
Cal. Health & Safety Code § 124981 • Summary	Federal and State statutes/laws	California	2000	Genetic Testing and Counseling
Cal. Health & Safety Code § 1399.804(c) • Summary	Federal and State statutes/laws	California	2000	Employment/Insurance Discrimination
Cal. Ins. Code § 10123.35 • Summary	Federal and State statutes/laws	California	2000	Genetic Testing and Counseling, Privacy of Genetic Information
Cal. Ins. Code § 10140.1 • Summary	Federal and State statutes/laws	California	2000	Genetic Testing and Counseling, Privacy of Genetic Information

Cal. Ins. Code § 10901.2 • Summary	Federal and State statutes/laws	California	2000	Employment/Insurance Discrimination
Cal. Ins. Code § 742.407 • Summary	Federal and State statutes/laws	California	2000	Employment/Insurance Discrimination, Genetic Testing and Counseling, Privacy of Genetic Information
Cal. Health & Safety Code § 1357.03(f)(6) • Summary	Federal and State statutes/laws	California	1999	Employment/Insurance Discrimination, Genetic Testing and Counseling
Cal. Health & Safety Code § 1374.7 • Summary	Federal and State statutes/laws	California	1999	Employment/Insurance Discrimination, Privacy of Genetic Information
Cal. Ins. Code § 10123.3	Federal and State statutes/laws	California	1999	Employment/Insurance Discrimination
Cal. Ins. Code § 10123.3, 10123.31 • Summary	Federal and State statutes/laws	California	1999	Employment/Insurance Discrimination, Genetic Testing and Counseling
Cal. Health & Safety Code § 125000-125001 • Summary	Federal and State statutes/laws	California	1998	Genetic Testing and Counseling
Cal. Health & Safety Code § 125070 • Summary	Federal and State statutes/laws	California	1998	Genetic Testing and Counseling
Cal. Health & Safety Code § 1357.52 • Summary	Federal and State statutes/laws	California	1998	Employment/Insurance Discrimination
Cal. Ins. Code § 10140(b)-(d) • Summary	Federal and State statutes/laws	California	1998	Employment/Insurance Discrimination
Cal. Ins. Code § 10705(j) • Summary	Federal and State statutes/laws	California	1998	Employment/Insurance Discrimination
Cal. Ins. Code § 742.405 • Summary	Federal and State statutes/laws	California	1998	Employment/Insurance Discrimination
Cal. Ins. Code § 10198.9 • Summary	Federal and State statutes/laws	California	1997	Employment/Insurance Discrimination
Cal. Fam. Code § 8706 • Summary	Federal and State statutes/laws	California	1995	Nonmedical Applications (Adoption)
Cal. Fam. Code § 8817 • Summary	Federal and State statutes/laws	California	1995	Nonmedical Applications (Adoption)
Cal. Health & Safety Code § 103825 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code §	Federal and	California	1995	Genetic Testing and

124975 • Summary	State statutes/laws			Counseling, Privacy of Genetic Information
Cal. Health & Safety Code § 124995 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125025 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125030 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125050 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125055 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125060 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125065 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Health & Safety Code § 125110 • Summary	Federal and State statutes/laws	California	1995	Genetic Testing and Counseling
Cal. Ins. Code § 10123.31	Federal and State statutes/laws	California	1995	Employment/Insurance Discrimination
Cal. Ins. Code § 10140.5 • Summary	Federal and State statutes/laws	California	1995	Employment/Insurance Discrimination
Cal. Ins. Code §§ 10146-10149.1 • Summary	Federal and State statutes/laws	California	1994	Employment/Insurance Discrimination, Genetic Testing and Counseling, Privacy of Genetic Information
Cal. Health & Safety Code § 1367.7 • Summary	Federal and State statutes/laws	California	1979	Genetic Testing and Counseling
Cal. Ins. Code § 10123.9 • Summary	Federal and State statutes/laws	California	1979	Genetic Testing and Counseling
Cal. Ins. Code § 10143 • Summary	Federal and State statutes/laws	California	1977	Employment/Insurance Discrimination

CALIFORIA "Genetics" Laws

NCSL Genetics Tables

State Embryonic and Fetal Research Laws

SEE NCSL'S Genetics Legislative Activity page for pending legislation.

State statutes on embryonic and fetal research have evolved with the development of new technologies. Currently, a great deal of attention has centered around stem cell research. There are four primary sources for embryonic stem cells: existing stem cell lines, aborted or miscarried embryos, unused in vitro fertilized embryos, and cloned embryos. Current federal policy limits federally funded research to research conducted on embryonic stem cell lines created before August 2001. Federal funding of research involving cloning for the purpose of reproduction or research is prohibited. However, there is no federal law banning human cloning altogether. The Food and Drug Administration has claimed authority over the regulation of human cloning technology as an investigational new drug (IND) and stated that at this time, they would not approve any projects involving human cloning for safety reasons, but Congress has not passed legislation confirming the FDA's authority to prohibit cloning.

State laws may restrict the use of embryonic stem cells from some or all sources or specifically permit certain activities. State laws on the issue vary widely. Approaches to stem cell research policy range from laws in California, Connecticut, Massachusetts and New Jersey, which encourage embryonic stem cell research, including on cloned embryos, to South Dakota's law, which strictly forbids research on embryos regardless of the source. States that specifically permit embryonic stem cell research have established guidelines for scientists such as consent requirements and approval and review processes for projects.

Many states restrict research on aborted fetuses or embryos, but research is often permitted with consent of the patient. Almost half of the states also restrict the sale of fetuses or embryos. Louisiana is the only state that specifically prohibits research on in vitro fertilized (IVF) embryos. Illinois and Michigan also prohibit research on live embryos. Finally, Arkansas, Indiana, Iowa, Michigan, North Dakota and South Dakota prohibit research on cloned embryos. Virginia's law also may ban research on cloned embryos, but the statute may leave room for interpretation because human being is not defined. Therefore, there may be disagreement about whether human being includes blastocysts, embryos or fetuses. California, Connecticut, Massachusetts, New Jersey and Rhode Island also have human cloning laws. These laws prohibit cloning only for the purpose of initiating a pregnancy, or reproductive cloning, but allow cloning for research.

Several states limit the use of state funds for cloning or stem cell research. Missouri forbids the use of state funds for reproductive cloning but not for cloning for the purpose of stem cell research, and Arizona prohibits the use of public monies for reproductive or therapeutic cloning. Nebraska limits the use of state funds for embryonic stem cell research. Restrictions only apply to state healthcare cash funds provided by tobacco settlement dollars. State funding available under Illinois Executive Order 6 (2005) may not be used for reproductive cloning or for research on fetuses from induced abortions.

Several states have authorized funding for stem cell research in 2004 and 2005. In early 2004 New Jersey became the first state to appropriate funds specifically for adult and embryonic stem cell research. State funding for adult stem cell research was already occurring in at least one state, Ohio. Over the last two years $8.5 million and $14.5 million in general revenues have been allocated to the New Jersey Stem Cell Institute, according to New Jersey's Commission on Science and Technology. In addition, a $230 million ballot initiative for stem cell research grants and $150 million in capital funds to build the Stem Cell Institute of New Jersey have been proposed. In November 2004 voters in California quickly followed the path of New Jersey with the passage of Proposition 71 to fund adult and embryonic stem cell research. The measure authorized the issuance of bonds in the amount of $3 billion beginning in 2005 not to exceed sale of over $350 million per year. If less than the amount is issued, the remainder may be carried over to the next year. In 2005 the Connecticut legislature passed Senate Bill 934, which created a fund to provide ten million dollars in grants a year over ten years to do the same. Finally, Illinois Governor Blagojevich signed an executive order to create the Illinois Regenerative Medicine Institute and provide for grants to medical research facilities for adult and embryonic stem cell research. Meanwhile, grant programs for stem cell research have yet to get underway in California and New Jersey with some obstacles related to funding or oversight issues. New Jersey is expected to award its first grants in December 2005.

This year the Virginia legislature also created a fund to support adult stem cell research only. Money was not appropriated at the time the fund was established. And legislators in Massachusetts enacted Senate Bill 2039, which became law after the legislature overrode the governor's veto. The measure creates a biomedical research advisory council, which will examine the appropriateness of public funding for research on stem cells from umbilical cord blood and assess the feasibility of establishing an institute for regenerative medicine at the University of Massachusetts Medical School. Indiana legislators created an adult stem cell research center at Indiana University. Funding was not appropriated at the time the center was established. Currently, efforts are underway to gather signatures

State Human Cloning Laws

Updated June 21, 2005

Fourteen states have laws pertaining to human cloning. The issue was first addressed by California legislature, which banned reproductive cloning, or cloning to initiate a pregnancy, in 1997. Since then, nine other states, including Arkansas, Connecticut, Indiana, Iowa, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia have enacted measures to prohibit reproductive cloning. Arizona and Missouri have measures that address the use of public funds for cloning. Louisiana also enacted legislation that prohibited reproductive cloning, but the law expired in July 2003.

Arkansas, Indiana, Iowa, Michigan, North Dakota and South Dakota laws extend their prohibitions to therapeutic cloning, or cloning for research purposes. Virginia's law also may ban human cloning for any purpose, but it may be open to varying interpretations because the law does not define the term "human being," which is used in the definition of human cloning. Rhode Island law does not prohibit cloning for research, and California and New Jersey human cloning laws specifically permit cloning for the purpose of research.

For a discussion of issues related to cloning in further detail, please see NCSL's magazine article on human cloning "Attack of the Clones" published in the April 2003 issue of *State Legislatures*. NOTE: This article does not reflect subsequent changes to state human cloning laws. Please see the table below for current state laws.

State	Statute Citation	Summary	Prohibits Reproductive Cloning	Prohibits Therapeutic Cloning	Expiration
California	Business And Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7	Prohibits reproductive cloning; permits cloning for research; provides for the revocation of licenses issued to businesses for violations relating to human cloning; prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; establishes civil penalties	yes	no	

No Reproductive Cloning

78

for proposed ballot initiatives on stem cell research in a few states, including Florida and Missouri. Several states also have established committees to study the state's role in stem cell research, including Arizona, North Carolina and Virginia.

For detailed information on funding for stem cell research in California, New Jersey, and Ohio, please visit the following URL's:
(NOTE: NCSL does not necessarily endorse any views expressed on Web sites below)

California: http://www.smartvoter.org/2004/11/02/ca/state/prop/71/
New Jersey: http://www.state.nj.us/treasury/omb/publications/05bib/pdf/bib.pdf
(Information about the New Jersey Stem Cell Institute is on page 21.)
Ohio: http://ora.ra.cwru.edu/stemcellcenter/

To view stem cell research legislation introduced in the states in 2005, please visit NCSL's database.

State/Jurisdiction Statute Section	Specifically permits research on fetus/embryo	Restricts research on aborted fetus/ embryo	Consent provisions to conduct research on fetus/embryo	Restricts research on fetus or embryo resulting from sources other than abortion	Restrictions of purchase/sale human tissue for research
California Health & Safety §§ 123440, 24185, 12115-7, 125300-320	Yes	Yes, prohibits research on aborted live fetus	Yes, consent to donate IVF embryo to research	No	Yes, prohibits sale for the purpose of reproductive cloning or for stem cell research

State Laws and Legislation:
Use, Storage and Disposal of Frozen Embryos

Updated March 2005

State	Statutes
California	California Penal Code §367g (2003) prohibits the use sperm, ova, or embryos in assisted reproduction technology in a manner other than stated on the written consent form of the provider of the sperm, ova or embryos. The statute also requires signed written consent to implant embryos or gametes. The use of sperm donated to a licensed tissue bank is excluded. California Health and Safety Codes § 125315 (2003) requires health care providers to give infertility patients the necessary information to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment. Patients must be offered several options, including storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. CA S.B. 771 (2003) amends §125315: requires the State Department of Health Services to establish and maintain a registry of embryos that would provide researchers with access to embryos for research purposes. The law specifies requirements for obtaining informed consent from an individual considering donating embryos for research. The law also requires a physician, surgeon or other health care provider to provide a form that sets forth advance directives regarding the disposition of embryos.

around the capitol

CALIFORNIA EMBRYO LAWS

{Caution}

CALIFORNIA HEALTH AND SAFETY CODE

125300. The policy of the State of California shall be as follows:

(a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given.

(b) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.

125305. (a) The department shall establish and maintain an anonymous registry of embryos that are available for research. The purpose of this registry is to provide researchers with access to embryos that are available for research purposes.

(b) The department may contract with the University of California, private organizations, or public entities to establish and administer the registry.

(c) This section shall be implemented only to the extent that funds for the purpose of establishing and administering the registry are received by the department from private or other nonstate sources.

125315. (a) A physician and surgeon or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment. The failure to provide to a patient this information constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. When providing fertility treatment, a physician and surgeon or other health care provider shall provide a form to the male and female partner, or the individual without a partner, as applicable, that sets forth advanced written directives regarding the disposition of embryos. This form shall indicate the time limit on storage of the embryos at the clinic or storage facility and shall provide, at a minimum, the following choices for disposition of the embryos based on the following circumstances:

(1) In the event of the death of either the male or female partner, the embryos shall be disposed of by one of the following actions:

(A) Made available to the living partner.

(B) Donation for research purposes.

(C) Thawed with no further action taken.

(D) Donation to another couple or individual.

(E) Other disposition that is clearly stated.

(2) In the event of the death of both partners or the death of a patient without a partner, the

embryos shall be disposed of by one of the following actions:

(A) Donation for research purposes.

(B) Thawed with no further action taken.

(C) Donation to another couple or individual.

(D) Other disposition that is clearly stated.

(3) In the event of separation or divorce of the partners, the embryos shall be disposed of by one of the following actions:

(A) Made available to the female partner.

(B) Made available to the male partner.

(C) Donation for research purposes.

(D) Thawed with no further action taken.

(E) Donation to another couple or individual.

(F) Other disposition that is clearly stated.

(4) In the event of the partners' decision or a patient's decision who is without a partner, to abandon the embryos by request or a failure to pay storage fees, the embryos shall be disposed of by one of the following actions:

(A) Donation for research purposes.

(B) Thawed with no further action taken.

(C) Donation to another couple or individual.

(D) Other disposition that is clearly stated.

(c) A physician and surgeon or other health care provider delivering fertility treatment shall obtain written consent from any individual who elects to donate embryos remaining after fertility treatments for research. For any individual considering donating the embryos for research, to obtain informed consent, the health care provider shall convey all of the following to the individual:

(1) A statement that the early human embryos will be used to derive human pluripotent stem cells for research and that the cells may be used, at some future time, for human transplantation research.

(2) A statement that all identifiers associated with the embryos will be removed prior to the derivation of human pluripotent stem cells.

(3) A statement that donors will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells.

(4) A statement that derived cells or cell lines, with all identifiers removed, may be kept for many years.

(5) Disclosure of the possibility that the donated material may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any future commercial development.

(6) A statement that the human pluripotent stem cell research is not intended to provide direct medical benefit to the donor.

(7) A statement that early human embryos donated will not be transferred to a woman's uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research.

125320. (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.

(b) For purposes of this section, "valuable consideration" does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

(c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.

MEDICAL CARE & HEALTH PROMOTION

NEWBORN SCREENING

1960's
Robert Guthrie
PKU screening test

(1) LAWS in MOST States REQUIRE **Mandatory** newborn screening IE disease CAN BE TREATED in newborn baby to Prevent Disease or Mitigate More Serious Aspects of Disease — MANDATORY PUBLIC HEALTH APPROACH!

(2) PKU, Galactosemia, Primary Congenital Hypothyroidism, Sickle Cell and other Hemoglobin diseases (California Newborn Screening Program).

(3) Only Legal ground for refusal is religious beliefs & practices in CA. Ethical?!

(4) New Mass Spectroscopy Screening in CA and other States have added 20 more tests for metabolic disorders voluntarily in a TRIAL research period.

(5) State pays although fee can be charged.

MANDATORY testing! ⇐

(6) IF Risks/Benefits of TREATMENT NOT clear, then CAN'T be MANDATORY & Left to Parental Discretion — OR NO TREATMENT

Laws Governing
- POLICE Powers
  - "promote general welfare"
  - "Parens patriae" authority to intervene to prevent person at risk from self-inflicted harm

MEDICAL CARE & HEALTH PROMOTION

CHILD / ADULT TESTING AND SCREENING

(1) Diagnostic Process to determine whether a person has Late onset genetic disease, confirm genetic disease, or to determine if person susceptible to cancer, hypertension, high cholesterol, etc. in order to take preventive action –

(2) **Cannot Make Mandatory** – personal autonomy "Life, Liberty, ... without due process of Law" – 5th / 14th Amendments to Constitution. Canterbury vs. Spence (1972) – informed consent. Can refuse necessary Medical care.

(3) Main issues – Access Voluntarily to all & Tort Liability

a. Legal Duty of Physicians to inform patients of availability of Test Results – If test reliable – then Standard of care tort Law is applicable

b. Physician has a Liability if patients interest in needing test not considered!!

(4) Cost Barriers / Universal Access / Health Insurance pay for tests

FAMILY PLANNING AND REPRODUCTIVE ISSUES

Major Impact - Hundreds of Genetic Disease genes can be screened for using BABI (PGD), Amniocentesis, or Chorionic villi testing (+) parental/family testing — with Human Genome Sequence - ALL Disease genes can be tested for!!!

CAN determine whether parents are carriers &/or embryo, fetus, child has genetic disease!

(2) Remember - ~ 1.2% of all Live births have genetic defect due to a mutation in a disease gene! And we all carry a few deleterious gene alleles!

(3) Legal Issues Controversial

a. abortion debate/embryo rights
b. women's rights/reproductive choice
c. eugenic concerns
d. genetic engineering of human cells

(4) Ethical & Legal Presumption of Voluntary Choice for Reproductive Matters - Voluntary testing & Woman's Right to Reproductive Choice -

a. VOLUNTARY TESTING
b. Griswold vs. Connecticut + Roe vs. Wade (contraception/abortion) right to privacy is conceptualize as a substantive 5th/14th amendment Liberty - Procreative choice is hedged by a number of

tradition embedded into Living constitution — right to privacy + subsidiary right to determine pregnancy — up to 1st Trimester —

(5) Main Legal Issue — Tort Liability

a. Gain access to knowledge + act on it by contraception, embryo testing, pre-natal testing, &/or abortion

b. Tort law states that couples have the right to avoid birth of handicapped children if tests or procedures to avoid birth are available

c. Wrongful birth/Life Cases

(1) Curlender vs. Bio-Science Laboratories (CA) Child/parents can bring tort suit against a lab that failed to carry out say-Sachs test properly giving birth to child — Legal Tort Liability

(2) Grodin vs. Grodin (MI)

Court held that boy can sue mother for causing his teeth to be brown because she took tetracycline during pregnancy!

Several States have now enacted statutes prohibiting wrongful Life suits against parents by children — CA — Turpin vs. Sortini — "purpose to eliminate any Liability or other economic pressure which might induce parents to abort or conceive a potentially defective child."

"Wrongful-Birth" Lawsuits Abolished in Georgia and In Michigan

By Liz Townsend

Courts in Michigan and Georgia have rejected attempts by parents of disabled children to sue doctors who, the parents claimed, failed to discover their babies' birth defects in time for an abortion.

The Michigan Court of Appeals and the Georgia Supreme Court ruled that these "wrongful-birth" lawsuits are invalid under state law. The Michigan appeals court warned that such suits "could quickly slide into applied eugenics and the elimination of supposedly unfit lives," while Georgia's high court held that state law "does not recognize a cause of action for wrongful birth."

Wrongful-birth lawsuits remain legal in 27 states. Doctors such as James Delahunty of New Jersey, founder of the Association of Pro-Life Obstetricians and Gynecologists, have lost suits that claimed they refused or neglected to offer amniocentesis or other diagnostic tests that could have identified babies' disabilities to pregnant women.

Last March Delahunty was ordered to pay $1.85 million to the parents of Michael Imber-gamo, a four-year-old little boy with Down syndrome. Michael's parents testified that they would have aborted him if they had discovered his condition before birth, the *Washington Times* reported.

"Some women want to kill their children because they are handicapped," said Delahunty, according to the *Times* . "If genetic tests give them wrong results, they blame the doctor. I was blamed."

Delahunty's lawyer said that wrongful-birth lawsuits are a product of technology that can more easily identify disabilities in unborn children. "Patients who had disabled children in the past didn't think of suing the doctor," Tom Chamsky told the *Times* . "But as technology has grown, some women think that their child's disability is someone else's fault."

Both the Georgia and Michigan cases concerned babies whose disabilities were not identified by doctors from ultrasound tests.

The Georgia case involved the son of Andrew and Jennifer Etkind, who was born with Down syndrome in September 1995. According to the Georgia Supreme Court's July 8 decision, Dr. Ramon Suarez told Jennifer Etkind (who is also a doctor) that her baby "was developing normally and that she was not at risk for birth defects" after two ultrasounds and a blood test, and advised against the more invasive amniocentesis procedure. Dr. Etkind did not have an amniocentesis.

After their son was born with Down syndrome and a malformed heart, the Etkinds sued Suarez. According to the court decision, the Etkinds asserted that "but for the treatment or advice provided by the defendant, [they] would have aborted the fetus, thereby preventing the birth." The Etkinds sought to have Suarez pay for the costs of raising their son, the *Atlanta Journal-Constitution* reported.

The Georgia Supreme Court had previously abolished wrongful-birth lawsuits in the 1990 *Atlanta Obstetrics & Gynecology Group v. Abelson* decision. The Etkinds asked the court to overturn *Abelson* on several grounds, including constitutional and due process concerns. However, the court, by a 6-1 majority, rejected all their arguments, ruling that "Georgia tort law does not recognize a cause of action for wrongful birth."

The Etkinds' main contention was that Dr. Suarez's failure to identify the baby's Down syndrome "interfered with their choice of whether to have an abortion" and that the ban on wrongful-birth suits also stands in the way of the abortion "right," according to the court decision.

However, the court insisted, "refusal to recognize wrongful birth, absent authorizing legislation, does not interfere with Dr. Etkind's constitutional right to an abortion."

In a strongly worded decision, the Michigan Court of Appeals rejected the lawsuit brought by the parents of four-year-old Shelby Taylor, who sued Dr. Surender Kurapati for finding "no visible abnormalities" in a December 4, 1993, ultrasound.

According to the June 25 appeals court decision, Shelby was born on April 19, 1994, with a "missing right shoulder, fusion of left elbow, missing digits on left hand, missing femur on left leg and short femur on right," according to the court. Her parents contended that "the failure to reveal the disabilities deprived the Taylors of their right to make a reproductive decision regarding the pregnancy," according to the court decision. They also alleged that Kurapati was liable for the "emotional distress" they suffered when their little girl was born.

Overturning prior decisions that had allowed such lawsuits, the Court of Appeals rejected the Taylors' arguments and ruled that wrongful-birth suits are not valid under state law. The court saw much danger in the theory behind these suits, that parents should be compensated if they were not able to abort a disabled child.

"The very phrase 'wrongful birth' suggests that the birth of the disabled child was wrong and should have been prevented," Judge J. Whitbeck wrote for the 2-1 majority. "If one accepts the premise that the birth of one 'defective' child should have been prevented, then it is but a short step to accepting the premise that the births of classes of 'defective' children should be similarly prevented, not just for the benefit of the parents but also for the benefit of society as a whole through the protection of 'public welfare.' This is the operating principle of eugenics."

The court also rejected the argument that wrongful-birth lawsuits are required to ensure the "right" to abortion that was legalized in *Roe v. Wade* . Whitbeck wrote that *Roe* allows the "state to make a value judgment favoring childbirth over abortion." For example, previous courts have found that the Michigan Consti-tution does not require the state to fund abortions, but Michigan does provide financial support for childbirth.

"As the state has no obligation to affirmatively aid a woman in obtaining an elective abortion by paying for it," Whitbeck wrote, "the state similarly has no obligation to take the affirmative step of imposing a civil liability on a party for failing to provide a pregnant woman with information that would make her more likely to have an elective, and eugenic, abortion."

The Michigan decision called attention to the "slippery slope" that is evident in wrongful-birth lawsuits, a slope that pro-lifers have been warning about for years. "[I]t is but another short half step from the concept of preventing the birth of an 'unfit' or 'defective' child to proposing, for the benefit of the child's overburdened parents and of the society as a whole, that the existence of the child should not be allowed to continue," Whitbeck wrote.

"After all, if that child never should have been born, then that child has no real right to go on living, thereby imposing the costs of the child's continued existence upon the parents and society. This, we conclude, is the logical end of the slippery slope inherent in the application of the benefits rule through the wrongful birth tort."

What Agencies & Laws Regulate Genetic Testing Products & Services?

Police Powers – "promote the general welfare"

(1) Test Products

Example: PATHWAY® – Her2 test for breast cancer

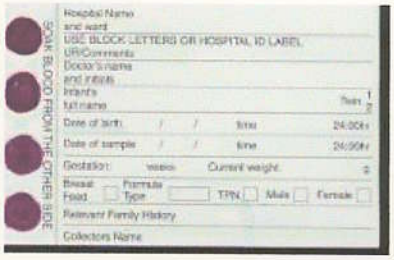
- The FDA regulates genetic testing kits, reagents, & machinery under the Medical Devices Act of 1976 & the Safe Medical Device Amendments of 1990.
- Intent is to provide safety & effectiveness – e.g., give proper results & distinguish between high risk, low risk, & false positives
- Premarket Approval (PMA) is required of all Medical devices Marketed for in vitro diagnosis

(2) Laboratory Services

- Clinical Laboratory Improvement Act of 1967 (CLIA67) –
- Department of Human & Health Services (HHS)
- CLinical Laboratory Improvement Amendments of 1988 – (CLIA88)

Materials from human body for purposes of diagnosis, prevention, or treatment of disease

Newborn Genetic and Metabolic Disease Screening



State public health programs screen an estimated 4.1 million infants annually for genetic and metabolic disorders. Early detection of these abnormalities can prevent severe disability, mental retardation or even death and may also save states and families money by avoiding financially burdensome medical costs and state institutional services. Comprehensive state newborn screening programs involve more than the initial screening. Diagnosis, follow-up, treatment and evaluation are also vital components to ensure that children with potentially life threatening conditions receive necessary care.

All state legislatures play a key role in the newborn screening system as the bodies responsible for appropriating funds or authorizing fees to make newborn screening possible. The extent of legislative involvement in the newborn screening system varies. In some cases, the panel of disorders screened for is set forth in state statutes while in other instances the state health department or other entity has the authority to alter the panel. State statutes or regulations also may address payment for newborn screening services, the provision of medical foods for treatment of a disorder, privacy and confidentiality issues, parent education about newborn screening, contracting services, laboratory standards and the storage, use and disposal of blood spots.

Whether a newborn is screened for a particular condition depends on his or her birthplace because newborn screening lists of conditions (referred to as a panels) differ state by state. Factors such as prevalence and severity of a condition, availability and effectiveness of treatment, and cost may help to determine whether a state screens for a particular disorder. Recent advances in technology have enabled some states to add a substantial number of conditions to the newborn screening panel in a relatively short timeframe.

Through tandem mass spectrometry, public health laboratories can now quickly analyze a blood sample for dozens of conditions. These developments prompted the Health Resources and Services Administration (HRSA) to request a report on newborn screening that would include a recommendation for a uniform panel of conditions. The report Newborn Screening: Toward a Uniform Panel and System was recently completed by the American College of Medical Genetics and a public comment period on the report concluded in early May 2005. Public comments on the report will be discussed at the next meeting of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children ACHDGDNC.

Citations and links to newborn screening program statutes and 2005 enacted legislation in the states and the District of Columbia are below. The list of statutes and bills does not necessarily include sections pertaining to program funding or payment for or coverage of services and treatment. A list of disorders screened for by state is available on-line through the National Newborn Screening and Genetics Resource Center.

NOTE: NCSL does not have a position with respect to newborn screening or the ACMG report. The above links to outside organizations are provided for informational purposes only.

Alabama Ala. Code §22-2-03

Alaska Alaska Stat. §18-15-200, 210

Featured Links

- Newborn Screening Webcast - September 2005
- Genetics Legislation Database
- Newborn Hearing Screening
- Folic Acid Postcard

State Genetic Counselor Licensing Laws

NOTE: This page is updated on a monthly basis.

California, Illinois and Utah are the only states with requirements for the licensing of genetic counselors. California has not issued any licenses to date because the regulations necessary to begin the program have not been promulgated while Utah has begun issuing licenses. Illinois' Genetic Counselor Licensing Act took effect recently on September 29, 2004.

To view a list of genetic counselor licensing bills considered in 2004, please visit NCSL's Genetics Legislation Database.

State and Statute	Personal Access to Genetic Information Required	Confidentiality Requirements	Sets Minimum Qualifications for Obtaining a Genetic Counselor License	Sets Minimum Requirements for Obtaining a Temporary Genetic Counselor License	Specific Penalties for Violations
California Health and Safety §124975-124996	X	X	X		X
Utah §58-75		X	X	X	X
Illinois Public Law 093-1041		X	X	X	X

Source: NCSL, West Group.
For additional information, please contact:
Alissa Johnson
NCSL, Health Program
alissa.johnson@ncsl.org

Genetic Technologies Project

Denver Office: Tel: 303-364-7700 | Fax: 303-364-7800 | 7700 East First Place | Denver, CO 80230 | Map
Washington Office: Tel: 202-624-5400 | Fax: 202-737-1069 | 444 North Capitol Street, N.W., Suite 515 | Washington, D.C. 20001

Newborn Genetic Screening Privacy Laws

Health Programs

Updated July 2002

Currently, **28 states** require consent to either perform or require genetic testing or to obtain, retain or disclose genetic information through genetic-specific privacy laws. In addition, Washington includes genetic information in the definition of protected health information under the state's health privacy statute. Many of the states with genetic privacy laws exempt newborn screening from consent provisions, including Delaware, Illinois, Louisiana, Massachusetts, Michigan, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon and Vermont. The chart below does not address consent requirements or exemptions for newborn screening that may be found in state administrative codes.

At least **23 states** have laws that allow for an exemption to the newborn genetic screening requirements if parents object on religious grounds (Alabama, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, New Jersey, New York, North Dakota, Ohio, Rhode Island, South Carolina, Texas, Utah, Virginia, Washington and Wisconsin). Two states--Florida and Wyoming--allow for an exemption to the newborn genetic screening requirements if parents object on any grounds.

At least **12 states** have confidentiality requirements related to newborn screening laws (Arizona, Colorado, Florida, Hawaii, Iowa, Louisiana, New Jersey, North Dakota, Ohio, South Carolina, Virginia and Wisconsin).

At least **six states** and the District of Columbia have laws related to obtaining consent from the parents of children before performing genetic tests (Hawaii, Ohio, Nebraska, Texas, Wisconsin and Wyoming). Kansas requires informed consent in order to monitor infants with genetic disorders.

Many states have laws regulating newborn hearing screening, but these laws do not necessarily apply to newborn genetic screening.

State	Newborn Genetic Screening Privacy Laws	Law Allows for a Religious Exemption	Genetic Privacy Law Allows for an Exemption for Newborn Screening
California	Cal. Health & Safety Code § 124975 clarifies that participation of people in hereditary disorders programs should be wholly voluntary, except for initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program. All information obtained from people involved in hereditary disorders programs in the state should be held strictly confidential. Cal. Health & Safety Code § 124980 prohibits tests from being performed on any minor over the objection of the minor's parents or guardian. Tests may not be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders and is given reasonable opportunity to object to the testing. No testing, except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation. The law requires all testing results and personal information generated from hereditary disorders programs to be made available to individuals over 18 years of age, or to the individual's parent or guardian. All testing results and personal information from hereditary disorders programs shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released.	Cal. Health & Safety Code § 125000	

California

Newborn Screening Contact Information

NBS Laboratory	Follow-up Program
John Sherwin, Ph.D. jsherwin@dhs.ca.gov 510-231-1728	Fred Lorey, Ph.D. florey@dhs.ca.gov 510-412-1490

Click here to go to this programs newborn screening website

Approximate Births
529,500

Major Racial/Ethnic Groups
White: 81% American Indian: 1%
African American: 7% Asian/Pacific islander: 11%

Hispanic Ethnicity: 49% (may also be included in race categories above)

California Statute
Cal. Health & Safety Code § 125000 and 125001 (1998) - addresses testing, counseling, information and fees.
Cal. Health & Safety Code § 125000 and 125001 (1998) - addresses insurance coverage for testing.
For more information click on this link: National Conference of State Legislators

Screening Requirement
Testing required by law on all newborns.

NBS Fee: $78.00

Disorders

Click here for a list of disorders states screen for

California Department of Health Services
Genetic Disease Branch
Newborn Screening Program
Disorders Detectable by NBS Program as of July 11, 2005[1]

I. Metabolic Disorders

A. Carbohydrate Disorders
- classical galactosemia

B. Amino Acid Disorders
- classical phenylketonuria (PKU)
- variant PKU
- guanosine triphosphate cyclohydrolase 1 (GTPCH) deficiency (biopterin deficiency)
- 6-pyruvoyl-tetrahydropterin synthase (PTPS) deficiency (biopterin deficiency)
- dihydropteridine reductase (DHPR) deficiency (biopterin deficiency)
- pterin-4α-carbinolamine dehydratase (PCD) deficiency (biopterin deficiency)
- argininemia/arginase deficiency
- argininosuccinic acid lyase deficiency (ASAL deficiency)
- citrullinemia, Type I/argininosuccinic acid synthetase deficiency (ASAS deficiency)
- citrullinemia, Type II (citrin deficiency)
- gyrate atrophy of the choroid and retina
- homocitrullinuria, hyperornithinemia, hyperammonemia –HHH
- homocystinuria/cystathionine beta-synthase deficiency (CBS deficiency)
- methionine adenosyltransferase deficiency (MAT deficiency)
- maple syrup urine disease – (MSUD)
- tyrosinemia

C. Organic Acid Disorders
- 2-methyl-3-hydroxybutyryl-CoA dehydrogenase deficiency
- 2-methylbutyryl-CoA dehydrogenase deficiency
- 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMGCoA lyase deficiency)
- 3-methylcrotonyl-CoA carboxylase deficiency (3MCC deficiency)
- 3-methylglutaconic aciduria (MGA), Type I (3-methylglutaconyl-CoA hydratase deficiency)
- beta-ketothiolase deficiency (BKT)
- ethylmalonic encephalopathy (EE)
- glutaric acidemia type-1 (GA-1)
- isobutyryl-CoA dehydrogenase deficiency
- isovaleric acidemia (IVA)
- malonic aciduria
- methylmalonic acidemia, mut –
- methylmalonic acidemia, mut 0
- methylmalonic acidemia (Cbl A, B)
- methylmalonic acidemia (Cbl C, D)
- multiple carboxylase deficiency (MCD)
- propionic acidemia (PA)

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D. Fatty Acid Oxidation Disorders

- carnitine transporter deficiency
- carnitine-acylcarnitine translocase deficiency (CAT deficiency)
- carnitine palmitoyl transferase deficiency-type 1 (CPT-1 deficiency)
- carnitine palmitoyl transferase deficiency-type 2 (CPT-2 deficiency)
- long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency)
- medium chain acyl-CoA dehydrogenase deficiency (MCAD deficiency)
- multiple acyl-CoA dehydrogenase deficiency (MAD deficiency)/glutaric acidemia type-2 (GA-2)
- short chain acyl-CoA dehydrogenase deficiency (SCAD deficiency)
- trifunctional protein deficiency (TFP deficiency)
- very long chain acyl-CoA dehydrogenase deficiency (VLCAD deficiency)

II. Endocrine Disorders

- primary congenital hypothyroidism
- variant hypothyroidism
- congenital adrenal hyperplasia-salt wasting (21-hydroxylase deficiency)
- congenital adrenal hyperplasia-simple virilizing (21-hydroxylase deficiency)

III. Hemoglobin Disorders

- sickle cell anemia (Hb S/S disease)
- sickle C disease (Hb S/C disease)
- sickle D disease (Hb S/D disease)
- sickle E disease (Hb S/E disease)
- Hb S/ hereditary persistence of fetal hemoglobin (Hb S/HPFH)
- sickle cell disease variant (other sickle cell disease, Hb S/V)
- Hb S/ Beta^0 thalassemia
- Hb S/Beta $^+$ thalassemia
- Hb C disease (Hb CC)
- Hb D disease (Hb DD)
- alpha thalassemia major
- Hb H disease
- Hb H/ Constant Spring disease
- beta thalassemia major
- Hb E/ Beta^0 thalassemia
- Hb E/Beta $^+$ thalassemia
- Hb E/ Delta Beta thalassemia
- Hb C/ Beta^0 thalassemia
- Hb C/Beta $^+$ thalassemia
- Hb D/ Beta^0 thalassemia
- Hb D/Beta $^+$ thalassemia
- Hb Variant/ Beta^0 thalassemia
- Hb Variant/Beta $^+$ thalassemia
- other hemoglobinopathies (Hb variants)

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[i] Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the Newborn Screening Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk to justify a diagnostic work-up, a negative screening result does <u>not</u> rule out the possibility of a disorder. Health care providers should remain watchful for any sign or symptoms of these disorders in their patients. A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider.

National Newborn Screening and Genetics Resource Center
Austin, Texas USA
NNSGRC

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D = likely to be detected (and reported) as a by-product of MRM screening (MS/MS) targeted by Law or Rule

STATE	Core[1] Conditions - Metabolic																			
	Fatty Acid Disorders					Organic Acid Disorders									Amino Acid Disorders					
	CUD	LCHAD	MCAD	TFP	VLCAD	GA-I	HMG	IVA	3-MCC	Cbl-A,B	BKT	MUT	PROP	MCD	ASA	CIT	HCY	MSUD	PKU	TYR-I
Alabama	●		●							●		●	●			●	●	●	●	●
Alaska	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Arizona																	●	●	●	
Arkansas																			●	
California	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Colorado	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	●	C
Connecticut	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
D. of Columbia	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Delaware		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Florida	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Georgia			●														●	●	●	●
Hawaii	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Idaho	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Illinois		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Indiana	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Iowa	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Kansas																			●	
Kentucky	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Louisiana			A												A	A	A	A	●	
Maine	D	●	●	D	●	●	●	●	●	●	●	●	●	D	●	●	●	●	●	●
Maryland		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Massachusetts	D	A	●	D	A	A	A	A	A	A	A	A	A	D	A	A	●	●	●	A
Michigan	A	A	●	A	A	A	A	A	A	A	A	A	A	A	●	●	●	●	●	A
Minnesota	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Mississippi	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Missouri		●	●	●	●	●	●	●	●	●			●		●	●	●	●	●	
Montana	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	●	B
Nebraska		A	●	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A	●	A
Nevada	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
New Hampshire			C														●	●	●	
New Jersey		A	●	A	●	●	●	●	●	●	A	●	●		●	●	A	●	●	A
New Mexico	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C	●	C
New York	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
North Carolina		●	●	●	●	●	●	●	●	●	●	●	●		●	●	●	●	●	
North Dakota		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Ohio		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
Oklahoma			C																●	
Oregon	A	●	●	A	●	●	●	●	●	A	A	●	●	A	●	●	●	●	●	●
Pennsylvania	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	●	●	B
Rhode Island	D		●														●	●	●	
South Carolina	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	
South Dakota	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Tennessee		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Texas																			●	
Utah	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Vermont	D	●	●	D	●	●	●	●	●	●	●	●	●	D	●	●	●	●	●	●
Virginia	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Washington			●														●	●	●	
West Virginia																			●	
Wisconsin	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Wyoming																			●	

[1] Terminology consistent with ACMG report - Newborn Screening: Toward a Uniform Screening Panel and System 2005, p. 63.

Deficiency/Disorder Abbreviations and Names (optional nomenclature)

3-MCC	3-Methylcrotonyl-CoA carboxylase	CUD	Carnitine uptake defect (Carnitine transport defect)	LCHAD	Long-chain L-3- hydroxyacyl-CoA dehydrogenase	PKU	Phenylketonuria/ hyperphenylalaninemia
ASA	Argininosuccinate acidemia	GA-1	Glutaric acidemia type 1	MCAD	Medium-chain acyl-CoA dehydrogenase	PROP	Propionic acidemia (Propionyl-CoA carboxylase)
BKT	Beta ketothiolase (mitochondrial acetoacetyl-CoA thiolase ; short-chain ketoacyl thiolase; T2)	HCY	Homocystinuria (cystathionine beta synthase)	MCD	Multiple carboxylase (Holocarboxylase synthetase)	TFP	Trifunctional protein deficiency
CBL A,B	Methylmalonic acidemia (Vitamin B12 Disorders)	HMG	3-Hydroxy 3 - methylglutaric aciduria (3-Hydroxy 3-methylglutaryl-CoA lyase)	MSUD	Maple syrup urine disease (branched-chain ketoacid dehydrogenase)	TYR-1	Tyrosinemia Type 1
CIT I	Citrullinemia type I (Argininosuccinate synthetase)	IVA	Isovaleric acidemia (Isovaleryl-CoA dehydrogenase)	MUT	Methylmalonic Acidemia (methylmalonyl-CoA mutase)	VLCAD	Very long-chain acyl-CoA dehydrogenase

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D = likely to be detected (and reported) as a by-product of MRM screening (MS/MS) targeted by Law or Rule

STATE	Secondary Target [1] Conditions																								
	Fatty Acid Disorders								Organic Acid Disorders						Amino Acid Disorders								Other Metabolic		Hbg
	CACT	CPT-Ia	CPT- II	DE-RED.	GA-II	MCKAT	M/SCHAD	SC AD	2M3HBA	2MBG	3MGA	Cbl-C,D	IBG	MAL	ARG	BIOPT-BS	BIOPT-RG	CIT-II	H-PHE	MET	TYR- II	TYR- III	GALE	GALK	Variant hemoglobins
Alabama												●						●	●		●	●			A
Alaska	●	●	●		●			●	●	●	●	●	●	●	●	B	B	●	●	●	●		B	B	●
Arizona																			●						A
Arkansas																			●				●	●	A
California	●	●	●		●			●	●	●	●	●	●	●	●	A	A	●	●	●	●	●			●
Colorado	C	C	C	C	C	C	C	C	C	C	C	C	C	C	C			C	●	C	C	C			●
Connecticut	●	●	●	●	●			●				●		●	●				●	●			●	●	A
D. of Columbia	●	●	●	●	●	A	●	●	A	●	●	●	●	●	●	A	A	●	●	●	●	A	●	●	A
Delaware	●		●		●	A		●	A	●	A	●	●		●	A	A	●	●	●	●	●	●	●	●
Florida	●	●	●		●			●				●						●	●	●	●				A
Georgia																B	B		●				●	●	●
Hawaii	●	●	●		●			●	●	●	●	●	●	●	●	B	B	●	●	●	●		B	B	A
Idaho	●	●	●		●			●	●	●	●	●	●	●	●	B	B	●	●	●	●		B	B	●
Illinois	●	●	●		●		●	●		●	●	●	●	●	●			●	●	●	●	●	●	●	A
Indiana	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			A
Iowa	●	●	●		●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			A
Kansas																			●						A
Kentucky								●											●						A
Louisiana																			●						A
Maine	D	D	●		●			●		D	D	●	D		●			●	●	D	●	D	●	●	●
Maryland	●		●		●		●	●		●	●	●	●		●	B	B	●	●	●	●	●	●	●	A
Massachusetts	D	D	A		A			A		D	D	A	D		A			A	●	D	A	D	●	●	●
Michigan	A	A	A	A	A	A	A	A	A	A	A	A	A	A	A			●	●						A
Minnesota	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Mississippi	●	●	●	A	●	A	●	●	A	●	●	●	●	●	●	A	A	●	●	●	●	A	●	●	●
Missouri	●	●	●		●			●				●						●	●	●	●	●			●
Montana	B		B	B	B	B	B	B		B	B	B	B	B		B	B	B	●	B	B	B			●
Nebraska	A		A		A			A		A		A	A	A	A			A	●	A	A		●	●	A
Nevada	●	●	●		●			●	●	●	●	●	●	●	●	B	B	●	●	●	●		B	B	A
New Hampshire																			●	D			●	●	B
New Jersey	A		A		A		A	●		A	A	●	A	A		●	●	●	●	A	A	A			A
New Mexico																			●						A
New York	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●			●	●	●	●	●			●
North Carolina					●			●		●		●	●						●	●	●	●			A
North Dakota	●	●	●		●	●	●	●	●	●	●	●	●	●	●			●	●		●				A
Ohio	●	●	●		●			●		●		●	●		●			●	●	●					A
Oklahoma																			●						A
Oregon	●	A	●		●			●	A	A	●	●	A	A	A	B	B	●	●	●	●		B	B	●
Pennsylvania	B	B	B	B	B		B	B		B	B	B	B	B	B	B	B	B	●	B	B	B	●	●	A
Rhode Island		D																	●				●	●	●
South Carolina	●		●		●	●		●	●	●	●	●	●			●	●	●	●	●			●	●	A
South Dakota	●	●	●		●			●		●	●	●	●	●	●			●	●	●	●	●			●
Tennessee	●	●	●	●	●			●	●	●	●	●	●	●	●			●	●	●	●	●			●
Texas																			●						A
Utah	●	●	●		●			●	●	●		●	●		●	●	●	●	●	●	●	●			●
Vermont	D	D	D		D					D	D	●			D			●	●	D	D	D	●	●	●
Virginia																			●						A
Washington																			●						A
West Virginia																			●				●	●	A
Wisconsin	●		●	●	●	●	●	●		●	●	●	●	●		●	●	●	●	●	●	●			●
Wyoming																			●						●

[1]Terminology consistent with ACMG report - Newborn Screening: Toward a Uniform Screening Panel and System 2005, p. 63.

Deficiency/Disorder Abbreviations and Names (optional nomenclature)

2M3HBA	2-Methyl-3-hydroxy butyric aciduria	**CACT**	Carnitine acylcarnitine translocase	**GA-II**	Glutaric acidemia Type II	**MAL**	Malonic acidemia (Malonyl-CoA decarboxylase)
2MBG	2-Methylbutyryl-CoA dehydrogenase	**CBL-C,D**	Methylmalonic acidemia (Cbl C,D)	**GALE**	Galactose epimerase	**MCKAT**	Medium-chain ketoacyl-CoA thiolase
3MGA	3-Methylglutaconic aciduria	**CIT-II**	Citrullinemia type II	**GALK**	Galactokinase	**MET**	Hypermethioninemia
ARG	Arginemia (Arginase deficiency)	**CPT-Ia**	Carnitine palmitoyltransferase I	**H-PHE**	Benign hyperphenylalaninemia	**SCAD**	Short-chain acyl-CoA dehydrogenase
BIOPT-BS	Defects of biopterin cofactor biosynthesis	**CPT-II**	Carnitine palmitoyltransferase II	**IBG**	Isobutyryl-CoA dehydrogenase	**TYR-II**	Tyrosinemia type II
BIOPT-REG	Defects of biopterin cofactor regeneration	**De-Red**	Dienoyl-CoA reductase	**M/SCHAD**	Medium/Short chain L-3-hydroxy acyl-CoA dehydrogenase	**TYR-III**	Tyrosinemia type III

National Newborn Screening Status Report
U.S. National Screening Status Report
Updated 03/03/06

The U.S. National Screening Status Report lists the status of newborn screening in the United States.

A dot "●" indicates that screening for the condition is universally required by Law or Rule
A = universally offered but not yet required, **B** = offered to select populations, or by request, **C** = testing required but not yet implemented
D = likely to be detected (and reported) as a by-product of MRM screening (MS/MS) targeted by Law or Rule

STATE	Core[1] Conditions									Additional Conditions Included in Screening Panel (universally required unless otherwise indicated)
	Hearing	Endocrine		Hemoglobin			Other			
	HEAR	CH	CAH	Hb S/S	Hb S/A	Hb S/C	BIO	GALT	CF	
Alabama	A	●	●	●	●	●	●	●		
Alaska	A	●	●	●	●	●	●	●		
Arizona	A	●	●	●	●	●	●	●		
Arkansas	●	●		●	●	●		●		
California	B	●	●	●	●	●		●		5-OXO; HHH; PRO
Colorado	●	●	●	●	●	●	●	●	●	
Connecticut	●	●	●	●	●	●	●	●	B	5-OXO; HHH; HIV[2]; NKH
D.C.	●	●	●	●	●	●	●	●	●	G6PD
Delaware	A	●	●	●	●	●		●		
Florida	●	●	●	●	●	●	●	●	C	
Georgia	A	●	●	●	●	●	●	●		
Hawaii	●	●	●	●	●	●	●	●		
Idaho	A	●	●	●	●	●	●	●		
Illinois	●	●	●	●	●	●	●	●		5-OXO
Indiana	●	●	●	●	●	●	●	●		
Iowa	●	●	●	●	●	●	●	●	●	HHH; NKH
Kansas	●	●		●	●	●		●		
Kentucky	A	●	C	●	●	●	C	●	C	
Louisiana	●	●		●	●	●	●	●		
Maine	A	●	●	●	●	●	●	●		HHH (A); CPS (D)
Maryland	●	●	●	●	●	●	●	●	C	
Massachusetts	●	●	●	●	●	●	●	●	A	TOXO; HHH (A); CPS (D)
Michigan	A	●	●	●	●	●	●	●		
Minnesota	A	●	●	●	●	●	●	●	●	
Mississippi	●	●	●	●	●	●	●	●	●	5-OXO; CPS; HHH
Missouri	●	●	●	●	●	●	C	●	C	
Montana	●	●	B	●	●	●	B	●	B	
Nebraska	A	●	●	●	●	●	●	●	●	5-OXO; HHH; NKH (A)
Nevada	A	●	●	●	●	●	●	●		
New Hampshire	A	●	C	C	C	C	C	●	C	TOXO
New Jersey	●	●	●	●	●	●	●	●	●	
New Mexico	●	●	●	●	●	●	●	●	C	
New York	●	●	●	●	●	●	●	●	●	HIV
North Carolina	●	●	●	●	●	●	●	●		
North Dakota	A	●	●	●	●	●	●	●	●	
Ohio	●	●	●	●	●	●	●	●		
Oklahoma	●	●	●	●	●	●		●	●	
Oregon	A	●	●	●	●	●	●	●		
Pennsylvania	●	●	●	●	●	●	B	●	B	5-OXO; CPS; G6PD; HHH; NKH (B)
Rhode Island	●	●	●	●	●	●	●	●		
South Carolina	A	●	●	●	●	●	●	●	●	
South Dakota	A	●	●	●	●	●	●	●	B	5-OXO; EMA; HHH; NKH
Tennessee	A	●	●	●	●	●	●	●		5-OXO; HHH; NKH
Texas	A	●	●	●	●	●		●		
Utah	●	●		●	●	●		●		
Vermont	A	●	●	●	●	●	●	●		CPS
Virginia	●	●	●	●	●	●	●	●	●	
Washington	A	●	●	●	●	●	●	●		
West Virginia	●	●		●	●	●		●		
Wisconsin	A	●	●	●	●	●	●	●	●	
Wyoming	●	●	●	●	●	●	●	●	●	

[1]Terminology consistent with ACMG report - Newborn Screening: Toward a Uniform Screening Panel and System 2005, p. 63.
[2]Newborn screened for HIV only if mother was not screened during pregnancy

Deficiency/Disorder Abbreviations and Names

BIO	Biotinidase	**CF**	Cystic fibrosis	**GALT**	Transferase deficient galactosemia (Classical)	**HB S/C**	Sickle – C disease	**HEAR**	Hearing screening
CAH	Congenital adrenal hyperplasia	**CH**	Congenital hypothyroidism	**HB S/S**	Sickle cell disease	**HB S/A**	S-βeta thalassemia		

Other Disorders

5-OXO	5-oxoprolinuria (pyroglutamic aciduria)	**G6PD**	Glucose 6 phosphate dehydrogenase	**NKH**	Nonketotic hyperglycinemia
CPS	Carbamoylphosphate synthetase	**HHH**	Hyperammonemia/ornithinemia/ citrullinemia (Ornithine transporter defect)	**PRO**	Prolinemia
EMA	Ethylmalonic encephalopathy	**HIV**	Human immunodeficiency virus	**TOXO**	Toxoplasmosis

around the capitol

CA Pre-natal Screening & Genetic testing Laws {Caution}

CALIFORNIA HEALTH AND SAFETY CODE

124975. The Legislature hereby finds and declares that:

(a) Each person in the State of California is entitled to health care commensurate with his or her health care needs, and to protection from inadequate health services not in the person's best interests.

(b) Hereditary disorders, such as sickle cell anemia, cystic fibrosis, and hemophilia, are often costly, tragic, and sometimes deadly burdens to the health and well-being of the citizens of this state.

(c) Detection through screening of hereditary disorders can lead to the alleviation of the disability of some hereditary disorders and contribute to the further understanding and accumulation of medical knowledge about hereditary disorders that may lead to their eventual alleviation or cure.

(d) There are different severities of hereditary disorders, that some hereditary disorders have little effect on the normal functioning of individuals, and that some hereditary disorders may be wholly or partially alleviated through medical intervention and treatment.

(e) All or most persons are carriers of some deleterious recessive genes that may be transmitted through the hereditary process, and that the health of carriers of hereditary disorders is substantially unaffected by that fact.

(f) Carriers of most deleterious genes should not be stigmatized and should not be discriminated against by any person within the State of California.

(g) Specific legislation designed to alleviate the problems associated with specific hereditary disorders may tend to be inflexible in the face of rapidly expanding medical knowledge, underscoring the need for flexible approaches to coping with genetic problems.

(h) State policy regarding hereditary disorders should be made with full public knowledge, in light of expert opinion and should be constantly reviewed to consider changing medical knowledge and ensure full public protection.

(i) The extremely personal decision to bear children should remain the free choice and responsibility of the individual, and should not be restricted by the state.

(j) Participation of persons in hereditary disorders programs in the State of California should be wholly voluntary, except for initial screening for phenylketonuria (PKU) and other genetic disorders treatable through the California newborn screening program. All information obtained from persons involved in hereditary disorders programs in the state should be held strictly confidential.

PRIVACY!

(k) In order to minimize the possibility for the reoccurrence of abuse of genetic intervention in hereditary disorders programs, all programs offering screening programs for heredity disorders shall comply with the principles established in the Hereditary Disorders Act (Section 27). The Legislature finds it necessary to establish a uniform statewide policy for the screening for heredity disorder in the State of California.

124977. (a) It is the intent of the Legislature that, unless otherwise specified, the program carried out pursuant to this chapter be fully supported from fees collected for services provided by

the program.

(b) (1) The department shall charge a fee to all payers for any tests or activities performed pursuant to this chapter. The amount of the fee shall be established by regulation and periodically adjusted by the director in order to meet the costs of this chapter. Notwithstanding any other provision of law, any fees charged for prenatal screening and followup services provided to persons enrolled in the Medi-Cal program, health care service plan enrollees, or persons covered by health insurance policies, shall be paid in full directly to the Genetic Disease Testing Fund, subject to all terms and conditions of each enrollee's or insured's health care service plan or insurance coverage, whichever is applicable, including, but not limited to, copayments and deductibles applicable to these services, and only if these copayments, deductibles, or limitations are disclosed to the subscriber or enrollee pursuant to the disclosure provisions of Section

1363.

(2) The department shall expeditiously undertake all steps necessary to implement the fee collection process, including personnel, contracts, and data processing, so as to initiate the fee collection process at the earliest opportunity.

(3) The director shall convene, in the most cost-efficient manner and using existing resources, a working group comprised of health insurance, health care service plan, hospital, consumer, and department representatives to evaluate newborn and prenatal screening fee billing procedures, and recommend to the department ways to improve these procedures in order to improve efficiencies and enhance revenue collections for the department and hospitals. In performing its duties, the working group may consider models in other states. The working group shall make its recommendations by March 1,

2005.

(4) Effective for services provided on and after July 1, 2002, the department shall charge a fee to the hospital of birth, or, for births not occurring in a hospital, to families of the newborn, for newborn screening and followup services. The hospital of birth and families of newborns born outside the hospital shall make payment in full to the Genetic Disease Testing Fund. The department shall not charge or bill Medi-Cal beneficiaries for services provided under this chapter.

(c) (1) The Legislature finds that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory and administrative procedures to obtain the most cost-effective electronic data processing, hardware, software services, testing equipment, and testing and followup services.

(2) The expenditure of funds from the Genetic Disease Testing Fund for these purposes shall not be subject to Section 12102 of, and Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of, the Public Contract Code, or to Division 25.2 (commencing with Section 38070). The department shall provide the Department of Finance with documentation that equipment and services have been obtained at the lowest cost consistent with technical requirements for a comprehensive high-quality program.

(3) The expenditure of funds from the Genetic Disease Testing Fund for implementation of the Tandem Mass Spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders, and screening for congenital adrenal hyperplasia may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts and shall not be subject to Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, and any policies, procedures, regulations or manuals authorized by those laws.

(d) (1) The department may adopt emergency regulations to implement and make specific this chapter in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Section 11346.1 and Section 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(2) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(3) The Legislature finds and declares that the health and safety of California newborns is in part dependent on an effective and adequately staffed genetic disease program, the cost of which shall be supported by the fees generated by the program.

124980. The director shall establish any regulations and standards for hereditary disorders programs as the director deems necessary to promote and protect the public health and safety. Standards shall include licensure of master level genetic counselors and doctoral level geneticists. Regulations adopted shall implement the principles established in this section. These principles shall include, but not be limited to, the following:

(a) The public, especially communities and groups particularly affected by programs on hereditary disorders, should be consulted before any regulations and standards are adopted by the department.

(b) The incidence, severity, and treatment costs of each hereditary disorder and its perceived burden by the affected community should be considered and, where appropriate, state and national experts in the medical, psychological, ethical, social, and economic effects or programs for the detection and management of hereditary disorders shall be consulted by the department.

(c) Information on the operation of all programs on hereditary disorders within the state, except for confidential information obtained from participants in the programs, shall be open and freely available to the public.

(d) Clinical testing procedures established for use in programs, facilities, and projects shall be accurate, provide maximum information, and the testing procedures selected shall produce results that are subject to minimum misinterpretation.

(e) No test or tests may be performed on any minor over the objection of the minor's parents or guardian, nor may any tests be performed unless the parent or guardian is fully informed of the purposes of testing for hereditary disorders and is given reasonable opportunity to object to the testing.

(f) No testing, except initial screening for phenylketonuria (PKU) and other diseases that may be added to the newborn screening program, shall require mandatory participation, and no testing programs shall require restriction of childbearing, and participation in a testing program shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participate in, any other program, except where necessary to determine eligibility for further programs of diagnoses of or therapy for hereditary conditions.

(g) Pretest and posttest counseling services for hereditary disorders shall be available through the program or a referral source for all persons determined to be or who believe themselves to be at risk for a hereditary disorder. Genetic counseling shall be provided by a physician, a certified advanced practice nurse with a genetics specialty, or other appropriately trained licensed health care professional and shall be nondirective, shall emphasize informing the client, and shall not require restriction of childbearing.

(h) All participants in programs on hereditary disorders shall be protected from undue physical and mental harm, and except for initial screening for phenylketonuria (PKU) and other diseases that may be added to newborn screening programs, shall be informed of the nature of risks involved in participation in the programs, and those determined to be affected with genetic disease shall be informed of the nature, and where possible the cost, of available therapies or maintenance programs, and shall be informed of the possible benefits and risks associated with these therapies and programs.

(i) All testing results and personal information generated from hereditary disorders programs shall be made available to an individual over 18 years of age, or to the individual's parent or guardian. If the individual is a minor or incompetent, all testing results that have positively determined the individual to either have, or be a carrier of, a hereditary disorder shall be given through a physician or other source of health care.

(j) All testing results and personal information from hereditary disorders programs obtained from any individual, or from specimens from any individual, shall be held confidential and be considered a confidential medical record except for information that the individual, parent, or guardian consents to be released, provided that the individual is first fully informed of the scope of the information requested to be released, of all of the risks, benefits, and purposes for the release, and of the identity of those to whom the information will be released or made available, except for data compiled without reference to the identity of any individual, and except for research purposes, provided that pursuant to Subpart A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations entitled "Basic HHS Policy for Protection of Human Subjects," the research has first been reviewed and approved by an institutional review board that certifies the approval to the custodian of the information and further certifies that in its judgment the information is of such potentially substantial public health value that modification of the requirement for legally effective prior informed consent of the individual is ethically justifiable.

(k) A physician providing information to patients on expanded newborn screening shall disclose

to the parent the physician's financial interest, if any, in the laboratory to which the patient is being referred.

(l) An individual whose confidentiality has been breached as a result of any violation of the provisions of the Hereditary Disorders Act, as defined in subdivision (b) of Section 27, may recover compensatory and civil damages. Any person who negligently breaches the confidentiality of an individual tested under this article shall be subject to civil damages of not more than ten thousand dollars ($10,000), reasonable attorney's fees, and the costs of litigation. Any person who knowingly breaches the confidentiality of an individual tested under this article shall be subject to payment of compensatory damages, and in addition, may be subject to civil damages of fifty thousand dollars ($50,000), reasonable attorney's fees, and the costs of litigation, or imprisonment in the county jail of not more than one year. If the offense is committed under false pretenses, the person may be subject to a fine of not more than one hundred thousand dollars ($100,000), imprisonment in the county jail of not more than one year, or both. If the offense is committed with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the person may be subject to a fine of not more than two hundred fifty thousand dollars ($250,000), imprisonment in the county jail of not more than one year, or both.

(m) "Genetic counseling" as used in this section shall not include communications that occur between patients and appropriately trained and competent licensed health care professionals, such as physicians, registered nurses, and physicians assistants who are operating within the scope of their license and qualifications as defined by their licensing authority.

Genetic Counselor

124981. (a) No person shall use the title of genetic counselor unless the person has applied for and obtained a license from the department.

(b) The applicant for a genetic counselor license shall meet minimum qualifications that include but are not limited to all of the following:

(1) Has earned a master's degree or above from a program specializing in or having substantial course content in genetics.

(2) Has demonstrated competence by an examination administered or approved by the department.

(c) The license shall be valid for three years unless at any time during that period it is revoked or suspended. The license may be renewed prior to the expiration of the three-year period.

(d) To qualify to renew the license, a licenseholder shall have completed 45 hours of continuing education units during the three-year license renewal period. At least 30 hours of the continuing education units shall be in genetics.

(e) The license fee for an original license and license renewal shall not exceed two hundred dollars ($200).

124985. A violation of any of the provisions of the Hereditary Disorders Act (Section 27) or any of the regulations adopted pursuant to that act shall be punishable as a misdemeanor.

124990. For the purposes of the Hereditary Disorders Act (Section 27), hereditary disorders programs shall include, but not be limited to, all antenatal, neonatal, childhood, and adult screening programs, and all adjunct genetic counseling services.

124995. The following programs shall comply with the regulations established pursuant to the Hereditary Disorders Act (Section 27):

(a) The California Children's Services Program under Article 5 (commencing with Section 123800) of Chapter 3 of Part

2.

(b) Prenatal testing programs for newborns under Sections 125050 to 125065, inclusive.

(c) Medical testing programs for newborns under the Maternal and Child Health Program Act (Section 27).

(d) Programs of the genetic disease unit under Section

125000.

(e) Child health disability prevention programs under Article 6 (commencing with Section 124025) of Chapter 3 of Part 2 and Section

120475.

(f) Genetically handicapped person's programs under Article 1 (commencing with Section 125125) of Chapter

2.

(g) Medi-Cal Benefits Program under Article 4 (commencing with Section 14131) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code.

124996. (a) The Genetic Disease Testing Fund is continued in existence as a special fund in the State Treasury. The department may charge a fee for any activities carried out pursuant to the Hereditary Disorders Act, including licensing activities conducted pursuant to Section

124980. All moneys collected by the department under the act shall be deposited in the Genetic Disease Testing Fund, that is continuously appropriated to the department to carry out the purposes of the act.

(b) It is the intent of the Legislature that the program carried out pursuant to the act be fully supported from fees collected under the act.

(c) The director shall adopt regulations establishing the amount of fees for activities carried out pursuant to the act.

(d) The "Hereditary Disorders Act" or "act" referred to in this section is the act described in subdivision (b) of Section

27.

around the capitol

{Caution}

CALIFORNIA HEALTH AND SAFETY CODE

125000. (a) It is the policy of the State of California to make every effort to detect, as early as possible, phenylketonuria and other preventable heritable or congenital disorders leading to mental retardation or physical defects. The department shall establish a genetic disease unit, that shall coordinate all programs of the department in the area of genetic disease. The unit shall promote a statewide program of information, testing, and counseling services and shall have the responsibility of designating tests and regulations to be used in executing this program. The information, tests, and counseling for children shall be in accordance with accepted medical practices and shall be administered to each child born in California once the department has established appropriate regulations and testing methods. The information, tests, and counseling for pregnant women shall be in accordance with accepted medical practices and shall be offered to each pregnant woman in California once the department has established appropriate regulations and testing methods. These regulations shall follow the standards and principles specified in Section

124980. The department may provide laboratory testing facilities or contract with any laboratory that it deems qualified to conduct tests required under this section. However, notwithstanding Section 125005, provision of laboratory testing facilities by the department shall be contingent upon the provision of funding therefor by specific appropriation to the Genetic Disease Testing Fund enacted by the Legislature. If moneys appropriated for purposes of this section are not authorized for expenditure to provide laboratory facilities, the department may nevertheless contract to provide laboratory testing services pursuant to this section and shall perform laboratory services, including, but not limited to, quality control, confirmatory, and emergency testing, necessary to ensure the objectives of this program.

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

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

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

Religion

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

(1) Testing and counseling services.

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

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

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

(f) The genetic disease unit shall evaluate and prepare recommendations on the implementation

of tests for the detection of hereditary and congenital diseases, including, but not limited to, biotinidase deficiency and cystic fibrosis. The genetic disease unit shall also evaluate and prepare recommendations on the availability and effectiveness of preventative followup interventions, including the use of specialized medically necessary dietary products. It is the intent of the Legislature that funds for the support of the evaluations and recommendations required pursuant to this subdivision, and for the activities authorized pursuant to subdivision (e), shall be provided in the annual Budget Act appropriation from the Genetic Disease Testing Fund.

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

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

125001. (a) The department shall establish a program for the development, provision, and evaluation of genetic disease testing, and may provide laboratory testing facilities or make grants to, contract with, or make payments to, any laboratory that it deems qualified and cost-effective to conduct testing or with any metabolic specialty clinic to provide necessary treatment with qualified specialists. The program shall provide genetic screening and followup services for persons who have the screening.

(b) The department shall expand statewide screening of newborns to include tandem mass spectrometry screening for fatty acid oxidation, amino acid, and organic acid disorders and congenital adrenal hyperplasia as soon as possible. The department shall provide information with respect to these disorders and available testing resources to all women receiving prenatal care and to all women admitted to a hospital for delivery. If the department is unable to provide this statewide screening by August 1, 2005, the department shall temporarily obtain these testing services through a competitive bid process from one or more public or private laboratories that meet the department's requirements for testing, quality assurance, and reporting. If the department determines that contracting for these services is more cost-effective, and meets the other requirements of this chapter, than purchasing the tandem mass spectrometry equipment themselves, the department shall contract with one or more public or private laboratories.

(c) The department shall report to the Legislature regarding the progress of the program on or before July 1,

2006. The report shall include the costs for screening, followup, and treatment as compared to costs and morbidity averted for each condition tested for in the program.

Area(s): Health Insurance
State: California
Description: Discrimination on the basis of genetic characteristics. California law provides that a health insurance plan cannot refuse to enroll or renew an individual on the basis of genetic characteristics, and cannot seek information about a person's genetic characteristics for any nontherapeutic purpose [Cal. Health and Safety Code § 1374.7(a), (b)]. Also, a plan cannot discriminate in the fees or commissions of an agent or solicitor on the basis of a subscriber's genetic characteristics [Cal. Health and Safety Code § 1374.7(c)]. Exclusion of eligible employees by health plan prohibited. Cal. Health and Safety Code Section 1357.52 provides that a health plan cannot exclude an otherwise eligible employee or dependent on the basis of genetic information. The Hereditary Disorders Act. This statute broadly entitles each person in the State of California to health care commensurate with his or her health care needs, and to protection from inadequate health services not in the person's best interests. This statute further provides that carriers of most deleterious genes should not be stigmatized or discriminated against. [Cal. Health and Safety Code § 124975(a, f).] The Insurance Information and Privacy Protection Act. This statute provides general rules for collection, use and disclosure of information gathered in connection with insurance transactions, but does not explicitly mention genetic characteristics. [§ 791.]

Area(s): Employment
State: California
Description: Employment without discrimination because of a medical condition is a civil right. California law recognizes and declares as a civil right the opportunity to seek, obtain and hold employment without discrimination because of a medical condition [§ 12921(a)]. Subjection of employee to genetic test is an unlawful employment practice. Section 12940(o) declares as an unlawful employment practice the direct or indirect subjection of an employee or applicant to a test for the presence of a genetic characteristic. Genetic discrimination prohibited in employee health insurance. California law prohibits a health plan from excluding an eligible employee or dependent on the basis of genetic information [§ 1357.52]. Also, several statutes prohibit employers from refusing to enroll an individual, requiring higher rates, setting different terms on the basis of an individual's genetic characteristics, or seeking information about a person's genetic characteristics for any nontherapeutic purpose. [§ 742.405 (multiple employer welfare arrangement); § 10123.3 (self-insured welfare benefit plans); § 10198.9 (disability insurer); § 10705(j) (small employer insurance carriers).] Section 1357.03(f) prohibits small employers seeking contracts for health care services from including genetic information as a factor for determining eligibility for an individual or dependent.

Area(s): Life, Disability, and Long-Term Care Insurance
State: California
Description: Discrimination by Life, Disability and Other Types of Insurance providers on the basis of genetic information prohibited. A provider of disability or life insurance cannot refuse to issue, cancel, or renew a policy, provide different terms or charge higher rates based on genetic characteristics of an insured [§ 10140(b)]. Also, such provider cannot seek genetic information for any nontherapeutic purpose [§ 10140(c)] or discriminate in fees of agents or brokers based upon genetic information [§ 10140(d), see also §§ 10148(g), 10143(c)]. Discrimination by Life, Disability and Other Types of Insurance providers solely on the basis of genetic information

prohibited. A provider of life or disability insurance cannot condition eligibility or set higher rates solely because a person carries a gene that may be associated with a disability [§ 10143(a)]. Further, such provider cannot include in the policy a condition that a carrier of a specific gene must accept a sum or service less than the full value of the policy in the case of a claim [§ 10143(b)]. Written and informed consent required, payment for genetic tests, no reduction of benefits. Section 10148 provides requirements and procedures for obtaining written and informed consent for genetic tests from an applicant for life or disability insurance [§ 10148(a, b, c)]. The statute also provides that a life or disability insurer cannot require a test for genetic information unless the insurer pays the cost of the test [§ 10148(d)]. In addition, an insurance provider's payment of benefits cannot be reduced if the claim is caused or contributed to by genetic characteristics, except to the extent the insurer limits coverage for loss caused by other medical conditions that increase risk [§ 10148(e)]. Genetic tests cannot be required for certain purposes. A life or disability insurer cannot require a genetic test for the exclusive or nonexclusive purpose of determining eligibility for hospital, medical, or surgical insurance coverage or eligibility for coverage under a nonprofit hospital service plan or health care service plan [§ 10149(b)]. No employee disability insurance exclusions on the basis of genetic information. Section 10198.9, which applies only to disability insurers, prohibits the exclusion of an otherwise eligible employee or dependant on the basis of genetic information. Brokers/agents prohibited from discouraging applications because of genetic information. Section 10901.2(c) prohibits carriers, agents, and brokers from discouraging eligible individuals from filing an application for coverage because of genetic information.

Programs and Services

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Insurance Coverage and Confidentiality Issues

Printer Friendly
Email to a Friend
Have Questions?

Insurance Coverage

The cost of a genetic consultation and testing is usually covered by health insurance plans, at least in part. Consultation fees range in price, depending upon the complexity of the referral. You should check with your health plan to learn if it will cover the costs of a genetic evaluation. You do not need a referral from a physician to schedule a consultation at the GenRISK Adult Genetics Program, although some insurance plans require a physician referral if they are to cover the cost of the consultation.

The fees for genetic testing are separate from the cost of the genetic consultation. These are typically paid to a laboratory that is not part of Cedars-Sinai Medical Center. Most health plans reimburse for the cost of genetic tests, at least in part. They may require a letter of medical necessity that explains the need for the testing and how the test results will influence your care. The GenRISK Adult Genetics Program can provide this information to your health plan.

You do not have to share your test results with your insurance company, even if they pay for genetic testing. It is against state law for your health insurer to ask for your test result without your permission. If you have concerns about discrimination, read about the laws below. You can also discuss these issues with your genetic counselor or you can consult the Genetic Alliance for more information about these issues.

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Genetic Discrimination

Some people worry that genetic risk for a disease will be considered a "pre-existing condition." They worry that their health plan will deny them health insurance or make them pay higher fees. In most cases, this kind of health insurance discrimination is against federal law (see the Health Insurance Portability and Accountability Act below) and California law (see summary below).

Many people are concerned about the potential for genetic discrimination. Fortunately, there is little proof of genetic discrimination by health insurers presently. The Genetic Alliance is currently conducting a survey to identify and document cases of perceived genetic discrimination and privacy abuse. Below are references for two articles written by M.A. Hall and S.S. Rich that discuss the lack of evidence of genetic discrimination.

- Patients' fear of genetic discrimination by health insurers: the impact of legal protections. By M.A. Hall and S.S. Rich. Genetics in Medicine, July 2000 volume 2 number 4, pages 214-221
- Laws restricting health insurers' use of genetic information: impact on genetic discrimination. By M.A. Hall MA and S.S. Rich. American Journal of Human Genetics, January 2000, volume 66, number 1, pages 293-307.

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Legal Protections Against Genetic Discrimination

There are federal laws and California State laws that forbid genetic discrimination. These laws focus mainly on health insurance discrimination. There are also laws against employment

discrimination. In February 2000, President Clinton signed an executive order that bans genetic discrimination in the federal workplace. This order prohibits federal departments and agencies from using genetic information to make decisions regarding hiring, firing and promoting federal employees. The Americans with Disabilities Act may also apply to people with genetic conditions. Below are some highlights of legislation. For more up-to-date information, you may need to consult other sources, the Genetic Alliance or the National Human Genome Research Institute for more information about these issues.

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Highlights of the Health Insurance Portability and Accountability Act (HIPAA), effective July 1, 1997.

(A version of this summary is distributed by Myriad Genetic Laboratories and should not be construed as legal advice. The law is very lengthy. This summary is only meant to provide general terms, not full statutory text. It should be used in conjunction with full text of the law. Click on

The law will prevent discrimination against most people who have genetic testing for common adult diseases in the areas of health insurance coverage and group premiums. The law:

- States clearly that genetic information should not be considered a preexisting condition.
- Stops group and individual insurers from refusing to renew or continue coverage because of genetic information.
- Keeps group plans from using genetic information to decide who can get coverage or to set premiums.
- Prevents group plans from charging different premiums within a group based on genetic information.
- Makes sure that a person (or family member) who changes to new group coverage will not be refused coverage or charged more than others in the group because of past or present medical problems.
- Prevents an uninsured person applying for group medical coverage from being refused coverage or charged more than other group members because of past or present medical problems.
- Assures that people leaving a group plan and seeking individual coverage can qualify regardless of past or present medical problems under some circumstances. (This depends on individual state laws).
- Stops insurance companies from denying coverage to a small business because of any employee's past or present medical problems. It does not stop insurance companies from charging the entire group more than another group because of past or present medical problems.

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California State Law

Below is a summary of current California state protections against genetic discrimination. It is taken from a 1997 article by Dr. George Cunningham printed in the Pacific Southwest Regional Genetics Network newsletter. Copies of the laws can be viewed at a public library.

"The Health and Safety Code Section 1374.7 prohibits prepaid heath care plans from denying, canceling, refusing to renew or charging more for coverage, or for providing different terms or benefits to a person based on genetic characteristics. 'Genetic characteristics' are defined as a family history of genetic disorder or gene alterations causing or increasing the risk of a disease or disorder. The definition does not include those already affected by a genetic disorder. Insurance Code Section 742.405 establishes the same prohibition for self-funded or partially self-funded employer welfare arrangements. Likewise, Insurance Code Section 10123.3 applies these same restrictions to self-insured employee welfare benefit plans. Insurance Code Section 11512.95 establishes the same prohibition for non-profit hospital service plans. Insurance Codes 10140 and 10146 to 10149.1 prohibit life and disability income insurance companies from discrimination based on genetic characteristics, prohibit companies from requiring genetic tests, and proscribe penalties for the unauthorized release of genetic test results. Civil Code Section 56.17 and Insurance Code 10123.35 provide broad protection against unauthorized disclosure of genetic test results by health care service plans. California law (H&S Code 1367.7, Insurance Code 10123.9 and 11512.18) requires that coverage for prenatal diagnosis of genetic disorders of the fetus be

offered and prohibits companies from requiring genetic tests or information for any non-therapeutic reason or from disclosing the results of tests without authorization."

For more information about the laws enacted in California and HIPAA (federal legislation), please contact the **Cancer Legal Resource Center**, a joint program of the Western Law Center for Disability Rights and Loyola Law School, at (213) 736-1455.

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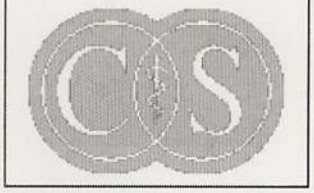

CALIFORNIA Genetics Life Insurance Law

INSURANCE CODE SECTION 10146-10149.1

10146. The purposes of this article are to establish standards regarding unfair discrimination among individuals of the same class in the underwriting of life or disability income insurance on the basis of tests of a person's genetic characteristics; to establish minimum standards for determining insurability which are sufficiently reliable to be used for life and disability income insurance risk classification and underwriting purposes; to require the maintenance of strict confidentiality of personal information obtained through a test of a person's genetic characteristics; and to require informed consent before insurers underwrite on the basis of a test of a person's genetic characteristics. This article and Sections 10140 and 10143 shall constitute the exclusive requirements for insurers' practices relating to genetic characteristics or to tests thereof.

10147. As used in this article:

(a) "Disability income insurance" means insurance against loss of occupational earning capacity arising from injury, sickness, or disablement, and includes insurance which provides benefits for overhead expenses of a business or profession when the insured becomes disabled.

(b) "Genetic characteristics" means any scientifically or medically identifiable gene or chromosome, or alteration thereof, that is known to be a cause of a disease or disorder, or that is determined to be associated with a statistically increased risk of development of a disease or disorder, and that is presently not associated with any symptoms of any disease or disorder.

(c) "Life or disability income insurer" means an insurer licensed to transact life insurance or disability income insurance in this state or a fraternal benefit society licensed in this state.

(d) "Policy" means (1) a life insurance policy or a disability income insurance policy delivered in this state, or (2) a certificate of life insurance benefits or disability income insurance benefits, issued under a group life or disability income insurance policy and delivered in this state by a life or disability income insurer or a fraternal benefits society, regardless of the location of the group master policy.

(e) "Test of a person's genetic characteristics" means a laboratory test which is generally accepted in the scientific and medical communities for the determination of the presence or absence of genetic characteristics.

10148. No insurer shall require a test for the presence of a genetic characteristic for the purpose of determining insurability other than for those policies that are contingent on review or testing for other diseases or medical conditions. In those cases, the test shall be done in accordance with the informed consent and privacy protection provisions of this article and Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1. Notwithstanding any other provision of law, this constitutes the exclusive requirements for informed consent and privacy protection for that testing.

(a) An insurer that requests an applicant to take a genetic characteristic test shall obtain the applicant's written informed consent for the test. Written informed consent shall include a description of the test to be performed, including its purpose, potential uses, and limitations, the meaning of its results, procedures for notifying the applicant of the results, and the right to confidential treatment of the results.

(b) The insurer shall notify an applicant of a test result by notifying the applicant or the applicant's designated physician. If the applicant tested has not given written consent authorizing a physician to receive the test results, the applicant shall be urged, at the time the applicant is informed of the test results, to contact a health care professional.

(c) The commissioner shall develop and adopt standardized language for the informed consent disclosure form required by this section to be given to any applicant for life or disability income insurance who takes a test for a genetic characteristic.

(d) A life or disability income insurer shall not require a person to undergo a test of the person's genetic characteristics unless the cost of the test is paid by the insurer.

(e) No policy shall limit benefits otherwise payable if loss is caused or contributed to by the presence or absence of genetic characteristics, except to the extent and in the same fashion as the insurer limits coverage for loss caused or contributed to by other medical conditions presenting an increased degree of risk.

(f) Nothing in this chapter shall limit an insurer's right to decline an application or enrollment request for a life or disability income insurance policy, charge a higher rate or premium for such a policy, or place a limitation on coverage under such a policy, on the basis of manifestations of any disease or disorder.

(g) No discrimination shall be made in the fees or commissions of agents or brokers writing or renewing a life or disability income policy on the basis of a test of that person's genetic characteristics.

10149. (a) All underwriting activities undertaken by insurers pursuant to this article shall be subject to all applicable provisions of Article 6.6 (commencing with Section 791) of Chapter 1 of Part 2 of Division 1.

(b) No life or disability income insurer shall require a genetic characteristic test if the results of the test would be used exclusively or nonexclusively for the purpose of determining eligibility for hospital, medical, or surgical insurance coverage or eligibility for coverage under a nonprofit hospital service plan or health care service plan.

10149.1. (a) This section shall apply to the disclosure of the results of a test for a genetic characteristic requested by an insurer pursuant to this article.

(b) Any person who negligently discloses results of a test for a genetic characteristic to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in this article or in Sections 1603.1 and 1603.3 of the Health and Safety Code, shall be assessed a civil penalty in an amount not to exceed one thousand dollars ($1,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(c) Any person who willfully discloses the results of a test for a genetic characteristic to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in this article or in Sections 1603.1 and 1603.3 of the Health and Safety Code, shall be assessed a civil penalty in an amount not less than one thousand dollars ($1,000) and no more than five thousand dollars ($5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(d) Any person who willfully or negligently discloses the results of a test for a genetic characteristic to a third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization, as described in subdivision (g), or except as provided in this article or in Sections 1603.1 and 1603.3 of the Health and Safety Code, which results in economic, bodily, or emotional harm to the subject of the test, is guilty of a misdemeanor punishable by imprisonment in a county jail for a period not to exceed one year, by a fine of not to exceed ten thousand dollars ($10,000), or by both that fine and imprisonment.

(e) Any person who commits any act described in subdivision (b) or (c) shall be liable to the subject for all actual damages, including damages for economic, bodily, or emotional harm which is proximately caused by the act.

(f) Each disclosure made in violation of this section is a separate and actionable offense.

(g) The applicant's "written authorization," as used in this section, applies only to the disclosure of test results by a person responsible for the care and treatment of the person subject to the test. Written authorization is required for each separate disclosure of the test results, and shall include to whom the disclosure would be made.

NOTE - POLICY CAN BE TURNED DOWN - NOT AUTOMATIC!

Genetic Technologies Project
NCSL Genetics Tables

Genetics and Health Insurance

State Anti-Discrimination Laws

The table below provides a current summary of state laws pertaining to the use of genetic information in health insurance. Restrictions on the use of genetic information in health insurance may address the use of genetic information in individual insurance, group insurance or both. These laws may restrict health insurers from engaging in certain activities, including using genetic information to determine eligibility or set premiums, requiring genetic testing of applicants, or disclosing genetic information without consent. The laws listed below do not govern the use of genetic information in employer-sponsored health benefit plans, which are under the purview of the federal government. For a policy brief on genetics and health insurance, please see NCSL's Genetics Briefs on-line.

The states with genetics and health insurance laws listed below also may have laws related to other genetics policy issues, such as genetic privacy or genetic discrimination in other settings. The legislature may have addressed these issues in conjunction with or separately from genetics and health insurance. For a full understanding of genetics law in a particular state, please go back to the Genetics Laws and Legislative Activity page and click on the other topical law tables. You also may want to view maps on state genetics laws created by Backbone Media for the PBS program *Bloodlines.* NOTE: NCSL does not endorse any of the views expressed at the *Bloodlines* Web site or in the program.

State	Citation	Type of Insurance Policy	May not Establish Rules for Eligibility based on Genetic Information	May not Require Genetic Tests/Genetic Information	May not Use Genetic Information for Risk Selection or Risk Classification Purposes	May not Disclose Information Without Informed Consent
California	Insurance Code: §§742.405, 7, 10140, 3, 6 to 9, 9.1	Individual and Group	X	X	X	X
Colorado	§10-3-1104.7	Individual and Group	X	X	X	X

State Genetic Nondiscrimination in Health Insurance Laws
Enforcement Provisions

The majority of state legislatures have enacted measures to prohibit genetic discrimination in some or all forms of health insurance. Under state genetic nondiscrimination statutes, a state insurance commissioner's power to enforce the law ranges from the ability to suspend an insurer's license to the authority to impose heavy administrative fines. In addition, some state statutes specifically provide individuals who are damaged as a result of genetic discrimination the right to sue an insurer in civil court. Finally, penalty provisions in state genetic nondiscrimination laws often permit the insurance officials to promulgate additional regulations within the limits set forth by the statute.

State	License Revoked or Suspended	Private Right of Action	Authorizes Regulatory Penalties	Civil Liability, Criminal Penalties and Administrative Fines
Alabama	√		√	
Alaska				Up to $2,500 fine
Arizona	√			Up to $1,000 for each violation or up to aggregate of $10,000 for six month period of unintentional violations; up to $5,000 for each violation or up to aggregate of $50,000 for six month period of intentional violations
Arkansas	√	√		Equitable relief; up to $1,000 fine for each violation or up to aggregate of $10,000 for unintentional violations; up to $5,000 for each violation or up to aggregate of $50,000 for intentional violations; up to $10,000 for each violation for failure to obey a cease and desist order
California			√	Up to $2,500 for the first unintentional violation and not more than $5,000 for each subsequent violation; Not less than $15,000 and not more than $100,000 for each intentional violation

NCSL Genetics Tables
Genetic Technologies Project
NCSL Health Privacy Page

State Genetic Privacy Laws

The majority of state legislatures have taken steps to safeguard genetic information beyond the protections provided for other types of health information. This approach to genetics policy is known as genetic exceptionalism, which calls for special legal protections for genetic information as a result of its predictive, personal and familial nature and other unique characteristics. Some commentators assert that treating genetic information the same as other health information is a more favorable approach. These individuals argue that genetic information is simply another form of health information and is, therefore, difficult to distinguish from other health information, all of which deserves equal protection under the law. With respect to privacy, Washington is the only state that explicitly treats genetic information the same as other health information by including genetic information in the definition of health care information under the state health privacy law.*

State genetic privacy laws typically restrict any or certain parties (such as insurers or employers) from carrying out a particular action without consent. Laws in 16 states require informed consent for a third party either to perform or require a genetic test or to obtain genetic information. Twenty-four states require informed consent to disclose genetic information. In addition, Rhode Island and Washington require written authorization to disclose genetic information. Alaska, Colorado, Florida, Georgia, and Louisiana explicitly define genetic information as personal property. Alaska also extends personal property rights to DNA samples. In 2001 Oregon repealed its property right to DNA samples and genetic information. Four states mandate individual access to personal genetic information, and 18 states have established specific penalties - civil, criminal or both - for violating genetic privacy laws.

The states with genetic privacy laws listed below also may have laws concerning other, related genetics policy issues, such as the use of genetic information in insurance and employment. The legislature may have addressed these issues in conjunction with genetic privacy or separately. For a full understanding of genetics law in a particular state, please go back to the Genetics Laws and Legislative Activity page and click on the other topical tables. You also may want to view maps on state genetics laws created by Backbone Media for the PBS program *Bloodlines.* NCSL does not necessarily endorse any of the views expressed at the *Bloodlines* Web site or in the program.

State and Statute	Personal Access to Genetic Information Required	Consent Required to				Define as Personal Property		Specific Penalties for Genetic Privacy Violations
		Perform/ Require Genetic Test	Obtain/ Access Genetic Information	Retain Genetic Information	Disclose Genetic Information	Genetic Information	DNA Samples	
California Insurance §10149.1					x			x

NCSL Genetics Tables

State Genetics Employment Laws

States first addressed the use of genetic information in employment decisions in the 1970s and '80s with protections from discrimination for job applicants with the sickle cell trait. Wisconsin was the first state to ban genetic testing and discrimination in the workplace in 1991. Genetic nondiscrimination in employment laws are now in place in 33 states. The scope and functions of these laws vary widely. All laws prohibit discrimination based on the results of genetic tests; many extend the protections to inherited characteristics, and some include test result of family members, family history and information about genetic testing, such as the receipt of genetic services. Most states also restrict employer access to genetic information, with some prohibiting employers from requesting, requiring and obtaining genetic information or genetic test results, or directly or indirectly performing or administering genetic tests.

Congress has not enacted legislation to specifically address the use of genetic information in employment decisions. However, in 1995 the Equal Employment Opportunity Commission interpreted "disability" in the Americans with Disabilities Act to include genetic predisposition to disease. Conflicting rulings raise questions whether the Supreme Court would accept this EEOC interpretation. In February 2000 President Clinton banned genetic discrimination in the federal workplace and called on Congress to pass a federal genetic information nondiscrimination law for private sector employment. Legislation that would prohibit discrimination in employment based on genetic information is currently pending in Congress.

State and Statute	Genetic discrimination prohibited in hiring, firing, and/or terms, conditions or privileges of employment	Prohibits Employer From				Specific Penalties for Genetic Discrimination in Employment
		Requesting Genetic Information Genetic Test	Requiring Genetic Information Genetic Test	Performing Genetic Test	Obtaining Genetic Information Genetic Test Result	
Total	**33**	**18**	**25**	**16**	**10**	**13**
California Govt. §12926, Govt. §12940	x			x		

Genetic Technologies Project
NCSL Genetics Laws and Legislative Activity

Genetics and Life, Disability and Long-term Care Insurance

Updated 10/03/03

SEE NCSL'S Genetics Laws and Legislative Activity page to access our database of 2004 state genetics legislation.

While a majority of states have enacted laws that strictly prohibit the use of genetic information for risk selection and risk classification in health insurance, fewer states restrict the use of genetic information in life, disability and long-term care insurance. Seven states prohibit genetic discrimination in life insurance without actuarial justification. Of these seven, Arizona, Maine, and New Jersey also prohibit genetic discrimination in disability insurance without actuarial justification, and Massachusetts, Montana and New Mexico extend their prohibitions to disability and long-term care insurance. Colorado, Massachusetts, Oregon and Vermont prohibit insurers from requiring applicants to undergo genetic testing for long-term care insurance but permit the use of test results. Some states mention life, disability or long-term care as exclusions to their genetic nondiscrimination legislation. For these states there are statute citations below but no columns are checked.

State and Statutes	Restricts Discrimination Based on Genetic Information in Life Insurance	Restricts Discrimination Based on Genetic Information in Disability Insurance	Restricts Discrimination Based on Genetic Information in Long-term Care Insurance	Requires Actuarial Justification to Use Genetic Information in Life Insurance	Requires Informed Consent to Use Genetic Information
California Insurance §§10146 to 10149.1	√	√	√		√[1]

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Special Reports:
. California Proposition 69
. Justice for All Act
. DNA Database Statutes
. Guide to DNA Database
. Post-Conviction Statutes
. Guide to Post-Conviction

ASLME Reports
. Legal Issues...Use of DNA

Summaries of Current News
. Archives

ASLME Reports: Legal Issues Concerning Forensic Use of DNA

You will need Adobe Acrobat Reader to view these reports 

- The Constitutionality of Forensic DNA Databanks: Fourth Amendment Issues (2004).
  David Winickoff (2004) Julie Park (2005 update)
- The Constitutionality of Forensic DNA Databanks: An Overview of State Court 4th Amendment Cases (2004).
  Juliana C. Russo (2004) Julie Park (2005 update)
- Forensic Use of DNA: Bibliography of Law Reviews and Legal Journals (2004).
  Laurie Burlingame
- Forensic Use of DNA: Summary of Selected Law Review and Law Journal Articles (2004).
  Ellen Moskowitz
- State Regulation on Low Stringency/Familial Searches of DNA Databases (2004).
  Seth Axelrad
- State Regulations on Quality Assurance for Forensic DNA Laboratories (2004).
  Seth Axelrad
- Use of Forensic DNA Database Information for Medical or Genetic Research (2005).
  Seth Axelrad
- State Statutes Declaring Genetic Information to be Personal Property (2005).
  Seth Axelrad

LEGAL ISSUES in LAW Enforcement

(1) DNA fingerprinting

a. Case law / Frye v Daubert → Use Scientific Method in testing & Witness Expertise

b. Constitution –

No obstacles to suspects in criminal case

(1) blood or voice samples are not "testimonials" & not protected by 5th Amendment Protection Against Self-incrimination.

(2) If probable cause – Search warrant can compel person to give DNA sample consistent with 4th Amendment!

(2) Data Banks

a. Convicted felons can be compelled to give DNA for FBI & State data banks! And data banks exist!

b. What about suspects?

c. What about everyone?!

COMBINED DNA Index System

National DNA Index System

CODIS generates investigative leads in crimes where biological evidence is recovered from the crime scene using two indexes: the forensic and offender indexes.

The **Forensic Index** contains DNA profiles from crime scene evidence.

The **Offender Index** contains DNA profiles of individuals convicted of sex offenses (and other violent crimes) with many states now expanding legislation to include other felonies.

Matches made among profiles in the Forensic Index can link crime scenes together; possibly identifying serial offenders. Based on a match, police in multiple jurisdictions can coordinate their respective investigations, and share the leads they developed independently. Matches made between the Forensic and Offender indexes provide investigators with the identity of the perpetrator(s). After CODIS identifies a potential match, qualified DNA analysts in the laboratories contact each other to validate or refute the match.

NDIS Profile Composition (as of January 2006)

Forensic Profiles in NDIS: 128,256

Convicted Offender Profiles in NDIS: 2,883,095

State Laws on DNA Data Banks

Qualifying Offenses, Others Who Must Provide Sample

December 2004

All 50 states require that convicted sex offenders provide a DNA sample, and states are increasingly expanding these policies to include offenders who have committed other serious crimes. To date, 39 states require that all convicted felons provide a DNA sample to the state's database.

Louisiana and Virginia have laws authorizing arrestee sampling; and Texas law allows post-indictment samples of certain sex offenders. California's Proposition 69, approved by voters on November 2, 2004, requires DNA samples of adults arrested for or charged with a felony sex offense, murder or voluntary manslaughter, or attempt of these crimes. Starting in 2009, the measure requires arrestee sampling be expanded to arrests for any felony offense. (This same measure requires collection from all convicted felons.)

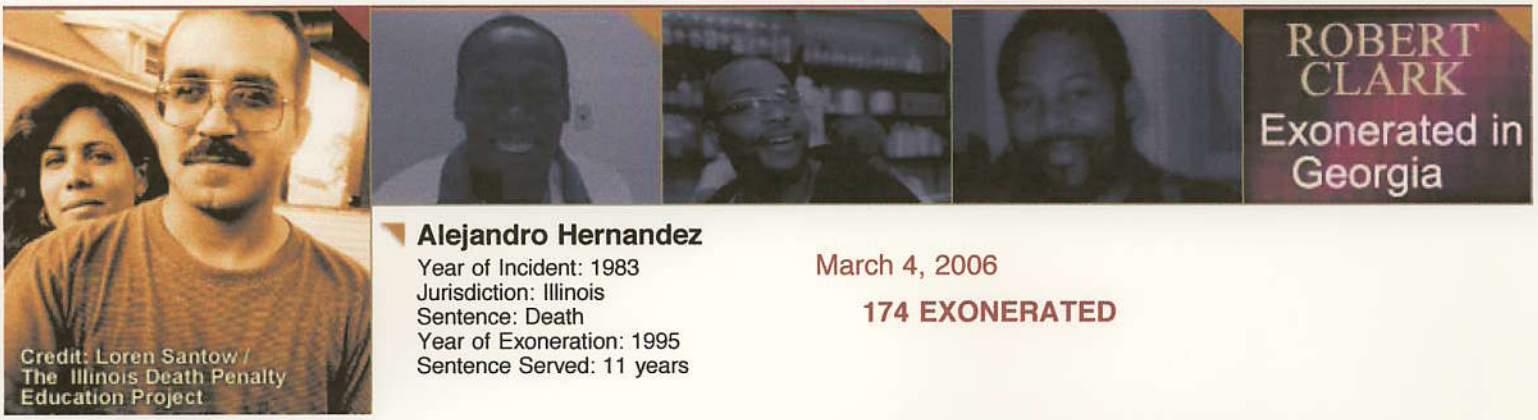
DNA data bases in all states today are connected to the National DNA Index System, which is run by the Federal Bureau of Investigation for federal and state information sharing.

State	All Felonies	Other	Juveniles
California	X	All convicted felons were added as a result of Proposition 69 in 2004, as were adults arrested for or charged with a felony sex offense, murder or voluntary manslaughter, or attempt of these crimes. Starting in 2009, arrestee sampling is expanded to arrests for any felony offense. California statute includes those not guilty by reason of insanity for qualifying offense; those convicted of terrorist activity in violation of weapons of mass destruction provisions; and those convicted of a qualifying offense in another state.	X

ALL Felonies! Adults & Juveniles

ALL FELONY ARRESTS (2008) - PROP 69

INNOCENCE PROJECT



Alejandro Hernandez
Year of Incident: 1983
Jurisdiction: Illinois
Sentence: Death
Year of Exoneration: 1995
Sentence Served: 11 years

March 4, 2006

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The Innocence Project at the Benjamin N. Cardozo School of Law at Yeshiva University, founded by Barry C. Scheck and Peter J. Neufeld in 1992, is a non-profit legal clinic and criminal justice resource center. We work to exonerate the wrongfully convicted through postconviction DNA testing; and develop and implement reforms to prevent wrongful convictions. This Project only handles cases where postconviction DNA testing can yield conclusive proof of innocence. For more information regarding what we do and what kinds of cases we handle, please click on the Innocence Project tab or visit our **FAQ** page.

RECENT DEVELOPMENTS:

- **Supreme Court weighs DNA evidence in case of death row inmate Paul Gregory House**
- **Innocence Network Conference to be held in March**
- **Robert Clark exonerated and freed in Georgia after 24 years**
- **George Rodriguez free 18 years after wrongful conviction**
- **Thomas Doswell exonerated and freed in Pennsylvania**

About This Innocence Project: A history of our project, what we do, who we are, other projects by state, and employment opportunities.

Case Profiles: Names, faces, and the stories of the wrongfully convicted. This page allows you to search by name, date, jurisdiction, and charge.

Causes & Remedies: What are the main causes of wrongful convictions and how can the system be fixed? Facts, statistics, and recommendations from our own study of DNA exonerations.

Support Us: How you can donate and support the work of the Innocence Project.

Policy: Find out what laws apply in your state and across the country. See what laws have been passed, which are pending, and what they contain.

Links: Links to other Projects by state as well as other organizations, articles, and areas of expertise.

The Innocents: Photographs by Taryn Simon, introduction by Barry Scheck and Peter Neufeld.

NATIONAL CONFERENCE of STATE LEGISLATURES

Comparison of State Post Conviction DNA Laws

STATE	Who Can Apply For Testing?	Who Pays?	Preservation Required?	Fiscal Analysis of Preservation
California	Incarcerated felons	State, but court can order the petitioner if able to pay	For time that offender remains incarcerated; entity has discretion to determine how to retain evidence; preservation portion of law is automatically repealed on 1/1/03	Quoted from fiscal note: "Potentially significant reimbursable local costs for evidence storage. Sheriff's offices and police departments differ in how long they store evidence, but most do not store evidence after appeals have been exhausted. By mandating storage, this bill creates annual costs that could be in the range of $1 million. For example, if Los Angeles City and County each have to purchase refrigeration units for biological evidence and rent additional storage facilities, the annual cost could exceed $200,000. Extrapolating statewide, the cost could reach $1 million since individual departments maintain their own facilities."

THE DNA DRAGNET

To find a killer, a town asks all its men to give a sample. Savvy policing or invasion of privacy?

THE VICTIM

KEVIN MINGORA—CAPE COD TIMES; BELOW: STEVE HEASLIP—CAPE COD TIMES

THE SWEEP

JUSTIN SUTCLIFFE—POLARIS

SWAB TEAM In the hunt for the murderer of Christa Worthington, right, a cop in Truro, Mass., asks a local man for a DNA sample, swiped from inside the cheek

THE KIT

By **AMANDA RIPLEY** TRURO

IN THE SUMMER OF 1847, A PANICKED mother in a small village in Barnstable, Mass., on Cape Cod, reported her 10-week-old son missing. The townsfolk fanned out to search for him. Within hours, his body was found floating in the harbor. Because no strangers were visiting that day, the villagers knew the killer was one of them. At the funeral the next day, each resident was asked to approach the tiny open coffin, lay hands on the body and declare his or her innocence, a scene described by Evan J. Albright in his book *Cape Cod Confidential*. The villagers were looking for signs of guilt. They had found none, and only the boy's family remained. His mother at first recoiled at the idea of touching her dead son. Then, as she did so, she yanked her hands away from the corpse as if they had been scalded. "I didn't do it! I didn't do it!" she blurted out. The village had found the murderer.

A small seaside town about an hour north of Barnstable began another unsparing manhunt this month in hopes of solving a three-year-old murder. Police in Truro, Mass., intend to collect the DNA of every one of the town's 790 males. After that, the cops may cast a wider net, reaching neighboring towns. They started by approaching men at Truro's few outposts—the post office, the pizza place, the grocery store—and politely asking each if they could swipe a lollipop-size swab inside his cheek. It's strictly voluntary, and the Truro men can say no. Then again, the police are taking the license-plate numbers of all the men they approach, and will be noting those who refuse the test.

Fifteen years ago, it was believed that such mass DNA collections—which began in Europe—would never catch on in the U.S., with its stalwart protections against invasive

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search and seizure. But the temptation to solve unspeakable crimes, particularly ones involving children, has proved powerful. Truro's is at least the 19th DNA dragnet in the U.S. As testing becomes faster and cheaper, such collections are becoming more frequent. And the debate about whether they are right sliced this seaside town in two last week, just it has Baton Rouge, La.; Charlottesville, Va.; and Miami.

On Jan. 6, 2002, Christa Worthington, 46, a former fashion writer, was found dead, stabbed through the heart in a doorway of her bungalow. Alive and clinging to her was Ava, 2½, her daughter, who had spent 36 hours alone with the body. The killer had stabbed Worthington so powerfully that the blade had left a mark in the floorboards beneath her. It appeared that Ava had tried to tend to her mother, dabbing her face with a washcloth. "Mommy fell down," she sobbingly told the person who found her.

Worthingtons had lived in Truro for generations. In fact, one of the first rescue workers at the scene was Christa's cousin. Christa had moved there from New York City to care for her sick mother. She had had an affair with a local fisherman, which produced Ava. After her mother died, Christa decided to stay. In her shingled house on a hill, surrounded by a tangle of spindly trees, she had started a new life, although not necessarily a frictionless one. What with family strains and frustrated romances, there were plenty of obvious suspects. Semen was found on Worthington's body, but it did not match any of them.

Truro has no main street, no stoplights, no trash pickup. Though the area bustles with writers and artists in the summertime, it is quiet, even suffocating, in the off-season. "In the winter, we pay too much attention to each other," a local told the Boston *Globe* after the murder. None of that attention had turned lethal since 1969, the year of the last homicide. "When you have an unsolved murder in your town, there's this free-floating anxiety," says Truro resident Maria Flook, who wrote a book about the killing.

On the third anniversary of Worthington's death, local and state police, advised by FBI profilers, began swabbing for DNA—hoping to finally find a match to the person with whom Worthington last had sex, even if he was not the murderer. The year-rounders, as they are called, were not shy in responding. About 10 locals called the state A.C.L.U. chapter, which quickly sent a letter of protest to law-enforcement officials and is considering litigation. Some men have refused to give a sample, though Cape and Islands district attorney Michael O'Keefe declines to say how many. "I have a tirade ready," says Michael Jerace, who intends to turn the police down. "It's very frightening. It's all part of the ambiance of the country right now." Others have gone to the cops, regarding it as a civic duty. Police chief John Thomas says at least 80% of his e-mail has been supportive. Fred Simonin, owner of the Highland Grill, where residents go to get Krispy Kreme doughnuts and pizza, readily complied, accepting a swab as he stood behind his counter. "Does it bother me? No. I don't plan on raping or killing anyone," says Simonin, in his orange Truro baseball cap.

When Michael Kaelberer made his regular trip to the dump on a recent Sunday, a friend going the other way tried to wave him off. "They're down there!" he warned. "Aw, man," Kaelberer said. He had heard about the DNA sweep, and he didn't like it. He had lived in Truro for 33 years precisely because this kind of nonsense didn't happen here. Still, he had decided to surrender. "What are you going to do? You got a truck full of garbage," he says. "This is a small town. It's not worth getting on a list if you're not guilty."

> **"I wish I could be bold enough to refuse. [But] it's a difficult situation. It's a small town . . . The word gets out. You already hear who has refused."**
>
> —MICHAEL KAELBERER, a Truro Little League coach

O'Keefe and the police have promised that the samples will be destroyed if they do not match the evidence. But state law does not require them to keep their promise, says the A.C.L.U. In Baton Rouge, police swabbed 1,200 men, most of them white, in 2002 and 2003, following tips. Although the early focus was on white men, it turned out the killer was black. Some of the samples ended up in the state crime database anyway. More than a dozen of the men are suing to have their samples removed. Corporal Don Kelly, a spokesman for the Baton Rouge police, defends the investigation but acknowledges the long-term dilemma: "Let's face it. If we took a DNA sample from every male child at birth, we could solve a lot of crimes. But is that a price we're willing to pay?"

Probably not. A better question might be, Do DNA dragnets work? The answer so far is, rarely. The largest sweep in the U.S. took place in Miami, where in 1994 cops sampled 2,300 men in search of a serial killer. The dragnet did not catch the killer. Of the 18 publicized U.S. sweeps, only one—a narrow sampling of 25 workers at a nursing home—has been successful, according to a 2004 study by criminologist Samuel Walker of the University of Nebraska at Omaha. Walker called the sweeps "unproductive" and said that if they are to continue, national guidelines are urgently needed.

In Britain, where the first ever mass DNA sweep took place in 1987 (indirectly leading to the conviction of a rapist and murderer who tried to escape detection by asking a co-worker to take the DNA test for him), the results have been more impressive—and the public far less resistant. The Forensic Science Service of England and Wales has carried out 292 DNA dragnets since it began counting in 1995. So far, 61—about 20% of all sweeps—have produced significant matches, helping push an investigation toward a suspect and, on numerous occasions, a conviction. In 1998 Strücklingen, Germany, undertook the largest collection to date. More than 16,000 men in a rural town were sampled after a girl, 11, was raped and strangled. In a quest to restore the town's innocence, entire soccer teams took the test together. The killer, pressured to participate by friends, also complied, sealing his fate.

Given the history of Massachusetts' crime lab, it's hard to imagine Truro's DNA samples getting processed anytime soon. It took several months just to get the DNA from the initial suspects processed in the Worthington case. But D.A. O'Keefe insists, without elaborating, that the effort will have "ancillary benefits." The rush of attention has clearly got the town talking again.

And maybe, somewhere, it has got someone nervous, says Chief Thomas. "I hope that whoever did this cannot sleep at night. And if they do sleep, I hope they have nightmares. I hope they wake up in a cold sweat. And I hope the person next to them realizes what's going on and says something." *—With reporting by Theunis Bates/London, Marc Hequet/St. Paul and Ruth Laney/Baton Rouge*

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Virginia Aggressively Uses DNA to Solve Other Cases

A law allows police to compel suspects in violent offenses to give samples for study in unsolved crimes. Issues of privacy are raised.

By STEPHEN BRAUN
Times Staff Writer

FAIRFAX, Va. — Hours after the new year dawned, two men were led into the booking area of the Fairfax County Detention Center and ordered to scrape their cheeks with tiny swabs. The same thing happened 160 miles away in the small town of Waverly, where a stabbing suspect had been brought in after a bloody fracas.

In both cases, the suspects provided police with DNA samples compelled under a new Virginia law that seeks to use genetic tests to broaden the hunt for suspects in unsolved crimes.

Soon after the tests were carried out, Fairfax sheriff's deputies took the DNA samples to a state forensic lab down the street. And Waverly Police Chief Aaron Britton drove 60 miles to Richmond to provide state officials with a sealed envelope containing genetic traces from the stabbing suspect held in the Sussex County jail.

Starting Jan. 1, Virginia unleashed the nation's most ambitious law enforcement effort to use genetic testing to match suspects with evidence found at unsolved crime scenes — an aggressive melding of science and law enforcement that civil libertarians warn will chip away at constitutional and privacy rights.

Under the law passed last year by the Virginia Legislature, police are authorized to order suspects being charged with violent crimes and some other felonies to provide DNA samples or forfeit their right to be released at their booking. The saliva traces are being entered into Virginia's DNA bank, where forensic workers will be able to search for links to crime scene evidence from among 170,000 DNA samples — a vast collection surpassed only by Britain's genetic bank.

Civil libertarians are always concerned when the government gathers a large amount of personal information for its own discretion."

In Waverly, Britton said his beleaguered seven-officer force has had a difficult time contending with transient criminals. He said last year's serial sniper killings in the Washington, D.C., suburbs reinforced the need to move quickly to match suspects to crime scenes. "It'll help for the kinds of crimes we're getting these days," he said. "You have people doing things all over the place, and we never know who we're dealing with when we arrest them."

Britton was one of the first to use the law. The process, he said, went as easily "as taking a fingerprint."

Constitutional experts expect the law will be challenged. Peter Neufeld, a New York criminal attorney and DNA specialist, said he worries that eagerness to use DNA samples to scan for other crimes will encourage officers and prosecutors to charge suspects solely "to strengthen weak cases while they fish for other charges."

And Christopher Amolsch, a Washington-area defense attorney, said he fears suspects acquitted of criminal charges may be haunted by DNA samples that will end up "floating around for years through the system" despite Virginia's assurances that such information will be safely expunged.

The law was pushed last year by Virginia's attorney general, Jerry W. Kilgore, as the next logical step in the state's buildup of a massive collection of genetic traces used to match against evidence at unsolved crime scenes.

"We think we're in the vanguard," said Paul B. Ferrara, head of the Virginia Division of Forensic Science. "Within the next few years, you'll see all the states applying this to their arrested felons."

Louisiana and Texas have attempted similar procedures. But Louisiana's effort to take DNA samples from those accused of serious crimes has stalled because of staffing and budget woes, and Texas is applying the tests only to those charged with a limited range of sex crimes.

Civil libertarians are also concerned about the government's growing use of DNA sampling as an investigative tool.

Unlike fingerprinting, a court-sanctioned technique that police have used for decades to identify the presence of suspects at crime scenes, DNA matching has become a powerful weapon over the last decade, providing authorities with the ability to find genetic traces in carpet fibers, hair, saliva — almost anything that a suspect contacts.

In the sniper case, for example, police have linked juvenile suspect Lee Boyd Malvo to one homicide scene because traces of his DNA were allegedly found on a grape stem recovered at the site.

But some legal experts suggest that the use of DNA sampling to search for a suspect's involvement in other crimes beyond the immediate offense raises serious constitutional problems.

"There may be plenty of new and wonderful law enforcement purposes for DNA sampling," said Ira Robbins, a professor of criminal law at American University, "but there's real concern whether this particular use is proper." While a convicted criminal "has lost the presumption of innocence," Robbins added, taking genetic samples from a newly arrested suspect "crosses a line I'm not sure we want to cross."

The most glaring concern, Neufeld said, is the damage done to suspects whose felony charges are dropped before trial or who are acquitted.

A provision of the Virginia law compels forensic officials to destroy the DNA samples soon after charges are dropped. But if copies end up in the hands of other agencies, there may be no way to ensure their destruction.

Katya Newton, counsel for the forensic division, acknowledged some looseness in the law that might pose other difficulties. It is unclear, for example, what happens when a trial results in a hung jury — a situation in which a suspect is not clearly acquitted, but also escapes a guilty verdict.

And the law does not spell out how to compel DNA testing of uncooperative suspects. The threat of being held for refusing to provide a genetic sample has

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DNA Data Bases & 4th Amendment

1. Special Needs
2. Not Used for Evidence / Convicted felons
3. Used for Identification / like fingerprint
4. Lost rights as convicted felon — State has a compelling Interest to know who felons are!

Summary of Key Provisions of the California Proposition 69 Initiative Statute

Alice A. Noble, J.D., M.P.H.

Grant No. 1 RO1-HG0002836-01

California Proposition 69, passed by the electorate on November 2, 2004, amends the California Penal Code. The proposition was enacted out of a perceived necessity "…to clarify existing law and to enable the state's DNA and Forensic Identification Database and Data Bank Program to become a more effective law enforcement tool." Calif. PENAL CODE § 295 (b)(3). The key provisions of the measure are outlined below.

Expanding the DNA Data Bank

Calif. Penal Code § 296(a)

The key provisions include expansion of categories of individuals from which a DNA sample may be taken for inclusion in the DNA data bank. These individuals include the following categories:

- All adults and juveniles convicted of any felony offense or adjudicated delinquent for committing a felony offense. The definition of "felony" also includes attempts to commit the felony.
- Adults and juveniles who are required to register as a sex offender or arsonist because of the commission of, or attempt to commit, a misdemeanor or felony; and adults and juveniles housed in a mental health facility or sex offender treatment program per referral of the court as a result of being charged with a felony offense.
- Adults arrested for or charged with felony sex offenses, murder, or voluntary manslaughter (or an attempt to commit such an offense)
- Beginning in 2009, adults arrested or charged with any felony offense

These provisions apply retroactively, thus authorizing the collection of DNA samples from those currently incarcerated for qualifying offenses, or those serving probation or parole for qualifying offenses. Upon arrest, a "buccal swab," a sample of the inner cheek cells of the mouth, will be obtained from those individuals charged with a qualifying offense, as noted above. Blood samples may be collected in certain situations at the discretion of the California Department of Justice.

Collection and Purging of Suspect Profiles and Samples

Calif. Penal Code § 297(b), (e), (f)

In the case of DNA profiles of suspects, including those who submit DNA samples voluntarily for the purpose of exclusion, the sample may be retained in the data band for two years. The sample may be compared to evidence from as many cases and investigations as necessary, and searched against DNA profiles in any available data bases.

The law enforcement agency that submits a sample from a suspect shall notify the appropriate crime lab(s) after a period of two years whether the individual continues to be considered a suspect in a criminal investigation. If the individual is no longer a suspect, the DOJ DNA laboratory shall remove the suspect sample from the data bank files.

Failure to purge or a delay in purging such samples, however, will not be grounds for an invalidation of an identification, warrant, or arrest, or for a dismissal of a prosecution, based on the samples in question.

The law states that the limitations on the types of offenses under Section 296(a) that qualify for inclusion of the individual's DNA into the database is for the purpose of facilitating the administration of this chapter by the DOJ, and these limitations shall not be the basis for dismissing an investigation or prosecution or for reversing a verdict of disposition. Moreover, the where a sample is obtained or placed or retained in the data bank by mistake, an arrest, conviction, or adjudication based on that sample will not be invalidated.

New Felony Offense: Tampering with DNA Samples
Calif. Penal Code§298.2(9)
The measure creates a new felony offense for anyone who is required to submit a specimen sample and (1) knowingly facilitates the collection of wrongfully attributed DNA samples with the intent to deceive as to its origins; or (2) knowingly tampers with any DNA sample or collection container with the intent to deceive as to the sample origins. Conviction under this provision is punishable by imprisonment for two, three, or four years.

Timely Collection and Analysis of Samples
Calif. Penal Code § 298.3
The measure encourages the timely collection and analysis of samples. The DOJ is required, contingent upon the availability of funding, to contract with other public or private labs for analysis of samples that are not fully analyzed and uploaded into state or federal data banks within six months of receipt.

Quarterly Reports
Calif. Penal Code § 295 (h)(4),(5)
The DOJ is required to file quarterly reports tracking the number of DNA samples obtained, analyzed and included in the state and federal data banks, as well as the number of "hits" and "investigations aided," as reported to the National DNA Index System. The report shall also document the lab's accreditation status, its participation in CODIS, and the money collected, expended, and disbursed pursuant to the statute. The quarterly reports will be posted on the DOJ web site and made accessible to the public.

The Department of Corrections is also required to make quarterly reports to be published electronically, which shall include the number of inmates yet to provide DNA samples to the DOJ DNA Laboratory and the number of samples yet to be forwarded to the DNA Laboratory within 30 days of collection.

Expungement Requests
Calif. Penal Code § 299
The measure permits certain individuals whose DNA have been included in the DOJ data bank to petition to have their DNA sample destroyed and the profile expunged from the data bank. The individual must have no past of present qualifying offense, or be subject

to any other legal basis for retaining their sample and profile. The individual may file a written request for expungement if one of the following are satisfied:

- Following arrest, no charges were filed;
- Underlying conviction serving as the basis for inclusion in the data bank has been reversed and the case dismissed;
- A finding of actual innocence of the offense in question; or
- A finding of not guilty or an acquittal has been entered as to the underlying offense.

[This represents a change. Under prior law, the court issuing the reversal, acquittal, or dismissal was required to issue an order that the DOJ expunge all identifiable information in the data bank and any criminal identification records pertaining to the person.]

The court has the discretion to allow or deny the request, and any such determination is final and nonreviewable. If the request is granted, the DOJ will destroy the sample and profile when it receives a court order acknowledging that the petitioner has met the requirements of the law. These include the written request of the individual, along with written documentation, as specified, that the requirements for expungement have been met, that adequate notice has been given to prosecutors and the DOJ and that they have not filed an objection, that no retrial or appeal is pending. Failure to expunge, or a delay in expunging, the sample and profile will not invalidate an identification, warrant, probable cause to arrest, or an arrest.

International Law Enforcement Database or Data Bank System

Calif. Penal Code § 296.6 (a)(b)

The statute contemplates California's participation in international data bank systems. It gives the Department of Justice responsibility for "liaison" with the FBI regarding the state's participation in national or international DNA data banks. Also, the statute permits the population databases and databanks of the DNA Laboratory to be made available to and searched by any national or international law enforcement database or data bank system.

Additional Funding

Calif. Government Code § 76104.6

The measure provides for additional funding to subsidize the DNA data bank expansion by adding $1 to every $10 in criminal penalties. The measure sets forth percentages for apportioning revenues realized from this surcharge between the state and local governments. After an initial phase-in period, local governments will receive 75% of the funds realized, with 25% apportioned to the state. At the local level, this funding will offset costs associated with DNA sample collection, and analysis, tracking and processing of crime scene samples.