Genetic Information Nondiscrimination Act (GINA)

- Signed into law on May 21st 2008
- Sponsored by Representative Louise M. Slaughter
- Purpose: Protect individuals from discrimination from insurers and employers, allowing individuals to get medically beneficial genetic tests without fear of losing their insurance or their jobs. It also reassures participants of research studies that their DNA will not be used against them.

Title I: Genetic Nondiscrimination in Health Insurance

- Health insurers cannot use your genetic test results to deny you health coverage or set the price you pay for health insurance.
- Covers health plans big and small, from group health insurance through employer to government-run insurance and individual health policies.

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

- Employers cannot use your genetic test results to make hiring and salary decision or set other job-related polices.
- Employers are prohibited from requiring you to take a genetic test except in very few cases to protect employee's safety.

egislative history of GINA

995: Genetic Privacy and Nondiscrimination Act

995: The Genetic Information Nondiscrimination in Health Insurance Act

996:The Genetic Fairness Act

996: Genetic Confidentiality and Nondiscrimination Act of 1996

003: Rep. Louise M. Slaughter introduced GINA.

xisting Anti-Discrimination Laws that could be extended to enetics.

mericans with Disabilities Act of 1990
protects discrimination against the disabled, symptomatic genetics disabilities ount as disabilities.

ealth Insurance Portability and Accountability Act of 1996 (HIPAA)
prohibits group health plans from using any health status-related factor, ncluding genetic information, as a basis for denying or limiting eligibility for overage or for increasing premiums.

IPAA National Standards to Protect Patients' Personal Medical Records 2002 - rotects privacy of medical records and other personal health information.

itle VII of the Civil Rights Act of 1964
genetic discrimination based on "racially or ethnically linked" genetic disorders onstitutes unlawful race or ethnicity discrimination.

The Human Genes Research Act: the Estonian precursor to GINA

Estonia is ahead of the United States in number of genomes sequenced and recorded.

2000: HGRA passed.

2001:Estonian Genome Project Foundation established by Estonian government.

2002: EGP started collecting tissue samples from gene donors in 2002. (The U.S. didn’t finish its genome project until 2003.)

Goal of EGP: to have 1,000,000 gene donors out of a population of 1,400,00. According to their website they have 20,000 donors already and more are eager to donate.

Pilot Project: 3 counties, 10,000 donors. Completed!

Main Project: 3/4 population of Estonia. Currently underway.

Scientists can use this large bank of genetic information, called GenBank, to do research and work toward cures for various genetic diseases

Contents of The Human Genes Research Act

-Gene Bank used only for scientific health research.

-only donor and donor's doctor have access to personalized information.

-the Gene Bank owns the blood samples and the genetic data. Donors will not receive remuneration for the samples they provide.

-only voluntary participation, not required.

-personal data separated from genetic data to protect privacy.

-Prohibits genetic discrimination.

-donor has a right to delete his genetic data.

-disclosing secret information, forcing a person to donate, or genetically discriminating is a *criminal* act.

Differences between HGRA and GINA

nder HGRA donor’s doctor has access to genetic information, hereas in the Direct to Consumer companies in the U.S., only the dividual has access to their genetic information.

GRA makes disclosing secret information, forcing a person to donate, r genetically discriminating a *criminal* act. In the U.S., insurers and nployers who violate GINA face punitive damages, a *civil*, not iminal, punishment.

GRA was passed a year *before* the Estonian Genome Project was arted, whereas GINA was passed five years *after* the Human Genome roject in the U.S. was completed.

Why do we need GINA?

o genetic-discrimination case bas been brought before U.S. courts, but ere have still been instances of discrimination.

EOC vs. Burlington Northern Santa Fe Railroad.

NSF secretly tested its employees for a rare genetic condition ereditary neuropathy with liability to pressure palsies - HNPP) that auses carpal tunnel syndrome as one of its many symptoms. Railroad aimed it was job-related. EEOC won.

Young boy had Fragile X Syndrome, an inherited form of mental etardation. The insurance company for the boy's family dropped his ealth coverage, claiming the syndrome was a preexisting condition.

A social worker lost her job within a week of mentioning that her mother ad died of Huntington's disease and that she had a 50% chance of eveloping it.

Why do we need GINA?

- In 1970’s employers refused to hire many healthy African-Americans because they were carriers of sickle cell anemia.
- A health insurance company refused to provide coverage for two unaffected children of a woman with anti-trypsin disease because the children were carriers.
- Victoria Grove took a personal genetic test that told her she would almost certainly develop emphysema, but she didn’t tell her doctor because she was afraid she would lose her insurance.
- Many patients pay in cash for DNA tests for inherited breast cancer to avoid submitting breast cancer claims.

How will GINA affect people’s willingness to have genetic tests?

“Testing services such as DNADirect of San Francisco, which offer access to a range of established tests, will probably benefit from the bill.”

-Myriad Genetics provides *BRCA1* and *BRCA2* tests.
Oren Cohen, senior vice president of clinical research strategies at CRO Quintiles Transnational:

> *"The BRCA test is one I'd expect to become much more sought-after now. There's pent-up demand for that test, because there was widespread fear of discrimination.”*

Quotations from *Nature*: Industry welcomes Genetic Information Nondiscrimination Act

How will GINA affect people’s willingness to have genetic tests?

David Resnick wants to be tested for a cancer-related mutation that he has a 16% chance of inheriting from his mother.

“I was waiting for GINA, because I was concerned [the mutation] could be considered a preexisting condition.”

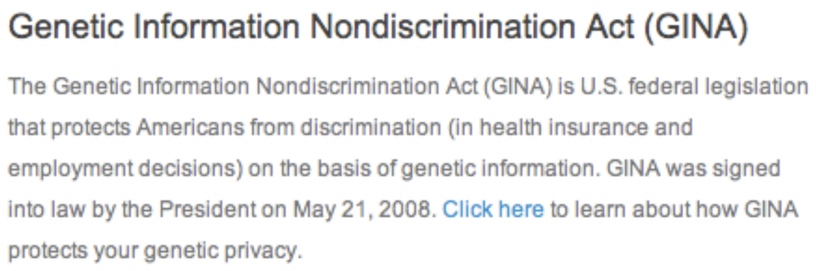
-Hopefully GINA will boost enrollment in clinical trials that include genetic testing. Raju Kucherlapati, a professor at Harvard Medical School and director of the Boston-based Harvard-Partners Center for Genetics and Genomics:

"If people hear a trial uses an electronic medical record, they are afraid the information will get to their insurance company and they could be discriminated against.”

Quotations from *Nature*: Industry welcomes Genetic Information Nondiscrimination Act

How will GINA affect the Direct to Consumer Market?

23andMe seeks to spread the word about GINA on its website by providing articles and “click here” information on the new law.



Genetic Information Nondiscrimination Act (GINA)

The Genetic Information Nondiscrimination Act (GINA) is U.S. federal legislation that protects Americans from discrimination (in health insurance and employment decisions) on the basis of genetic information. GINA was signed into law by the President on May 21, 2008. Click here to learn about how GINA protects your genetic privacy.

“Passage of the Act has been widely welcomed by commercial genetic testing services that seek a clearer framework for regulating the ndustry.” - *Nature*: Industry welcomes Genetic Information Nondiscrimination Act

Amy DuRoss, head of Policy and Business Affairs at Redwood Shores, California–based Navigenics.

> *"Having federal protection sends a message that the future is now for technology related to genetic information.”*

Helicos's CSO Patrice Milos:

> *"I am confident the public will take this as a positive signal. This shows we have an informed Congress now. They are knowledgeable about what the future of genomics holds.”*

What are the concerns that people have about GINA?

There is dissatisfaction from both patients and employers.

Criticism from the patient:

GINA does not include several things:

-GINA does not cover members of the military.

-The law does not cover life insurance, disability insurance and long-term care insurance, or other uses of genetic information.

-GINA's health insurance provisions do not apply to people who are symptomatic.

-Provisions do not apply to non-genetic predictive testing and information (epigenetics.)

What are the concerns that people have about GINA?

GINA is vague

Title I: Genetic Nondiscrimination in Health Insurance

> “Authorizes a penalty against any sponsor of a group health plan for any failure to meet requirements of this Act. Allows a waiver or limitation on such penalty if the failure was not discovered after exercising reasonable diligence or was due to reasonable cause.”

The sponsor of the insurance company won’t be punished for violating the act if they didn’t know they were violating it?

What constitutes “reasonable” diligence?

What qualifies as “reasonable” cause?

This broad statement allows wiggle room for insurers.

What are the concerns that people have about GINA?

The National Association of Manufactures, the National Retail Federation, the Society for Human Resource Management, and United States Chamber of Commerce, other members of the Genetic nformation Nondiscrimination in Employment Coalition, (GINE) and other critics of GINA claim that

Legislation is too broad and will create a flood of law suits and punitive damages.

The law is “burdensome.” Insurance companies must keep very horough records so that they do not accidentally disclose genetic nformation.

GINA will not successfully clarify conflicting state laws.

the law is unnecessary since technically there have been no cases of genetic discrimination brought to the courts.

GINA might force employers to provide health coverage for all reatments for genetically-related conditions.

Obviously insurers and employers oppose GINA because if they are equired to cover costs for genetically related disease it will increase heir costs dramatically.

Questions for Discussion

- Is the Estonian Gene Bank project in our future? Will we have a large donor population and gene bank in the U.S.? Will that accelerate genetic research and speed the process of finding cures for genetic diseases?
- HGRA passed eight years before GINA. Why are the Estonians so far ahead? Smaller population? Different governmental structure?
- GINA protects against discrimination from insurers and employees, but what about potential spouses and friends? ScientificMatch.com
- The Human Genome Project was completed in 2003, but we just passed GINA in 2008. There was a thirteen year hold up in the Senate before GINA was finally passed. Clearly legislation lags behind science. How can law keep up with science, and what will be the consequences if it can't?
- Are stricter (narrower, less vague) anti-genetic-discrimination laws in our future?
- Will genetic discrimination be a new field in law? So far no genetic discrimination cases have gone to court, but in the future are we going to have cases like *Roe vs.. Wade* or *Brown vj. Board* for genetics?

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