



**Huntington's Disease Society of America**

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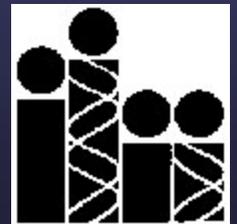
HDSA encourages all attendees to consult with their primary care provider, neurologist or other healthcare provider about any advice, exercise, medication, treatment, nutritional supplement or regimen that may have been mentioned as part of any presentation.

# Genetic Discrimination

## HDSA 2008: Pittsburgh

Cheryl Erwin, JD, PhD

University of Texas Medical School  
McGovern Center for Health, Humanities  
and the Human Spirit



# Presentation Overview

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What is genetic discrimination?

Why is it important?

How prevalent is discrimination?

There ought to be a law

Making a difference

# Concerns about genetic discrimination

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- Unfair treatment
- Loss of opportunities
- Any different treatment that adversely affects the person at risk
  - Example: the denial, limitation or increased price of insurance
- Based on genetic susceptibility, not manifest disease

# What is genetic discrimination?

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- We define genetic discrimination as the denial of rights, privileges or opportunities or other adverse treatment based solely on genetic information, including family history of HD
  - From the RESPOND-HD survey, 2007

SPECIAL REPORT

JANUARY 17, 1994 \$2.95

# TIME



## Genetics THE FUTURE IS NOW

New breakthroughs can cure diseases and save lives,  
but how much should nature be engineered?



10099

724404 1

# Is it important to understand genetic discrimination?

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- Insurance
- Employment
- Social consequences
  
- Limits on genetic based medicine

# Fear of genetic discrimination impacts personal decisions

The New York Times

February 24, 2008

February 24, 2008

THE DAMAGE

## Insurance Fears Lead Many to Shun DNA Tests

By [MELISSA MAZUR](#)

Victoria Grove wanted to find out if she was destined to develop the form of osteoporosis that ran in her family, but she did not want to ask her doctor for the DNA test that would tell her.

She worried that she might not be able to get health insurance, or even a job, if a genetic predisposition showed up in her medical records, especially since treatment for the condition, alpha-1 antitrypsin deficiency, could cost over \$100,000 a year. Instead, Ms. Grove sought out a service that sent a test kit to her home and returned the results directly to her.

Not did she tell her doctor when the test revealed that she was virtually certain to get it. Knowing that she could sustain permanent lung damage without immediate treatment for her bouts of emphysema, she made sure to visit her clinic at the first sign of infection.

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# Worries about privacy

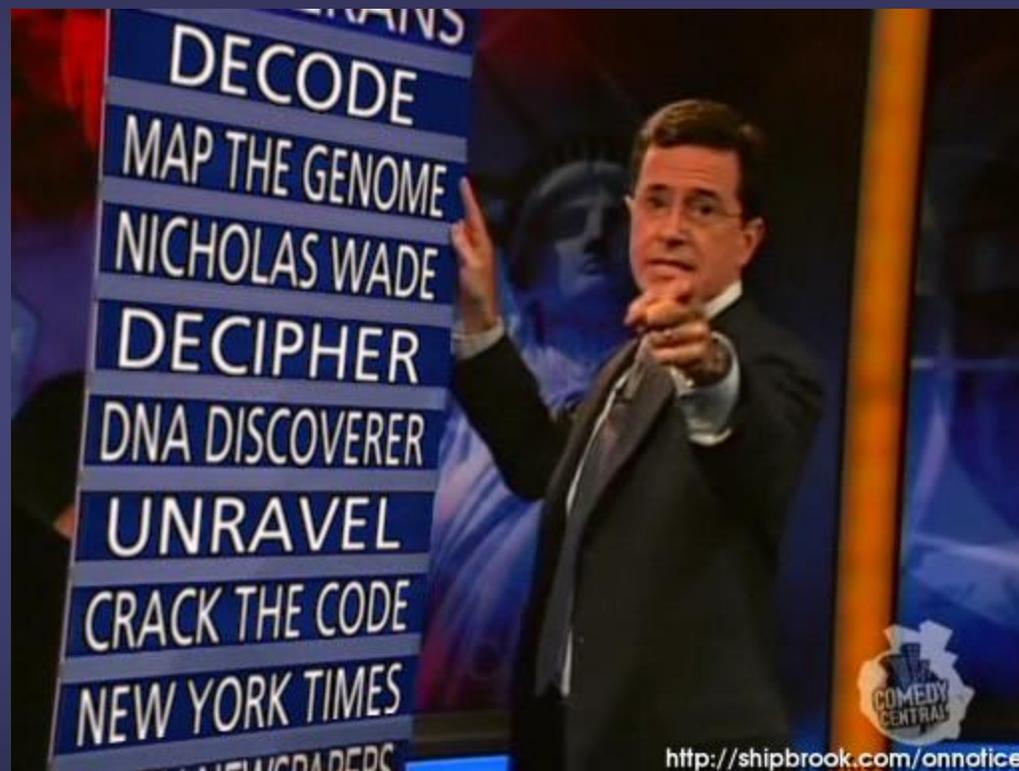
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- *How concerned are you that health information may be used to limit job opportunities?*
- 1999: 36% concerned
- 2005: 52% concerned
- *California Healthcare Foundation, 2005*



# Social consequences

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See: Hunter, David, et al., *Letting the Genome out of the Bottle – Will We Get Our Wish?* 358 NEJM 105, 2008

# How prevalent is genetic discrimination?

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- Case histories abound
  - “Discrimination as a consequence of genetic testing” Billings, et al., 50 Am J. Hum. Gen. 476, 1992
- Little systematic study
  - Survey of genetic counselors suggests little genetic discrimination occurs
    - Hall: “Genetic Privacy Laws and Patients’ fear of Discrimination by health insurers: The view from Genetic Counselors” 28 J Law, Med. & Eth., 245, 2000
    - 2007: Results confirmed in a study of Hemochromatosis patients
- Are these results generalizable across genetic disease spectrums?

# Discrimination in Huntington's Disease

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Woody Guthrie, 1912 - 1967

- Preliminary study:
- Employment
  - Of 9 who disclosed, 3 reported negative consequences
  - None reported they would disclose if given a second chance
  - Of those unemployed there was high concern for employability
- Insurance
  - Of 2 who disclosed, neither reported changes in insurance status
  - Majority feared disclosure and loss of insurance
  - High fears of medical expenses
- Relationships
  - Of 15 participants, 13 reported moderate changes in family and social systems (8 unfavorable, 4 mixed, 1 favorable) and 2 reported no change
  - Altered choices in important life relationships or circumstances
  - Fear of loss of valued interpersonal relationships

Penziner, et al., Perceptions of Discrimination Among Persons who have Undergone Predictive Testing for Huntington's Disease. American Journal of Medical Genetics: Neuropsychiatry, October 19, 2007.

# We just want a few questions answered...

**MODIFIED GUARANTEE ISSUE – Answer Questions in SECTION A only.**  
**SIMPLIFIED ISSUE- Answer Questions in SECTION A & B.**

**A**

1. During the last 6 MONTHS, have you been continuously and actively at work for your current employer for a minimum of 32 hours per week, at the worksite (away from home), except for vacation? .....  Yes  No
2. During the last 6 MONTHS, have you missed more than five consecutive days of work due to accidents, sickness or any physical or cognitive impairment?.....  Yes  No
3. During the last 12 MONTHS, have you ever required assistance or supervision of any kind to perform everyday activities, such as mobility (including the use of canes), taking medications, dressing, eating, walking, bathing, transferring, or toileting?.....  Yes  No

**If any question 4 – 8 is answered "Yes," You are not eligible for coverage.**

**B**

4. Have you EVER had, or been diagnosed, treated or had symptoms of any of the following conditions?  Yes  No  
 If "YES", please check the applicable condition(s):

<input type="checkbox"/> Alzheimer's disease	<input type="checkbox"/> Dementia	<input type="checkbox"/> Osteoporosis with fractures
<input type="checkbox"/> Amputation due to disease	<input type="checkbox"/> Mobility Deficit	<input type="checkbox"/> Paraplegia or Quadriplegia
<input type="checkbox"/> Amyotrophic Lateral Sclerosis (Lou Gehrig's disease)	<input type="checkbox"/> Multiple Sclerosis	<input type="checkbox"/> Parkinson's disease
<input type="checkbox"/> Arthritis with narcotic pain medication	<input type="checkbox"/> Muscular Dystrophy	<input type="checkbox"/> Polymyositis
<input type="checkbox"/> Cerebrovascular Accident* (Stroke, CVA, TIA)	<input type="checkbox"/> Myasthenia Gravis	<input type="checkbox"/> Scleroderma
	<input type="checkbox"/> Organic Brain Syndrome	<input type="checkbox"/> Senility
	<input type="checkbox"/> Huntington's Chorea	

\*If applicant has had a single Cerebrovascular Accident more than 2 years ago, complete the Full Underwriting Section C

5. During the last 3 YEARS, have you been diagnosed or treated for Diabetes using over 60 units of insulin or WITH COMPLICATIONS (Neuropathy, Retinopathy, Amputations, Stroke), Chronic Hepatitis or Cirrhosis, alcoholism, alcohol abuse, drug or prescription drug addiction, Transient Global Amnesia, confusion, disorientation, memory loss or Bipolar Disorder without continuous medication? .....  Yes  No
6. During the last 6 MONTHS, have you used a catheter, dialysis, oxygen equipment, a quad or three-pronged cane, ~~respirator, walker, wheelchair, crutches, motorized scooter or chair lift?~~ .....  Yes  No
7. During the last 6 MONTHS, have you been confined to a nursing home, assisted living facility, attended an adult day care facility, or required home health care? .....  Yes  No
8. If under age 50, do you have a direct family history (parents or siblings) of Huntington's Chorea or Polycystic Kidney Disease? .....  Yes  No
9. Are you currently taking, or within the last 6 months have you taken, or been prescribed any prescription drugs or medications? .....  Yes  No  
 If "Yes," please list all: \_\_\_\_\_  
 Check here if more space is needed, attach a signed and dated additional sheet.

PRIMARY PHYSICIAN'S NAME	TELEPHONE NUMBER	APPLICANT'S HMO/PPO ID#
ADDRESS		DATE LAST CONSULTED

# There ought to be a law

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Federal laws

One size fits all: ADA / HIPAA

State laws

The laboratory of democracy

How to define genetic information

What activity is proscribed / what is acceptable

# State Employment Laws Prohibit ...

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20 states limit the use of genetic information in hiring and firing decisions (including Iowa)

24 states prohibit employers from requiring access to genetic tests or results as condition of employment (including Iowa)

5 states require consent for genetic testing or disclosure of test results

1 state prohibits employers from requiring a test or inquiring into whether a genetic test was ever taken (Oregon)

1 state provides key exceptions that allow use or access to genetic information (Missouri, employee may consent)

Genetic information from testing is private or confidential and privileged – Sanctions (4 – TX, UT, WI, AZ)

For example Texas imposes a \$10,000 fine for disclosure of genetic information

Most laws do not prevent coerced consent as a condition of employment – some may encourage coercion

# State Health Insurance Laws

## Prohibit ...

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- 34 states limit use of genetic info for rates, terms, conditions of insurance (Iowa only restricts use for enrollment but can use to set rates)
- 22 states prohibit insurers from requiring access to genetic test or results as condition of insurability - if asymptomatic
- 28 require consent for genetic testing or disclosure of test results
- 12 prohibit inquiry into whether a genetic test was ever taken
- 19 states protect information about family members genetic tests or family history of a genetic condition
- 5 states provide key exceptions to important laws
- 12 states provide that genetic information from testing is private or confidential and privileged, or provide clear sanctions
  - For example: Texas creates prohibitions against compelled disclosure including by courts, but no specific monetary sanction is imposed

State insurance laws do not affect self-insured plans

# Federal Laws: HIPAA

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- Health Insurance Portability and Accountability Act (HIPAA):
  - Genetic predisposition cannot be considered a pre-existing condition unless manifest
  - Does not apply to employers
  - Does not apply to individual insurance market
  - Does not prevent use of genetic information in group rating
  - Self insured companies can easily access genetic information
  - Does not prevent
    - inadvertent access
    - use of family history information
    - collection of information for billing purposes
    - voluntary disclosures
    - coerced consent

# Federal Laws: ADA

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- Americans with Disabilities Act (ADA)
  - Section 102 d: Prohibits pre-employment physical exams
  - After the offer of employment the employer may require medical exam unlimited in scope as a pre-placement qualification
  - Coerced consent to undergo genetic testing is not addressed
  - Does not cover all persons with the HD gene as a class unless symptomatic  
*Laws v Pact* 2000 WL 777926 (N.D. Ill. 2000)

**Genetic Privacy and Nondiscrimination Act of 1995 (Introduced in House)**

HR 2690 TH

104th CONGRESS

1st Session

**H. R. 2690**

To establish limitation with respect to the disclosure and use of genetic information, and for other purposes.

**IN THE HOUSE OF REPRESENTATIVES**

**November 29, 1995**

Mr. STEARNS introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Government Reform and Oversight and Economic and Educational Opportunities, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

**A BILL**

To establish limitation with respect to the disclosure and use of genetic information, and for other purposes.

No. 41

October 2, 2003

## **S. 1053 – Genetic Information Nondiscrimination Act of 2003**

Calendar No. 247

*Favorably reported by the Health, Education, Labor and Pensions (HELP) Committee without objection on July 31, 2003 with an amendment in the nature of a substitute. S. Rept. 108-122.*

### **NOTEWORTHY**

- A unanimous consent request was made to begin consideration of S. 1053, the Genetic Information Nondiscrimination Act of 2003, on October 2, 2003. Under the requested unanimous consent agreement, the Snowe amendment will be made in order. This incorporates the committee substitute amendment with additional findings.
- The measure, sponsored by Senator Snowe, prohibits discrimination on the basis of genetic information with respect to health insurance and employment. Both the original underlying bill and the manager's amendment have bipartisan support.
- In a June 19 report to the HELP Committee, the Congressional Budget Office estimated that the budgetary impact of this legislation would be minimal. CBO reported that the number of individuals obtaining insurance due to passage of the bill would increase by less than 500 people per year. As a result, federal revenues would decrease by less than \$500,000 in each year from 2004 and 2013 due to the tax deductibility of premiums paid by those newly insured individuals.



Jon Kyl, Chairman

347 Russell Senate Office Building  
Washington, DC 20510  
202-224-2946  
<http://rpc.senate.gov>

No. 2

February 16, 2005

## S. 306 – Genetic Information Nondiscrimination Act of 2005

Calendar No. 3

*Favorably reported by the Health, Education, Labor and Pensions (HELP) Committee on February 10, 2005; no written report.*

### NOTEWORTHY

- The Senate began consideration of S. 306, the Genetic Information Nondiscrimination Act of 2005, on February 16, 2005. There will be 90 minutes of debate on the bill.
- The measure prohibits discrimination on the basis of genetic information with respect to health insurance and employment. The bill has bipartisan support.
- This bill is similar to S. 1053 of the 108<sup>th</sup> Congress, which passed the Senate by a 95-0 vote on October 14, 2003 (see Record Vote Analysis 377 of 2003 for details). The House did not act on the bill in the 108<sup>th</sup> Congress.
- In a February 14, 2005 report to the HELP Committee on S. 306, the Congressional Budget Office estimated that the budgetary impact of this legislation would be minimal: federal revenues would be expected to decrease by less than \$500,000 in each year over the 2006-2015 period, due to the tax deductibility of premiums paid by newly insured individuals.

110TH CONGRESS  
1ST SESSION

# H. R. 493

To prohibit discrimination on the basis of genetic information with respect to health insurance and employment.

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IN THE HOUSE OF REPRESENTATIVES

JANUARY 16, 2007

Mrs. SLAUGHTER (for herself, Mrs. BIGGERT, Ms. ESHOO, Mr. WALDEN of Oregon, Mr. GEORGE MILLER of California, Mr. DINGELL, Mr. RANGEL, Mr. ACKERMAN, Mr. ALEXANDER, Mr. ALLEN, Mr. BACHUS, Mr. BAKER, Ms. BALDWIN, Mr. BARTLETT of Maryland, Mr. BILIRAKIS, Mrs. BLACKBURN, Mr. BLUMENAUER, Mrs. BONO, Mr. BOUSTANY, Mr. BROWN of South Carolina, Ms. GINNY BROWN-WAITE of Florida, Mr. BURTON of Indiana, Mr. CALVERT, Mrs. CAPITO, Mrs. CAPPS, Mr. CAPUANO, Mr. CASTLE, Mr. CHABOT, Mr. CHANDLER, Mr. COLE of Oklahoma, Mr. CONAWAY, Mr. CONYERS, Mrs. DAVIS of California, Mr. TOM DAVIS of Virginia, Mr. DAVIS of Kentucky, Ms. DeGETTE, Mr. DICKS, Mr. DOGGETT, Mrs. DRAKE, Mr. DUNCAN, Mr. EHLERS, Mr.

# Despite wide support...

NATURE | Vol 448 | 9 August 2007

NEWS



Better times? The jury is out on whether natural-product synthesis has a place in modern chemistry.

admits that total synthesis is not a fashionable pursuit but he insists that it will endure. "Anybody who downplays the Ley achievement as anything other than a landmark is simply jealous." Baran is driven by what he describes as "the creation of beauty" and says: "If you focus on generating complexity in new ways, you have the opportunity to open up new realms of chemical space." He cites

Lowé dismisses this idea. "You're more likely to find new chemistry if you're looking for it," he says. But he admits that Ley's work is different, because Ley invented new reagents and general synthetic routes to reach his goal.

Ley himself is well aware of the debates surrounding total synthesis, which he attributes to a squeeze on funding, and says that those



## KOREAN STEM CELLS UNMASKED

Disgraced biologist's cell line was first of its kind, but not cloned.  
[www.nature.com/news](http://www.nature.com/news)

LEE HWAN-UP

## US genetics bill blocked again

US Senator Tom Coburn is single-handedly blocking the passage of a bill through the Senate that aims to protect people from genetic discrimination.

Coburn (Republican, Oklahoma) is using a legislative tactic called a hold to block a Senate vote on the Genetic Information Nondiscrimination Act (GINA), which was passed in April by the House of Representatives on a vote of 420 to 3 (see *Nature* 447, 14–15; 2007). The bill would make it illegal for employers or insurers to use genetic information in hiring, firing, promotion or insurance-coverage decisions. President George W. Bush has promised to sign the bill into law should it reach his desk.

"I believe the bill, as drafted, contains unintended consequences," Coburn wrote in a 1 August letter to his constituents, who have since deluged his office with complaining letters, e-mails and phone calls. "Congress has both the moral and legal responsibility to pay

attention to details and get them right. I want to assure you that my hold on GINA is not because I oppose the bill's purpose, but because I am concerned about its lack of precision."

Coburn, who has holds on 87 bills, voted for essentially the same bill when the Senate passed it unanimously in 2005. At that time, both the House and

M. GELBERG/PA

# Finally !!!

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May 2, 2008

## Congress Passes Bill to Bar Bias Based on Genes

By [AMY HARMON](#)

Correction Appended

A bill that would prohibit discrimination by health insurers and employers based on the information that people carry in their genes won final approval in Congress on Thursday by an overwhelming vote.

The legislation, which President Bush has indicated he will sign, speaks both to the mounting hope that genetic research may greatly improve health care and the fear of a dystopia in which people's own DNA could be turned against them.

On the House floor on Thursday, Democrats and Republicans alike cited anecdotes and polls illustrating that people feel they should not be penalized because they happened to be born at higher risk for a given disease.

"People know we all have bad genes, and we are all potential victims of genetic discrimination," said Representative [Louise M. Slaughter](#), Democrat of New York, who first proposed the legislation. The measure passed the House on Thursday by a 414-to-1 vote, and the Senate by 95-to-0 a week earlier.

If the bill is signed into law, more people are expected to take advantage of genetic testing and to participate in genetic research. Still, some experts said people should think twice before revealing their genetic information.

Doctors say a fear of discrimination on the part of patients has prevented thousands at risk of genetic disease from taking advantage of tests that might help them make better health care choices. Some patients worry that they may be denied jobs or face higher insurance premiums if a genetic red flag shows up in their medical records.

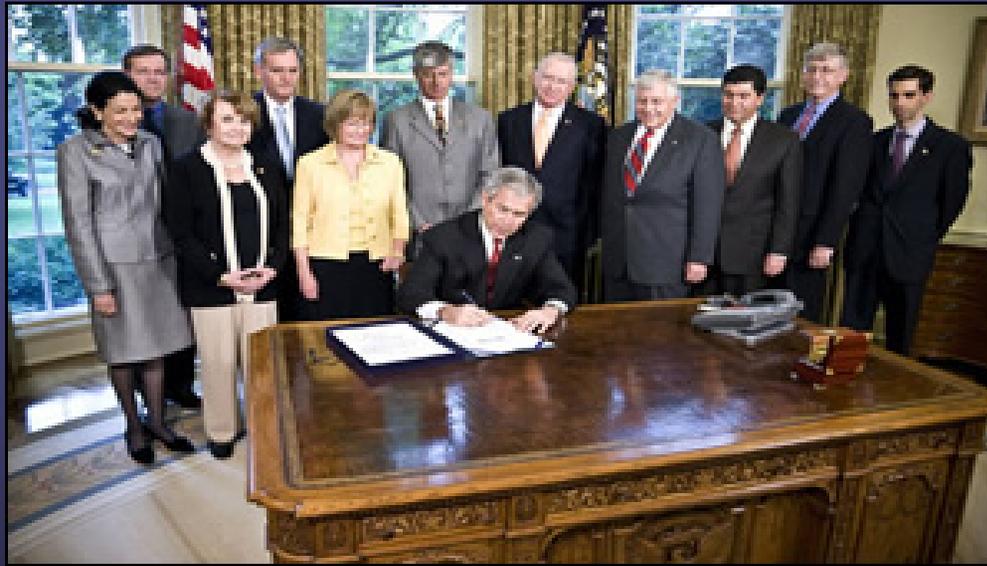
Many who do learn that they are at higher risk for a disease opt not to ask their insurance companies to cover the costs of the genetic test, to keep the information secret. Some try to persuade medical professionals not to enter the test results in their health records; others keep the information from even their own doctors.

The measure did not always have such overwhelming support. Similar legislation had floundered for over a decade in the face of opposition from employers and insurers and skepticism from lawmakers over its necessity: virtually no cases of genetic discrimination have ever been documented.

# First Major Civil Rights Legislation in 20 years

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- Signed into law by President Bush on May 21, 2008



*President George W. Bush signs H.R. 493, the Genetic Information Nondiscrimination Act of 2008, Wednesday, May 21, 2008, in the Oval Office. White House photo by Eric Draper.*

# Implementing GINA

- GINA takes effect 18 months after it is signed into law
- Regulatory agencies are required to formulate policies
  - Equal Employment Opportunity Commission (employment issues)
  - Department of Labor (ERISA issues)
  - Secretary of Health and Human Services (HIPAA and certain group health insurance issues)
  - Secretary of Treasury (IRS issues)

-

## The Genetic Information Nondiscrimination Act

### What the Legislation Does

Prohibits group and individual health insurers from using a person's genetic information in setting eligibility or premium or contribution amounts.

Prohibits health insurers from requesting or requiring that a person undergo a genetic test.

Prohibits employers from using a person's genetic information in making employment decisions such as hiring, firing, job assignments, and promotions.

Prohibits employers from requesting, requiring, or purchasing genetic information about an individual employee or family member.

### What the Legislation Does Not Do

Does not prohibit medical underwriting based on current health status.

Does not mandate coverage for any particular medical tests or treatments.

Does not interfere with the ability of a treating health care professional to request that a person or family member undergo a genetic test.

Does not subject employers to remedies and procedures that are different from those in other civil-rights laws, such as Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act.

Does not prohibit workplace collection of genetic information for genetic monitoring programs, employer-sponsored wellness programs, administration of federal and state family and medical-leave laws, and in certain cases of inadvertent acquisition of information. However, this genetic information may not be used or disclosed by the employer.

It does not prevent employers and insurers from accessing genetic information from all sources

Title VII prohibits discrimination based on race, color, religion, sex, national origin. Burden is placed on employee to prove damages, prove illegal use, and sue.

Pre-employment "consent" to disclose medical information is not addressed

Broad definition of "genetic information" raises questions of what is covered. Can employers use information about time off to care for family members?

Hudson. Prohibiting Genetic Discrimination. NEJM 356:20,  
2021-2023

# Post-GINA

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- Are the sanctions provided in GINA a sufficient deterrent to really prevent discrimination?
- Should genetic discrimination legislation be extended to long-term care insurance?

# Post-GINA: Genetic testing and consumer issues

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- How can we regulate the genetic test market in direct-to-consumer testing?
  - Accuracy of the testing (CLIA regulation)
  - Utility of the test (truth in marketing)
  - Interpreting test results (non clinical settings)
- Why do people seek home testing? How many people do this?
- Should minors be allowed to request home testing? Can this be prevented?

## Post-GINA: other issues...

- How does the potential for universal health care affect issues such as
  - Choosing genes for future children
  - Retention of samples after genetic testing
  - Social coercion to test or not to test
  - The right of adult children to remove parents' genetic information from databases or registries

# RESPOND-HD

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- Knowing the real-life consequences of genetic information will aid in providing informed consent prior to genetic testing
- Increased knowledge of genetic discrimination will assist education of consumers about genetics, confidentiality, and legal issues and will help shape policy

# RESPOND-HD

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- We need to document consequences before effective legal reform will become a reality
- Knowledge of the prevalence of genetic discrimination will support informed health care policy decisions in the next 10 years

# Resources

- National Human Genome Research Institute:  
<http://www.genome.gov/24519851>
- Summary of the legislation:  
[http://www.sourcewatch.org/index.php?title=Genetic\\_Information\\_Non-Discrimination\\_Act](http://www.sourcewatch.org/index.php?title=Genetic_Information_Non-Discrimination_Act)
- Genetics & Public Policy Center:  
[http://www.dnapolicy.org/news.release.php?action=detail&pressrelease\\_id=95](http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=95)
- Human Genome Project website at ORNL:  
[http://www.ornl.gov/sci/techresources/Human\\_Genome/elsi/legislat.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml)