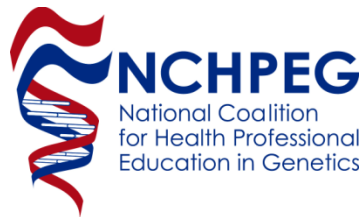


# GINA for Health Professionals

## The Genetic Information Nondiscrimination Act May 2010

Developed Under a Grant from The Pew Charitable Trusts



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# Consider the following...

A woman who has a family history of breast cancer is interested in genetic testing. She asks her health-care provider whether a positive test result could be used to deny her health insurance, life insurance, or employment.

**These practices are examples of genetic discrimination**



# **GINA**

## **Genetic Information Nondiscrimination Act**

Signed into law on 21 May 2008 by  
President George W. Bush

Law in effect since  
21 November 2009

# GINA and HIPAA

## Genetic Information Nondiscrimination Act

- Protects against the use of genetic information to discriminate in health insurance and employment

## Health Insurance Portability and Accountability Act

- Protects the privacy of health-related information

# What does GINA do?

## Health Insurers

- Prohibits 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

## Life insurers

- At this time, GINA does not affect life, disability, or long-term-care insurance.

**GINA DOES NOT AFFECT THE PRACTICE OF MEDICINE.  
IT AFFECTS HEALTH INSURERS AND EMPLOYERS.**

# What does GINA do?

## Employers

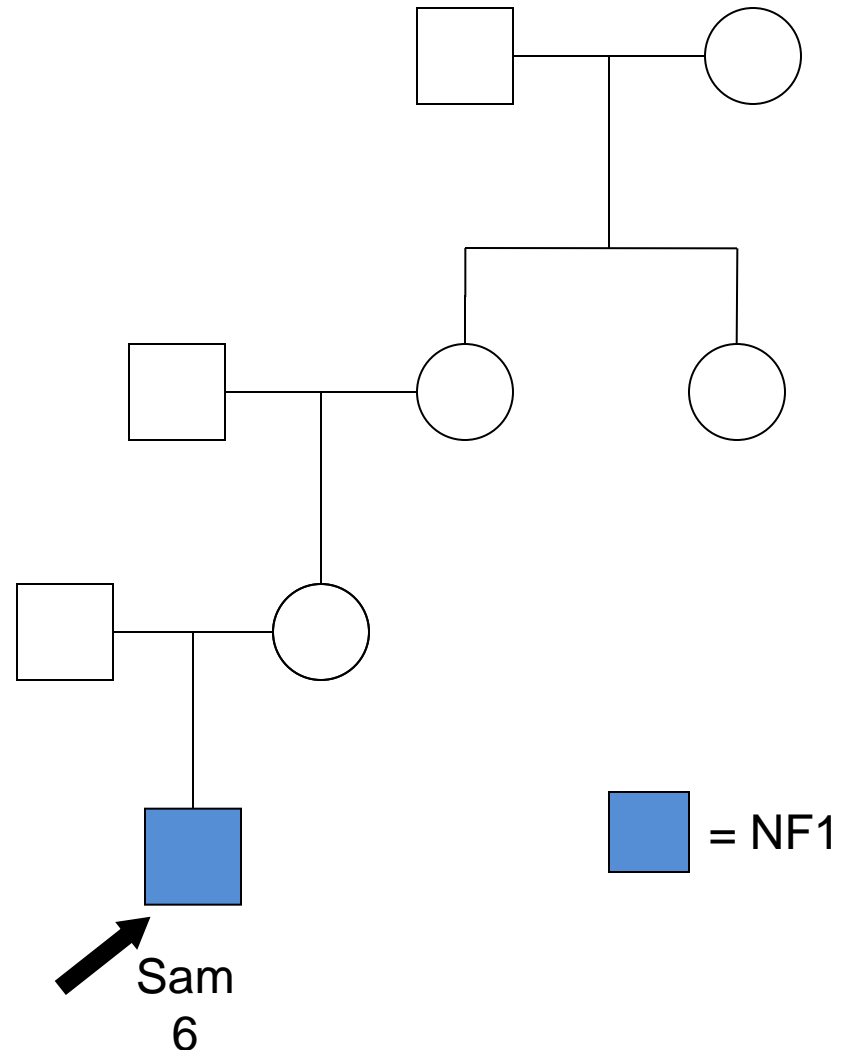
- Prohibits use of a person's genetic information in decisions such as hiring, firing, job assignments, and promotions
- Prohibits requesting, requiring, or purchasing genetic information about an individual employee or family member

# This presentation introduces you to GINA through four case studies

1. GINA and family history
2. GINA and genetic testing
3. GINA, manifest disease, and predisposition
4. GINA and prenatal issues

# Case 1: GINA and Family History

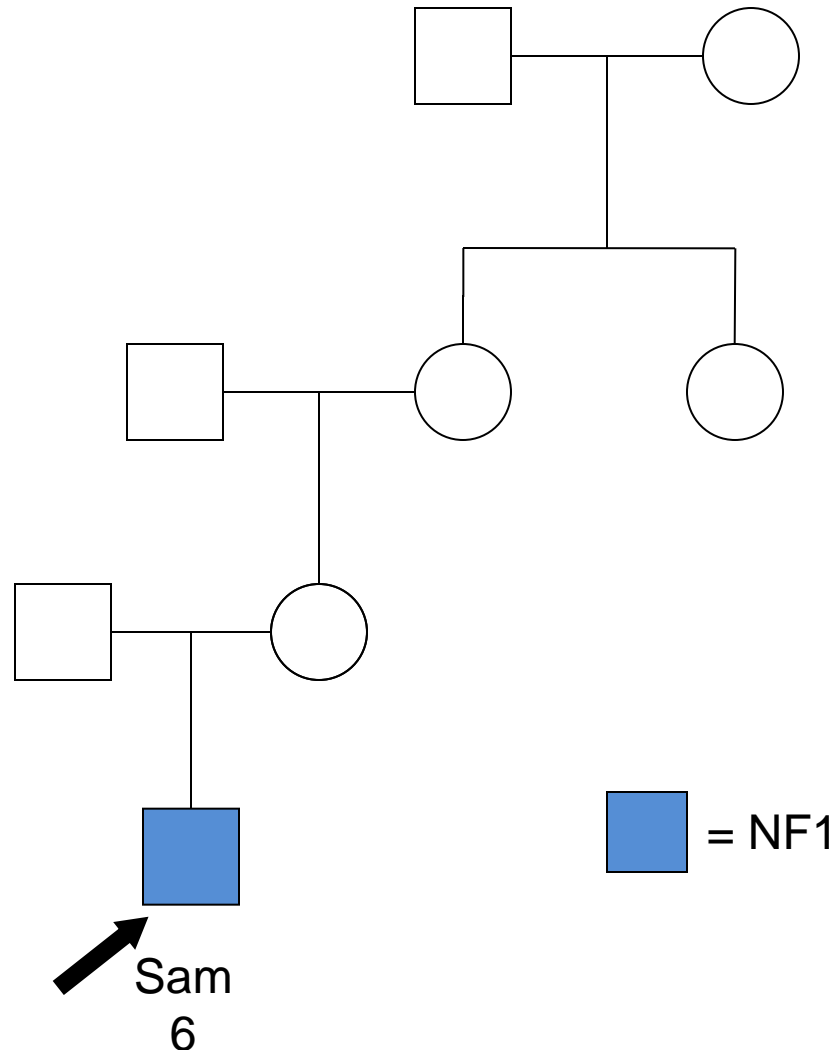
- Woman and 6 yo son, Sam, present for routine care
- Sam is known to have Neurofibromatosis type 1 (NF1)
- Provider takes three-generation pedigree – at right



# Case 1: GINA and Family History

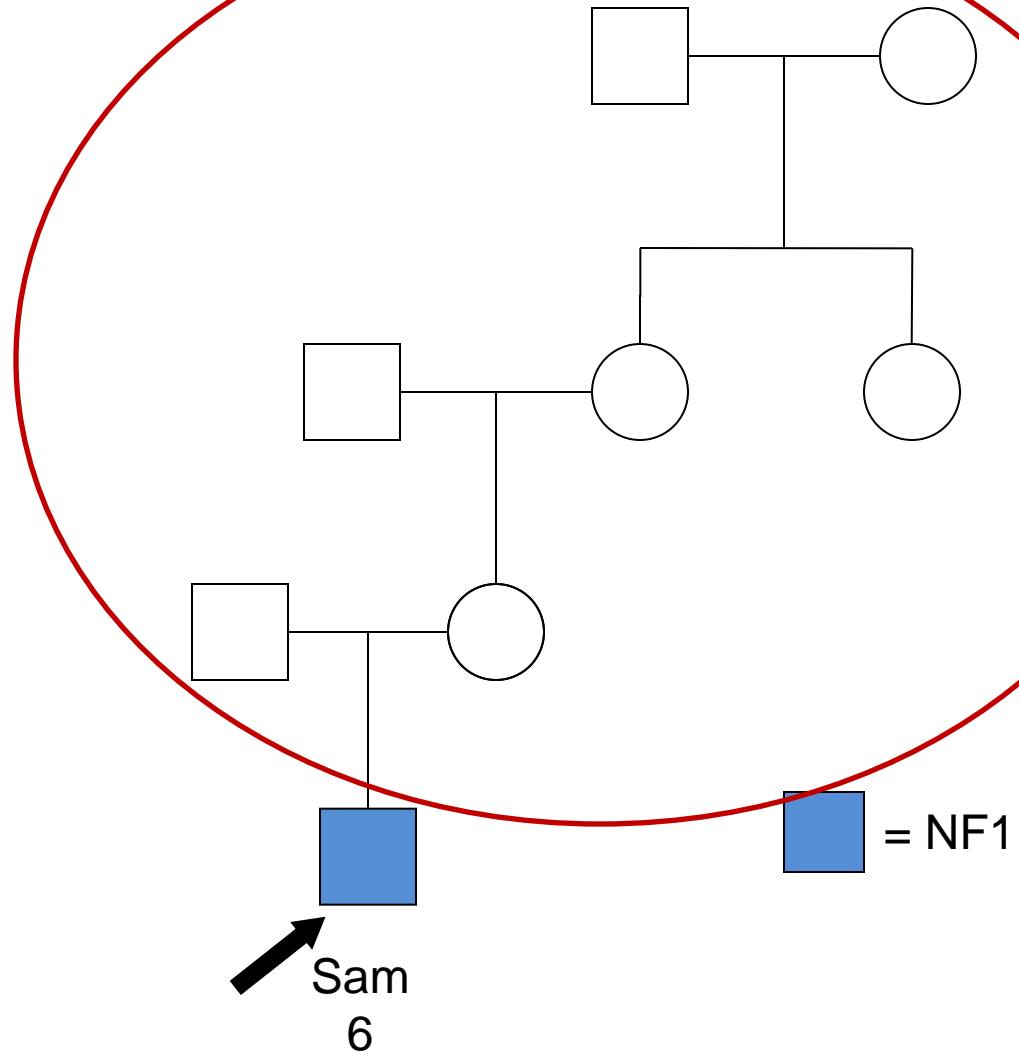
## Step 1: What is NF1?

- Neurofibromatosis type 1
- Autosomal dominant condition – 50% chance to pass on changed *NF1* gene to offspring
- Multiple benign tumors (neuromas)
- Can sometimes affect the brain and spinal cord



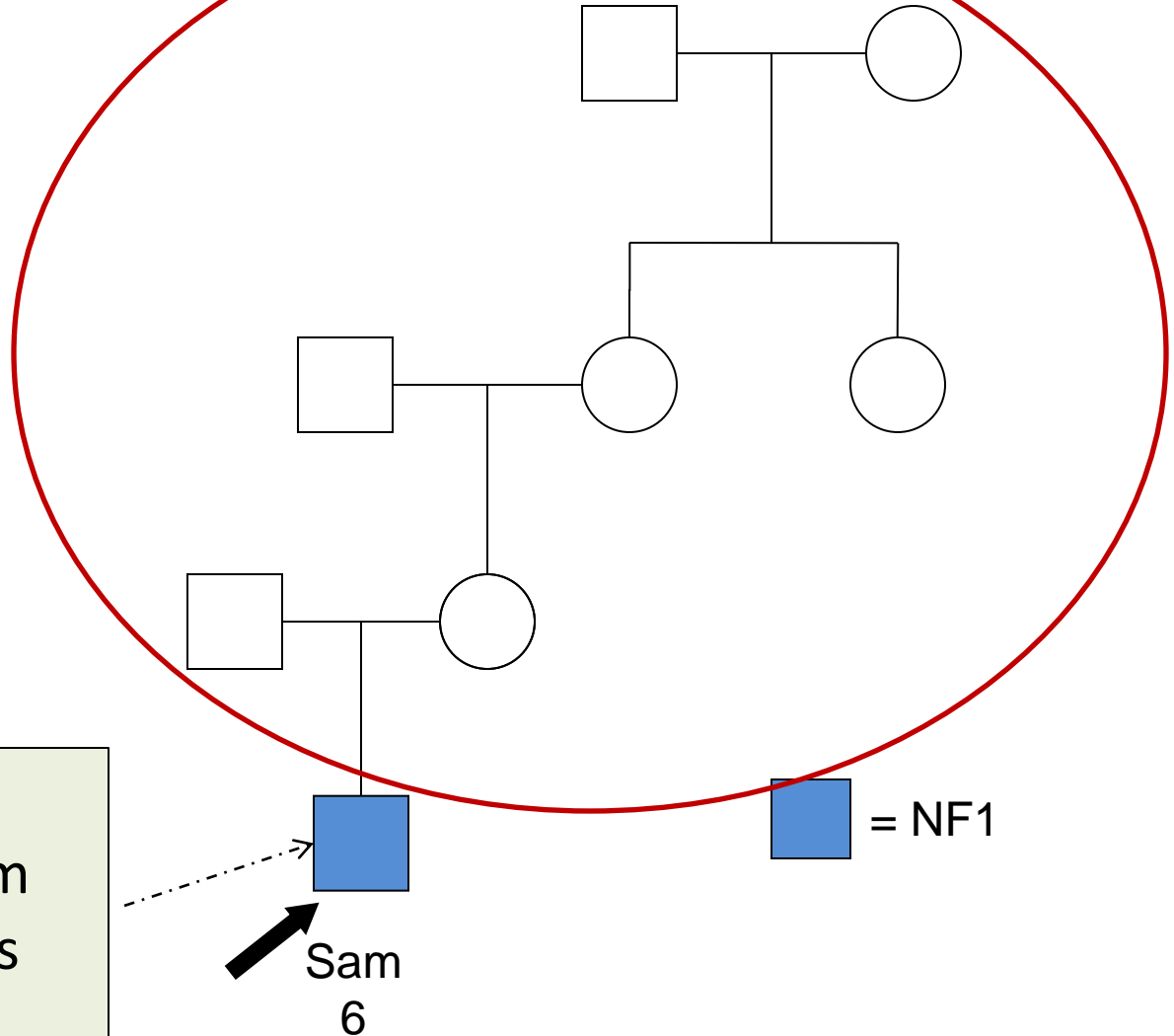
# Case 1: GINA and Family History

Step 2: Who in the family is at risk for NF1?



# Case 1: GINA and Family History

Who in the family is protected from genetic discrimination, based on the family history of NF1?



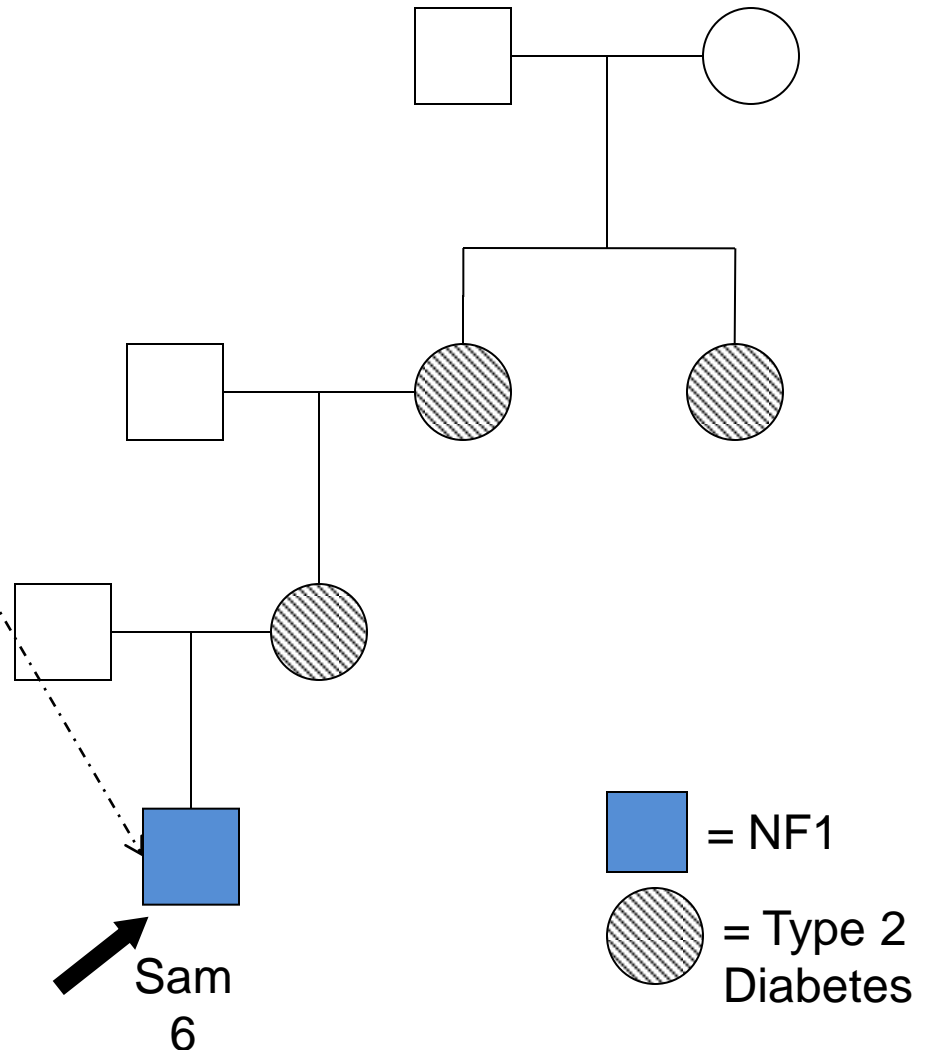
For Sam, does GINA prohibit an insurer from using the NF1 diagnosis for underwriting purposes?

# Case 1: GINA and Family History

Now, consider a family history of Type 2 diabetes:

For Sam, can an insurer use the family history for Type 2 diabetes for underwriting purposes?

Under GINA, is the insurer allowed to request Sam's medical and/or family history information for the purpose of determining eligibility for medical services?



# GINA Summary for Case 1

- Under GINA, the definition of genetic information includes the manifestation of a disease in a family member, which includes a first-, second-, third-, or fourth- degree relative.
  - This family history information is protected under GINA.
  - The insurer may not use family history information for underwriting purposes.
- GINA **does not prohibit** an insurer from reviewing medical and family history to determine eligibility for further medical surveillance, testing, or preventive care or treatment. GINA **does prohibit** the insurer from using that information to make decisions about underwriting.

This law should not keep you from taking a comprehensive family history.

# Case 2: GINA and Genetic Testing

- 25-year-old male has Direct-to-Consumer genetic testing
- Results show apoE4 genotype, increasing risk for cardiovascular disease (CVD) and Alzheimer disease

Can an insurer use this information about his future risk for CVD for underwriting purposes?

Can his insurer request this genetic testing result to determine medical necessity for lipid profile screening and surveillance ?

# GINA Summary for Case 2

- The patient's genetic profile obtained through his DTC test is protected and cannot be used to deny him access to medical insurance.
- The patient-related discussions and medical history obtained by his medical provider also are protected.
- GINA does not require health insurers to cover the cost of genetic testing or follow-up care.
- The insurer can request the test results to determine medical necessity for lipid profile screening and surveillance, and Alzheimer surveillance later in life.

The law does not compel you to order genetic tests that you would not have ordered otherwise.

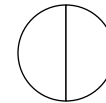
## Case 3: GINA, Manifest Disease, and Predisposition

- Rachel, a 39 yo woman, presents with mass in right breast
- Biopsy is positive for invasive breast cancer
- Referred for GC and testing because of young age and Ashkenazi Jewish background
- Positive for BRCA1 mutation
- Opts for bilateral mastectomy

**Is Rachel protected under GINA because she has a genetic cause for her breast cancer?**

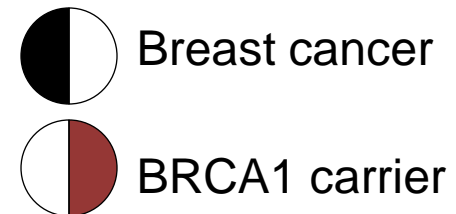
**BRCA1 mutations are associated with increased risk for breast and ovarian cancer. Does GINA prohibit the insurance company from denying Rachel coverage for surveillance and risk-reduction procedures for ovarian cancer?**

Ashkenazi Jewish



Rachel  
breast ca  
dx. 39 yo

bilateral  
mastectomy

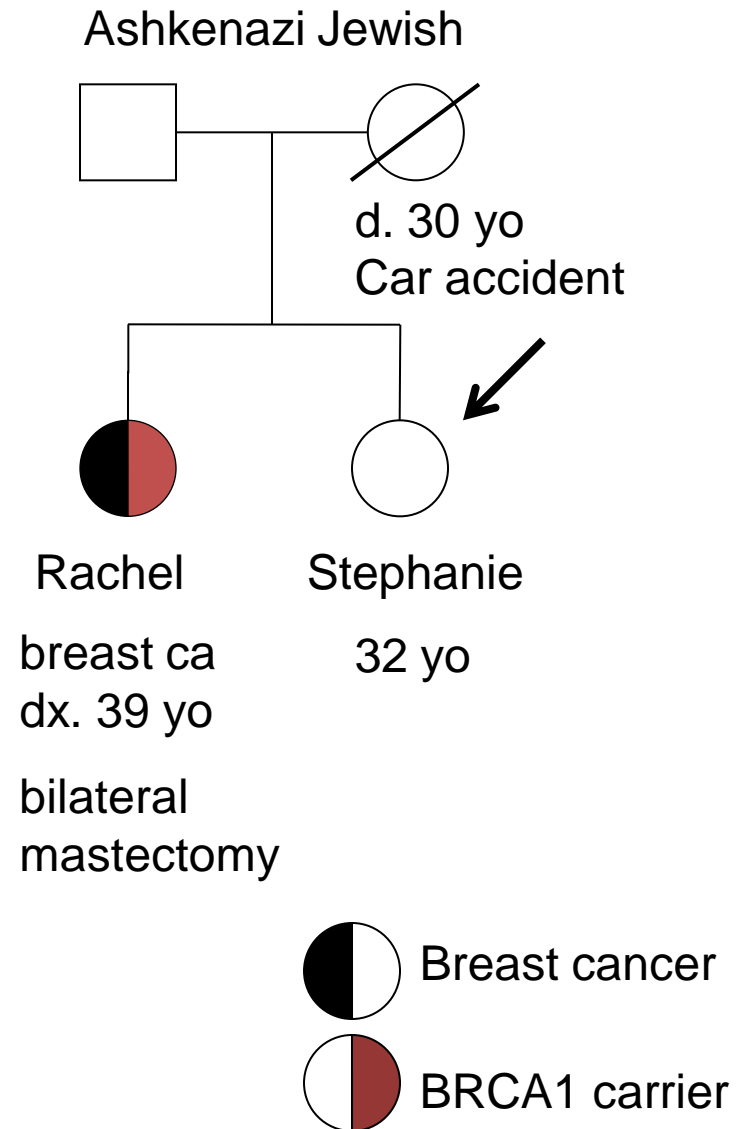


# Case 3: GINA, Manifest Disease, and Predisposition

- Rachel tells 32 yo sister, Stepanie, she may be at risk for BRCA1 mutation and early cancer
- Stepanie desires testing

**If Stephanie shares Rachel's BRCA1 status with her doctor, can the insurance company use that information?**

**If Stephanie gets genetic testing and is a BRCA1 carrier, will her insurance company be allowed to deny her treatment if she develops breast cancer?**

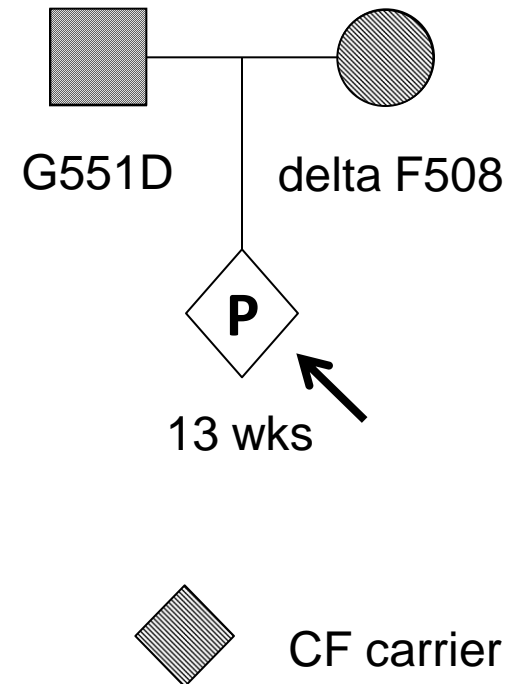


# GINA Summary for Case 3

- GINA doesn't prohibit insurers from using information about an existing condition – even if that condition has a genetic basis.
- The increased risk of other cancers based on the patient's BRCA1 mutation is genetic information and is protected.
- GINA protects Stephanie against misuse of information about a family history of hereditary breast cancer.
- Stephanie's insurer can request family history information to determine the necessity of BRCA testing. Under GINA, this information cannot be used to keep her from obtaining and continuing her medical insurance, regardless of her BRCA status.
- The law should ease concerns about sharing information within families and with providers.

# Case 4: GINA and Prenatal Issues

- 33 yo white female: accepts cystic fibrosis (CF) screening at 13 weeks gestation
- Screening shows she carries the delta F508 mutation
- Patient's partner tested: carries different CF mutation
- Couple offered genetic counseling and amniocentesis for prenatal diagnosis



**Would a prenatal diagnosis of CF constitute a pre-existing condition for this child's health insurance after birth?**

# GINA Summary for Case 4

- Under GINA, health insurance companies cannot consider genetic information a pre-existing condition.
- All of the following genetic information is protected under GINA:
  - family history of CF mutations in the parents,
  - prenatal CF DNA results in the fetus,
  - biochemical newborn-screening results for the infant, and
  - CF DNA results for the infant.
- If the child is born with CF, coverage decisions related to treatment may be subject to decisions by the insurance carrier.

# GINA and Health-Care Reform

The new health legislation (enacted in March 2010):

- some aspects do not take effect for several years,
- provides health insurance coverage to uninsured,
- seeks to improve coverage for millions of Americans, and
- will provide access to care to some individuals not helped by GINA, such as those with manifest genetic conditions.

# General Summary

## What GINA Does

GINA affects health insurers and employers.

The law's protections might ease concerns some patients have when considering genetic testing.

### **Under GINA, group and individual health insurers cannot**

- use a person's genetic information to set eligibility requirements or establish premium or contribution amounts.
- request or require that a person undergo a genetic test.

### **Under GINA, employers cannot**

- use a person's genetic information in decisions about hiring, firing, job assignments, or promotions.
- request, require, or purchase genetic information about an employee or family member.

# General Summary

## Types of Protected Genetic Information

- Family medical history
- Carrier testing
  - e.g., cystic fibrosis, sickle cell anemia, spinal muscular atrophy, fragile X, and other conditions
- Prenatal genetic testing
  - e.g., amniocentesis, chorionic villus sampling, and other techniques
- Susceptibility testing
  - e.g., BRCA testing for breast cancer risk, testing for Huntington disease, or testing for HNPCC for colon cancer risk
- Analysis of tumors or other assessments of genes, mutations, or chromosomal changes

# General Summary

## What GINA Does Not Do

- Protect information about disease simply because it is genetic, when the disease is already diagnosed and manifest
- Apply to life, disability, or long-term-care insurers, as of the date listed on this presentation
- Protect information about current health status
- Provide employment protections in organizations with fewer than 15 employees
- Protect certain groups, including the military and federal employees (see next slide)

# General Summary

## Exemptions to GINA

- Information about sex, age, or common blood tests such as CBC or cholesterol testing is not covered.

### **GINA Does NOT Apply To**

- life, disability, or long-term-care insurers.
- employers with fewer than 15 employees
- members of the United States Military,
- veterans obtaining health care through the Veteran's Administration
- individuals using the Indian Health Service, or
- federal employees enrolled in the Federal Employees Health Benefits program (FEHB).

# GINA Resources



**GINA Materials for the Public & Healthcare Providers**

<http://www.GINAhelp.org>

**Guide to the Genetic Information Nondiscrimination Act**

<http://www.geneticfairness.org/ginaresource.html>

**Frequently Asked Questions from Genetics and Public Policy Center**

<http://www.dnapolicy.org/gina/>

**Human Genome Research Institute & Genetic Discrimination Fact Sheet**

<http://www.genome.gov/10002328>

**Organizations Involved With Development of This Resource**

[www.geneticalliance.org](http://www.geneticalliance.org) / [www.dnapolicy.org](http://www.dnapolicy.org) / [www.nchpeg.org](http://www.nchpeg.org)