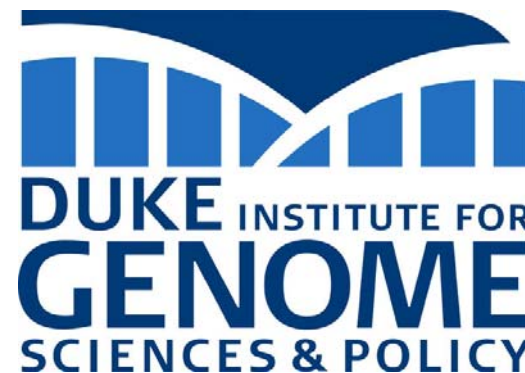


The Genetic Information Nondiscrimination Act (GINA)

What Does It Mean for Patients and Researchers?

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**Genomic and Personalized Medicine Forum
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May 21, 2008

One Hundred Tenth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Thursday,
the third day of January, two thousand and eight*

An Act

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Genetic Information Nondiscrimination Act of 2008”.

**Genetic
Information
Nondiscrimination
Act of 2008
(GINA)**

Outline of talk

- What GINA does
- What GINA does not do
- Real world cases & concerns
- What GINA means for you
- Final “take-away” points

What GINA Does

GINA prohibits genetic discrimination

- Health insurance (Title I)
- Employment (Title II)

Two basic strategies

- Restricts the use of genetic information
- Restricts the collection of genetic information

KEY DEFINITION

“Genetic Information” includes:

1. An individual’s genetic tests
2. Family members’ genetic tests
3. Family members’ disease or disorder
(“*Family History*”)
4. Genetic services or participation in clinical research

Does NOT include sex or age

KEY DEFINITION

“Manifest disease”

- A disease is “manifest” when a person has been or could reasonably be diagnosed by a health care professional with appropriate expertise.
- A disease is not “manifest” if a diagnosis is based primarily on genetic information.
- Asymptomatic versus symptomatic

Title I

“Genetic Nondiscrimination
in Health Insurance”

Cannot use genetic information
to set premium

- BUT may adjust premium based on
manifest disease

May not require someone to take a genetic test

- BUT may obtain and use genetic tests for determining payment

May not collect genetic information
for underwriting or enrollment

- **BUT** not a violation to acquire genetic information *incidental* to acquiring other information about an individual

May not use genetic information
to determine eligibility or pre-existing
conditions

Does not preclude health insurer from
establishing rules based on the
manifestation of a disease

Title II

“Prohibiting Employment
Discrimination on the basis of
Genetic Information”

Employer may not use genetic information

- To make hiring or firing decisions
- To limit or classify employees

Employer may not acquire genetic information, *except--*

1. Where an employer inadvertently requests family medical history (“water cooler” exception)
2. As part of voluntary company wellness program
3. When family medical history is needed to comply with the Family & Medical Leave Act
4. Where an employer purchases documents that are publicly available (newspapers, magazines, but not medical databases) that include family medical history (“obituary notice”)
5. For genetic monitoring of the biological effects of workplace toxins

What GINA Does NOT Do

GINA does not cover

- Life insurance
- Disability insurance
- Long-term care insurance
- Other entities interested in genetic information

GINA does not prevent health insurers or employers from getting *any* genetic information

Insurers and employers may still acquire *incidental* genetic information

GINA does not apply to

- Employers with fewer than 15 employees
- Members of the military who receive their care through the military health system
- Veterans who receive their care through the Veteran's Administration
- The Indian Health Service
- Federal employees who receive care through the Federal Employees Health Benefits Plans

“Real-world”
Cases & Concerns

Cases under GINA

- 80+ complaints filed with EEOC
 - Cases where employers improperly acquired or disclosed genetic info
- First employment discrimination claim
 - Pamela Fink case in Connecticut
 - Issues raised by case

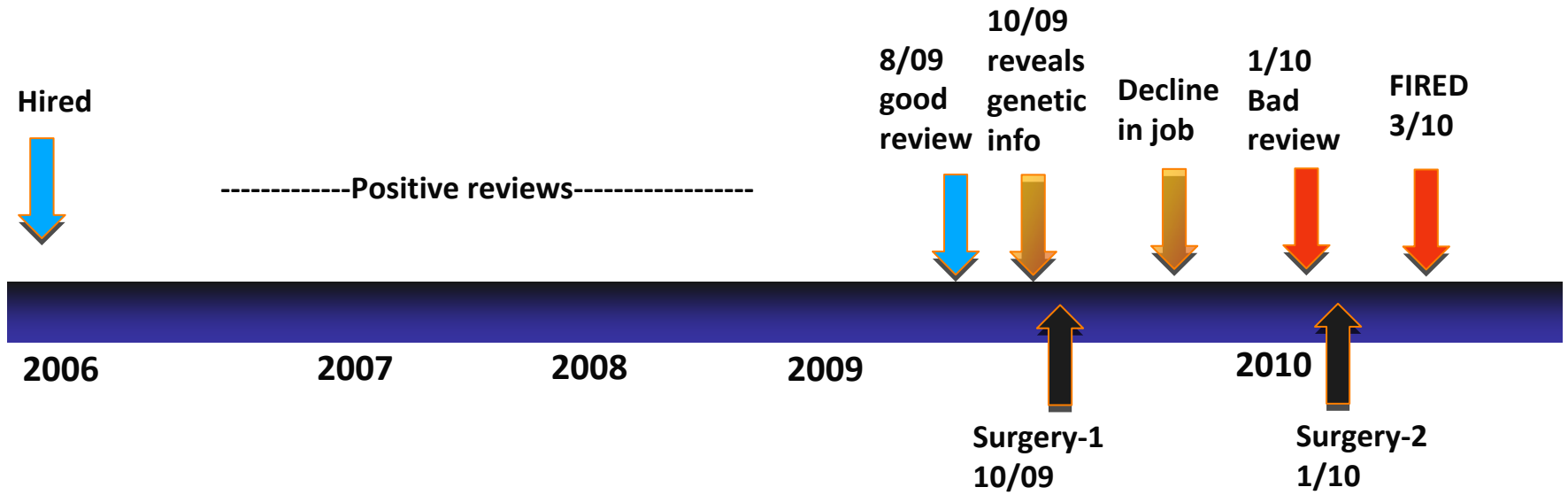
Pamela Fink case (Her version)

- **2004** - Had genetic test: positive for BRCA2
- **Jan 2006** - Starts job as public relations director
- **August 2009** - Good performance review
- **August 2009** - Tells supervisor & company president the reason for upcoming surgery (her genetic test results)
- **Oct 2009** - 2 weeks medical leave for double mastectomy
- **Jan 2010** - Receives “scathing” negative review
- **Jan. 2010** - Reconstructive surgery
- **Feb 2010** - Returns to work after surgery
- **March 2010** - Fired

MXenergy CEO and President Jeffrey Mayer's response

- The case is "completely without merit."
- "I can assure [you] that there is far more to the story than has been reported. When all of the facts are known, we are confident that this issue will be seen in a different light and our actions warranted, not criticized."

Pamela Fink case: Timeline



Employment Discrimination Lawsuits

- Discrimination is hard to prove
- Plaintiffs usually do not win

GINA & Wellness Programs

- Health Risk Assessment (HRA)
 - Typically done before enrollment
 - Collects family history information
 - Reward for participating
- Title I (Health Insurance)
 - Can not collect genetic information prior to or in connection with enrollment
 - Can not ask for genetic information for underwriting purposes

Options

- Give reward, but don't ask for family medical history
- Ask for family medical history but don't give reward
- Do both (2 forms)

Title II (Employment)

- Restrictions on collecting genetic information, *except—*
 - As part of voluntary company wellness program
 - Similar language under the American with Disabilities Act says that a wellness program is voluntary as long as an employer neither requires participation nor penalizes employees who do not participate.
 - Q: Does “voluntary” mean no financial incentive, or is a small incentive permitted?

Wellness Programs—stay tuned

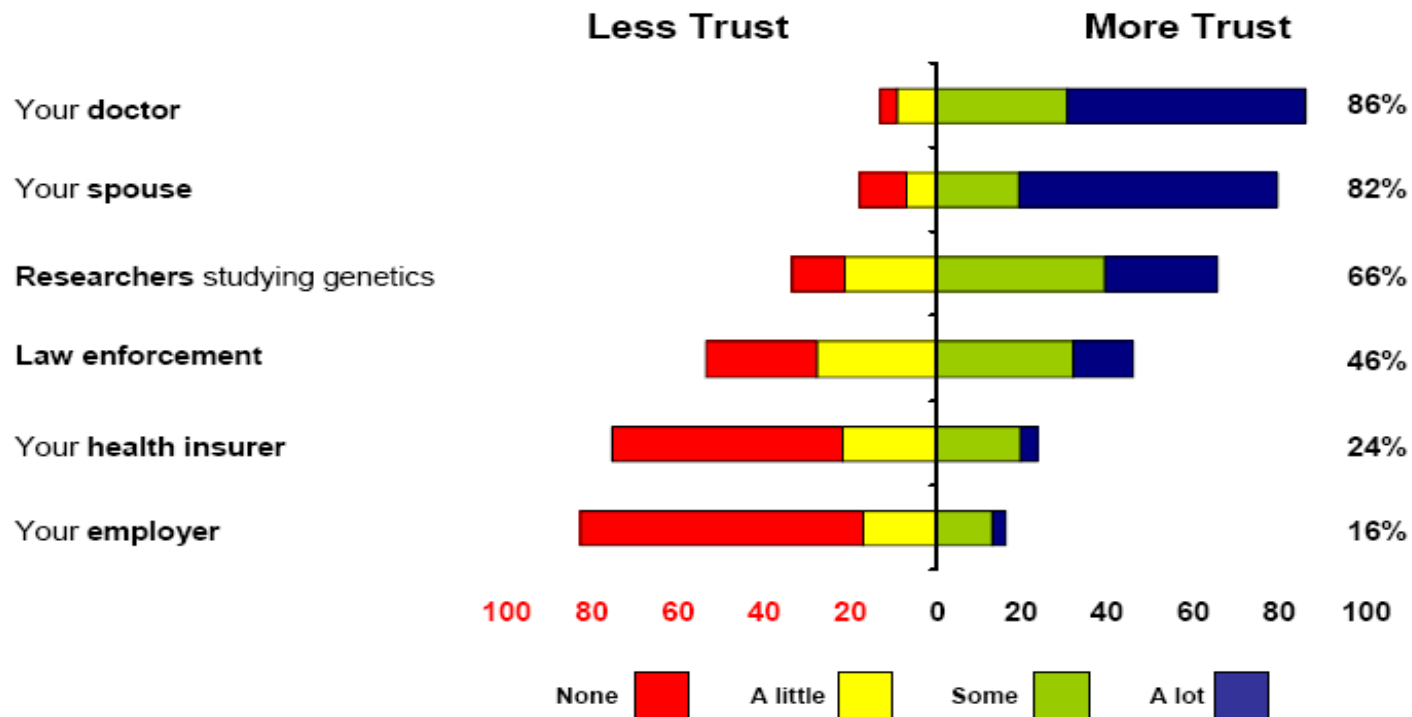
- GINA poses difficulties for Wellness Programs (as currently designed)
- But: Broad exceptions for Wellness Programs could create a huge loophole in GINA

What GINA means for
physicians, counselors,
researchers



2007 Survey

How much do you trust each of the following to have access to your genetic test results?



The good news

- You can tell worried patients or potential research subjects about GINA

The bad news

- Insurance NOT covered by GINA:
 - Life insurance
 - Disability insurance
 - Long-term care insurance
- Entities not covered by GINA may be interested in genetic information
- Insurers and employers may still acquire *incidental* genetic information
- Discrimination cases are hard to prove, and difficult to win

Take-Away

Key points to remember

- Applies to health insurance & employment
- Protected “genetic information” is broadly defined
- “Manifest disease” not protected by GINA
- GINA is in addition to state laws; (*Floor not ceiling*)
- Does not eliminate all concerns
- Still need to treat genetic information with care—no one wants to be in a lawsuit
- New law with new regulations

Resource: www.GINAhelp.org

Genetic Alliance

<http://www.geneticalliance.org>



Genetics and Public Policy Center

<http://www.dnapolicy.org>

National Coalition for Health Professional Education in Genetics

<http://www.nchpeg.org>



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GINA NONDISCRIMINATION ACT

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Genetic Information

What is genetic information and why is it important?

GINA & Health Insurance

What are GINA's health insurance protections?

GINA & Employment

What are GINA's employment protections?

What is GINA?

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects individuals from genetic discrimination in health insurance and employment. Genetic discrimination is the misuse of genetic information. This resource provides an introduction to GINA and its protections in health insurance and employment. It includes answers to common questions and examples to help you learn. Choose from one of the boxes to the left to begin!

- ✉ Have questions, comments or suggestions? [Send us a note.](#)
- 🖨 [Click here](#) for a printer friendly version.
- ✉ For healthcare provider resources [click here.](#)
- 🖨 [Click here](#) for the GINA & You Information Sheet

GINA GENETIC INFORMATION NONDISCRIMINATION ACT

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GINA & YOUR JOB

Genetic Information

GINA & Health Insurance

GINA & Employment

GINA makes it against the law for employers to use your genetic information in the following ways:

- To make decisions about hiring, firing, promotion, pay, privileges or terms
- To limit, segregate, classify, or otherwise mistreat an employee

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

It is also against the law for an employer to request, require, or purchase the genetic information of a potential or current employee, or his or her family members. There are a few exceptions to when an employer can legally have your genetic information. If an employer does have the genetic information of an employee, the employer must keep it confidential and in a separate medical file.

