

GENETICS AND CANCER

INTRODUCTION:

Genetics is a topic of concern for many cancer survivors, people coping with genetic risk, and their relatives. It can be important to learn about risk factors for cancer so that individuals can have control over and be proactive about their health. Understanding individual risk factors, family history, or genetic predisposition for cancer lets individuals take charge of their health through potential preventative measures and early detection.

This can be very empowering, but it can also be scary, raise many questions, and pose some legal concerns. Several issues can arise from genetic information in the employment and insurance realms. For example, may an employer use genetic information to discriminate against a potential employee or current employee? Or, may an insurance company use genetic information to determine whether or not to insure someone, increase premiums, or impose a pre-existing condition exclusion period?

You may be asking yourself why an insurance company or employer would want to treat an individual differently based on their genetics. Imagine a young woman named Lucy. She has a family history of breast cancer. First, she applies for health insurance. Because her health insurance company wants to maximize profits, they could be motivated to see what risks they are taking on if they were to insure Lucy. By knowing Lucy's family medical history, they may decide that Lucy may cost the company more money in the future because she is more likely to get cancer than the average person her age. Second, Lucy applies to work at a small business. The company may want to learn about Lucy's family medical history to see if she may cost them more in insurance premiums or if she is more likely to take time off work in the future. But, can these two companies legally access Lucy's family history or use this information against her? To address these questions and concerns, this chapter will cover the basics of genetic testing and the laws that protect people against genetic discrimination.

I. UNDERSTANDING GENETICS

Scientists estimate that approximately 5% of all cancers are strongly hereditary.¹³⁸ In these cases, a gene mutation that is associated with an increased risk of cancer passes from one generation to another. The abnormal gene is not cancer itself, nor is it a guarantee that an individual will develop cancer. It is a gene abnormality whose presence puts an individual at a higher risk for getting cancer. This increased risk is called a genetic predisposition. Although many types of cancer can run in the family, the most common of these are breast, ovarian, prostate, and colon cancer.

A. Risk Factors for Hereditary Cancer

- 1) **Introduction:** There are many factors that are common indicators of hereditary cancer. These include:
 - (i) Multiple cases of a type of cancer within a family (e.g., if a patient's aunt and grandmother on one side of the family both had breast cancer, it could indicate that hereditary breast cancer runs in the family);
 - (ii) Family members with cancer occurring at younger than average ages for that cancer (e.g. the average age of a prostate cancer diagnosis is 70 years old, if a patient is diagnosed with prostate cancer at 50, this could be an indicator that the cancer is hereditary);

¹³⁸ American Cancer Society, *Cancer Facts and Figures 2011*, page 1.

- (iii) Family members with cancer not commonly associated with that sex (e.g., a male patient with breast cancer is an indication of hereditary cancer);
 - (iv) Family members with multiple primary tumors in the same organ or bilateral primary tumors in paired organs (e.g., a patient has multiple tumors within one organ that are not caused by the original tumor spreading or the patient has had primary tumors in paired organs such as tumors in both breasts or both kidneys).
- 2) Note: when examining a patient's family history of cancer, it is important to look at each side of the family separately, since the gene for increased risk for cancer can come from either an individual's maternal or paternal side. Do not forget to consider both sides of the family for all types of cancer. For example, a woman can inherit a predisposition for breast cancer from either her mother's or her father's side of the family and a man can inherit a predisposition for prostate cancer from either his mother's or his father's side of the family.

II. **GENETIC TESTING**

- A. **Introduction:** For some cancers there are genetic tests available to determine whether an individual has inherited the altered gene that is associated with the increased risk for cancer. Genetic tests are laboratory tests that examine an individual's DNA to identify any changes in chromosomes, genes, or proteins. In some circumstances, the test can find alterations that are associated with an increased risk of cancer. For example, the BRCA1 and BRCA2 genetic tests are available to test for genetic predispositions for breast and ovarian cancer. Additionally, there are genetic tests available to test for genetic predispositions for colon cancer, such as the test for hereditary non-polyposis colorectal cancer (HNPCC).
- 1) Note: To learn more about any risks associated with an individual's family history and the genetic tests that may be available, speak to a health care provider or consider communicating with a certified genetic counselor.
- B. **Costs of Genetic Testing:** The cost of genetic testing can range from under \$100 to more than \$3,000, depending on the nature and complexity of the test. The costs increase if more than one test is necessary or if multiple family members are tested to obtain a meaningful result. Additionally, the length of time it takes to receive results can range from a few weeks to several months. The doctor or genetic counselor who orders a particular test can provide information about the cost and time frame associated with that test.
- 1) Does insurance pay for genetic testing?
- (i) Every insurance policy is different in their coverage. Some private insurers cover genetic testing, but others do not. Additionally, some insurers will cover some genetic tests, but not others. Individuals should check with their insurance company for more information.
 - (ii) Some state Medicaid programs also cover genetic testing. For example, 26 states currently offer coverage for a genetic test for breast and ovarian cancer. These states are Alaska, Arizona, California, Colorado, Delaware, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New York, New Mexico, Ohio, Oregon, Tennessee, Texas, Utah, Virginia, Washington, West Virginia.¹³⁹

¹³⁹ Financial Help. FORCE: Facing Our Risk of Cancer Empowered. www.facingourrisk.org/info_research/finding-health-care/financial-help/index.php

C. **Positive Results:** In general, positive results indicate that the test has found a genetic alteration. This does not mean that a patient has cancer or that the patient will definitely develop cancer. A positive test result indicates that the patient is at a higher risk of developing cancer at some point in time. A negative result indicates that the test could not find a genetic alteration. This does not mean however that a patient's risk for developing that type of cancer is eliminated. In some situations this may be an inconclusive result, depending on whether a mutation has previously been identified in the patient's family. In other situations, this means that a patient's risk of developing cancer is the same as the risk for the general population.¹⁴⁰

- 1) **Managing Cancer Risks:** Knowledge about a patient's risk for cancer can help the patient manage his or her risk. For example, individuals with a genetic predisposition for cancer can pursue medical options such as increased surveillance or screenings, preventive drug therapy, or preventive surgery. It is important to perform regular cancer screenings in order to detect any cancer as soon as possible, as early detection is the key to improved survival rates. Prophylactic surgery, which is a preventative surgery, may also be done and involves removing as much of the "at-risk" tissue as possible in order to reduce the chance of developing cancer. Additionally, there are some FDA approved medications that help to reduce the risk of cancer in high risk patients, such as Tamoxifen for breast cancer.
 - (i) Note: As indicated above, it is always important to speak with a health care provider to determine what options are best in each individual's case.

III. **GENETIC DISCRIMINATION**

- A. **What is Genetic Discrimination:** Genetic discrimination occurs when an individual is treated differently based on his or her hereditary predisposition to a particular disease. There is a potential for genetic discrimination to occur in both employment and insurance contexts. Because of the fear that genetic characteristics may be used against them, some individuals decide not to disclose information to health care professionals and decline early screening or preventative measures, which may be crucial for their medical care.
- B. **Genetics and the Law:** There are several federal and state laws that protect against genetic discrimination. However, these laws apply to different entities and cover different aspects of genetic discrimination. It is important to understand the complete patchwork of available protections in order to be able to weigh the legal implications of genetic testing.

Law:	Applies to:	Prohibition:
GINA	Employment/Health Insurance	Use of genetic information
ADA	Employment	Disability discrimination
EO 13145	Federal Employment	Genetic discrimination
HIPAA*	Group Health Insurance	Use of genetic information to determine eligibility

*Additionally, HIPAA covers the privacy of genetic information

C. **Genetic Discrimination in Employment:**

- 1) **Genetic Information Nondiscrimination Act (GINA):**¹⁴¹ In 2008, the Genetic Information Nondiscrimination Act (GINA) was signed into law. GINA prohibits genetic discrimination in both employment and health insurance.

¹⁴⁰ <http://ghr.nlm.nih.gov/handbook/testing/interpretingresults>

¹⁴¹ Genetic Information Nondiscrimination Act of 2008, 42 USCA § 20000ff et.seq.

2) How Does GINA Define Genetic Information?:

- (i) Under GINA, the definition of genetic information is broad. It includes the family medical history of an individual, the results of an individual or family member's genetic test, and the use of genetic services. Genetic services include the use of genetic counseling, other genetic services, and participation in genetic research.
- (ii) An individual's current health status or manifested diseases and conditions are not considered genetic information.
 - For example: If a patient has taken a BRCA genetic test to determine her risk of breast cancer, this is genetic information. However, if the patient has been diagnosed with cancer, the cancer diagnosis itself is not genetic information, even though the manifested breast cancer may be hereditary.
- (iii) In GINA, a family member includes any relative within four degrees of the individual. Examples of second degree relatives include grandparents, grandchildren, aunts, uncles, nephews and nieces and third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles and first cousins.

(iv) GINA in Employment:

- **Which Employers does GINA Apply To?:**¹⁴² GINA applies to employers with 15 or more employees. It also includes employment agencies, labor organizations, or joint labor-management committees. However, Indian tribes, and bona fide private clubs are not employers under GINA. Therefore, protections under GINA do not apply to employees under these groups. GINA applies to some federal employees, but not all.
- **What does GINA Prohibit?:**¹⁴³ GINA offers protections to individuals in the workplace. It prohibits an employer from discriminating against an employee because of genetic information. Some examples of discrimination include firing or failing to hire an employee, or discriminating with respect to compensation, terms, and conditions. The GINA regulations make it clear that the legislation applies to current employees, applicants and former employees. Additionally, GINA does not allow limiting, segregating, or classifying employees because of genetic information. Under GINA, an employer is prohibited from misusing genetic information and acquiring genetic information. The law makes it illegal for an employer to request, require, or purchase an employee's genetic information. There are, however, a number of exceptions to this rule; if an employer does gain genetic information through one of these exceptions they are not allowed to use the information for discriminatory purposes and they must treat the information as confidential medical records.¹⁴⁴
 - ⇒ Inadvertent acquisition/"water cooler exception:" An employer does not violate GINA by inadvertently learning about an employee's genetic information, such as by overhearing a conversation in the break room.
 - ⇒ Publicly available information: If an employee's genetic information is available publicly, such as in a newspaper article or website, an employer does not violate GINA by learning of that information.

¹⁴² 42 USCA § 2000ff(2)(B)

¹⁴³ 42 USCA § 2000ff-1(a)

¹⁴⁴ 42 USCA § 2000ff-1(b)

- ⇒ Voluntary health or wellness programs: If the employer has a strictly voluntary health or wellness program, then genetic information can be gathered in this program. Genetic information cannot be gathered if there are incentives given to employees for participation in the wellness program.
- ⇒ Certification requirements of FMLA leave: An employer can ask for genetic information to determine if leave is approved.
- ⇒ Genetic monitoring of the biological effects of toxic substances in the workplace: An employer does not violate GINA by using genetic information to monitor the biological effects of toxic substances in the workplace. This exception however has very explicit rules for when testing can be done under the circumstances.
- ⇒ DNA analysis conducted for law enforcement purposes: If the employer conducts DNA analysis for law enforcement purposes, as a forensic laboratory or for purposes of human remain identification, it is not a violation of GINA's protections.

- **What does GINA Protect?:**¹⁴⁵ GINA also provides protections for genetic information possessed by an employer. It requires an employer that possesses any genetic information to maintain such information in separate files and treat such information as a confidential medical record. Employers are further prohibited from disclosing such genetic information, except: to the employee upon request; to an occupational or other health researcher; in response to a court order; to a government official investigating compliance with GINA; in connection with the employee's compliance with certification provisions of the Family and Medical Leave Act or state family and medical leave laws; or to a public health agency.

(v) **GINA Enforcement in Employment:**¹⁴⁶ If an individual feels that he or she has been discriminated against in the employment context, contact the Equal Employment Opportunity Commission (See the **STATE APPENDICES**).

- 3) **Americans with Disabilities Act (ADA):** Although the ADA does not explicitly address genetic information, the Equal Employment Opportunity Commission (EEOC) has interpreted the ADA to prohibit workplace discrimination of healthy persons based on genetic status.¹⁴⁷ This interpretation has never been tested in court. Additionally, some individuals with genetic predispositions for cancer may fall under the ADA whereby the law protects individuals who are regarded as having a disability. See the Employment Rights chapter of this guide for more information.)
- 4) **Executive Order 13145:** President Clinton signed Executive Order 13145 in 2000. This order prohibits the federal government from discriminating against applicants, employees, and former employees on the basis of genetics. Although the order bans genetic discrimination, it does not provide a private right to individuals to enforce this requirement. There may, however, be recourse under Section 501 of the Rehabilitation Act, which prohibits discrimination against an individual with a disability.¹⁴⁸

¹⁴⁵ 42 USCA § 2000ff-5(6)

¹⁴⁶ 42 USCA § 2000ff-6

¹⁴⁷ www.eeoc.gov/policy/docs/902cm.html

¹⁴⁸ <http://www.eeoc.gov/policy/docs/qanda-genetic.html>

- (i) The Executive Order defines protected genetic information as:
- Information about an individual's genetic tests or genetic tests of that individual's family members; and
 - Information about the occurrence of disease, or medical condition, or disorder in family members of the individual.

D. Genetic Discrimination in Health Insurance

1) **Genetic Information Non-Discrimination Act (GINA):** In addition to providing employment protections, GINA also provides protections in the health insurance arena. The definitions of genetic information and family member are the same for both employment and insurance (See the Genetic Discrimination in Employment section above.)

(i) **GINA in Health Insurance**

- **Which Health Insurance Companies Does GINA Apply To?:**¹⁴⁹ GINA's insurance protections apply to both group and individual plans. It also applies to Medigap policies, which are Medicare supplemental policies. GINA does not apply to the Veterans Health Administration, the Indian Health Service, TRICARE military health system, or to the Federal Employees Health Benefits Plan. For those individuals who have insurance through a company that does not fall under GINA, there may be other laws or policies that would apply. For example, the United States military has set up policies against genetic discrimination.
⇒ Note: The insurance provisions in GINA only apply to health insurance. Therefore, GINA does not apply to life, long-term care, or disability insurance. These insurances are regulated at the state level, but the state laws vary widely. Contact the CLRC for more information.
- **What Does GINA Prohibit?:**¹⁵⁰ In the health insurance context, GINA prohibits health insurers from discriminating based on genetic information. Health insurance companies are not allowed to restrict enrollment or adjust premiums, contribution amounts, or coverage terms based on an individual's genetic information. Remember, the definition of genetic information does *not* include manifested diseases in an individual. Therefore, an insurance company cannot raise an individual's premiums because they have a family history of colon cancer, but they can raise premiums if they were to develop the disease. However, under this exception, the insurance company can only ask for the minimum amount of information necessary to decide whether to pay for the requested procedure. Health insurance companies are also limited from acquiring genetic information.¹⁵¹ They can neither request nor require an individual to take a genetic test. Also, they cannot purchase an individual's genetic information.

¹⁴⁹ www.ginahelp.org

¹⁵⁰ 29 USCA § 1182(3)(A); 42 USCA § 300gg-1(3)(A); 42 USCA § 300gg-52(a)(1); 6 USCA § 9802(3)(a); 42 USCA § 1395ss(E)

¹⁵¹ 29 USCA § 1182(c)(1); 42 USCA § 300gg-1(c)(1); 42 USCA § 300gg-52(d)(1); 26 USCA § 9802(c)(1); 42 USCA § 1395ss(x)

- ⇒ Exception: A health insurer can request genetic information to determine whether to pay for a requested procedure.¹⁵² For example, if a patient seeks prostate cancer screenings before the standard age, the insurance company may ask for genetic information to determine whether early screening is medically necessary. However, under this exception, the insurance company can only ask for the minimum amount of information necessary to decide whether to pay for the requested procedure.
- ⇒ Note: Under GINA, genetic information cannot be considered a pre-existing condition.¹⁵³

- **Medical Records:** Under GINA health insurance companies are prohibited from acquiring an individual's genetic information. Under GINA regulations, if a health insurance company sends a request for medical records to a doctor or facility, they must include a notice that states that no genetic information should be included in the records. It is then the doctor's responsibility to redact the patient's genetic information from the medical records.¹⁵⁴
 - ⇒ Note: If the healthcare professional fails to redact the information, the insurance company is not in violation of GINA for getting genetic information.
 - ⇒ Therefore, if a patient wants to ensure that his or her genetic information does not get transferred to an insurance company, he or she should be proactive in speaking to the doctor about redacting all genetic information.

- (ii) **GINA Enforcement in Insurance:** If individuals feel that they have been discriminated against in the insurance context, they can contact their state insurance commissioner's office (See **STATE APPENDICES**).

2) **Health Insurance Portability and Accountability Act (HIPAA):**¹⁵⁵ Under HIPAA, group health plans and HIPAA individual plans are prohibited from using genetic information to determine insurance eligibility. However, private individual insurance is not covered under HIPAA. Additionally, asymptomatic genetic information cannot be treated as a pre-existing condition in the absence of a diagnosis or manifestation of the condition.

- (i) **What Does HIPAA Prohibit?:** Although HIPAA protects against genetic discrimination during eligibility, it does not prohibit insurance plans from establishing limitations or restricting coverage or benefits. An insurance company may do this if they treat all similarly situated individuals in the plan the same. For example, a plan could exclude coverage for a particular treatment, such as prophylactic mastectomies. HIPAA also regulates patient privacy.

Note: GINA amends HIPAA to explicitly state that genetic information is confidential medical information and prohibits the use or disclosure of genetic information.¹⁵⁶ Although GINA applies only to certain types of health insurance, HHS has issued proposed regulations that apply the privacy rules of GINA to:

¹⁵² Ex: 29 USCA § 1182(c)(3)

¹⁵³ Ex: 42 USCA § 300gg-52(c)(1)

¹⁵⁴ Prohibiting Discrimination Based on Genetic Information; Interim Final Rules; HIPAA Administrative Simplification; Genetic Information Nondiscrimination Act; Proposed Rules, October 7, 2009.

¹⁵⁵ 42 U.S.C.A. § 300gg-3

¹⁵⁶ Sec. 1180

- Long-term care policies (excluding nursing home fixed-indemnity policies)
- Employee welfare benefit plans or other arrangements established or maintained for the purpose of offering or providing health benefits to employees of two or more employers (to the extent they are not group health plans or health insurance issuers)
- State high-risk pools
- Certain public benefit programs, such as Medicare Part A and B, Medicaid, the military and veterans health care programs, the Indian Health Service program, and others
- Any other individual or group plan, or combination of individual or group plans that provides or pays for the cost of medical care

Therefore, the privacy protections of GINA apply to more entities than the other provisions of GINA.¹⁵⁷

E. **State Laws:** There is very little consistency at the state level regarding genetic information and discrimination. The majority of state legislatures have taken steps to safeguard the privacy of genetic information beyond the protections provided for under federal law. State laws that protect genetic privacy typically restrict any or certain parties (such as insurers or employers) from carrying out a particular action without consent. As mentioned above, GINA’s insurance regulations only apply to health insurance companies, not to life, long-term care, and disability insurance companies. Accordingly, many states have regulated such markets by passing specific state laws. For more information about state laws, please contact the CLRC.

- 1) **Life Insurance:** As of January 2008, fourteen states restricted discrimination based on genetic information in life insurance.¹⁵⁸
- 2) **Long-Term Care Insurance:** As of January 2008, fifteen states restricted discrimination based on genetic information in long-term care insurance.¹⁵⁹
- 3) **Disability Insurance:** As of January 2008, nine states restricted discrimination based on genetic information in disability insurance.¹⁶⁰

IV. RESOURCES

<p>For information about GINA and the ADA with respect to employment discrimination: Equal Employment Opportunity Commission (See the STATE APPENDICES)</p>	<p>For information about state laws that protect against genetic discrimination in employment: State Fair Employment Agency (See the STATE APPENDICES)</p>
<p>For information about state laws that protect against genetic discrimination in insurance: State Insurance Agency (See the STATE APPENDICES)</p>	<p>For information about GINA and HIPAA with respect to health insurance: State Insurance Agency (See the STATE APPENDICES)</p>

¹⁵⁷ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, Office for Civil Rights, HHS, Proposed rule, October 7, 2009.

¹⁵⁸ National Conference of State Legislatures, *Genetics and Life, Disability and Long-term Care Insurance*, January 2008, www.ncsl.org/default.aspx?tabid=14283

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*