



## AN OVERVIEW OF THE GENETIC INFORMATION NONDISCRIMINATION ACT

G.I.N.A. Title I--- Prohibits discrimination in health coverage based on genetic information.

G.I.N.A. Title II-- Prohibits discrimination in employment based on genetic information. Title II of G.I.N.A. prohibits use of genetic information in the employment context, restricts employers and other entities covered by Title II from requesting, requiring, or purchasing genetic information, and strictly limits such entities from disclosing genetic information.

The law forbids discrimination on the basis of genetic information when it comes to any aspect of employment, including hiring, firing, pay, job assignments, promotions, layoffs, training, fringe benefits, or any other term or condition of employment. Genetic information includes information about an individual's genetic tests and the genetic tests of an individual's family members, as well as information about any disease, disorder, or condition of an individual's family members (i.e. an individual's family medical history).

### WHO ENFORCES G.I.N.A ?

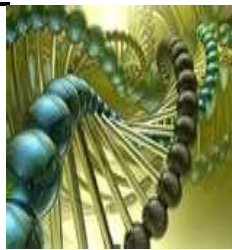
The Department of Labor, the Department of the Treasury, and the Department of Health and Human Services have specific responsibilities for enforcing the health insurance provisions. The E.E.O.C is responsible for enforcing the employment provisions.

### WHAT IS GENETIC DISCRIMINATION?

“Genetic discrimination occurs if people are treated unfairly because of differences in their DNA that increase their chances of getting a certain disease.”



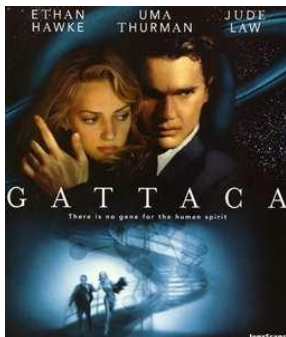
### WHAT IS AND WHAT IS NOT A GENETIC TEST



- “Genetic test” refers to “analysis of human DNA, RNA, chromosomes, proteins, or metabolites that detects genotypes, mutations, or chromosomal changes.”

- “Tests to determine whether an individual carries the genetic variant evidencing a predisposition to breast cancer, colorectal cancer are genetic tests.”
- “Tests for infectious and communicable diseases that may be transmitted through food handling, complete blood counts, cholesterol tests, and liver-function tests are not genetic tests.”

### GENETIC TESTING ISSUES HAVE POPPED UP IN A VARIETY OF CONTEXTS, FOR EXAMPLE IN FILM AND IN MAJOR LEAGUE BASEBALL



*“Officially they are called ‘In-valids’ ...They are the ‘healthy ill’. They don’t actually have anything yet—they may never have. But since few of the pre-conditions can be cured or reversed, it is easier to treat them as if they were already sick.”*---Columbia Pictures, *Gattaca*<sup>1</sup>, 1997

In July, 2009, Major League Baseball is reported to have used DNA testing to determine if Miguel Sano, a prospect from the Dominican Republic, was really 16 years old. MLB said that testing in the Dominican Republic is used “in very rare instances and only on a consensual basis to deal with the identity fraud problem that the league faces in that country.” The statement added that the results of the tests were not used for any other purpose. Also in July 2009, the New York Yankees are reported to have voided the signing of an amateur from the Dominican Republic after a DNA test conducted by Major League Baseball’s department of investigations showed that the player had misrepresented his identity.

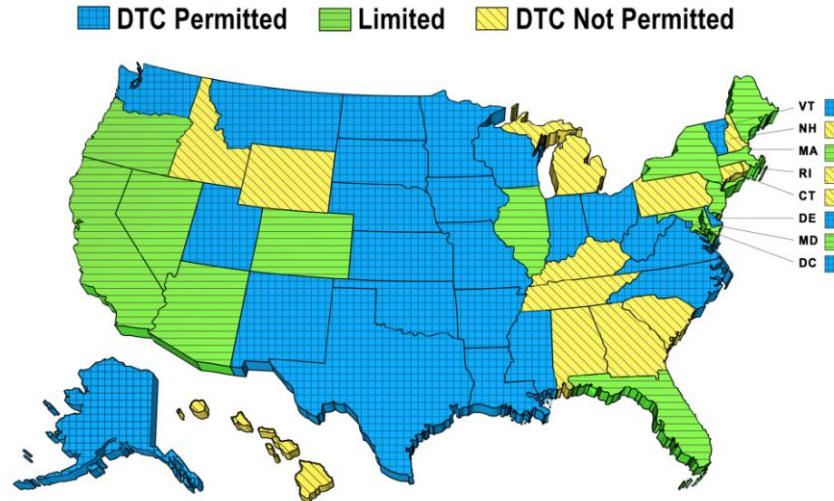
### GENETIC TESTING AND STATE INTERVENTION

There is increasing state regulation that prohibits or limits so-called direct access testing without a doctor or other medical professional’s involvement. G.I.N.A. sets a floor, not a ceiling. States can go beyond G.I.N.A., and some are proposing legislation doing just that.

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<sup>1</sup> “In the not-too-distant future, a less-than-perfect man wants to travel to the stars. Society has categorized Vincent Freeman as less than suitable given his genetic make-up and he has become one of the underclass of humans that are only useful for menial jobs. To move ahead, he assumes the identity of Jerome Morrow, a perfect genetic specimen who is a paraplegic as a result of a car accident. With professional advice, Vincent learns to deceive DNA and urine sample testing. Just when he is finally scheduled for a space mission, his program director is killed and the police begin an investigation, jeopardizing his secret.”  
<http://www.imdb.com/title/tt0119177/plotsummary> “Gattaca Corp. was an aerospace firm in the future. During this time society analyzes your DNA and determines where you belong in life. A man with a congenital heart condition tries to assume the identity of a former athlete with perfect genes in order to fulfill his dream of traveling in space. The corporate name Gattaca was derived from the four basic chemical building blocks or nucleotides of DNA: Guanine (G), Adenine (A), Thymine (T), and Cytosine (C).”

# State DTC Testing Statutes and Regulations



Source: Genetics and Public Policy Center, <http://www.dnapolicy.org/resources/DTCStateLawChart.pdf>

## THE GROWTH OF GENETIC TESTING AND THE DIRECT TO CONSUMER MARKET

In 1995, only about 300 genetic tests were available. Most of those tests were for rare diseases and were usually performed in research settings. Today, more genetic tests are available to health care consumers and providers, and in a variety of settings, including churches and direct mail. The Direct-to-consumer (DTC) genetic testing market is rapidly expanding. There are now some 1,300 things you can be genetically tested for – including a genetic susceptibility to cystic fibrosis, muscular dystrophy, hemophilia, Huntington's chorea, sickle cell disease, multiple sclerosis, Cohn's disease, breast cancer, diabetes, heart disease and Alzheimer's.

In March 2011, the FDA's Molecular and Clinical Genetics Advisory Panel recommended that "Certain types of genetic tests that are available for at-home use without a prescription should not be used without the involvement of a physician or genetic specialist. The panel wasn't clear on whether that would mean a physician would have to order the test, or if a physician would have to interpret the test, or both. That will ultimately be up to the FDA to decide."<sup>2</sup>

## THREE UPSHOTS FROM THE GROWTH IN GENETIC TESTING IN THE DTC MARKET



- #1. A lot more information is going to be available to users of the tests.
- #2. The meaning of DTC genetic test results may be misinterpreted. (False Negatives and False Positives)

<sup>2</sup> <http://abcnews.go.com> March 12, 2011, 2011.

#3. Users of the test may tell someone their test results at work. That information could be overheard, and



misused.

**G.I.N.A. IN THE WORKPLACE: A CASE SCENARIO --WHAT WOULD YOU TELL CAROL? WHAT WOULD YOU TELL TED?**



While on a break at a work water cooler, Carol talks with her co-worker Bob, and tells Bob about the battle her mom is having with Huntington’s disease. Carol tells Bob that Huntington’s disease is a progressive, degenerative disease that causes certain nerve cells in the brain to waste away. As a result, a person may experience uncontrolled movements, emotional disturbances and mental deterioration. Carol tells Bob that she is at risk for this genetic disease. Carol’s super visor, Ted, walks by and overhears the conversation. Carol becomes concerned that she may be fired due to her risk for developing Huntington’s disease. Carol also starts reading about the disease during her lunch time at work.

Q1. Can Carol be fired or denied a promotion due to her risk of Huntington’s disease?



Q2. If Carol needs to take a leave under FMLA to care for her mom, can the employer use the information on



the forms to discriminate against Carol?”

A1. “GINA indicates when an employer can legally have genetic information about an employee, two examples: (1) An employer accidentally becomes aware (overhearing a conversation); (2) When an employee provides information for family and medical leave.

A2. When an employer has genetic information, the employer can not use it to discriminate against an employee, and the information must be kept in a separate and confidential file.”<sup>3</sup>

## **FINAL REGULATIONS UNDER G.I.N.A.—THE WATER COOLER EXCEPTION**



The 'water cooler problem' arises when an employer unwittingly receives otherwise prohibited genetic information in the form of family medical history through casual conversations with an employee” or by overhearing conversations among co-workers. Congress did not want casual conversation among co-workers regarding health to trigger federal litigation whenever someone mentioned something that might constitute protected family medical history. The Commission's proposed regulation therefore noted that a covered entity inadvertently acquires family medical history where a manager or supervisor overhears a conversation among co-workers that includes information about family medical history (e.g., a conversation in which one employee tells another that her father has Alzheimer's disease).

### **SIX IMPORTANT THINGS FOR EMPLOYERS TO DO/NOT DO**



1. Understand what G.I.N.A. requires you to do and not to do.
2. Map out a compliance strategy engaging key individuals with leadership skills to serve on a cross-functional compliance team: Management, Legal, Human Resources, and EEO-AA. If you have a corporate Medical Department, engage a leader from that group as well.

Policies &  
Procedures

3. Do update your non-discrimination policies and procedures to include G.I.N.A.
4. Do incorporate the safe harbor language into the forms you utilize for requesting business related health information (including ADA accommodation, FMLA or state equivalent).

### **SAMPLE LANGUAGE: SAFE HARBOR PROVISION**

“The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits employers and other entities covered by GINA Title II from requesting or requiring genetic information of employees or their family members. In order to comply with this law, we are asking that you not provide any genetic information when

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<sup>3</sup> Case and answers from the Genetics and Public Policy Center website

responding to this request for medical information. ‘Genetic information,’ as defined by GINA, includes an individual’s family medical history, the results of an individual’s or family member’s genetic tests, the fact that an individual or an individual’s family member sought or received genetic services, and genetic information of a fetus carried by an individual or an individual’s family member or an embryo lawfully held by an individual or family member receiving assistive reproductive services.’”

5. Do not discriminate or retaliate against a person on the basis of protected genetic information in any employment context.

6. Do not request, require, or purchase genetic information about an individual or their family members, for example, a wellness program with a premium discount or waiver if the participant takes a health risk assessment.

### **WHAT ABOUT G.I.N.A. AND CORPORATE WELLNESS AND DISEASE MANAGEMENT PROGRAMS?**



This is a potential minefield. However, an employer is allowed to collect genetic information for corporate wellness and disease management programs with three provisos.

#1: That employees give “prior, knowing, voluntary, and written consent”.

#2: That the employer only receives the genetic information in aggregate form.

#3: That the employee does not have to fill out a health risk assessment form in order to get a reward.

