Genetic Testing and GINA the Genetic Information Nondiscrimination Act, 2008

Jeff Kaufhold MD FACP HEC’C

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Miami University

Our use of genetics has evolved over the last 100 years

- The early science of genetics became the basis of State laws that provided for the sterilization of persons having presumed genetic "defects" such as mental retardation, mental disease, epilepsy, blindness, and hearing loss, among other conditions.
- The first sterilization law was enacted in the State of Indiana in 1907. By 1981, a majority of States adopted sterilization laws to "correct" apparent genetic traits or tendencies.
- Many of these State laws have since been repealed, and many have been modified to include essential constitutional requirements of due process and equal protection.

Advances in Genetics

- Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress.
- New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun.
- Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments.

But a word of Caution

- However, these advances give rise to the potential misuse of genetic information to discriminate in health insurance and employment.

- Although genes are neutral markers, many genetic conditions and disorders are associated with particular racial and ethnic groups and gender.
- Because some genetic traits are most prevalent in particular groups, members of a particular group may be stigmatized or discriminated against as a result of that genetic information.
- Congress in 1972 passed the National Sickle Cell Anemia Control Act, which withholds Federal funding from States unless sickle cell testing is voluntary.

Legal precedents

- There are examples of genetic discrimination in the workplace. These include the use of pre- employment genetic screening at Lawrence Berkeley Laboratory, which led to a court decision in favor of the employees in that case
- Norman-Bloodsaw v. Lawrence Berkeley Laboratory (135 F.3d 1260, 1269 (9th Cir. 1998))

Basis for the GINA Act

- Congress has collected substantial evidence that the American public and the medical community find the existing patchwork of State and Federal laws to be confusing and inadequate to protect them from discrimination.
- Therefore Federal legislation establishing a national and uniform basic standard is necessary to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.

How GINA works

- Oversight by the Equal Employment Opportunity Commission as created by section 705 of the Civil Rights Act of 1964
- Includes the patients own Genetic results
  - The genetic test results of family members
  - Any manifestation of a hereditary disease or disorder in an individual or family member.
- Includes protection for obtaining genetic services and participation in genetic research.

GINA protections

- Alllows for Genetic monitoring.--the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the workplace.
- But removes the risk of an employee having their status in the organization affected by such injury

GINA protections

- Allows for Genetic monitoring but must be
  - Included as part of a wellness or Occuptaional health program
  - With the employee's permission
    - In advance, voluntary, and documented
  - Only the employee and the licensed health provider or Board certified Genetic Counselor involved in the service receive individually identifiable information regarding results.
  - The result is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;

GINA Protections

- Employer can’t use information disclosed or provided on FMLA forms
- If an employer obtains genetic information, such information shall be maintained on separate forms and in separate medical files and be treated as a confidential medical record of the employee or member.
- Disclosure of such information is limited to:
  - The individual or their family
  - Federal state or local public Health Agency only under limited circumstances.

Relationship to HIPAA act of 1996

- GINA does not prohibit a covered entity under HIPAA or the Social Security Act from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of the HUS Secretary to modify such regulations.

- US EEOC website.