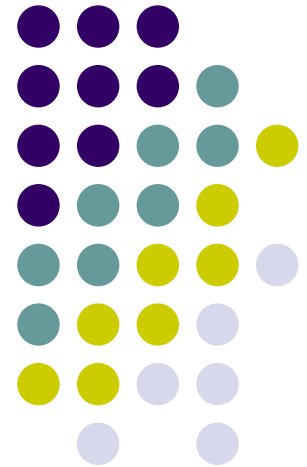


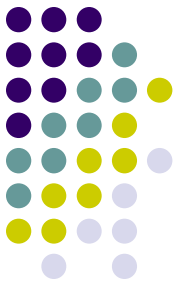
Genetic Information Nondiscrimination Act of 2008 and EEOC's Final Regulation

**Federally Employed Women's
National Training Program
July 18-22, 2011**

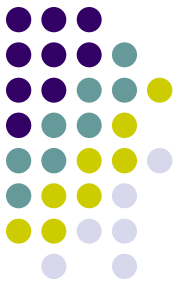
Presenter: Barbara Dougherty, EEOC



GINA and ADA



- **ADA prohibits discrimination on the basis of manifested conditions that meet the definition of disability.**
- **GINA prohibits discrimination based on genetic information and not on the basis of a manifested condition.**



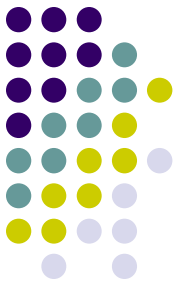
GINA's Purposes

- **Enacted in response to developments in the field of genetics, the decoding of the human genome, and advances in genomic medicine.**
- **Congress was concerned that people were not taking advantage of genetic tests that could provide beneficial information because of concerns about discrimination by insurers or employers with access to their genetic information.**

Basic Rules Related to Employment



- Prohibits use of genetic information to discriminate in employment
 - Includes prohibition on harassment and retaliation
- Restricts employers and other entities covered by GINA from requesting, requiring, or purchasing genetic information
- Requires that covered entities keep genetic information confidential, subject to limited exceptions



Coverage

- GINA applies to:
 - **Employers covered under Title VII of the Civil Rights Act of 1964 (15 or more employees)**
 - **Federal executive branch agencies**
 - **State and local government employers**
 - **The Executive Office of the President**
 - **The U.S. House and Senate**

What is Genetic information?

Part 1



- Genetic Information means information about:
 1. An individual's **genetic tests (1635.3(f))**
 2. Genetic tests of **family members (1635.3(a))**
 3. The manifestation of a disease or disorder in family members (**family medical history – all conditions - not limited to conditions currently known to be inheritable - 1635.3(b)**)

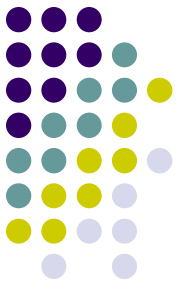
What is Genetic Information?

Part 2



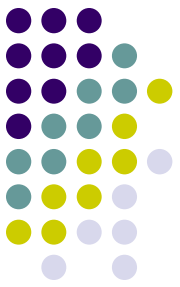
- Genetic information includes:
 4. **Request for or receipt of genetic services by an individual or family member**
 - **Meaning: genetic test, counseling, education**
 5. **Genetic information of a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using an assisted reproductive technology.**

Genetic Information Does NOT Include



- Information about an individual's or family member's race, sex, ethnicity, or age
- The fact that an individual currently has a disease or disorder (manifested condition) – this individual would be protected by the ADA if the disease rises to the level of a disability.

Examples of Genetic Tests



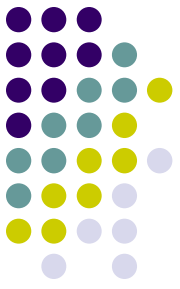
- Test for the BRCA1 or BRCA2 gene evidencing increased risk of breast cancer or ovarian cancer
- Tests evidencing predisposition to, or increased risk of acquiring, certain forms of colon cancer
- Test for a genetic variant for Huntington's Disease
- Carrier screening for adults to determine risk of transmission of a gene to offspring (e.g. cystic fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome)

Examples of Genetic Tests (cont'd)



- Newborn screening analysis that uses DNA, RNA, protein, or metabolite analysis to detect or indicate genotypes, mutations, or chromosomal changes, such as a test for PKU performed so that treatment can begin before a disease manifests
- Preimplantation genetic diagnosis performed on embryos created using invitro fertilization
- Pharmacogenetic tests that detect genotypes, mutations, or chromosomal changes that indicate how an individual will react to a drug or a particular dosage of a drug
- DNA testing to detect genetic markers that are associated with information about ancestry
- DNA testing that reveals family relationships, such as paternity

Tests That Are Not Genetic Tests



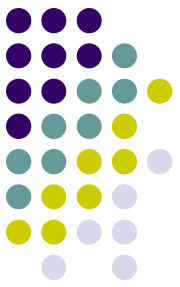
- A test for a virus that is not composed of human DNA, RNA, proteins or metabolites – e.g. HIV test
 - Liver function tests
 - Cholesterol test
 - Blood glucose test
 - A test for infectious and communicable diseases that may be transmitted through food handling
 - Test for drug or alcohol use
- NOTE:** All of these tests (except test for current illegal drug use) are subject to ADA rules concerning medical exams

Acquisition of Genetic Information Prohibited



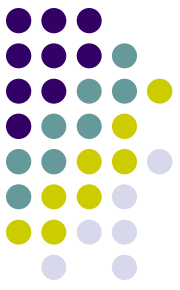
- **General Rule – 1635.8(a)**
 - **Covered entities *shall not request, require, or purchase* genetic information of an applicant or employee**
 - **There are *6 narrow exceptions* to this general prohibition.**
 - ***Specific intent* to acquire genetic information *not necessary to violate this provision.***

1. No Liability for Inadvertent Acquisition – 1635.8(b)(1)



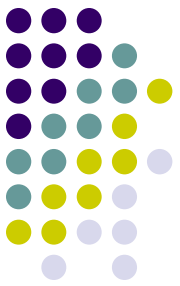
- Protects covered entity that unwittingly receives otherwise prohibited genetic information
- Examples of inadvertent acquisition – 1635.8(b)(1)(ii):
 - **receipt of unsolicited email message that includes genetic information about an employee;**
 - **during a casual conversation or in response to a general inquiry about the individual's or family member's well-being, e.g., "How are you?" "How's your son feeling today?" or "Did they catch it early?" asked of an employee whose mother has just been diagnosed with cancer.**

Prohibition on Requesting Genetic Information during Medical Exams Related to Employment – 1635.8(d)



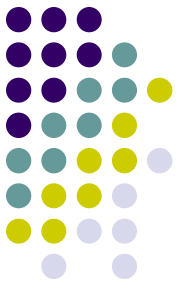
- **ADA**: Employers may conduct post-offer medical examinations/inquiries or fitness-for-duty examinations consistent with ADA requirements
- **GINA**: Employers must direct their doctors not to collect genetic information when conducting employment-related medical exams (e.g. post-offer or fitness-for-duty medical examinations)

Employers Requesting Health Information – 1635.8(b)(1)(i)



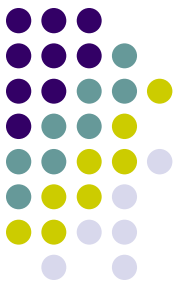
- If employer warns (verbally or in writing) individuals and their health care providers from whom employer sought information that genetic information must not be provided to the employer, but it receives genetic information anyway, that receipt will be considered inadvertent and not a violation of GINA.
- If employer does not give such a notice, it may still establish that its receipt of genetic information was inadvertent if its request was “not likely to result in the employer obtaining genetic information.”

Model Language for Warning – 1635.8(b)(1)(i)(B)



- 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 an individual or family member of the individual, except as specifically allowed by this law. To comply with this law, we are asking that you not provide any genetic information when 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.

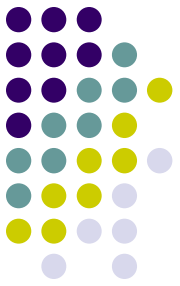
2. Permissible to Acquire Genetic Information Through Employer-Sponsored Health or Genetic Services – 1635.8(b)(2)



- **Employer may request genetic information as part of a health or genetic service, such as a wellness program, that meets specific requirements:**
 - **Voluntary: employer must not require participation nor penalize employees who do not participate**
 - **Prior, knowing, voluntary, and written authorization**
 - **Information goes only to individual and health care provider**
 - **Employer gets information only in aggregate form**
 - **No financial inducements (e.g., cash, gift cards, t-shirts) may be offered in return for the provision of genetic information**

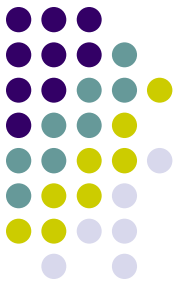
Financial Inducements That Are Not Prohibited by GINA

1635.8(b)(2)(ii) and (iii)



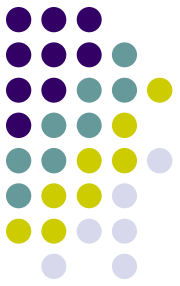
- Offering \$150 to employees to fill out a 100-question HRA that includes 20 questions about genetic information IF directions make clear that \$150 will be given whether or not the 20 questions concerning genetic information are answered and clearly identify those questions
- Offering \$150 to those who choose to participate in weight management program as long as participation and inducement is offered based on voluntarily provided genetic information, as well as information concerning current health status and life-style choices
- Same as above, offering prizes totaling \$150/year for achieving certain health goal like losing weight or lowering cholesterol.

3. Permissible to Acquire Family Medical History under FMLA – 1635.8(b)(3)



- Individual requesting leave under FMLA OR other similar local or state laws, OR company policy, to care for family member with serious health condition will be required to provide family medical history
- Covered entity who receives this information does not violate GINA, but must keep it in separate medical file and treat it as a confidential medical record

4. Permissible to Acquire Genetic Information Through Commercially & Publicly Available Documents – 1635.8(b)(4)



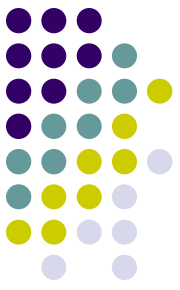
- Newspapers, periodicals, magazines, books
- Information obtained through electronic media such as television, movies, or the Internet

Exception Does Not Apply if Employer Acquires Genetic Information Through These Sources

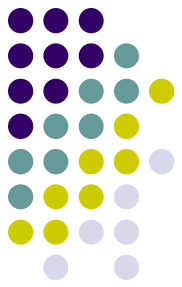


- **medical databases, court records, or research databases available to scientists on a restricted basis.**
- **sources with limited access (i.e. those that require permission to access from a specific individual or where access is conditioned on membership in a group)**
- **commercially and publicly available sources that the covered entity accessed with the intent to obtain genetic information**
- **sources, whether or not they are commercially and publicly available, if the covered entity is likely to acquire genetic information by accessing that source.**

5. Permissible to Acquire Genetic Information Through Genetic Monitoring – 1635.8(b)(5)



- **Must meet certain requirements:**
 - **Written notice and knowing, voluntary authorization (unless required by law or regulation)**
 - **Information goes only to individual and health care provider or certified genetic counselor involved in monitoring program**
 - **Covered entity gets information only in the aggregate**



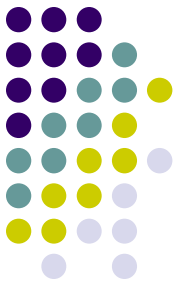
6. Permissible to Acquire for DNA Testing – 1635.8(b)(6)

- **Applies only to employers that engage in DNA testing for law enforcement purposes as a forensic laboratory or for purposes of human remains identification**
- **These employers may require genetic information from employees only to the extent that such genetic information is used for analysis of DNA markers for quality control to detect sample contamination**



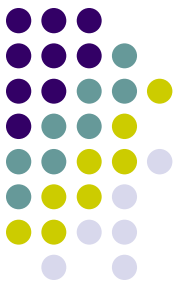
Confidentiality - 1635.9

- Beginning Nov. 21, 2009, and thereafter, genetic information that an employer has must be kept confidential and placed in a separate medical file (ADA file is OK)
- Limited disclosure rules, some similar to ADA's rules, others unique to GINA



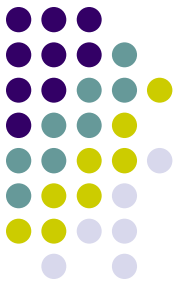
Confidentiality (cont'd)

- **Exceptions – 1635.9(b)**
 - **To the individual or family member to whom the information pertains, subject to written request**
 - **For research purposes pursuant to 45 CFR Pt. 46**
 - **For FMLA purposes**
 - **To government officials investigating compliance with GINA, where relevant**
 - **Pursuant to court order, but only the genetic information expressly authorized by the order**
 - **To federal, state, or local public health agency where an individual's family member has a contagious disease that presents imminent hazard of death or life-threatening illness**



The Firewall

- Specific section addresses relationship between GINA Titles I (health insurance) & II (employment)
- Basic point: Employers and other entities covered by Title II are liable for actions that violate Title II; health plans and health insurance issuers are liable for actions that violate Title I. The same actor cannot be held liable under both, but the same act may lead to liability for both employer and health plan.



Remedies

- GINA remedies modeled on Title VII
 - **Equitable relief, including injunctive relief and back pay**
 - **Punitive and compensatory damages to the extent allowed under Title VII**
 - **Punitive damages unavailable against federal, state, and local government employers**