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**A PRIMER ON TITLE II OF THE GENETIC INFORMATION  
NONDISCRIMINATION ACT OF 2008 (“GINA”) AND IT’S IMPLEMENTING  
REGULATIONS**

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**I. INTRODUCTION**

On May 21, 2008, Congress enacted the Genetic Information Nondiscrimination Act of 2008, (“GINA”). Title II<sup>1</sup> of GINA, which took effect on November 21, 2009, prohibits discrimination in employment on the basis of “genetic information.” 42 U.S.C. § 2000ff, et. seq. The Equal Employment Opportunity Commission (“EEOC”) issued its final regulations implementing Title II of GINA on November 9, 2010. This paper is intended to familiarize the reader with the provisions of Title II of GINA and it’s implementing regulations and to explore areas of the statute that are expected to give rise to future litigation.

Title II of GINA makes it an unlawful employment practice for an employer to discriminate against an employee, applicant or former employee in hiring, discharge or with respect to other terms and conditions of employment, on the basis of genetic information. 42 U.S.C. §2000ff-1(a)(1); 29 C.F.R. §1635.2(c). GINA further prohibits employers from limiting, segregating or classifying employees in any way that would deprive or tend to deprive an employee of employment opportunities, or otherwise affect the employee’s status as an employee because of genetic information. 42 U.S.C. §2000ff-1(a)(2) GINA also makes it unlawful for an employer to request, require or purchase genetic information with respect to an employee or a family member of the

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<sup>1</sup> Title I of GINA, which is not the subject of this paper addresses the use of “genetic information” in health insurance.

employee. 42 U.S.C. §2000ff-1(a)(3). In addition, Title II of GINA requires that employers who come into possession of genetic information of an employee maintain that information in a separate file and treat it as a confidential medical record of the employee in accordance with the Americans with Disabilities Act, 42 U.S.C. §12101, et. seq. (“ADA”). 42 U.S.C. §2000ff-5(a). GINA also places certain limitations of the disclosure of genetic information. 42 U.S.C. §2000ff-5(b)(1)-(6). Each of these prohibitions/requirements will be discussed in detail below.

#### **A. Employers Covered by GINA**

GINA applies to both public and private sector employers with 15 or more employees, employment agencies, labor organizations and joint labor-management training or apprenticeship programs. *See*, 42 U.S.C. §2000ff-1 – 42 U.S.C. §2000ff-4. Indian tribes and bona fide private clubs (other than labor organizations) that are exempt from taxation under Section 501(c) of the Internal Revenue Code of 1986 are not governed by GINA. 29 C.F.R. §1635.2(d). While not specifically set forth in the regulations, the supplementary information to the EEOC’s GINA regulations notes that, because the statute defines employers to include employers as defined by Title VII of the Civil Rights Act of 1964 (“Title VII”), and because numerous courts have held that Title VII did not intend to create individual liability, there is no individual liability under GINA. 42 U.S.C. §2000e, et. seq.

#### **B. Genetic Information**

GINA defines genetic information as including information about (1) an individual’s genetic tests; (2) the genetic tests of an individual’s family members; (3) a family member’s medical history (the manifestation of disease or disorder in an

individual's family members); (4) an individual's request for, or receipt of genetic services, or the participation in clinical research that includes genetic services by the individual or family members of the individual; and (5) the genetic information of a fetus carried by an individual or by a pregnant woman who is a family member of the individual and the genetic information of any embryo legally held by the individual or family member using assisted reproductive technology. 42 U.S.C. §2000ff (4)(A) and (B); 29 C.F.R. §1635.3 (c)(1)(i)-(v). Genetic information does not include information about the sex or age of an individual, the sex or age of family members, or information about the race or ethnicity of the individual or family members that is not derived from a genetic test. 42 U.S.C. §2000ff (4)(C); 29 C.F.R. §1635.3 (c)(2).

### **C. Genetic Tests and Genetic Services**

“Genetic test” is defined as “an analysis of human DNA, RNA, chromosomes, proteins or metabolites that detects genotypes, mutations, or chromosomal changes.” 42 U.S.C. §2000ff (7)(A). Examples of genetic tests include (1) tests to determine whether an individual has a certain genetic marker evidencing a predisposition to a particular disease; (2) carrier screen using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, or spinal muscular atrophy in future offspring; (3) amniocentesis and other evaluations used to determine the presence of a genetic abnormality in a fetus; (4) newborn screening that uses DNA, RNA, protein or metabolite analysis to detect genotypes, mutations or chromosomal changes; (5) preimplantation genetic diagnosis performed on embryos created using invitro fertilization; (6) pharmacogenetic tests that detect genotypes, mutations or chromosomal changes that indicate how an individual will react to a drug; (7) DNA testing to detect genetic markers

associates with information about ancestry ; and (8) DNA tests that reveal family relationships, such as a paternity test. 29 C.F.R. §1635.3(f)(2)(i) – (viii). In addition, a test to determine the presence of a genetic predisposition for alcoholism or drug use is a genetic test. 29 C.F.R. §1635.3(f)(4)(ii).

“Genetic test” does not include an analysis of proteins or metabolites that does not detect genotypes, mutations or chromosomal changes. 42 U.S.C. §2000ff (7)(B). Thus, medical tests that test for the presence of a virus that is not composed of human DNA, RNA chromosomes, proteins or metabolites are not “genetic tests.” 29 C.F.R. §1635.3(f)(3)(ii). Likewise tests for infectious diseases that may be transmitted through food handling, complete blood counts, cholesterol tests and liver function tests are not considered “genetic tests.” 29 C.F.R. §1635.3(f)(3)(iii) – (iv). Tests for the presence of alcohol or illegal drugs are not “genetic tests.” 29 C.F.R. §1635.3(f)(4)(i).

“Genetic services” include genetic tests, genetic counseling (obtaining, interpreting or assessing genetic information) and genetic education. 42 U.S.C. §2000ff (6)(A) – (C); 29 C.F.R. §1635.3(e). The supplementary information provided with respect to Section 1635.3(e) of the EEOC’s GINA regulations notes that “making an employment decision based on knowledge that an individual has received genetic services violates GINA even if the covered entity is unaware of the specific nature of the services received or the specific information exchanged in the course of providing them.”

#### **D. Family Members**

Included in GINA’s definition of “genetic information” is the genetic information of an individual’s “family members” and information about the manifestation of a disease or disorder in an individual’s family members. Therefore, a proper understanding of the

definition of “family members” is important. GINA defines the family members of an individual as anyone who is a dependent of that individual as a result of marriage, birth, adoption or placement for adoption (29 C.F.R. §1635.3(a)(1)) and any relative of the first-degree, second-degree, third-degree or fourth-degree. 29 C.F.R. §1635.3(a)(2).

The Section-by-Section Analysis of this provision of the regulations notes that spouses and adopted children are included within the definition of family members, even though their genetic information will have no bearing on whether the employee protected by GINA might acquire a disease or disorder. This indicates that Congress intended to prevent employers from discriminating against employees because of concerns over potential increased health insurance rates.

GINA defines relatives of the first-degree as, an individual’s children, siblings and parents. 29 C.F.R. §1635.3(a)(2)(i). Second-degree relatives include an individual’s grandparents, grandchildren, uncles, aunts, nephews, nieces, and half-siblings. 29 C.F.R. §1635.3(a)(2)(ii). Great-grandparents, great-grandchildren, great-aunts, great-uncles and first cousins are relatives of the third-degree. 29 C.F.R. §1635.3(a)(2)(iii). Fourth-degree relatives include great-great-grandparents, great-great-grandchildren and first cousins once removed (i.e. the children of the individual’s first cousins). 29 C.F.R. §1635.3(a)(2)(iv). Interestingly, GINA defines “family member” broader than the healthcare industry does. The American Medical Association’s form intake questioner for an adult medical history includes information about only first and second-degree relatives and some third-degree relatives (cousins). Thus, it appears that, by including all relatives of the fourth-degree in GINA’s definition of family member, Congress intended

to provide broad protection against employment discrimination on the basis of genetic information.

## **II. THE PROHIBITION OF DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION**

Congress used language similar to that used in Title VII of the Civil Rights Act of 1964, to set forth the employment practices prohibited by GINA. Specifically, GINA provides that it is unlawful for an employer “(1) to fail or refuse to hire or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions or privileges of employment of the employee, because of genetic information with respect to the employee, or (2) to limit, segregate, or classify the employee of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information. 42 U.S.C. §2000ff-1(a)(1) – (2). The use of this language evinces Congress’ intent to prohibit a broad range of employment practices. The Section-by-Section Analysis to the EEOC’s regulations specifically notes that this broad language indicates that Congress intended to prohibit harassment on the basis of genetic information. *See*, Section-by-Section Analysis of 29 C.F.R. §1635.4.

GINA also prohibits retaliation against any individual because such individual has opposed any act or practice made unlawful by GINA, or because such individual made a charge, testified, assisted or participated in any manner in an investigation, proceeding or hearing under GINA. 42 U.S.C. §2000ff-6(f); 29 C.F.R. §1635.7. The Section-by-Section Analysis to the EEOC’s regulations notes that given the similarities in the anti-retaliation provisions of GINA to those of Title VII, the proper standard for determining



what constitutes retaliatory conduct under GINA will be the same standard used in Title VII cases, as announced by Supreme Court in *Burlington Northern & Santa Fe Railway Co. v. White*, 548 U.S. 53 (2006). Thus, to constitute retaliation, conduct need not be related to employment and it need not rise to the level of an adverse employment action, so long as it is “materially adverse” and “well might” dissuade a reasonable person from making or supporting a charge of discrimination. *Id.* at 57-58.

At the present time there is no cause of action available under GINA for disparate impact. The statute specifically excludes claims for disparate impact on the basis of genetic information from coverage. 42 U.S.C. §2000ff-7(a); 29 C.F.R. §1635.5(b). However, it is possible that, at some time in the future claims for disparate impact will be permitted. GINA provides for the establishment, in May of 2014, of a commission, to be known as the “Genetic Nondiscrimination Study Commission” to review developments in the science of genetics and to make recommendations to Congress regarding whether a disparate impact cause of action should be included under GINA. 42 U.S.C. §2000ff-7(b).

### **III. THE PROHIBITION ON REQUESTING, REQUIRING AND PURCHASING GENETIC INFORMATION**

GINA also makes it unlawful for employers to acquire the genetic information of their employees. Specifically GINA prohibits employers from requesting, requiring or purchasing genetic information with respect to an employee or a family member of an employee unless one of six enumerated exceptions is applicable. 42 U.S.C. §2000ff-1(b). A “request” includes “conducting an Internet search on an individual in a way that is likely to result in a covered entity obtaining genetic information, actively listening to third-party conversations or searching an individual’s personal effects for the purpose of

obtaining genetic information; and making requests for information about an individual's current health in a way that is likely to result in a covered entity obtaining genetic information." 29 C.F.R. §1635.8(a).

The statute sets forth six specific exceptions to the general prohibition on requesting or requiring genetic information including (1) where an employer inadvertently requests or requires the family medical history of the employee or family member of the employee; (2) where health or genetic services are offered by the employer, including as part of a wellness program, provided certain conditions are met; (3) where the employer requests or requires family medical history from the employee to comply with the certification provisions of the Family Medical Leave Act, 29 U.S.C. §2601, et. seq. ("FMLA") or a similar state family and medical leave law; (4) where the employer purchases documents that are commercially and publically available (newspaper, magazines, periodicals and books) which contain family medical history; (5) where the information is obtained in the course of genetic monitoring of the biological effects of toxic substances in the workplace, provided certain conditions are met; and (6) where the employer conducts DNA analysis for law enforcement purposes as forensic laboratory or for purposes of human remains identification and requests or requires employee genetic information to be used exclusively for quality control and/or to detect sample contamination. 42 U.S.C. §2000ff-1(b)(1) – (6).

## **A. Inadvertent Requests**

The GINA regulations make it clear that if an employer acquires genetic information in response to a lawful request for medical information,<sup>2</sup> the request will only be considered inadvertent if the employer directs the individual or entity providing the information not to provide any genetic information. 29 C.F.R. §1635.8(b)(1)(i)(A). The regulations provide that where the following “safe harbor” language is used when requesting medical information, any receipt of genetic information in response to the request will be deemed inadvertent. The safe harbor language set forth in the regulations is as follows:

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.

29 C.F.R. §1635.8(b)(1)(i)(B). The regulations note that failure to give the safe harbor notice set forth above will not prevent an employer from establishing that receipt of certain genetic information was inadvertent if the request for medical information was not likely to result in the employer obtaining genetic information (*i.e.*, where an overly broad

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<sup>2</sup> Lawful requests for medical information may include a request for documentation to support a request for reasonable accommodation under the ADA or state law, where the disability or need for accommodation is not obvious; a request in support of an employee’s request for leave under the FMLA, a state family and medical leave law or other state leave of absence statute or where an employee complies with the FMLA’s return to work certification requirements. 29 C.F.R. §1635.8(b)(1)(i)(D)(1) – (3).

response is received in response to a specifically tailored inquiry). 29 C.F.R. §1635.8 (b)(1)(i)(C).

Importantly, it is mandatory for employers to instruct the healthcare professionals, that they use to provide employment-related medical examinations, not to collect any genetic information including family medical history as part of any employment-related medical examination. 29 C.F.R. §1635.8 (d). Employers are required to take “reasonable measures” within their control if the employer learns that the healthcare provider is requesting or requiring genetic information in connection with employment-related medical examinations. *Id.* These “reasonable measures” selected by the employer will depend on the facts and circumstances under which the healthcare provider requested the genetic information, and may include no longer using the service of any healthcare provider who continues to request or require genetic information after being instructed not to do so. *Id.*

There are additional situations in which the exception for inadvertent acquisition of genetic information may be applicable, including when information is obtained passively in the course of casual workplace conversation, commonly referred to as talk around the “water cooler.” Thus, where a manager or supervisor acquires an individual’s genetic information by overhearing a conversation, receiving it from the individual or a third party by overhearing a conversation in the workplace or by receiving it directly during casual conversation or in response to an ordinary expression of concern the acquisition will be deemed inadvertent. 29 C.F.R. §1635.8(b)(1)(ii)(A) – (B). Thus, the regulations note that a general health inquiry such as “How are you?” or “Did they catch it early?” and “Is your child feeling better today?” which elicits a response containing

genetic information, will be deemed an inadvertent acquisition. 29 C.F.R. §1635.8(b)(1)(ii)(B). However, the exception will not apply if the employer follows a general question with more probing health related inquiries, such as asking whether other family members have the condition or whether the individual has been tested for the condition. 29 C.F.R. §1635.8(b)(1)(ii)(B). In addition, unsolicited acquisition of genetic information (*i.e.*, receipt of an email about the health of an employee or an employee's family member) will be deemed inadvertent acquisition. 29 C.F.R. §1635.8 (b)(1)(ii)(C). Finally, where a manager or supervisor is given permission by an employee to access a social media platform maintained by the employee (*i.e.*, the manager and the employee are Facebook friends) and the manager acquires genetic information about the employee or employee's family members via that social media platform, the acquisition will be deemed inadvertent. 29 C.F.R. §1635.8(b)(1)(ii)(D).

**B. Wellness Programs and Providing Health and Genetic Services**

The second exception to GINA's prohibition on the acquisition of an employee's genetic information where health or genetic services are offered by the employer, including such services offered as part of a wellness program, provided that (1) the employee provides prior, knowing, voluntary and written authorization; and (2) only the employee and licensed healthcare professional or board certified genetic counselor involved in providing the services receive individually identifiable information concerning the results of the genetic services; and (3) any individually identifiable genetic information provided in connection with the services is only available for purposes of those services and shall not be disclosed to the employer except in aggregate

terms that do not disclose the identity of specific employees. 42 U.S.C. §2000ff-1(b)(2)(A) – (D).

**1. *Knowing Authorization***

To be knowing, the authorization must (1) be written so that it is likely to be understood by the individual from whom the genetic information is being sought; and (2) describe the type of genetic information that will be obtained and the general purpose for which it will be used; and (3) describe the restrictions on disclosure of genetic information. 29 C.F.R. §1635.8(b)(2)(i)(B)(1) – (3).

**2. *Written Authorization***

The regulations permit the authorization to be provided in electronic format, provided that the electronic authorization is required before the program will permit the individual to answer any questions that request genetic information. 29 C.F.R. §1635.8(b)(2)(i)(B).

**3. *Voluntary Authorization***

The GINA regulations provide that this exception applies only where the provision of genetic information is “voluntary,” which means that the employer cannot require an employee to provide genetic information and cannot penalize employees who choose not to provide genetic information. 29 C.F.R. §1635.8(b)(2)(i)(A).

Many wellness programs offer financial incentives for employees to participate. GINA does not prohibit financial incentives, but it requires that where they are offered, they be equally available to employees who elect not to provide genetic information. Thus, the regulations explain that an employer “may

not offer a financial inducement to individuals to provide genetic information, but may offer financial inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear, in language reasonably likely to be understood by those completing the health risk assessment, that the inducement will be made available whether or not the participant answers questions regarding genetic information.” 29 C.F.R. §1635.8(b)(2)(ii). Thus, to be voluntary, a health risk assessment that offers a financial inducement to individuals that complete it, which contains questions seeking genetic information must specifically identify the questions that seek genetic information and must inform the individual providing the information that they need not answer the questions seeking genetic information to receive the financial inducement.<sup>3</sup>

Employers may also offer financial inducements to encourage individuals who have voluntarily provided genetic information (*i.e.*, in a health risk assessment) that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or other programs designed to promote a healthy lifestyle. However to comply with GINA these programs must also be offered to individuals with current health

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<sup>3</sup> It should be noted that, while GINA permits financial inducements to be offered for participation in a wellness program, subject to the conditions set forth above, the ADA does not specifically address, and the EEOC has not taken a position as to, whether employers may be permitted to offer a financial incentive for employees to participate in a wellness program that includes disability-related inquiries such as questions about the employee’s current health status on a health-risk assessment. *Incentives for Workplace Wellness Programs*, June 24, 2011, (EEOC Informal Discussion Letters) ([http://www.eeoc.gov/eeod/fois/letters/2011/ada\\_gina\\_incentives.html](http://www.eeoc.gov/eeod/fois/letters/2011/ada_gina_incentives.html)) (Last visited August 22, 2011).

conditions and/or to individuals whose lifestyle choices put them at an increased risk of developing a condition. 29 C.F.R. §1635.8(b)(2)(iii).

Importantly, in offering financial inducements in an employee wellness program, employers must be cognizant of the need to comply with the requirements of the ADA and the Health Insurance Portability and Accountability Act (“HIPAA”). Specifically, if a financial inducement that requires individuals to meet certain health goals is included in a wellness program, an employer must make reasonable accommodations to the extent required by the ADA. If the wellness program provides medical care, the program may constitute a “group health plan” and therefore, may be required to comply with the special requirements for wellness programs that condition rewards on an individual satisfying a standard related to a health factor, including the requirement to provide an individual with a “reasonable alternative” under HIPAA when it is “unreasonably difficult due to a medical condition to satisfy,” or “medically inadvisable to attempt to satisfy” the otherwise applicable standard. 29 C.F.R. §1635.8(b)(2)(iv).

#### ***4. Disclosure of Genetic Information in the Aggregate***

The GINA regulations state that employers are only permitted to receive information obtained through health or genetic services offered by the employer (including employee wellness programs) in aggregate terms that do not disclose the identity of specific individuals. In the Section-by-Section Analysis of 29 C.F.R. §1635.8, the EEOC indicated that where an employer receives genetic information in aggregate terms that, for reasons outside the control of the provider



of the information or the employer (such as a small number of participants), makes the genetic information of a particular individual readily identifiable with no effort on the employer's part, there will be no violation of GINA. However, efforts undertaken by the employer to link the genetic information to a particular employee will violate GINA.

### **C. FMLA Certification**

The third exception permits employers to request family medical history to comply with the certification provisions of the FMLA or state or local family and medical leave laws, or pursuant to a policy that permits the use of leave to care for a sick family member and requires employees to provide information about the health condition of that family member to substantiate the need for the leave. 42 U.S.C. §2000ff-1(b)(3); 29 C.F.R. §1635.8(b)(3).

### **D. Commonly and Publicly Available Sources**

GINA is not violated where an employer purchases documents that are commercially and publically available (including newspapers, magazines, periodicals, and books, or through electronic media, such as information communicated through television, movies or the Internet that include family medical history. 42 U.S.C. §2000ff-1(b)(4); 29 C.F.R. §1635.8(b)(4). This exception does not apply to medical databases or court records. 42 U.S.C. §2000ff-1(b)(4); 29 C.F.R. §1635.8(b)(4)(i). The Section-by-Section Analysis of the regulations note that while the statutory language in this provision references only "family medical history," the EEOC reads this exception as applying to all "genetic information," obtained through commercially and publically available sources, not exclusively to family medical history. *See*, 29 C.F.R. § 1635.8

(b)(4). The regulations note that, media sources with limited access, such as social networking sites (*i.e.*, Facebook, Linked In, MySpace) and other media sources which require a specific individual's permission to access them, or to which access is limited to members of a particular group are not considered "commercially and publically available" unless it can be demonstrated that access is "routinely granted to all who request it." 29 C.F.R. §1635.8(b)(4)(ii). Importantly, even where the source from which the genetic information is obtained is "commercially and publically available," if the employer seeks access to the source with the intent of obtaining genetic information, or if the source is one from which the employer is likely to acquire genetic information (*i.e.*, a website that focuses on issues such as genetic testing of individuals), this exception will not apply. 29 C.F.R. §1635.8(b)(4)(iii) – (iv). The Section-by-Section Analysis of this section of the GINA regulations states that, "the requirements and prohibitions of GINA do not apply to acquisitions of genetic information outside the employment context." Thus, it appears that where an employer can demonstrate that the source from which genetic information was acquired was accessed by a manager or human resource professional outside his or her role as an employer, the GINA prohibition on acquiring genetic information will not apply. However, in the event that genetic information about an employee is acquired, whether through a commercially and publically available course or outside the employment context, that information may not be used to discriminate in the employment context.

#### **E. Genetic Monitoring**

GINA permits employers to engage in genetic monitoring of the biological effects of toxic substances in the workplace, as long as that monitoring meets certain

requirements. 42 U.S.C. §2000ff-1(b)(5). These requirements are that (1) the employer must provide written notice of the genetic monitoring to the employees; (2) the employee must provide prior, knowing, voluntary and written authorization for the genetic monitoring, or the monitoring must be required by federal or state law; (3) the employee must be informed of his/her individual monitoring results; (4) the monitoring must be in compliance with any federal and/or state genetic monitoring regulations; and (5) the employer, excluding any licensed healthcare professional or board certified genetic counselor, may receive the results of the monitoring only in aggregate terms that do not disclose the identity of the specific employees. 42 U.S.C. §2000ff-1(b)(5)(A) – (E). Employers may not retaliate or otherwise discriminate against any individual because he/she refuses to participate in a voluntary genetic monitoring program that is not required by federal or state law. 29 C.F.R. §1635.8(5). Employees who refuse to participate in voluntary genetic monitoring programs should be informed of the potential dangers of foregoing genetic monitoring, including the potential for exposure to toxins in the workplace and the possible consequences that might result if such exposure is not identified. Importantly, the employer may not take any adverse employment action because an employee refuses to participate in a voluntary genetic monitoring program.

***1. Prior, Knowing, Voluntary, Written Authorization***

To satisfy the requirement of a prior, knowing, voluntary, written authorization, the employer must use an authorization form that (1) is written in a manner that is reasonably likely to be understood by the individual from whom the authorization is sought; (2) describes the genetic information that will be

obtained; and (3) describes the restrictions on disclosure of genetic information.  
29 C.F.R. §1635.8(5)(i)(A) – (B).

## **2. *Results of Genetic Monitoring***

When genetic monitoring is conducted, regardless of whether the testing is required by federal or state law, GINA requires that each individual monitored, receive his/her individual monitoring results (29 C.F.R. §1635.8(b)(5)) and that the employer receive the results only in “aggregate terms that do not disclose the identity of specific individuals.” 29 C.F.R. §1635.8(b)(5)(iii); 42 U.S.C. §2000ff-1(b)(5)(C) and (E). Consistent with its position in cases dealing with employer provided health or genetic services, the EEOC states in the Section-by-Section Analysis applicable to the genetic monitoring provision that there will be no violation of GINA where an employer receives information only in aggregate terms, but is able to identify the genetic information of specific individuals for reasons outside the employer’s control and with no effort on its part.

### **F. *Employers who engage in DNA testing***

Employers who engage in DNA testing for law enforcement purposes such as in a forensic laboratory or for purposes of human remains identification are permitted to request or require genetic information from their employees for the sole purpose of using that information for analysis of DNA identification markers for quality control to detect sample contamination. 42 U.S.C. §2000ff-1(b)(6); 29 C.F.R. §1635.8(6). The Section-by-Section Analysis of the GINA regulations relative to this exception notes that this is a “very limited exception” and that a proper analysis of this sort should not be required by an employer to obtain health-related genetic information.

## **G. Manifested Disease in a Family Member**

Within the confines set by the ADA, employers may make medical inquiries with respect to a manifested disease, disorder or condition of an employee, because information about a manifested disease of an employee is not “genetic information” pursuant to GINA. Information about a manifested disease, disorder or condition of a family member of an employee is considered “family history” and therefore, it is considered “genetic information” under GINA. Thus, under the express language of the statute, there is potential for a conflict to arise when an employer employs two or more members of the same family and has a need to request information about a manifested disease of one of the family members, perhaps in the course of identifying a reasonable accommodation for that employee under the ADA. While GINA permits the employer to acquire this information with respect to the employee with the manifested condition, it prohibits the acquisition of this information with respect to the family member(s) also employed by the employer because, with respect to them, it is considered “genetic information.” To eliminate this conflict the GINA regulations make clear that an employer does not violate GINA’s prohibition on the acquisition of genetic information when it “requests, requires or purchases information about a manifested disease, disorder, or pathological condition of an employee . . . whose family member is an employee for the same employer.” 29 C.F.R. §1635.8(c)(1). Similarly, where an employee’s family member with a manifested disease, disorder or pathological condition is voluntarily receiving health or genetic services through a program provided by the employer, the employer will not violate GINA by seeking information about that manifested disease, disorder or condition. 29 C.F.R. §1635.8(c)(2). The GINA regulations state that an

employer “does not unlawfully acquire genetic information about an employee when it asks the employee’s family member who is receiving health services from the employer if her diabetes is under control.” *Id.*

#### **IV. CONFIDENTIALITY REQUIREMENTS AND LIMITATION ON DISCLOSURE OF GENETIC INFORMATION**

GINA also requires that employers maintain genetic information about their employees in a confidential manner and it limits the circumstances under which the employer is permitted to disclose an employee’s genetic information. 42 U.S.C. §2000ff-5.

##### **A. Confidentially Requirements**

GINA requires employers who possess genetic information about their employees to maintain that information in separate medical files and to treat it as a confidential medical record of the employee. Employers will be considered to have satisfied the confidentiality requirement if they maintain the genetic information in accordance with the confidentiality medical records requirements set forth in Section 102(d)(3)(B) of the Americans with Disabilities Act (42 U.S.C. §12112(d)(3)(B)), which requires that the information be “maintained on separate forms and in separate medical files” and that it be “treated as a confidential medical file.” 42 U.S.C. §2000ff-5(a). Genetic information may be maintained in the same file in which the employer maintains confidential medical information subject to the ADA. 29 C.F.R. §1635.9(a)(2). If an employer receives genetic information orally, that information need not be reduced to writing. 29 C.F.R. §1635.9(a)(3). Genetic information acquired through commercially and publically available sources is not considered “confidential genetic information” and it is not subject

to the confidentiality provisions of the GINA regulations. However, it may not be used to discriminate against the individual. 29 C.F.R. §1635.9(a)(4).

The GINA regulations clarify that “genetic information placed in personnel files prior to November 21, 2009 need not be removed and a covered entity will not be liable under this part for the mere existence of the information in the file.” 29 C.F.R. §1635.9(a)(5). However, the Section-by-Section Analysis of this section of the GINA regulations notes that in the event the personnel files of an employee containing genetic information acquired prior to November 21, 2009 must be disclosed, for any reason, that genetic information must be removed. In addition, because most genetic information will also be considered “medical information” subject to the ADA’s confidentiality requirements since 1992, it is not anticipated that removing such information from personnel files would impose a significant burden on employers.

**B. Limitations on Disclosure of Genetic Information**

In addition, an employer that lawfully possesses genetic information (except for genetic information acquired through commercially and publically available sources) may not disclose that information except (1) to the employee (or family member if the family member is receiving genetic services) at the written request of the employee (or family member); (2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under 45 C.F.R. Part 46, which governs research involving human subjects; (3) in response to a court order, but only as expressly authorized by that order and only where the employer informs the employee or family member that the information was disclosed pursuant to the order; (4) to government officials investigating compliance with GINA; (5) in

connection with the employee's compliance with the certification provisions of the FMLA or other state and family medical leave laws; and (6) to a federal, state or local public health agency provided the disclosure is limited to information about the manifestation of a contagious disease that presents an imminent hazard of death or life-threatening illness, and the employee whose family member is the subject to the disclosure is notified of the disclosure. 42 U.S.C. §2000ff-5(b)(1) – (6).

It should be noted that the exception for disclosure of genetic information pursuant to a court order is an extremely limited exception requiring that the genetic information disclosed must be carefully tailored to the specific terms of the court order. 42 U.S.C. §2000ff-5(b)(3)(A) – (B). The Section-by-Section Analysis of this provision of the GINA regulations notes that, “this exception does not allow disclosure in other circumstances during litigation, such as in response to discovery requests or subpoenas that are not governed by an order specifying that genetic information must be disclosed.”

## **V. ENFORCEMENT AND REMEDIES FOR VIOLATIONS**

GINA incorporates by reference the enforcement and remedy provisions already in place for redressing other types of employment discrimination. 42 U.S.C. §2000ff-6. Thus, the enforcement mechanism applicable and remedies available to employees covered by Title VII are applicable to GINA as well.<sup>4</sup> Thus, prior to instituting litigation, employees must first exhaust their administrative remedies, by filing a charge of discrimination on the basis of genetic information with the EEOC. The EEOC will investigate the charge and, where the EEOC believes a violation of GINA has occurred,

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<sup>4</sup> Employees covered by the Government Employee Rights Act of 1991, or the Congressional Accountability Act of 1995 or Chapter 5 of Title 3, of the United States Code or Section 717 of the Civil Rights Act of 1964 are subject to the procedural requirements of those statutes respectively.



the agency will attempt to conciliate the matter. The EEOC has the power to commence litigation in its name to compel compliance with GINA.

An aggrieved individual may recover pecuniary and non-pecuniary damages, including compensatory and punitive damages under GINA. 42 U.S.C. §2000ff-6(a)(3); 29 C.F.R. §1635.10(b)(1). GINA also incorporates the statutory cap on combined compensatory damages for future pecuniary losses, emotional pain and suffering, inconvenience, mental anguish, loss of enjoyment of life and punitive damages, based on the size of the employer as set forth in 42 U.S.C. §1981a(b)(3). 42 U.S.C. §2000ff-6(a)(3); 29 C.F.R. §1635.10(b)(1) .

In addition, GINA authorizes the court, in its discretion, to allow the prevailing party in GINA litigation, reasonable attorney's fees and costs. Expert witness fees may be included as part of the attorney's fees award. 42 U.S.C. §2000ff-6(a)(2); see also 42 U.S.C. §1988(b) – (c); 29 C.F.R. §1635.10(b)(2).

Injunctive relief, including reinstatement, hiring, backpay and other equitable remedies available under Title VII are also available under GINA. 42 U.S.C. §2000ff-6(a)(3); 29 C.F.R. §1635.10(b)(1); see also 42 U.S.C. §2000e-5(g).

The GINA regulations require that employers post a notice describing GINA's applicable provisions in a conspicuous place, where notices to employees and applicants for employment are customarily posted. 29 C.F.R. §1635.10(c)(1). The EEOC has issued a revised EEO poster incorporating this information which satisfies this requirement. A willful violation of this posting requirement is punishable by a fine of not more than \$100 for each separate offense. 29 C.F.R. §1635.10(c)(2).

## **VI. EMPLOYERS IN THE HEALTHCARE INDUSTRY**

Employers who provide healthcare service (*i.e.*, hospitals, clinics and doctors offices) may have employees who are also patients of the employer. Where this is the case, there are additional issues of which the employer must be aware with respect to confidentiality and storage of medical records and genetic information.

### **A. Compliance with the HIPAA Privacy Rule**

GINA makes it clear that it does not limit the rights or protections provided under any other federal or state statute that provides equal or greater protections. 42 U.S.C. §2000ff-8(a). In this regard, the GINA regulations specifically state that they do not apply to genetic information that constitutes “protected health information” subject to the HIPAA Privacy Rule. Thus, employers subject to the HIPAA Privacy Rule must continue to apply the requirements of that Rule, not the requirements of GINA Title II and its implementing regulations, to genetic information that is also protected health information. 42 U.S.C. §2000ff-8(a); 29 C.F.R. §1635.11(d). The Section-by-Section Analysis of this provision of the GINA regulations provides the following example of genetic information that is also protected health information subject to the HIPAA Privacy Rule:

If a hospital subject to the HIPAA Privacy Rule treats a patient who is also an employee of the hospital, any genetic information that is obtained or created by the hospital in its role as a healthcare provider is protected health information and is subject to the requirements of the HIPAA Privacy Rule and not those of GINA. In contrast, however, any genetic information obtained by the hospital in its role as employer, for example, as part of a request for leave by the employee, would be subject to GINA Title II.

Thus, employers covered by the HIPAA Privacy Rule, must first determine in which context genetic information of an employee was acquired, and then apply the applicable provisions of either HIPAA or GINA.

**B. Combining Personal Medical Records and Occupational Health Records**

Another area of concern for employers in the business of providing healthcare services is whether a healthcare service provider should have access to the personal health information of its employees who have received treatment unrelated to their employment, and conversely, whether, in its role as a healthcare service provider, the entity should have access to the occupational health records of a patient who also happens to be an employee. The EEOC has issued guidance, in the form of an Informal Discussion Letter, addressing this topic. Confidentiality Requirements (5/31/2011) (EEOC Informal Discussion Letters) ([http://www.eeoc.gov/eeoc/foia/letters/2011/ada\\_gina\\_confidentrequire.html](http://www.eeoc.gov/eeoc/foia/letters/2011/ada_gina_confidentrequire.html)) (Last visited August 22, 2011). In this letter, the EEOC reviews the provisions of the ADA, which limits an employer's ability to access the personal medical records of an employee or applicant and the provisions of GINA, which places further limitations on when an employer may request personal health information which is also "genetic information." The EEOC concludes that because both the ADA and GINA strictly limit an employer's right to access such information, there is a real possibility that maintaining personal medical records and occupational health records in the same file could result in a violation of the ADA or GINA or both. Thus, it is recommended that employers maintain this information separately.