GINA — We Hardly Know You Yet

The Genetic Information Nondiscrimination Act of 2008 and Its Impact on Other Federal Laws And Illinois Law©

Ambrose V. McCall
Hinshaw & Culbertson LLP
416 Main Street
Sixth Floor
Peoria, Illinois 61602
309-674-1025
amccall@hinshawlaw.com

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I. THE GINA STATUTORY AMENDMENTS AND REGULATIONS

A. GINA First Amended ERISA - Compliance and Penalties

The GINA amendments to the Employee Retirement Income Security Act ("ERISA") became effective upon being enacted into law on May 21, 2008. Pub. L. Now 110-233, Title I, §101(e), May 21, 2008, amending 29 U.S.C. §1132, and amended Pub.L.Now-233, Title I, §101(a)2(c), May 21, 2008, 122 Stat. 883 amending 29 U.S.C. §1182 and amended Pub.L.110-233, Title I, §101(d), May 21, 2008, 122 Stat. 885 amending 29 U.S.C. amending §1191(b).

The amendments to 29 §1132(a)(6) provide that the Secretary of Labor ("Secretary") may file a civil action to recover civil penalties from plan sponsors of a group health plan or any health insurance issuer offering health insurance coverage in connection with the plan, under 29 U.S.C. §1132(c)(9). Covered plan sponsors and health insurance issuers may incur liability for any failure by such sponsor or issuer to meet the requirements imposed by 29 U.S.C. §1182(a)(1)(F), (b)(3), (c), or (d), §1181, or 1182(b)(1) of ERISA. The cited provisions in 29 U.S.C. §1182 bar discrimination against individual plan participants and beneficiaries, based on health status, or based on the use of genetic data. The amount of the penalty imposed shall be $100.00 for each day of the non-compliance, with respect to each participant or beneficiary to whom such failure relates. 29 U.S.C. §1132(c)(9)(B)(i). The non-compliance is calculated as beginning with the date the failure first occurred and ending on the date the failure is corrected. 29 U.S.C. §1132(c)(9)(B)(ii)(I), (II).

The GINA amendments to ERISA do not stop there. They also impose a minimum penalty where a failure, with respect to a participant or beneficiary, is not corrected before the date on which the plan receives a notice from the Secretary of such violation and which occurred or continued during the period involved. 29 U.S.C. §1132(c)(9)(C)(i)(I)(II). The amount of the penalty imposed by reason of such failures with respect to such participant or beneficiary shall in that case not be less than $2,500. 29 U.S.C. §1132(c)(9)(C)(i). Moreover, to the extent that any violations, which any person is liable for any year, qualify as being more than de minimis, the minimum fine is then increased to $15,000.00 with respect to such person. 29 U.S.C. §1132(c)(9)(C)(ii).

The GINA amendments, however, also provide that no penalty will be imposed for a failure during a period where the Secretary agrees or finds that the person otherwise liable for the penalty did not know, and with the exercise of reasonable diligence would not have known, that such a failure existed. 29 U.S.C. §1132(c)(9)(D)(i). Furthermore, no penalty shall be imposed if it is shown that the failure occurred due to a reasonable cause, and did not happen due to willful neglect, and was corrected during the thirty-day period beginning on the first day the person otherwise liable knew, or with reasonable diligence would have known, that the failure existed. 29 U.S.C. §1132(c)(9)(D)(ii)(I), (II). When failures are due to reasonable cause and not to willful neglect, the penalty imposed under sub-paragraph §1132(c)(9)(A), for the afore cited failures, shall not exceed the amount equal to the lesser of ten percent of the aggregate amount

paid or incurred by the plan sponsor, or predecessor planned sponsor, during the preceding taxable year for group health plans, or $500,000.00. 29 U.S.C. §1132(c)(9)(D)(iii)(I), (II).

The Secretary retains the discretion to waive part or all of any penalty imposed under §1132(c)(9)(A) to the extent that the payment of such penalty would be excessive relative to the failure involved. 29 U.S.C. §1132(c)(9)(E). Of significance, the terms used in the amended paragraph found under 29 U.S.C. §1132(c)(9) are defined in §29 U.S.C. §1191(b). 29 U.S.C. §1132(c)(9)(F).

B. What Do the GINA Anti-Discrimination Amendments to ERISA Bar?

In the section of ERISA prohibiting discrimination against individual participants and beneficiaries based on health status, ERISA now directly prohibits a group health plan or health insurance issuer [that offers health insurance coverage with a group health plan], from establishing eligibility rules for enrollment that are based on various health status factors of the individual or dependent specified as the following:

A. Health Status,
B. Medical Condition (including both physical and mental illnesses),
C. Claims Experience,
D. Receipt of Healthcare,
E. Medical History,
F. Genetic Information,
G. Evidence of Insurability (including condition arising out of acts of domestic violence), or
H. Disability.

29 U.S.C. §1182(a)(1)(A)-(H).

However, also contained in 29 U.S.C. §1182 is a provision stating that to the extent consistent with 29 U.S.C. §1181, the language contained in 29 U.S.C. §1182(a)(1) shall not be construed to do either of the following:

A. To require a group health plan, or group health insurance coverage, to provide particular benefits other then those provided under the terms of such plan or coverage, or
B. To prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

29 U.S.C. §1182(a)(2)(A),(B).

Before the above noted GINA Amendments were enacted so as to modify ERISA, the 8th Circuit held that even though an insurer rescinded coverage based on the claimed non-disclosure of an employee's preexisting neck conditions on a medical survey, such action did not directly violate the Health Insurance Portability and Accountability Act ("HIPAA"). The congressional intent behind the enactment of HIPAA was a factor in determining whether the policy of the insurer in automatically rescinding such coverage constituted a breach of its fiduciary duty as a benefits decision maker under ERISA. *Werdehausen v. Benicorp Ins. Co.*, 487 F.3d 660, 668

(8th Cir. 2007)("However, though the Werdehausens have no direct ERISA claim for a violation of HIPAA, as we have explained the congressional intent underlying HIPAA as relevant in determining whether Benicorp's policy of automatic rescission breached its fiduciary duty as an ERISA benefits decision-maker."). The HIPAA laws were one of several grounds the 8th Circuit relied on when reversing the District Court's order granting the insurer's summary judgment motion and thereby reviving the plaintiff's ERISA claims. *Id* at 669.

After GINA amended ERISA, but in litigation involving the pre-GINA amended version of ERISA, the 11th Circuit rejected an argument by a defendant that an insurer's claim for reimbursement violated ERISA's anti-discrimination provision to the extent it forced the defendant to make a greater contribution to the plan than similarly situated participants. Defendant urged that such a distinction was unlawful and resulted in his receiving fewer or lesser benefits under the plan than similarly situated participants. *Zurich American Ins. Co. v. O'Hara*, 604 F.3d 1232, 1238 (11th Cir. 2010), *cert. denied*, ___S. Ct.___, 2011 WL 55457 (U.S. Jan. 10, 2011). The *O'Hara* court focused on the fact that the ERISA §702(b)(1) provision barring a group health plan from requiring an individual to pay a premium or contribution greater than a similarly situated individual based on health status-related factor did not apply. *Id*. The *O'Hara* court characterized the reimbursement sought by the insurer as not involving a premium or contribution on the basis of any health status-related factor to be paid out of the plaintiff's general assets. *Id*. Rather, the insurer's action was to recover specific and identifiable funds advanced to cover the defendant's accident related medical expenses which the court characterized as "being held in trust" by the defendant's counsel. *Id*.

Moreover, the *O'Hara* court rejected the contention that the reimbursement and subrogation provision limited or restricted benefits in an unlawful or discriminatory manner because it applied uniformly to all participants and required reimbursement from any participant or beneficiary who received medical benefits under the plan and then subsequently recovered sums from a third party. *Id., citing*, 29 C.F.R. §2590.702(b)(2)(i)(B)(2010)(stating that "benefits provided under a plan …must be uniformly available to all similarly situated individuals"). The *O'Hara* court characterized the fact that the plaintiff was affected by the plan's right to subrogation because he obtained a tort recovery from third parties did not render the plan discriminatory. *Id.*, 604 F.3d at 1238-39. Furthermore, the court explained that §702(a)(2)(B) of ERISA, codified at 29 U.S.C. §1182(a)(2)(B), states that nothing in the act "prevent[s]… a plan or coverage from establishing limitations or restriction on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage." 29 U.S.C. §1182(a)(2)(B), *O'Hara*, 604 F.3d at 1238, n 5.

Another federal court has recently held that based on HIPAA not providing for either an express or implied private right of action required entering summary judgment on a claim that an insurer's action in terminating a particular type of coverage in a small group market was unlawful. The plaintiff based its action on the statutory language providing that "the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered...." 42 USC §300gg-12(c)(1)(C). That provision, from HIPAA, however did not create a cause of action on behalf of the plaintiff. *Warren Pearl Const. Corp. v. Guardian Life Ins. Co. of America*, 639 F.Supp.2d 371, 376-77 (S.D. N.Y. 2009). How such claims will fare when pursued under the GINA amendments to ERISA, and other GINA provisions elsewhere, or the recently effective GINA regulations, remains to be seen.

C. How do the GINA amendments to ERISA define the covered genetic information?

Genetic information includes not only the individual or family member of an individual enrolled in a plan, but also the fetus of a pregnant plan individual, or pregnant family member of a plan individual. The statutory term of "genetic information" also encompasses the genetic information of any embryo legally held by the plan individual or family member who is using an assisted reproductive technology. 29 U.S.C. §1182(f)(1),(2).

In 29 U.S.C. §1191b(6)(A), the term "genetic information" is specified as meaning:

i. **Such individual's genetic tests,**
ii. **the genetic tests of family members of such individual, and**
iii. **the manifestation of a disease or disorder in family members of such individual.**

29 U.S.C. §1191b(d)(6)(A)(i)-(iii).

The term "genetic information" also includes any request for, or receipt of, genetic services, or participation in clinical research which encompasses genetic services, by the individual or family member of said individual. 29 U.S.C. §1191b(d)(6)(B). The term "genetic information" excludes data about the sex or age of any plan individual. 29 U.S.C. §1191b(d)(6)(C).

The statutory term "genetic test" encompasses an analysis of human DNA, RNA, chromosomes, proteins or metabolites, that detect genotypes, mutations, or chromosomal changes. 29 U.S.C. §1191b(d)(7)(A). However, the term "genetic test" excludes analysis of proteins or metabolites that do not detect genotypes, mutations, or chromosomal changes. 29 U.S.C. §1191b(d)(7)(B)(i). The term "genetic test" also excludes any analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that a health professional could reasonably detect with appropriate training and expertise in the involved field of medicine. 29 U.S.C. §1191b(d)(7)(B)(ii).

The term "genetic services" means the following:

i. **a genetic test,**
ii. **genetic counseling (including obtaining, interpreting, or assessing genetic information); or**
iii. **genetic education.**

29 U.S.C. §1191b(d)(8)(A)-(C).

In its comments on the proposed final GINA regulations, the American Benefits Council states that Title I of GINA establishes comprehensive rules prohibiting discrimination based on genetic information for group health plans, and broadly bars the use of genetic information in setting plan premiums and contributions, and requesting or requiring genetic testing, and gathering genetic data. (American Benefits Council, May 1, 2009 comment letter, at n.1, Document: EEOC-2009-0008-0014; Docket: EEOC-2009-08). Yet, given the existing HIPAA nondiscrimination rules, the Council recommended, in response to Title I of GINA, that the Department of Labor implement guidance that would clarify the gathering and employment of

genetic information is allowed for the purposes of administering wellness programs, in accord with Congressional intent. (American Benefits Council, December 9, 2008 comment letter to Department of Labor, p. 3). The Council also inquired as to what circumstances the collection of family medical history might qualify as incidental, and whether the granting of rewards without regard to a particular response would fall outside the GINA definition of "underwriting." Id. Will or did the Council receive its requested clarifications? The recently effective GINA regulations, later discussed, provide a response.

Another question that may arise under ERISA involves whether an employer provides multiple programs and options that qualify as one or multiple ERISA plans. In *Loren v. Blue Cross & Blue Shield of Michigan*, 505 F.3d 598 (6th Cir. 2006), *on remand*, 2008 WL 723537 (E.D. Mich. March 17, 2008), *reconsideration denied*, 2008 WL 1925050 (E.D. Mich. May 1, 2008), the Sixth Circuit had to decide whether multiple coverage options constituted one plan under ERISA, a question of first impression for the court. *Id.* at 604. The number of plans became an issue because the plaintiffs urged that a breach of fiduciary duty allegedly occurred because the defendant negotiated rates more favorable for its related network than for the self-insured plans of plaintiffs' employers, which the defendant also administered. *Id.* at 601-602. The *Loren* court found that one plan had been created based upon the presumption provided by the HIPAA default rule that all medical benefits offered by an employer are considered to form part of one ERISA health plan. Indeed, in *Loren*, the employers filed and registered one plan document rather than multiple plan documents. *Id.* at 605-06. Of interest, the referenced HIPAA rule was only a proposed regulation at the time of the *Loren* court's decision, but the administrative interpretation provided therein was used by the *Loren* court in its decision. *Id.* at 604-605, citing, Notice of Proposed Rulemaking for Health Coverage Portability, 69 Fed. Reg. 788800-001 (proposed Dec. 30, 2004) (to be codified at 29 C.F.R. Part 2590) (jointly issued by the Department of Labor and the Department of Health and Human Services). Because the employers failed to overcome the cited presumption that filing one plan document creates a single ERISA plan, the court held that the employers maintained a single ERISA group health plan with multiple benefit options. *Id*. at 606. The principle discussed in *Loren* should stay on the radar of personnel who are designing employee wellness programs and who must track which program or programs include, contain and identify who administers the wellness programs as one of its possible components, benefit options or plans.

D. GINA Amendments to the Civil Rights Act

Title II of GINA, found at 42 U.S.C., §2000ff, took effect on November 21, 2009, eighteen months after Congress enacted GINA. Pub.L.110-233, Title II, §213. (Effective Date). Title II of GINA, unlike Title I, is enforced by the Equal Employment Opportunity Commission ("EEOC"). 42 §2000ff(1); 42 U.S.C. §2000ff-6.

The GINA amendments to the Civil Rights Act expand the scope of the Civil Rights Act's coverage to include and impose limitations and certain prohibitions on the collection, use, and disclosure of genetic information in connection with employment. GINA governs all employers covered by Title VII, (employers having fifteen or more employees), in addition to employment agencies, unions, state and other governmental employers, including various federal, legislative, and executive branch entities. 42 U.S.C. §2000ff(2)(A), (B), (C).

With respect to employment, the most significant provision in the GINA amendments bars employers from compelling or asking an individual employee to undergo individual testing

or to disclose genetic test results as a condition of employment. 42 U.S.C. §2000ff-2(b). To further buttress the largely prohibited acquisition or inquiries regarding genetic information, (with specific exceptions noted under 42 U.S.C. §2000ff(b)), employers are also barred from discriminating against employees or applicants based on genetic information. 42 U.S.C. §2000ff-1(a).

The discrimination GINA bars includes refusing or failing to hire applicants, or discharging employees, or otherwise discriminating against employees, with respect to their compensation, terms, conditions, or privileges of employment - because of their genetic information. 42 U.S.C. §2000ff-1(a)(1). Additionally prohibited as unlawful discriminatory conduct is the limiting, segregating, or classifying of employees in any way that would deprive, or tend to deprive employees, or otherwise adversely effect their status, because of their genetic information. 42 U.S.C. §2000ff-1(a)(2). Moreover, a plaintiff claiming genetic discrimination under Title II of GINA has the same remedies available to other anti-discrimination plaintiffs who sue under the Civil Rights Act, such as the ability to recover costs, attorney's fees, compensatory damages spanning from $50,000 to $300,000, depending upon the size of the employer, and punitive damages, in addition to obtaining injunctive relief as well. 42 U.S.C. §2000ff-6(a)(1)-(3), *cross-referencing provisions including*, 42 U.S.C. §§1981a, 1988. The major exception from the incorporated Civil Rights Act appears in the GINA amendment which specifies that no cause of action for disparate impact exists under GINA. 42 U.S.C. §2000ff-7(a).

Do other key provisions of Title II of GINA impact the Civil Rights Act? As similarly reflected by the Title I GINA amendments to ERISA, Title II of GINA also bars, now as an unlawful employment practice, any employer from requesting, requiring or purchasing genetic information with respect to an employee or family member of an employee. 42 U.S.C. §2000ff(b). As a result, the general rule prohibits an employer from making direct or indirect inquiries regarding an employee's genetic information. Id. There are, of course, exceptions. Whether they are available to an employer depends upon the context indicating why such information is needed, and its intended application, purpose, or use.

Some of the statutory exceptions to the general prohibition rule include where:

> 1. an employer inadvertently requests or requires family medical history of the employee or family member of the employee;
> 2. health or genetic services are offered by the employer, including such services being offered as part of a wellness program.

42 U.S.C. §2000ff-1(b)(1), (2)(A).

So does Title II of GINA permit employers to ask for or obtain genetic information as part of a wellness program? Can an employer solely rely on the permitted use or disclosure of health information allowed through the incorporated HIPAA regulations? 42 U.S.C. §2000ff-5(c)? Some clarity arrives with the later discussed recent GINA regulations promulgated by the EEOC.

At any rate, the overlapping nature of these laws should give all employers pause before procuring or using genetic information for any purpose. Indeed, Title II of GINA compels all covered employers, employment agencies, labor organizations, and joint labor-management

committees who possess genetic information to maintain such data on separate forms, and in separate medical files, and to treat and maintain such data as confidential medical records of the employee or member. 42 U.S.C. §2000ff-5(a). The statutory limitations on disclosure here do not include or reference wellness programs. 42 U.S.C. §2000ff-5(b). Fortunately, the later discussed regulations provide us with some insight.

Yet, until a court otherwise finds, or Congress enacts another statutory amendment, a critical provision remains unchanged in the ADA, which permits an employer, after making a conditional offer of employment, to lawfully require an individual to submit to a medical exam that results in the disclosure of medical history and data, subject to confidentiality protections. 42 U.S.C. §12112(d)(3).

The potential issue generated here is what is the most reasonable way for an employer to separately maintain non-genetic information in paper or electronic formats from other media containing genetic information, and whether an employer decides to navigate the shoals created by the general prohibition rules in order to qualify for a particular exception, or decline obtaining any genetic information as part of a wellness program to avoid running aground.

E. The EEOC's First Warning Flare

With increasing frequency, the EEOC posts its responses to inquiries regarding the complex interactions between the Americans with Disabilities Act ("ADA"), GINA, EEOC regulations, and other laws. On August 10, 2009, in response to an inquiry asking whether the ADA permitted a client to compel its employees to complete a Health Risk Assessment ("HRA") in order to receive monies from an employer-funded health reimbursement arrangement, the agency's analysis examined some of the questions posed in the HRA. While primarily discussing the analysis within the context of the ADA, the responding EEOC lawyer dropped the following footnote in the agency's response, regarding the EEOC's interpretation and proposed application of GINA.

> As of November 21, 2009, [GINA] will prohibit employers from obtaining any genetic information (which includes family medical history) from applicants or employees, except under very limited circumstances. It, therefore, generally will be unlawful for employers to ask applicants and employees whether a relative has or ever had certain medical conditions, such as cancer, diabetes, or heart disease. Although questions about the health of an employee's family member arguably are not likely to elicit information about whether an employee currently has a disability, GINA, generally will prohibit such questions. Your client, therefore, will likely violate GINA if it continues to ask questions about an employee's family medical history (questions 9-16) as of November 21, 2009, even if the questions are considered part of a wellness program since, like the ADA, GINA requires that such a program be voluntary. As we explain in our analysis of the ADA, *infra*, even if your client's questionnaire is part of a wellness program, we do not believe it would be considered voluntary.

(EEOC informal discussion letter, ADA: Health Risk Assessments, August 10, 2009 at n.2, Peggy Mastroianni, Assistant Legal Counsel EEOC).

F. Employers Respond to Pre-Finalized GINA Regulations

The EEOC is not alone in reading GINA as barring inquiries regarding the family medical history of an employee. In the public submission of Navistar, sent in response to the proposed final GINA regulations, the company generally commented that a key element of its HRA program was a series of family medical questions. The company also asserted that the interim final regulation under Title I of GINA would severely impact its wellness program. How so? Navistar contended that the final regulation would prohibit it from providing financial incentives to individuals who complete HRAs that request family medical history and offering rewards to employees for meeting certain health-related goals. The employer also stressed that wellness programs constitute one of the few options available for employers to control soaring health costs. The company proclaimed that prohibiting the use of financial incentives to garner family medical history in HRAs undermined its ability to try to hold down medical costs and encourage its employees to assume more active control of their health. (Public submission docket EBSA-2008-0020 from Navistar, Inc.).

Employers must also note that the eligibility rules for enrollment in a plan encompass and include rules defining any applicable waiting period for enrollment. 29 U.S.C. §1182(a)(3).

Group health plans and covered health insurance issuers are also barred from requiring any individual as a condition of enrollment, or continued enrollment, in a covered plan to pay a premium or contribution greater than the premium or contribution charged to a similarly situated individual enrolled in the plan on the basis of any health related factors of the individual or dependent. 29 U.S.C. §1182(b)(1).

For wellness programs, the significant provision appears in 29 U.S.C. §1182(b)(2)(B), which states that nothing in 29 U.S.C. §1182(b)(1) prevents a group health plan and covered health insurance issuer from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

The GINA amendments bar a group health plan and covered health insurance issuer from adjusting premium or contribution amounts for the covered group, under the plan, on the basis of genetic information. 29 U.S.C. §1182(b)(3)(A). However, the health insurance issuer may increase the premium for an employer based on the manifestation of a disease or disorder of an enrolled individual in the plan, but the manifestation cannot be used as genetic information about other group members to further increase the employer's premium. 29 U.S.C. §1182(b)(3)(B).

Group health plans and covered health insurance issuers are also barred from requesting or requiring an individual or a family member of such individual to take a genetic test. 29 U.S.C. §1182(c)(1). However, healthcare professionals providing healthcare services to such an individual may still ask the individual to take a genetic test. 29 U.S.C. §1182(c)(2). Within the context of offering group health insurance coverage, the limitation on requesting or requiring genetic testing is <u>not</u> to be construed as prohibiting a group health plan or covered health insurance issuer from obtaining and using the results of a genetic test in making a determination regarding payment consistent with the enrollment eligibility conditions imposed under 29 U.S.C. §1182(a). 29 U.S.C. §1182(c)(3)(A). When making payment decisions, however, group health plans or covered health insurance issuers may only request a minimum amount of information necessary to accomplish the intended purpose in making payment determinations. 29 U.S.C. §1182(c)(3)(B).

Group health plans and covered health insurance issuers are barred from requesting, requiring, or purchasing genetic information for underwriting purposes. 29 U.S.C. §1182(d)(1). The same entities are also barred from collecting genetic information with respect to an individual before his or her enrollment in a plan or coverage in connection with the enrollment. 29 U.S.C. §1182(d)(2). The group health plans and covered health insurance issuers are not to be considered to have violated the genetic anti-discrimination provisions contained in 29 U.S.C. §1182(d)(2) to the extent they obtain such genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual and are otherwise not in violation of 29 U.S.C. §1182(d)(1). 29 U.S.C. §1182(d)(3).

G. The GINA Regulations Enacted by the EEOC

On November 9, 2010 the EEOC issued its GINA related regulations. 29 C.F.R. Part 1635. These regulations became effective on January 10, 2011. *Id.*, at Summary. The EEOC acted pursuant to its authority granted by 42 U.S.C. §2000ff. The agency clarified the purpose for its regulations implementing Title II of GINA, found at 42 U.S.C. §2000ff et. sec., known as Title II of GINA, which is to implement the prohibition against the use of genetic data in employment decision making. 29 C.F.R. §1635.1(a)(1). The intent behind GINA is also to restrict employers and other entities subject to Title II of GINA from requesting, requiring or purchasing genetic data. 29 C.F.R. §1635.1(a)(2). Further, the regulations require that covered entities store genetic data as a confidential medical record and comply with strict limits on disclosure of such data. 29 C.F.R.§1635.1(a)(3). The regulations also clarify that GINA provides remedies for individuals whose genetic data is acquired, used, or disclosed in violation of the Act's protections. 29 C.F.R. §1635.1(a)(4).

There are exceptions to the scope and coverage of the EEOC's GINA regulations. They do not apply to covered entities to the extent the actions at issue do not relate to the status of an individual as an employee, member of a labor organization or participant in an apprenticeship program. 29 C.F.R. §1635.1(b). Such non-covered actions include a medical exam of an individual for diagnosis and treatment regarding something unrelated to employment, conducted by a healthcare professional at a hospital or other healthcare facility where the individual is an employee. 29 C.F.R. §1635.1(b)(1). Another exception encompasses activities of a covered entity carrying on in its capacity as a law enforcement agency investigating criminal conduct, even where the subject of the investigation is an employee of the covered entity. 29 C.F.R. §1635.1(b)(2). The first exception is intended to promote the control of a healthcare facility or hospital so as to combat disease or infection. The second exception, the "CSI exception," means that law enforcement officers of a covered agency may pursue their investigations to the extent otherwise provided by law, regarding the use of genetic data, and permits the use of such investigations as a part of a law enforcement agency's internal affairs investigations.

Another exception to the coverage of GINA includes alcohol and drug testing which is specifically described by the regulations as not constituting a genetic test. 29 C.F.R. §1635.3(f)(4). Again, alcohol and drug testing falls outside of GINA if it a test solely detecting the presence of alcohol or illegal drugs. 29 C.F.R. §1635.3(f)(4)(i). A test, however, to find whether an individual has a genetic predisposition for drug use or alcoholism does constitute a genetic test covered by the GINA regulations. 29 C.F.R. §1635.3(f)(4)(ii). Another example of a test or procedure that is not a covered genetic test includes an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes. 29 C.F.R.

§1635.3(f)(3)(i). Another test or procedure not covered by the GINA regulations is a medical exam that tests for the presence of a virus that is not composed of human DNA, RNA, chromosomes, proteins, or metabolites. 29 C.F.R. §1635.3(f)(ii). Another test falling outside the scope of the GINA regulations is a test for infectious and communicable diseases that may be transmitted through the handling of food. 29 C.F.R. §1635.3(f)(iii). Finally, an additional example of a medical exam or test falling outside the scope of GINA includes complete blood counts, cholesterol tests, and liver-function tests. 29 C.F.R. §1635.3(f)(iv).

The GINA regulations specify that genetic tests include but are not limited to the following:

1. **Tests to determine whether someone has the BRCA 1 or BRCA 2 variant indicating a predisposition to breast cancer;**
2. **A test to determine whether someone has a genetic variant associated with hereditary nonpolyposis colon cancer;**
3. **A test for a genetic variant for Huntington's Disease;**
4. **Carrier screening for adults using genetic analysis to determine the risk of conditions such as cystis fibrosis, sickle cell anemia, spinal muscular atrophy, or fragile X syndrome in future offspring;**
5. **Amniocentesis and other evaluations used to determine genetic abnormalities in a fetus during pregnancy;**
6. **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 commence before a disease manifests;**
7. **Pre-implantation genetic diagnosis performed on embryos created through the process of invitro fertilization;**
8. **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;**
9. **DNA testing to detect genetic markers associated with information about ancestry; and**
10. **DNA testing that reveals family relationships including paternity.**

29 C.F.R. §1635.3(f)(2)(i)-(viii).

For the individual, what is the scope of the regulations that encompass their "family". Specifically, a family member includes a dependent of the individual as a result of marriage, birth, adoption, or placement for adoption. 29 C.F.R. §1635.3(a)(1). The term "family member" also includes first, second, third, or fourth degree relatives of the individual or a dependant of the individual as previously referenced. 29 C.F.R. §1635.3(a)(2). The specific designations of first through fourth degree relatives are specified in the regulations at 29 C.F.R. §1635.3(a)(2)(i)-(iv).

H. What Genetic Data is Covered by the GINA Regulations?

Genetic data or information means information that includes the following:

i. **an individual's genetic tests;**
ii. **a genetic test of the individual's family members;**

iii. **the manifestation of disease or disorder in family members of the individual (family medical history);**
iv. **an individual's request for, or receipt of, genetic services, or the participation in clinical research that includes genetic services by the individual or a family member of the individual; or**
v. **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 an assisted reproductive technology.**

29 C.F.R. §1635.3(c)(1)(i)-(v).

Data specifically excluded from the regulatory definition of genetic information includes data about the sex or age of the individual person, 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. 29 C.F.R. §1635.3(c)(2).

The regulations state that family medical history equates with information about the manifestation of disease or disorder in family members of the covered individual. 29 C.F.R. §1635.3(b). Furthermore, the term, "manifestation" or "manifested" are specifically designed to mean with respect to a disease, disorder, or pathological condition to encompass an individual who has been or could reasonably be diagnosed with a disease, disorder, or pathological condition by a healthcare professional with appropriate training and expertise in a field of medicine involved, but such disease, disorder, or pathological condition is not manifested for purposes of the regulations if the diagnosis is based principally on genetic information. 29 C.F.R. §1635.3(g).

I. Who Receives the Protections of Title II of GINA?

Covered entities include any employer, employing office, employment agency, labor organization, or joint labor-management committee. 29 C.F.R. §1635.2(b). Covered employees include any individual employed by a covered entity, in addition to applicants for employment and former employees – if associated with an entity engaged in an industry affecting commerce that has 15 or more employees for each working day in each of 20 or more calendar weeks in the current or proceeding calendar year and any agent of such a person. 29 C.F.R. §1635.2(c)(1). Under GINA, the term employee is construed expansively to include a number of governmental employees at the federal, state, or political subdivision level, and certain appointed federal personnel. 29 C.F.R. §1635.2(c)(2)-(5). Similarly, a labor organization must have 15 or more members to be covered by the GINA regulations. 29 C.F.R. §1635.2(h). Moreover, members include applicants for membership in a labor organization. 29 C.F.R. §1635.2(i). The regulations also broadly define "person." 29 C.F.R. §1635.2(j).

J. Enforcement and Remedies

Under Title II of GINA, employees or union members may file an action pursuant to the Civil Rights Act of 1964 and assert discrimination claims. 29 C.F.R. §1635.10(a)(1) *cross-referencing* 42 U.S.C. 2000e-4 through 2000e-6 and 2000e-8 through 2000e-10. Persons protected by the Government Employees Rights Act may also pursue discrimination complaints

if they are a covered employee. 29 C.F.R. §1635.10(a)(2) cross-referencing 42 U.S.C. 2000e-16b through 2000e-16c and 29 C.F.R. part 1603. Other federal legislative and executive employees also have avenues to pursue GINA violation claims. 29 C.F.R. §1635.10(a)(3) through (a)(5).

The intent behind the separate regulation referring to remedies is to state that similar to other federal anti-discrimination laws, GINA provides for recovery of pecuniary and non-pecuniary damages, and compensatory and punitive damages. Such damages are recoverable for specified violations of §§202, 203, 204, 205, 206, and 207(f) of GINA. The remedies available include compensatory and punitive damages, subject to the limitations on the recovery of compensatory damages for future pecuniary losses, emotional pain, and suffering imposed by 42 U.S.C. §1981a. 29 C.F.R. §1635.10(b)(1). Therefore, punitive damages are not available for claims against federal, state or local government employers. *Id., citing*, 42 U.S.C. §1981a(a)(1) and (b) and Fed. Reg. Vol. 75, No. 216, 11/9/10 at 68929. Successful claimants may recover reasonable attorney's fees including expert fees to the extent permitted by 42 U.S.C. §1988(b),(c). 29 C.F.R. §1635.10(b)(2). Successful complainants may also obtain injunctive relief including reinstatement and hiring, back-pay, and other equitable remedies provided for and limited by 42 U.S.C. §2000e-5(g). 29 C.F.R. §1635.10(b)(3).

Furthermore, employers and covered entities are required to post notices regarding GINA in a format to be prepared or approved by the EEOC. 29 C.F.R. §1635.10(c)(1). Willfully failing to post such notices results in employers potentially being subject to a fine of not more than $100 for each separate offense. 29 C.F.R. §1635.10(c)(2).

K. The Manifestation of a Disease, Disorder, or Pathological Condition and its Consequences

The GINA regulations identify the manifestation of a disease, disorder, or pathological condition to mean that an individual has been or could reasonably be diagnosed with any such conditions by a healthcare professional with appropriate training and expertise in the field of medicine involved. 29 C.F.R. §1635.3(g). However, the same definition states that a disease, disorder, or pathological condition is not manifested if the diagnosis is principally based on genetic data. *Id*.

This definition of "manifestation" or "manifested," already significant, becomes even more relevant within the exceptions to the general prohibition against acquiring, requesting, or purchasing genetic data. A covered entity does not violate the general prohibition when it requests, requires, or purchases data about a manifested disease, disorder, or pathological condition of an employee whose family member is also an employee of the same entity. 29 C.F.R. §1635.8(c)(1). As an example, the regulations state that an employer will not violate the GINA regulations by asking someone whose sister also works for the employer to take a post-offer medical exam that does not include requests for genetic data. *Id*. Furthermore, a covered entity does not violate the GINA regulations by requesting, requiring, or purchasing genetic data or information about the manifestation of a disease, disorder, or pathological condition of an individual's family member who receives health or genetic services on a voluntary basis. 29 C.F.R. §1635.8(c)(2). The GINA regulations also provide that an employer does not commit an unlawful act by requiring genetic data 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*.

L. Employment Related Medical Examinations

The general rule barring the obtaining of genetic data including family medical history applies to medical exams related to employment. 29 C.F.R. §1635.8(d). That means a covered entity must tell healthcare providers not to collect genetic data, including family medical history, as part of a medical exam intended to determine the ability of an employee to perform a job. *Id*. Moreover, the covered entity must take reasonable measures within its control if it learns that genetic data is being requested or required. *Id*. The same regulation specifies that reasonable measures depend on the facts and circumstances arising from the request for genetic data and may include no longer using the services of a healthcare professional who continues to request or require genetic data during medical exams after being told not to do so. *Id*.

M. Confidentiality – How Do Employers Comply?

Covered entities that hold genetic data in writing about an employee or a member must keep such data on forms and in medical files, even if in electronic form, separate from personnel files and treat such data as a confidential medical record. 29 C.F.R. §1635.9(a)(1). A covered entity may maintain genetic data about an employee or a member in the same file in which it contains confidential medical information covered by the ADA. 29 C.F.R. §1635.9(a)(2). Genetic data that a covered entity receives verbally need not be reduced to writing or documented but may not be disclosed unless otherwise permitted by the GINA laws and regulations. 29 C.F.R. §1635.9(a)(3). Genetic data that a covered entity obtains through sources that are commercial and publicly available and subject to other regulations under GINA is not considered confidential genetic data, but may not be used to discriminate against individuals. 29 C.F.R. §1635.9(a)(4). Further, genetic data placed in personnel files before November 21, 2009 need not be removed. 29 C.F.R. §1635.9(a)(5). Therefore, a covered entity will not incur a liability under the regulations in GINA for the mere existence of such pre-11/21/09 data in the file. Id. Nevertheless, the rules barring the use of genetic data apply to all genetic data that meets the statutory definition, including where such information was requested, required, or purchased before November 21, 2009. *Id*.

In addition, the EEOC states that use of the following language in requests for medical records will render any production of genetic data inadvertent, and therefore not unlawful. While these regulations detail that covered entities include employers, employing offices, employment agencies, labor organizations and joint labor-management committees, 29 CFR 1635.2(b), the term employer is expansively defined to include any agent of an employer. 29 CFR 1635.2(d). Further, the definition for the term employee includes current and former employees, and applicants. 29 CFR 1635.2(c). The regulatory language to use in order to qualify for the inadvertent exception when requesting medical records on behalf of employers or other covered entities provides 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 CFR 1635.8(b)(1)(i)(B).

N. Exceptions to Limitations on Disclosure

Where covered entities have genetic data that was not acquired through commercially and publicly available sources, they may disclose such data to the employee or family member about whom the information pertains to upon receiving a written request from the employee or member. 29 C.F.R. §1635.9(b)(1). In addition, such information may be disclosed to an occupational or other health researcher if the research is conducted in compliance with specified federal regulations and protections. 29 C.F.R. §1635.9(b)(2) cross-referencing 45 C.F.R. part 46. Moreover, such information can be disclosed in response to a court order except that the covered entity may disclose only the genetic data expressly authorized by such order. 29 C.F.R. §1635.9(b)(3). However, if a court order was obtained without the knowledge of the employee or member to whom the information pertains, the covered entity shall inform the employee or member of the court order and any genetic data that was disclosed under the court order. *Id*. Moreover, genetic data may be disclosed to government officials investigating compliance under GINA if the data is relevant to the investigation. 29 C.F.R. §1635.9(b)(4). Further, such genetic data may be disclosed to the extent disclosure is made in support of an employees compliance with the FMLA certification requirements or similar requirements under State family and medical leave laws. 29 C.F.R. §1635.9(b)(5). Furthermore, genetic data may be disclosed to a federal, state, or local public health agency but only in connection with and regard to data about the manifestation of a disease or disorder that involves a contagious disease that presents an imminent hazard of death or life-threatening illness, and provided that the individual whose family member is the subject of the genetic data disclosure is notified of such disclosure. 29 C.F.R. §1635.9(b)(6).

O. The Regulatory Prohibitions

The GINA regulations clarify that an employer commits an unlawful act when it discriminates against an individual based on the genetic data of the individual in regard to hiring, discharge, compensation, terms, conditions, or privileges of employment. 29 C.F.R. §1635.4(a). Employment agencies may not fail or refuse to refer an individual for employment or otherwise discriminate against an individual because of that individual's genetic data. 29 C.F.R. §1635.4(b). Further, a labor organization may not exclude or expel a member from its organization or otherwise discriminate against a member because of that member's genetic data. 29 C.F.R. §1635.4(c). Similarly, an employer, labor organization, or joint labor-management committee controlling apprenticeship or other training programs may not discriminate against

individuals because of their genetic data in admission to, or employment in, any such program. 29 C.F.R. §1635.4(d).

The prohibitions extend to barring a covered entity from limiting, segregating, or classifying an individual because of that individual's genetic information. 29 C.F.R. §1635.5(a). The same provision also bars covered entities from failing or refusing to refer individuals for employment or in any way deprive or tend to deprive individuals of employment opportunities or affect their employment status because of such individual's genetic data. *Id.* However, a covered entity is not committing a violation of the GINA regulations if it limits or restricts the job duties of an employee based on genetic data because it was required to do by law or regulation requiring genetic monitoring, such as regulations promulgated by the Occupational and Safety Health Administration (OSHA), *Id., cross-referencing* 29 C.F.R. §1635.8(b)(5) and §1635.11(a).

P. Most Important for Employers - Beyond Compliance

The GINA regulations state that in spite of any language to the contrary, no cause of action alleging disparate impact is available under the Civil Rights Act of 1964, 42 U.S.C. §2000e-2(k). 29 C.F.R. §1635.5(b); see also 42 U.S.C. §2000ff – 7(a)("Notwithstanding any other provision of this Act, 'disparate impact,' as that term is used in section 2000e – 2(k) of this title, on the basis of genetic discrimination does not establish a cause of action under this Act.").

The Supreme Court has previously held that disparate impact claims were available under the Age Discrimination in Employment Act of 1967 ("ADEA"). *Smith v. City of Jackson*, 544 U.S., 228, 230-32 (2005). In that case, plaintiffs' disparate-treatment claim was that the City deliberately discriminated against them because of their age, and thereby paid the public safety officer plaintiffs over age 40 less than the officers under age 40. *Id.*, at 231. The plaintiffs' disparate-impact claim was that the City's pay plan itself adversely impacted them because of their age. Both the cited statutory and regulatory provisions eliminate the disparate-impact claim as a viable option for plaintiffs. Therefore, GINA plaintiffs are barred from establishing a prima facie case of genetic discrimination by showing that an employer or covered entity "uses a particular employment practice that causes a disparate impact" on the basis of genetic tests or data, under 42 U.S.C. §2000e – 2(k)(1)(A)(i), as plaintiffs can with other types of discrimination claims, including race, color, religion, sex, national origin, and now age under the cited *Smith* opinion. The significance of this distinction results in GINA plaintiffs having to prove some discriminatory intent on the part of defendant covered entities. *Lewis v. City of Chicago*, 130 S. Ct. 2191, 176 L.Ed.2d 967, No. 08-974, SCOTUS blog, http://www.supremecourt.gov-opinions-09pdf-08-974.pdf, [U.S. 5/24/10], slip op. at 8-9(discussing how disparate treatment plaintiffs must show deliberate discrimination, and explaining that disparate impact plaintiffs bear no such burden), *and citing*, *Ledbetter v. Goodyear Tire & Rubber Co.*, 550 U.S. 618, 640 (2007); *Lorance v AT&T Technologies, Inc.*, 490 U.S. 900, 904, 908-09 (1989).

Q. Most Important Provision for Consultants

Consultants for employers must keep in mind that the regulatory definition of employer encompasses the agents of employers. 29 C.F.R. §1635.2(c)(1), and (d). Further, a covered entity may not cause or attempt to cause another covered entity, or its agent, to the extent it is covered by GINA, to discriminate against an individual in violation of the regulations with

respect to an individual's participation in an apprenticeship or other training or retraining program or with respect to a member's participation in a labor organization. 29 C.F.R. §1635.6. The EEOC's analysis of its regulations seeks to clarify that use of the term "agent" does not impose individual liability on any person under GINA. Fed. Reg. Vol. 75, No. 216, 11/9/10, Rules and Regulations, at 68914. Unfortunately, the courts may have to determine the scope of any supposed covered entity liability as an agent.

R. Protection Against Retaliation

The GINA regulations detail that a covered entity is barred from discriminating against any individual who has opposed any act or practice made unlawful by GINA or its regulations or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing held under GINA or the cited regulations. 29 C.F.R. §1635.7.

S. May the Employer Acquire Genetic Data on the Free Market?

The general response to the stated inquiry is no. 29 C.F.R. §1635.8(a). As a result, unless it qualifies for an exception, a covered entity is barred from requesting, requiring, or purchasing genetic data of an individual, or family member of the individual, unless such activity qualifies for one of the specifically detailed exceptions. *Id*.

T. Exceptions to General Prohibition Against Acquiring Genetic Data

Exceptions to the general prohibition include where a covered entity inadvertently asks for or compels genetic data from an individual or an individual's family member. 29 C.F.R. §1635.8(b)(1). Requests for medical information are described as encompassing several situations, including where a covered entity obtains genetic data in response to a lawful request for medical information. Such an acquisition will not generally be considered inadvertant unless the covered entity directs the individual or healthcare provider from whom it requests information in writing or verbally not to provide genetic data. 29 C.F.R. §1635.8(b)(1)(i)(A).

** - The key regulatory language for attorneys handling cases where they represent employers or agents of employers is the provision containing the language to use in requests for medical information so as to qualify for the inadvertant exception. That language, again, is as follows:

> "The Genetic Information Non-Discrimination 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 and 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).

If an employer or its agent does not use the above quoted language, it may still qualify for the inadvertant exception if it can show that its request for medical information was not "likely to result in a covered entity obtaining genetic information," such as in the instance where an overly broad response is provided in response to a tailored request for medical data. 29 C.F.R. §1635.8(b)(1)(i)(C).

U. The Reasonable Accommodation Process Exception

The reasonable accommodation process undertaken by employers pursuant to the Americans with Disabilities Act ("ADA") often leads to employers trying to determine the medical status of the employee seeking a reasonable accommodation. The EEOC's GINA regulations and supplementary information indicate that a covered entity or employer is limited to requiring only the documentation that is needed to establish that a person has a disability within the meaning of the ADA, and to show that the disability requires a reasonable accommodation. Fed. Reg. Vol. 75, No. 216 on November 9, 2010 at 68921, containing analysis of §1635.8(b)(1)(i)(D)(1). As a result, the analysis and resulting final rule indicate that the medical documentation request can only be made in the reasonable accommodation context when the disability and/or the accompanying need for accommodation is not obvious. *Id.*, *see also,* 29 C.F.R. §1635.8(b)(1)(i)(D)(1). The EEOC clarifies its position in the following sentence contained in its summary information analysis of its regulations – "For example, an employer cannot request a person's complete medical records because they are likely to contain information unrelated to the disability at issue and the need for accommodation." Fed. Reg. Vol. 75, No. 216, 11/9/10, Rules and Regulations at 68921. Furthermore, if the individual seeking accommodation has more than one disability, the employer is limited to requesting data pertaining only to the disability that requires a reasonable accommodation. *Id*., *citing*, EEOC's Enforcement Guidance on Reasonable Accommodation and Undue Hardship Under the Americans with Disabilities Act, EEOC notice No. 915.002 (Oct. 17, 2002), available at http://www.eeoc.gov/policy/docs/accommodation.html. The EEOC again proclaims its intent to limit, if not eliminate, requests for the production of genetic data as part of the ADA accommodation process. ("The Commission knows of no reason why a covered entity would need to request genetic information to determine an individual's current physical or mental limitations and whether those limitations can be accommodated." Fed. Reg. Vol. 75, No. 216, 11/9/10 at 68921. Therefore, as a general rule, employers should keep in mind GINA's prohibitions against asking for, requiring, or purchasing genetic data as controlling during the interactive process employed to identify appropriate reasonable accommodations. *Id*.

V. Family and Medical Leave Act – Requests for Medical Records Under GINA

The EEOC's analysis of its regulations, provided in the summary information section of the Federal Register, indicates that a covered entity can inadvertently receive genetic data in circumstances where an employee's request for FMLA leave is to attend to the employee's own

serious health condition. Another inadvertant receipt of genetic data can occur in connection with the return to work certification requirements of the FMLA, even though an employee is not required to provide genetic data in either situation. Fed. Reg. Vol. 75, No. 216, 11/9/10, at 68921; See also 29 C.F.R. §1635.8(b)(1)(i)(D)(2). The general rule barring covered entities from requesting, requiring, or purchasing genetic data does not apply where the covered entity asks for family medical history in order to comply with the certification provisions of the FMLA, or state or local family medical leave laws, or pursuant to a policy that permits the use of leave to care for a sick family member and that requires all employees to provide data about the health condition of the family member to substantiate the need for leave. 29 C.F.R. §1635.8(b)(1)(i)(D)(2).

W. Other Exceptions to Prohibition of Acquiring Genetic Data

Additional exceptions may encompass an instance where a covered entity asks for documentation to support an employee's request for leave that is not governed by federal, state, or local laws requiring leave, but only if the documentation sought to support the request otherwise complies with ADA requirements, or complies with any other laws limiting access to medical information by a covered entity. 29 C.F.R. §1635.8(b)(1)(i)(D)(3).

Other inadvertant acquisition exceptions to the general prohibition against acquiring genetic data include situations where a supervisor learns genetic data about an individual by overhearing a conversation between the individual and other persons. 29 C.F.R. §1635.8(b)(1)(ii)(A). Another exception occurs when the acquisition of genetic data involves communications where a covered entity, acting through a supervisor or other official, receives family medical history directly from an individual following a general health inquiry. 29 C.F.R. §1635.8(b)(1)(ii)(B)(consisting of questions such as "how are you?" or "did they catch it early?"). The same exception also encompasses situations where casual questions between colleagues or a supervisor and subordinate touch on the general well-being of an individual's parent or child. *Id.*, ("how's your son feeling today?"). Furthermore, the same exception governs situations where an employee participates in casual conversation that leads to disclosure of a family member who was just diagnosed with cancer. *Id.*, ("will your daughter be ok?"). Covered entities can lose the protection provided by this exception by following up such a casual conversation or question with probing inquiries including asking whether other family members of the individual have the same condition or whether the individual has been tested for the condition. Id. The regulatory reason for losing such an exception is that such questions should put the covered entity on notice that it is likely to result in obtaining genetic data through such probing questions. Id.

One specified exception to the general prohibition specifically cites the use of social media. For example, if a manager, supervisor, union representative, or employment agency representative inadvertently learns of genetic data through use of a social media platform, which he or she was given permission to access by the creator of the profile, then such acquisition of genetic data qualifies for the inadvertant acquisition of genetic data exception to the general prohibition against acquiring such data. 29 C.F.R. §1635.8(b)(ii)(D). Furthermore, the general rule barring covered entities from acquiring genetic data does not apply where the covered entity obtains genetic data from documents commercially and publicly available for review or purchase, such as newspapers, magazines, periodicals or books, or through electronic media. This exception, however, does not apply to medical databases, court records, or research

databases available to scientists on a restricted basis. Nor does the exception encompass genetic data acquired through sources with limited access, such as social networking sites or other media sources that require the granting of permission from the specific individual, unless such access is routinely granted to all who request it. The inadvertant exception also does not allow a covered entity to obtain genetic data through commercially and publicly available sources if the covered entity sought access to such data with the intent of obtaining genetic data. In addition, the inadvertant exception does not permit a covered entity to obtain genetic data through media sources, whether publicly available or not, if the covered entity is likely to acquire genetic data by accessing such sources, including websites and online discussion groups that focus on genetic testing and genetic discrimination issues or similar matters. 29 C.F.R. §1635.8(b)(4)(i)-(iv).

Covered entities are permitted to acquire genetic data for use in genetic monitoring of the biological effects of workplace toxic substances. The covered entity, however, must provide written notice of the monitoring to the individual along with the individual monitoring results. 29 C.F.R. §1635.8(b)(5). Moreover, the covered entity may not retaliate or otherwise discriminate against an individual should he or she refuse to participate in genetic monitoring that is not required by federal or state law. *Id*. In order to qualify for the genetic monitoring exception, a covered entity must show that such monitoring is either required by federal or state law regulation, or is conducted only where the individual previously gave a knowing, voluntary, and written authorization. The authorization form used must be reasonably likely to be understood, and must detail the genetic data to be obtained, and must describe the restrictions on disclosing genetic data. The genetic monitoring must be conducted in compliance with any federal genetic monitoring regulations such as those promulgated by the Secretary or Labor, or pursuant to State genetic monitoring regulations. 29 C.F.R. §1635.8(b)(5)(i)-(ii). Moreover, such monitoring programs must provide for the reporting of the monitoring results to the covered entity in aggregate terms that do not identify a specific individual, while permitting such individually identifiable data to be provided to a licensed healthcare professional or board certified genetic counselor involved in the genetic monitoring program. 29 C.F.R. §1635.8(b)(5)(iii).

X. Wellness Programs – GINA and the Health Insurance Portability and Accountability Act ("HIPAA")

The GINA regulations permit covered entities to provide certain kinds of financial inducements to encourage employee participation in health promotion activities or genetic services under certain circumstances. Nevertheless, covered entities may not offer any inducement for individuals to provide their genetic data. Fed. Reg. Vol. 75, No. 216, 11/9/10 at 68923. The specific regulation states that a covered entity may qualify for certain regulatory exceptions when offering a voluntary wellness program, but only where the individual's act of supplying genetic data is voluntary. The non-penalty requirement means that such individuals are not penalized should they provide genetic data. 29 C.F.R. §1635.8(b)(2)(i)(A). Moreover, the individual who provides such data must do so through a knowing, voluntary, and written authorization which can be obtained in an electronic format. 29 C.F.R. §1635.8(b)(2)(i)(B). The authorization form must be written so that the individual executing the form is likely to understand it. The form must also detail the type of genetic data obtained, and state the general purposes for which it will be employed, and specify the restrictions on disclosing such genetic data. *Id*. 29 C.F.R. §1635.8(b)(2)(i)(B)(1)-(3). Moreover, the individually identifiable genetic

data may be provided only to the individual and the licensed healthcare professionals or board certified genetic counselors involved in providing such services. Therefore such data cannot be accessible to managers, supervisors, or others who make employment decisions, and cannot be accessible to anyone else in the workplace. 29 C.F.R. §1635.8(b)(2)(i)(C). Moreover, to the extent any such individually identifiable genetic data supplied by the individual is used, it may only be available for purposes of such services and cannot be disclosed to the covered entity except in aggregate terms that do not identify a specific individual. 29 C.F.R. §1635.8(b)(2)(i)(D).

The GINA regulations do not apply to genetic data that is protected health information subject to the regulations issued by the Secretary of Health and Human Services under §264(c) of HIPAA. See 29 C.F.R. §1635.9(c); 29 C.F.R. §1635.11(d).

The GINA regulations also show how an employer may use a $150 offer to employees to complete a health-risk assessment containing 100 questions. The financial inducement must be clarified as being provided to all employees who respond to the 80 questions that do not concern family medical history or genetic data. Therefore, the wellness assessment questionnaire must clarify that for the questions seeking family medical history or other genetic data, no answers are required in order to qualify for the financial inducement. 29 C.F.R. §1635.8(b)(2)(ii)(A). However, an assessment form that does not clarify which questions request genetic data, or that fails to make obvious which questions must be answered in order to qualify for the financial inducement, results in violating Title II of GINA. 29 C.F.R. §1635.8(b)(2)(ii)(B).

Moreover, employees who voluntarily disclose a family medical history, for example, of diabetes, heart disease, or high blood pressure on a health-risk assessment form that meets GINA regulatory requirements, permits an employer to offer $150 to such persons who have a current diagnosis of such conditions to participate in a wellness program to encourage weight loss and a healthy lifestyle. 29 C.F.R. §1635.8(b)(2)(iii)(A). Also acceptable under the GINA regulations is an identical program that additionally offers more inducement to individuals who obtain certain health outcomes. Such examples include programs where participants earn points toward prizes totaling $150 in a single year for lowering their blood pressure, glucose and cholesterol levels, or for losing weight. 29 C.F.R. §1635.8(b)(2)(iii)(B).

One final warning, the GINA regulations state that nothing contained therein limits the rights or protections provided to an individual under the Americans with Disabilities Act, (ADA) or the Civil Rights Laws, or the Health Insurance Portability and Accountability Act (HIPAA), even as amended by GINA. 29 C.F.R. §1635.8(b)(2)(iv).

II. HIPAA NON-DISCRIMINATION REGULATIONS

Under HIPAA, a group health plan and covered health insurance issuer:

> …may not establish rules for eligibility, (including continued eligibility), of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependant of the individual:
>
> (a) Health status,
> (b) Medical condition (including both physical and mental illnesses),
> (c) Claims experience,

(d) Receipt of health care,
(e) Medical history,
(f) Genetic information,
(g) Evidence of insurability (including conditions arising out of acts of domestic violence), and
(h) Disability.

42 U.S.C. §300gg-1(a).

A subsequent provision in the same statutory section of HIPAA generally categorizes as unlawful actions by employer sponsored health plans to vary individual premium contributions based on the health status of an employee or covered dependent. 42 U.S.C.§300gg-1(b)(1). Yet nothing in the rule restricting the variation of individual premiums bars the employer from being charged more for group coverage, as long as the health insurance issuer does not commit unlawful group based discrimination. 42 U.S.C. §300gg-1(b)(1), (3).

Nevertheless, HIPAA states it should not be construed to bar a group health plan, or a covered health insurance issuer, from establishing premium discounts or rebates, or modifying otherwise applicable copayments or deductibles, in return for adherence to qualified wellness programs. 42 U.S.C. §300gg-1(b)(2)(B).

The federal regulations provide for the enforcement of the nondiscrimination HIPAA provision by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services since the joint rules became effective on July 1, 2007. 71 Fed. Reg. 75014 (Dec. 13, 2006), codified at 26 CFR Part 54, 29 CFR Part 2590, and 45 CFR Part 146. The rules, which these three federal agencies are jointly tasked with enforcing, seek to procure nondiscrimination in wellness programs and health coverage in the group market. The following programs, discussed in the cited rules, need not satisfy the bona fide wellness program elements of the nondiscrimination HIPAA regulations so long as participation in such programs are made available to all similarly situated individuals pursuant to:

(1) A program that reimburses all or part of the cost for membership in a fitness center;
(2) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes;
(3) A program that encourages preventive care through the waiver of a deductible or copayment requirement under a group health plan for the cost of, for example, prenatal care or well-baby visits;
(4) A program that reimburses employees for the cost of smoking cessation programs, without regard to whether the employee actually quits smoking; and
(5) A program that provides a reward to employees for attending a monthly health education seminar.

29 CFR §2590.702(f)(1).

However, more detailed regulations govern if the employee must satisfy conditions for obtaining a reward that involve meeting a standard connected to a health factor. In those circumstances, the following provisions must be met:

(1) The reward for the wellness program, in this instance, a weight loss program, must not exceed 20% of the cost of employee-only coverage under the plan or, if dependents are also covered under the plan, 20% of the cost of the employee and any dependents covered under the plan. In other words, the coverage cost is determined based on the total amount of employer and employee contributions for the benefit package under which the employee currently receives coverage. Moreover, every reward for participation can include a discount, rebate of a premium, or waiver of all or part of a cautionary mechanism such as co-payments and deductibles, subject to the 20% figure.

(2) The program must be reasonably designed to promote good health or to prevent disease. Individuals must be given the chance to qualify for the reward under the program at least once a year, to show their eligibility, in order to establish that the program is reasonably designed to promote good health or to prevent disease.

(3) The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(4) The reward under the program must be available to all similarly situated individuals. Therefore, covered employees or individuals with documented medical conditions must receive an opportunity to qualify for the reward by alternative means.

(5) The plan must disclose in all plan materials detailing the program, the availability of a reasonable alternative standard or waiver of the applicable standard. In such plan materials, an employer may provide language that details the availability of a reasonable alternative without specifying exact terms. 29 CFR §2590.702(f)(2)(i)-(v). For example, such plans might provide the following:

> [If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] or contact us at [e-mail] and we will work with you to develop another way to qualify for the reward.]

The above discussed regulations regarding reasonable alternatives will likely prove critical in administering a successful wellness weight loss program. Some affected employees, particularly in situations where health plans provide for significant reductions in employee premiums pegged on weight loss, may challenge the qualifying standard. Such employees may also question the time they are allotted to satisfy the weight loss standard and the method for determining whether they have met such standards and any rules regarding relapses.

With these contrasting concerns and objectives kept in mind, specific issues may arise from the administration and formulation of weight loss or other wellness programs which may include the following:

Given the maximum permissible reward of 20% of the health plan cost, and the ever rising nature of health plan costs, will some employees perceive such an incentive as a financial figure forcing them to participate, even though a substantial incentive to participate in the program is expressly permissible under HIPAA?

Employers should understand that a good faith standard governs the determination of whether a wellness program is reasonably designed to promote health and to prevent disease. Under the good faith standard, absent discriminatory or other unlawful actions, some deference is given to the actions of plan sponsors in formulating a weight loss wellness program. Still, employers must also consider whether simply providing an alternative method for qualifying for a reward that satisfies the HIPAA regulation also complies with the ADA, the GINA amendments to the Civil Rights Act, and the GINA regulations.

As part of HIPAA, Congress directed the Secretary of Health and Human Services to promulgate privacy standards for individually identifiable health information. These standards are generally known as the "privacy rule." 45 CFR Parts 160, 164. The intent behind the HIPAA privacy rule is to both provide for more efficient health claims processing through standard electronic transactions while simultaneously protecting the privacy of patients' health information conveyed through electronic transactions. *Id*.

The privacy rule governs only three types of covered entities: healthcare providers, health clearinghouses, and health plans. 45 CFR §160.102. The privacy rule does not apply to employers, life insurers, schools or other persons that may have health information unless they perform functions of a covered entity, such as providing and billing for health services. [Remember – the GINA amendments impose separate privacy obligations on employers, and other covered entities.].

Determining whether the privacy rule applies to an employment situation is not always a simple endeavor. As stated, employers are not covered entities under the HIPAA privacy rule. Yet employer sponsored health plans are covered by the privacy rule. 45 CFR §160.103. As a result, employers must separate their covered functions, such as health benefits, from non-covered functions, such as human resources. To do so requires separately maintaining and compiling health claims information separately and apart from personnel data. 45 CFR §164.504(c)(2). Even though the Department of Health and Human Services has not filed numerous enforcement actions in court under the privacy rule, some employers may fail to appreciate or understand the care they should take to separately maintain such data and records. Moreover, employers must stay aware of the potential for abuse of their databases that can cause unauthorized access to or mixing of such covered records and non-covered records.

In §13404 of the American Recovery and Reinvestment Act of 2009. Pub. L. 111-5 (2009), Congress broadened the privacy rule to cover business associates of covered entities. This amendment bears significance because many contracts between vendors and employers are

even titled as "business associate" contracts. Employer sponsored health plans use such contracts to procure wellness program services. In such agreements, vendors typically promise to comply with the HIPAA privacy rule. As first issued, the privacy rule did not cover business associates. 45 CFR §164.5.1(e)(1). Now, with the cited 2009 legislation, Congress compels covered entities to monitor the actions of their business associates and insist that business associates correct practices that violate the HIPAA privacy rule. The practical effect of the 2009 Congressional legislation is that employers may need to consider methods of evaluating their vendors' compliance with the HIPAA privacy rule. Such monitoring efforts, for example, could include technological audits to be paid for and provided by the employer or vendor as part of such contracts. Indeed, as a result of the HIPAA amendments contained in the Health Information Technology for Economic and Clinical Health Act, (the "HITECH Act"), the discussed heightened privacy and security standards of HIPAA apply both to covered entities and their business associates. 42 U.S.C. §§17931, 17934.

In sum, records generated by running an employee wellness program should be treated as confidential material. Illinois federal courts have previously recognized the privacy of medical records under HIPAA and Illinois law. For example, the Seventh Circuit affirmed a trial court ruling quashing a subpoena served by the U.S. Department of Justice. The subpoena sought various redacted abortion proceeding records from a Chicago hospital. When affirming the district court's ruling quashing the subpoena, the court stressed the privacy protections afforded by HIPAA and the more stringent Illinois privilege afforded medical records, even when certain data was redacted. *See, Northwestern Memorial Hospital v. Ashcroft*, 362 F.3d 923, 924-25 (7th Cir. 2004), *citing*, 42 U.S.C. §1320d-2, Note, 45 C.F.R. §§160.202(6), 160.203(b), and 735 ILCS 5/8-802.

In addition, employees may exercise their right to stop release of their medical information pursuant to a revocable HIPAA release. If the doctor or healthcare provider of the employee has not released any protected information in reliance on a previously signed release, then there has been no waiver of the HIPAA privilege. *See, Koch v. Cox*, 489 F.3d 384, 391-92 (D.C. Cir. 2007). The *Koch* plaintiff also successfully argued that he had not put his depression at issue because he made no claim for recovery of damages based on his mental or emotional state in his lawsuit that alleged violations of the ADEA, the ADA, and other laws. *Id.* at 391.

III. FACTORS TO CONSIDER UNDER THE AMERICANS WITH DISABILITIES ACT ("ADA")

The EEOC can respond to disability-related inquiries and did so on March 6, 2009 through a letter published on its website. The posting does not identify the employer recipient. The responding EEOC counsel recounted the inquiry as a county employer asking whether it could require employers to participate in a health risk assessment as a condition for participating in its health insurance plan. In a January 6, 2009 letter from EEOC legal counsel, the agency asserted that although the EEOC had not taken a formal position, it believed that the policy would violate provisions of the ADA, which required disability-related questions or medical examinations of employees to be job-related and consistent with business necessity. 42 U.S.C. §12112(d). The EEOC response then proceeded to describe the circumstances under which employers could offer employees inducements to participate in wellness programs without violating the ADA. To be ADA compliant, a wellness program would first be voluntary. Second, any disability-related inquiries or medical exams conducted in connection with such a program would not violate the ADA as long as the inducement to participate in the program did

not exceed 20% of the cost of the employee's [plus any dependents'] coverage under the plan, consistent with the HIPAA regulations.

On March 6, 2009 the EEOC wrote again to state that because the employer's letter did not raise the question of what level of inducement to participate in the program was permissible under the ADA, the EEOC rescinded the portion of its January 6, 2009 letter that discussed that issue and enclosed a revised letter. The revised letter reveals that the EEOC continues to examine what level, if any, of financial inducement to participate in an employer's wellness program is permissible under the ADA. In the revised letter, the EEOC counsel stated that while the agency had not taken a formal position, it would appear that requiring employees to take a health risk assessment that encompasses disability-related inquiries, and medical exams, all in order to obtain health insurance coverage, did not appear to be job-related and consistent with business necessity. Therefore, the employer's policy violated the ADA.

Disability-related inquiries or medical exams of employees may be job related and consistent with business necessity when an employer has "a reasonable belief, based on objective evidence, that; (1) an employee's ability to perform essential job functions will be impaired by a medical condition; or (2) an employee will pose a direct threat due to a medical condition." March 6, 2009 EEOC letter citing Q&A 5, at 405:7708. The cited enforcement guidance is what the EEOC relied upon when further noting that an employer may pursue disability-related information, or require a medical exam that follows up on a "request for reasonable accommodation when the disability or need for accommodation is not known or obvious." *Id*., Q&A 7&10, at 405:7711,7713. [*See also*, GINA Regulations, 29 C.F.R. §1635.8(b)(1)(i)(D)(1).] In addition, such inquiries and medical exams are described by the EEOC as permitted where the examination or other monitoring conduct is performed under specific circumstances, such as periodic medical exams required of employees in public safety jobs. *Id.*, Q&A at 14-20, 405:7715-18.

Finally, of specific interest for wellness programs, the [revised] March 6, 2009 EEOC letter states the following:

> "Disability-related inquiries and medical examinations are also permitted as part of a voluntary wellness program. A wellness program is voluntary if employees are neither required to participate nor penalized for non-participation. *Id*. Q&A 22, at 405:7718-19. In this instance, however, an employee's decision not to participate in the health-risk assessment results in the loss of the opportunity to obtain health coverage through the employer's plan. Thus, even if the health-risk assessment could be considered part of a wellness program, the program would not be voluntary, because individuals who do not participate in the assessment are denied a benefit (i.e. penalized for non-participation) as compared to employees who participate in the assessment.

(EEOC March 6, 2009 Letter ADA: Disability-Related Inquiries and Medical Examinations; Health-Risk Assessment).

The ADA bars discrimination by employers on the basis of an employee's disability. The Act applies to state and local government employers and private sector employers who have 15 or more employees. 42 U.S.C. §§12101-12213; 42 U.S.C. §12111(5)(A). The Rehabilitation

Act is the federal law governing the disability discrimination claims of federal government employees. 29 U.S.C. §791(a). The ADA places limits and conditions on the category of medical examinations and questions an employer may use depending on the state or phase of the employment relationship. For example, before an employment relationship is established, employers shall not ask applicants whether they have a disability. At this stage, employers may only ask an applicant about the ability to perform job related functions. Following a conditional offer of a job, an employer may then compel a medical examination. A conditional job offer may not be withdrawn by the employer for a health reason unless the applicant, with or without reasonable accommodation, cannot perform the essential functions of the job. With respect to current employees, employers may not require such employees to have medical examinations or to answer medical related questions unless such measures are job related and consistent with business necessity. 42 U.S.C. §12112(d)(4)(A).

The ADA treats wellness programs differently. An employer "may conduct voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at the work site." 42 U.S.C. §12112(d)(4)(B). Consequently, the presentation of a health risk reduction program ("HRRP") to current employees would not violate the ADA. Yet employers should stay aware of the possibility that financial inducements associated with HRRPs could potentially violate the ADA if they have the affect of discriminating against employees on the basis of disability. For example, if the reduction in health plan premiums or receipt of rewards is based on eligibility factors that exclude employees with certain physical impairments, there is potential ADA liability exposure. Second, the provision of benefits for satisfying specific health promotion plan targets must also be evaluated for potential ADA liability exposure. If specified targets cannot be met by certain employees due to their disability that prevents them from satisfying the target, and winning the associated reward, then potential ADA liability exposure exists when no alternative targets are provided.

With respect to health plan information, the ADA also requires employers to store health information in files separate and apart from Human Resources records. There are those who have contended that whether or not an individual has satisfied the definition of an individual with a covered ADA disability, the ADA is violated if the following three sets of records become mixed and are not kept or maintained separately:

- **i.** Employee personnel information that does not have any health information,
- **ii.** Employee health information procured by medical examinations and inquiries; and
- **iii.** Health plan claims data and Health Risk Reduction Program information.

Rothstein Ma, Craver CB, Schroeder EP, Shoben EW, *Employment Law*, 3rd Ed. Vol. 1. St. Paul, MN: Thomson/West; 2004: 463.

Federal courts have examined the issue of what may or may not constitute a reasonable accommodation at the workplace. The key component of this inquiry focuses on whether a specific task constitutes an essential function of the job, or is a marginal function of the position. This analysis proves crucial when courts must decide whether an individual is qualified for the job at issue under the ADA. In *EEOC v. Wal-Mart Stores, Inc.*, 477 F.3d 561, 568-69 (8th Cir.

2007), separate and apart from the issue of pretext, or what reasons the employer gave for not hiring a candidate for the jobs of cashier or greeter, the court's discussion of reasonable accommodation provides concrete examples of how the accommodation process works:

> Second, the EEOC has made a "facial showing" that a reasonable accommodation would enable Bradley to perform the essential functions of both the greeter and cashier positions. Jayne, the EEOC's main expert, proposed specific accommodations that would enable Bradley to have the requisite mobility and standing required for both jobs. For the cashier position, Jayne suggested several accommodations, including a sit-to-stand wheelchair, a drafting-type high stool with arm rests for additional balance, a narrow wheelchair, the removal of several inches of the divider beside the check stand to accommodate a regular wheelchair, supplying Bradley with a hand scanner, and installing a convex mirror. For the greeter position, Jayne recommended that Bradley use an electronic scooter or similar device.

EEOC v. Wal-Mart Stores, Inc., 477 F.3d at 569.

The quoted portion of the above Wal-Mart opinion suggests that employers perform individualized assessments of what elements comprise a job position. Employers may also apply the same analytical framework to employee wellness programs so as to broaden the extent of their potential use by employees. Nevertheless, the Eighth Circuit has also held that where an employee says that he had numerous devices that he can use to perform the job, such a statement is not considered a request for an accommodation. Buboltz v. Residential Advantages, Inc., 573 F.3d 864, 870 (8th Cir. 2008). Still, employers should view themselves as generally bearing the burden of making their weight loss wellness programs open to employees, whether or not a proper request for an accommodation is made under the ADA. In recent amendments to the ADA, Congress overruled contrary Supreme Court precedent [Sutton v. United Air Lines, Inc., 527 U.S. 471 (1999)], to the extent it instructed courts to consider the effects of all ameliorative medicines and devices when determining if a plaintiff is disabled, Pub. L. No. 110-325, §3(4)(E)(i), *codified at*, 42 U.S.C. §12102(4)(E)(i)(I)-(IV). Moreover, the ADA regulations define "reasonable accommodation," as including "[m]odifications or adjustments" to application processes, work environment, and access to benefits and privileges of employment. 29 C.F.R. §1630.2(o)(1); *see also*, 42 U.S.C. §12111(9) (discussing in subparagraph (A) that example of "reasonable accommodation" includes "[m]aking existing facilities used by employees readily accessible to and usable by individuals with disabilities;"), *and see examples in*, 29 C.F.R. §1630.2(o)(2).

As an example of possible over-cautiousness, the Ninth Circuit found that an issue of fact arose over whether an employer may properly rely on a safety regulation, beyond the scope of its coverage, when preventing hearing impaired drivers from operating certain categories of trucks. *Bates v. United Parcel Service, Inc.*, 511 F.3d 974, 998 (9th Cir. 2007); *see also, Rohr v. Salt River Project Agricultural Imp. and Power Dist.*, 555 F.3d 850, 862 (9th Cir. 2009)(stating that absence of annual respirator certification did not bar plaintiff's ADA claim). Employers should also remain mindful that there are those who have postulated that if a health risk assessment identifies an employee as having an increased risk of a disabling condition, or of using greater

amounts of healthcare resources, such data might implicate the ADA. Health Risk Reduction Programs and Employer-Sponsored Health Plans: Part II-Law and Ethics, M. Rothstein, H. Harrell, Journal of Occupational and Environmental Medicine, Vol. 51, No. 8, August 2009 at 953.

Moreover, the ADA provides claimants with a type of claim known as "association discrimination." The ADA bars an employer from discriminating against an employee as a result of "the known disability of an individual with whom [the employee] is known to have a relationship or association." 45 U.S.C. §12112(b)(f). Such claims are known as "association discrimination." While federal courts have struggled over how to interpret and apply the "association discrimination" provision contained in the ADA, the Seventh Circuit has underscored that an employer may incur liability under this provision. In *DeWitt v. Proctor Hospital*, 517 F.3d 944 (7th Cir. 2008), *appeal after remand*, 381 Fed. Appx. 585 (7th Cir. 2010)(affirming summary judgment for employer), the former employee's husband was receiving extensive chemotherapy radiation and cancer treatment. The employer was self insured and paid for the covered medical costs of its members up to $250,000 per year. In the two years leading up to the former employee's discharge, the annual medical claim dollar figure for the employee's husband jumped from $71,684 to $177,826. During the last eight months of her employment, the expenses were $67,281.00. The plaintiff was fired in August 2005 and designated as ineligible for rehire. The employer provided no explanation for designating the plaintiff as ineligible for rehire. The plaintiff's husband died in August 2006. The *DeWitt* court examined prior case law and explained how a plaintiff with a claim of association discrimination, who lacked direct evidence of discrimination, could prove a case. To succeed, the plaintiff must establish that:

i. She was qualified for the job at the time of the adverse employment action;
ii. She was subjected to an adverse employment action;
iii. She was known by her employer at the time to have a relative or associate with a disability; and
iv. Her case falls into one of three relevant categories of:
(1) Expense
(2) Disability by association
(3) Distraction

Under the expense scenario, the *DeWitt* court noted that an employee fired because his spouse has a disability that is costly to the employer, and is covered by the company's health plan, falls within the intended scope of the association discrimination provision of the ADA.

In *DeWitt*, however, the court found that the plaintiff had substantial circumstantial evidence which suggested that her case should best be viewed as relying on direct evidence. Such evidence would permit the jury to conclude that the employer, facing a significant financial struggle of unknown length, displayed concerns through communications about the status of plaintiff's husband as a cancer patient for an indefinite period of time. The court also noted that the evidence reflected that the employer terminated the plaintiff's employment within three months after warning employees about impending "creative" cost-cutting measures. The *DeWitt* court concluded that a reasonable jury could find that the motivation shown by plaintiff's direct evidence could establish that "association discrimination" may have motivated the employer in

its decision to terminate the plaintiff. Therefore, material and genuine issues of fact precluded summary judgment. Given the *DeWitt* interpretation of the association discrimination provision in the ADA, wellness programs aimed at weight loss or the objectives must steer clear of the association discrimination provision of the ADA.

Interestingly, in *DeWitt*, the Seventh Circuit also examined whether § 510 of ERISA applied and provided plaintiff with another cause of action. Under § 510, an employer may not terminate "a participant or beneficiary for exercising any right to which he is entitled under the provisions of the employee benefit plan." 29 U.S.C. §1140. The intent behind the ERISA provision is to discourage or prevent employers from firing or harassing their employees as part of an attempt to stop them from using their pension or medical benefits. *Id.* The *DeWitt* plaintiff urged on appeal that the trial court erred in barring her from amending her complaint to add an ERISA retaliation claim. In this context, the *DeWitt* court had to decide whether the trial court ruling, rejecting the proposed amendment as futile, survived a motion for summary judgment. Because the employer had not argued that the plaintiff was fired for insubordination, the *DeWitt* court found that the plaintiff should have been allowed to amend her complaint to add an allegation of ERISA retaliation. The court found that a reasonable jury could find that the employer retaliated against the plaintiff and thereby committed an ERISA violation. The court also, however, noted that on remand, given that the plaintiff's ERISA retaliation claim overlapped with her earlier discussed ADA claim, both claims asked the same question – why did the employer fire the plaintiff? The *DeWitt* court suggested that, on remand, the trial court should give "some thought" as to whether having two claims rather than one did anything other than unduly complicate the case. *Id.* Still, the Seventh Circuit reversed the trial court's decision denying the plaintiff's motion for leave to amend her complaint and left it to the district court and parties to decide how to proceed.

The potential for ADA liability exposure also exists for an employer who perceives an employee with a genetic condition as disabled. One such example could possibly involve an employer viewing an obese employee as disabled. The Supreme Court explained this possibility more than a decade ago when distinguishing employees who prove they have a disability that qualifies as a physical or mental impairment that substantially limits one or more of their major life activities, under 42 U.S.C. §12102(2)(A), from employees who show that their employers regard them as disabled, even though they do not actually have a substantially limiting impairment. The "perceived" disabled employee is still protected by the ADA under 42 U.S.C. §12102(2)(C).

There are two ways in which "perceived" disabled individuals may fall within this statutory definition:

> 1. A covered entity mistakenly believes that a person has a physical impairment that substantially limits one or more major life activities, or
> 2. A covered entity mistakenly believes that an actual, non-limiting impairment substantially limits one or more major life activities.
>
> In both cases, it is necessary that a covered entity entertain misperceptions about the individual – it must believe either that one has a substantially limiting impairment that one does not have

> or that one has a substantially limiting impairment when, in fact, the impairment is not so limiting.

Sutton v. United Air Lines, Inc., 527 U.S. 471, 489 (1999).

Nevertheless, the Sixth Circuit later held that non-physiological morbid obesity does not qualify as an impairment under the ADA. *EEOC v. Watkins Motor Lines, Inc.*, 463 F.3d 436, 441-443 & n. 3 (6th Cir. 2007). The *Watkins* court bolstered its analysis by citing the regulatory requirement that a "physical impairment" must qualify as a physiological disorder or condition. *Id.* at 441, *citing*, 29 C.F.R. §1630.2(h)(1). Indeed, relying on *Sutton*, the *Watkins* court stressed if a physical characteristic does not qualify as an impairment, employers are free, [pre-GINA], to prefer one physical characteristic over another. *Id.*, *citing*, *Sutton*, 527 U.S. at 473. In *Watkins,* the EEOC failed to even establish that the employee suffered from a type of obesity that qualified as an ADA impairment. Therefore, the court never considered whether the employer perceived the plaintiff driver and dock worker as substantially limited in any of his major life activities. *Id.* at 438, 443. The *Watkins* holding, however, must be read as only addressing the second prong of the *Sutton* framework – that an employer mistakenly believes that an employee has an actual, non-limiting impairment that substantially limits one or more major life activities when no such impairment is present. *Id.* at 440. Therefore, any employer that still mistakenly believes that an obese or overweight employee has a physical impairment that substantially limits one or more major life activities can still have exposure to a "perceived" disability discrimination claim under the first prong of the *Sutton* analysis, where an ADA impairment does exist, but does not limit one or more major life activities of the employee.

Congress has not expressly rejected this portion of the *Sutton* holding. Instead, for purposes of specifying what type of employer conduct qualifies as an employer perceiving or regarding an employee as having an impairment under 42 U.S.C. §12102(1)(C), Congress delineated as follows:

> An individual meets the requirement of "being regarded as having such impairment" if the individual establishes that he or she has been subjected to an action prohibited under this chapter because of an actual or perceived physical or mental impairment whether or not the impairment limits or is perceived to limit a major life activity.

42 U.S.C. §12102(3)(A).

The above formulation does not apply to transitory and minor impairments that have an actual or expected duration of six months or less. 42 U.S.C. §12102(3)(B). Subsequent federal court opinions will instruct how the newly configured or remodeled version of "perceived as" disability discrimination will apply under the ADA amendments, post-GINA. It would appear, however, that employers, before taking action against employees based on perception, might consider evaluating an employee's job performance abilities, obtain an objective assessment of job performance duties or functions, and look at the entire picture within the framework of business necessity.

IV. ILLINOIS LAW ON GENETIC DATA AND RELATED PRIVACY ISSUES

The Illinois legislature passed the Genetic Information Privacy Act in 1998, a decade before Congress passed GINA. Since GINA, the Illinois General Assembly passed numerous amendments to the State Act, all of which became effective on January 1, 2009. This portion of the paper will focus on the statutory amendments to the Illinois Act.

The Illinois amendments contain new definitions that acknowledge GINA, but also mark potentially new coverages and exceptions under Illinois law. Under Illinois law, the term "Employer" encompasses the State of Illinois, any local governmental unit, and any board, commission, department, institution, or school district. 410 ILCS 513/10 ("Employer"). Entities covered as an "Employer" also include any party to a public contract, any joint apprenticeship or training committee within Illinois, and every other person employing employees within the State. *Id*. Restated, under the Illinois Act, no coverage limitation exists based on the number of employees. The Act also defines "Employment agency" to explicitly include public and private employment agencies, or union hiring halls that regularly procure working, recruitment, reference, or placement opportunities, whether compensated or not. 410 ILCS 513/10. "Employment agency." The Illinois definition of "Family member," unlike GINA's focus on several levels or categories of relatives, stresses the status of the family member as a "dependant" or "covered dependant," while still encompassing a person's spouse and children. 410 ILCS 513/10. "Family member."

The Act provides that data about

i. the individual's genetic tests;
ii. the genetic tests of a family member of the individual; and
iii. the manifestation or possible manifestation of a disease or disorder in a family member of the individual[;]

all constitute "Genetic information" under the Act. 410 ILCS 513/10. "Genetic information." As with GINA, "Genetic information" does not include data about the sex or age of any individual. *Id*. Nothing in the Act's definitions of "Genetic monitoring" or "Genetic services" appears markedly different from GINA's definitions of the same terms. *Compare*, 410 ILCS 513/10. "Genetic monitoring"; "Genetic services," *with*, 29 C.F.R. §1635.3(e) Genetic services.

The Illinois Act's definition of "Genetic testing" and "genetic test" uses a different structure than the GINA regulations. The GINA regulations specify what quality as genetic tests, but states that such examples "include, but are not limited to" the earlier discussed categories of tests. 29 C.F.R. §1635.3(f)(2). In contrast, the Illinois Act states "Genetic testing," and "genetic test" each concern:

> … a test or analysis of human genes, gene products, DNA, RNA, chromosomes, proteins, or metabolites that detect genotypes, mutations, chromosomal changes, abnormalities, or deficiencies, including carrier status that:
>
> i. are linked to physical or mental disorders or impairments,
> ii. indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or
> iii. demonstrate genetic or chromosomal damage due to environmental factors.

410 ILCS 513/10. "Genetic testing" and "genetic test" (emphasis supplied with that). As a result, Illinois law requires that such data bear some linkage with or indication of certain disorders or impairments, whether physical or mental, or show specified genetic or chromosomal damage.

The Illinois Act also contains some uniquely phrased exceptions to the terms "Genetic testing" and "genetic test." Such tests, under Illinois law, do not include:

> … routine physical measurements;
> chemical, blood and urine analyses that are widely accepted and in use in clinical practice;
> tests for use of drugs;
> tests for the presence of the human immunodeficiency virus;…

410 ILCS 513/10.

The statutory definition also excludes protein and metabolite analyses that either do not detect genetic data or that are directly related to a manifested (perhaps exhibited or known?) disease, disorder, or pathological condition which an expert healthcare provider in the relevant field of medicine could reasonably detect. *Id.* This portion of the Illinois exclusions bears resemblance to the GINA regulatory definitions that exclude some genetic or other data from the term "Genetic test." *Id., compare with*, 29 C.F.R. §1635.3(f)(3); (g).

The Illinois Act generally bars any person from disclosing, or compelling another to disclose, the identity of any person upon whom a genetic test has been performed, or the results of a genetic test. 410 ILCS 513/30(a). This means that such identity or genetic testing information is confidential and privileged, and may only be released to the individual tested or persons specifically authorized, in writing, to receive such data. 410 ILCS 513/15(a), *in accordance with*, 410 ILCS 513/30(a)(2).

These restrictions do not apply to biological samples police officers obtain for use in criminal investigations or prosecutions, or to the data derived from genetic testing of such samples, as long as disclosure of identification data is limited to appropriate law enforcement authorities who are conducting the investigation or prosecution. 410 ILCS 513/15(b). Such data may be used without the consent of the individual and shall be admissible evidence in court. *Id.* Further, such data may be used by appropriate law enforcement authorities for specified corrections purposes. *Id., cross-referencing*, 730 ILCS 5/5-4-3. To underscore its intent, the Illinois legislature provides that genetic information "shall be confidential and may be disclosed only for purposes of criminal investigation or prosecution." 410 ILCS 513/15(b). Moreover, once a subject of a criminal investigation is found innocent, or not subject to criminal penalties, the court records with such genetic data are expunged within 30 days after the final legal proceeding. 410 ILCS 513/15(c).

In civil actions, genetic testing and data obtained through such tests can be obtained with a protective order in actions alleging violations of the Illinois Genetic Information Privacy Act, actions seeking to enforce or compel permitted disclosures of genetic data under 410 ILCS 513/30 of the Illinois Genetic Information Privacy Act and through the Illinois Insurance Code, actions alleging discriminatory genetic testing or use of genetic data under the Illinois Human Rights Act and Civil Rights Act of 2003, or workers' compensation claims pursued under the Illinois Workers' Compensation Act. 410 ILCS 513/15(b).

The other significant exception arises where the genetic test results indicate that the individual, at the time of the testing, is afflicted with a disease, whether or not the disease is currently symptomatic. 410 ILCS 513/15(d). The results of such testing are not governed by the confidentiality requirements of the Illinois Genetic Information Privacy Act. *Id*.

Furthermore, the Illinois Act does not bar or restrict the use of or ordering of DNA tests or other tests to determine inherited characteristics by a court in a judicial proceeding under the Illinois Parentage Act, 750 ILCS 45/1 et seq., or by the Department of Healthcare and Family Services in an administrative proceeding under the Illinois Public Aid Code, 305 ILCS 5/10-1 et seq., or its accompanying administrative rules. 410 ILCS 513/22.

Unless a party qualifies for one of the exceptions provided by the Illinois Genetic Information Privacy Act, genetic data is not discoverable and is not admissible as evidence. 410 ILCS 513/15(a).

The Illinois Genetic Information Privacy Act directs that employers, employment agencies, unions and licensing agencies treat genetic testing and genetic data in a manner consistent with federal law, including GINA, the ADA, Title VII of the Civil Rights Act of 1964, the FMLA, the Occupational Safety and Health Act of 1977, and the Atomic Energy Act of 1954. 410 ILCS 513/25(a). Employers may only release genetic testing data in accordance with specified provisions of the Act. 410 ILCS 513/25(b), *cross-referencing*, 410 ILCS 513/15 and 513/30. The additional provisions contained in 410 ILCS 513/25, limiting the use of genetic testing information, seems to track or compact with GINA until Illinois State and federal courts otherwise rule. See, 513 ILCS 513/25(a), (c), (d), (h), (i). As with GINA, the Illinois Act contains an anti-retaliation provision. 410 ILCS 513/25(c)(4).

The Illinois Act permits limited used of genetic data in employee wellness programs, but only if the employer offers health or genetic services, with the employee providing specified written and informed consent. 410 ILCS 513/25(e)(1),(2). Moreover, only the employee, family member, and licensed healthcare provider or genetic counselor providing services can receive individually identifiable genetic data. 410 ILCS 513/25(e)(3). Further, no individually identifiable genetic data may be used outside the confines of the cited health services and genetic counseling, and the employer may only receive aggregate data that does not disclose the identity of individual employees. 410 ILCS 5113/25(e)(4).

Upon giving the required consent, employees may voluntarily request and subject themselves to genetic testing by their employer for the purpose of initiating a workers' compensation claim. 410 ILCS 513/25(f). In addition, even upon lawfully obtaining genetic testing or genetic data, employers, employment agencies, labor organizations and licensing agencies still may not disclose or use such genetic tests or data in violation of the Act. 410 ILCS 513/25(j). Finally, in addition to the litigation exceptions and limitations, the Act provides additional controls, limitations, and exceptions for the disclosure of genetic tests and data involving spouses, physicians, healthcare facilities, state agencies, local health authorities, and authorized representatives of individuals. 410 ILCS 513/30(a)(1)-(7).

The Illinois Act gives plaintiffs a right of action in state court or in federal court as a supplemental claim. 410 ILCS 513/40(a). Unlike GINA, the Illinois Act provides remedies that include liquidated damages. Any party who negligently violates the Act is subject to liquidated damages of $2,500 or actual damages, whichever is greater, for each violation. 410 ILCS 513/40(a)(1). Parties who intentionally or recklessly violate the Act become subject to liquidated damages of $15,000 or actual damages, whichever is greater, for each violation. 410 ILCS 513/40(a)(2). Successful plaintiffs can recover their reasonable attorney's fees and costs, and

expert witness fees along with other litigation expenses. 410 ILCS 513/40(a)(3). Injunctions and other relief are also available as the court finds appropriate. 410 ILCS 513/40(a)(4).

For actions against insurers over alleged disclosure violations of the Act, 410 ILCS 513/30, claimants are limited 215 ILCS 5/40 of the Illinois Insurance Code as their exclusive remedy. 410 ILCS 513/40(b). In addition, persons seeking a preliminary injunction to bar the release or disclosure of their genetic testing or genetic data may use the Illinois Act in state court, or as part of a supplemental claim in federal court. 410 ILCS 513/40(c).

Additional Illinois privacy law appears in the Right to Privacy in the Workplace Act. 820 ILCS 55/5(a). The Illinois Department of Labor has the assigned task of administering and enforcing the provisions of the Illinois Privacy in the Workplace Act. 820 ILCS 55/15(a). The Illinois Department of Labor's regulations state that the purpose of the Act is to prohibit employers from discharging or otherwise retaliating against employees or prospective employees who use lawful products outside of the workplace. Ill. Admin. Code Title 56: Labor and Employment §360.100 Purpose and Scope. The Illinois Department of Labor defines "lawful products" as to include, "but shall not be limited to," food and tobacco products, alcoholic beverages, and over-the-counter or legally prescribed drugs. Ill. Admin. Code Title 56, §360.110(g). Employees who believe that their privacy rights have been violated may file a complaint with the Illinois Department of Labor alleging a violation of the Illinois Right to Privacy in the Workplace Act within 180 days after termination or the complained of incident. Ill. Admin. Title 56, §360.120(a). The Illinois Department of Labor reviews such complaints and determines whether they provide a cause of action for investigation. Ill. Admin. Title 56, §360.120(b).

Illinois law also provides for the privacy of genetic information in its Adoption Act, 750 ILCS 50/18.16; and the Genetic Counselor Licensing Act, 225 ILCS 135/1, *et seq.*, which details the privileges and exceptions afforded to communications made to such healthcare professionals, (225 ILCS 135/90); among other laws.