

April 15, 2009

DRAFT COMMENTS ON NOTICE OF PROPOSED RULEMAKING
GENETIC INFORMATION NONDISCRIMINATION ACT
EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
29 CFR Part 1635

EXECUTIVE SUMMARY

As part of an ongoing collaboration funded by The Pew Charitable Trusts, the Genetics and Public Policy Center at Johns Hopkins University and the Council for Responsible Genetics are pleased to submit the following comments in response to the notice of proposed rulemaking (NPRM) from the Equal Employment Opportunity Commission (EEOC) implementing Title II of the Genetic Information Nondiscrimination Act (GINA).

We are pleased with the approach taken by EEOC in most areas of the NPRM. We look forward to working with EEOC to ensure that employers are made aware of new requirements under GINA and have the tools they need to comply with the law.

There are a few sections of the NPRM where we believe additional attention is warranted; thus, we call for:

- strong and unambiguous definitions of key terms,
- narrowly crafted exceptions to the rule against employer acquisition of genetic information, and
- federal agencies regulating under GINA to clarify the interaction of Title I and Title II of GINA and ensure that both Titles are implemented and enforced with consistency and clarity.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

COMMENTS

We appreciate the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) from EEOC implementing the Genetic Information Nondiscrimination Act. Our interest in genetic discrimination policy is inexorably linked to our belief that genetic research will illuminate the role of genetics in health and disease and help drive the development of new diagnostic tools and treatments. Researchers now have powerful tools to dissect the genetic, environmental, and lifestyle factors that contribute to health and disease, and our nation's robust biotechnology and pharmaceutical industries are translating those findings into new diagnostics and medicines to preserve health and prevent disease. We long have been concerned that genetic discrimination and the fear expressed by many that genetic test results could be used against them, inhibits volunteers from participating in genetic research and deters individuals from pursuing recommended genetic testing in their own health care. The regulations that implement GINA must carry out the intent of Congress by clearing the way for new scientific and clinical advancements aimed at improving the health of all Americans.

Even before the passage of GINA, EEOC played a critical leadership role in establishing that genetic information could not be used to discriminate in the workplace. EEOC's interpretation of the Americans with Disabilities Act (ADA) as it relates to genetic information and the agency's involvement in cases such as *EEOC v. Burlington N. Santa Fe Ry. Co.*, No. C 01-4013-MWB (N.D. Iowa 2001) have laid the groundwork for strong protections under GINA.

As the NPRM demonstrates, GINA need not and should not create a burden for employers. Employers who are already following good employment and human resources practices in complying with existing laws such as Title VII, the ADA, and the Family and Medical Leave Act (FMLA) should find that GINA's requirements are consistent with those laws in terms of procedures and enforcement.

Our comments emphasize the following points:

1. EEOC should maintain strong and unambiguous definitions of key terms, provide clear examples and remain flexible as science changes.
2. Employers are prohibited from requesting, requiring, or purchasing genetic information, and the exceptions to this rule must be narrowly crafted. We urge EEOC to clarify and

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

strengthen the rules and procedures for employers to avoid inadvertent collection of genetic information and we provide detailed comments on the exceptions to this rule.

3. EEOC must continue to work closely with the Department of Labor (DOL), the Department of Health and Human Services (HHS) and the Department of the Treasury and Internal Revenue Service, the agencies that will be enforcing Title I (relating to health insurance) of GINA to ensure that protection under GINA is consistent and seamless for employees. Regulations, policy guidance, implementation and enforcement of GINA should reflect the reality that many Americans receive their healthcare benefits through their employer, and that particularly in smaller companies, the person controlling human resource functions such as health benefits may also administer many aspects of hiring, firing, promotion, and requests made under the ADA or the Family and Medical Leave Act (FMLA). Thus it is critical that EEOC further clarify the firewall between Title I and Title II. The regulations and future policy guidance should be specific about what the firewall will and will not mean for individuals seeking to enforce their rights under GINA.

1. DEFINITIONS IN GINA:

EEOC specifically has requested comments on several definitions in GINA. In general, definitions that appear in the final law are the core of the law and reflect a compromise reached after many years of negotiations.¹

The definition of key terms related to genetics historically has presented a challenge for policymakers. For example, a problematic definition promulgated under HIPAA included, as part of the definition of genetic test, any information derived from “physical medical examinations,” (29 CFR 2590.701-2) which created far too broad a scope. Conversely, state law definitions sometimes have been far too narrow, excluding family history or other aspects of genetic information. Rapid advances in genetic research and new technologies add to the challenge; some laws reflect an early understanding of genetics, but actual scientific progress quickly outpaces statutory language.

¹ For a history and analysis of the compromises reached during GINA negotiations, see Baruch, S., and K. Hudson. 2008. [Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World](#). *The American Journal of Human Genetics* 83: 435-444 and Hudson, K.L, M.K. Holohan, and F.S. Collins. 2008. [Keeping Pace with the Times — The Genetic Information Nondiscrimination Act of 2008](#). *New England Journal of Medicine* 358: 2661-2663.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

The key terms in GINA are “genetic test,” “genetic information,” and “genetic services.” EEOC has added a definition of the term “manifestation or manifested.”

GENETIC TEST

In the preamble to Section 1635.3(f), EEOC invites comment on the scope of the term “Genetic Test.” Under GINA, a “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, to detect genotypes, mutations, or chromosomal changes.

According to the definition in Title II, the health insurance provisions of the law, “genetic test” does *not* include “an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes;”² We read this “exception” as simply restating part of the rule in the definition – that unless a test of proteins and metabolites measures genotypes, mutations, or chromosomal changes, it does not meet the definition.

We believe it is useful for the GINA regulations to provide examples of protected tests and those that are not included. We agree with the examples mentioned in the preamble to the NPRM as genetic tests: tests to determine whether an individual carries the genetic variant evidencing a predisposition to breast cancer (BRCA1 or BRCA2 variant), tests to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer, or a test for a genetic variant for Huntington’s Disease.

We recommend the proposed rule also specify that the following list of tests would be protected under the definition of “genetic test” in GINA:

- Carrier screening of adults using genetic analysis to determine the risk of conditions such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and fragile X syndrome in future offspring. Carrier screening provides information to prospective parents about the risk of a future child having the disease. These tests generally are performed on human DNA to detect genotypes.

² As noted in the proposed rule, the Title II definition of genetic test does not have the express exclusion that Title I does for “(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.” Although this exception appears in Title I, it was not included in Title II because Congress determined that these uses “are not applicable in the employment context.”

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

- Amniocentesis, chorionic villus sampling, or other prenatal testing to detect abnormalities in a fetus during pregnancy. These are tests of the fetus’s human DNA or chromosomes to look for genotypes, mutations or chromosomal changes. Under GINA, the pregnant woman and her family members explicitly are protected from discrimination on the basis of this genetic information.
- Newborn screening tests. These tests use either DNA or RNA analysis or protein or metabolite analysis to detect genotypes, mutations, or chromosomal changes. Tests for conditions such as PKU allow preventative treatment to begin before disease manifests in a newborn.
- Preimplantation genetic diagnosis performed on embryos created using *in vitro* fertilization. These are tests of the embryo’s DNA or chromosomes to look for genotypes, mutations or chromosomal changes. Under GINA, the individuals and family members who “legally hold” the embryos explicitly are protected from discrimination on the basis of this genetic information.
- Pharmacogenetic tests. Tests to detect genotypes/mutations that are associated with how a person will react to a particular drug or drug dosage.
- DNA testing to detect genetic markers that are associated with information about ancestry.
- DNA testing that reveals family relationships, such as paternity.

While the last two examples are unlikely to be of interest or relevance to employers, we include them to illustrate that Congress wrote definitions that do not rely on the purpose or intended use of the test.

We also agree with the examples offered in the proposed rule of tests that are not genetic tests, such as a virus not composed of human DNA, RNA, chromosomes, proteins, or metabolites (which we note would include HIV, a retrovirus that inserts itself *into* human DNA.) Measuring the presence of infectious agents such as bacteria, viruses, and fungi does not constitute a genetic test under the law’s definition. We also agree that a test for the presence of drugs or alcohol would not be a genetic test, but a test that purports to screen individuals for genetic propensity to alcoholism or drug use would be a genetic test. And, as described in the preamble, a test for infectious and communicable diseases that may be transmitted through food handling would not be a genetic test, nor would “routine tests such as complete blood counts, cholesterol tests, and liver-function tests.”

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

We urge EEOC and the agencies regulating under Title I of GINA to consult in an ongoing way with scientific experts in this field such as the National Human Genome Research Institute or the American Society for Human Genetics to ensure that all genetic techniques are included.

GENETIC INFORMATION, FAMILY MEMBER, AND FAMILY MEDICAL HISTORY

The term “genetic information” means information about an individual’s genetic tests, the genetic tests of that person’s family members, and the manifestation of a disease or disorder in an individual’s family members (sometimes referred to as “family history.”) It also includes any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by an individual or family members. The proposed rule defines “family member” and “family medical history.” “Genetic services” is defined separately and addressed below.

The definition of genetic information also includes the genetic information of a fetus or embryo of an individual or family member.

The definition of “genetic information” specifically includes the manifestation of a disease or disorder in a family member. “Family member” is defined as a first-, second-, third-, or fourth-degree relative. As noted in the NPRM, individuals may become family members by birth, marriage, adoption, or intent to adopt. The proposed rule helpfully and accurately gives examples of first-, second-, third-, or fourth-degree relatives with one exception: a half-sibling should be considered a second-degree relative rather than a first-degree relative.

Senate Report No. 110-48 describes the concept of family history using an adult family history medical form developed by the American Medical Association. Although this form requests information up to and including third-degree relatives, GINA includes fourth-degree relatives as well.

“Genetic information” does not include information about sex or age.

Regulations should clarify that all genetic information that meets the definition is protected. For example, genetic information of an individual (whether from family history or genetic testing) that was obtained by an employer *before GINA’s effective date* is nevertheless the genetic information of that individual and is protected by GINA.

MANIFESTATION OR MANIFESTED

GINA section 201(4)(A)(iii) defines genetic information and refers to the “manifestation of a disease or disorder in family members” of an individual, and section 210, entitled “Medical

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

information that is not genetic information” refers to a “manifested disease, disorder or pathological condition.” We agree with the proposed definition in Section 1635.3(g) of “manifestation or manifested” including the limitation stating that a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information or on the results of one or more genetic test. As noted in the preamble, the mere presence of a genetic variant does not mean that an individual has an associated condition, disease, or disorder; other signs or symptoms must be present for manifestation to have occurred.

We also urge EEOC to clarify that the genetic information of an individual with a manifested disease is protected under GINA. So, for example, an individual with breast cancer might undergo genetic testing and learn that because she tests positive for a BRCA mutation, she is at increased risk for ovarian cancer. She may not be discriminated against on the basis of the variant.

GENETIC SERVICES

“Genetic services” includes any of the following: a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education. The definition of genetic test is addressed above.

Genetic counseling and genetic education may take a variety of forms.

Example: A woman who seeks BRCA testing (genetic testing for breast and ovarian cancer risk). Typically, this woman would seek and receive genetic counseling and/or education before and/or after the genetic testing.

- Before testing, a counselor or doctor would explain the risks and benefits of testing and what the test results mean.
- Before and after testing, a counselor or doctor would explain her lifetime risks of developing breast or ovarian cancer.
- Whether or not the woman decides to have the genetic test to learn about her risks, a counselor or doctor would review with her clinical options that can reduce her risks, and perhaps make recommendations. Options in the case of BRCA might include earlier and more frequent mammograms and preventive measures such as taking tamoxifen or having preventive surgery to remove the ovaries or breasts.

The regulations should specify that GINA protects all of the above examples. Thus an employer cannot request or require an employee to reveal whether or not she has had these genetic

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

services, and if the employer learns that the employee has had genetic services the employer may not discriminate on the basis of that fact.

The definition of genetic services should explicitly include information about preventive therapies and screenings that patients may *consider or undergo* to reduce their risks revealed by genetic information. During consideration of GINA, many Members of Congress stressed that ending genetic discrimination is critical to allowing new preventive measures to be developed and pursued without fear.³ Most patients today undergo genetic testing for the express purpose of learning their risk status and available preventive options. If GINA were to protect only a patient's test results, but nothing that might subsequently be done to reduce risk, its protections would be hollow.

2. PROHIBITION ON EMPLOYER REQUEST OR REQUIRE GENETIC INFORMATION

Under GINA, employers are prohibited from requesting, requiring, or purchasing genetic information. Exceptions to this rule must be narrowly crafted.

Before commenting on how Title II addresses employer acquisition of genetic information we would like to respond to language in the preamble to the proposed rule, “§1635.1 Purpose of GINA.”

The language used in the final law was the result of many years of deliberation and compromise. The use of language in GINA is both specific and intentional. It is important that the preamble accurately describe the language, tone, and intent of the final law. The preamble states “Title II of GINA restricts the deliberate acquisition of genetic information by covered entities.” However, the use of the word “deliberate” in describing the prohibited acquisition of genetic information does not accurately reflect its intent.

Section 202(b) of GINA makes it an unlawful employment practice for a covered entity to “request, require, or purchase” genetic information. While these are intentional acts, nowhere does GINA require that the actor have the deliberate intent of acquiring genetic information when engaging in these acts. There is no *mens rea* requirement. A covered entity would be in violation of GINA if it acquired genetic information because it failed to modify the way medical inquiries are made to avoid obtaining genetic information, even if the covered entity did not have the specific intent of acquiring such information.

³ See, for example, floor remarks of Senators Enzi (page S 3365), Levin (S 3372), and Reid (S 3372), *Congressional Record*, April 24, 2008.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

Covered entities are significantly less likely to make the modifications in their practices that the drafters of GINA envisioned if they have the implicit understanding that they will be in violation of the law only if there is evidence that they specifically sought out genetic information. Intentional acts, not a guilty mind, are a violation of GINA. The preamble needs to make this distinction clear. We recommended modifying the language in the preamble to read: “GINA prohibits use of genetic information in employment decision-making, restricts deliberate acts that result in the acquisition of genetic information...”

§1635.8 Acquisition of Genetic Information:

Under the best of circumstances employment discrimination cases are difficult to prove. Employers are often the only party with access to information supporting a discrimination claim. As a result, employees often are unaware that discrimination has even occurred. Preventing access to information that can lead to discrimination is the best way to ensure that discrimination does not happen. The proposed regulations must make it clear that covered entities will have to modify their medical inquiries, such as those related to post-offer applicants, to reflect the prohibitions on acquisition of genetic information in GINA. The regulations should offer specific examples of acceptable language for this purpose. Such language should be clear and conspicuous.

As Senator Snowe, a primary and original sponsor of GINA, so succinctly put it: “As demonstrated by the Burlington Northern case, the threat of employment discrimination is very real, and therefore it is essential that we take this information off the table, so to speak, before the use of this information becomes more widespread.”⁴

This concern dominated the Congressional history of GINA. Both the House of Representatives and the Senate described it thusly:

“To this end, the legislation makes it unlawful for an employer, labor organization, employment agency, or joint labor-management committee to request, require, or purchase genetic information, ***except under limited circumstances***” (emphasis added).⁵

There are six enumerated exceptions to the general rule prohibiting covered entities from requesting, requiring, or purchasing genetic information. These exceptions are specific and limited and should be interpreted accordingly.

⁴Introductory Remarks of Senator Olympia Snowe (R-ME) on the Genetic Information Nondiscrimination Act - January 22, 2007.

⁵ House Report 110-028 - GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007.

Senate Report 110-048 - GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

§1635.8(b)(1) Inadvertent Acquisition of Genetic Information Exception:

GINA has an exception to the rule against acquisition of genetic information where the acquisition of family history, rather than genetic information more broadly, is inadvertent. There is clear intent in the Congressional record to limit this exception to impromptu casual conversations in the workplace or so called “water cooler conversations.” The proposed regulations indicate such and the legislative history of this section is rife with statements indicating the limited applicability of this exception.

The Senate report stated, “The first exception addresses the so-called “water cooler problem,” in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker. The committee recognizes that conversations among co-workers about the health of a family member are common and intends to prevent such normal interaction from becoming the basis of litigation under this Act. Without the exception, the committee is concerned that discussion in the workplace of a family member’s health condition that is genetically based could be interpreted as an employer requesting or requiring genetic information from an individual.”⁶

Limiting the exception to the inadvertent acquisition of family history, rather than genetic information more broadly, demonstrates that Congress intended the exception to be limited to the type of information that would arise in casual conversation. We would agree with the proposed regulations that in this context it is consistent with Congress’s intent to extend the exception to other genetic information but only in this limited context.

Furthermore the regulation should make clear both by language and example that this exception does not apply to conversations or similar forms of acquisition where it can be demonstrated that the covered entity knows or should know that genetic information would be acquired. For example, a manager who engages in a series of highly specific and probing questions that do not specifically ask for genetic information, but for which it is clear to a reasonable person that genetic information will be offered, should not be protected by this exception. In the example offered in §1635.8(b)(1)(i) of a manager who overhears a conversation, the employer should not be protected if the manager intentionally places himself in a position to overhear a conversation that reveals genetic information.

While the proposed regulations acknowledge the Congressional intent and limitations of this exception, they also extend it to matters involving reasonable accommodation requests under the ADA with Disabilities Act and similar Federal, state and local law as long as the request for

⁶ Senate Report 110-048 - GENETIC INFORMATION NONDISCRIMINATION ACT OF 2007

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

documentation was lawful. There is no indication that this exception was meant to apply to formal processes. Certainly the proposed regulations make clear that other medical inquiries, such as those related to post-offer job applicants and job related inquiries of current employees must be modified to comply with GINA. In contrast, the proposed regulation relegates modification of a reasonable accommodation request to voluntary “best practices.” We believe that GINA requires modifications to the requests be made in this context as well: Reasonable accommodation requests are highly prone to disclosure of genetic information; thus, it is exactly this type of interaction between employer and employee that GINA was meant to address.

The EEOC’s own guidance in this area reveals the dangers inherent in this type of interaction. The agency indicates that after receiving a request for reasonable accommodation, the employer and the employee should engage in an “informal” and “interactive” process to clarify the individual’s need and the appropriate response.⁷ Only after this process may the employer “ask the individual for reasonable documentation about his/her disability and functional limitations” when the disability or need for accommodation is not obvious.⁸ An employer under such circumstances already is limited to requiring “only the documentation that is needed to establish that a person has an ADA disability.”⁹ It would not be difficult for an employer also to notify the individual that genetic information is not needed and should not be included.

An employer who fails to reference the limitations on access to genetic information in GINA when making any type of request relating to medical information should be considered in violation of GINA when genetic information is returned as part of the response. The proposed rule fails to state that in order for the protections of the exception to apply, employers must modify their requests to indicate that the covered entity is not requesting genetic information. The proposed regulation should offer model language for employers to use in making medical inquiries or requiring medical reports. Proactive measures must be required; otherwise, this exception will quickly consume the rule. Any time an employer engages in a request for medical information, he or she is aware of the possibility that genetic information will be part of the record. Employers are already quite familiar with making limited requests for information in other contexts including the ADA and worker’s compensation laws,

§1635.8(b)(2) Health or Genetic Services Exception:

⁷ Enforcement Guidance: Reasonable Accommodation and Undue Hardship under the Americans with Disabilities Act, <http://www.eeoc.gov/policy/docs/accommodation.html> (accessed April 14, 2009).

⁸ Id.

⁹ Id.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

Employers understandably are concerned with the rising cost of health care. Eighty percent of employers agree that they have a responsibility to promote wellness among their employees and well over half of employers sponsor some form of wellness program.¹⁰ Eighty-three percent of employer-based wellness programs either use or consist exclusively of health risk assessments.¹¹ Health risk assessments are questionnaires designed to identify preventable health risks on an individual and group level. Typically they cover all areas of behavior such as seatbelt use, tobacco use, alcohol use, and frequency of exercise. They also ask about family history of disease and illness. It is essential that individuals be protected from employer or other third-party access to genetic information through such programs.

GINA allows for the acquisition of genetic information by a bona fide employer-based wellness program but only as long as the employee voluntarily consents (along with other requirements). Over a third of wellness programs offer what they call “incentives” for employees to participate in such programs.¹² These incentives can include anything from direct monetary rewards, to airline miles and travel awards and merchandise. These incentives often are distributed through such common employment based programs as medical savings accounts, wellness gain sharing, flex plans, flexible spending accounts, well day rewards, combined leave bonus days, and sick leave accrual bonuses. Whatever terms chosen to describe such programs, the end result is that employees who fail to participate in such programs are in a lesser financial position than employees that do participate. The failure to participate in such programs can cause employees to lose access to hundreds and even thousands of dollars and merchandise.¹³

No program that puts an employee in a lesser financial position for failure to participate in such program should be considered voluntary for purposes of GINA. Particularly in today’s economy, these programs are coercive: Few people are in any financial position to turn down tangible or even intangible incentives.

Furthermore, no such programs can be considered voluntary that condition participation on divulging family history or other private genetic information. An employee who participates in such a program should be given the opportunity to opt out of the elements of the program that require them to provide family history or other genetic information without financial or other penalty. Moreover, elements of wellness programs such as health questionnaires that do require family history and genetic information should be highlighted or otherwise flagged for

¹⁰ 2004 American Management Association “Survey on Health and Wellness Programs.”

¹¹ Forrester Research, “What Consumers do with Health Risk Assessments.” Oct. 2007.

¹² 2004 American Management Association “Survey on Health and Wellness Programs”.

¹³ Mercer Human Resource Consulting “Health Risk Assessment (HRA) and Wellness Incentives.”

<http://www.pugetsoundhealthalliance.org/resources/documents/CompanieswithIncentivesv2.pdf>

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

the employee in the program description, in order to satisfy the requirement that consent to participation be “knowing.”

Finally, we urge EEOC to require that if genetic information offered through wellness programs is provided to the employer in the aggregate, care is taken to ensure that it is not possible for employers to link the data with individual employees, particularly in cases where only a small number of individuals choose to participate.

§1635.8(b)(4) Commercially and Publicly Available Information:

We agree with the proposed regulation that the intent of GINA is to include in this exception any medium that is widely available without restriction to the general public including elements of electronic media. We note, though, that the distinction GINA makes is not exclusively between media that are public and media that are private.

The distinction GINA makes is between media that are widely available and sufficiently generalized without limitation and media that are less easily accessible, are limited, or are at heightened risk for containing private genetic information. This exception is meant to protect covered entities that might otherwise casually pick up a magazine at the corner news stand and inadvertently read an article containing genetic information about an employee. This exception is clearly not meant to insulate a covered entity that conducts a search for genetic information through media that are at heightened risk of containing genetic information.

GINA specifically eliminates medical databases and court records from the protections of this exception despite the fact that many are public. Virtually every state not only allows public access to court records but also allows some form of that access in electronic form on the Internet. A number of medical databases also are accessible to individuals other than researchers and medical professionals. These are prohibited mediums under GINA because they contain a sufficiently heightened risk for containing private genetic information that the Congress believed they needed to remain protected to safeguard the general rule protecting such information from access by employers.

We strongly urge that the proposed regulation emphasize this distinction rather than the public vs. private dichotomy. Where any element of any medium requires permission for access, or where access is conditioned on membership in a particular group, or where the medium clearly indicates a heightened risk of containing genetic information, such media should not fall within the protections of the exception. These would include but not be limited to medical journals, social and professional networking sites, private membership-only websites, Internet-based chat rooms, legal databases such as Westlaw, and professional trade materials such as those

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

offered by the Society for Human Resource Professionals, the American Bar Association, or the American Medical Association.

§1635.8(b)(5) Genetic Monitoring:

Some employers have programs that conduct genetic tests of workers in specific hazardous environments to determine if they are being exposed to toxic substances that are causing genetic changes in employees. Genetic monitoring enables an employer to deal with the effect of workplace toxins and to attempt to control their affect on employees. Employers who work with beryllium, for example, use such testing to identify workers who are at heightened risk for contracting chronic beryllium disease from exposure to beryllium dust. Such genetic monitoring programs are allowed under GINA.

However, GINA makes an important change in the law on this subject. Currently, employers can require employees to be tested. Under the ADA, an employer may make disability-related inquiries and **require** medical examinations as long as they are job-related and consistent with business necessity. The “job-related” standard provides the employer with the opportunity to demonstrate that the existence of a genetic predisposition is a relevant and appropriate subject for inquiry. Under GINA, participation in such programs must be voluntary. Thus if an employee wants to keep working in the potentially hazardous area (perhaps because of the opportunity for higher pay), the employer cannot require the employee to submit to testing, no matter how good a reason or benevolent an intent the employer has.

GINA does not address what, if anything, an employer can do if an employee fails to give consent to be tested under these circumstances. GINA is clear that an employer under these circumstances would be limited by the restrictions set out in §1635.4 and §1635.5 of the Act, namely that the employer could not discriminate in terms of hiring, discharge, compensation, terms, conditions or privileges of employment. Nor could the employer limit, segregate, or classify an individual in any way that would otherwise affect the status of the individual as an employee.

Under such situations, we strongly recommend the proposed regulations offer guidance as to what would be acceptable responses by an employer to such a situation. We believe it would be acceptable in such a situation to transfer an employee who refuses testing to another part of the facility but only as long as the new position is substantially similar in all respects to the employee’s current position. We also recommend that the regulations make clear that nothing in GINA should be read to limit an employer’s responsibility for maintaining the safety and health of its workplace and responsibilities under the Occupational Safety and Health Act and any other relevant state and Federal workplace health and safety laws.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

§1635.8(b)(6) Law Enforcement or Human Remains Quality Control Purposes:

The purpose of Section 1635.8(b)(6) is to permit genetic testing laboratories engaged in genetic testing for law enforcement forensics or human remains identification to analyze DNA identification markers of employees, apprentices, or trainees for quality control purposes. This provision strives to protect the genetic privacy of individuals without comprising the integrity of DNA analysis by these laboratories. Checking samples to make sure they do not contain lab technicians' DNA profiles can detect contamination and is a frequently-used quality control method in forensics. As is stated in the preamble, this is a limited exception for a small subset of laboratories performing genetic testing, and if properly performed these programs do not obtain genetic information related to health.

We agree with the EEOC that the genetic information be "used for analysis of DNA identification markers for quality control" as is specified in the statute. We also support EEOC's addition that the employee's genetic information be "maintained in a manner consistent with such use" as is added in the proposed rule. Thus, an employee's DNA should be analyzed for a limited set of markers that do not include health-related genetic information, the employee's DNA sample should be destroyed after a designated period of time, and the sample and results of the DNA analysis must be kept solely in the laboratory for quality control and not entered into any law enforcement database. As with other exceptions to Section 1635.8, genetic information that is obtained may not be used to discriminate and must be kept confidential.

3. FIREWALL BETWEEN TITLE I AND TITLE II

§1635.11(b) Relationship to Other Federal Laws Governing Health Coverage:

We agree with the proposed regulations that a covered entity is not immunized from liability for decisions and actions that violate Title II, even if such employment decisions are based on health benefits governed by Title I. To interpret the GINA "firewall" otherwise would allow employers to escape liability for intentional acts of discrimination. We would make the additional point that an employer who intentionally causes or attempts to cause a third party insurer governed by Title I to engage in an act that violates the terms and conditions of the individual's employment also should be governed by the protections of Title II. A large employer, for example, who uses financial leverage to cause or attempt to cause a health insurer to engage in an adverse decision against one of their employees should be equally responsible for a violation of Title II for an intentional act that affects the terms and conditions of the employment relationship.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu

CONCLUSION

We appreciate the opportunity to comment on the proposed rule. As GINA implementation moves forward, we look forward to the opportunity to continue to work with EEOC and the other federal agencies charged with enforcing this important new law.

Prepared by the Genetics and Public Policy Center in collaboration with Jeremy Gruber of the Council for Responsible Genetics

For more information, please contact the Genetics and Public Policy Center at GINAInfo@jhu.edu