

The Genetic Information Non-Discrimination Act (GINA) 2007

A position paper prepared for Congressman Joseph Sestak

Respectfully submitted by the members of STSC 428: Genetics and Social Policy
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I. Summary

The Genetic Information Non-Discrimination Act of 2007 prohibits health insurers and employers from discriminating against people on the basis of information about their genetic constitution—or, to put it another way, information about their genomes.

GINA has already passed in the House, but is stalled in the Senate. With just a few reservations (see Recommendations) we believe that you should vote **YES** on GINA, in the event that it should come back to the House, either in this or succeeding sessions.

- **GINA is proactive.** We found little evidence of current serious discrimination by health insurers and/or employers, but we did find evidence of widespread **fear** of such discrimination and substantial reasons to believe that discrimination will be **likely to occur** in the future, when more and more accurate genetic tests will be on the market.
- **Genetic information is not explicitly covered** by current federal legislation (notably HIPAA and ADA) that seeks to protect the privacy of other kinds of medical information and/or seeks to prevent discrimination against disabled people.
- **State legislation** which seeks to protect the privacy of genetic information and to prevent discrimination in health insurance and employment on the basis of genetic information is **inconsistent** and most members of the public do not know that it exists. GINA will certainly remedy the first situation—and possibly also the second.

II. Historical and Legislative Background

A. “Findings are Exaggerated”

Both the House and the Senate versions of the bill begin with five Congressional findings. Three of these (Findings 2, 3 and 4) are historical—and all are exaggerated.

Many states permitted involuntary sterilization of the feeble-minded, and such sterilizations were conducted for many years, but, in fact, **the number of such sterilizations declined precipitously after 1950**. For the last 50 years, American courts and legislatures have reacted so

negatively to the practice that today it is exceedingly difficult for parents and guardians of severely retarded young women to obtain sterilization even *with consent* from their daughters (on the grounds that the young women will be unable to care for offspring) without extensive judicial and medical review.

Similarly, during the early 1970s *some* state legislatures began requiring genetic screening for sickle cell disease, **but most of those laws were either repealed, or left unfunded or unexecuted very quickly**. The laws were intended as public health measures, to uncover the numerous childhood cases of the disease previously left undiagnosed, so that correct treatment could be offered. Some African Americans experienced workplace, educational and insurance discrimination based on these testing regimens, but the number for which sound evidence of such discrimination has been found is very small, numbering no more than 100, if that. Much of the fear that was generated in African-American communities was generated by groups, such as the Black Panthers, who wanted to conduct the testing themselves.

Many ethnically based testing regimens have been developed since the early 1970s (e.g., testing for Tay-Sachs disease and for β -thalassemia in the Ashkenazi Jewish population) **without any of the affected groups experiencing discrimination**. Even the case referred to in Finding (4), *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, does not provide evidence of *genetic* discrimination in the workplace. Lawrence Berkeley Laboratory was found liable for testing its employees without obtaining proper informed consent, and discriminating on the basis of *race* and *sex*, since it only tested African-American employees for sickle cell trait and female employees for pregnancy. No workplace or health insurance discrimination was alleged. (**See Recommendation 1.**)

B. History of State Legislation

Most state legislatures have now taken steps to protect and maintain the privacy of genetic information. These policies tend to reflect the notion that genetic information is inherently different from all other medical data and, as a result, raises distinctive social issues.¹ In 1991, Wisconsin passed the first law to prevent genetic discrimination in health care and employment. The following year, Rhode Island and Iowa passed laws prohibiting genetic discrimination in the workplace. Then, in 1995 Oregon enacted the first comprehensive genetic privacy act. Since then numerous states have followed Oregon's lead by passing laws that deal with the privacy of genetic information, employment and insurance discrimination, genetic testing and counseling, informed consent, and DNA databanks and databases. In 2002 Washington modified its health privacy law to include the definition of protected health information. In doing so, it became the first state to treat genetic information as equivalent to other health information.¹¹

Currently, 43 states have a wide range of laws that address genetic privacy concerns while only seven states lack sufficient legislation pertaining to genetic privacy. For example, Mississippi has passed three laws from 2002 to 2005 which focus only on newborn screening. Some states, such as Texas and Georgia, use a narrow definition of genetic information; whereas states such as Virginia and New Jersey use broad ones. Some states, such as Michigan, Arkansas, and Florida, fall in the middle and try to limit broad definitions, thereby excluding results from physicals, chemical tests or indirect manifestations of genetic disorders from protection in their

legislation. Interestingly, five states (Alaska, Colorado, Florida, Georgia and Louisiana) define genetic information as personal property, allowing individuals to own their genetic information.

Clearly, genetic privacy legislation varies greatly across the country. A complete and concise agreement among the states does not exist; each state approaches different aspects of genetic privacy. **A comprehensive federal law like GINA would provide baseline genetic privacy protection for all Americans, thus alleviating fears and concerns related to genetic discrimination.**

C. History of Federal Legislation

Every Congress since 1995 has seen some form of a genetic nondiscrimination bill on the agenda; none have become law.

Initially the proposed legislation was focused on *limiting* the collection and analysis of DNA samples in order to protect the privacy of individuals and thus to protect them from stigmatization as well as from discrimination in health insurance and employment. Gradually, the focus has changed to *allowing* the collection and analysis of DNA samples, while at the same time protecting individuals from discrimination.

No bill was voted on until 2003, at which time the Genetic Information Nondiscrimination Act passed the Senate with a vote of 95-0. A nearly identical bill passed the Senate again in 2005 with a vote of 98-0. Both bills failed to pass the House.

In 2000, President Clinton issued an executive order prohibiting federal employers from requiring genetic tests for hiring purposes, for determining eligibility for benefits, or for assessing an employee's current or future ability to perform his or her job. Furthermore, the executive order prohibited federal employers from obtaining genetic information about an employee unless it is necessary to provide medical treatment, to ensure workplace safety, or to provide authorized health researchers access to data.ⁱⁱⁱ

H.R. 493, the Genetic Information Nondiscrimination Act of 2007, passed the House of Representatives on April 25, 2007 with a vote of 420-3. **The House of Representatives' version of GINA contains a provision that prevents private insurers and employers from using the genetic information of a fetus or embryo to discriminate against the parents of that fetus or embryo.** This provision allows parents to take advantage of prenatal testing possibilities without fear that the results of these tests will be used to deny them or, later, their children, health insurance or employment opportunities. This provision was considered controversial and objectionable to pro-life representatives. **The Senate version of the bill, S. 358, no longer contains this provision. (See Recommendation 3)**

Several existing federal laws might easily be interpreted to afford protection against genetic discrimination absent a law specific to genetics. The Americans with Disabilities Act of 1992, the Health Insurance Portability and Accountability Act of 1996 and Title VII of the Civil Rights Act of 1964 are the primary examples of such federal legislation. In reviewing the case law regarding genetic discrimination and examining the boundaries of these

statutes, however, it is clear the existing laws pertaining to discrimination are insufficiently potent in this arena and warrant the passage of a comprehensive federal law specific to genetic discrimination.

III. Implications of GINA for clinical genetic testing

There are many different forms of clinical genetic testing that are offered to patients. Clinical testing can be done prenatally, on newborns, in childhood, and in adulthood; each of these forms of testing entails its own medical and ethical challenges. Prenatal testing usually checks for specific mutations that will cause a disease in the child after birth, so that the parents can decide whether to terminate the pregnancy, or so that they can learn how to cope with their child's condition. Newborn testing is usually done to detect genetic diseases for which early therapeutic intervention provides benefits. Child and adult testing can take many forms. Doctors may test for somatic genetic mutations or for mutations in tumors; they can test for mutations that are 100% penetrant (meaning that the patient is bound to be symptomatic) or for mutations that only increase an individual's susceptibility for developing a disease. In some cases testing is done on individuals who may be carriers of a recessive mutation; in others the testing is performed on someone who has reason to suspect susceptibility; in yet others the testing is done on a person who already has a disease—in which case the results are used to clinch a diagnosis or determine the best course of treatment.

A. Impact of GINA

GINA predominantly speaks to prenatal testing, newborn carrier testing and susceptibility testing, because in the other types of testing disease symptoms are already manifest, which means that existing laws already protect the patient from discrimination. With carrier, prenatal and susceptibility testing there exists a potential, not certainty, of developing a disease. One example is BRCA 1 and 2 mutations, which significantly heighten a woman's risk for developing breast and ovarian cancer.

The number of available prenatal, newborn and carrier tests has been growing for the last four decades, but at the present time not many adult onset susceptibility tests are available, other than the tests for BRCA 1 and 2. Nonetheless, researchers are actively looking for more genetic variants that may increase susceptibility for certain diseases. **Insurance companies claim that they are not currently making wide use of any form of genetic testing in determining premiums because it is usually less expensive overall for the test to be performed and for individuals to take preventive action than for insurance to cover the costs of treating afflicted patients.** Absent GINA, this situation, of course, could change if more specific mutation tests are developed and/or the price of testing rises.

Nevertheless, there seems to be a widespread general perception that insurance companies and employers will use all forms of genetic testing, but in particular susceptibility testing, for discrimination. There are few published studies on this subject but most demonstrate the existence of this fear. A study conducted at the University of Michigan in 2002 examined reasons for declining BRCA 1 or 2 genetic testing. Researchers concluded that 62% of patients

who declined testing did so for fear of insurance discrimination or costs, a substantial percentage.^{iv} A study at the University of Pennsylvania came to a similar conclusion; the vast majority of genetics counselors interviewed said they would pay for the test themselves if they needed it, instead of submitting the claim to their insurance provider, for fear of discrimination.^v

Whether or not genetic discrimination is currently an issue, it appears that there are people who refuse to undergo susceptibility testing for fear that they will be discriminated against. Advocates of GINA argue that the bill would provide such patients with the assurance that insurance companies cannot use their genetic information against them. The Coalition for Genetic Fairness represents many disease-specific patient advocacy groups as well as health, professional, and research organizations (including the American College of Medical Genetics, the American Society of Human Genetics and the National Society of Genetic Counselors), and corporate entities (such as IBM Corporation, Affymetrix, Inc., and 23andME, Inc.) with interests in clinical genetic testing. The Coalition argues that fear of discrimination prevents some people from getting themselves or their children tested.

IV. Implications of GINA for the Conduct of Research and the Assembling of Research Databases

DNA databases are compiled for research purposes in two distinct ways. The first are populational databases in which samples are collected from members of a geographic population to correlate multiple genes with countless phenotypic expressions. The second are disease-specific databases in which information is collected from patients and their families to find genetic variations that correlate to a particular disease. Both types of databases have been used to develop diagnostic tests that can reveal the likelihood that an individual will develop a disease, as well as drug treatments for specific diseases. Collected biological samples are stored in **databanks**. The genetic information obtained from these samples is stored in **databases** corresponding to phenotypic information which can include medical records, physical characteristics and/or genealogical information.

A. Populational Databases

In the last 10 years, large scale populational databases have been created in several countries, such as the federally supported and funded UK Biobank, Sweden's civil, academic, and commercial databank, UmanGenomics, and the database created by deCODE, a U.S. biopharmaceutical company in Iceland. The projects propose to collect DNA samples and health information from populations ranging between 10,000 and 500,000 individuals. These databases consist of information obtained from volunteers after providing individual informed consent. DeCODE's attempt to use presumed consent passed under Icelandic federal law in 1997, but was met with international outrage and was declared unconstitutional by the Icelandic supreme court in 2003. This led to the implementation of thorough informed consent procedures.

To create databases, biological samples (tissue, blood, saliva and/or urine) are collected and stored in a databank. A variety of measures have been implemented to ensure privacy, depending on the database size and collection methods. Privacy is maintained through data

encryption, a process that removes all identifiable characteristics from the participant file and assigns it a random identification number.

From these samples, Single Nucleotide Polymorphisms (SNPs) are analyzed along with the corresponding phenotypic information to determine correlations between SNPs and specific diseases or characteristics. Identification of SNPs has led to the development of diagnostic tests for genetic predisposition. Furthermore, the correlation of SNPs and phenotypes reveals areas of the genome in which to look for genes involved in the expression of specific traits. The isolation of genes has led to advances in drug development. In the past month, three companies have launched direct to consumer commercial genomic services to trace ancestry and genetic risk for specified diseases. While these companies are careful to say that they are not offering medical services, this might not be apparent to consumers, generating an issue that may need to be addressed by U.S. law.

B. Disease-Specific Databases

Disease-specific databases collect genetic and medical information from a targeted population with a specific type of disease. By comparing the genotypes and phenotypes of thousands of individuals, the information in these DNA databases can be used to identify gene variants that may be an underlying cause of the disease. Pharmacogenetics is a subfield of genetic research that aims to optimize drug dosages for individuals. Individual differences in drug metabolism have made it extremely difficult for health care workers to predict drug toxicity and efficacy in certain patients because there is a large variation in drug-metabolizing enzymes encoded by gene variants. Thus, pharmacogenetic research uses disease-specific DNA databases not to predict the risk of disease, but rather to determine the optimal drug dosages that can be tailored for each individual.

The protocols for assembling DNA databases differ somewhat based on the type of research. Typically, researchers solicit participants through their clinical practices. If a patient agrees to participate, they will then read and sign an informed consent form and allow researchers to extract DNA samples from their blood, saliva or tissue sample. After each DNA sample is collected, it is sequenced and stored at the discretion of the research team.

Participants in disease-specific database research do not necessarily receive genetic counseling because they are not notified of test results and have already been medically diagnosed with the genetic condition tested for. Despite the lack of genetic counseling in disease-specific research, investigators still provide informed consent and ensure patients that they will make every effort to maintain the confidentiality of test results.

C. Impact of GINA

If GINA is enacted into law, the effects that it will have on research practices will vary by the type of research and type of DNA databank that is being created

Both disease-specific and populational databanks contribute to the development of tests and treatments for genetic disorders and both require participation from the general public. From the

position of advocacy groups, the distinction between the two types of databanks is not relevant. Instead, they are concerned with the research conducted on the samples in these databanks. **Advocacy groups and researchers concerned with the issue of genetic non-discrimination argue that federal legislation like GINA is necessary to alleviate the fear of discrimination that causes many people to opt-out of clinical trials.** The Coalition for Genetic Fairness represents many disease-specific patient advocacy groups as well as health, professional, and research organizations (including the American College of Medical Genetics, the American Society of Human Genetics and the National Society of Genetic Counselors), and corporate entities (such as IBM Corporation, Affymetrix, Inc., and 23andME, Inc.) with interests in DNA technology and databanks. The Coalition believes that lack of participation in trials (and, though not explicitly stated, perhaps DNA databanks and repositories as well) will severely limit genetic research and the development of tests, treatments and drugs.

However, the genetics researchers in Philadelphia whom we interviewed seem relatively confident that individuals' results would not be disseminated, nor do they feel that they are suffering from lack of participation because of fear of discrimination. Researchers are clear in their informed consents that the potential for discrimination exists when dealing with genetic diseases, but in general **no DNA databank research involves returning genetic test results to patients or their doctors.** For this reason, the chances that insurance companies or employers could discover the results are slim. This seems to be understood by participants in the research; the general consensus of genetics researchers was that very few people declined to participate in their studies because of fear of discrimination. Other reasons, such as fear of needles (to draw blood) or discomfort with genetic testing in general were more important to potential participants when they decided whether or not to participate in the study.

Those researchers whose work is linked to clinical genetic testing also did not seem to suffer from lack of participants; this is probably because those individuals receiving clinical testing have already crossed any mental barrier against genetic testing. Individuals may also be less likely to withhold consent because they have invested a substantial amount of time in the qualification process.

If research involves genetic testing for mutations that cause a disease, GINA will have little effect because participants will already know they have a disease; any possible insurance or employment discrimination would have already occurred. **In contrast, participants involved in susceptibility testing, as in the case of BRCA 1 and 2 testing, could be affected by GINA because they are being tested for a *risk factor* for certain kinds of cancer. However, it was previously stated that none of these results are returned to the people involved in these DNA databank research projects, nor is the information placed in their medical records. Therefore, results from genetic testing for research purposes could not easily be used for discrimination.**

On the other hand, researchers involved in susceptibility testing argue that the necessity of GINA **lies in the perception of the people that discrimination exists.** Researchers generally felt that there is an overwhelming idea in America that genetic discrimination will happen eventually, even if it is not a current problem. **Passing GINA would help to alleviate their fears and**

perhaps encourage some of those not currently involved to participate in clinical and research testing.

In HR 493, the only provision in which “research” is mentioned is 101, B, 4:

“Allows a group health plan to request, but not require, a participant or beneficiary to undergo a genetic test for research purposes if certain requirements are met, including: (1) the plan clearly indicates that compliance is voluntary and that noncompliance will have no effect on enrollment status or premium or contribution amounts; (2) no genetic information collected or acquired is used for underwriting purposes; and (3) the plan notifies the Secretary of Health and Human Services that it is conducting activities pursuant to this exception and includes a description of the activities.”

This provision allows researchers to have access to the populational databases managed by insurance companies. This would be an enormous resource for researchers because they would have access to thousands of individuals’ medical information while the protections offered by GINA would eliminate any fear of discrimination. With this research exception, GINA would allow insurance companies to request that a beneficiary undergo a genetic test solely for the purpose of independent research, provided the genetic information collected would be protected by GINA from any other use by the insurance company such as underwriting. Further protection is offered under the privacy rule in HIPAA, which requires a signed authorization by the individual or a waiver granted by an IRB before any data is disclosed for research purposes. Also, HIPAA permits covered entities to disclose patient data if it is sufficiently decoded so that the probability of identification is very low.

V. Implications of GINA for Discrimination in Health Insurance

Underwriting is one of the strategies health insurance companies employ to remain solvent. Individuals that are most likely to cost the company money, as determined through medical examinations and histories, are either denied coverage or made to pay higher premiums. Genetic tests that predict if an individual may develop a costly medical condition in the future could arguably be of value to an insurance company during the underwriting process. GINA seeks to prohibit the use of genetic information for this purpose. However, there is very little evidence that insurance companies have requested or used genetic information from their applicants or beneficiaries in a discriminatory manner since genetic testing became widely available in the 1980s.

To date there have been no claims of genetic discrimination in health insurance raised in state or federal court. Empirical evidence regarding consumer perceptions of discrimination in insurance is conflicting, but **most studies show that individuals want access to their genetic information if encouraged by their physicians.**

Although one study conducted by the Genetics and Public Policy Center at Johns Hopkins University in March of 2007 found that 92 percent of respondents were concerned that genetic

information could be used to harm them,^{vi} only nine percent of respondents in a similar study would not reveal test results to an insurance company because of a genetic condition.^{vii}

In 2002, Aetna's Chairman and CEO publicly endorsed efforts to prevent the use of genetic information as a condition for coverage or as a determinant of risk classification, and declared Aetna itself would not use genetic information for underwriting purposes. Although these are promising signs, there is by no means sufficient evidence that genetic discrimination in health insurance will not occur in the future. In a study by Georgetown University Child Development Center of 332 individuals who had a family history of a genetic condition, twenty-two percent believed they had been denied health insurance coverage as a result.^{viii} As more accurate tests are developed for an even greater number of genetic conditions, the appeal of using this information to control costs – in the same manner that other medical information is used today – is likely to prove compelling to insurance companies.

Advocacy groups and individuals speaking on the impact of GINA on health insurance present two different views of this issue. Though there have been few cases of genetic discrimination by health insurance companies, testimony to Congress indicates that groups such as the Coalition for Genetic Fairness and researchers, including some at NIH and others in health policy research, have found that **fear of losing health insurance deters people from seeking genetic testing for clinical or research purposes**. They argue that GINA will protect insurability and allow those with genetic diseases to benefit from breakthrough treatments available through clinical trials and the promise of personalized medicine.

Opposing this view is that of the National Association of Health Underwriters and the health insurance industry. They argue that the genetic information protected by GINA should only include testing done for predictive purposes in undiagnosed individuals. NAHU believes that insurance companies and employers should not discriminate on the basis of predictive genetic tests in order to to promote preventive screening and disease management. NAHU argues genetic testing that is used for diagnostic purposes in symptomatic persons, however, should not be protected information under GINA, but rather considered “health status information” along with such metrics as age, gender, cholesterol levels and blood pressure. This information is currently used for underwriting purposes in health insurance in order to control costs. NAHU argues that protecting all genetic information could impede the ability of insurers to underwrite and cause health insurance providers to withdraw from the market, leading to fewer coverage benefits and higher costs for the consumer.

VI. Implications of GINA for Employment Discrimination

Unlike health insurance, there have been several recorded cases of genetic discrimination in employment. One high profile instance in 2005 involved Eddy Curry, a basketball player, who refused to undergo a genetic test for a hereditary cardiac condition at the behest of his employer, the Chicago Bulls. The team consequently refused to allow him to play, stirring up a relatively brief controversy until the issue was rendered moot when Curry was traded to the New York Knicks. In April of 1999, Terri Sargent of North Carolina was found to have the debilitating genetic disease Alpha-1-antitrypsin deficiency and subsequently lost her job. She filed with the

EEOC and alleged the company had terminated her employment in order to avoid the increase in premiums associated with her necessary and expensive treatment. On November 21, 2000 the EEOC announced its investigation supported her claim of genetic discrimination under the ADA, though the case was never addressed in court.

In rare instances the issue of genetic discrimination in employment has, in fact, been raised in federal court. The most relevant and successful claim was brought in 2001 by the Equal Employment Opportunity Commission on behalf of 36 employees of the Burlington Northern Santa Fe Railway Corporation (BNSF). Upon claiming benefits for work-related carpal tunnel syndrome, the 36 plaintiffs were required to undergo thorough medical examinations, including a genetic test for a very rare genetic risk factor for carpal tunnel. The EEOC argued that this amounted to unlawful disability discrimination under Title I of ADA. BNSF settled the case for \$2.2 million and agreed not to require any further genetic testing of its employees. This case should not be construed as evidence for the adequacy of current anti-discrimination laws in genetics, as argued by some employer lobbyists, however. The case was settled out of court so it did not establish a usable precedent for the future, and most legal scholars agree that the case would probably have been adjudicated in favor of the defendants given the Supreme Court's tendency to favor a very narrow interpretation of ADA.

The dearth of genetic discrimination cases in the courts might be evidence that employers have shied away from using genetic information in a discriminatory manner. Given the prevalence of anecdotal evidence of discrimination, however, it is more likely that the nature of discrimination lawsuits discourages plaintiffs from coming forward. The burden of proof in such cases lies with the plaintiff and it can be very difficult to prove, as required by ADA, that the employee was “regarded as” having a genetic disorder and was discriminated against on that basis. Studies show that up to 98 percent of employment discrimination cases are handed down in favor of the defendant-employer.^{ix} **The lack of a comprehensive genetic anti-discrimination statute could exacerbate this trend with regard to genetic discrimination suits.**

One study found that 63 full-time workers from a range of industries considered the inability to find future employment or retain a current job to be a “moderately likely” result of seeking genetic information.^x If employees fear genetic discrimination, they are likely to avoid genetic tests, thereby preventing an actionable claim for genetic discrimination from ever arising. As genomic medicine matures and employees seek access to the technology, the impetus for genetic discrimination in employment can only grow.

While there has been little evidence of genetic discrimination in employment in the courts, employers represented by the Genetic Information Nondiscrimination in Employment coalition (GINE) have argued that GINA will have unintended consequences. GINE believes that GINA increases the liability that employers could face for receiving genetic information for purposes permitted by HIPAA for other protected health information. The excessive punitive and compensatory damages could make people who have had genetic tests or those with genetic disorders more difficult to employ, similar to the effect ADA had on individuals with disabilities. GINE feels that any federal legislation should take into account existing protections offered by HIPAA, ADA and other laws. Like the insurance industry representatives, GINE believes that genetic information in GINA should be narrowly defined as including only predictive tests.

VII. Unintended Consequences

(1) Some researchers have noted the difficulty that HIPAA caused for the approval of research grants. There is also a possibility that genetics researchers might need to modify their informed consent to include a more elaborate explanation about the privacy of test results from third parties such as insurance companies. **Time is money and health so one unexpected outcome of GINA may be to delay potentially beneficial research.**

(2) In addition to increased overhead costs and administrative responsibilities, employers fear the broad provisions in GINA **could generate frivolous and unfounded lawsuits.** Employment discrimination suits can be extremely expensive and time-consuming to litigate, for plaintiff and defendant alike, often regardless of the merit of the initial claim. Furthermore, critics of the legislation argue the provisions would be difficult to enforce. Despite the penalties and mechanisms outlined in Section 207, employers predict adherence to the provisions set forth in GINA would primarily be enforced by the court through *tort* proceedings.

(3) **It is quite possible that insurance companies in the individual coverage market would withdraw from the business,** due to adverse selection of persons who know their genetic susceptibility to serious disease. The population of persons who purchase individual coverage may well have a higher proportion of symptomatic persons in it than in the group health market, which **will mean that the level of health insurance discrimination against persons with the symptoms of a genetic disease could rise.** This result, of course, would be exactly the opposite of what GINA intended to accomplish. Some people believe that when more tests are developed the net effect of GINA will be that companies providing health insurance will withdraw from the market, **necessitating health care reform.**

(4) The provision that protects the genetic information of a fetus from discrimination has been stricken from the Senate version, S. 358. **If GINA were to be passed without that provision, parents may decide to avoid prenatal testing.** If a test reveals the likelihood that the baby will be born with a serious illness, insurers would be allowed to deny family coverage or increase the premiums for family coverage. Furthermore, parents may fear coercion to terminate the pregnancy from their health insurer who could refuse to insure the disabled child.

Thus, without explicit protection for the genetic information of a fetus or embryo, **GINA may have the unanticipated impact of reducing the use of prenatal testing.** In addition, since genetic information of parents can be learned from the genetic information of a fetus, without that provision **GINA would, in effect, nullify itself.**

VIII. Recommendations

Our research has led us to believe that enacting comprehensive federal legislation protecting consumers of genetic testing from discrimination in the workplace and insurance is a necessary

and prudent policy objective. If and when the Senate passes S. 358, there are several provisions in both versions of GINA that we believe should be addressed in conference.

- (1) **The Congressional findings 2, 3, and 4 should be dropped** or significantly rewritten. Although these findings are not a matter of law, and are merely meant as an introduction to the bill, Congress should not be in the business of perpetuating falsehoods, however well intended.

- (2) During the reconciliation process, **the House should not agree to the Senate's version of GINA as it stands today.** Since genetic information about a fetus necessarily reflects upon the genetics of its parents, the absence of a provision protecting fetal genetic information runs counter to the goals of the legislation. Furthermore, the information garnered from prenatal testing could potentially become part of the child-to-be's medical records upon birth, and therefore must be afforded the same protections as any other form of genetic information.

Endnotes

ⁱ Suter, Sonia M., "The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?". Washington University Law Quarterly, Vol. 79, No. 3, 2001 Available at SSRN: <http://ssrn.com/abstract=276875> or DOI: [10.2139/ssrn.276875](https://doi.org/10.2139/ssrn.276875)

ⁱⁱ "A Time-Line of Genetic Discrimination Legislation, 1990-2005." National Human Genome Research Institute. <<http://www.genome.gov/12513983>>. Accessed 4 Dec. 2007

ⁱⁱⁱ Clinton, William, "Executive Order 13145—To Prohibit Discrimination in Federal Employment Based on Genetic Information." Federal Register, Vol. 65, No. 28, February 10, 2000. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2000_register&docid=fr10fe00-165.pdf

^{iv} Peterson, Emily et al. "Health Insurance and Discrimination Concerns and BRCA1/2 Testing in a Clinic Population." *Cancer Epidemiology, Biomarkers & Prevention*. January 2002;11:79-87

^v Matloff, ET et al. “What would you do? Specialists' perspectives on cancer genetic testing, prophylactic surgery, and insurance discrimination.” *Journal of Clinical Oncology*. June 2000;18(12):2484-92

^{vi} “U.S. Public Opinion on Uses of Genetic Information and Genetic Discrimination.” Genetics and Public Policy Center. April 24, 2007. <<http://www.dnapolicy.org/policy.privacy.php>> Accessed

^{vii} Lapham EV, Kozma C, et al. “Genetic Discrimination: Perspectives of Consumers.” *Science* Vol. 274, 25 October 1996. p 621-4.

^{viii} Ibid. p 621-4.

^{ix} Selmi, Michael. “Employment Discrimination and the Problems of Proof: Why are Employment Discrimination Cases so Hard to Win?” *Louisiana Law Review*, Spring 2001. 61 *La. L. Rev.* 555.

^x Roberts LW, Geppert CMA, et al. “Perspectives on use and protection of genetic information in work settings: results of a preliminary study.” *Social Science and Medicine* Vol. 60 (2005), p 1855-8.