Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World

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Evidence is emerging of a growing societal consensus about appropriate and inappropriate uses of genetic information. The Genetic Information Nondiscrimination Act of 2008 provides new legal protections to Americans by prohibiting the discriminatory use of genetic information by health insurers and employers. Additionally, the United States military recently created new policies for fair use of genetic information in the determination of benefits for servicemen and servicewomen leaving military service. Although critical issues remain, such as the potential for genetic information to be used to deny people other forms of insurance, and how the military will use genetic medicine overall, significant progress has been made.

Introduction: GINA, Health, and Society

After more than 12 years of consideration by Congress, a new federal law has been enacted aimed at quelling a deep fear of millions of Americans—that information about their genetic makeup could be used by health insurers and employers to discriminate against them. The Genetic Information Nondiscrimination Act (commonly known as GINA) prohibits health insurers and employers from asking or requiring a person to take a genetic test and from using genetic information in setting insurance rates or making employment decisions.[1] GINA prevents health insurers from denying coverage or adjusting premiums on the basis of genetic information, or from requesting that an individual undergo a genetic test. For the 175 million Americans in the group health-insurance market, this new law augments protections already afforded under the Health Insurance Portability and Accountability Act by prohibiting cost increases for a group based on the genetic information of group members. And for the one in four Americans who will buy or attempt to buy individual health insurance in the next three years,[2] GINA provides new and comprehensive federal protection from the use of genetic information for underwriting. In addition, the new law prohibits employers from using genetic information to make hiring, firing, or promotion decisions and sharply limits their ability to request, require, or purchase an employee's genetic information.

President George W. Bush signed GINA into law on May 21, 2008. Federal agencies are currently writing the regulations that will implement the new law; all provisions of the law are slated to be in effect by November 21, 2009.

Many clinicians, researchers, and patients are still unclear about what GINA does and does not accomplish and what it means for them. Although GINA does not answer every concern facing individuals contemplating genetic testing, it goes a long way toward removing fears that have dogged the delivery and translation of genetics in both healthcare and research. Until now, protection from the collection and use of genetic information by health insurers and employers came only from a patchwork of state and federal laws and regulations. As research into human genetics advances at a rapid pace, GINA is a necessary and laudable policy response to the ongoing revolution in genetics and human health.

To be sure, some have criticized GINA as narrow and limited in scope.[3] GINA is, like most enacted laws, a compromise and reflects a strategic and delicate balancing of interests of all key stakeholders including providers, patients, insurers, employers, researchers, and lawmakers. Technically speaking, GINA amends laws that are themselves compromises, and many of the critiques of GINA, closely examined, are actually critiques of the underlying laws or policies. For example, GINA prohibits insurers in the individual market from using genetic information to determine an individual's eligibility for health insurance or to set his or her premium—but it does not prohibit underwriting altogether. This means that individuals with genetic diseases, like individuals with diseases without a known genetic basis, may continue to have a difficult time obtaining affordable health insurance in the individual market.

Overall, GINA's passage is strong evidence of a growing societal consensus that discrimination on the basis of our genes is simply unfair, given the many complicated health risks—genetic and environmental, knowable and unknowable, controllable and uncontrollable—that we all face. It took more than 12 years for GINA to pass, but when it finally overcame the opposition of a few members of Congress who controlled the rules of the House and Senate for many years, it passed almost unanimously, with strong bipartisan support.

GINA's lasting legacy, however, may be seen as much in its reflection of emerging social consensus about the appropriate and inappropriate uses of genetic information as in its legal reach per se. As further evidence—albeit less well publicized—of this growing consensus, the U.S. Department of Defense recently began a dramatic transformation in long-standing discriminatory policies regarding the use

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of genetic information in the military. These changes come as advances in our understanding of genetics have led the military to consider how genetic testing might best be used to maximize effective training and staffing of the armed forces in wartime.

Why GINA?

Researchers in human genetics, geneticists, and other healthcare providers, as well as many patients, know well how important GINA's passage really is. For many years, patients who might have benefited from genetic testing avoided it—or obtained it anonymously or under assumed names—out of concern about possible repercussions. The fear of genetic discrimination has affected both individual health care and clinical research to their detriment. When people opt not to be tested or keep their results secret, they put themselves in serious danger by losing the opportunity to seek monitoring and preventive care to avoid conditions for which they are at heightened risk. In one recent case, parents who were aware of a Factor V Leiden mutation in their family (a condition that raises the risk of blood clots) were advised that their daughter should not have a genetic test for the condition until legislation protecting against genetic discrimination passed. Subsequently, the young girl almost died from a massive clot. Fortunately, she survived and is expected to recover.[4] But cases like this dramatically illustrate the dangers inherent in the fear of genetic discrimination and ultimately inspired the near-unanimous passage of GINA in Congress.

GINA benefits genetic research as well as individuals. Linking gene variants to health outcomes often requires studies involving large numbers of people, but scientists long have reported that potential research participants have been deterred by fears that their information could be used against them by employers and insurers. This fear has presented serious obstacles to research. Consent forms and counseling of research participants necessarily have included warnings that participants may experience genetic discrimination in the future.[5–8] Now, scientists and researchers can assure study participants that neither their participation in a research study nor their genetic information legally can be used against them by their employers or health insurers.

At times during Congressional deliberations, health insurers stated that GINA was unnecessary on the grounds that they do not use genetic information in underwriting or coverage decision and that widespread public concern about genetic discrimination is baseless. However, key work published by researchers at Georgetown University during the final months of Congress' deliberations showed otherwise.[9] In the study, individual health insurers were asked to medically underwrite pairs of hypothetical applicants. Each pair differed only in whether they had received a genetic test result indicating elevated risk of future disease or had received genetic services such as counseling about treatment options to reduce inherited disease risk. A substantial number of medical underwriters indicated that they would deny coverage, charge higher premiums, or impose exclusion riders to limit covered benefits based on genetic information or receipt of genetic services.

This is an extraordinary time for human genetics. More than 1300 genetic tests are available clinically now, any individual can obtain genetic testing (of various scope, value, and legitimacy) over the Internet, and our understanding of the links between genes and health is expanding, particularly through the use of genome-wide association studies. In an online, international registry of clinical trials maintained by the National Institutes of Health, at least 1500 of the studies currently listed appear to involve or relate to genetic testing.

Ethical concerns about potential misuses of genetic information have proliferated since the beginning of the Human Genome Project in 1990. A robust body of legal and policy scholarship has probed the issue of genetic discrimination against civilians in employment and insurance. Some question the underlying rationale for enacting special protections for genetic information, sometimes called genetic exceptionalism.[10,11] Others argue that the predictive nature of genetic information, its implications for family members, its use historically to support prejudice, and heightened public concern about genetic privacy points to the need for additional protections.[12] Other scholarship has yielded key insights regarding the values that are threatened—including respect for persons,[13,14] privacy,[15,16] and equality[17]—when genetic information is used to deny someone employment or insurance or place additional burdens on access to these societal goods.

There is a lengthy history of ethical issues surrounding genetic testing.[18–24] During the 1970s, African Americans were forced to undergo screening for sickle cell anemia as a condition for school attendance and marriage licenses,[25] and those who tested positive as carriers faced discrimination in employment, despite the fact that they did not have the disease.[23,25] This led the federal government to pass the Sickle Cell Anemia Control Act of 1972,[26] which made sickle cell screening voluntary. It also led some states to pass laws prohibiting the use of specific recessive genetic mutations, such as for sickle cell disease and Tay Sachs, in underwriting decisions.[27] These laws were limited in scope and premised on the fact that actuarial justification for requiring testing of recessive mutations was lacking because the mutation does not bear on an individual's health risk.[27]

The detrimental impact of fear of genetic discrimination on individual and public health is well established.[28] Empirical research has documented the negative impact this fear has on an individual's willingness to utilize genetic services[29–35] or to participate in biomedical research.[36] Numerous studies have documented the attitudes and experiences of research participants,[32,34] patients,[29–31,33,35,37–42] healthcare providers,[37,43–47] and the general public[48–50] related to genetic discrimination.

In 2004, our own public opinion survey of 4834 Americans showed that 80% of respondents felt that health insurers should not have access to an individual's genetic test results. Even more (92%) felt that employers should not have access to such information. Although concern about privacy did not vary based on most demographic variables (e.g., sex, age, political affiliation), attitudes did vary by educational level, with more than 97% of respondents with a college education opposing employer access.[51–53] In 2007, we conducted a related survey of 1199 Americans to assess the level of trust in various individuals and entities that might have access to genetic information, views about privacy protection for various types of medical information (e.g., HIV status, genetic information, mental health information), and opinions about access to and use of genetic information by health insurers and employers. More than three-quarters of respondents believed that there should be a law that prevents employers from using genetic test results about risk of future disease to make decisions about hiring and promotion; three-quarters also believed there should be a law to prevent health insurers from using genetic test results about risk of future disease to deny or limit insurance or charge higher prices.[51,54,55] These data helped bolster the case for legislative action and the resolve of federal legislators.

A Legislative History

Concern about genetic discrimination, particularly by insurers, led to a variety of state laws. In 1991, Wisconsin became the first state to enact a law prohibiting health insurers from requesting genetic information or using such information to make eligibility or risk classification decisions. However, comprehensive analyses of the inadequacies of many early laws to protect against genetic discrimination[56–60] and examples of actual and attempted discrimination by employers and insurers[41,60–64] led to additional policy proposals, including federal legislative efforts that began in the mid-1990s. There have been numerous versions of federal genetic discrimination legislation, and more than 40 states now restrict the use of genetic information by insurers. More than 30 states have passed laws that prohibit genetic discrimination in employment (see database of state genetic laws online). GINA does not affect state laws that are more protective. However, state laws that are less protective than GINA will be trumped by the new federal law. In many cases, state laws' definitions of genetic information are narrower than GINA's: some do not include family history, and some cover tests in the research setting and exclude those that become part of routine clinical practice. Under GINA, state health-insurance regulations must conform to federal law by GINA's effective date, May 21, 2009. After that date, if states do not have in place protections that meet or exceed GINA standards, federal enforcement can be triggered.

Before GINA's passage, a handful of federal laws provided some limited protection from genetic discrimination in group health insurance and on the job. In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA),[65] which included two specific provisions putting in place some restrictions on group health insurers' use of health-related information in making coverage decisions and setting premiums. Congress specifically recognized and listed genetic information as protected health information. HIPAA further states that genetic information in the absence of a diagnosis (e.g., predictive genetic test results) cannot be considered a pre-existing condition.

In the workplace setting, the Equal Employment Opportunity Commission (EEOC) has interpreted the Americans with Disabilities Act (ADA)[66]—in particular its protection of people who are "regarded as" having a disability[67]—to provide some protections from the use of genetic information by employers. In one United States Supreme Court decision, *Bragdon v. Abbott*, the Court ruled that people with HIV infection may be covered under the ADA even if they are free of symptoms. In a dissenting opinion, Chief Justice Rehnquist wrote that the argument adopted by the majority opinion, "taken to its logical extreme, would render every individual with a genetic marker for some debilitating disease 'disabled' here and now because of some future effects."[68] In part because of that dissenting opinion, some questioned whether the ADA would in practice provide meaningful protection against genetic discrimination if challenged in court.[56,69]

In 2000, President Clinton evidenced his support for genetic nondiscrimination when he issued Executive Order 13145, To Prohibit Discrimination in Federal Employment Based on Genetic Information. The Executive Order explicitly prohibits discrimination on the basis of protected genetic information in all aspects of civilian federal government employment and limits federal departments' and agencies' access to, and use of, genetic information.[70]

Both President Clinton and President George W. Bush strongly supported federal legislation to ban genetic discrimination in health insurance and employment.[70,71] Since the first version of GINA was introduced in 1995, the legislation also had the support of a majority of Congress. Legislation nearly identical to GINA passed the Senate unanimously in 2003 and 2005. From 2003 to 2006, the Republican Congressional leadership simply refused to allow the legislation to be considered by the House of Representatives. But with the 2006 election and the change in control of Congress, GINA began to move rapidly toward enactment. After consideration by a total of four committees of jurisdiction in the House and the Senate and numerous votes in both chambers, GINA was finally enacted by Congress and signed into law by President Bush in 2008.

GINA's Strengths and Limitations

Hailed by many as the first civil rights legislation of the 21st century, GINA represents significant progress in protecting civilians from genetic discrimination in employment and health insurance.[1,72] For researchers and research participants, GINA means that fear of genetic discrimination by health insurers or employers no longer will be a barrier to timely progress in genetics research. GINA allows clinicians and researchers to provide reassurance to patients and research participants that they need not fear genetic discrimination.

Yet it is also important for researchers, clinicians, and patients to understand what GINA does not do. For example, GINA provides no guarantee that health insurers will pay for particular genetic tests or the medical care, diagnostic tests, or treatments that a genetic test indicates are appropriate. In some circumstances it may be necessary to reveal a test result or family history to an insurer to prove medical necessity—for example, if a woman chooses to undergo a prophylactic removal of her breasts and ovaries because of a positive BRCA test or a strong family history of breast and ovarian cancer, the insurer may ask for the family history information or genetic test result as evidence that the surgery is medically necessary. However, the insurer may request only the minimum amount of information necessary to accomplish the intended purpose. In some cases, a medical record indicating that a patient is at higher risk for ovarian cancer based on her own personal history of cancer may be sufficient.

GINA does not include protection from genetic discrimination in life insurance, disability insurance, or long-term-care insurance. GINA also does not apply to members of the United States military, to veterans obtaining healthcare through the Department of Veterans Affairs (VA), or to the Indian Health Service because the laws amended by GINA do not apply to these groups and programs.

Clinicians should note that GINA does not interfere with the ability of a treating healthcare professional to request or recommend that an individual or family member undergo a genetic test. Nor does it limit the authority of health insurers to notify individuals about genetic tests or provide information to enrollees about a genetic test. For example, a geneticist is free to recommend BRCA testing to an individual with a family history of breast and ovarian cancer. A health insurer may notify all enrollees of the availability of BRCA testing and provide information about when such testing may be indicated. But a health insurer may not request or require that a particular individual take a genetic test.

Under certain limited circumstances, an employer would not be held liable under GINA for acquiring genetic information. For example, some genetic information may be collected as part of a toxic monitoring or wellness program in the workplace, and employers will not be penalized for inadvertently collecting genetic information (such as knowledge of the existence of a genetic disease in a family member) through an employee's request for leave under the Family and Medical Leave Act.

Some early versions of GINA included privacy and discrimination protections for individuals with a diagnosed genetic disease or condition. These proposals essentially prohibited medical underwriting on the basis of diagnosed genetic illness, an approach that would have dramatically changed individual health-insurance market practices and the U.S. healthcare system. Ultimately this approach was determined to be outside the core purpose of GINA. Similarly, GINA does not prohibit employment discrimination on the basis of an already manifest genetic disease—such circumstances have been and will continue to be handled under provisions of the ADA.[66] Many of GINA's sponsors and supporters would have liked to strengthen the existing legal protections for people with genetic diseases but ultimately felt that it would be unfair to provide such protection only to people whose diagnosed disease had a known genetic basis. Such a rule rapidly would have become unwieldy and unworkable as individuals would have to prove the genetic basis of their disease even as our understanding of the genetic basis of disease continues to evolve. The final version of GINA protects genetic information that predicts an individual's risk of disease in the future, as well as the genetic test results of people already affected by a genetic disease.[72]

There have been other concerns raised about GINA, including the argument that GINA permits excessive sharing of genetic information by applying the privacy rules of HIPAA to genetic information.[73] HIPAA permits data sharing among covered entities without patient consent in connection with treatment, payment, and oversight of the healthcare system, often referred to as healthcare operations. This criticism appears to be primarily based in a belief that underlying HIPAA privacy regulations are not strong enough, a limitation that GINA did not attempt to address. However, GINA does specifically prohibit underwriting decisions made on the basis of any genetic information held by a HIPAA-covered entity.

Definition of Terms

GINA defines key terms such as "genetic information," "genetic services," and "genetic test."

"Genetic information" means information about genetic tests, the genetic tests of family members, and the manifestation of a disease or disorder in family members (a "family member" is defined as a first-, second-, third-, or fourth-degree relative). It also includes any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by an individual or his or her family members. "Genetic services" may include a genetic test, genetic counseling (including obtaining, interpreting, or assessing genetic information), or genetic education. The law states specifically that genetic information does not include information about sex or age. Further clarification about the scope of these definitions is expected through the federal regulatory process, currently under way.

The definition of "genetic test" is quite specific. Under GINA, genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites to detect genotypes, mutations, or chromosomal changes. However, according to the law, genetic test does not include:

> "(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal

> changes; or (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 healthcare professional with appropriate training and expertise in the field of medicine involved."

It is important to note that (ii) does not appear in the employment section of the law—in the workplace, this exception to the definition of genetic test would not apply. In other words, GINA does not prohibit insurers from underwriting based on information that reveals information about current health status. However, employers may not use such information to make employment decisions.

How GINA Will Be Enforced

GINA amends the four federal laws that govern the provision of health insurance in the United States: the Employee Retirement Income Security Act (ERISA), the Public Health Services Act (PHSA), HIPAA, and the Internal Revenue Code. GINA also was crafted to apply to those employers covered by Title VII of the Civil Rights Act of 1964, which bans discrimination on the basis of race, color, religion, sex, or national origin. Under Title VII, employers with fewer than 15 employees are not included.

GINA's enforcement mechanisms and penalties are consistent with provisions of all of the above laws. Some earlier versions of the legislation provided more substantial penalties for violations. However, during Congressional deliberation, the bill's sponsors decided that to mandate harsher penalties for violations of GINA than for violations of other privacy and discrimination laws would be an irrational and unfair approach. It also was believed that consistency with other laws would ease the burden on health insurers and employers in complying with the bill and help ensure its passage. The law will be enforced by federal agencies including the Department of Health and Human Services (HHS), the Department of Labor (DOL), and the EEOC. In addition, relief may be available to individuals under state laws that are stronger than GINA.

Imagine a woman, Irene, who believes she has experienced genetic discrimination. If she has been denied an individual health-insurance policy and wishes to seek enforcement under GINA, she would be well advised to go first to her state health-insurance agency for assistance: States may have laws that are at least as protective as those required by GINA. Many are expected to pass such laws in order to maintain their enforcement jurisdiction. HHS will enforce GINA protections when states fail to provide equally strong protections.

The employment provisions in GINA will be enforced by the EEOC. Irene would need to obtain what is known as a "right to sue" letter from EEOC in order to move forward with a lawsuit against an employer.

Finally, if the discrimination occurred through her group health plan at work, Irene should start with the DOL, which has primary jurisdiction over employer health-benefit plans: The Secretary of Labor has authority to fine employer-sponsored health-benefit plans that do not comply with GINA. In addition, the Internal Revenue Service (IRS) has authority to assess tax penalties on employer-sponsored health-benefit plans that do not comply with GINA.

Military Use of Genetic Information

As the use of genetic testing becomes widespread in civilian society, the use of genetic testing and genetic information by our military system is rapidly evolving. Service members and their families rely on the Department of Defense (DoD) for employment, healthcare and for a variety of health and disability benefits. Although GINA does not apply to the United States military, recent policy shifts at DoD in many ways mirror the changes brought by GINA. Currently, DoD collects and uses the genetic information of service members in several ways. All U.S. service members, including active duty and reserve military personnel, must provide a DNA sample that may be used to identify their remains should they die in battle (see Armed Forces Institute of Pathology database online).[74,75] These samples are housed in the Armed Forces Repository of Specimen Samples for the Identification of Remains. As of 2002, the United States military's DNA repository contained 3.2 million samples.[74] In general, retrieval and analysis of these samples is performed only to identify human remains. However, a provision in the 2003 National Defense Authorization Act overrode the policy of allowing access to the repository for limited law-enforcement purposes.[75] Since then, there has been some discussion of whether the repository could or should be used for other purposes, such as research.[76] Soldiers have occasionally challenged the requirement of providing a sample to the repository, but federal courts have found that the mandatory collection does not violate the Fourth Amendment protection against unreasonable search and seizure.[77] However, individuals have the right to request that their samples be destroyed when they conclude their relationship with DoD.

All individuals entering the military also receive genetic tests for sickle cell anemia and G6PD (Glucose 6-phosphate dehydrogenase) deficiency (M.H. Fries, personal communication).[78] The military may use the test results to ensure the safety of enlisted individuals by keeping them from environments or jobs that are believed to trigger disease or exacerbate health concerns. By determining such susceptibilities, the military hopes to prevent injury or disruption of duty.[78] A positive test result for a genetic disorder is noted on a service member's dog tags and in his or her medical records, which superiors consult before making assignments and promotions. For example, depending on the branch of armed forces, persons who are sickle cell carriers or have sickle cell disease may opt out of service, be excused from severe exertion, or be kept from assignments involving high altitudes. They may wear special red sashes or armbands during basic training to alert drill instructors to their sensitivity to strenuous activity. Individuals with G6PD deficiency are not assigned to locations that would require them to take malaria medications because doing so could lead to adverse events (M.H. Fries, personal communication).[78] The initial medical exam administered to service members also may identify a genetic or nongenetic disorder that could be the basis for determining that they are unfit for duty.

As genetic testing rapidly expands, with a wide range of tests becoming available for a broad range of conditions, in the future DoD may consider using additional genetic testing, particularly at enlistment. At a time when DoD is struggling to maintain a strong and well-staffed military, high-level officials in the Pentagon with responsibility for health policy have expressed at least a theoretical interest in any tools that might help the services manage the impact of common diseases such as diabetes, orthopedic issues, and mental illness (e.g., post traumatic stress disorder and depression) (as discussed at a November 2007 DoD meeting with the Genetics and Public Policy Center in Falls Church, VA). Although DoD is not pursuing genetic testing in these areas currently, DoD officials with whom we have met acknowledge the impact that such diseases have on maintaining staffing and recognize the potential of effective and accurate genetic testing programs to alert them to disease risks in service members.

There has been only limited examination of the criteria the military uses to determine that an individual is not fit for duty, of genetic testing's role in this process, or of how these policies compare to policies applicable to civilian employers. One recent significant change in policy concerns how the military uses genetic information for benefits determination.

Until March 2008, DoD had the following policy: Upon entering active duty, service members are presumed to be in sound physical and mental condition, except for any medical defects and physical disabilities noted at the time of entrance. After active duty commences, any injury or disease discovered "is presumed to have been incurred in the line of duty," unless it results from the enlistee's misconduct or negligence. When injury or disease renders service members unfit for duty, they receive a medical discharge and disability benefits, regardless of their length of service.[79]

However, this policy excluded genetic diseases, stating, "Any injury or disease discovered after a Service member enters active duty—with the exception of congenital and hereditary conditions—is presumed to have been incurred in the line of duty."[80]

Thus, in circumstances in which an active-duty service member developed a disease with a known genetic basis, the armed forces considered the genetic predisposition to disease to be equivalent to a disease existing prior to service and denied benefits. An exception to the policy sometimes was possible if the genetic disorder was aggravated by military service.

In one case, a Marine Corps drill instructor who was diagnosed with cancer after 15 years of service was denied healthcare and disability benefits after he was determined to have Von Hippel-Lindau syndrome, a genetic condition. Benefits were reinstated once he successfully argued that the underlying condition may have been exacerbated by environmental exposures during his tours of duty.[81] After this case, DoD permitted benefits to be awarded in cases of genetic disease if a service member had completed at least eight years of active duty.[80]

However, just as GINA has changed the landscape of genetics for millions of civilians, service members leaving the military because of a genetic disease now have better protection from genetic discrimination than under previous policies. Changes have resulted from a combination of factors: a changed understanding of genetic science, shifting policy terrain in the civilian world through passage of GINA, public and media attention to this issue, political pressures to improve healthcare for service members generally, and the challenge of recruitment during wartime.

The key change is embedded in one section of the National Defense Authorization Act of 2008 (NDAA).[82] Section 1641 states that service members may be medically retired with benefits if they have been in the military for more than six months, and if "the disability was not noted at the time of the member's entrance on active duty (unless compelling evidence or medical judgment is such to warrant a finding that the disability existed before the member's entrance on active duty)."[82]

Furthermore, in implementing the NDAA, *new* DoD Instruction E3.P4.5.2.2. on "Hereditary and/or Genetic Diseases" states, "Hereditary or genetic disease shall be evaluated to determine whether compelling evidence or medical judgment establishes that the disability was incurred prior to entry on active duty. However, even if the conclusion is that the disability was incurred prior to entry on active duty, any aggravation of that disease, incurred while the member is entitled to basic pay, beyond that determined to be due to natural progression shall be determined to be service aggravated."[83]

The new policy has several important components. The NDAA sets forth (in the title of Section 1641) an intention to adopt the approach of the VA in establishing eligibility for benefits. In the case of hereditary and genetic disease, the VA's approach to administering healthcare benefits to millions of veterans has been particularly favorable to veterans. The primary statute governing this issue for the VA, 38 USC § 1111, states, "Every veteran shall be taken to have been in sound condition when examined, accepted, and enrolled for service, except as to defects, infirmities, or disorders noted at the time of the examination, acceptance, and enrollment, or where clear and unmistakable evidence demonstrates that the injury or disease existed before acceptance and enrollment and was not aggravated by such service."[84] Thus, it appears that in the VA health system, an individual who develops a disease with a genetic basis is not considered to have had a pre-existing condition that renders him or her ineligible for benefits. Additional regulations and opinions from the VA's Office of General Counsel (OGC) govern how this statute has been interpreted. For example, in one case, the OGC issued an opinion stating, "The mere genetic or other familial predisposition to develop the symptoms, even if the individual is almost certain to develop the condition at some time in his or her lifetime, does not constitute having the disease." The opinion also finds that only when an individual develops symptoms or pathology "can he or she be said to have developed the disease." Ultimately, the opinion holds that a hereditary disease does not always rebut the presumption of soundness articulated in 38 USC § 1111.[85] Thus, the explicit intent to adopt the approach of the VA signals a significant change by DoD. On a related note, there are indications—including pending federal legislation—that DoD will relinquish the responsibility of benefits determination entirely in the future, allowing VA to do all benefits determination.[86,87]

Under the NDAA and the new DoD Instructions, there is a stronger presumption of fitness at enrollment for people with more than 180 days of service in all cases of illness. Benefits may not be denied unless the disability was actually noted at entry or "compelling evidence or medical judgment" exists that the disability was incurred prior to entry. This strong presumption holds true in the case of hereditary and/or genetic disease as well.[82,83] Service members with more than eight years of service will continue to be granted benefits without any inquiry into the disease's existence at entry.

Finally, DoD policymakers are in the process of adding language to the instruction that will include the following clarification: "Findings will be made on the basis of objective evidence in the record as distinguished from personal opinion, speculation, or conjecture. When the evidence is not clear concerning whether the condition existed prior to service or if the evidence is equivocal, the presumption will not be deemed to have been rebutted and the member's condition will be found to have been incurred in service."[83]

In sum, the new DoD policy appears to mean that if a service member has served for at least six months and develops a genetic (or any) condition or illness requiring medical retirement, DoD will use the VA's presumption of sound condition upon enrollment and grant benefits unless compelling medical evidence exists to prove the "disability" existed at enrollment. It is our assumption that the choice of the word "disability" is significant because it suggests that a mere genetic marker without symptoms is not enough to rebut the presumption of sound condition—an actual disability (i.e., symptoms and/or impairment) would be required.

It will be important to see how DoD implements and monitors the new policy and its effects and to what extent implementation mirrors implementation of GINA. In addition, additional study is needed of current and future potential uses of genetic testing by DoD. The more generous separation policy may increase pressure for additional uses of genetic testing at enlistment and in health care during active duty: DoD now may have a stronger financial interest in excluding from service those individuals who are likely to develop genetic illness. New enlistees will not necessarily be permitted to serve if they do not consent to whatever genetic testing DoD deems appropriate and useful.

There also may be increased interest in conducting research on active duty and retired military personnel to better understand what genetic markers are linked to those diseases that have the greatest impact on military readiness, such as PTSD and depression.[88,89] Interest in studying the genetic and environmental contributors to these common diseases among service members could result in renewed interest in the samples available from the Armed Forces Repository of Specimen Samples for the Identification of Remains.

There are of course beneficent reasons to increase testing, such as to protect individual service members from avoidable harm. And given current shortages in staffing and enrollment, there will be reluctance to utilize questionable genetic testing that would weed out potential service members unnecessarily. It is not clear how the identification of genetic contributors to common complex diseases will affect the interpretation and imposition of military policies. Many common complex diseases have both genetic and environmental contributors. How the military will assess these factors and whether it would try to distinguish between environmental exposures prior to and during service is unknown.

Conclusion: What's Next?

Enactment of GINA and recent changes in military policy for the use of genetic information in awarding benefits reflect society's growing understanding of the importance of fair policies for the use of information revealed through genetic research and medicine. GINA is a first step: Future policy work will need to examine closely the issues that remain, such as the potential for genetic information to be used to deny people life insurance, disability insurance, and long-term-care insurance. Similarly, although changes in DoD regulations are encouraging in establishing rules for fair use of genetics in benefits determinations by the United States military, questions remain as to how the military will use genetic medicine overall and what the potential impact will be.

Most immediately, researchers, providers, and patients, as well as health insurers and employers, need to understand their new rights and responsibilities under GINA. Overall, we believe that individuals considering genetic testing as a part of clinical care or research should feel reassured, yet should also understand that there are limits to GINA's scope. As we move forward and regulations implementing GINA are finalized, additional public education will be necessary, and researchers, clinicians, and institutional review boards will need more information about how to manage genetic information and how to communicate the risks and benefits of genetic testing. Our collective future work will continue as we strive to create the foundation necessary for genetic medicine and genetic research to thrive.

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Web Resources

The URLs for data presented herein are as follows:

Armed Forces Institute of Pathology database, http://www.afip.org
Genetics and Public Policy Center, http://www.dnapolicy.org
National Conference of State Legislatures, Genetics Tables, http://www.ncsl.org/programs/health/genetics/charts.htm
National Institutes of Health, clinical trials database, http://www.Clinicaltrials.gov

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