8-1-2014

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THE NEED TO REEXAMINE GINA: A CALL FOR A BUSINESS NECESSITY EXCEPTION TO THE GENETIC INFORMATION NONDISCRIMINATION ACT

*Alyson Horn*

INTRODUCTION

With the passage of the Genetic Information Nondiscrimination Act (GINA or the Act) in 2008, it became a violation of federal law for employers to discriminate against employees or job applicants based on their genetic information.¹ The Act prohibits employers from using genetic information in employment decisions and places restrictions on employers requesting or requiring genetic information as a condition of employment. Similar to the way in which the Americans with Disabilities Act (ADA) prevents employers from discriminating against employees on the basis of disabilities,² GINA seeks to offer protection to individuals who may suffer discrimination on the basis of a genetic predisposition for a particular disease or condition. While it offers a limited number of exceptions, GINA does not offer a business necessity exception as found under the ADA.³

This Note argues that GINA is too limited and that there are certain workplace situations that necessitate a business necessity exception, or,

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³ Under the ADA, a business necessity exception allows employers to use qualification standards or other selection or screening criteria that exclude, or tend to exclude, an individual or a class of individuals with a disability because of their disability when the standards or criteria relate to an essential function of the job and a reasonable accommodation is not possible. 29 C.F.R. § 1630.10 (2011). The concept of business necessity is explained in greater detail in section II.A. of this Note.
alternatively, an exception for when there is a direct threat to health and safety. There is a particular need for such an exception in non-traditional work environments such as those faced by employees of the State Department, Peace Corps, and civilians in the Department of Defense (DOD). While soldiers who are deployed to zones where malaria is prevalent (such as Afghanistan) are subject to glucose-6-phosphate dehydrogenase (G6PD) testing, the passage of GINA could now prevent similar testing of civilian Federal employees. A G6PD deficiency can produce a hematologic disorder, specifically hemolytic anemia, which can be seriously aggravated by primaquine, a medication routinely given to those who are in areas prone to malaria infections. If employees of the Foreign Service, Agency for International Development (USAID), and Peace Corps (who may be sent to many malaria-ridden regions of the world) cannot lawfully be tested for a G6PD deficiency, their health may be put at serious risk.

Though decisions about military deployments for uniformed personnel can be informed by the results of this testing, civilian employees could potentially be prevented from obtaining the benefit from such preventive measures due to the restrictions imposed by GINA. The potential for serious medical complications for a G6PD-deficient employee given primaquine is a perfect example of a situation in which there is a clear benefit to amending GINA. This Note advocates for the inclusion of a business necessity exception to the Act, proposing that the potential life-saving consequences far outweigh the privacy and discrimination concerns that were the driving forces behind the Act.

Section I of this Note begins with a discussion of the recent advances made in the world of genetics and the corresponding rise in the fear of potential discrimination based on a person’s genetic predisposition for a disease or condition. Section II provides an overview of the legal options

6. Compare Susannah Baruch & Kathy Hudson, Civilian and Military Genetics: Nondiscrimination Policy in a Post-GINA World, 83 AM. J. HUM. GENETICS 435, 437 (2008) (stating that GINA does not apply to members of the United States Military, to veterans obtaining healthcare through the Department of Veterans Affairs, or to the Indian Health Service); see also the Act’s definition of “employee,” 42 U.S.C. 2000ff(2)(A) (2008) (referring to the definition provided in 42 U.S.C. 2000e(f), which states that an employee “means an individual employed by an employer” and “include[s] employees subject to the civil service laws of a State government, governmental agency or political subdivision”).
considered to be potential shields against genetic discrimination, including the ADA, judicial interpretations, and Executive Order 13145. A description of the major elements of GINA is then provided in Section III of this Note, including a brief discussion of the Act’s legislative intent. Section IV delves more deeply into the why a business necessity exception is necessary, and begins with a brief medical overview of G6PD deficiency. While no cases have gone to litigation on this matter, this Section also offers a case study of genetic discrimination in an employment claim made by a Peace Corps applicant who was denied placement in a malarial zone due to his G6PD deficiency. Finally, turning to the potential negative consequences that may arise out of the disparate treatment of uniformed versus civilian employees with regards to G6PD testing, the facts are combined to make a case for a business necessity exception to GINA in order to ensure the safety of employees in the workplace.

I. ADVANCES IN GENETIC KNOWLEDGE AND THE RESULTING FEAR OF DISCRIMINATION

It is now widely known and accepted that the functioning of most living organisms is determined by the chemical compound Deoxyribonucleic acid (DNA). However, more than half a century ago scientists knew very little about the connection between genetics and disease. Giant leaps in scientific discovery took place between 1953, when James Watson and Francis Crick first described the double helix structure of DNA and 1990, when the National Institutes of Health and the Department of Energy collaborated with international partners on what is known as the Human Genome Project. The ambitious goal of this Project was to sequence the 3 billion base letters found in the complete set of DNA in the human body called the human genome. Finished in 2003, the ultimate aim of the study was to serve as a resource for a wide range of biomedical research, including the

7. A Brief Guide to Genomics: DNA, Genes and Genomes, Nat’l Hum. Genome Res. Inst., Nat’l Insts. Health (last updated Apr. 14, 2014), http://www.genome.gov/18016863 (explaining that every DNA strand is comprised of four chemical units, called nucleotide bases, which comprise the genetic “alphabet.” The bases are “adenine (A), thymine (T), guanine (G), and cytosine (C)”).
9. Id.
10. Id.
11. Id. The fact sheet compares the possession of a complete sequence of the human genome to having all required pages to a manual needed to make the human body. It is the interpretation of this newly discovered content of these pages that is identified as the next challenge. Id.
genetic variants that increase chances for the development of specific types of diseases, how the genome works and the genetic basis for health and disease.\textsuperscript{12} Due to the work of the Human Genome Project, researchers have discovered more than 1,800 disease genes and now have the ability to find a gene suspected of causing an inherited disease in a matter of days, rather than the years it took previously.\textsuperscript{13} At present, less than ten years after the Project’s completion, the process of genetic sequencing is much faster and a great deal less costly, and some predict we are not too far off from the $1,000 genome.\textsuperscript{14}

\textbf{A. The Current State of Genetic Testing}

More than 2,000 tests have been developed to detect a large number of genetic conditions, enabling patients to learn their risks for diseases and assisting doctors with a more accurate diagnosis.\textsuperscript{15} The process of genetic testing gathers cells from an individual through various means including from samples of blood, “saliva, the inside of the cheek, or any other tissue.”\textsuperscript{16} While a positive test result for certain genetic mutations is nearly determinative of the possibility of manifesting that disorder, like the test for Huntington’s Disease, genetic tests for other conditions like breast cancer, cystic fibrosis and Alzheimer’s Disease are less than certain.\textsuperscript{17} However, the

\begin{footnotesize}
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\item[12.] A Brief Guide to Genomics: DNA, Genes and Genomes, supra note 7.
\item[13.] HUMAN GENOME PROJECT FACT SHEET, supra note 8, at 1.
\item[14.] As Genetic Sequencing Spreads, Excitement, Worries Grow, NAT’L PUB. RADIO (Sept. 18, 2012, 3:34 AM), http://www.npr.org/templates/transcript/transcript.php?storyId=160958948 (statement by NPR’s Rob Stein, stating that the current cost per individual gene sequencing is approximately $4,000); see also Eryn Brown, What a $1,000 Genome Could Mean for Medicine, L.A. TIMES (Jan. 10, 2012), http://articles.latimes.com/2012/jan/10/news/la-heb-1000-dollar-genome-20120110 (explaining that biotechnology firms have been on the quest to offer machines capable of sequencing a human genome in about one day at a cost of approximately $1,000, with the idea that the price drop will enable doctor’s to provide a more “personalized medicine” for more accurate patient diagnosis and care).
\item[15.] HUMAN GENOME PROJECT FACT SHEET, supra note 8; see also A Brief Guide to Genomics: DNA, Genes and Genomes, supra note 7 (noting that genome-based research is enabling medical researchers “to develop more effective diagnostic tools, to better understand the health needs of people based on their individual genetic make-ups, and to design new treatments for disease”).
\item[16.] Paul Steven Miller, Is there a Pink Slip in My Genes? Genetic Discrimination in the Workplace, 3 J. HEALTH CARE L. & POL’y 225, 229-30 (2000).
\item[17.] Id. at 230-31 (stating that while a person who tests positive for the Huntington’s Disease gene will develop the disease by middle age with a “chilling certainty,” a woman who tests positive for a type of gene mutation known as the BRCA 1 mutation will have an eighty percent chance of developing breast cancer if there is a clear history of breast cancer in her family). Tests can additionally be used to identify carriers of certain types
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common misperception is that genetic testing offers a completely accurate prediction as to whether an individual will manifest a genetic disease or condition that could lead to discrimination.\textsuperscript{18}

\textbf{B. Fear Engendered by Newly Available Genetic Information}

Unfortunately, history has proven that the specter of genetic discrimination is a real concern.\textsuperscript{19} For example, out of the mistaken belief that heredity was the cause of criminality, mental conditions and pauperism, Indiana passed the first state eugenic law in 1907, mandating forced sterilizations.\textsuperscript{20} The U.S. Supreme Court soon after sanctioned this type of practice in its 1927 decision, \textit{Buck v. Bell}, holding that states could involuntarily sterilize individuals based on their so-called flawed genetics.\textsuperscript{21} In discussing Carrie Buck, who like her mother, was committed to the Virginia State Colony for Epileptics and Feeble Minded, Justice Holmes rationalized the holding by stating that, “\textit{[t]hree generations of imbeciles are enough.”}\textsuperscript{22} Even as recently as the 1970s, state legislatures enacted mandatory screening laws with the goal of identifying those with sickle cell anemia with the hope of reducing the incidence of the disease.\textsuperscript{23} The fact of disease or conditions. Carriers may never actually develop the disease, but may still possess the recessive genes and pass them onto their children who may go on to develop the condition. \textit{Id.} at 229.

\textsuperscript{18}. \textit{Id.} at 232 (explaining that there are a variety of factors at play beyond a genetic disposition for the disease, that influence its severity, the timing of its onset, and ultimately, whether the disease will ever actually manifest itself at all).


\textsuperscript{22}. \textit{Buck v. Bell}, 274 U.S. 200, 207 (1927) (justifying decision by stating that forced sterilization is a better societal solution than the alternative which would involve “waiting to execute degenerate offspring for crime [or letting] them starve for their imbecility”).

\textsuperscript{23}. \textit{Genetic Screening and Discrimination: Relevance of Historical Experience, NAT’L HUM. GENOME RES. INST., NAT’L INSTS. HEALTH}, http://www.genome.gov/25019904 (last updated Apr. 2, 2012) (explaining that an inadequate level of education and counseling led to confusion about the sickle cell trait and actual sickle cell disease). Sickle cell anemia is the most common form of sickle cell disease and the disorder causes the normally doughnut-shaped red blood cells to resemble a crescent, or “sickle.” The abnormally shaped cells die at a much faster rate than they can be replaced, and those suffering from the condition can experience chronic pain and/or fatigue. \textit{What is Sickle Cell Anemia, NAT’L HEART, LUNG, & BLOOD INST., NAT’L INSTS. HEALTH}, http://www.nhlbi.nih.gov/health/health-topics/topics/sca/ (last visited Nov. 14, 2012).
that African Americans were disproportionately affected, along with the inadequate privacy measures with regards to the results of these tests, gave rise to a legitimate fear in lawmakers that there was a real possibility this would lead to discrimination in employment. Ultimately, Congress passed the National Sickle Cell Anemia Control Act in 1972, which withheld federal funding from those states that utilized mandatory testing.

While the past few decades have been an extremely exciting time in scientific discovery, it is nonetheless unsurprising that many individuals have grown concerned about the possibility of genetic discrimination. For example, from 2001-2003, over 86,000 adults were surveyed about their willingness to undergo genetic testing, and forty percent of the participants revealed they did not believe such testing was a good idea, mostly due to fear of losing insurance coverage. Similarly, results in several studies conducted by the Genetics and Public Policy Center at Johns Hopkins University showed an increasingly high level of public concern about an employer having access to genetic information, rising from eighty-six percent in 2002 to ninety-two percent in 2004. These concerns extend to health care professionals as well, with one study showing that 108 of 159 of genetic counselors would not submit charges for genetic tests to insurance companies out of fear of possible discrimination. Even more worrisome were those studies showing that individuals were deciding to forgo genetic

24. Baruch & Hudson, supra note 6, at 436; Melinda B. Kaufmann, Genetic Discrimination in the Workplace: An Overview of Existing Protections, 30 LOY. U. CHI. L.J. 393, 402-03.
27. Id. at 71 (explaining that this type of reluctance is detrimental to America’s public health and the potential future benefits of scientific research).
28. Id.
29. Genetic counseling is described as:
[T]he professional interaction between a healthcare provider with specialized knowledge of genetics and an individual or family. The genetic counselor determines whether a condition in the family may be genetic . . . [whether] another relative may be affected . . . and offer[s] and interpret[s] genetic tests that may help eliminate risk of disease.
30. Slaughter, supra note 26, at 71.
testing altogether due to the potential for discrimination, even if the early
detection of a genetic mutation could help in preventing an early death.31

II. LEGAL OPTIONS PRIOR TO GINA

A. The Americans with Disabilities Act (1990)

Out of this concern for possible discriminatory use of genetic information
arose a search for legislative guidance on the issue. In offering protection
against discrimination based on disabilities, the ADA was viewed as a
possible shield against genetic discrimination.32 Enacted in 1990, the ADA
was the Congressional response to the growing concern that people with
disabilities were facing discrimination and a lack of employment
opportunities.33 After its passage, an employer was no longer able to make
a request for medical information prior to extending an offer of employment.34
After an offer of employment has been made, however, an employer may
conduct or request a medical examination to determine whether the
employee may perform the essential functions of the job.35 If required, the
exam must be given to all entering employees and the employer must
demonstrate that the reason for the exam is both job-related and consistent
with business necessity.36 Based on the results of these pre-employment
exams, the employer is permitted to screen out those with disabilities who
cannot meet qualification standards or who cannot perform the essential
functions of the job even with reasonable accommodation.37 Furthermore,
the employer is permitted to screen out those who would pose a “direct
threat to the health or safety of other individuals in the workplace.”38 The
ADA defines “direct threat” in the statute as “a significant risk to the health

31. Slaughter, supra note 26, at 71 (outlining further that twenty-five percent of
respondents said they would use an alias to obtain a genetic test while sixty percent
indicated they would not share the information with a colleague out of privacy concerns
and fear of discrimination).

32. U.S. EEOC, Notice No. 915.002, Policy Guidance on Executive Order 13,145:
To Prohibit Discrimination in Federal Employment Based on Genetic Information (July

also Nicole Silvestri, Echazabal and the Threat to Self-Defense: The Most Recent Call
for a Consistent, Interstate Genetic Non-Discrimination Policy, 7 U. PA. J. LAB. & EMP.
L. 409, 413 (2005) (describing the ADA as one of the first “empowering pieces of
disability legislation”).


35. Id. at § 12112(d)(4)(A).

36. Id. at § 12112(d)(3)-(4)(A).

37. Id. at § 12112(b)(5)(A).

38. 42 U.S.C. § 12113(b).
or safety of others that cannot be eliminated by reasonable accommodation.” The Equal Employment Opportunity Commission (EEOC) regulations expanded the statutory definition to include a threat-to-self situation, an expansion upheld by the Supreme Court in *Chevron USA Inc. v. Echazabal*. In this case, Echazabal, a long-time oil refinery worker, brought suit when his offer of employment from Chevron was revoked after he failed a required medical exam showing that he had asymptomatic, chronic active hepatitis C. The Court clarified that a direct threat is one that is “made on the basis of individualized risk assessments,” and upheld Chevron’s decision to withdraw the offer on the basis that exposure to solvents and chemical in the oil refinery process could worsen his condition, or in other words, that it would be a threat to the employee himself.

In *Bragdon v. Abbot*, the Supreme Court addressed the idea that the ADA also covers discrimination for a condition that has not yet manifested itself by demonstrating actual physical symptoms. In this case, the plaintiff brought suit against her dentist for his refusal to fill a cavity due to her HIV positive status. Though her condition had not manifested itself as full-blown AIDS, the Court found that someone infected with HIV qualified as “disabled” under the ADA since it “substantially limits” life activities. Justice Rehnquist urged caution in his partial dissent, however, arguing that if “taken to its logical extreme [the majority opinion] would render every

39. *Id.*
40. 29 C.F.R. § 1630.2.
41. Silvestri, *supra* note 33, at 422 (explaining that this more expansive definition was first put forward by the EEOC in its interpretation of the statutory language of the ADA); *see also* Chevron USA Inc. v. Echazabal, 536 U.S. 73, 81-82 (2002) (concluding that the Congressional omission of the threat-to-self-language does not preclude it from being included in a more expansive understanding of legislative intent).
42. Silvestri, *supra* note 33, at 422-23. Echazabal was tested each of the two times he applied for a position with the company and the exams showed liver abnormality and/or function. The cause was later determined to be from Hepatitis C. *Chevron*, 536 U.S. at 76.
43. *Chevron*, 536 U.S. at 86 (clarifying that the defense must be “based on a reasonable medical judgment that relies on the most current medical knowledge and/or the best available objective evidence”).
45. Bragdon v. Abbot, 524 U.S. 624, 628-29 (1998). The dentist stated that he was willing to fill the cavity at the local hospital with no extra charge, however, the plaintiff would be responsible for covering the cost of using the hospital facilities. *Id.* at 628.
46. *Id.* at 630 (clarifying that due to the immediacy of the damage to an affected individual’s white blood cells, HIV is to be determined as “an impairment from the moment of infection”).
individual with a genetic marker for some debilitating disease ‘disabled’ here and now because of some future effects.” 47 This dissenting argument engendered a level of concern, for some, as to whether the ADA would, in fact, be a meaningful tool in combating genetic discrimination. 48

B. Executive Order 13,145

Recognizing the lack of a comprehensive federal legislative response to genetic discrimination, on February 8, 2000, President Clinton signed Executive Order 13,145 to address the issue in the federal workforce. 49 The Order prohibits federal employers from using “protected genetic information” along with information from genetic testing, including genetic testing of family members, in employment decisions. 50 This prohibition includes using genetic information as a basis for a refusal to hire or a decision to fire, as well as its use in depriving an employee of workplace opportunities. 51 In its limited application to those employees who work for federal agencies, however, the Order fell short of offering a more widespread protection against genetic discrimination. 52

III. THE GENETIC INFORMATION NONDISCRIMINATION ACT (2008)

A. Legislative Intent

The “patchwork of laws and interpretations” 53 on the issue of genetic discrimination finally received a comprehensive federal legislative response

47. Id. at 661 (Rehnquist, J., concurring in part and dissenting in part) (contending that the plaintiff was unable to demonstrate how she was “utterly unable” to engage in those activities identified by the majority).
48. Baruch & Hudson, supra note 6, at 437.

It is the policy of the Government of the United States to provide equal
employment opportunity in Federal employment for all qualified persons and
to prohibit discrimination against employees based on protected genetic
information, or information about a request for or the receipt of genetic
services. This policy of equal opportunity applies to every aspect of Federal
employment.

Id.
50. Id.
51. Id.
52. Silvestri, supra note 33, at 418.
with the passage of GINA in 2008.\textsuperscript{54} Hailed by former Senator Edward Kennedy of Massachusetts as “the first major new civil rights bill of the new century,”\textsuperscript{55} GINA offers protection from genetic discrimination by both insurers and employers.\textsuperscript{56} It was a hard-fought, multi-year battle, with opponents from the insurance industry and employers arguing that existing legislation rendered the Act’s passage unnecessary and that to do so would only create confusion and unnecessary costs.”\textsuperscript{57} Furthermore, employers argued that the limited number of cases brought on the subject demonstrated that genetic discrimination was not common enough in the workplace to warrant its own legislation.\textsuperscript{58}

The situation facing Phil Hardt, a man who tested positive for the Huntington’s Disease genetic mutation, paints the story another way.\textsuperscript{59} Confronted not just with the reality of his personal health discovery, Mr. Hardt also had contend with the fact that his daughter was denied health insurance due to her genetic predisposition for the disease that was discovered as a direct result of his diagnosis.\textsuperscript{60} Congress recognized the importance of offering comprehensive protection against genetic discrimination for just this sort of situation, and wanted to provide a way for the public to take advantage of the benefits of genetic testing without fear of reprisal by insurance companies or in the workplace.\textsuperscript{61} Due to the limited documentation of genetic discrimination occurring in the workplace, the Act was seen as being a preemptive measure intended to circumvent a type of discrimination that may take place in the future, not one that has existed in recent history.\textsuperscript{62} Senator Kennedy explained that with the passage of GINA,
the door has been “open[ed] to modern medical progress for millions and millions of Americans.” Indeed, the greater the number of individuals who take advantage of genetic testing, the greater the pool of information for researchers to use in order to perfect and refine a diagnosis based on genetics.

B. Summary of the Law

GINA is divided into two sections and Title I focuses on health insurance, prohibiting group health plans and health insurance providers offering group coverage from establishing rules of eligibility or altering premium amounts for an individual on the basis of genetic information. Title II focuses on the workplace, prohibiting employers from using genetic information in employment-related decisions, including as a justification for not hiring an individual, a reason to discharge an employee, or with respect to compensation or the terms and conditions of employment. Further, this prohibition extends to any employer requesting that an individual undergo a genetic test or actively seeking and purchasing genetic information about its employees.

GINA defines “genetic information” as information on the genetic tests of an individual or of an individual’s family members, including information on those family members who have already manifested a disease or condition. This encompasses the request or receipt of the genetic information of an individual, or of an individual’s family member’s genetic information, including testing, counseling, education, and participation in clinical research that involves genetic services. In practice, this definition

63. Id.
64. Id. at 233.
66. 42 U.S.C. § 2000ff-1(a) (2012). The statute outlines that it is unlawful for employers:
   (1) [T]o fail or refuse to hire, or to discharge, any employee, or otherwise to discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of genetic information with respect to the employee; or (2) to limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of genetic information with respect to the employee.

Id. at §§ 2000ff-1(a)(1)-(2).
68. Id. at § 2000ff (4)(A) (2012).
69. Id. at § 2000ff (4)(B) (2012). “Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical
would even include a company doctor from taking an employee’s family medical history as part of a routine examination.\(^70\) While also including genetic information about a fetus that is carried by a covered individual,\(^71\) the Act specifically excludes information pertaining to both sex and age.\(^72\) Furthermore, GINA does not offer coverage for individuals who have manifested physical symptoms of a disease, even if it is genetically linked, as such an instance would be covered under the protections of the ADA.\(^73\)

GINA does, however, provide for six very limited exceptions to this rule.\(^74\) First, an employer is exempt from the rule’s requirements when it inadvertently requests family medical information.\(^75\) Nor is it a violation to receive aggregate information about employees under the following conditions: 1) When an employer provides or sponsors a health or genetic service or program; 2) the employee provides voluntary, written authorization for employers to obtain family genetic information obtained through that service; 3) only the employee and health care professional receive individually identifiable information on those services rendered; and 4) the employer only receives information that pertains to those services that is in the aggregate form, and does not disclose the identities of individual participants in the employer-provided health service.\(^76\) Furthermore, employers are authorized to request family medical information in order to comply with the Family and Medical Leave Act of 1993.\(^77\) Employers are

research which includes genetic services, by such individual or any family member of such individual.” \(\text{Id.}\)

70. \(\text{Id. at §2000ff-1(b).}\)
71. \(\text{Id. at § 2000ff-8(b)(1) (2012).}\)

Any reference in this chapter to genetic information concerning an individual or family member of an individual shall—(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and (2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

\(\text{Id.}\)

72. \(\text{Id. at § 2000ff(4)(C) (20012).}\)
73. Abigail Lauren Perdue, Justifying GINA, 78 TENN. L. REV. 1051, 1065 (2011); see also Jessica L. Roberts, The Genetic Information Nondiscrimination Act as an Antidiscrimination Law, 86 NOTRE DAME L. REV. 597, 625 (2011) (explaining that the ADA can be understood as retrospective in application, looking to existing discrimination to justify protecting against future harm, while GINA is more forward looking in its attempt to preempt discrimination before it becomes entrenched).

76. \(\text{Id. at § 2000ff-1(b)(2).}\)
77. \(\text{Id. at § 2000ff-1(b)(3).}\)
not prohibited from purchasing commercially and publicly available documents that contain family medical information of an employee. An employer may also require genetic information from an employee if it is used to genetically monitor the biological effects of toxic substances in the workplace, provided the employer gives written notice and obtains a voluntary and written authorization from the employee. Finally, employers may conduct DNA analysis for law enforcement purposes or when necessary to identify human remains.

IV. THE CASE FOR A BUSINESS NECESSITY EXCEPTION TO GINA

In response to the fearful environment created by the potential for genetic discrimination and the possibility of stifling unprecedented scientific discovery, Congress omitted a business necessity exception to GINA. In fact, in a 2009 EEOC hearing on the proposed rule to implement the Act, Jeremy Gruber of the National Council for Responsible Genetics echoed this sentiment that informed the legislation, stating that, “over the course of many years it was very difficult for even the best minds to come up with ways or examples” where a job-related, business necessity exception would be necessary. Congress, however, was too limited with its exceptions to GINA and, like with the ADA, GINA would benefit from the addition of a business necessity exception. In lieu of a general business necessity exception, Congress should, at a minimum, adopt the ADA’s direct threat to the health and safety of self or others standard.

78. Id. at § 2000ff-1(b)(4); see generally Family and Medical Leave Act of 1993, Pub. L. No. 111-84, 123 Stat. 124.
80. Id. at § 2000ff-1(b)(6).
82. Notice of Proposed Rulemaking, supra note 81.
83. Title VII of the Civil Rights Act of 1964 also has a business necessity exception, applicable to disparate impact. 42 U.S.C. § 2000e-2(k).
Situations do in fact exist where genetic testing by an employer could prevent a threat to the health of an employee.\textsuperscript{85} Multiple situations arise where a business necessity defense could be justified on these grounds.\textsuperscript{86} One of the most dramatic situations implicated by the absence of a business necessity/direct threat exception is where an employee’s health is endangered by the inability to receive a genetic test (or by the fear of offering a test that could be deemed a genetic test). As referenced previously, this is a situation faced by employees of the State Department, Peace Corp, USAID, and civilians in the DOD operating in malaria-infested parts of the world. However, individuals such as these could avoid an adverse reaction to a common anti-malaria medication if limited genetic testing were permitted as part of a business necessity exception to GINA.\textsuperscript{87}

\textit{A. G6PD Deficiency}

G6PD deficiency is the most common enzyme deficiency in the world, and “[a]pproximately 400 million people are affected worldwide.”\textsuperscript{88} This deficiency occurs with more frequency throughout Asia, Africa, the Mediterranean, and the Middle East.\textsuperscript{89} In the United States it is estimated that ten percent of African American males are affected.\textsuperscript{90} The condition primarily affects red blood cells, which are responsible for carrying oxygen from the lungs to the rest of the body.\textsuperscript{91} A defect in the G6PD results in a premature breakdown of these cells at a much faster rate than the body is capable of replacing them.\textsuperscript{92}

Though the carriers of this deficiency are often asymptomatic, in certain instances acute hemolysis can occur.\textsuperscript{93} Hemolysis (or hemolytic anemia) is characterized by the breakdown of the red blood cells\textsuperscript{94} and can cause “paleness, yellowing of the skin and whites of the eyes (jaundice), dark

\begin{itemize}
\item \textsuperscript{85} See generally Chevron USA Inc. v. Echazabal, 536 U.S. 73 (2002).
\item \textsuperscript{86} For example, there could be instances where taking a family medical history could be important to evaluating an individual’s ability to safely perform a job.
\item \textsuperscript{87} Baruch & Hudson, supra note 6, at 438.
\item \textsuperscript{88} Jennifer E. Frank, Diagnosis and Management of G6PD Deficiency, 72 AM. FAMILY PHYSICIAN 1277, 1277 (2005).
\item \textsuperscript{89} Id.
\item \textsuperscript{90} Id.
\item \textsuperscript{91} Glucose-6-phosphate Dehydrogenase Deficiency, GENETICS HOME REFERENCE, NAT’L INSTS. HEALTH (last updated Aug. 18, 2014), http://ghr.nlm.nih.gov/condition/glucose-6-phosphate-dehydrogenase-deficiency.
\item \textsuperscript{92} Id.
\item \textsuperscript{93} Frank, supra note 88, at 1277.
\end{itemize}
urine, fatigue, shortness of breath and a rapid heart rate.” While rarely fatal, there are extreme cases where a severe reaction can necessitate a life-saving blood transfusion. Differing types of gene mutations associated with this condition dictate the level of deficiency and the resulting severity of symptoms experienced by the individual. Adverse reactions within carriers of this condition are often the result of exposure to certain oxidative stressors, including infection, oxidative drugs, or fava beans. Generally, “treatment is geared towards avoidances of these and other stressors.” An example of an oxidative drug that may trigger a reaction in someone with this condition is the common anti-malaria drug, primaquine. This drug, in fact, has been identified by some sources as being the most common agent leading to hemolysis in G6PD-deficient persons.

B. G6PD Testing as Potential Genetic Discrimination

While no case has been litigated on the subject of whether G6PD testing is a form of genetic discrimination, early in 2012 a complaint was filed in the United States District Court for the Southern District of New York alleging that the United States Peace Corps violated GINA when it based an employment decision on the results of a G6PD test. The complainant, Imaote Ipaalinyang Omulepu, applied for a Peace Corps Response Kavango Basket Liaison position based in northern Namibia in March of 2011. Omulepu was ultimately offered a position as a Peace Corps Response Volunteer (PCRV); however, his final acceptance was contingent upon successful completion of all legal and medical clearances. Pursuant to the provided instructions, the complainant completed the required medical

95. Frank, supra note 88, at 1277.
96. Id.
97. Id. (explaining that individuals who are homozygous for the deficiency typically have more severe reactions than those who are heterozygous).
98. Id.
99. Id.
100. Murray, supra note 4. Primaquine, the brand name for primaquine phosphate, is used with other medications to both prevent and treat malarial infections that are a result of mosquito bites. Primaquine focuses on destroying the parasites that cause malaria. Primaquine, MEDLINE PLUS, NAT’L INSTS. HEALTH, http://www.nlm.nih.gov/medlineplus/druginfo/meds/a607037.html (last visited Apr. 20, 2014).
101. Id. G6PD deficiency was first discovered, in fact, out of an investigation of cases of hemolytic anemia occurring in some individuals being treated for malaria with the same class of drugs. Beutler, supra note 5, at 16.
103. Id. at 4.
104. Id. at 5.
examination and tests, which included a screening for G6PD deficiency.\textsuperscript{105} Omulepu tested positive for the deficiency, both in the initial blood test and a subsequent re-testing, which was undertaken to rule out the possibility that the initial results indicated a false positive.\textsuperscript{106}

A nurse employed by the Peace Corps informed the complainant that the agency had implemented a new policy in 2008 that stated individuals who tested positive for the G6PD deficiency were ineligible to serve in malaria-endemic countries.\textsuperscript{107} Based on the two sets of test results, the Peace Corps Pre-Service Review Board was unable to clear Omulepu for service in Namibia.\textsuperscript{108} The Board offered the complainant the opportunity for appeal, but despite a letter from a hematologist stating that Omulepu was not at significant risk for “significant primaquine induced hemolysis,” the Board denied his appeal.\textsuperscript{109} He was not, however, deemed ineligible to work for the Peace Corps and was informed he had the opportunity to serve as a PCRV in areas outside malaria zones.\textsuperscript{110} Omulepu claimed that the Peace Corps violated GINA, in part, by allowing its employment decision to be based on the results of a genetic test.\textsuperscript{111} He further claimed that as a result of this action, he suffered a lack of employment opportunities while his confidence in seeking a career path on the African continent was diminished.\textsuperscript{112}

In its response to the complainant’s filing, the Peace Corps asserted that its guideline for G6PD deficiency was informed by recommendations made by the Center for Disease Control and Prevention (CDC).\textsuperscript{113} It cited CDC literature indicating that primaquine is contraindicated in people with the deficiency, and accordingly, the Peace Corps will not place such people in a malarial area where primaquine is required due to the health concerns that may arise.\textsuperscript{114} In addition, the Peace Corps contended that it did not obtain

\begin{itemize}
\item \textsuperscript{105} Id.
\item \textsuperscript{106} Id. at 5-6.
\item \textsuperscript{107} Id. at 6.
\item \textsuperscript{109} Id. at 7.
\item \textsuperscript{110} Id.
\item \textsuperscript{111} Id. at 10. The plaintiff, who represented himself in this matter, demonstrated an imprecise understanding of the statute, mistakenly outlining that GINA was violated, in part, by what he perceived as the Peace Corps making the assumption that testing positive for the genetic variant was a definite diagnosis of the disease. Id.
\item \textsuperscript{112} Id. at 2.
\item \textsuperscript{113} Id. at 3.
any genetic information from Omulepu, but rather only required a blood test
to determine whether there was a deficiency in the G6PD enzyme.\textsuperscript{115} The
agency further denied use of the test as the basis of its employment decision,
as Omulepu was offered the opportunity to pursue alternative PCV positions
outside malarial zones.\textsuperscript{116} Finally, the Peace Corps maintained that, if GINA
were to prohibit the use of such a blood test, the agency would be put in a
position in which it may place PCVs in areas where there is an increased risk
of serious health consequences.\textsuperscript{117} Accordingly, the Peace Corps asserted
that placing volunteers in malaria-endemic countries without the G6PD
testing would be acting both irresponsibly and medically unethically.\textsuperscript{118}

This case was never brought to trial; a Stipulation and Order of Settlement
and Dismissal was filed on September 4, 2012.\textsuperscript{119} According to the terms of
the settlement, the action was dismissed with prejudice against the Peace
Corp “without costs or disbursements.”\textsuperscript{120} Furthermore, the terms mandated
that as soon as practicable after the date of the Order, the Agency shall use
its “best efforts” in order to place Omulepu in a PCV position.\textsuperscript{121} Significantly, the settlement called for the Peace Corps to place the
complainant in a malarial region, despite his G6PD deficiency.\textsuperscript{122} While
settlement of the case prevented a ruling on whether the Peace Corps’
actions constituted genetic discrimination under GINA, the settlement may
very well lead to more employers being forced to place employees in harm’s
way, despite their reasoned assessment of the dangers of the situation.

C. G6PD Testing and the Military

The lengthy amount of time that the United States has recently spent in
both Iraq and Afghanistan, and the resulting strain on our military, has the

\begin{footnotesize}
Peace Corps, Dr. Barry Simon asserted that it would be a violation of medical ethics to
administer Primaquine to an individual such as the complainant.

\textsuperscript{115} Id. at 8. This Note takes no position on the legal question of whether a G6PD
test is a genetic test under GINA (on which there is no case law or other legal guidance).

\textsuperscript{116} Id. at 9.

\textsuperscript{117} Id.

\textsuperscript{118} Id.

\textsuperscript{119} Stipulation and Order of Dismissal, Omulepu v. United States Peace Corps, No.

\textsuperscript{120} Id.

\textsuperscript{121} Id.

\textsuperscript{122} Id. The order stipulates, however, that it does not constitute an admission of
liability or fault of any party, nor does it constitute an admission of liability or fault on
behalf of any of their departments, agencies, offices, agents, officials, or employees. Id.
\end{footnotesize}
The Need to Reexamine GINA

DOD looking to civilian employees to fill in the manpower gaps. Currently, it is DOD policy to rely on a mix of “capable military members and DoD civilian employees to meet DOD global national security mission” needs. DOD identifies safeguarding the health of its deployed civilian employees as a matter of serious concern, and requires such employees to undergo an annual medical assessment to determine eligibility for worldwide deployment. While GINA’s restrictions do not apply to uniformed members of the military, its regulations still apply to DOD civilian employees.

As explained in a 2006 seminar focusing on genetics perspectives on policy, the members of the military are thought to require “special [consideration] because they face ‘unusual occupational health challenges,’” due to their assignment to a vast range of jobs in a vast range of environments. It is standard for the military to collect DNA samples for identification purposes should a service member die in battle. A positive result for a genetic disorder is noted on a soldier’s medical records and is taken into consideration for decisions regarding assignments. Particularly relevant to this case, U.S. Armed Forces routinely test for G6PD deficiency to ensure the safety of the uniformed personnel, making the deliberate choice to keep those who are G6PD deficient out of malarial zones or, in the

124. Id.
125. Id.
126. Baruch & Hudson, supra note 6, at 438.
127. Genes in Uniform: Don’t Test, Don’t Tell, Genetic Perspectives on Pol’y Seminar, Jan. 10, 2006, available at http://www.dnapolicy.org/news.past.php?action=detail&p past_event_id=25 (last visited Oct. 14, 2012). Panelists included Susannah Baruch, senior policy analyst at The Genetics and Public Policy Center; Dr. Mark Nunes, a former military physician who is now a clinical and laboratory geneticist at both Children’s Hospital in Columbus and at Ohio State University; and Jay Platt, an author, coach, motivation speaker and formerly a United States Marine Corps drill instructor. While representatives of the Department of Defense were invited, they declined to participate. Id.
129. Baruch, supra note 6, at 438; E-mail from Catherine Takacs Witkop, MD, MPH, Chief, Preventative Medicine, United States Air Force to Alyson Horn, JD Candidate, Catholic University Columbus School of Law (Oct. 1, 2013, 09:21 AM) (on file with the author) [hereinafter Witkop Email].
alternative, to provide them with an alternate anti-malarial drug. This is particularly noteworthy because of the prevalence of malaria in Afghanistan. If the G6PD test were deemed a genetic test, then deployed civilians would lack the same health protections afforded to uniform personnel.

D. An Argument for the Amendment of GINA

Jeremy Gruber, an influential voice behind the scenes of the drafting of the language of GINA, testified that experts could think of no examples that warranted a business necessity exception. This, however, simply reflects a lack of consideration of the reality faced by those who work outside the traditional workplace. Civilian employees of DOD, members of the State Department, and those employed by the Peace Corps, among others, often work in environments far removed from the stereotypical office setting and, as a result, face a range of different and difficult challenges. The Peace Corps expressed legitimate concerns, informed in part by guidance provided by the CDC, when it initially refused to place Omulepu in a malarial region to prevent a potential negative reaction to the use of primaquine. Because GINA contains no business necessity exception, the Peace Corps was forced into entering a settlement—the type of dilemma similar employers will surely face in the future. Barring legislative change, more and more employers will find themselves in a position where, against their better judgment, they will knowingly place employees in harm’s way.

A business necessity exception amendment to GINA, similar to the business necessity exception to the ADA, would help alleviate the potential threats faced by employees in non-traditional work environments. While the business necessity exception to the ADA covers a “direct threat” to one’s self or others that arises out of a condition with physical manifestations, the exception to GINA would be for genetic conditions, like G6PD deficiency, which may manifest as a direct result of stressors or other conditions in the workplace. To prevent abuse of discretion, it is sound policy to require

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130. Baruch, supra note 6, at 438.
131. Malaria is found from April through December in areas of Afghanistan at altitudes above 6,500 feet. See CDC Malaria Map Application, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/malaria/map/index.html (last visited Apr. 15, 2014).
135. 42 U.S.C. § 12113(b).
that the employer have the burden of proving that no reasonable accommodation to ensure employee safety can be made prior to denying an employee or applicant a position based on a genetic condition. Any business necessity exception that arises out of this proposed change should be extremely limited and carefully considered to prevent abuse as society continues to learn more about human genetics. However, based on what we now know, such an exception has the ability to make work safer for those in both traditional and non-traditional workplace environments.

CONCLUSION

While uniformed members of the armed forces who test positive for G6PD deficiency are either not assigned to locations that would require them to take malaria medication or are given an anti-malarial medication other than primaquine, the G6PD status of Peace Corp, State Department, and DOD civilians, who are often in malaria-infested locations comparable to their uniformed colleagues, potentially cannot be factored into decisions about assignments under GINA. This disparate treatment has the potential to pose a direct threat to the health of these civilian employees. The Peace Corps specifically recognized the potential dangers of assigning G6PD deficient employees to malarial areas, stating in its response to Imoite Ipaalinyang Omulepu's complaint that sending such a person to a location where primaquine is required would be not just irresponsible, but medically unethical. Though the Peace Corps maintains that their required blood test is not a request for genetic information, the Agency agreed in settlement to place Omulepu in a malaria-endemic region, going against what it believed to be medically ethical. By pushing forward with this complaint, Omulepu is placing himself in potentially serious danger (a direct threat-to-self), in the form of an adverse reaction to primaquine as a result of his G6PD deficiency.

The facts therefore suggest that situations arise where a business necessity exception, or a direct threat to the health or safety of the employee or others rule similar to that found under the ADA, is warranted for the protection of individuals in the workplace. If such testing were permitted in limited circumstances, such as under the conditions faced by the federal employees assigned to work in malaria-infested regions like Afghanistan and sub-

136. Baruch & Hudson, supra note 6, at 439; Witcop Email, supra note 129.
137. Complaint, supra note 133, at 9.
138. Id.
140. See generally Murray, supra note 4, at 905.
Saharan Africa, the threat of an adverse reaction to a common medication like primaquine could largely be avoided by military and civilians alike. Clearly these atypical workplaces were not contemplated when GINA was drafted.

While critics may posit that such an exception is not required based on the reality of the workplace, the example faced by employees of the State Department, Peace Corps and civilians in the DOD sent to malarial regions suggests differently. Looking more broadly, the case of G6PD deficiency is only one such example where a business necessity exception could benefit both employer and employee. Recognizing that situations would need to be evaluated carefully to prevent discrimination, and similar to the ADA exception, the employer should have the burden of demonstrating an adequate justification for the need for genetic testing.\footnote{42 U.S.C. §12112(d)(4)(A) (2000).} Thus, amending GINA to have the flexibility of a business necessity exception is sound public policy for the safety of workers.