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PREDICTIVE TESTING IN THE WORKPLACE—COULD THE GERMAN MODEL SERVE AS A BLUEPRINT FOR UNIFORM LEGISLATION IN THE UNITED STATES?

Eva Lorenz

This Comment focuses on the problems associated with the use of employment-based genetic testing. Recently, the German National Ethics Council ("NEC") drafted a list of recommendations to regulate the use of predictive testing in the workplace. This problem of genetic testing is not limited to Germany—similar cases have been reported in the United States. The lack of a federal framework to regulate the use of genetic testing in the workplace creates uncertainty for employees and employers. Though it is likely that any federal framework will require amendments, the increased certainty associated with a uniform federal law will likely outweigh any shortcomings. This Comment analyzes the recommendations of the NEC as a possible blueprint for a uniform law in the United States.

"[O]nce a tool is developed there are considerable pressures for implementation."\(^2\)

I. INTRODUCTION

Imagine you are a thirty-six year old woman who always wanted to become a teacher. You have finished high school, graduated from college, passed all of the professional tests, and are now on the verge of getting a tenure track position to teach. Just one more test and you will be there. There is a problem, however,
and it is that the final test is a physical examination, which is a requirement for public servants seeking tenure track positions. Part of the physical is a questionnaire that seeks information about family health history. You put down that your father has Huntington’s disease (“HD”, also called Huntington’s chorea). You pass your physical, but are still denied a teaching position by the state. Why? Because you have a high risk of carrying the Huntington’s gene and therefore have a high likelihood of developing an incurable disease that may force you to seek early retirement.

While this sounds like a fictional story from George Orwell or Aldous Huxley, this was the reality faced by a young woman in Germany, and it could happen in any country where medicine has advanced enough to enable testing for inherited diseases. The fact that the young woman had a fifty percent chance of carrying a disease gene was deemed sufficient by a lower court in Germany to deny her a teaching position. The woman appealed, arguing that she has a fifty percent chance of being healthy and that questions regarding the health status of close relatives should not be part of a physical that seeks to determine whether she is fit to teach. The administrative court granted her relief and she was given a teaching position.

Despite the positive outcome for the plaintiff, some concerns remain. The language of the decision and the recommendations of

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5 ALDOUS HUXLEY, BRAVE NEW WORLD (Harper Perennial Modern Classics 1998) (1932).
6 Huntington’s Disease Frequently Asked Questions, at http://www.hdsa.org/ (follow “Get Help/Info/Learn” hyperlink; then follow “FAQs” hyperlink) (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology). “HD affects males and females equally and crosses all ethnic and racial boundaries. Each child of a person with HD has a 50/50 chance of inheriting the fatal gene. Everyone who carries the gene will develop the disease.” Id.
the German National Ethics Council7 ("NEC") leave open what kind and how much information should be shared with third parties as part of pre-employment physicals.

This Comment presents a critical analysis of the NEC recommendations for the use of predictive testing in the workplace and their possible use as a blueprint for comparable legislation in the United States. A federal law would generate certainty regarding the use of predictive testing in the workplace by replacing the existing patchwork of laws and regulations. While many people already view genetic testing with suspicion, it is important to keep in mind that predictive testing can be useful in determining whether certain people are at an increased risk for exposure-related illnesses. A balance between the benefits of predictive testing in protecting workers from exposure hazards and the possible abuses of testing for discriminatory purposes is best achieved through a uniform law at the federal level that covers all employees and employers. Part II of this Comment is a primer on genetics and genetic testing. Part III provides a brief introduction to the NEC and analyzes the recommendations of the NEC dealing with the use of predictive testing in the workplace. The NEC recommendations are compared to existing legislation in the United States to determine whether the NEC proposal should serve as a template for uniform federal laws in the United States.8 While the United States does not have a national law regarding the use of genetic testing to determine employment eligibility, the Americans

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8 Heidrun Graupner, Angst, Hysterie und das Schubladen-Prinzip: Die Diskussion um die Gendiagnostik am Beispiel einer Lehrerin (Sie sollte nicht Beamtin werden dürfen, weil ihr Vater an Chorea Huntington litt—ihr Fall macht deutlich, dass es dringend eines Gesetzes bedarf), Sueddeutsche Zeitung, Mar. 11, 2005, at 3 (stating that, in Germany, roughly 90,000 genetic tests are performed and that private laboratories offering genetic testing have a growth rate of forty to fifty percent).
with Disabilities Act, state-based laws, and pending federal legislation indicate that there have been attempts to regulate genetic testing in this country. Part IV summarizes the existing case law, which demonstrates the need for a better legal framework, and will also reiterate the danger of using genetic testing as a discriminatory tool in the workplace. Part V analyzes the split in the minority community regarding access to genetic testing, which underscores the need for an in-depth debate on the future use of employment-based predictive testing in the United States.

Currently, genetic information about employees in this country is protected to some degree through a mixture of case law, state-based legislation, and federal statutes. However, a uniform federal framework is necessary to minimize the abuses and uncertainties that are possible under the current system, and the proposal by the NEC may provide some guidance for the establishment of such a federal framework. While attempts at establishing such a framework may evoke opposition from groups that fear possible discriminatory uses, the increased certainty associated with uniform federal rules as well as the possibility of covering all employees lend support to establishing such a framework at the federal level to replace the existing patchwork of laws and statutes. This Comment, therefore, uses the comparison with the NEC recommendations to point out how a federal law regulating genetic testing in the workplace could be structured for use in the United States in order to increase the certainty associated with the use of predictive testing in the workplace.

II. PRIMER ON GENES AND GENETIC TESTING

Before analyzing the recommendations by the National Ethics Council of Germany, a short introduction to genetic testing is helpful. The following paragraphs explain and highlight the basics
of genetic testing, its current applications, and some of its weaknesses.¹¹

DNA, short for deoxyribonucleic acid, is the carrier of genetic information, and its content determines such things as the physical appearance of the person, as well as what diseases a person may have inherited from his or her parents. The physical appearance and the effects of any inherited diseases, referred to as the phenotype, are differentiated from the genetic make up of a person called genotype.¹² DNA is transcribed into messenger ribonucleic acid ("mRNA").¹³ RNA is closely related to DNA in its chemical composition. mRNA is translated into proteins, such as enzymes, that regulate all biological processes in mammals and are therefore crucial for biological functions, such as metabolism, growth, and healing. Since changes in the DNA, called mutations,¹⁴ translate into changes in the proteins that may affect the function of enzymes, much of modern day medicine is intent on discovering the underlying mutations that cause diseases ranging from asthma to cystic fibrosis ("CF").

Some diseases, such as cystic fibrosis¹⁵ or Huntington’s chorea, can be linked to mutations in a single gene. Other diseases, called complex diseases, which include asthma or heart disease, are believed to be caused by a number of genetic changes as well as environmental influences. Determining the genetic causes for

¹² Many studies are so-called genotype-phenotype correlation studies, in which changes in the genetic makeup of a person (genotype) are correlated with effects on the phenotype, such as the development of certain diseases or specific features of a person. Obesity is not only a topic of lawsuits against fast food restaurants, but also an area of intense genetic research, in which a number of genes during the past years have been implicated as possible causes.
¹³ The specific chemical structure of RNA, DNA, and the various other carriers of genetic information are not important to the understanding of genetic aspects covered in this paper. The interested reader can find an introduction to basic genetic principles in any introductory genetics textbook. One commonly used textbook is by Anthony J. F. Griffiths et al., Introduction to Genetic Analysis (W.H. Freeman, 8th ed. 2004).
¹⁵ See Rowntree, infra note 17.
complex diseases is still in the initial stages and disease prevention is currently limited to identifying risk factors for the development of such diseases. Merely knowing that mutations in only one gene underlie a specific disease does not mean that physicians or genetic counselors can answer all the questions a person may have regarding disease severity, age of onset or life expectancy. This lack of conclusive information regarding the resulting phenotype is based on differences in penetrance.\(^\text{16}\) In some genes, such as the cystic fibrosis Transmembrane Reporter ("CFTR"), a large number of mutations throughout the gene have been identified that cause phenotypes ranging from a very mild form of CF that may go unnoticed until adulthood, to severe forms, in which the disease manifests itself in early childhood.\(^\text{17}\) In Huntington's chorea, penetrance of the disease phenotype is based on a number of trinucleotide repeats.\(^\text{18}\) Such repeats are present throughout the human genome and can range from three bases to five or more bases being repeated. The mutations in Huntington's chorea are limited to a stretch of nucleotide repeats that even in healthy adults differ in lengths. The fact that even healthy individuals display a variability in the number of repeats makes the job of the genetic counselor all the more difficult, since the initial diagnosis with Huntington's is often followed by questions from the tested

\(^{16}\) Penetrance is a measure of how strongly a mutation will be evident in the phenotype. Complete penetrance means that in almost all carriers of the mutation, the presence of the mutation will result in some change in the phenotype. An example of complete penetrance is the mutation for Tay-Sachs disease. Carriers of this disease develop symptoms of the disease shortly after birth and have a very limited life span. Mutations that show a weak penetrance, by contrast, may go unnoticed in many individuals. See Daniel Eisenberg, The Ethics of Genetic Screening, Jan. 9, 2005, available at http://www.aish.com (follow hyperlink "society today"; then follow hyperlink "society"; and click on "The Ethics of Genetic Screening") (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology).


\(^{18}\) Trinucleotide is defined as a "a nucleotide consisting of three mononucleotides in combination." WEBSTER'S NEW COLLEGIATE DICTIONARY 1262 (9th ed. 1990). In Huntington's chorea the specific repeat is "CAG."
individual related to age of onset and disease severity.\textsuperscript{19} For Huntington's, less than thirty repeats do not precipitate the development of the disease, while affected individuals have more than thirty-six repeats.\textsuperscript{20}

The autosomal dominant nature of the disease explains why every person who has more than thirty-six CAG repeats develops Huntington's chorea.\textsuperscript{21} In the inheritance of disease traits, autosomal dominant means that one copy of the mutation or disease-causing gene is sufficient to exhibit disease traits.\textsuperscript{22} In

\begin{itemize}
  \item[\textsuperscript{19}] See Huntington's Disease Society of America, Frequently Asked Questions about HDSA and HD, supra note 6.
  \item[\textsuperscript{20}] Zenjiro Matsuyama et al., \textit{Molecular Features of the CAG Repeats of Spinocerebellar Ataxia 6 (SCA6)}, 6 \textit{Hum. Mol. Gen.} 8, 1283 (1997).
  \item[\textsuperscript{21}] Id.
  \item[\textsuperscript{22}] Chris Winkelman, \textit{Genomics: What Every Critical Care Nurse Needs to Know about the Genetic Contribution to Critical Illness}, \textit{Critical Care Nurse}, Vol. 24, No. 3, Jun. 2004, at 36. The autosomal dominant is defined as:
\end{itemize}

Autosomal dominant: In this pattern, an abnormality or abnormalities appear with only a single copy of the disease allele; usually the abnormality appears in every generation. Each child of an affected parent has a 50% chance of inheriting the disease. Males and females are equally likely to have and transmit the disease. The 50% chance of inheriting the disease is based upon the calculation that each parent has two copies of the respective gene (in this case Huntington's) and that
terms of inheritance, autosomal dominant diseases are inherited with fifty percent likelihood by the children (sons and daughters) of an affected parent. Therefore, the autosomal dominant nature of Huntington’s chorea means that the teacher described in the Introduction has a fifty percent chance of inheriting the disease. Testing for disease-associated mutations has become more efficient and affordable as genotyping techniques advance. Usually, genetic testing involves using small amounts of blood to extract the DNA for polymerase chain reaction ("PCR")-based genotyping. PCR denotes a process by which short stretches of the one parent suffering from Huntington’s will have a mutated copy of the gene. Of the four copies of the Huntington’s gene present in the parents, one out of four will therefore be able to carry the disease into the offspring generation. Since each child will only inherit one copy of the gene from each parent (to generate the pairs of chromosomes present in each human being), two out of the four copies of the gene will be inherited by the children. The parent suffering from Huntington’s has a 50% chance that the copy of the gene he or she passes on to the child will carry the mutation, giving the child a 50% chance of developing the disease. This calculation is based on the assumption that the parent suffering from Huntington’s has only one copy of the mutated gene, which is the case in the vast majority of cases. If the parent were to express two copies of a mutated gene, inheritance of a disease would be 100%, since any copy of the gene passed on by the parent to the child would express the mutation. Autosomal modes of inheritance mean that sons and daughters have equal chances of inheriting the mutated gene, since autosomes are inherited by children of any sex. Dominant mode of inheritance means that one copy of the mutated gene, inherited from either mother or father, is sufficient to cause expression of the disease.

Id.

23 Id.

24 Id.


26 Ayalew Tefferi et al., Primer on Medical Genomics Part II: Background Principles and Methods in Molecular Genetics, 77 MAYO CLIN. PROC. 8, 785–808 (2002) (providing an introduction to molecular genetics, including commonly used terms).
DNA known to carry the disease gene are amplified and a certain banding pattern is used to determine the presence of the mutation.27

In many cases, simply finding a specific mutation associated with a disease does not indicate that the carrier (the person expressing the mutation) will actually develop the disease.28 The differences in penetrance of genes determine whether a mutation will actually cause the carrier to develop signs of the disease.29 In addition, mutations can have varying effects depending on the remaining genetic makeup of the person; some genes are modulated in expression by other genes so that the effect of a mutation is dependent on genes throughout the DNA.30

In the example of Huntington’s chorea, more than thirty-six repeats will identify a person as a carrier who will eventually develop the disease because of its autosomal dominant nature.31 A troubling aspect in counseling Huntington’s chorea patients is related to the uncertainty of when the disease will manifest itself and the life expectancy of the patient.32 In the case of the teacher in Germany, a genetic test would determine whether she is a carrier for the disease or not. The optimum outcome of such a test would indicate the presence of thirty or fewer CAG repeats in the Huntington’s gene, indicating that she will not develop the disease. A more troubling outcome would be the detection of more than

27 Id.

28 Winkelman, supra note 22, at 37 ("Penetrance refers to the probability that disease will appear when a disease-related genotype is present.").

29 Id. The meaning of “penetrance” is defined as:

[a] trait with incomplete penetrance is characterized by a specific genotype but a varied phenotype; that is, persons with the same genetic anomaly (abnormal genotype) do not have the same abnormal signs, symptoms, and complex disease. An example of a trait with incomplete penetrance is the polydactyl trait. The same genotype might “penetrate” as an extra finger, a small tag, or not at all.

Id.


31 Richard H. Myers, Huntington’s Disease Genetics, 1 NEURORX 255 (2004).

32 Id. at 257 ("The 34-year span in onset demonstrates not only the poor predictive power for onset of the repeat size, but also the substantial variation in onset age that is not explained by the HD repeat.").
thirty-six CAG repeats. The age of onset may be the most troubling aspect of genetic counseling for Huntington's disease carriers. While it is possible for the first sign of Huntington's to be visible in a carrier's early forties\(^3\) and to affect the carrier's ability to work as a teacher before she reaches the retirement age, it is equally possible that the young teacher will have no symptoms until after she reaches the retirement age.\(^4\) In the latter case, a diagnosis as a carrier of Huntington's chorea, while perhaps putting a heavy psychological burden on the individual, would in no way affect her physical ability to work as a teacher. This situation exemplifies the problems associated with some genetic testing. While disease carriers can be identified in a straightforward way, the uncertainty about the effect the disease will have on their lives remain unanswered. This uncertainty, especially in the case of debilitating diseases such as Huntington's, often exacts a toll on the individual that is as significant as the eventual physical effects. Add into this equation the potential of losing one's job or health insurance and it becomes understandable that some people who know they are at risk for specific genetic diseases refuse to get tested and prefer to live with the uncertainty of their carrier status.

The ability of genetic testing to determine who is at risk for inherited diseases is an area not properly addressed by existing laws. This will become obvious in the later sections of this Comment dealing with employees in the United States who seek protection against workplace discrimination through the ADA. Employees at risk for inherited diseases such as Alzheimer's, Multiple Sclerosis, or Huntington's may find it more difficult to fight discriminatory employment practices than employees with obvious disabilities, even though they are currently asymptomatic. So far, no studies have addressed how positive genetic test results fit into the spectrum of disabilities.\(^5\) All developed countries have

\(^3\) Id.
\(^4\) Id.

\(^5\) Meera Adya & Brian H. Bornstein, Genetic Information and Discrimination in Employment: A Psycho-Legal Perspective, 32 WM. MITCHELL. L. REV. 265, 285 (2005) (providing an in depth discussion on how the various disabilities are viewed in an employment context). Adya and Bornstein cite various studies that
taken part in the genetics revolution that makes genetic testing for inherited diseases possible. The proposals and frameworks developed in other countries for regulating such genetic testing may serve as a template for uniform federal regulation in the United States. This Comment discusses one such proposal by the NEC.

III. ANALYSIS OF THE NEC RECOMMENDATIONS AND CURRENT UNITED STATES LAW

A. History and Function of the German National Ethics Council

As a response to the technological advances in the life sciences and the need to get up-to-date policy recommendations, the NEC was founded by a mandate of the German Government on June 8, 2001.\(^{36}\) The purpose of the NEC is to generate a forum for dealing with ethical questions related to life sciences.\(^{37}\) The NEC has twenty-five permanent members with backgrounds in the natural sciences, medicine, theology, philosophy, economics, ecology, law, and social sciences.\(^{38}\) The members, who are nominated by the Chancellor, constitute an independent forum that is only bound to adhere to the duties enumerated in the initial mandate.\(^{39}\) The NEC is expected to work with the public and similar organizations

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\(^{36}\) See NEC, Function, available at http://www.ethikrat.org (follow hyperlink “English version”; then follow hyperlink “about us”) (describing the mission of the NEC) (last visited Mar. 6, 2006) (on file with the North Carolina Journal of Law & Technology). It is important to note that the NEC does not have lawmaking authority, but has a purely advisory role.

\(^{37}\) Id.

\(^{38}\) Id.

throughout Germany and the rest of the world. In response to the case of the young teacher at risk of developing Huntington’s, the NEC compiled a series of recommendations to regulate predictive testing in the workplace. The NEC’s recommendations will be addressed in more detail in the subsequent sections of this comment.

B. Summary of Issues Raised by the Court’s Decision

In 2004, the administrative court in Darmstadt determined that the denial of a tenure-track position to a teaching candidate at risk for developing Huntington’s chorea was not legal. This decision propelled the issue of genetic testing in the workplace into the headlines and, in part, contributed to the development of the NEC recommendations. Though the court found in favor of the plaintiff, the decision also indicates that genetic testing and inquiries into genetic risks are acceptable in certain situations. For example, the court stated that it was permissible to inquire about the presence of inheritable diseases among the applicant’s family members without the family members’ consent. The court justified such inquiries with the government’s right to hire only people who are sufficiently physically fit to work until they reach

40 See NEC, supra note 36 (stating that the NEC is seeking to collaborate with other ethics societies in Germany and groups with similar interests in other countries).


the legal retirement age and held that inquiries into the health of family members were necessary to serve this purpose. The court concluded that in these situations, state-based privacy laws allow such questioning without consent of the affected individuals. At the same time, the court rejected a government’s right to demand genetic testing under existing law and opined that this would constitute an impermissible invasion of privacy. The court reasoned that appropriate laws would have to be passed in order to demand such testing. Since the court based its decision on several areas of law, such as privacy rights and the special responsibilities of public servants, it is worthwhile to analyze the specific NEC recommendations in detail.

C. Summary of the NEC Recommendations

The NEC recommendations begin with the basic premise that the predictive power of genetic testing is comparable to the predictive power of more traditional disease-causing risk factors, such as blood chemistry and radiology. Since traditional approaches, such as using blood pressure measurements to determine a person’s risk for developing heart disease, can also be used to assess the development of a future disease, genetic testing is seen as a modern extension of these traditional means.

44 Id.  
45 Id. The judges specifically stated that in determining the health of a job applicant, information regarding inherited diseases of family members is required. Id.  
46 Id.  
47 Id.  
48 Id.  
50 Id.  
51 Medical Experts Redefine Hypertension, BIOTECH WEEK, June 8, 2005, at 77 (“Leading U.S. hypertension experts have expanded the definition of hypertension beyond the numbers obtained from a blood pressure reading, and instead, urge that blood pressure be viewed as a part of a patient’s overall risk
recommendations by the NEC therefore apply to all kinds of predictive testing, including non-genetic tests. The NEC, in general, permits questions regarding the physical health of the applicant so long as the information contributes to assessing the health of the applicant at the time the job begins. However, inquiries regarding possible future problems are only permitted if they relate to the disease or disability-risk within a contractually set time-frame after the job starts during which the employment contract may be canceled by either party, such as a six-month training period. Inquiries about family history of diseases are explicitly forbidden and all tests require the consent of the applicant. The physician performing the physical may only share the general assessment of the job applicant fitness for the job with a prospective employer; no specifics regarding the results of any tests are to be shared with third persons. However, in professions


53 See NEC, infra note 55, at 53 ("Unlike a private-sector employer, who can dismiss an employee on the grounds of ill health, his public-sector counterpart lacks the possibility of terminating a permanent civil servant's contract if he becomes permanently unfit for work owing to illness. In this situation, the public-sector employer has an understandable interest, when a candidate undergoes an official medical examination for the purposes of appointment as a permanent civil servant, not only in establishment of the candidate's current health-related fitness, but also in predictions of his likely future fitness.").

54 See NEC, infra note 55, at 56 ("This suggests that it should be permissible for predictive and prognostic health information to be demanded and used only in the case of conditions and predispositions with more than a 50% probability of having a non-negligible effect on an applicant's health-related fitness within the next five years.").


56 Id. at 59 (Recommendation #8).
involving possible risks to third persons, such as pilots, applicants may be subject to further tests in order to minimize the risk to the public.\textsuperscript{57} Also allowed are specific tests used to assess the risk that an individual will develop diseases due to workplace exposure.\textsuperscript{58} If such tests are not required by law, the applicant must be informed of the availability of such tests for his own physical protection.\textsuperscript{59}

The NEC loosens some of these recommendations with respect to civil servants, most of whom will reach a tenured employment status and whose contracts cannot be dissolved in case of disability or serious illness.\textsuperscript{60} The NEC states that the government and the general public have a significant interest in hiring only physically fit persons as public servants so as to ensure long-term employment.\textsuperscript{61} The NEC further states that due to the low incidence of job applicants for whom genetic testing can be used to predict disability, enabling such persons to achieve tenured status will not significantly increase the numbers of public servants seeking early retirement.\textsuperscript{62} Therefore, the NEC recommends a five-year limit in which a disease would have to manifest itself to

\begin{itemize}
\item \textsuperscript{57} \textit{Id.} at 58 (Recommendation \#5) ("More thoroughgoing examinations for currently symptom-free or predictable conditions are permissible if they are necessary having regard to the principle of proportionality in order to preclude specific third-party risks inherent in the nature of the activity (e.g. in the case of pilots, bus drivers or kitchen staff.").
\item \textsuperscript{58} \textit{Id.} at 59 (Recommendation \#9).
\item \textsuperscript{59} \textit{Id.} at 59 (Recommendation \#10).
\item \textsuperscript{60} \textit{See} NEC, \textit{supra} note 7, at 60. The limits on disclosure of information are:
\item By analogy with the regulations applicable in the individual Federal Länder to the appointment of severely disabled persons as permanent civil servants, it should be permissible to demand and use predictive and prognostic information only if it relates to disorders or predispositions that will have non-negligible effects on an applicant's health-related fitness in the next five years.
\item \textit{Id.}
\item \textsuperscript{61} \textit{Id.} at 59 (Recommendation \#11) ("The principles set out above cannot be applied without reservation to the appointment of permanent civil servants. In this instance, the public-sector employer assumes a duty of care towards and hence an obligation to provide for the welfare of, a civil servant that persist throughout his life (even in the event of premature incapacity for work.").
\item \textsuperscript{62} \textit{Id.} at 60 (Recommendation \#12).
\end{itemize}
justify excluding an applicant from obtaining tenured positions.\textsuperscript{63} Essentially, the NEC recommends that predictive information about future diseases can only be ascertained and used in judging the applicant's fitness for the job in the public sector if there is more than fifty percent risk of developing a disease that will significantly affect the fitness of the applicant to perform his assigned duties within the first five years of the employment contract.\textsuperscript{64}

\textbf{D. Current Legislation in the United States Regarding Genetic Discrimination in the Workplace}

There is an obvious need for uniform, national legislation that regulates the use of predictive testing in the workplace. As stated previously, there currently is no such uniform law regulating the use of predictive testing for non-federal employees in the workplace.\textsuperscript{65} While concern about the discriminatory use of predictive testing has been widespread, an Executive Order by President Clinton in February 2000 was the first attempt to create a federal policy that prohibits federal agencies from obtaining genetic information about their employees or job applicants, or from using genetic information in hiring and promotion decisions.\textsuperscript{66} In justifying the Executive Order, President Clinton cited "equal treatment under the law" as an important basis for his decision.\textsuperscript{67} While mostly cited in the context of health insurance

\textsuperscript{63} Id. (Recommendation #13).

\textsuperscript{64} Id. (Recommendation #14).


coverage, the possibility of genetic discrimination in the workplace has also given rise to state legislation since the 1990s. Today, most states have enacted legislation that prohibits genetic discrimination in the workplace and in obtaining health insurance coverage. In addition, many bills are being introduced at the state level seeking to clarify existing legislation or aiming to introduce protection against genetic discrimination. These state efforts have been the impetus to pass similar legislation at the federal level.

In February 2005, the Senate unanimously passed Senate Bill S.306, “Genetic Information Non-Discrimination Act of 2005,” by a vote of 98-0. This bill mirrors prior Senate legislation prohibiting genetic discrimination in the workplace and in health insurance coverage. The bill is pending in the House. The

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North Carolina Journal of Law & Technology). Bill Clinton made the following statement:

We must not allow advances in genetics to become the basis of discrimination against any individual or any group. We must never allow these discoveries to change the basic belief upon which our government, our society, and our system of ethics is founded—that all of us are created equal, entitled to equal treatment under the law.

Id.

68 See Billings, infra note 69 (citing Sally Lehrman, California Law Will Prohibit Genetic Discrimination, 371 NATURE 468 (1994)).


70 See Billings, supra note 69, at 559.

71 See Billings, supra note 69, at 559.

72 Experts Say Bill Banning Genetic Discrimination Faces Tough Road, 8 HR ON CAMPUS 4 (Apr. 1, 2005).


74 National Human Genome Research Institute, Genetic Discrimination, available at http://www.genome.gov/ (follow “Policy & Ethics” hyperlink; then
House bill, entitled "Genetic Information Non-Discrimination Act of 2005," (HR 1227), was introduced in March 2005. At present, the bill awaits deliberations in the Committee on Education and the Workforce, the Committee on Energy and Commerce, and the Committee on Ways and Means.

The pending legislation proposes the protection of workers in all industries from discrimination based on genetic information. The legislation would limit how employers and organizations, such as unions and labor committees, could use genetic information in hiring and other employment decisions. Furthermore, "employers, labor organizations, employment agencies, and joint labor-management committees are prohibited from using, acquiring or disclosing the genetic information of an individual or his/her family members." In stark contrast to the ruling in the labor dispute involving the German teacher, protection of genetic information would thereby extend to the employee's spouse and all of the employee's blood-relatives as well as any adopted children.


75 Id.
76 Id.
78 Id. (describing the use of genetic information in the employment context: "Title II—Employment: The bill would prohibit employers, labor organizations, employment agencies and joint labor-management committees from using genetic information to discriminate against an individual through hiring, firing, or other employment decisions. Employers are also prohibited from requesting, requiring, or purchasing genetic information of employees.").
79 Id.
80 See Genetic Information Nondiscrimination Act of 2003, S. REP. NO. 108–122, at 26 (2003). Family history should be included in the definition of genetic information because:

For this reason, the committee believes it is important to include family medical history in the definition of "genetic information." In so doing, the committee followed the recommendations of numerous leading experts in genetic science. Further, the bill applies to spouses and adopted children of an individual because of the potential discrimination an employee or member could face because of an
Inadvertently obtaining genetic information, while not sanctioned by the legislation, is not penalized, as long as there is no discriminatory use.\textsuperscript{81} It is worth noting that the Senate bill stipulates that genetic information from employees may be collected to maintain employee health. For example, genetic information can be used to limit permanent health effects from workplace exposure to dangerous substances.\textsuperscript{82} However, this use is explicitly limited by a prohibition on disclosing genetic information of the employee to anyone but the employee, health researchers, or others in compliance with federal and state law.\textsuperscript{83}

If genetic information is disclosed or subsequently used to discriminate, penalties may be levied using prior anti-

employer's or other entities' concern over potential medical or other costs and their effect on insurance rates.

\textit{Id.}

\textsuperscript{81} \textit{Id.} at 27. Some of the problems encountered when dealing with the genetic information at work include:

\textit{[t]he first exception addresses the so-called “water cooler problem,” in which an employer unwittingly receives otherwise protected genetic information in the form of family medical history through casual conversations with a worker. The committee recognizes that conversations among co-workers about the health of a family member are common and intends to prevent such normal interaction from becoming the basis of litigation under this Act. Without the exception, the committee is concerned that discussion in the workplace of a family member's health condition that is genetically based could be interpreted as an employer requesting or requiring genetic information from an individual. Under the legislation, an employer, labor organization, employment agency, or joint labor-management committee will not violate the ban on acquiring genetic information where it “inadvertently requests or requires family medical history” of the individual or family member of the individual.}

\textit{Id.}

\textsuperscript{82} \textit{Id.} ("The second exception—which preserves employer-sponsored wellness programs—is necessary to achieve the bill's stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer.").

\textsuperscript{83} \textit{Id.} ("[S]afeguards must be in place to ensure that the sponsoring employer, labor organization, employment agency, or joint labor-management committee does not have access to individually identifiable health information, as defined under the HHS medical privacy regulations.").
discrimination legislation such as Title VII of the Civil Rights Act. \(^84\) This would align one's genetic information with discriminatory parameters associated with race, color, sex, and religion. Claims would be filed through the Equal Employment Opportunity Commission ("EEOC") or the appropriate state agency. \(^85\) Currently, disparate impact claims are not permitted, but the bill directs the formation of a commission six years after enactment to determine whether disparate impact claims should be permissible. \(^86\)

Legislation at the federal level would create a uniform set of rules related to workplace discrimination, comparable to the American with Disabilities Act ("ADA"), which prohibits discrimination based on disability. \(^87\) In this context, it is significant that the ADA protects workers from workplace discrimination in some circumstances, such as in cases where the disease is evident

\(^85\) Id. at 29.
\(^86\) See S. REP. NO. 108–1053, at 29 (2003). Future developments may alter the current recommendations:

[d]ue to the unique nature of genetic information and our current understanding of this developing area of science, the Committee has determined that only disparate treatment cases should be permitted under this legislation at this time. The bill contemplates that the science could change in the future and has called for the creation of a study commission six years after the date of enactment to review this issue. The Commission's purpose is to advise Congress on the advisability of providing for a disparate impact cause of action in the future.

Id.

\(^87\) Id. at 30. The available statutes under which individuals may seek redress include:

[t]he Committee recognizes that both the ADA and the Rehabilitation Act of 1973 regulate the use of genetic information in some manner. The first rule of construction expressly states that nothing in Title II shall be construed to limit the rights or protections of an individual under those two laws. Individuals remain free to seek redress for violations of the ADA, the Rehabilitation Act, and the Genetic Information Nondiscrimination Act.

Id.
and is associated with some degree of disability. Until uniform federal guidelines cover all workers, the ADA may also protect the job candidate from discrimination based on the possibility of developing a disease.

Extending protection under the ADA to cases involving genetic discrimination has been achieved in a few cases. The courts in these important, but rare, cases have ruled in favor of more protection from employment-related predictive tests and have shown the need to establish basic rules that address recent developments in genetic testing. These cases are analyzed in more detail in Part IV.

IV. GENETIC TESTING IN THE WORKPLACE—IMPLICATIONS OF PRIOR CASE LAW

A. Genetic Testing in the Workplace—Two Case Studies

While only a few cases have dealt with genetic discrimination at work, research completed by Harvard and Stanford universities includes the case of a worker at risk for Huntington’s and

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88 Bryce A. Lenox, Genetic Discrimination in Insurance and Employment: Spoiled Fruits of the Human Genome Project, 23 DAYTON L. REV. 189, 205-06 (1997) ("Two current sources of federal protection against genetic discrimination in employment and insurance are the Americans with Disabilities Act (ADA) and the Health Insurance Portability and Accountability Act of 1996.").

89 See S. REP. NO. 108-122, at 27 (2003) ("The second exception—which preserves employer-sponsored wellness programs—is necessary to achieve the bill’s stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer.").

90 Norman-Bloodsaw et al. v. Lawrence Berkeley Lab., 135 F.3d 1260, 1273 (1998) (describing the limits of the ADA protection related to privacy: "Thus, the ADA imposes no restriction on the scope of entrance examinations; it only guarantees the confidentiality of the information gathered, §12112(d)(3)(B), and restricts the use to which an employer may put the information.") (emphasis in original).

91 Billings, supra note 69, at 559–60.
illustrates workplace discrimination due to genetic risk. In the case, a twenty-four year old woman was fired from her job, despite three promotions and outstanding performance reviews in the prior eight months. Once the young woman revealed to her employer that a family member had Huntington's, she received a bad performance review without any examples of poor performance being cited. A co-worker informed her that the employer was worried about the young woman being at risk for developing Huntington's Chorea. This case illustrates that genetic discrimination is not only a reality in Germany, but also the United States.

Up to now, very little case law involves genetics discrimination in the workplace, possibly because genetic testing is a very recent technological development. The following two cases involve genetic testing, in addition to possible elements of racial discrimination and efforts to cut health-care costs. In Norman-Bloodsaw v. Lawrence Berkeley Laboratory, several employees filed a lawsuit against their employer, Lawrence Berkeley Laboratory, for including testing for "highly private and sensitive medical and genetic information, such as syphilis, sickle cell trait, and pregnancy, in a general employee health examination." The plaintiffs brought charges against the employer based on violations of Title VII of the Civil Rights Act of 1964, the ADA, and their right to privacy as guaranteed by both the United States and the State of California Constitutions. Since the ADA is considered to offer protection against genetic testing at the workplace, this Comment will limit the analysis to the claims that were brought under the ADA. The court in Norman-Bloodsaw agreed with the

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93 Id. (citing Lisa N. Geller et al., Individual, Family, and Societal Dimension of Genetic Discrimination: A Case Study Analysis, 2.1 SCI. & ENGINEERING ETHICS, 71–88 (1996)).
94 Id.
95 135 F.3d 1260, 1264 (9th Cir. 1998).
96 Id.
97 One problem faced by the plaintiffs in Norman-Bloodsaw is the fact that some testing took place prior to the enactment of the ADA. Since the ADA does
plaintiffs that the employment-entrance exams they were subjected to were one of the categories of medical testing covered by the ADA. The court went on to clarify that the ADA is not intended to protect against the collection of information through medical testing, only to safeguard the confidentiality of such information and prevent the use of such information for discriminatory purposes.

The Ninth Circuit affirmed the district court’s dismissal of the ADA-based claims for two reasons. First, the plaintiffs did not test positive for any medical condition, nor were they subjected to discriminatory action by the employer. Second, the ADA does not limit the scope of such exams to job-relatedness or business purposes necessity. According to the court, the only possible claim under the ADA would be an allegation that the employer failed to properly safeguard the collected information as mandated.

not apply retroactively, only testing done after the ADA was passed could be considered by the courts.

98 Norman-Bloodsaw, 135 F.3d at 1273. The court goes on to explain what categories of medical inquiries are covered by the ADA:

The ADA creates three categories of medical inquiries and examinations by employers: (1) those conducted prior to an offer of employment ("preemployment" inquiries and examinations); (2) those conducted "after an offer of employment has been made" but "prior to the commencement of . . . employment duties" ("employment entrance examinations"); and (3) those conducted at any point thereafter. It is undisputed that the second category, employment entrance examinations, as governed by §12112(d)(3), are the examinations and inquiries to which Fuentes and Garcia were subjected.

Id.

99 Id.

100 Id. ("Because the ADA does not limit the scope of such examinations to matters that are ‘job-related and consistent with business necessity,’ dismissal of the ADA claims was proper."). The Supreme Court came closest to addressing the problem of asymptomatic individuals being discriminated against and their possible recourse under the ADA in Bragdon v. Abbott, 524 U.S. 624 (1998). In Bragdon, an individual with an HIV infection, but not full-blown and symptomatic AIDS, sought protection under the ADA. The Court justified extension of the ADA to an HIV-positive, but otherwise asymptomatic person on the fact that the HIV infection constituted a "physical or mental impairment that substantially limits one or more of the major life activities." Bragdon, 524 U.S. at 630 (referring to limited reproductive ability of the plaintiff).
under §12112(d)(3)(B) of the ADA. Since the plaintiff did not specifically allege such a violation, the Ninth Circuit found no possible basis for a violation of the ADA regulations by the employer. The narrow reading of the ADA with respect to genetic testing underscores the need for a comprehensive law that protects employees against workplace genetic testing and is not limited to guaranteeing proper use of any information collected through such testing.

Another case involved a lawsuit filed by the Brotherhood of Locomotive Engineers with the EEOC on behalf of workers at Burlington Northern Santa Fe Railroad ("BNSF"). Here, the employer allegedly used genetic tests to identify a possible basis for symptoms resembling carpal tunnel syndrome in order to avoid financial responsibility for the medical treatment. The tests were allegedly not done on a voluntary basis; every employee who submitted a claim for work-related carpal-tunnel syndrome was forced to submit to a blood draw to test for a chromosome 17 deletion. This genetic testing was done despite the lack of a firm

101 Id. at 1274.
102 Id. The plaintiffs lost under the ADA because:

[to] the extent that one can construe the complaint to allege that the defendants are in violation of §12112(d)(3)(B), the bare allegation that defendants have not provided, or adequately described, safeguards fails to state a violation of the ADA requirements as set forth in §12112(d)(3)(B) or as implemented in Department orders.

Id.

scientific basis that a direct link existed between the chromosomal alteration and the development of carpal tunnel syndrome. Based on the frequency of carpal tunnel syndrome in the workers, the test for mutation could not have explained all, if any, of the work-related injuries. In addition, one worker stated that he was threatened with losing his job if he refused to submit to the testing. Interestingly, in support of the plaintiffs’ lawsuit, the EEOC Commissioner stated that the genetic testing violated the ADA. The commissioner argued that under the ADA, only work-related testing that was based on business necessity was

North Carolina Journal of Law & Technology). A deletion on a chromosome indicates that a small part of the chromosome is missing. This change in the chromosome can be associated with the development of diseases, if the missing chromosomal region contained important genes. In this case, the chromosome 17 deletion affected the PMP 22 gene. See NC Center for Genomics, infra note 107.

106 Id.


HNPP is estimated to occur in approximately 2–5 people per 100,000. It is a rare condition. Perhaps 10% of Burlington Northern workers were afflicted with carpal tunnel syndrome. The PMP 22 gene could not begin to explain all those cases—it is far too rare a syndrome. It appears that the company vastly overestimated the predictive value of the genetic tests.

Id.

108 See id.

109 U.S. Equal Employment Opportunity Commission, supra note 105. EEOC Commissioner Paul Steven Miller explained:

The Commission takes the position that basing employment decisions on genetic testing violates the ADA. In particular, employers may only require employees to submit to any medical examination if those examinations are job related and consistent with business necessity. Any test which purports to predict future disabilities, whether or not it is accurate, is unlikely to be relevant to the employee’s present ability to perform his or her job.

Id.
permitted, thereby expanding the protection under the ADA as compared to the holding in Norman-Bloodsaw. The EEOC used the definitions of "individual with a disability" and "prohibited inquiries and examinations" of the ADA to explain their opposition to the testing done by BNSF. This case was settled out of court for $2.2 million.

B. Workplace-Related Testing—Employer’s Duty to Disclose

The aforementioned cases demonstrate the need for legislation that creates a unified national framework for the use of genetic information in the workplace. Genetic testing should be regulated to protect workers against invasions of privacy from unwarranted and overreaching tests. At the same time, genetic testing should also be regulated on the federal level to protect employers. Failure to disclose potential health risks that were revealed in pre-employment physicals may expose the employer to subsequent liability if the employment candidate should develop an incurable disease or suffer other negative consequences due to nondisclosure.

In Coffee v. McDonnell-Douglas Corporation, the Supreme Court of California held that "an employer generally owes no duty to his prospective employees to ascertain whether they are physically fit for the job they seek, but where he assumes such duty, he is liable if he performs it negligently." In this case, a pre-employment physical revealed a blood disorder indicative of a possible cancerous disease that the employer did not disclose to the

110 See id.
111 See Burlington Northern Santa Fe Railroad Employees Subjected to Genetic Testing for Carpal Tunnel Syndrome, available at http://www.sboh.wa.gov/Priorities/Genetics/GTF2002_02-25/documents/Tab05-BNSF_summary.pdf (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology) ("The EEOC considers that employers who discriminate against employees on the basis of predictive genetic tests "regard" the employees as having a disabling impairment and are therefore acting in violation of the ADA.").
112 North Carolina Center for Genomics and Public Health, supra note 107. The case was settled in May 2002.
113 Id.
114 503 P.2d 1366, 1370 (Cal. 1972).
prospective employee, and after working for the company for several months the employee collapsed due to bone marrow cancer. Even though the blood test did not involve genetic testing, it is easy to see how pre-employment genetic testing can put a similar burden on the employer to handle test results as the court required in Coffee. In this context, it is important to note that genetic testing for known workplace exposures to hazardous substances is specifically allowed by the German NEC's recommendations and by Senate bill S.306. Also, under the Occupational Safety and Health Act ("OSHA"), employees have a right to access their employment medical records if they are, or have been, exposed to toxic or harmful substances at work.

However, a current employee's right to access employee records, which have to be kept by the employer for the duration of the employment plus thirty years, does not extend to job applicants. As such, as far as the job applicants are concerned,

116 Id.
118 See S. REP. No. 108-122 at 27 (2003) ("The second exception—which preserves employer-sponsored wellness programs—is necessary to achieve the bill's stated goal of encouraging employees to take advantage of genetic technologies and opportunities to improve human health without fear of discrimination by their employer.").
120 Id. at § 1910.1020(d)(1)(i)(A), (B). It is also important to note that if an employee works for the less than one year at the company, the employer has the option of releasing the records kept to the employee and thereby free himself of any duty to maintain the records for the statutory period. § 1910.1020(d)(1)(i)(C).
121 Id. at § 1910.1020(c)(4).
their best and possibly only protection is the ADA and its prohibition to discriminate based on medical testing. However, based on Norman-Bloodsaw, the ADA does not prohibit genetic testing for employment purposes per se, merely discrimination based on the results of such testing.

The proposed legislation under the House and Senate version of the "Genetic Information Non-Discrimination Act of 2005" would go significantly further. Instead of simply limiting the right of the employer to perform medical tests without appropriate employee consent, the proposed legislation would extend to prospective employees and prevent genetic discrimination in hiring decisions. In addition to privacy concerns, the use of genetic testing also raises concerns, particularly among minorities, about the potential abuse of genetic testing for discriminatory purposes.

C. Genetic Testing in the Workplace—Modern Backdoor to Old-Fashioned Discrimination?

In Norman-Bloodsaw, one aspect of the case the court overlooked in its analysis was the possible use of genetic testing for race-based discrimination. While the pregnancy testing done by Lawrence Berkeley Laboratory was limited to female workers, the testing for sickle cell anemia was limited to African-Americans. Interestingly, the Norman-Bloodsaw court acknowledged that testing for this disease was stopped by the

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122 See S.1053, 108th Cong. (2003). See § 202(b)(5). Testing by the employer is allowed in the following situations:

- the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if—(A) the employer provides written notice of the genetic monitoring to the employee; (B)(i) the employee provides prior, knowing, voluntary, and written authorization; or (ii) the genetic monitoring is required by Federal or State law.

123 Norman-Bloodsaw v. Lawerence Berkley Lab., 135 F.3d 1260, 1265 (9th Cir. 1998). "They also allege that only black employees were tested for sickle cell trait and assert the obvious fact that only female employees were tested for pregnancy." 124 Id.
employer in part because African-American newborns were routinely tested for the disease by then. The two plaintiffs that had possible claims under ADA had negative test results, and one can only speculate whether positive results for sickle-cell anemia would have resulted in discriminatory hiring decisions. However, there is evidence that the availability of genetic testing may be abused to discriminate against certain population groups. Sickle-cell anemia is an incurable and debilitating disease, prevalent in African-Americans. In an age of ever-increasing health care costs and fiscal concerns governing medicine, employers that provide comprehensive health care coverage to their employees may be tempted to reduce costs for everyone by only hiring people without potential or obvious genetic diseases.

125 Norman-Bloodsaw, 135 F.3d at 1274. The following rationale was provided by the court to explain why the claims by the plaintiffs failed:

Defendants have not carried their heavy burden of establishing either that their alleged behavior cannot be reasonably expected to recur, or that interim events have eradicated the effects of the alleged violation. First, they do not contend that the Department will never again require or permit, or that Lawrence will never again conduct, the tests at issue. They assert only that syphilis testing was discontinued because of its limited usefulness in screening healthy populations, and that sickle cell trait testing was discontinued as redundant of testing that most African-Americans now receive at birth.

Id.

126 Id. at 1273. ("Plaintiffs do not allege that defendants made use of information gathered in the examinations to discriminate against them on the basis of disability; indeed, neither Garcia nor Fuentes received any positive test results.").


128 Charles Pegelow & Ashok Raj, Sickle Cell Anemia, Jun. 23, 2004, available at http://www.emedicine.com/ped/topic2096.htm (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology). It is ironic that the plaintiffs in Norman-Bloodsaw allege discrimination based on the testing for sickle cell anemia, when the National Sickle Cell Anemia Control Act was passed by congress in 1972 to ensure adequate federal funding for voluntary testing as a result of efforts by black leaders that alleged insufficient medical attention to this disease. See Pagnattaro, supra note 92 at 146–47.

129 Andrews, supra note 127, at 896.
In the United States, genetic science has been abused for discriminatory purposes, perhaps most prominently during the eugenics movement. Initially, forced sterilization was thought to be a cost-effective remedy for improving the genetic make-up of society. The most infamous case involving restricting personal rights in the name of eugenics may be the 1927 case of Buck v. Bell, where the plaintiff, Carrie Buck, underwent forced sterilization based on the judgment of Justice Holmes that "three generations of imbeciles" are enough. It was later shown by Paul Lombardo that Carrie Buck was not an imbecile, but had done well in school, as had her daughter, and that the likely reason for the sterilization was her "immoral" behavior for having a child out of wedlock. Shockingly, Carrie Buck was not only forcibly sterilized, but she was also confined to an institution for the "feebleminded." Based on the history of abusing genetic science for discriminatory purposes, modern society must take extra precautions not to repeat past mistakes.

Evidence indicates that access and use of genetic testing may be biased in favor of Caucasians. Lori Andrews has

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130 Webster's New Collegiate Dictionary defines eugenics as "a science that deals with the improvement (as by control of human mating) of hereditary qualities of a race or breed." See WEBSTER'S NEW COLLEGIATE DICTIONARY 428 (9th ed. 1990).
131 Andrews, supra note 127, at 895.
133 Id. at 207.
135 Andrews, supra note 127, at 906–07 (discussing the political use of genetics exemplified by Buck v. Bell).

Latinas and African-Americans were much less likely to undergo prenatal diagnosis than were whites and Asians. Racial/ethnic differences exist in prenatal diagnostic test use and associated outcomes in women ages 35 and older. Socioeconomic factors are partially responsible. Further research is needed to determine the roles of
summarized several studies that indicate disparate treatment of women and ethnic groups through availability of genetic testing or use of informed consent prior to genetic testing. Studies comparing the use of informed consent for genetic testing related to cystic fibrosis, a genetic disorder most prevalent in Caucasians, and sickle cell anemia, which is prevalent in African-Americans, indicate that informed consent procedures are more prevalent in the identification of potential carriers of the cystic fibrosis gene, while screening for sickle cell anemia is done with minimal informed consent procedures.

Notably, this analysis may compare two diseases that are very different in terms of the effect that early diagnosis has on the carriers. Cystic fibrosis is caused by mutations in one gene, but the number of mutations identified in the gene is extensive, and research illustrates that some carriers of the disease will not show any phenotypic effects of the disease until late in life and that the phenotypic effects in patients diagnosed with cystic fibrosis vary greatly. In addition, early intervention in cystic fibrosis patients will never cure the disease and there is little therapy available in terms of preventing complications. By contrast, sickle cell anemia is a disease with a clear phenotypic effect that is easily identified in testing. Testing for sickle cell anemia may be likened to testing in neonates for phenylketonuria ("PKU"), a disorder in

structural issues in the delivery of care, provider attitudes, patient education, patient preferences, and other factors.

Id. 137 Lori B. Andrews is a Distinguished Professor of Law and the Director of the Institute for Science, Law & Technology at the Chicago-Kent College of Law. She has published more than 100 articles on genetics, alternative modes of reproduction, and biotechnology. Her biography can be found at http://www.kentlaw.edu (follow hyperlink "Faculty" and select "full time faculty" under Faculty lists hyperlink; then select "Lori B. Andrews") (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology).

138 Andrews, supra note 127.
139 Id. at 909–10.
which, similar to sickle cell anemia, early diagnosis can limit the effects of the underlying genetic alteration and in which a conclusive test can easily be done in the newborn. In both sickle cell anemia as well as phenylketonuria, DNA testing is not required for a conclusive diagnosis, even though the blood testing involved will point towards the carriers having the relevant mutations.

Nevertheless, Lori Andrews rightly points to the long history of discriminatory uses of genetic testing, and cases such as

142 March of Dimes, Newborn Screening Recommendations, available at http://www.marchofdimes.com/ (select hyperlink “Professionals and Researchers”; then select “Newborn screening” hyperlink and open the document “March of Dimes Newborn Screening Recommendations”) (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology). While access to medical care may limit the benefits of early detection, antibiotic treatment in neonates suffering from sickle anemia “dramatically reduces the risk of these infections and the deaths that result from them.” Id.

143 The following information is compiled from the Mayo Clinic Information about Screening and Diagnosis of PKU, cystic fibrosis, and sickle cell anemia. In Phenylketonuria, the underlying genetic mutation is affecting the gene for metabolizing an amino acid called phenylalanine. Missing this enzyme will result in high levels of phenylalanine in the blood that can be detected by a simple blood test without involving DNA extraction. See www.mayoclinic.com/ (follow hyperlink “Diseases and Conditions”; follow hyperlink under “P” and select “phenulketonuria”; section “Screening and Diagnosis”). Similarly, sickle cell anemia can be detected using a simple blood test that does not require DNA extraction. See www.mayoclinic.com. (follow hyperlink “Diseases and Conditions”; follow hyperlink under “S” and select “sickle cell anemia”; section “Screening and Diagnosis”). Newborns are screened for both diseases, since early intervention is essential to prevent some of the complications associated with the diseases. By contrast, the standard test for cystic fibrosis is not blood-based. A sweat test is performed to determine the salt levels, since cystic fibrosis patients have consistently high salt levels in the sweat. In newborns, this test is not reliable during the first month of life and therefore physicians either delay the test until the baby is several months old or perform a genetic test. See www.mayoclinic.com/ (follow hyperlink “Diseases and Conditions”; follow hyperlink under “C” and select “cystic fibrosis”; section “Screening and Diagnosis”). Delaying the diagnosis of cystic fibrosis beyond the newborn will not result in any permanent disability to the baby. (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology).

Norman-Bloodsaw indicate that lack of informed consent and targeting of specific population groups for predictive testing exemplifies problems in the way society is handling access to modern genetic tools. It is equally important to point out that not all advocates of minority rights are in favor of greater access to genetic testing; some warn that efforts to equalize access to genetic testing may also be discriminatory. The split opinion regarding the approach that best includes minorities in the genetics revolution is addressed in Part V.

V. INDIVIDUALIZED MEDICINE AND MINORITIES

"Once a tool is developed there are considerable pressures for implementation."

The sequencing of the human genome and the availability of high throughput genotyping technologies create powerful tools in the hands of researchers. A more individualized medicine approach can optimize drug efficacy, limit possible side-effects of prescription drugs, and improve the effectiveness of medical treatments in general. However, individualized medicine also puts additional pressures on physicians, health care providers and other groups with access to personal information, including genetic information, to safeguard the privacy of patients. The public outcry following the approval by the Federal Drug Administration of a blood pressure medication geared towards African-Americans may be indicative of the future challenges facing individualized medicine. Since African-Americans were suffering from heart

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145 See Wiesenthal, supra note 2.
146 "High throughput technologies" are defined as genotyping methods that involve robotics and allow screening of large numbers of samples in one experiment. See Michael M. Shi, Enabling Large-Scale Pharmacogenetic Studies by High-Throughput Mutation Detection and Genotyping Technologies, 47 CLINICAL CHEM. 164 (2001).
147 Jim Hopkins, Personalized Drugs Draw Biotech Dollars, USA TODAY, Oct. 20, 2005, at 1B.
disease at higher rates\textsuperscript{149} than other ethnic groups, improved treatments were demanded by some community activists.\textsuperscript{150} Others in the African-American community were concerned with the precedent that drugs optimized for specific groups within the population can set.\textsuperscript{151} Akin to the reactions voiced by the Supreme Court when dealing with cases involving affirmative action, some view the preferential treatment of minorities as necessary to overcome a history of discrimination,\textsuperscript{152} while others view race-specific prescription drugs as a first step on the way to

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\textsuperscript{149} Val B. Kennedy, \textit{FDA Panel OKs Heart Drug for African-Americans}, Jun. 17, 2005, \textit{available at} www.marketwatch.com ("According to NitroMed, about 750,000 African-Americans have heart disease. In addition to suffering in greater numbers, most do not respond as well to standard cardiac drugs as patients of other ethnic backgrounds.")

\textsuperscript{150} \textit{Id.} ("Because of this, BiDil has enjoyed considerable support from African-American health activists, including the Association of Black Cardiologists, which co-sponsored some the clinical trials.")

\textsuperscript{151} M. Gregg Bloche, \textit{Race-Based Therapeutics}, \textit{NEW ENG. J. MED.} 2035, 2036, Nov. 11, 2004. ("This argument is a reassuring response to concern that emphasis on biologic differences among social groups risks stigmatizing some groups and, in recent history, has led to much worse consequences.") (citing RJ Lifton, \textit{The Nazi Doctors: Medical Killing and the Psychology of Genocide} (Basic Books, 1986)).

\textsuperscript{152} Grutter v. Bollinger, 288 F.3d 732, 737 (6th Cir. 2002) (\textit{cert. granted}, 537 U.S. 1043 (2002) ("[I]ts admissions policy describes 'a commitment to racial and ethnic diversity with special reference to the inclusion of students from groups which have been historically discriminated against, like African-Americans, Hispanics and Native Americans, who without this commitment might not be represented in our student body in meaningful numbers.").
discrimination against minorities. The lessons from affirmative action cases indicate that using genetics to create individualized medical treatments harbors certain dangers, such as the fear of race-based discrimination. Researchers and the Congress need to be aware of these concerns and should strive to create as broad a consensus as possible when proceeding with individualized medicine.

Other methods of targeting minorities in medicine have been received with less criticism. The National Institutes of Health have focused on an increased inclusion of minorities in clinical trials in an attempt to optimize the application of results to the population as a whole. One inherent concern of merely including minorities at the levels at which they are present in the general population is the fact that, in small studies, statistical power may not be high enough to generate conclusive results. Increasing minority enrollment above the population average in clinical trials dealing with diseases from which minorities suffer to a disproportionately high degree may again elicit concerns as raised by M. Gregg Grutter v. Bollinger, 539 U.S. 306, 349 (2002) (Justice Thomas citing Frederick Douglass: "In regard to the colored people, there is always more that is benevolent, I perceive, than just, manifested towards us. What I ask for the negro is not benevolence, not pity, not sympathy, but simply justice.").

The NIH guidelines for inclusion of minorities and women state:

Ideally, women and minorities in the study population are in the same proportions as in the U.S. population having the disease entity being studied. If prevalence is unknown, the NHLBI standard for evaluation of the proposed study population is the composition of the population of the United States which, according to the 2000 census, is 51% women and 25% minorities.

Id.
Bloche, even though such an increased enrollment of minorities may be necessary to generate statistically interpretable results.

To complicate matters, geneticists have started to question the importance of race as a parameter in genetic studies. The increased use of high throughput genotyping has afforded scientists the luxury of screening for larger numbers of single nucleotide polymorphisms and allowed a comparison between the so-called "self-identified race" and the genetic background of a person. Having more than 20% of participants in some studies self-identify their racial background as different from their race based on genetic screening and the increase in interracial families may lessen the impact of race in genetics in favor of a truly individualized approach to medicine. Some geneticists, therefore, suggest an increased focus on the socio-economic environment when analyzing genetic data and limiting self-identified race to an initial screening tool.

The preceding examples illustrate the difficulties encountered by the increased use of genetics and some of the concerns that may be raised with respect to the treatment of minorities. The precedent set by the ADA for federal anti-discrimination laws and the general acceptance of ADA standards for the treatment of people with disabilities may serve as a guideline to expand the ADA to the use of and access to genetic information. The eventual goal should be parallel legislation based on a broad consensus that

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155 See Bloche, supra note 151. Mr. Bloche is concerned that singling out certain ethnic groups, even for what may initially seem like beneficial reasons, could, in the long run, lead to possible stigmatization of these groups.


157 Single nucleotide polymorphisms denote mutations that affect a single nucleotide in the DNA sequence. A polymorphism is a specific point in the human genome that shows variability, such as is seen in mutations. See Tefferi, supra note 26.

158 Shields, supra note 156, at 90.


160 See Shields, supra note 156, at 95.
specifically aims at mandating how genetic information should be collected and accessed.

VI. CONCLUSION

Passing the pending legislation in the House, combined with assurances by President Bush that he will sign such legislation, should alleviate some of the concerns about genetic testing giving rise to discrimination in the workplace. However, technological advances have made genetic testing more affordable to employers and increased the number of testable genetic diseases. These technological advances, as well as the affordability of genotyping, have led to an increase in genetic testing in the workplace. For example, as early as 1982, 1.6% of companies confirmed the use of genetic testing for employment purposes. Later figures found six to ten percent of employers conducting such testing in 1997.

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164 Editorial Desk, *Government Plan Threatens Patients' Privacy; Genetic Discrimination*, N.Y. TIMES, Sept. 17, 1997, at A30. When considering the results, it is important to keep in mind that the reported frequency of genetic tests may include tests that are merely blood-based, but do not include the determination of genetic information. *Id. See also* University Publications of America Employment Testing, *AMA Finds Uncertainty over Genetic Testing*, ...
Since twenty-two percent of employees at risk for genetic conditions reported some form of discrimination, a federal law may be the best way to create uniform regulations regarding the use of genetic testing in the workplace.\(^{165}\)

The NEC recommendations attempt to create such uniform guidelines for Germany.\(^{166}\) While these guidelines are a step in the right direction, some of the suggestions in the guidelines have been met with criticism. For instance, the NEC guidelines set different standards for employees in the public and private sectors, with public servants being subject to more stringent testing due to the increased responsibility of the state to cover disability payments in case of a disease manifesting itself.\(^{167}\) This is in contrast to the current situation in the U.S., where the executive order by President Clinton secures higher protection for federal employees...

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\(^{165}\) See Pagnattaro, supra note 92 (citing Lisa N. Geller et al., Individual, Family, and Societal Dimension of Genetic Discrimination: A Case Study Analysis, 2.1 SCI. & ENGINEERING ETHICS, 71–88 (1996)).

\(^{166}\) See NEC, supra note 55.

\(^{167}\) See NEC, supra note 55. The NEC specifically points this out in the abbreviated English version of its recommendations. "The principles outlined above cannot be applied without reservation to the appointment of civil servants. In this instance, the employer assumes a duty of care towards, and an obligation to provide for the welfare of, a civil servant that persist throughout the employee’s life." Id.
than is currently in place for private sector workers.\footnote{Executive Order No. 13145 (order to Prohibit Discrimination in Federal Employment Based on Genetic Information, Feb. 8, 2000). The central tenet that:} Even more troubling than the different standards is the NEC's rationale for implementing these standards.\footnote{See NEC, \textit{supra} note 55. Citing the duty of care assumed by the federal government for civil servants, the NEC then goes on to state that genetic testing may be demanded in certain cases including:}

Citing increased health care costs due to tenured status of public servants, the NEC uses a cost-benefit analysis to justify deciding how much of a privacy invasion is necessary to determine an employee's fitness for a job.\footnote{See President Clinton's Comments on the Signing of Executive Order 13145 (Feb. 8, 2000), \textit{available at} http://www.genome.gov/10002346 (last visited Mar. 3, 2006) (on file with the North Carolina Journal of Law & Technology). President Clinton made the following statement to summarize the main points of the executive order:

The executive order I will sign in just a couple of minutes will be the first executive order of the 21st century to help meet this great 21st century challenge. It prohibits the federal government and its agencies from using genetic testing in any employment decision. It prevents federal employers from requesting or requiring that employees undergo genetic tests of any kind. It strictly forbids employers from using genetic information to classify employees in such a way that deprives...} This disparate treatment, between public and private employers, would contradict the notion of equality before the law, one of the reasons cited by President Clinton for his executive order.\footnote{Id.} The current
legislation in the United States suggests that privacy concerns rather than cost-benefit analysis will be used as a basis for future legislation.\textsuperscript{172}

It remains to be seen whether rising healthcare costs,\textsuperscript{173} combined with achieving some form of national health care,\textsuperscript{174} will reduce or eliminate the bans on genetic testing currently in place or proposed under the pending legislation. One thing is certain: with the increased availability of high throughput genotyping techniques and associated increased use of genetic testing, society cannot afford to delay embarking on a comprehensive effort to regulate genetic testing, unless it wants to risk establishing possible discriminatory practices associated with genetic testing. The public, the courts, and Congress must understand that despite advances in genetic testing, affected persons will not be able to have all their questions answered by a genetic counselor. It should therefore be the duty of society as a whole to create a framework, in which the genetic research can have the utmost benefit, while minimizing the possible detrimental effects of genetic testing on the individual. Passing and signing into law the "Genetic

\textsuperscript{172} See NEC, supra note 55.

\textsuperscript{173} Nick Bunkley, Increased Costs May Stall Auto Industry; But Southeast Michigan's Economy is Expected to Grow, Business Leaders Say, DETROIT NEWS, Dec. 7, 2004, at 1C. The problems faced by employers' attempt to pay for health insurance coverage include:

To compensate for increasing expenses, automakers are likely to offer buyers fewer incentives next year, said J.T. Battenberg, Delphi Corp.'s chairman and chief executive. The cost of materials has jumped 50 percent in the past year alone, and health insurance premiums are expected to increase nearly 14 percent. Ford Motor Co., General Motors Corp. and DaimlerChrysler AG paid a combined $9 billion for employee health care in 2003.

\textsuperscript{174} Mike Dennison, Elections Heating Up as Tuesday Vote Nears, GREAT FALLS TRIBUNE, June 6, 2004, at A111.
Information Non-Discrimination Act” would be an important first step. But as the ethics recommendations by the NEC indicate, the devil is often in the details and amendments will have to be made as physicians, employers, employees, and Congress learn how to incorporate genetic testing into the workplace.