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On behalf of the Genetic Information Nondiscrimination in Employment Coalition
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Hearing on "H.R. 493: The Genetic Discrimination Nondiscrimination Act"
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Chairman Pallone, Ranking Member Deal, and distinguished members of the subcommittee. Thank you for this opportunity to testify on the issue of genetic discrimination. I commend the subcommittee for taking a role in the drafting of this far-reaching bill and the potential it creates to complicate or undermine the provision of health care, the administration of health insurance, and needlessly to intrude into the business of employers and the lives of employees. My statement will focus on the impact genetic nondiscrimination legislation will have on employers and employees.

My name is Burton Fishman. I am Of Counsel to the Washington, D.C. law firm of Fortney & Scott. By way of introduction, I served as Deputy Solicitor for National Operations at the U.S. Department of Labor under Secretary Lynn Martin, during the term of President George. H. W. Bush. I was "present at the creation" of the Americans with Disabilities Act (ADA) and have remained involved in the administration and application of that law. I have written numerous books and articles on the subject and have been involved in a number of matters with respect to the statute. That background served as a natural preface to my concerns with the issue and the bill before you today.

I appear before you this afternoon as Counsel to the Genetic Information Nondiscrimination in Employment Coalition, the GINE Coalition, which is a business Coalition of trade associations, professional organizations, individual companies and their representatives, including the Society for Human Resource Management (SHRM), the U.S. Chamber of Commerce, the National Association of Manufacturers (NAM), the National Retail Federation (NRF), and the College & University Professional Association for Human Resources (CUPA-HR), to name a few. In addition to the hundreds of thousands of members of those associations and the millions of employees they employ, representatives from biotechnology, pharmaceutical research, health care, information technology, and other industries have joined in the Coalition's deliberations. Among the Coalition's members are a number of employers who run health care facilities, provide a full-spectrum of health care services, or offer nursing, EMT, or first aid services to their employees. Their efforts to assist and treat their employees must not be impeded by this legislation.

The focus of the GINE Coalition is the issue of genetic non-discrimination in employment. However, so long as the proposed bill focuses, as it does, on the **flow** of information rather than the discriminatory misuse of information, the bill will *inevitably* be plagued by serious, negative, albeit unintended consequences. The Coalition has worked diligently and faithfully with all participants in the debate on the substance of federal legislation on the subject of genetic non-discrimination. We acknowledge and appreciate the work of the Sub-Committee on Health, Education, Labor and Pension and of the positive amendments that have made record-keeping less burdensome and have allayed fears of endless lawsuits seeking to mandate insurance coverage and/or require expanded treatment options. We nonetheless believe that the bill can be improved.

We believe that there is no need for protections of genetic information that far exceed those provided for Personal Health Information (PHI) under HIPAA or for medical information under the Americans with Disabilities Act. We believe there is no need to require that employers, who have devoted long months of effort to master the privacy rules of HIPAA, must now learn another, more expansive regimen for an ill-defined, endlessly growing body of information. We believe that **predictive** genetic information should be the focus of the bill and that this information can be acquired without inadvertently preventing the prompt provision of care or the slowing of the very research at the heart of this law. We believe that predictive genetic information can be protected without needlessly complicating the work of employers and burdening the lives of employees. In today's testimony before the Committee, I will address those issues largely in the context of Title II, as others will be focusing on Title I.

Let me be clear from the outset: **the GINE Coalition strongly supports genetic nondiscrimination and confidentiality**. The Coalition believes that employment decisions should be based on an individual's qualifications and ability to perform a job, not on characteristics that have no bearing on job performance. Although it is beyond the Coalition's brief, Coalition members' opposition to genetic discrimination in employment also extends to providing and administering health insurance to employees in a nondiscriminatory manner. Others today will speak to those insurance issues.

BACKGROUND

Members of the GINE Coalition, like the rest of society, are thrilled by and enthusiastically support the scientific research and truly spectacular breakthroughs relating to the sequencing of the human genome. Scientists in academia and industry have identified genes responsible for diseases from deafness to kidney disease to cancer. Through their efforts, we are uncovering hereditary factors in heart disease, diabetes, Parkinson’s disease, bipolar illness, asthma, and other common illnesses of our society. As Dr. Francis Collins predicted a few years ago:

> “Quite possibly before the end of the first decade of this new millennium, each of us may be able to learn our individual susceptibilities to common disorders, in some cases allowing the design of a program of effective individualized preventive medicine focused on lifestyle changes, diet and medical surveillance to keep us healthy. This will also enable us to focus our precious health care resources on maintaining wellness, instead of relying on expensive and often imperfect treatments for advanced disease.
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> “These same discoveries about genetics will lead us to predict who will respond most effectively to a particular drug therapy, and who may suffer a side effect and ought to avoid that particular drug. Furthermore, these remarkable advances will lead us to the next generation of designer drugs, focused in a much more precise way on the molecular basis of common illnesses, giving us a much more powerful set of targeted interventions to treat disease. (Testimony of Dr. Francis Collins before the Senate Health, Education, Labor and Pension Committee, July 20, 2000).”

One comes away from such predictions with an exhilarating sense of hope and optimism for the future of medical science. Every human being has one or more defective genes, or genetic “markers,” indicating a predisposition to certain abnormal traits or conditions. Given the rapid pace of genetic discoveries, in the near future, we hope, the hereditary basis for many of the profound diseases which afflict us today will not only be identified, but such knowledge will also be useful for purposes of prevention and cure. At that time, such genetic information will be vital to an individual and his/her physician, and perhaps also to the individual's employer. The information could be used for purposes of preventing exposure to conditions in the workplace that would accelerate the onset of a particular disease or, as Dr. Collins suggested, for the purpose of fashioning individualized, employer-provided wellness programs to help prevent a disease from occurring.

However, this exhilaration is compromised by a bill, such as H.R. 493, the Genetic Information Nondiscrimination Act of 2007, which creates an amorphous definition of "genetic information" and then characterizes such information as "forbidden." We believe that penalizing the flow of information is not an appropriate response. Our concern is that the very progress in medical science that Dr. Collins envisions will be delayed and deterred by legislation such as has been proposed here. Our concern is that treatment of employee/patients will be hampered. Our concern is that employers will not be able to assist employees dealing with the various requirements of health care providers and health insurers for fear of misunderstanding the complex distinctions in the bill and being sued for their efforts.

We recognize that some people – we believe wrongly – *fear* that genetic information *may* be used by employers not for beneficent purposes but as the basis for employment discrimination. In the research community, the concern is that such fears will discourage individuals from participating in genetic research and testing. Such fears are fed by anecdotal but apocryphal stories and, of course, on the rare but highly publicized case involving Burlington Northern-Santa Fe Railroad, from nearly a decade ago.[1] The fact that the employees in this case were able to seek and gain redress under current law indicates that no additional legislation is

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[1] *EEOC v. Burlington Northern Santa Fe Railroad* (N.D Ia, settled April 18, 2001).

required. As significant, what occurred there was an *unusual and unrepeated* event, one that should not serve as the basis for sweeping legislation.

Indeed, there are surveys conducted by neutral bodies such as the American Management Association which show that few employers seek or even understand genetic information. Further, in the more than 30 states which have laws prohibiting genetic discrimination, there have been ***no*** reported cases, even though several statutes were enacted decades ago. Thus, there is no empirical evidence of genetic discrimination in employment, unlike the mountains of evidence of discriminatory conduct which preceded passage of other nondiscrimination laws, such as Title VII of the 1964 Civil Rights Act, the Age Discrimination in Employment Act, and the Americans with Disabilities Act.

Somewhere in the distracting mix of irrational fears, a rational understanding of the benefits of genetic research has been lost. Somewhere, the important assistive role that employers, hospitals, and insurers play in transmitting and explaining often complicated rules and regulations has been forgotten. Somewhere, the legitimate concern for worker safety by government and by employers has been overlooked and replaced with notions of the sanctity of the genome. But the product of genetic research is not employment discrimination. The product of genetic research will be to help people – employees and employers – make health-driven choices based on shared knowledge. But viewed through the distorting prism of H.R. 493, the response to advances in genetic research is to prohibit the spread of information. H.R. 493 responds to fear and ignores hope. It limits the spread of information in the name of worker fear rather than finding ways of applying that information in the name of worker safety. That is not how Congress has responded in the past and should not be how Congress responds today. Fear should not be the predicate for federal legislation.

This is particularly true in the still-nascent field of genetic testing. Currently, the predictive ability of genetic tests and other forms of genetic information has little practical workplace utility since, in the current state of medical and scientific diagnostics, genetic tests reveal only the possibility that a particular trait, condition, or illness may develop in the future. There is no medical certainty that such illnesses will, in fact, ever develop; neither is there any certainty as to how far in the future they may become manifest. Thus, such information is simply too remote and too speculative on which to base current employment decisions, even if an employer were interested in doing so – a conclusion utterly unsupported by actual conduct. Furthermore, because of the awe-inspiring speed at which scientific knowledge is expanding, legislation based on today's understanding will likely respond to a scientific context that has already fallen into obsolescence. In fact, many of the states which passed legislation early on, have already had to amend laws rendered obsolete by the advance of scientific knowledge.

Yet, it is the opinion of the sponsors and supporters of pending federal genetic nondiscrimination bills that such legislation is necessary. Although we do not share that view, as a Coalition that stands squarely against employment discrimination, we do not oppose legislation that focuses on the discriminatory misuse of genetic information. To achieve that goal, we believe the proposed bill should continue to be amended and improved. We hope to work with Congress to craft an effective, efficiently administered, practical law that avoids unintended consequences and baseless lawsuits, and which will not impede progress in science.

THE GINE COALITION'S POSITION ON GENETIC NONDISCRIMINATION

The GINE Coalition has developed a set of core principles by which it measures genetic nondiscrimination legislation. The Genetic Information Non-Discrimination in Employment (GINE) Coalition endorses the following legislative principles:

- The members of the Coalition believe that employment decisions should be made based on an individual's qualifications and ability to perform a job, not on the basis of characteristics that have no bearing on job performance. Therefore, we strongly oppose employment discrimination on the basis of a person's predictive genetic information.
- Possession of genetic information must be differentiated from the use of this information for discriminatory purposes. Any proposed statute should be directed at controlling discriminatory conduct, rather than attempting to regulate the flow of information. As we like to say, genetic discrimination is about discrimination, not genetics.
- We believe that genetic discrimination is wrong, and if a company intentionally discriminates, remedies should be available. However, the Coalition opposes legislation that would provide excessive punitive and compensatory damages or that would expose employers to baseless litigation. Furthermore, no employer should be at risk of liability for innocently receiving information that is deemed "genetic" or disclosing such information for the purposes permitted by HIPAA for Personal Health Information (PHI). Nor should employers face punitive damages for technical or recordkeeping violations.
- Duplicative efforts to guard against genetic discrimination are costly and confusing. Any legislative proposals regarding genetic discrimination should take into account the protections already offered by the HIPAA and its regulations, the ADA, and other federal, state, and local statutes and regulations.

In sum, the GINE Coalition's Statement of Principles embraces the letter and spirit of nondiscrimination and espouses the idea that discrimination, not information, should be the target of any such legislation. These principles are explained in more detail as follows.

Let me state again, the GINE Coalition supports the policy of nondiscrimination in employment based on an individual's genetic makeup or pre-disposition to certain diseases or conditions. Employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of other characteristics or imputed attributes that have no bearing on job performance.

Further, being mindful of the rapid developments in genetic research and Dr. Collin's predictions regarding the beneficial use of genetic information in the near future, we believe that genetic non-discrimination legislation must be carefully and narrowly drafted. "Genetic information" should be precisely defined to include only **predictive** genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing. ***Possession*** of genetic information must be differentiated from the ***use*** of such information for discriminatory purposes. Legislation should be directed at controlling and punishing discriminatory conduct, rather than regulating and burdening the flow of information. The law should not trigger liability based on an employer's mere receipt of genetic information, such as through conversations concerning a relative's illness or derived from such normative behavior as visiting the sick and consoling the bereaved.

Thus, our hope today is to sound a note of caution and urge this Committee to carefully consider the impact of its actions. In light of the absence of any evidence of the use of genetic information for discriminatory purposes, there is no urgent need to act speedily.

As Congress has the time to act with deliberation and care to draft a law, we urge the subcommittee to ensure that any genetic discrimination legislation:

1. Defines "genetic information" narrowly to include only predictive genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing;
2. Adopts the protections and permits the acquisition, use, and disclosure of genetic information for the same purposes as permitted for Personal Health Information under HIPAA;
3. Resolves conflicts among Federal laws and between Federal and state standards with respect to employment discrimination and the administration of employee welfare benefit plans;
4. Creates a single Federal standard;
5. Permits the request and receipt of genetic information not only under the FMLA, but also under the ADA, HIPAA, and other more likely sources of such information; and
6. Protects employers from punitive damages for technical violations.

Definition of "Genetic Information"

In January, 2007, Rep. Slaughter, a principal sponsor of H.R. 493, testified to her understanding of this bill's purpose. She stated that "GINA prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based **solely on a genetic predisposition to develop a disease in the future**." (emphasis added). We believe this bill should reflect that purpose. The definition of "genetic information" as currently stated in H.R. 493 dispenses with a focus on predictive genetic information related to an inheritable but currently asymptomatic disease. In its place is a definition that is so broad as to include “the occurrence of a disease or disorder in family members of the individual” (Sec. 201 (4)(A)(iii)), without **any** limitation. We do not believe that Congress intended colds and the flu, upset stomachs and chicken pox to be part of this bill. The definition of “genetic information” should be limited to **predictive** genetic information regarding inherited alterations in genetic material or genes which are associated with a disease or illness that is asymptomatic at the time of testing.

Protections and Exceptions of HIPAA

As currently drafted, H.R. 493 creates a protective program for “genetic information” that far exceeds that for PHI under HIPAA. We do not understand why information relating to a distant, contingent eventuality requires protections different from and greater than those for existing medical problems. We do not understand why a separate protective program needs to be invented and mastered **after** employers have labored so long to understand and put the highly reticulated HIPAA program into place.

Further, the protective program of H.R. 493, as articulated in Sections 206 and 210, does not promote patient care or sound public policy. There is no general exception for disclosures for treatment; there is no exception for disclosures to treating physicians, to unfolding police investigations, to government officials investigating something other than compliance with *this* law, and so on. Because Section 210 permits only the disclosure of “medical informant that is not genetic information,” for example, a company nurse could **not** advise an EMT or physician that the trauma patient she is treating ***for a manifested condition*** just disclosed that his father also had heart trouble. That cannot be your intent.

Under the HIPAA privacy regulations, disclosures of PHI are allowed for a variety of purposes including for treatment, for civil and criminal litigation (including disclosures to litigation counsel) under clearly stated, limited circumstances, to government public health officials, for law enforcement, to identify a victim of a crime or to apprehend a criminal, and more. These disclosures were permitted after a lengthy regulatory process including considerable pubic comment. The fruits of that process should be respected here and the exceptions in the HIPPA privacy scheme should be incorporated here. (A chart presenting the differences in the protective schemes of H.R. 493 and that of HIPAA is attached to this testimony.)

Indeed, this bill should clearly state that it does not create any new restrictions or requirements with respect to the actions or communications regarding the delivery of health care including any health services, pharmacies, health records services, health counseling, or health education even if provided for or sponsored by an employer for employees.

Conflict among Federal Laws and Between Federal and State Standards

Should a new federal genetic discrimination law be enacted, the Coalition believes it is essential that it be made to precisely mirror the requirements and protections of existing employment statutes and that it not conflict with current laws or disrupt existing nondiscriminatory employment practices.

As a practical consideration, there is always concern that new employment legislation will be drafted without due consideration being given to its impact on and its interaction with existing laws. The interrelationship and interaction among the ADA, FMLA and state workers' compensation law, all of which impose different legal requirements, demonstrates this problem.

Because each law was passed at a different time and has a different policy objective, an employer's efforts to comply with one law can easily cause it to be in conflict with provisions of the other laws. Employment laws are most effective when compliance with one federal or state law does not contradict other laws or does not require employers to violate one law to satisfy another.

Any genetic nondiscrimination legislation must be balanced, objective, and developed with existing law in mind. Any legislative proposals regarding genetic discrimination should take into account and be in accordance with the protections already offered by the HIPAA and its regulations, the ADA, and other federal, state, and local statutes and regulations. Duplicative efforts to guard against genetic discrimination are costly, confusing, and unnecessary.

Lack of a Single Federal Standard

H.R. 493 would not create a single federal standard, but unfortunately would allow a patchwork of state standards to impose inconsistent requirements. Any Federal legislation should recognize the problems faced by employers as they try to comply with the numerous genetic discrimination laws already in existence. More than 30 states have enacted laws prohibiting discrimination based on genetic information. However, these laws vary widely. If Congress enacts legislation barring employment discrimination based on genetic information then it should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination. There should be only one standard, *your* standard.

Permitting Receipt of Genetic Information

Under the proposed bill, genetic information may lawfully be acquired from *some* sources, such as FMLA medical certifications and workers' compensation forms, whereas the same information from more likely sources, such as employer-provided sick or family leave that is not FMLA qualifying, ADA accommodations or discussions regarding health insurance coverage under HIPAA or COBRA, is not allowed.

The interplay of the proposed legislation and the ADA and HIPAA creates significant difficulties. Employer efforts to make timely and accurate determinations regarding requests for accommodations or claims brought under current law should not be inhibited or made illicit.

Finally, many employers provide leave for illnesses not covered by the FMLA, or beyond what is mandated by the FMLA for medical and family reasons or provide similar leave but fall below the 50 employee threshold under the FMLA. In order to administer these leave programs, employers routinely require employees to provide documentation of the need for leave. Exposing employers to liabilities for requiring documentation will discourage them from offering these leave benefits.

It is imperative that legislative efforts be focused on prohibiting the discriminatory use of genetic information, not on the flow of such information. There should be a broad exception permitting the acquisition of all such information, if collected pursuant to law and retained in confidential files. The information should not be the issue; the misuse of the information should.

Punitive Damages for Technical Violations

All parties share the goal of eliminating discrimination in the workplace, from the hiring process to providing benefits. When a company intentionally discriminates, remedies should be available. However, the Coalition opposes legislation that that would expose employers to baseless litigation and would provide punitive and compensatory damages *absent* actual discrimination. To assist an employee in receiving health insurance coverage or benefits should never give rise to a cause of action. Relating pertinent family history to an Emergency Medical Technician or other health care provider should never be the basis of a lawsuit. Given the availability of significant protections under other laws, administrative enforcement and equitably based remedies (including loss of wages and benefits) should be sufficient to allay fear of possible discrimination while mitigating the risk of a dramatic increase in baseless and inherently expensive litigation. Unfortunately, the House bill resorts to jury trials with punitive and compensatory damages for *any* violation, without distinction, which will necessarily invite additional litigation.

The balance of our submission is a discussion of existing state and federal laws which have a bearing on genetic discrimination in the workplace, and specific concerns with pending federal legislation. We believe they support the Coalition's belief that the current absence of claims of genetic discrimination in employment grows that the fact that (1) employers have no interest in acquiring such data and (2) current laws already prohibit and punish such conduct. That, in turn, supports the Coalition's belief that Congress faces no urgent need to act and can duly deliberate the implications of this or any legislation regarding genetic discrimination in the workplace.

CURRENT LAWS RELATING TO GENETIC NONDISCRIMINATION

A. State Laws

State legislatures have been the pioneers in enacting laws governing various aspects of genetic information in the workplace. To date, laws enacted in over 30 states address (in one form or another) the issue of genetic discrimination in employment. In addition, other state laws may address additional select aspects of genetic information.

The state experience is valuable for a number of reasons—not least of these is that it shows the 'cost' of hasty legislation in a rapidly developing area. No fewer than six states have already had to revise their laws to keep pace with scientific advances. More than any other feature of state law, this promises to be model for federal legislation.

The 1948 McCarran-Ferguson Act explicitly grants insurance regulation to the states. The Employee Retirement Income Security Act of 1974 ("ERISA") preempts state laws pertaining to self-funded employee benefits plans. In 1996, the Health Insurance Portability and Accountability Act ("HIPPA") became the first federal law to directly address genetic information. The law prohibits health insurance discrimination based on any "health status-related factor," including genetic information, for group health plans. Laws governing genetic discrimination in 34 states have complemented HIPPA protections related to health insurance.

B. Executive Order 13145

On February 8, 2000, President Clinton signed Executive Order 13145, which prohibits discrimination in federal employment on the basis of genetic information. The EEOC was assigned responsibility for the Executive Order and its enforcement under the Americans with Disabilities Act. On July 26, 2000, the EEOC issued a Policy Guidance explaining the definitions, Prohibitions, and exceptions in Executive Order 13145.

C. Title VII of the Civil Rights Act of 1964

Title VII of the 1964 Civil Rights Act may provide some protection against genetic discrimination where such discrimination may have “disparate impact” based on race, sex, religion or national origin, e.g., sickle cell anemia (African-Americans), Tay Sachs (Ashkenazi Jews).

D. Genetic Information and the Americans with Disabilities Act

State and federal statutes prohibiting disability discrimination in employment are the most likely source of genetic information protections. The ADA protects individuals with one or more physical or mental impairments that substantially limits the individual in performing a major life activity; an individual with a record of such impairment; or an individual who is “regarded as” having such an impairment. It is clear that the ADA covers individuals who have a genetically-related disability once it is manifest and substantially limits a major life activity. Also, the ADA covers individuals with a prior record of a genetically-related disability that is manifest. However, the courts have not yet determined definitively whether the ADA should be construed to cover employment discrimination on the basis of genetic information concerning diagnosed, but asymptomatic, genetic conditions which are not manifest. To this point, virtually no case law exists regarding ADA coverage of genetic discrimination in the workplace.

That being said, the EEOC has long taken the position that the Americans with Disabilities Act protects individuals with asymptomatic genetic conditions from discrimination in employment. The EEOC successfully filed against Burlington Northern-Santa Fe Railroad based on genetic testing of employees for a genetic marker related to carpal tunnel syndrome.

The notoriety of that incident demonstrates that it was a unique event. It also demonstrates that current laws were able to resolve the matter completely. After swift government enforcement actions, the parties reached a settlement on the EEOC suit in April 2001, in which the railroad agreed to stop testing. As was stated before the House on July 24, 2001 by one of those improperly tested by Burlington-Northern, the EEOC's actions were exceptional, effective, and exemplary.

Given the EEOC's guidance on this issue, as well as their enforcement history, employers should expect EEOC enforcement actions and individual charges under the "regarded as" prong of the ADA, if they choose to make employment decisions involving individuals with genetic disorders based upon myths, fears, or stereotypes, rather upon the person's ability to perform specific required job tasks, with or without reasonable accommodation, in a safe manner.[2]

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[2] We should recognize, however, that there may be perfectly valid and non-discriminatory reasons for an employer to consider an employee's genetic information in order to ensure that the employee is working in an environment that would not exacerbate the employee's genetic predisposition to an illness or other health condition. The ADA recognizes that an employer may impose the qualification standard that an employee not poses a "direct threat" to the health or safety of others in the workplace. 42 U.S.C. Sec. 12113(b). The EEOC has expanded this statutory definition to include the individual with a disability. 29 C.F.R. Sec. 1630.2(r). Protection of a worker may mean that for his or her health and the safety of others, the individual should not be assigned to a job. In *Echazabal v. Chevron*, 536 U.S. 73 (2002), the Supreme Court unanimously ruled that the EEOC's interpretation was correct and that an employer may legitimately object to idly permitting an employee's self-inflicted exposure to injury or worse.

LIMITATIONS ON GENETIC TESTING IN THE WORKPLACE

An employer's ability to engage in genetic testing and to use the results of such testing in making a variety of employment decisions may already be limited in a number of ways by the provisions of the Americans with Disabilities Act. 42 U.S.C. Sec. 12101, *et seq*. Genetic testing is a medical examination and the ADA contains specific provisions limiting the manner in which an employer may conduct medical examinations and inquiries.

The ADA contains specific provisions dealing with the ability of an employer to request or obtain medical information or to require medical examinations. The ADA prohibits absolutely any medical inquiries or medical examinations at the pre-offer stage of the employment application process. 42 U.S.C. Sec. 12112(d)(2)(A). Genetic screening clearly constitutes a medical inquiry or examination and, hence, the ADA would prohibit an employer, for example, from requiring all job applicants to undergo genetic screening.

Once an offer of employment has been made, the employer may condition Sec. that offer upon the successful completion of a medical examination. *Id*. at Sec. 12112(d)(3). This so-called conditional offer medical examination specifically is authorized under the ADA and the statute contains no limitations upon the scope of such an examination. Hence, the ADA, at this stage of the employment process, would not prohibit or limit the ability of an employer to engage in genetic screening. To give a conditional offer examination, however, an employer must satisfy three requirements. First, the examination must be given to all entering employees regardless of disability. *Id*. at Sec. 12112(d)(3)(A). Second, the information obtained must be collected and maintained in a confidential manner. 42 U.S.C. Sec. 12112(d)(3)(B).[3] Third, the

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[3] The ADA authorizes disclosure of medical information obtained from a conditional medical examination only in the following circumstances:

statute requires that the results of any medical examination may be used only in accordance with the non-discrimination requirements of the statute. *Id*. Sec. 12112(d)(3)(C). Generally, this requirement means that an employer may revoke a conditional offer of employment only if the results of the medical examination demonstrate that the individual cannot perform the essential functions of the job with or without reasonable accommodation.

Finally, the ADA limits an employer's ability to conduct medical examinations or make medical inquiries of current employees to those circumstances where the examination or inquiry can be shown to be "job related and consistent with business necessity." 42 U.S.C. Sec. 12112(b)(4)(A). This standard has been interpreted by the EEOC as relating to an employee's present ability to perform the job. *See* 29 C.F.R. App. Sec**.** 1630.10 (there should be "a fit between job criteria and an applicant's (or employee's) actual ability to do the job."). Because genetic testing normally addresses what may occur in the future, not an individual's actual ability to perform specific job tasks, in most cases, it is unlikely the ADA would allow genetic testing of current employees under the "job relatedness" standard.[4]

The current trend of judicial decisions recognizes that non-disabled individuals may enforce the statute's restrictions on medical inquiries.[5] Hence, even if an individual with a genetic marker or defect is not deemed to be "disabled" within the definition of the ADA, the

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- To supervisors and managers who need to be informed about necessary restrictions on the work duties of the employee and any necessary accommodation;
- To first aid and safety personnel; and
- To government officials investigating compliance with the ADA.

42 U.S.C. Sec. 12112(d)(3)(B)(i)-(iii).

[4] An exception may arise where federal regulations, such as those promulgated by OSHA, would require an employer to engage in medical monitoring of employees. *See*, *e.g.*, 29 U.S.C. ' 655(c)(7) (providing for the monitoring of employee exposure for employee safety).

[5] See *Cossette v. Minnesota Power & Light Co.*, 188 F.3d 964 (8th Cir. 1999); *Griffin v. Steel Tech, Inc.*, 160 F.3d 591, 594 (10th Cir. 1998); *Fredenburg v. Contra Costa County Dept. of Health Services*, 172 F.3d 1176, 1182 (9th Cir. 1999).

statue still protects the person from being required to undergo genetic testing unless the testing complies with the above requirements.

CONCLUSION

In closing, the Genetic Information Nondiscrimination in Employment Coalition believes that genetic discrimination is wrong. To reiterate, we believe that employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of characteristics that have no bearing on job performance.

The GINE Coalition believes that any federal legislation prohibiting genetic discrimination in employment should focus on controlling discriminatory conduct, not the flow of information, should conform to other federal employment discrimination laws, should create a single federal standard, should avoid duplicative administrative burdens, and should not impede the beneficent results of the remarkable research now taking place. Finally, such legislation should not be so broadly constructed as to encourage frivolous litigation. By acknowledging the principles set forth in this testimony, the subcommittee can help make this legislation more effective.

Again, I thank the subcommittee for listening to our perspective on the issue of genetic discrimination and for its invitation to testify today. The Coalition looks forward to working with you – in the future, as in the past – to make this the best possible law. I will be happy to answer any questions you may have.

COMPARISON OF H.R. 493 and HIPAA PRIVACY PROGRAMS

H.R. 493	HIPAA
Permitted Uses and Disclosures	
(1) to the employee (or family member if the family member is receiving the genetic services) or member of a labor organization at the request of the employee or member of such organization;	**(1) To the Individual.** A covered entity may disclose protected health information to the individual who is the subject of the information.
	(2) Business Associates [*45 CFR 164.502(e), 164.504(e),164.532(d) and (e)*] The Privacy Rule allows covered providers and health plans to disclose protected health information to these "business associates" if the providers or plans obtain satisfactory assurances that the business associate will use the information only for the purposes for which it was engaged by the covered entity, will safeguard the information from misuse, and will help the covered entity comply with some of the covered entity's duties under the Privacy Rule. Covered entities may disclose protected health information to an entity in its role as a business associate *only* to help the covered entity carry out its health care functions – not for the business associate's independent use or purposes, except as needed for the proper management and administration of the business associate.
	(3) Treatment, Payment, Health Care Operations. A covered entity may use and disclose protected health information for its own treatment, payment, and health care operations activities. A covered entity also may disclose protected health information for the treatment activities of any health care provider, the payment activities of another covered entity and of any health care provider, or the health care operations of another covered entity involving either quality or competency assurance activities or fraud and abuse detection and compliance activities, if both covered entities have or had a relationship with the individual and the protected health information pertains to the relationship.

	Treatment is the provision, coordination, or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another. ***Payment*** encompasses activities of a health plan to obtain premiums, determine or fulfill responsibilities for coverage and provision of benefits, and furnish or obtain reimbursement for health care delivered to an individual[i] and activities of a health care provider to obtain payment or be reimbursed for the provision of health care to an individual. ***Health care operations*** are any of the following activities: (a) quality assessment and improvement activities, including case management and care coordination; (b) competency assurance activities, including provider or health plan performance evaluation, credentialing, and accreditation; (c) conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; (d) specified insurance functions, such as underwriting, risk rating, and reinsuring risk; (e) business planning, development, management, and administration; and (f) business management and general administrative activities of the entity, including but not limited to: de-identifying protected health information, creating a limited data set, and certain fundraising for the benefit of the covered entity. Most uses and disclosures of psychotherapy notes for treatment, payment, and health care operations

	purposes require an authorization as described below. Obtaining “consent” (written permission from individuals to use and disclose their protected health information for treatment, payment, and health care operations) is optional under the Privacy Rule for all covered entities.[ii] The content of a consent form, and the process for obtaining consent, are at the discretion of the covered entity electing to seek consent.
	(4) Uses and Disclosures with Opportunity to Agree or Object. Informal permission may be obtained by asking the individual outright, or by circumstances that clearly give the individual the opportunity to agree, acquiesce, or object. Where the individual is incapacitated, in an emergency situation, or not available, covered entities generally may make such uses and disclosures, if in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual. ***Facility Directories.*** It is a common practice in many health care facilities, such as hospitals, to maintain a directory of patient contact information. A covered health care provider may rely on an individual’s informal permission to list in its facility directory the individual’s name, general condition, religious affiliation, and location in the provider’s facility.[iii] The provider may then disclose the individual’s condition and location in the facility to anyone asking for the individual by name, and also may disclose religious affiliation to clergy. Members of the clergy are not required to ask for the individual by name when inquiring about patient religious affiliation. ***For Notification and Other Purposes.*** A covered entity also may rely on an

	individual's informal permission to disclose to the individual's family, relatives, or friends, or to other persons whom the individual identifies, protected health information directly relevant to that person's involvement in the individual's care or payment for care. This provision, for example, allows a pharmacist to dispense filled prescriptions to a person acting on behalf of the patient. Similarly, a covered entity may rely on an individual's informal permission to use or disclose protected health information for the purpose of notifying (including identifying or locating) family members, personal representatives, or others responsible for the individual's care of the individual's location, general condition, or death. In addition, protected health information may be disclosed for notification purposes to public or private entities authorized by law or charter to assist in disaster relief efforts.
	(5) Incidental Use and Disclosure. The Privacy Rule does not require that every risk of an incidental use or disclosure of protected health information be eliminated. A use or disclosure of this information that occurs as a result of, or as "incident to," an otherwise permitted use or disclosure is permitted as long as the covered entity has adopted reasonable safeguards as required by the Privacy Rule, and the information being shared was limited to the "minimum necessary," as required by the Privacy Rule.
(2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;	**(6) Research.** "Research" is any systematic investigation designed to develop or contribute to generalizable knowledge.[iv] The Privacy Rule permits a covered entity to use and disclose protected health information for research purposes, without an individual's authorization, provided the covered entity obtains either: (1) documentation that an alteration or waiver of individuals' authorization for the use or disclosure of protected health information about them for research purposes has been approved by an Institutional Review Board or Privacy

	Board; (2) representations from the researcher that the use or disclosure of the protected health information is solely to prepare a research protocol or for similar purpose preparatory to research, that the researcher will not remove any protected health information from the covered entity, and that protected health information for which access is sought is necessary for the research; or (3) representations from the researcher that the use or disclosure sought is solely for research on the protected health information of decedents, that the protected health information sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is sought. A covered entity also may use or disclose, without an individuals' authorization, a limited data set of protected health information for research purposes (see discussion below).
(3) in response to an order of a court, except that-- (A) the employer, employment agency, labor organization, or joint labor-management committee may disclose only the genetic information expressly authorized by such order; and (B) if the court order was secured without the knowledge of the employee or member to whom the information refers, the employer, employment agency, labor organization, or joint labor-management committee shall provide the employee or member with adequate notice to challenge the court order;	**(7) Required by Law.** Covered entities may use and disclose protected health information without individual authorization as *required by law* (including by statute, regulation, or court orders).
	(8) Public Health Activities. Covered entities may disclose protected health information to: (1) public health authorities authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability and to public health or other government authorities authorized to receive reports of child abuse and neglect; (2) entities subject to FDA regulation regarding FDA regulated

	products or activities for purposes such as adverse event reporting, tracking of products, product recalls, and post-marketing surveillance; (3) individuals who may have contracted or been exposed to a communicable disease when notification is authorized by law; and (4) employers, regarding employees, when requested by employers, for information concerning a work-related illness or injury or workplace related medical surveillance, because such information is needed by the employer to comply with the Occupational Safety and Health Administration (OHSA), the Mine Safety and Health Administration (MHSA), or similar state law.
	(9) Victims of Abuse, Neglect or Domestic Violence. In certain circumstances, covered entities may disclose protected health information to appropriate government authorities regarding victims of abuse, neglect, or domestic violence.
	(10) Health Oversight Activities. Covered entities may disclose protected health information to health oversight agencies (as defined in the Rule) for purposes of legally authorized health oversight activities, such as audits and investigations necessary for oversight of the health care system and government benefit programs.
	(11) Judicial and Administrative Proceedings. Covered entities may disclose protected health information in a judicial or administrative proceeding if the request for the information is through an order from a court or administrative tribunal. Such information may also be disclosed in response to a subpoena or other lawful process if certain assurances regarding notice to the individual or a protective order are provided.
(4) to government officials who are investigating compliance with this title if the information is relevant to the investigation; or	**(12) Law Enforcement Purposes.** Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following six circumstances, and

	subject to specified conditions: (1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; (2) to identify or locate a suspect, fugitive, material witness, or missing person; (3) in response to a law enforcement official's request for information about a victim or suspected victim of a crime; (4) to alert law enforcement of a person's death, if the covered entity suspects that criminal activity caused the death; (5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises; and (6) by a covered health care provider in a medical emergency not occurring on its premises, when necessary to inform law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime.
	(13) Decedents. Covered entities may disclose protected health information to funeral directors as needed, and to coroners or medical examiners to identify a deceased person, determine the cause of death, and perform other functions authorized by law.
	(14) Cadaveric Organ, Eye, or Tissue Donation. Covered entities may use or disclose protected health information to facilitate the donation and transplantation of cadaveric organs, eyes, and tissue.
	(15) Serious Threat to Health or Safety. Covered entities may disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal.
	(16) Essential Government Functions. An authorization is not required to use or disclose protected health information for certain essential government functions.

	Such functions include: assuring proper execution of a military mission, conducting intelligence and national security activities that are authorized by law, providing protective services to the President, making medical suitability determinations for U.S. State Department employees, protecting the health and safety of inmates or employees in a correctional institution, and determining eligibility for or conducting enrollment in certain government benefit programs.
	(17) Workers' Compensation. Covered entities may disclose protected health information as authorized by, and to comply with, workers' compensation laws and other similar programs providing benefits for work-related injuries or illnesses.
	(18) Limited Data Set. A limited data set is protected health information from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed. A limited data set may be used and disclosed for research, health care operations, and public health purposes, provided the recipient enters into a data use agreement promising specified safeguards for the protected health information within the limited data set.
(5) to the extent that such disclosure is made in connection with the employee's compliance with the certification provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws.	**N/A**
