

**THE WHITE HOUSE**  
**Office Of The Vice President**

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FOR IMMEDIATE RELEASE  
TUESDAY, January 20, 1998

CONTACT: 202-456-7035

**VICE PRESIDENT CALLS FOR LEGISLATION ON GENETIC DISCRIMINATION**  
**Says Employees Should Not Be Discriminated Against On Basis of Genetic Information**

WASHINGTON -- In an effort to ensure that genetic progress does not become a new excuse for discrimination, Vice President Al Gore today (1/20) called for legislation that will bar employers from discriminating against their employees on the basis of genetic information.

"The fear of genetic discrimination is prompting Americans to avoid genetic tests that could literally save their lives," the Vice President said during an address to the Genome Action Coalition's Third Annual James Watson Lecture at the National Academy of Sciences. "But genetic progress should not become a new excuse for discrimination. Genetic discrimination is wrong -- and it's time that we end it."

The Vice President released an Administration report, Genetic Information and the Workplace, which documents the current and future problems of genetic discrimination in the workplace and outlines principles for federal legislation to guard against these abuses. He was joined at today's event by Department of Health and Human Services Secretary Donna Shalala; Department of Labor Deputy Secretary Kitty Higgins; Equal Employment Opportunity Commissioner Paul Miller; Dr. Harold Varmus, Director of National Institutes of Health; Dr. James Watson, Nobel Laureate, Author of "The Double Helix," and President of Cold Spring Harbor Laboratory; and Dr. Kay Jamison, Chair of the Steering Committee of the Genome Action Coalition.

Specifically, the legislation that the Vice President called for today will prohibit employers from requesting or requiring genetic information for hiring; prevent on-the-job discrimination; and ensure that genetic information is not disclosed without the explicit permission of the individual.

"Miraculous scientific achievements can help build an America that is healthier in body and in spirit. That's no small feat. But science and society must always advance together, for neither can every truly advance alone," the Vice President said.

(MORE)

**NATIONAL HUMAN GENOME  
RESEARCH INSTITUTE, NIH**



**FAX TRANSMITTAL SHEET**

**TO:** Sarah Bianch  
202-456-5557

**FROM:** Dr. Kathy Hudson

**DATE:** January 16, 1998

# of pages including cover sheet: several

Return FAX number: (301) 402-0837

If there are problems, call (301) 402-0955.

Comments: Please see attached.



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January 16, 1998

Albert Gore  
Vice President  
The White House  
1600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20501

Dear Mr. Vice President:

The Alliance of Genetic Support Groups welcomes your active support for legal safeguards to prevent discrimination based on genetic information. Your personal leadership can bring these important issues to the full attention of the American public.

The Alliance is thrilled with the pace of genetic discoveries. With each step forward, we come closer to finding new treatments for genetic disorders and to unlocking secrets about common diseases as well. With these scientific advances come great promise, however, without federal protections they can also bring us closer to the risk of misuse of genetic technologies and the potential for harm.

The Alliance of Genetic Support Groups is an active champion for children, adults and families identified with, or at risk for genetic-related disorders -- a list that is growing rapidly every year. Representing a coalition membership of more than a million families, genetics professionals and members of genetic support groups, the Alliance works to promote access to employment opportunities and quality health care, to protect individuals from genetic discrimination and to educate professionals and the public about these issues. Our toll-free help line serves as a direct link to families who are struggling with circumscribed employment opportunities, denial of health insurance coverage, and more subtle and general forms of discrimination. We are asking all of our umbrella members to demonstrate their affirmation of the principles we all share.

Every American -- regardless of genetic inheritance -- deserves the protection federal legislation alone can provide. We appreciate all the wisdom and leadership you bring to resolution of these problems.

Sincerely,

*Mary E. Davidson*      *Joan Burns*      *Joan O. Weiss*

Mary E. Davidson, M.S.W.  
Executive Director

Joan K. Burns, M.S.  
President

Joan O. Weiss, M.S.W.  
Founding Director

cc: Chris Jennings  
Francis Collins



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Founding Director

cc: Chris Jennings  
Francis Collins



## The Genome Action Coalition

do Cavaracchi ■ Rustle ■ Associates

317 Massachusetts Avenue, NE, Suite 100

Washington, DC 20002

202-546-4732

202-546-5051 Fax

January 15, 1998

The Vice President  
The White House  
Washington, DC 20500

Dear Mr. Vice President:

The Genome Action Coalition, comprised of more than 125 organizations, foundations and corporations, would like to congratulate you and thank you for extraordinary leadership that the President and you have shown with regard to the difficult issues which come about as a result of the progress of the Human Genome Project.

The scientific advances from the research conducted at and funded by the National Institutes of Health have opened a new era in molecular medicine. Government, industry and academia are working together in an unprecedented manner to unlock the secrets of the genome and develop treatments, cures and preventions for a wide range of physical and mental illnesses and disorders.

The Clinton-Gore administration has shown great vision in addressing the complex ethical, legal and social issues that have arisen from this effort. The Genome Action Coalition is pledged to continue to work with you, with the rest of the administration and with the Congress in this comprehensive effort to advance knowledge for the benefit of all our citizens.

Again, we thank you for your leadership at this critical time and look forward to your remarks on January 20.

Sincerely,

Kay Redfield Jamison, Ph.D.  
Steering Committee Chair  
Professor of Psychiatry,  
The Johns Hopkins University  
School of Medicine



**NATIONAL ACTION PLAN ON BREAST CANCER**  
**A Public/Private Partnership**

The Vice President  
United States Senate  
Washington, D.C. 20510

Dear Mr. Vice President:

The Hereditary Susceptibility Working Group of the National Action Plan on Breast Cancer applauds your leadership and support of legislation to prevent employment discrimination based on genetic information. We are grateful for your personal commitment to bring this issue to the attention of the American public.

Even though dramatic scientific advances are being made in the understanding of the genetic basis of breast cancer, the benefits of this research cannot be fully realized if individuals suffer discrimination based on the results of genetic tests. A genetic test for inherited breast cancer, for example, will allow scientists to explore improved prevention strategies and treatments for all high risk families. Yet this research is greatly hampered by patient fear of participation in genetics research. Scientists are already reporting difficulty in recruiting patients for studies requiring genetic testing because they fear the information will be used to prevent access to employment, career advancement, and other job opportunities. Moreover, women fear these discriminatory practices may be extended to family members, particularly, their daughters.

Because many genetic susceptibility genes affect certain ethnic groups disproportionately, genetic discrimination may also provide a justification for race discrimination.

Page 2 - The Vice President

The establishment of legal and ethical safeguards to protect the utilization of this new technology will be a dramatic step toward maximizing the use of genetic information for patient care and medical research. Thank you for your leadership in providing a safe environment for the use of new and valuable medical advances by the citizens of the United States.

Sincerely yours,



Mary Jo Ellis Kahn, MSN, RN  
National Breast Cancer Coalition  
Virginia Breast Cancer Foundation,  
Co-Chair, Hereditary Susceptibility Working Group

cc:

The President  
Chris Jennings



January 14, 1998

Vice President Albert Gore, Jr.  
Old Executive Office Building  
Washington, DC 20501

*Mr. Vice President*

Dear Vice President Gore:

The Women's Legal Defense Fund applauds your leadership on an issue of tremendous importance to women and their families -- prohibiting genetic discrimination, particularly in employment. Thanks to ground-breaking genetics research, millions of women and their families will some day benefit from improved prevention, detection and treatment of life-threatening diseases. The benefits to medical science and women's health presented by genetics research are enormous. However, there is growing concern that genetic information may be used in ways that hurt patients and research participants, thereby impeding the very research that could increase our understanding of the genetic basis of disease.

The decision about whether or not to have genetic tests performed is a complex one, with far-reaching ramifications not only for the individual women involved, but also for members of their families. Women need to be able to make decisions about undergoing genetic testing and participating in scientific research without fear that they (or their loved ones) will lose their insurance or their jobs.

Without adequate protection against discrimination and misuse, the potential for genuine medical benefits from genetic advances may be outweighed by harmful consequences, such as the loss of health insurance or employment. We look forward to working with you and Congress to promote genetic research and to put in place the federal laws that will protect individuals from discrimination and allow research to flourish.

Sincerely,

*Judy*  
Judith L. Lichman  
President

*Mr. Vice President  
Your leadership means a great  
deal to us.  
my personal thanks -*

*J.*



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Date: January 16, 1998

To: Chris Jennings

FAX No. 202-456-5557

From: The Alliance of Genetic Support Groups

Total number of pages (including this page): 3

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Remarks:

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**DARN GOOD DRAFT BY LESLIE**  
January 15, 1998

To: Sarah  
From: Kathy Hudson

**DRAFT**

Third Annual James D. Watson Lecture

Genes, Jobs, and Justice for All

Al Gore

Vice President of the United States

January 20, 1998

National Academy of Sciences  
Washington, DC

Thank you, Dr. Jamison. As you know, my wife Tipper has long been an activist in the mental health community. And that gives us a special bond with Kay. In addition to making significant contributions to mental health research, Dr. Jamison has been very successful in bringing an understanding of psychiatric disorders to the public. She has examined for us the brilliance as well as the darkness of some of history's most creative individuals--composers, painters, poets and indeed, herself. Kay's most recent book, *An Unquiet Mind*, is her own story. With extraordinary honesty, she has laid bare her personal struggles with mental illness, and in so doing, has revealed to her readers the courage and hope of someone living with manic-depressive illness. Her book has been an inspiration to people with psychiatric illness and their loved ones and a call to action for everyone else. Tipper and I were both affected deeply by it.

I would also like to thank The Genome Action Coalition, for giving me this opportunity to speak about issues I care very deeply about. My work in technology policy, and genetics and public policy in particular, goes back a long way, and I am delighted to be in this great hall with the some of the keenest minds in science. The Coalition, of course, was created only three years ago to bring together the diverse players from private industry to patient advocacy groups, into a discussion about how this country will embrace genome research so all of us benefit. Our administration looks forward to working with you all to achieve that goal.

Let me welcome the other guests here today. Secretary Shalala, whose department leads the Human Genome Project, has been working closely with the President and me on legislation to prohibit genetic discrimination in health insurance. Deputy Secretary Kitty Higgins has just presented me with a compelling report from the Department of Labor about an issue I have cared about for over 15 years: genetic discrimination in the workplace. And Francis Collins, director of the Human Genome Project at the National Institutes of Health, who has demonstrated exceptional leadership in not only advancing the science of the project but also in his conviction that genetic technologies should be used to enrich the health and well being of our citizens, not to stigmatize or shame them.

You probably know that Dr. Collins delivered this address last year and ended it on a musical note. [Make fun of Francis or some kind of joke here about V.P.'s musical abilities.]

On a more serious note, we are here today to honor a truly extraordinary figure, Jim Watson, whose name is virtually synonymous with modern molecular biology. Jim's list of achievement and recognition is indeed lengthy--from 1953 when he carried out the Nobel Prize-winning experiments that proved the double helix structure of DNA, to directing a world-class genetics laboratory at Cold Spring Harbor, to becoming founding director of the Human Genome Project at the National Institutes of Health. Most recently, he received last month from the President the National Medal of Science, our own country's equivalent of the Nobel Prize. On behalf of the National Science Foundation, we present that award to leaders in scientific research for their innovation and imagination. Their achievements have opened new scientific frontiers, enabled new products, and created new capabilities that have transformed our lives and that will shape our future. Though Jim's discovery was almost a half a century ago, it was the dawn of unprecedented achievement in genetics and DNA research. As we stand at the threshold of a new millennium, the Human Genome Project is showing us things about our genetic selves most mortals could never have imagined, but Jim did.

Being here today is special for me because of my own history with genetics and public policy. In both the House and the Senate, I was involved in many legislative matters having to do with the responsible deployment of technology into our society. Because of the sheer pace of advances in genetics, and the Human Genome Project in particular, none is more important or compelling than ensuring that our ability to understand the instructions in our genetic material, DNA, does not prevent Americans from access to good health, a decent wage, and the fulfillment of their life goals.

(Insert reference Vice President's 1989 hearing on Genome Project here)

What kind of scientific progress am I talking about? Marvelous, almost fantastic achievements that promise better health by providing insights into the mysteries of the human cell, how it works, and why sometimes it doesn't work. How to fix it or prevent the malfunction from

leading to disease.

Five years ago, only a few of the human genome's 80,000 or so genes had been identified. Scientists isolated genes one at a time, and tried to figure out how a single gene might throw the whole body out of whack. Today, scientists use Human Genome Project tools to discover thousands of genes each year, many which turn out to be involved in disease predisposition. Indeed some of you in this audience have made tremendous progress in identifying the genetic components of cancers and neurological disorders, and have isolated genes associated with rare disorders that promise to shed light on basic cellular functions.

In a few short months, the project will reach its half-way mark, and it has surpassed even the most ambitious expectations. Since the project's beginning, the increasing detail and quality of genome maps have reduced the time it takes to find a gene from years, to months, to weeks, now to just days. Thanks to a new on-line gene map, disease-gene hunters will soon have about a 40 percent chance the gene they are looking for has already been characterized by this effort.

Now, imagine going to a laboratory freezer and pulling out a tray of vials that contains a copy of the human genome in a neatly ordered set of DNA pieces. And you have instructions about how to put them back together, like a puzzle, to make a replica of the entire human genome. Fantasy? Not at all. This past year, genome scientists completed such a replica, which now serves as a handy resource for gene hunters and DNA sequencers. And you don't even have to go to a freezer, you can find it on the Internet.

So you map your gene to one of those pieces of DNA, and you go to the computer and log on and the database says that DNA region contains genes for this trait or that, or maybe even a disease. It tells you one of those genes is likely related to the medical problem you are studying. More and more, it will tell you what the gene's exact DNA sequence looks like and what it does, if not in humans, then in mice, or fruitflies, or bacteria. This is no longer the life's work of a geneticist. It can now be done in a week or so.

In the 1980's, before the tools of the Genome Project were available, took years for Dr. Collins and his colleagues nine years to pinpoint the precise location of the gene for cystic fibrosis and ultimately to clone it. Last year, with DNA from families with hereditary Parkinson's disease in hand, scientists were able to precisely map the gene responsible in 9 days. That's the kind of stunning pace I'm talking about.

→ precisely map in 9 days.

In the years ahead, the full DNA sequence of the human will give us unprecedented opportunities to observe and understand the human being as an orchestra of molecular systems. But those experiments are already taking place in micro-organisms, because for the first time, scientists have spelled out the complete genomes for almost a dozen such germs. The full DNA sequence of those microbes gives scientists a powerful new tool to observe life not just one gene and one trait at a time, but to understand complete and interactive processes, such as metabolism, the control of gene activity, substance transport, and cell division. Imagine using that knowledge to engineer synthetic tissues or implantable biological systems to deliver missing biochemicals or drugs.

For me, it doesn't get much better than DNA and computers. We all know how the silicon computer chip revolutionized our lives in ways we could never have imagined. They run scores of everyday items like watches, car engines, cell phones, even toys, and they support a multi-billion dollar computer industry. Let me tell you what happens when you combine DNA and semiconductors to study human biology and disease. At the root of these studies is a relatively tiny device commonly called a "DNA chip"--a thin slice of silicon about the size of a postage stamp. [GIVE HIM A DNA CHIP TO SHOW THE AUDIENCE.] When a DNA sample, say from someone with a family history of cancer, is added to the chip, it seeks out its match and tells you whether the person's DNA contains changes linked to that form of cancer.

- chip which can read your dna & tell whether cancer.

Suppose, for example, several of your forty something relatives have developed colon cancer. The possibility that you have the same predisposition concerns you, especially now that you have a milestone birthday coming up. You could schedule yearly colonoscopy exams, which

are effective at spotting pre-cancerous tumors while they are easy to treat and have the best chance for cure. But what about all your other relatives who never developed colon cancer? If you are like them, yearly colon exams would mean unnecessary discomfort, expense, and even risk of injury.

*explain DNA chip*

In the not too distant future, a DNA chip might be loaded with gene sequences associated with many of today's common disorders. You give a blood sample at the doctor's office, and a computer printout tells you which of those gene sequences might be important to your health. As health research moves forward, new preventions and treatments may help keep you from becoming ill.

The capacity of DNA chips doubles about as quickly as it does for semiconductors. So, chips that once held a few hundred DNA threads now hold up to a quarter of a million. That kind of capacity makes them useful for looking for large numbers of DNA variations, even in entire populations, that correlate with disease risk.

[insert a paragraph on the impact of DNA chips on business (quote from recent Forbes article on DNA chips perhaps) and mention that Affymetrix, one of the developers/manufacturers of DNA chips was founded with a grant from the NIH]

Just last week, the Human Genome Project began a new initiative to catalog in the U.S. population the different spellings of DNA sequence at a long list of genetic sites. Most of these spellings will differ by only a single letter in the code, but they will help scientists begin to define which genetic differences are associated with a propensity for a specific disease. That information could help explain why, although we all carry the same genes, some individuals, families, and even ethnic groups appear to be more likely than others to develop certain diseases.

*Kathy pls explain this project*

Eventually, DNA chips and new knowledge about genetic variation may even be used to identify which patients are most likely to respond to specific therapies. Diseases may be classified

by their underlying genetic configuration rather than by physical symptoms. Administering drugs aimed only at that particular genetic subtype could minimize side effects and reduce treatment time wasted on ineffective therapies.

Genetic tests for glaucoma, colon cancer, inherited kidney cancer, and other disorders are already helping to identify high-risk individuals before they become ill. In a Chicago hospital, for example, "Patty," who had tested positive for a cancer-related gene mutation called MEN2, had her thyroid gland removed. She inherited the altered gene from her father who also had thyroid cancer. Because his children have a 50-50 chance of inheriting the altered gene, doctors tested Patty and her only sibling. Patty turned out to carry the MEN2 alteration. Because this mutation placed Patty at very high likelihood of developing thyroid cancer, her doctors recommended that she have her thyroid removed. At the time of surgery, Patty's thyroid gland already contained small, potentially lethal, cancers. She now takes a pill every day to replace her thyroid hormones, but her chance of developing MEN2-related cancer is very low.

Health care professionals too are coming to grips with the new challenges genetics is bringing to how they care for patients. An impressive organization has sprung up in the past year under the leadership of the American Medical Association, the American Nurses Association, and the genome Institute to ensure that our nation's health care providers have the knowledge, skills and resources to integrate responsibly new genetic knowledge into health care. The National Coalition for Health Professional Education in Genetics represents approximately 100 organizations of health care professionals, consumer groups, industry, genetics professional organizations, and government agencies.

I am no Benjamin Franklin, nor did I know him (ha, ha), but I can appreciate his wisdom when he said he was sorry to have been born so soon because he would not -- and I quote -- "have the happiness of knowing what will be known 100 years hence." I'm sure if Mr. Franklin were here today, he would be as filled with awe and pride as I am that the American tradition of innovation he helped to establish is still driving our nation forward.

So I have just set the clock forward only slightly to give you a glimpse of how genetic technologies can improve our health and well being. The scenarios of better health and quality of life will have come true, and we recognize that the differences among us strengthen the human fabric. Or, will we allow ourselves to become a nation in which the spelling of our DNA determines whether we have health insurance or a job, or keeps us from reaching our full potential? Will we find ourselves grappling with "genetic" discrimination--when people, either as groups or individuals, are treated unfairly because of the content of their DNA--after we have worked so hard to unite our communities into one America?

Last summer, the President announced his support for legislation that builds on The Health Insurance Portability and Accountability Act and solves the problem of genetic discrimination in health insurance once and for all. I am pleased today to receive from Deputy Secretary Higgins a report drafted by her staff at the Department of Labor working together with the Department of Health and Human Services, the Equal Employment Opportunities Commission and the Department of Justice. This report outlines the problem of genetic discrimination in the workplace, and making suggestions for how to prevent it. Indeed, no able American worker should suffer job discrimination based on his or her genetic make up.

Now let me set the clock back 16 years to October 1982, when as a representative in the House, I was holding hearings on genetic screening in the workplace. "It is not going to be very long," I said then, "before you can take a small blood sample or a skin sample and run a relatively quick computer analysis and find, and produce, a voluminous printout showing percentages of probability that the individual in question will be more or less susceptible to a variety of potential hazards....I could see where there would be a great temptation to exclude that person from the workforce because of health problems...."

To borrow from Labor Secretary Herman, "next to family and faith, the most sacred thing in our lives is the work we do. Because in America, work has a spiritual dimension, a moral value that transcends the accountant's measure of profit and loss. It affirms our humanity; it strengthens

our soul. It is dignity.”

In many ways, America's workers are in better shape than they have been in a generation. After all, our economy is the healthiest in a generation. Unemployment has dropped to a 24-year low. We have added nearly 13 million new jobs in the past five years. Our Gross Domestic Product is climbing at a healthy rate. Inflation is at historic lows and has remained essentially flat for several months. Corporate profits are rising and setting records. These are indeed prosperous times.

Today, like no other time in history, we are witnessing a convergence of science and technology and intellectual and economic prosperity. Half of our economic growth in the past half-century has come from technological innovation and the science that supports it.

But, does this prosperity belong only to a genetically acceptable few, or will all Americans have the opportunity to claim their fair share? In the House hearings, I learned there are at least two sides to this complex issue. On the one hand, employers may wish to use genetic screening to monitor the exposure of workers to harmful substances and take action to protect them. On the other hand, employers may use genetic information about an employee to bar them from work or deny health insurance. I asked then, “at what point does screening according to innate characteristics constitute insidious discrimination?” Will employers chose instead to weed out genetically susceptible workers rather than clean up the workplace?

I predicted at that time that--and I'm quoting from the hearing transcript--“I think that it's almost certain that 10 years from now, or 15 years from now, or 20 years from now (the timing was just about right), we will see libraries of genetic information combined with epidemiological studies which converge into a catalog of probability figures, which will tell employers what the percentage of occupational disease is likely to be at variance from the norm for a specific individual applying for a job.” [HOLD UP THE CHIP]

Although in those hearings 16 years ago, I called for the Congress to consider whether there should be any legally acceptable basis for excluding someone from the workforce as a result of genetic screening, there is still no comprehensive federal approach to address use and misuse of and access to genetic information in the workplace. I certainly share the philosophy of the Human Genome Project that we ought to identify and set out to resolve the challenges technology presents to society before it is so mature that we have trouble dealing with them.

A 1989 survey of large businesses, private utilities, and labor unions found that 5 percent of the 330 organizations responding conducted genetic screening or monitoring of its workers.

Another 1989 survey of 400 firms, conducted by Northwestern National Life Insurance, found that 15 percent of the companies planned, by the year 2000, to check the genetic status of prospective employees and their dependents before making employment offers. The economic incentive to discriminate based on genetic information is likely to increase as genetic research advances and the costs of genetic testing decrease.

That fear of genetic discrimination prompts people to hide genetic information about themselves and avoid genetic tests that could be beneficial to them. A young man at risk for inheriting Huntington's disease from one of his parents, who wished to enlist in the Marines to serve in the Persian Gulf War, believed that knowledge of his risk status would disqualify him from service. Because it was unlikely he would become symptomatic during his tour of duty, he answered "no" to questions regarding hereditary disorders on his application and did not include Huntington's disease in his family medical history. Sometimes people even lie about the cause of death in obituaries of relatives who die from genetic diseases because they do not want their employer to know that they too, by virtue of their genes, may be susceptible.

Sixty-three percent of the participants in a 1997 national telephone survey of more than 1000 people reported they would not take genetic tests if health insurers or employers could get access to the results. Eighty-five percent felt employers should be prohibited from obtaining information about an individual's genetic conditions, risks, and predispositions.

One individual was screened and learned he was a carrier of a single mutation for Gaucher's disease. His carrier status indicates that he might pass this mutation to his children, but that he would never develop Gaucher's disease himself. He revealed this information when applying for a job and was denied the job because of his genetic mutation even though it had no bearing on his present or future ability to perform a job.

An employee's [SHE MIGHT BE IN THE AUDIENCE AND THE VP COULD IDENTIFY HER?] parent developed Huntington's disease-indicating that the employee had a 50 percent chance of inheriting the mutated gene that would cause her to develop the disease. She decided to be tested. A genetic counselor advised her to secure life and health insurance before testing, because a positive test result would not only mean she would get the disease but would probably mean loss of health insurance as well. A co-worker who overheard her making arrangements to be tested reported the employee's conversations to their boss. Initially, the boss seemed empathetic and offered to help. When the employee eventually shared the news that her test results indicated that she did carry the mutated gene, she was fired from her job, even though she was entirely well. In the 8-month period prior to her termination, she had received three promotions and outstanding performance reviews. Frightened by their sister's experience, none of her siblings are willing to undergo genetic testing for fear of losing health insurance or jobs. Consequently, they must live with the uncertainty of not knowing whether they have inherited the genetic trait that leads to Huntington's disease.

[MAY HAVE SECOND STORY OF INDIVIDUAL WHO LOST JOB BASED ON DISCRIMINATION. WE HOPE THIS PERSON WILL BE THERE AS WELL.. STORY TO COME]

Despite these cases, some argue that genetic discrimination on the job is non-existent or so rare we don't need federal legislation to prevent it. We may not yet really know how often it happens, but we do know the consequences are grave. We also know that airplanes are the safest way to travel. Catastrophic consequences of air travel, apart from lost or damaged

luggage, late arrivals and departures, uncomfortable seats and really tiny bathrooms, (ha, ha) are remarkably low considering the number of people who fly every day. Does that mean we have no responsibility to protect the safety of our citizens who avail themselves of that technology? If you imagine that each flying jet today is a genetic test, and the skies are criss-crossed with vapor trails, it is a good idea to make sure the passengers land safely.

Or because fires in skyscrapers are rare, should we not require smoke alarms and sprinkler systems? In job or health insurance discrimination, the consequences of even one misuse of genetic information may be deadly serious.

Some may say the Americans with Disabilities Act (ADA) already prevents workplace discrimination. Under the ADA, individuals whose genetic make up has led to a disability are protected against discrimination just like individuals whose disabilities arise from other causes. But what about the majority of workers who are healthy but may have an increased risk for a disease? Are they protected if their risk is only 10 percent? Twenty percent? Fifty percent?

This administration does not believe anyone should have to endanger their personal health or their very lives to make a living for their families, to live a life of dignity. Workers should not be forced to risk their lives in unsafe work environments for their livelihoods, nor should they be forced to forego medical care because they fear it will cost them their jobs. Yes, federal legislation is needed to ensure that advances in genetic technology and research are used to address the health needs of the nation--and not to deny individuals employment opportunities and benefits. [MIGHT WORK T.S ELIOT QUOTE VP HAS USED BEFORE "Between the idea and the reality, between the notion and the act, falls the shadow"]

I have been working with the Occupational Safety and Health Administration to fit the needs of an information age that is less bureaucratic and that recognizes that the way we protected workers safety in the last 25 years may not be the best way to do it in the next 25 years. That is why we're encouraging businesses to form partnerships with OSHA so that government

*not using this argument*

and industry work together to do the right thing for workers. We're working to make sure that worker safety rules are as simple and sensible and flexible as they can be. We have redesigned OSHA's offices to produce safety, not just citations. We're cutting the time between the complaint by a worker and the resolution of a problem in half. Giving employers a choice, common sense regulation, common sense enforcement -- that's the new OSHA -- the right way to protect the safety of people in the American workplace. We have a public responsibility to work for safer workplaces.

At the same time, we must preserve the ability of scientists to do their work--to continue the research, including studies of occupational health and safety, that is so vital to expanding our knowledge of genetics and a healthier workplace. Today, on behalf of the President, I propose that Congress enact a law to ensure that discoveries made possible by the Human Genome Project are used to improve health and not to discriminate against workers or their families. In principle, the law should consider the following:

- Employers should not require or request that employees or potential employees take a genetic test or provide genetic information as a condition of employment or benefits.
- Employers should not use genetic information to discriminate against, limit, segregate, or classify employees in a way that would deprive them of employment opportunities.
- Employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.
- Genetic testing and the use of genetic information by employers should be permitted under certain circumstances to ensure workplace safety and health and to preserve research opportunities as long as the information is maintained in confidential medical records.
- With the informed consent of an employee and assurance of confidentiality, an employer under

certain circumstances should be permitted to monitor employees for the effects of a particular substance found in the workplace to which continued exposure could cause genetic damage. Employers may use the results only to identify and control adverse conditions in the workplace and to take action necessary to prevent significant risk of substantial harm to the employee or others.

I thank Secretary Herman, Deputy Secretary Higgins, and all of you who put this report together for your fine work.

For five years in a row, this administration has increased our investments in science and technology while bringing down the deficit. These ground-breaking innovations could not have happened without dedication, downright genius, and government investment. These investments have surely paid off -- in higher paying jobs, better health care, stronger national security, and improved quality of life for all Americans. Science is working. People are working.

But as the President has said, the strength of our nation is that we are one America. The only America worthy of the name is one America -- where prosperity is broadly shared and all people can truly fulfill the heights of their potential. Technology cannot manufacture it. Enlightened minds cannot theorize it. Power cannot dictate it. In the end, the President is right: it must flow from the human spirit.

Thank you

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## **Genetic Discrimination and Health Insurance: An Urgent Need for Reform**

Kathy L. Hudson, Karen H. Rothenburg, Lori B. Andrews,  
Mary Jo Ellis Kahn, and Francis S. Collins

# Genetic Discrimination and Health Insurance: An Urgent Need for Reform

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The accelerated pace of gene discovery and molecular medicine portend a future in which information about a plethora of disease genes can be readily obtained. As at-risk populations are identified, research can be done to determine effective prevention and treatment strategies that will lower the personal, social, and perhaps the financial costs of disease in the future. We all carry genes that predispose to common illnesses. In many circumstances knowing this information can be beneficial, as it allows individualized strategies to be designed to reduce the risk of illness. But, as knowledge about the genetic basis of common disorders grows, so does the potential for discrimination in health insurance coverage for an ever increasing number of Americans.

The use of genetic information to exclude high-risk people from health care by denying coverage or charging prohibitive rates will limit or nullify the anticipated benefits of genetic research. In addition to the real and potentially devastating consequences of being denied health insurance, the fear of discrimination has other undesirable effects. People may be unwilling to participate in research and to share information about their genetic status with their health care providers or family members because of concern about misuse of this information. As genetic research progresses, and preventive and treatment strategies are developed, it will be increasingly important that discrimination and the fear of discrimination not be a roadblock to reaping the benefits. To address these issues, the National Institutes of Health-Department of Energy (NIH-DOE) Working Group on Ethical, Legal, and Social Implications (ELSI) of the Human Genome Project and the National Action Plan on Breast Cancer

have jointly developed a series of recommendations for state and federal policymakers which are presented below.

In the past, genetic information has been used by insurers to discriminate against people. In the early 1970s, some insurance companies denied coverage and charged higher rates to African Americans who were carriers of the gene for sickle cell anemia (1). Contemporary studies have documented cases of genetic discrimination against people who are healthy themselves but who have a gene that predisposes them or their children to a later illness such as Huntington's disease (2). In a recent survey of people with a known genetic condition in the family, 22% indicated that they had been refused health insurance coverage because of their genetic status, whether they were sick or not (3).

As a case example, Paul (not his real name) is a healthy, active 4-year-old, but he has been twice denied health insurance. Paul's mother died in her sleep of sudden cardiac arrest when Paul was only 5 months old. Paul's maternal uncle also died of sudden cardiac arrest when he was in his twenties. After these sudden and unexpected deaths, Paul's family began a hunt to discover the cause. Their search finally led to a research geneticist who was able to determine that several family members, including Paul and his mother, carried an alteration in a gene on chromosome 7. This gene is one of several genes that causes the long QT syndrome, so-called because of the distinctive diagnostic pattern on an electrocardiogram.

Several years ago, Paul's father, Bob, lost his job and with it the group policy that provided health insurance coverage for Paul and him. Paul's father has repeatedly applied for a family health insurance policy with a major insurance company. The company agreed to cover Bob but refused to issue a family policy that would cover Paul because he has inherited the altered gene for the long QT syndrome from his mother.

The story of Jackie and Emma further illustrates the social, ethical, and legal dilemmas presented by the revelation of genetic information. Sisters Jackie and Emma, along with many other members of their family, have been tested as part of a research protocol for alterations in the gene, *BRCA1*, that confers hereditary susceptibil-

ity to breast and ovarian cancer. Both were offered an opportunity to learn the results of their genetic tests and both accepted. They each learned they carry an altered form of the gene, putting them at increased risk for breast and ovarian cancer.

After finding out the results of her genetic test, Emma had a mammogram that showed a very small lesion in her breast. A subsequent biopsy revealed carcinoma, and Emma decided to proceed with a bilateral mastectomy because of the substantial risk of cancer arising in the opposite breast. Her lymph nodes were negative for cancer, so her prognosis for cure is very good.

Emma's sister Jackie also tested positive for the same alteration in the *BRCA1* gene, though no cancer was detected. Although the benefit of prophylactic mastectomy in reducing the risk for breast cancer is not yet known, she decided to have a bilateral prophylactic mastectomy. Emma and Jackie feel strongly that they have benefited from knowing this genetic information but are fearful that it will be used against them and their family by insurers and employers. They both keep their genetic status secret and are so fearful of losing their health insurance that they used assumed names when sharing their story at a recent workshop on genetic discrimination (4).

Emma and Jackie's story is not unique. An estimated 1 in 500 women carry a mutation in the *BRCA1* gene that may confer as much as an 85% chance of breast cancer and a 50% chance of ovarian cancer (5). Although substantial uncertainty exists about the relative value of the available options (surgery compared with intensive surveillance) for a woman with a *BRCA1* mutation, it is likely that ultimately this information will be medically useful.

## Health Insurance in the United States

Because of high costs, insurance is essentially required to have access to health care in the United States. Over 40 million people in the United States are uninsured (6). Group insurance, individual insurance, self-insurance, and publicly financed insurance (for example, Medicare and Medicaid) are the principal forms of health insurance in the United States for the ~240 million Americans with coverage. Most people get their health insurance through their employer. Many employers provide health insurance coverage through self-funded plans in which the employer, either directly or through a third party, provides health insurance coverage. For individuals and small groups, insurance providers use medical history as well as individual risk factors, such as smoking, to determine whether to provide coverage and under what terms. This is

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known as underwriting. Insurers argue that underwriting is essential in a voluntary market to prevent "adverse selection," in which individuals elect not to purchase insurance until they are already ill or anticipate a future need for health care. Insurers fear that individuals will remain uninsured until, for example, they receive a genetic test result indicating a predisposition to some disease such as breast or colon cancer.

In the absence of the ability to detect hereditary susceptibility to disease, the costs of medical treatment have been absorbed under the current health insurance system of shared risk and shared costs. Today, our understanding of the relation between a misspelling in a gene and future health is still incomplete, thus limiting the ability of insurers to incorporate genetic risks into actuarial calculations on a large scale. As genetic research enhances the ability to predict individuals' future risk of diseases, many Americans may become uninsurable on the basis of genetic information.

### State and Federal Initiatives

A recent survey has shown that a number of states have enacted laws to protect individuals from being denied health insurance on the basis of genetic information (Fig. 1) (7). The first laws addressing genetic discrimination were quite limited in scope and focused exclusively on discrimination against people with a single genetic trait such as sickle cell trait (8). Since the Human Genome Project was launched in 1990, eight states have enacted some form of protection against genetic discrimination in health insurance. The recently enacted state laws are not limited to a specific genetic trait but apply potentially to an unlimited number of

genetic conditions. These state laws prohibit insurers from denying coverage on the basis of genetic test results, and prohibit the use of this information to establish premiums, charge differential rates, or limit benefits. A few of these states, including Oregon and California, integrate protection against discrimination in insurance practices with privacy protections that prohibit insurers from requesting genetic information and from disclosing genetic information without authorization.

Two factors limit the protection against discrimination afforded by current state laws. First, the federal Employee Retirement Income Security Act exempts self-funded plans from state insurance laws. Nationwide, over one-third of the nonelderly insured population obtains health insurance coverage through a self-funded plan. Second, nearly all of the state laws focus narrowly on genetic tests, rather than more broadly on genetic information generated by family history, physical examination, or the medical record (7). Limiting the scope of protection to results of genetic tests means that insurers are only prohibited from using the results of a chemical test of DNA, or in some cases, the protein product of a gene. But insurers can use other phenotypic indicators, patterns of inheritance of genetic characteristic, or even requests for genetic testing as the basis of discrimination. Meaningful protection against genetic discrimination requires that insurers be prohibited from using all information about genes, gene products, or inherited characteristics to deny or limit health insurance coverage.

No federal laws are currently in place to prohibit genetic discrimination in health insurance (9). The Clinton Administra-

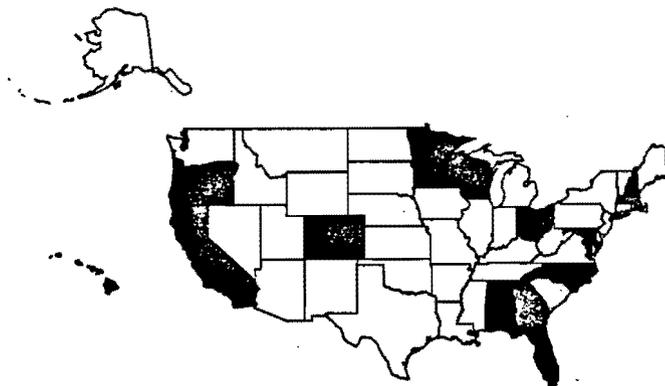
tion's proposal to reform the health care system and provide health insurance for all Americans did prohibit limiting access or coverage on the basis of "existing medical conditions or genetic predisposition to medical conditions" (10). Congressional efforts to reform the health care system in 1995 have been much more modest and are targeted at guaranteeing access, portability, and renewability of coverage and at leveling the playing field in the insurance market so that the same rules apply to insured and self-funded plans. Recent federal health insurance reform proposals attempt to guarantee the availability of health care by prohibiting insurers from denying coverage on the basis of health status, medical condition, claims experience, or medical history of a participant. Most of the proposals permit exclusions for pre-existing conditions, but these are time limited.

It is not clear if the current health insurance reform proposals would prohibit insurers from denying coverage on the basis of genetic information. Genetic information is distinct from other types of medical information because it provides information about an individual's predisposition to future disease. In addition, genetic information can provide clues to the future health risks for an individual's family members. If enacted, current health reform proposals would prohibit denying insurance to those currently suffering from disease or with a past history of disease. But these proposals may not protect people like Paul, who are healthy but have a genetic predisposition to disease, from being refused insurance coverage. Current proposals also may fail to protect couples who, although healthy themselves, carry the gene for a recessive disorder such as cystic fibrosis that might affect their children or future children.

### Recommendations

Planners of the Human Genome Project recognized from the beginning that maximizing the medical benefits of genome research would require a social environment in which health care consumers were protected from discrimination and stigmatization based on their genetic make-up. Genome programs at both the DOE and the National Center for Human Genome Research, a component of NIH, have each set aside a portion of their research budget to anticipate, analyze, and address the ELSI of new advances in human genetics. The original planners also created the NIH-DOE ELSI Working Group, which has a broad and diverse membership including genome scientists; medical geneticists; experts in law, ethics, and philosophy; and consumers, to explore and propose options for the development of sound professional and public

**Fig. 1.** State laws on the use of genetic information in health insurance (7). States shown in purple were the first states to enact legislation addressing genetic issues in insurance. Florida and Alabama laws prohibit insurers from denying coverage on the basis of the sickle cell trait. North Carolina prohibits insurers from denying coverage because the applicant has the hemoglobin C or sickle cell trait.



Maryland prohibits discrimination in rates based on any genetic trait unless there is actuarial justification. States shown in green (California, Oregon, Colorado, Minnesota, Wisconsin, Ohio, Georgia, and New Hampshire) prohibit insurers, to varying degrees, from requiring or requesting genetic tests or their results, from denying coverage on the basis of genetic tests, and from using tests to determine rates and benefits. California, Colorado, Oregon, and Wisconsin laws include provisions to protect the privacy of genetic information. States shown in orange (Massachusetts and Hawaii) have related bills pending.

policies related to human genome research and its applications. The ELSI Working Group has long been involved in discussions about the fair use of genetic information. In a 1993 report, "Genetic Information and Health Insurance" (11), the ELSI Working Group recommended a return to the risk-spreading goal of insurance. The Working Group suggested that individuals be given access to health care insurance irrespective of information, including genetic information about their past, current, or future health status. Because denial of insurance coverage for a costly disease such as breast cancer may prove to be a death sentence for many women, the National Action Plan on Breast Cancer (NAPBC), a public-private partnership designed to eradicate breast cancer as a threat to the lives of American women, has identified genetic discrimination in health insurance as a high priority (12).

Building on their shared concerns, the NAPBC (13) and the ELSI Working Group (14) recently cosponsored a workshop on genetic discrimination and health insurance (4). Scientists, representatives from the insurance industry, and members of the ELSI Working Group and the NAPBC participated in the 1-day session. On the basis of the information presented at the workshop, the ELSI Working Group and the NAPBC developed the following recommendations and definitions for state and federal policymakers to protect against genetic discrimination.

1) Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements.

2) Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.

3) Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.

4) Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

The definitions are as follows. Genetic

information is information about genes, gene products, or inherited characteristics that may derive from the individual or a family member. Insurance provider means an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded.

These recommendations have been endorsed by the National Advisory Council for Human Genome Research (NACHGR) (15). The NACHGR stresses the positive value of genetic information for improving the medical care of individual patients and the need to ensure the freedom of patients and their health care providers to use genetic information for patient care. The NACHGR views the elimination of the use of genetic information to discriminate against individuals in their access to health insurance as a critical step toward these goals.

The ability to obtain sensitive genetic information about individuals, families, and even populations raises profound and troubling questions about who will have access to this information and how it will be used. The recommendations presented here for state and federal policy-makers are intended to help ensure that our current social, economic, and health care policies keep pace with both the opportunities and challenges that the new genetics present for understanding the causes of disease and developing new treatment and preventive strategies.

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5. D. F. Easton *et al.*, *Am. J. Hum. Genet.* **52**, 678 (1993); D. Ford *et al.*, *Lancet* **343**, 692 (1994).
6. *Employee Benefit Research Institute Special Report SR-28*, issue brief number 158, February 1995.
7. K. H. Rothenberg, *J. Law Med. Ethics*, in press.
8. North Carolina, NC ST: 58-65-70 (1975), Florida, FL ST: 626.9707 (1978), Alabama, AL ST: 27-5-13 (1982). In 1987, Maryland passed a law, Art. 48A, 223(b)(4), prohibiting health insurers from discrimination in rates based on genetic traits unless there was

"actuarial justification."

9. In March 1995, the U.S. Equal Employment Opportunity Commission (EEOC) released official guidance on the definition of the term "disability." The EEOC's guidance clarifies that protection under the Americans with Disabilities Act (ADA) extends to individuals who are discriminated against in employment decisions solely on the basis of genetic information about an individual. For example, an employer who makes an adverse employment decision on the basis of an individual's genetic predisposition to disease, whether because of concerns about insurance costs, productivity, or attendance, is in violation of the ADA because that employer is regarding the individual as disabled. Issuance of the EEOC's guidance is precedent setting; it is the first broad federal protection against the unfair use of genetic information.
10. *Health Security Act*, Section 1516, S. 1757/HR 3600.
11. "Genetic information and health insurance: Report of the task force on genetic information and insurance" (NIH-DOE Working Group on the Ethical, Legal, and Social Implication of Human Genome Research, 10 May 1993).
12. The NAPBC has as its mission to reduce the morbidity and mortality from breast cancer and to prevent the disease. Specific goals include the following: (i) to promote a national effort to establish and address priority issues related to breast cancer etiology, early detection, treatment, and prevention; (ii) to promote and foster communication, collaboration, and cooperation among diverse public and private partners; and (iii) to develop strategies, actions, and policies to improve breast cancer awareness, services, and research.
13. NAPBC steering committee: Susan J. Blumenthal (co-chair), Zora Kramer Brown, Doris Browne, Anna K. Chacko, Francis S. Collins, Nancy W. Connell, Kay Dickersin, Arlyne Draper, Nancy Evans, Harmon Eyre, Leslie Ford, Janyce N. Hedetniemi, Mary Jo Ellis Kahn, Amy S. Langer, Susan M. Love, Alan Rabson, Jane Reese-Coulbourne, Irene M. Rich, Barbara K. Rimer, Susan Sieber, Edward Sondik, and Frances M. Visco (co-chair). NAPBC hereditary susceptibility working group: Kathleen A. Calzone, Francis S. Collins (co-chair), Sherman Elias, Linda Finney, Judy E. Garber, Ruthann M. Giusti, Jay R. Harris, Joseph K. Hurd Jr., Mary Jo Ellis Kahn (co-chair), Mary-Claire King, Caryn Lerman, Mary Jane Massie, Paul G. McDonough, Patricia D. Murphy, Philip D. Noguichi, Barbara K. Rimer, Karen H. Rothenberg, Karen K. Steinberg, and Jill Stopfer.
14. ELSI working group: Betsy Anderson, Lori Andrews (chair), James Bowman (dissenting), David Cox, Troy Duster, (vice chair), Rebecca Eisenberg, Beth Fine, Neil Holtzman, Philip Kitcher, Joseph McInemey, Jeffrey Murray, Dorothy Nelkin, Rayna Rapp, Marsha Saxton, and Nancy Wexler.
15. NACHGR council members: Anita Allen, Lennette J. Benjamin, David Botstein, R. Daniel Camerini-Otero (dissents with recommendation 3), Ellen W. Clayton, Troy Duster, Leroy E. Hood, David E. Housman, Richard M. Myers, Rodney Rothstein, Diane C. Smith, Lloyd M. Smith, M. Anne Spence, Shirley M. Tilgham, and David Valle.

For the opportunity to participate in a discussion of the issues raised in this Policy Forum, go to the following URL (<http://sci.aaas.org/aaas/policy>).

## **Attachment 4**

Appendix 3  
**GENETIC INFORMATION AND HEALTH INSURANCE  
 ENACTED LEGISLATION\***

STATE	CITATION	DESCRIPTION
Alabama (1982)	AL ST: 27-5-13	Prohibits health insurers from denying coverage because applicant has sickle cell anemia.
Arizona (1997)	H 2144	<p>Prohibits disability insurers (includes health insurers) from rejecting an application or determining rates, terms or conditions on the basis of a genetic condition - in the absence of a diagnosis of the condition.</p> <p>Prohibits a person from requiring the performance of or performing a genetic test without written informed consent.</p> <p>Prohibits the release of the results of a genetic test without consent.</p> <p>Prohibits employers from failing or refusing to hire, from discharging or from otherwise discriminating on the basis of the results of a genetic test.</p>
California (1994)	<p>Insurance Code:            §10123.3; §10140;            §10148; §10149;            §10149.1; §11512.95</p> <p>Health &amp; Safety            Code:            §1374.7</p>	<p>Prohibits health insurance plans from refusing to enroll or accept persons based on genetic characteristics;</p> <p>Prohibits health insurers from requiring a higher rate or charge on the basis of genetic characteristics;</p> <p>Provides for privacy protection of genetic information.</p>

\*This chart reflects legislation enacted as of May 15, 1997. These state laws were designed to address discrimination and/or privacy issues specifically regarding genetic information and health insurance. In addition to these laws, at least eight states have enacted health insurance portability laws in 1997. These portability laws contain provisions preventing health insurers from basing eligibility on genetic information.

This chart supplements K. H. Rothenberg, *Genetic Information and Health Insurance: State Legislative Approaches*, 23 JOURNAL OF LAW, MEDICINE & ETHICS 312 (1995). Chart prepared by Professor Karen Rothenberg, University of Maryland School of Law, and Ms. Barbara Fuller, NAPBC.

<p>California (1995)</p>	<p>Insurance Code:  §10123.3; §10140;  §10147; §11512.95;  §10123.31;  §10123.35; §10140.1;  §10140.5; §11512.96;  §11512.965</p> <p>Health &amp; Safety  Code:  §1374.7; §1374.9</p>	<p>Prohibits health insurance plans from offering or providing different terms, conditions or benefits on the basis of genetic characteristics.</p>
<p>California (1996)</p>	<p>Civil Code: §56.17</p> <p>Health &amp; Safety  Code: § 1374.7</p> <p>Insurance Code:  §742.24; §742.405;  §742.407; § 10123.3;  §10123.35; §10140;  §10140.1</p>	<p>Prohibits health insurers from seeking, using or maintaining genetic information for any nontherapeutic purposes.</p> <p>Prohibits health insurers from discriminating in the renewal of policies on the basis of genetic characteristics.</p> <p>Revises the definition of genetic characteristics to include family history.</p> <p>Applies prohibitions on genetic discrimination by health insurers to "multiple employer welfare arrangements."</p>
<p>Colorado (1994)</p>	<p>Title 10, Art. 3, Part  II: §10-3-1104.7</p>	<p>Prohibits the utilization of information derived from genetic testing from being used to deny access to health care insurance.</p> <p>Provides for privacy protection of genetic information.</p>
<p>Florida (1978)</p>	<p>FL ST: 626.9707</p>	<p>Prohibits insurers from refusing to issue and deliver any policy of "disability" insurance, which "affords benefits and coverage for any medical treatment or service," solely because a person has the sickle cell trait.</p> <p>Prohibits a "disability" insurance policy from charging a higher rate solely because a person has the sickle cell trait.</p>
<p>Florida (1992)</p>	<p>FL ST: 760.40</p>	<p>Provides for informed consent and privacy protection of genetic information.</p> <p>Provides for mandatory reanalysis if the utilization of genetic information results in a denial of insurance.</p>

This chart supplements K. H. Rothenberg, *Genetic Information and Health Insurance: State Legislative Approaches*, 23 JOURNAL OF LAW, MEDICINE & ETHICS 312 (1995). Chart prepared by Professor Karen Rothenberg, University of Maryland School of Law, and Ms. Barbara Fuller, NAPBC.

Georgia (1995)	Title 33, Chapter 54	<p>Prohibits the use of genetic testing except to obtain information for therapeutic or diagnostic purposes.</p> <p>Provides for written consent prior to genetic testing.</p> <p>Provides for privacy protection of genetic information.</p> <p>Prohibits health insurers from seeking information derived from genetic testing.</p>
Indiana (1997)	H 1684	<p>Prohibits insurers, other than life insurers, from obtaining the results of any genetic screening or testing without a separate written consent.</p> <p>Provides that an insurer is not liable if they inadvertently receive the results of genetic testing or screening.</p> <p>Provides that an insurer that inadvertently receives testing or screening results may not use the genetic testing or screening results in violation of other sections of the law.</p> <p>Prohibits health insurers from requiring an individual to submit to genetic screening or testing when processing an application for coverage or in determining insurability.</p> <p>Prohibits health insurers from considering any information obtained from genetic screening or testing in a manner adverse to the applicant or an individual already covered.</p> <p>Prohibits health insurers from inquiring, directly or indirectly, into the results of genetic screening or testing, or from using such information to cancel, refuse to issue or renew, or limit benefits.</p> <p>Prohibits health insurers from making a decision adverse to an applicant based on entries related to the results of genetic testing or screening in medical records or other reports of genetic screening or testing.</p> <p>Prohibits health insurers from developing and asking questions regarding the medical history of an applicant that reflect the results of or are questions designed to ascertain the results of genetic screening or testing.</p> <p>Prohibits health insurers from canceling, refusing to issue, refusing to renew, or refusing to enter into a contract based on the results of genetic screening or testing.</p>

Indiana (1997) - continued	H 1684 - continued	<p>Prohibits health insurers from delivering, issuing for delivery, renewing or executing a contract that limits benefits or establishes premiums based on the results of genetic screening or testing.</p> <p>Provides for health insurers to consider the results of genetic screening or testing if the results are voluntarily submitted by the applicant seeking renewal of coverage AND if the results are favorable to the applicant.</p>
Maryland (1986)  Maryland (1996)	<p>Insurance Code: Art. 48A, §223(b)(4)</p> <p>S 276 (Ch. 24)</p>	<p>Prohibits health insurers from making or permitting differentials in rates based on any genetic trait, unless there is actuarial justification.</p> <p>Prohibits health insurers from using a genetic test or the results of a test to reject, deny, limit, cancel, refuse to renew, increase the rates of, affect the terms or conditions of, or otherwise affect a health insurance policy or contract.</p> <p>Prohibits health insurers from requesting or requiring a genetic test for the purpose of determining whether or not to issue or renew health benefits coverage.</p> <p>Prohibits the release of the results of a genetic test without the prior written authorization of the individual.</p>
Minnesota (1995)	S.F. No. 259	<p>Prohibits health insurers from utilizing information from genetic testing to determine eligibility, establish premiums, limit coverage, or renew coverage.</p> <p>Prohibits health insurers from requiring a genetic test and from inquiring or determining whether or not an individual has had a genetic test.</p>
New Hampshire (1995)	NH ST: Chapter 141-H	<p>Prohibits health insurers from conditioning the provision of health insurance coverage on the results of genetic testing.</p> <p>Prohibits health insurers from considering genetic testing in the determination of rates or benefits.</p> <p>Prohibits health insurers from requiring a genetic test and from inquiring or determining whether or not an individual has had a genetic test.</p>

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—Toby

File Genetic  
Sweeping

# Testing Genes to Save a Life Without Costing You a Job

By NICHOLAS WADE

**H**UMAN genes hold a wealth of information that physicians hope will help them avert illnesses that may be passed on from one generation to the next. Yet the information, still a trickle but about to arrive in deluges, is so powerful that it will need to be handled with care.

A foretaste of its power was offered by the recent report of a genetic change, or mutation, that has been found to double an individual's lifetime risk of colon cancer; the mutation occurs in 6 percent of Ashkenazi Jews. Those who test positive for the gene can periodically have colonoscopies, in which a physician examines the colon and removes the slow-growing polyps from which colon cancer originates. The procedure is thought likely to reduce the risk of colon cancer from significant to near zero.

The finding promises to avert thousands of cases of the disease. Although the Johns Hopkins Oncology Center, where the mutation was discovered, is recommending now that only people with a family history of colon cancer be tested, the advice is likely to be extended to everyone of Ashkenazi heritage — that is, Jews of Eastern European descent, who account for the great majority of American Jews — if the preliminary estimates of the mutation's risk are confirmed. The Lerner Foundation of Cleveland has offered to pay for the test for anyone who cannot afford it. (The test can be given at Hopkins; it is not yet available in New York.)

But the knowledge comes with certain hazards. To be tested for genetic disposition to any disease exposes one to being denied a job or medical insurance. Laws to forbid such discrimination are not yet fully in place.

The new finding also risked singling out a particular group and creating the impression that people of Ashkenazi heritage are at higher risk of genetic disease — an impression that is almost certainly false. So far, the colon cancer mutation has not been found in non-Ashkenazis. A dozen other genetic diseases, including Tay-Sachs disease and cystic fibrosis, are commoner among Ashkenazis than other population groups.

"The Jewish community has been understandably concerned about the possibility of discrimination against Ashkenazi Jews on the basis of such findings," said Lois Waldman, an officer of the American Jewish Congress.

Under the human genome project at the National Institutes of Health, all three billion genetic letters in human DNA are expected to be deciphered by 2005. Will the project generate information about particular population groups that will prove to be divisive?

"This is a serious issue, that the research doesn't inadvertently stigmatize a particular group just because the group has features that make it advantageous

to study," said Dr. Francis Collins, head of the human genome project. He hastened to dispel the idea that Ashkenazi Jews are likely to have any greater burden of genetic disease than other groups.

Among population groups that are descended from a small number of founders, and have intermarried for many generations, the founders' disease-causing mutations are still often relatively common. This is true of small or once-small populations such as Ashkenazis, Finns and Icelanders, who for that reason are much studied by medical geneticists. Larger populations have more different kinds of founder mutation, though each is less common, doubtless making for the same overall burden of genetic disease, Dr. Collins said.

## So Far, the Same

The mere act of defining human populations as genetically different holds potential for mischief, even if no significant differences should emerge. So far, however, it seems that at least in geneticists' eyes all human populations will prove to be boringly alike.

The trivial differences that have developed typically take the form of genetic variants that may be somewhat more common in certain groups but are far from universal. Some 6 percent of Ashkenazi Jews may carry the colon cancer mutation, for example, but 94 percent have the same version of the gene as do non-Ashkenazis.

"I think that as more and more genetic information on the human species is emerging, there is ever more basis for saying that the level of genetic differentiation among human populations is relatively trivial," said Dr. Douglas Futuyma of the State University of New York at Stony Brook.

Nonetheless, genetic ideas have led to some horrifying consequences. Reports emerged last month that up until the 1970's some 60,000 people had been sterilized in Sweden, and 11,000 in Finland, under government policies designed to weed out properties like poor eyesight and Gypsy features.

Dr. James Watson, a leading biologist and proponent of the human genome project, argues that past crimes committed in the name of eugenics should not prevent individuals from being allowed to choose the benefits that genetic engineering can offer in the future.

"Anyone who proclaims we are now perfect as humans has to be a silly crank," he writes in the annual report of the Cold Spring Harbor Laboratory on Long Island, of which he is president. "If we could honestly promise young couples that we knew how to give them offspring with superior character, why should we assume they would decline?"

Public opinion is probably not yet prepared for the forward kind of genetic engineering that Dr. Watson is suggesting. But the rapid progress of genetic understanding is bringing these choices ever closer.



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## RECOMMENDATIONS ON GENETIC INFORMATION AND THE WORKPLACE

The National Action Plan on Breast Cancer and the NIH-DOE Working Group on  
Ethical, Legal and Social Implications of Human Genome Research

Within the past few years, scientific research has increased dramatically the ability to identify mutations within genes. These mutations are identified not only in the context of people who have already been diagnosed with a disease but, in some cases, determine a predisposition to a specific disease in a healthy person. This new ability to identify individuals at increased risk for disease could have a significant impact on the practice of medicine and the potential to improve human health. Yet, increased ease of access to this potentially powerful information by employers raises concerns that this information will be used to discriminate against individuals.

Genetic information has already been used to discriminate in the workplace against certain segments of society. In the early 1970's, some employers denied employment to African-Americans who were identified to have a mutation for sickle cell anemia, even though they were themselves healthy and would never develop the disease. At present, there is no scientific evidence to substantiate a relationship between unexpressed genetic factors and an individual's inability to perform his or her job functions. Thus, employers could not prove that the use of genetic information in the workplace is "job related and consistent with business necessity," the standard often applied in Federal and state antidiscrimination laws. Nevertheless, employers that cover health care costs for employees and their dependents have economic incentives to deny employment to individuals they assume are more likely to consume health care resources.

As knowledge about the genetic basis of common disorders and behavioral traits grows, so does the possibility for discrimination in the workplace for an ever increasing number of Americans. For example, as the genetic contributions to breast and prostate cancer unfold and tests to detect cancer-causing mutations in DNA become available, individuals may increasingly face workplace discrimination based on this genetic information. Although a genetic test for inherited breast cancer will allow women to find out whether they carry the altered gene and potentially provide them with alternative follow-up strategies, many women may choose not to be tested out of fear the information will be used to deny them employment, and consequently, access to health insurance.

At present, there is some Federal protection, though limited, for those individuals who are denied employment or otherwise discriminated against based on genetic information. In 1995, the Equal Employment Opportunity Commission updated the Compliance Manual for the Americans with Disabilities Act (ADA) to define "disability" to apply to those individuals who are subjected to discrimination on the basis of genetic information. However, individuals with an ADA discrimination claim must be able to prove their employer "regards" them as disabled and has discriminated against them because of this perception. In addition, it is not clear whether or not this coverage will extend to unaffected individuals who have recessive or X-linked mutations. Even this limited protection has yet to be tested in a court of law.

On the state level, legislation has been passed in at least eleven states that addresses issues surrounding workplace genetic testing and provides for protection against genetic discrimination in the workplace. These state laws vary widely in the scope of those protected and in the type of protections provided to individuals. Some of these laws attempt to prevent access to and utilization of genetic test results. A few of these laws provide for the use of genetic test results if the information is job related. To date, there is no comprehensive Federal law or uniform state law to prevent misuse of genetic information in the workplace.

Genetic information is just one component of medical information. Privacy protection for all medical information needs to be addressed by uniform state and Federal laws. Genetic information, like all medical information, might be used for unfair discrimination and could make individuals unwilling to share information with their health care providers or family members and could make them unwilling to participate

in research. Comprehensive legislation should be adopted to improve the protection of all medical information, including genetic information. If such broad legislation is not currently politically feasible, it would be worthwhile to enact legislation limited to protecting genetic information as a first step toward protecting all sensitive medical information.

The National Action Plan on Breast Cancer (NAPBC) recently joined with the NIH-DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research (ELSI Working Group) to address the issue of genetic information and the workplace. This effort builds on their combined efforts to address genetic discrimination in health insurance, the ELSI Working Group's long involvement in the privacy and fair use of genetic information and the NAPBC's mandate to address the priority issues related to breast cancer. The recommendations on genetic information and the workplace should be considered along with the NAPBC and ELSI Working Group recommendations on genetic information and health insurance promulgated and disseminated in 1995. The following recommendations are designed to offer guidance for state and federal policymakers to protect against genetic discrimination and to promote privacy in the workplace. This guidance should be considered in context with Federal and state disability laws, other antidiscrimination laws, employment laws and medical privacy protections.

### RECOMMENDATIONS

Employment organizations should be prohibited from using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits or termination of employment unless the employment organization can prove this information is job related and consistent with business necessity.

Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all other circumstances, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law. Written and informed consent should be required for each request, collection or disclosure.

Employment organizations should be restricted from access to genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs, and other sources.

Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made.

Violators of these provisions should be subject to strong enforcement mechanisms, including a private right of action.

### DEFINITIONS

"Employment organizations" include, but are not limited to, employers, labor organizations, employment agencies and licensing agencies.

"Genetic information" is information about genes, gene products, or inherited characteristics that may derive from the individual or a family member.

For more information, contact: NAPBC, U.S. Public Health Service's Office on Women's Health, Room 718F, 200 Independence Ave., S.W., Washington, D.C. 20201. (202) 401-9587.

# Clinton to Support Legislation Guarding Against Gene-Test Bias

## Inherited Risk for Disease Has Kept Some From Getting Insurance

By Rick Weiss  
Washington Post Staff Writer

President Clinton today will endorse legislation that would make it illegal for health insurance companies to discriminate against healthy people on the basis of their genetic inheritance and would help assure the privacy of genetic information, White House sources said.

Clinton's call for legislation with more protections against genetic discrimination than those included in last year's Kassebaum-Kennedy health law comes as rapid-fire biological discoveries are giving doctors and researchers increasing ability to predict who will succumb to various inherited diseases.

Already, widely available blood tests can reveal whether a person harbors aberrant genes that increase the risk of getting breast cancer, colon cancer, melanoma, or brain diseases such as Alzheimer's and Huntington's disease. Dozens of other predictive genetic tests are available through research studies and may make their way to the market in the next few years.

In some cases the information can motivate a person to get more frequent checkups or take preventive action. But genetic information is imprecise and can stigmatize healthy people. Public policy regarding its use has lagged behind the science.

Clinton's decision to push for heightened protections reflects recommendations in a report to be presented to the president today by Health and Human Services Secretary Donna E. Shalala. The report, based on findings of a federal task force, warns that the potential benefits of genetic testing may never be realized if people reject the tests out of fear that the information may be used against them.

A number of genetic discrimination cases have come to light in recent years, most of them involving people who were denied health insurance because of test results indicating they were at increased risk of cancer or other diseases. In some cases people have been discriminated against simply for having requested genetic tests, as insurers assumed that anyone asking for such a test was probably at increased risk for an inherited disease.

The legislation to be endorsed by Clinton is a slightly modified version of a bill introduced in January by Rep. Louise M. Slaughter (D-N.Y.) that already has bipartisan support with more than 135 co-sponsors. The president's decision to get involved could rejuvenate a Senate bill with language identical to the House version, introduced by Sen. Olympia J. Snowe (R-Maine).

"The president is well aware that people are both excited and nervous by all the recent changes rooted in the biological revolution, and he believes that [the legislation] will provide a security blanket," said Christopher Jennings, deputy assistant to the president for health policy development. "It tells Americans we are watching the health care system, and people are going to be protected."

The president's hopes of warming the Senate to his plan were bolstered over the weekend when Sen. Bill Frist (R-Tenn.) agreed to back the effort. Frist's support was considered crucial, administration sources said, because he is the Senate's sole physician and chairs the subcommittee on public health and safety.

The Slaughter legislation would prohibit health insurers from denying, canceling, refusing to renew or changing the terms, premiums or conditions of health coverage on the basis of genetic information. It also would prevent health insurers from demanding a genetic test as a condition of coverage and, with few exceptions, would require a patient's written consent before the insurer could disclose genetic information to a third party. Companies found in violation of these protections could be sued for compensation and also would be liable for punitive damages.

The Health Insurance Portability and Accountability Act passed last year prevents health insurers from denying insurance on the basis of genetic information to people moving from one group plan to another. But the measure, which was sponsored by Sens. Nancy Landon Kassebaum (R-Kan.) and Edward M. Kennedy (D-Mass.), places no controls on how expensive that coverage might get. The act also offers no protections for people covered by individual, rather than group, plans.

"The Slaughter legislation definitively closes the loopholes left by Kassebaum-Kennedy and would offer comprehensive protections against genetic discrimination in health insurance," said Wendy McGoodwin, executive director of the Council for Responsible Genetics, an advocacy group based in Cambridge, Mass.

Congressional and administration sources said they believe there is a good chance that the proposed legislation or something close to it can become law this year. Ongoing changes in the health care system and especially the growth of managed care have raised so many concerns in both parties, one source said, that there is wide support for almost any issue that falls under the umbrella of protecting patients.

Indeed, several geneticists said, a ban on genetic discrimination in health insurance is one of the easier gene issues facing Congress—stirring only modest dissent even from health insurers, which are already restricted by similar laws in dozens of states. More difficult issues in-

clude a comprehensive ban on genetic discrimination in employment, possible restrictions on the use of genetic tests in life insurance underwriting and stricter regulation of the genetic testing industry.

Nell A. Holtzman, director of genetics and public policy studies at Johns Hopkins University, warned against interpreting the president's words today as an endorsement of widespread genetic testing. Holtzman chairs a federal task force that recently completed a study of genetic testing in the United States. The study is soon to be forwarded to Shalala.

The task force concluded that many genetic tests are being developed and administered without proper oversight, are being performed in inadequately regulated laboratories and are interpreted by physicians and others with insufficient training or proof of competence.

Other experts have criticized the rapidly growing genetic testing industry for offering many tests that have no proven medical usefulness for patients.

"Certainly the biotech industry will support a bill like [Slaughter's] because it removes a barrier to testing," Holtzman said. "Does that mean that people should flock to these tests? I don't think so."

Nonetheless, Holtzman and others said, some genetic tests are clearly useful, but people will not benefit from them if they are too afraid to take them.

"Increasingly we are finding that people are worried about participating in genetic research or clinical testing because of the great concern—and justifiably so—that it might be used against them," a senior National Institutes of Health official said. "It hinders research and hinders people's ability to take advantage of preventive medical strategies. We can really celebrate the fact that the president is giving this issue this degree of visibility and personal commitment."

The Washington Post

Monday, July 14, 1997

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TO PROHIBIT DISCRIMINATION IN FEDERAL EMPLOYMENT  
BASED ON GENETIC INFORMATION

By the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, it is ordered as follows:

Section 1. Nondiscrimination in Federal Employment on the Basis of Protected Genetic Information.

1-101. It is the policy of the Government of the United States to provide equal employment opportunity in Federal employment for all qualified persons and to prohibit discrimination against employees based on protected genetic information, or information about a request for or the receipt of genetic services. This policy of equal opportunity applies to every aspect of Federal employment.

1-102. The head of each Executive department and agency shall extend the policy set forth in section 1-101 to all its employees covered by section 717 of Title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000(e)-16).

1-103. Executive departments and agencies shall carry out the provisions of this order to the extent permitted by law and consistent with their statutory and regulatory authorities, and their enforcement mechanisms. The Equal Employment Opportunity Commission shall be responsible for coordinating the policy of the Government of the United States to prohibit discrimination against employees in Federal employment based on protected genetic information, or information about a request for or the receipt of genetic services.

Sec. 2. Requirements Applicable to Employing Departments and Agencies.

1-201. Definitions.

- (a) The term "employee" shall include an employee, applicant for employment, or former employee covered by section 717 of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000(e)-16).
- (b) Genetic monitoring means the periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order

to identify, evaluate, respond to the effects of, or control adverse environmental exposures in the workplace.

- (c) Genetic services means health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic or therapeutic purposes, or for genetic education or counseling.
- (d) Genetic test means the analysis of human DNA, RNA, chromosomes, proteins, or certain metabolites in order to detect disease-related genotypes or mutations. Tests for metabolites fall within the definition of "genetic tests" when an excess or deficiency of the metabolites indicates the presence of a mutation or mutations. The conducting of metabolic tests by a department or agency, which are not intended to reveal the presence of a mutation, shall not be considered a violation of this order, regardless of the results of the tests, provided that test results revealing a mutation shall be subject to all other provisions of this order.
- (e) Protected genetic information.
  - (1) In general, protected genetic information means:
    - (A) information about an individual's genetic tests;
    - (B) information about the genetic tests of an individual's family members; or
    - (C) information about the occurrence of a disease, or medical condition or disorder in family members of the individual.
  - (2) Information about an individual's current health status (including information about sex, age, physical exams, and chemical, blood, or urine analyses) is not protected genetic information unless it is described in subparagraph (1).

1-202. In discharging their responsibilities under this order, departments and agencies shall implement the following nondiscrimination requirements.

- (a) The employing department or agency shall not discharge, fail or refuse to hire, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of that employee, because of protected genetic information with respect to the employee, or because of information about a request for or the receipt of genetic services by such employee.

- (b) The employing department or agency shall not limit, segregate, or classify employees in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect that employee's status, because of protected genetic information with respect to the employee or because of information about a request for or the receipt of genetic services by such employee.
- (c) The employing department or agency shall not request, require, collect, or purchase protected genetic information with respect to an employee, or information about a request for or the receipt of genetic services by such employee.
- (d) The employing department or agency shall not disclose protected genetic information with respect to an employee, or information about a request for or the receipt of genetic services by an employee except:
  - (1) to the employee who is the subject of the information, at his or her request;
  - (2) to an occupational or other health researcher, if the research conducted complies with the regulations and protections provided for under part 46 of title 45, of the Code of Federal Regulations;
  - (3) if required by a Federal statute, congressional subpoena, or an order issued by a court of competent jurisdiction, except that if the subpoena or court order was secured without the knowledge of the individual to whom the information refers, the employer shall provide the individual with adequate notice to challenge the court order, unless the court order also imposes confidentiality requirements; or
  - (4) to executive branch officials investigating compliance with this order, if the information is relevant to the investigation.
- (e) The employing department or agency shall not maintain protected genetic information or information about a request for or the receipt of genetic services in general personnel files; such information shall be treated as confidential medical records, and kept separate from personnel files.

Sec. 3. Exceptions.

1-301. The following exceptions shall apply to the nondiscrimination requirements set forth in section 1-202.

- (a) The employing department or agency may request or require information defined in section 1-201(e)(1)(C) with respect to an applicant who has been given a conditional offer of employment or to an employee if:
- (1) the request or requirement is consistent with the Rehabilitation Act and other applicable law;
  - (2) the information obtained is to be used exclusively to assess whether further medical evaluation is needed to diagnose a current disease, or medical condition or disorder, or under the terms of section 1-301(b) of this order;
  - (3) such current disease, or medical condition or disorder could prevent the applicant or employee from performing the essential functions of the position held or desired; and
  - (4) the information defined in section 1-201(e)(1)(C) of this order will not be disclosed to persons other than medical personnel involved in or responsible for assessing whether further medical evaluation is needed to diagnose a current disease, or medical condition or disorder, or under the terms of 1-301(b) of this order.
- (b) The employing department or agency may request, collect, or purchase protected genetic information with respect to an employee, or any information about a request for or receipt of genetic services by such employee if:
- (1) the employee uses genetic or health care services provided by the employer (other than use pursuant to section 301(a) of this order);
  - (2) the employee who uses the genetic or health care services has provided prior knowing, voluntary, and written authorization to the employer to collect protected genetic information;
  - (3) the person who performs the genetic or health care services does not disclose protected genetic information to anyone except to the employee who uses the

services; for treatment of the individual; pursuant to section 1-202(d) of this order; for program evaluation or assessment; for compiling and analyzing information in anticipation of or for use in a civil or criminal legal proceeding; or, for payment or accounting purposes, to verify that the service was performed (but in such cases the genetic information itself cannot be disclosed);

(4) such information is not used in violation of sections 1-202(a) or 1-202(b) of this order.

(c) The employing department of agency may collect protected genetic information with respect to an employee if the requirements of part 46 of title 45 of the Code of Federal Regulations are met.

(d) Genetic monitoring of biological effects of toxic substances in the workplace shall be permitted if all of the following conditions are met:

(1) the employee has provided prior, knowing, voluntary, and written authorization;

(2) the employee is notified when the results of the monitoring are available and, at that time, the employer makes any protected genetic information that may have been acquired during the monitoring available to the employee and informs the employee how to obtain such information;

(3) the monitoring conforms to any genetic monitoring regulations that may be promulgated by the Secretary of Labor; and

(4) the employer, excluding any licensed health care professionals that are involved in the genetic monitoring program, receives results of the monitoring only in aggregate terms that do not disclose the identity of specific employees.

(e) This order does not limit the statutory authority of a Federal department or agency to:

(1) promulgate or enforce workplace safety and health laws and regulations;

- (2) conduct or sponsor occupational or other health research that is conducted in compliance with regulations at part 46 of title 45, of the Code of Federal Regulations; or
- (3) collect protected genetic information as a part of a lawful program, the primary purpose of which is to carry out identification purposes.

Sec. 4. Miscellaneous.

1-401. The head of each department and agency shall take appropriate action to disseminate this policy and, to this end, shall designate a high level official responsible for carrying out its responsibilities under this order.

1-402. Nothing in this order shall be construed to:

- (a) limit the rights or protections of an individual under the Rehabilitation Act of 1973 (29 U.S.C. 701, et seq.), the Privacy Act of 1974 (5 U.S.C. 552a), or other applicable law; or
- (d) require specific benefits for an employee or dependent under the Federal Employees Health Benefits Program or similar program.

1-403. This order clarifies and makes uniform Administration policy and does not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its officers or employees, or any other person.

THE WHITE HOUSE,