

THE WHITE HOUSE

WASHINGTON

February 8, 2000

MEMO FOR JACK LEW

FROM: BRUCE REED *BR*

SUBJECT: PROPOSED EXECUTIVE ORDER TO PROHIBIT DISCRIMINATION IN
FEDERAL EMPLOYMENT BASED ON GENETIC INFORMATION

Attached is a proposed executive order to prohibit discrimination in Federal employment based on genetic information. The proposed order, which was prepared by this office, would prohibit every civilian Federal Department and agency from using genetic information in any hiring or promotion action and prevent critical information from genetic tests used to help predict, prevent, and treat diseases being used against them by their employer.

This proposed order would: prohibit Federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits; prohibit Federal employers from using protected genetic information to classify employees in a manner that deprives them of advancement opportunities; and provide strong privacy protections to any genetic information used by employers for medical treatment and research.

We request that you process this order pursuant to Executive Order 11030, as amended, as soon as possible.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

'00 FEB 4 PM 7:35

DRAFT

2-4-2000
7:15 p.m.

THE DIRECTOR

MEMORANDUM FOR THE PRESIDENT

FROM: Jacob J. Lew
Director

SUBJECT: Proposed Executive Order Entitled "To Prohibit Discrimination in Federal Employment Based on Genetic Information"

SUMMARY: This memorandum forwards for your consideration a proposed Executive order that was prepared by the White House Domestic Policy Council. The proposed order states that it is the policy of the Government of the United States to provide equal employment opportunities in Federal employment and to prohibit discrimination against employees based on protected genetic information. It would require Executive departments and agencies to extend this nondiscrimination policy to all employees covered by Section 717 of Title VII of the Civil Rights Act of 1964, as amended.

BACKGROUND: The Equal Employment Opportunity Commission and the National Institutes of Health have become aware of instances where genetic information has been used to discriminate against persons employed in the private sector. To forestall this type of discrimination in the executive branch of the Federal Government, the proposed order would direct Executive departments and agencies ("agencies") to take certain actions.

The order would bar the agencies from: (a) hiring or firing persons based on protected genetic information; (b) classifying or segregating persons based on genetic information; or (c) requesting, collecting or purchasing protected genetic information. Protected genetic information is defined as: (1) information about an individual's genetic tests; (2) information about genetic tests of family members of the individual; and (3) information about the occurrence of a disease or disorder in family members of the individual. Information about an individual's current health status (including information about sex, age, physical exams, and chemical, blood, or urine analysis), unless genetically organized, would not be protected genetic information. Further, the definition of "genetic test" in the order covers the analysis of human DNA to detect disease-related genotypes or mutations. The analysis of DNA for human identification or forensic purposes does not fit within the definition. Accordingly, the order does not bar the collection or use of information obtained through such analysis for law enforcement purposes.

The exceptions to the order would permit agencies to require prospective employees to provide family history genetic information if: (a) consistent with the Rehabilitation Act or applicable law; (b) used to assess whether further medical evaluation is needed to diagnose a medical condition or disorder; and (c) such medical condition or disorder could prevent the employee from performing the essential functions of the desired position.

Agencies could also collect protected genetic information if the employee uses the health care services provided by the agency for if the information is needed for the monitoring of biological effects of toxic substances in the workplace.

if contain other requirements are met,
None of the affected agencies objects to the proposed Executive order.

RECOMMENDATION: I recommend that you sign the proposed Executive order.

Attachments

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. 2. 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 or 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.

Briefing in Residence

150 - 2²⁰ pm

THE WHITE HOUSE

WASHINGTON

July 12, 1997

GENETIC SCREENING EVENT

DATE: July 14, 1997
TIME: 2:30 pm - 3:40 pm
LOCATION: The East Room
FROM: Bruce Reed
Maria Echaveste

I. PURPOSE:

(1) To pledge to enact bipartisan legislation to prohibit health plans from inappropriately using genetic screening information to deny coverage or set premiums, or distributing confidential information; (2) To receive a new report from HHS on the promise and perils of genetic screening; and (3) To announce that the Republican Chair of the Senate Labor and Human Resources Committee, Senator Jim Jeffords, and the Public Health and Safety Subcommittee Chair, Senator and Doctor Bill Frist, have indicated their support for passing a bipartisan bill consistent with the goals and recommendations of the HHS Report.

II. BACKGROUND:

While progress in genetic testing has helped millions of Americans, genetic testing can be used by insurance companies and others to discriminate and stigmatize groups of people. Studies show that 22 percent of people in families where someone has a genetic disorder report that they, or a member of their family, have been discriminated against by an insurance plan. In addition, 85 percent of Americans are extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family.

Nineteen states have already enacted laws to restrict the use of genetic information in health insurance and many others have introduced legislation. However, state legislation is insufficient to solve this problem for three reasons: (1) private sector employer sponsored health plans, which cover half of all Americans, are exempt from state insurance laws due to ERISA preemption; (2) current state laws generally focus on genetic tests rather than a broader definition of genetic information such as family history, medical records, and physical exams; and (3) the variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

Kassebaum-Kennedy took steps to prohibit genetic discrimination by preventing insurers from using genetic information as a "pre-existing condition" and denying or limiting coverage in group markets. However, Kassebaum-Kennedy falls short in three areas. It does not: (1) prevent insurers in the individual market from denying coverage on the basis of genetic information; (2) assure that premiums settings are in no way based on genetic information both in the group and individual market; and (3) prevent insurance companies from disclosing genetic information to other insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

III. PARTICIPANTS:

Briefing Participants

Bruce Reed

Maria Echaveste

Chris Jennings

Jordan Tamagni

Event Participants

The Vice President

Secretary Shalala

Congresswoman Louise Slaughter

Mary Jo Ellis Kahn, breast cancer survivor.

[Mary Jo's mother was diagnosed with breast cancer. She was the mother of 5 children and died at the age of 47. Her four daughters knew they were at increased risk of breast cancer because of their mother's history. Mary Jo was diagnosed with breast cancer at age 39 and her older sister was diagnosed at age 42. The two younger sisters then decided to undergo preventive mastectomies. Mary Jo believes that the option of seeking genetic testing to discover the breast cancer gene will only be real if there is no chance of insurance discrimination.]

Audience

The audience consists of Members of Congress and 150 representatives of organizations endorsing Congresswoman's Slaughter's legislation, including breast cancer and consumer groups. Members of the working groups of the Human Genome Research Institute and the National Action Plan on Breast Cancer will also be in attendance.

Pre-Event Meet and Greet

- Mary Jo Ellis Kahn and family.

- Dana Glover, a fellow Arkansan, who at the age of 28 developed third stage breast cancer as a result of a mutated gene. She wrote to the White House several times and received no response, but when you saw her letter you asked that she be invited to the White House for an event.

IV. SEQUENCE OF EVENTS:

- You will be announced onto the stage with other participants.
- The Vice President will make welcoming remarks and introduce Secretary Shalala.
- Secretary Shalala will make remarks and introduce Congresswoman Slaughter.
- Congresswoman Slaughter will make remarks and introduce Mary Jo Ellis Kahn.
- Mary Jo Ellis Kahn will make remarks and introduce you.
- You will make remarks and then depart.

V. PRESS COVERAGE:

Open

VI. REMARKS:

Prepared by Jordan Tamagni.

PREVENTING INSURANCE DISCRIMINATION BASED ON GENETIC INFORMATION

Today the President pledged his commitment to enacting bipartisan legislation in this Congress to prohibit health plans from inappropriately using genetic screening information to deny coverage or set premiums, or distributing confidential information. In so doing, he released a new report from the Department of Health and Human Services that summarizes the promise and perils of genetic screening. He also announced that the Republican Chair of the Senate Labor and Human Resources Committee, Senator Jim Jeffords, and the Public Health and Safety Subcommittee Chair, Senator and Doctor Bill Frist, have indicated their support for passing a bipartisan bill that is consistent with the goals and general recommendations of the HHS report.

The Progress and Promise of Genetic Testing. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. Tests for genetic predisposition to certain diseases and conditions -- such as Huntington's disease and certain types of breast cancer -- are already available and more genetic tests are on the horizon.

Genetic Discrimination: The Perils of This Progress. But genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. Studies have shown that:

- Over one-fifth of people in families where someone has a genetic disorder report that they, or a member of their family, had been discriminated against by an insurance plan.
- 85 percent of Americans report that they are extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family.

Building on Kassebaum-Kennedy. Kassebaum-Kennedy took steps to prohibit genetic discrimination by preventing insurers from using genetic information as a "pre-existing condition" and denying or limiting coverage in group markets. However, Kassebaum-Kennedy falls short in three areas. It does not: (1) prevent health plans in the individual market from denying coverage on the basis of genetic information; (2) assure that premiums settings are in no way based on genetic information both in the group and individual market; and (3) prevent health plans from disclosing genetic information to insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

State laws are insufficient. Nineteen states have already enacted laws to restrict the use of genetic information in health insurance and many others have introduced legislation. However, state legislation is insufficient to solve this problem. First, private sector employer sponsored health plans, which cover half of all Americans, are exempt from state insurance laws due to ERISA preemption. Second, current state laws generally focus on genetic tests rather than a broader definition of genetic information such as family history, medical records, and physical exams. Finally, the variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

Building on the existing bipartisan commitment to the President's challenge. Several bills have been introduced in this Congress which prohibit health plans from requesting or using genetic information to deny health care coverage or raise premiums. The bipartisan legislation introduced by Rep. Louise Slaughter, H.R. 306, addresses the three major gaps left by the HIPAA legislation and represents a strong foundation for this much-needed reform. It has already attracted over 150 cosponsors. The HHS report released today recommends building on this legislation and enacting a bill that protects all Americans from the threat of genetic discrimination.

WHITE HOUSE STAFFING MEMORANDUM

DATE: 7/12/97 ACTION/CONCURRENCE/COMMENT DUE BY: 7/14 9:00am

SUBJECT: Remarks for the Genetic Screening Event (7/14/97)

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	McCURRY	<input type="checkbox"/>	<input checked="" type="checkbox"/>
BOWLES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	McGINTY	<input type="checkbox"/>	<input type="checkbox"/>
McLARTY	<input type="checkbox"/>	<input type="checkbox"/>	NASH	<input type="checkbox"/>	<input type="checkbox"/>
PODESTA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RUFF	<input type="checkbox"/>	<input type="checkbox"/>
MATHEWS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SMITH	<input type="checkbox"/>	<input type="checkbox"/>
RAINES	<input type="checkbox"/>	<input type="checkbox"/>	REED	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BAER	<input type="checkbox"/>	<input type="checkbox"/>	SOSNIK	<input checked="" type="checkbox"/>	<input type="checkbox"/>
ECHAVESTE	<input type="checkbox"/>	<input type="checkbox"/>	LEWIS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EMANUEL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	YELLEN	<input type="checkbox"/>	<input type="checkbox"/>
GIBBONS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	STREETT	<input type="checkbox"/>	<input type="checkbox"/>
IBARRA	<input type="checkbox"/>	<input type="checkbox"/>	SPERTING	<input type="checkbox"/>	<input type="checkbox"/>
RADD	<input type="checkbox"/>	<input type="checkbox"/>	TARULLO	<input type="checkbox"/>	<input type="checkbox"/>
MARSHALL	<input type="checkbox"/>	<input type="checkbox"/>	VERVEER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HILLEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>	WALDMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
KLAIN	<input type="checkbox"/>	<input type="checkbox"/>	<u>Jummings</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BERGER	<input type="checkbox"/>	<input type="checkbox"/>	<u>Klein</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
LINDSEY	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

REMARKS: Comments to Jordan Tamagni x65701

RESPONSE:

PRESIDENT WILLIAM J. CLINTON
REMARKS FOR GENETIC SCREENING EVENT
THE EAST ROOM
JULY 14, 1997

Acknowledgments: V.P. Gore (for leadership in Congress and continued commitment); Sec. Shalala (for new report, "Health Insurance in the Age of Genetics"); Rep. Slaughter (for sponsorship of legislation); Mary Jo Ellis Kahn, breast cancer survivor (for courage and willingness to talk about her family's experience with breast cancer); Dr. Francis Collins, head of the Human Genome Project, (for groundbreaking new research and guidance).

Like Mary Jo Ellis Kahn's family, my own family has been deeply affected by the tragedy of breast cancer, and nearly every American family has had its own experience with serious illness. That is why the remarkable strides in genetic research and testing we are talking about today are so important. And that is why we must make sure that all Americans get the benefits of these breakthroughs, and the health care they need and deserve.

As Secretary Shalala's report makes so clear, we are living in an era of scientific discovery, a moment when science is unlocking the mysteries of the human body, and offering unprecedented new ways of preventing disease. But along with these amazing new developments comes the risk that they could be used improperly -- and the responsibility to make sure that they are not.

Nowhere is the promise -- and the peril -- of scientific discovery more apparent than in genetic testing. Used in the right way, genetic testing has the potential to save millions of lives and revolutionize health care. But when insurance companies can use genetic information to deny coverage -- as they did in the 1970s with some African Americans who carried sickle cell anemia -- we know that something is wrong. When people are being driven from their doctors because they are afraid that genetic information will be used against them -- as too many women who may carry the gene for breast cancer fear it will be -- we know that something is wrong.

That something is discrimination, and it is more than wrong. It is a life-threatening abuse of a potentially life-saving discovery. And we must do everything in our power to prevent it.

Last year, we took the first step by prohibiting group health plans from using genetic information to deny coverage. Today, I am pleased to announce that my administration is taking the next step by putting its full support behind new legislation that bans all health plans -- both group and individual -- from denying coverage or raising premiums on the basis of genetic tests. And it prohibits all health plans from disclosing genetic information that could be misused by other insurers. I am pleased that Representative Slaughter is sponsoring this new legislation, and that Senator Frist and Senator Jeffords share our commitment to ban discrimination based on genetic tests.

This legislation is an example of the step-by-step approach we are taking to provide every American family with the health care they need to thrive. We have already ensured that a job change or an illness in the family doesn't mean losing health insurance. We have made it easier for self-employed people to buy health insurance for their families. And the balanced budget agreement I reached with Congress in May will extend health care to millions of uninsured children, ensure that more older women can have mammograms, and protect Medicare and Medicaid.

We cannot afford to let our progress be undermined by the misuse of the miracle of genetic testing. Americans should never have to choose between saving their health insurance, and taking the test that could save their lives. And with these efforts, we will ensure that no American ever has to make that choice.

Thank you and God bless you.

MEMORANDUM

July 14, 1997

TO: ✓ Bruce Reed, Elena Kagan
FR: Chris J. and Sarah B.
RE: Documents for the Genetic Discrimination Event

Attached are the documents we put together for today's genetic information event. They include:

- (1) One page fact sheet;
- (2) An Executive Summary of the HHS report "Health Insurance in the Age of Genetics";
- (3) One page summary of the legislation;
- (4) Q&As;
- (5) An impressive list of quotes from supportive Members and organizations;
- (6) Today's *Post Story*.

We hope you find this information helpful. Please call with any questions.

PREVENTING INSURANCE DISCRIMINATION BASED ON GENETIC INFORMATION

Today the President pledged his commitment to enacting bipartisan legislation in this Congress to prohibit health plans from inappropriately using genetic screening information to deny coverage, set premiums, or to distribute confidential information. In so doing, he released a new report from the Department of Health and Human Services that summarizes the promise and perils of genetic screening. He also announced that the Republican Chair of the Senate Labor and Human Resources Committee, Senator Jim Jeffords, and the Public Health and Safety Subcommittee Chair, Senator and Doctor Bill Frist, have indicated their support for passing a bipartisan bill that is consistent with the goals and general recommendations of the HHS report.

The Promise of Genetic Testing. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. Tests for genetic predisposition to certain diseases -- such as Huntington's disease and certain types of breast cancer -- are already available and more such tests are on the horizon.

Genetic Discrimination: The Perils of This Progress. Genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. Studies have shown that:

- Over one-fifth of people in families where someone has a genetic disorder report that they, or a member of their family, had been discriminated against by an insurance plan.
- 85 percent of Americans report that they are extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family.

Building on Kassebaum-Kennedy. The Kassebaum-Kennedy law took steps to prohibit genetic discrimination by preventing insurers from using genetic information as a "pre-existing condition" and denying or limiting coverage in group markets. However, it does not: (1) prevent health plans in the individual market from denying coverage on the basis of genetic information; (2) assure that premiums settings are in no way based on genetic information; and (3) prevent health plans from disclosing genetic information to insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

State laws are insufficient. Although 19 states have already enacted laws to restrict the use of genetic information in health insurance, state laws are insufficient to solve this problem. First, employer sponsored self-insured health plans, which cover half of all Americans, are exempt from state insurance laws due to ERISA preemption. Second, current state laws generally focus on genetic tests rather than a broader definition of genetic information such as family history, medical records, and physical exams. Finally, the variability among state bills will lead to a lack of uniformity across the nation.

Building on the existing bipartisan commitment to the President's challenge. Bipartisan legislation introduced by Rep. Louise Slaughter (H.R. 306) and Senator Snowe (S. 422) addresses the three major gaps left by the HIPAA legislation and represents a strong foundation for this much-needed reform. It has already attracted over 130 cosponsors in the House. The legislation that the President will be forwarding to the Hill builds off the Slaughter/Snowe bill and strengthens it by explicitly specifying that genetic information cannot be disclosed to insurers, plan sponsors (the employer), and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers. It also gives the Secretary the authority to define other situations where it is appropriate to allow genetic information to be disclosed. This modification will ensure that genetic information can still be used, where appropriate, to help improve important biomedical research efforts.

HEALTH INSURANCE IN THE AGE OF GENETICS AN EXECUTIVE SUMMARY

The "Health Insurance in the Age of Genetics" report responds to the President's request for information on the potentials and perils of genetic testing. It includes information on the current state of legislation about genetics as well as recommendations for Federal legislation to improve protections against genetic discrimination.

The Progress and Promise of Genetic Testing. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. Tests for genetic predisposition to certain diseases and conditions -- such as Huntington's disease and certain types of breast cancer -- are already available and more genetic tests are on the horizon. In the next few years we will know the location of nearly every human gene and we are learning more and more about how genes interact. As genetic information becomes increasingly common, it will revolutionize our health care system. With this new technology, Americans will be able to determine conclusively whether or not they are in fact genetically predisposed to a disease. Those who are can begin early and often life-saving treatment and those who are not will gain much-needed peace of mind.

Genetic Discrimination: The Perils of This Progress. While progress in genetics can help millions of Americans, we know that genetic testing can be used by insurance companies and others to discriminate and stigmatize groups of people. Even those who have not yet or may never show signs of a disease are still at risk for discrimination. Studies have shown that eighty-five percent of Americans are still extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family. Twenty-two percent of people in families where someone has a genetic disorder report that they have been discriminated against by an insurance plan. In genetic testing studies at the National Institutes of Health (NIH), nearly a third of eligible people offered a test for breast cancer refused to take it. The overwhelming majority of those who refused tests cite concerns about health insurance discrimination and loss of privacy as the reason why.

State Initiatives and Why These Laws Are Insufficient. Nineteen states have already enacted laws to restrict the use of genetic information in health insurance and many others have introduced legislation. However, state legislation is insufficient to solve this problem for a number of reasons. First, private sector employer sponsored health plans, which covers half of all Americans, are exempt from state insurance laws due to ERISA preemption. Second, current state laws generally focus on genetic tests rather than a broader definition of genetic information such as family history, medical records, and physical exams. Finally, the variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

HIPAA: Gaps in the Current Federal Legislation. HIPAA took steps to prohibit genetic discrimination by preventing insurers from using genetic information as a "pre-existing condition" and denying or limiting coverage in group markets. However, HIPAA falls short in three areas. It does not: (1) prevent insurers in the individual market from denying coverage on the basis of genetic information; (2) assure that premiums are in no way based on genetic information both in the group and individual market; and (3) prevent insurance companies from disclosing genetic information to other insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

Recommendations for Federal Legislation. Any Federal legislation should address the three major areas not included in HIPAA:

Access in the individual market. The HIPAA protections should be extended to the individual market in the absence of a diagnosis. Only then will all Americans rest assured that they or their families will not be denied or lose their health care coverage based on their genetic information.

Affordability in the individual and group market. HIPAA did not prevent insurers -- in either the individual or the group market -- from increasing group premium rates based solely on knowledge about genetic information. New legislation must ensure that health plans do not use genetic information in any way when determining premiums.

Disclosing Genetic Information. New legislation should protect the privacy and confidentiality of genetic information by preventing health plans from releasing or demanding access to genetic information. It should impose restrictions on the disclosure of genetic information to other insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

Congressional Initiatives. Several bills have been introduced in this Congress which prohibits health plans from requesting or using genetic information to deny health care coverage or raise premiums. The bipartisan legislation introduced by Rep. Louise Slaughter, H.R. 306, addresses the three major gaps left by the HIPAA legislation and represents a strong foundation for this much-needed reform. The report recommends that the Administration build on this legislation and enact a bill that protects all Americans from the threat of genetic discrimination.

Summary of the President's Genetic Anti-Discrimination Legislative Priorities

- **Assuring access in the individual market.** Assures that Americans who are insured through the individual market will not be denied or lose their health care coverage based on their genetic information.

- **Enhancing affordability in the individual and group market.** Prevents insurers -- in either the individual or the group market -- from increasing group premium rates based on knowledge about genetic information. New legislation must ensure that health plans do not use genetic information in any way when determining premiums.

- **Protecting against inappropriate disclosure of genetic information.**
 - Protects the privacy and confidentiality of genetic information by preventing health plans from releasing or demanding access to genetic information.

 - Specifically imposes restrictions on the disclosure of genetic information to other insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

 - Gives the Secretary additional authority to determine other situations where it is inappropriate for health plans to disclose genetic information.

 - Protects biomedical research efforts by specifying which entities cannot receive genetic information from health plans. In so doing, it provides safe harbors for situations in which it is appropriate and, in fact, often extremely beneficial to disclose genetic information, including for important biomedical research efforts.

- **Providing for other technical modifications.** Contains other important technical changes to ensure that any legislation from the Hill does not undermine the Kassebaum-Kennedy legislation, does not interfere with the doctor-patient relationship, and does not impose undue administrative hassles on health plans.

**QUESTIONS AND ANSWERS
ON PREVENTING GENETIC DISCRIMINATION
IN HEALTH INSURANCE**

Q: IS THERE ANY EVIDENCE THAT INSURANCE COMPANIES ARE DISCRIMINATING AGAINST PEOPLE WITH A GENETIC PREDISPOSITION TO A DISEASE?

A: Medical researchers and physicians have reported that people are refusing to get genetic testing or to participate in medical research because they fear that this information could be used against them or a member of their family. We know that genetic information has been used to discriminate against people in the past.

In the early 1970's, health insurance coverage and jobs were denied to many African-Americans who were identified as carriers of sickle-cell anemia. We also know that a leading reason women refuse genetic testing for breast cancer is because they fear that insurance companies may charge excessively high premiums or deny health care coverage to either themselves or members of their families.

Moreover, over one-fifth of people who live in families where someone has a genetic disorder report that they have been discriminated against by an insurance plan. (Lapham et al., Science, October, 1996).

A 1985 Harris Poll of the general public revealed that over 85 percent of those surveyed indicated they were very concerned or somewhat concerned that insurers or employers might have access to and use genetic information.

Q: HOW MUCH WOULD THIS LEGISLATION COST?

A: We do not have any formal estimates on how much this legislation would cost. However, states that have enacted legislation in this area have not experienced any significant costs associated with it.

Q: HOW MANY AMERICANS WOULD BE AFFECTED BY THIS LEGISLATION?

A: This legislation would protect all Americans from having to pay higher premiums based on genetic information and from having their genetic information disclosed.

Q: WHY ISN'T THE ADMINISTRATION ADDRESSING THE PROBLEM OF EMPLOYMENT DISCRIMINATION BASED ON GENETIC SCREENING INFORMATION WITH THE SAME RIGOR IT IS TAKING IN THE HEALTH INSURANCE ISSUE?

A: Genetic discrimination by employers is no less an important issue. The Department of Labor, in conjunction with the Equal Employment Opportunity Commission, the Department of Justice, and the Department of Health and Human Services, is currently considering the feasibility of extending protections beyond current law for this explicit purpose. We anticipate that we will have their findings and recommendations sometime later this year. As we review this issue, we look forward to working with Members of Congress -- such as Senator Tom Daschle -- who have shown an interest in this area.

Q: DIDN'T THE KASSEBAUM-KENNEDY HEALTH REFORM LEGISLATION TAKE CARE OF THIS PROBLEM?

A: The Kassebaum-Kennedy legislation did take important steps to prevent health insurers from discriminating on the basis of genetic information. However, this legislation builds on these provisions in three important areas. It: (1) prevents insurers in the individual market from discriminating on the basis of genetic information in the absence of a positive diagnosis or treatment; (2) assures that group premiums, both in the group and the individual market, are not based on genetic information; and (3) restricts insurers and health plans from disclosing genetic information.

Access in the individual market. The HIPAA protections should be extended to the individual market. Only then will all Americans rest assured that they or their families will not be denied or lose their health care coverage based on their genetic information.

Affordability in the individual and group market. The Kassebaum-Kennedy legislation did not prevent insurers -- in either the individual or the group market -- from increasing group premium rates based on knowledge about genetic information. New legislation must ensure that health plans do not use genetic information in any way when determining premiums.

Disclosing Genetic Information. New legislation should protect the privacy and confidentiality of genetic information by preventing health plans from releasing or demanding access to genetic information. It should impose restrictions on the disclosure of genetic information to other insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

Q: THERE ARE A NUMBER OF BILLS ON THE HILL ON THIS ISSUE. WHY DOES THE PRESIDENT LIKE THE ONE INTRODUCED BY REPRESENTATIVE SLAUGHTER AND SENATOR SNOWE?

A: While there are many bills on the Hill and many important legislators with commendable commitments in this area, the President believes that this is the strongest bill to build on. The bill is based on the joint recommendations made by the National Institutes of Health's Working Group on Ethical, Legal, Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) to address the issue of genetic discrimination and health insurance. It addresses the three major gaps left by Kassebaum-Kennedy: (1) preventing health plans in the individual market from denying coverage on the basis of genetic information; (2) assuring that premiums settings are in no way based on genetic information; and (3) preventing health plans from disclosing genetic information to insurers, to plan sponsors, and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers.

Q: WHAT ARE THE DIFFERENCES BETWEEN THE SLAUGHTER-SNOWE LEGISLATION AND THE LEGISLATION THAT PRESIDENT IS SENDING TO CONGRESS?

A: The legislation that the President will be forwarding to the Hill builds off the Slaughter/Snowe bill and strengthens it by explicitly specifying that genetic information cannot be disclosed to insurers, plan sponsors (the employer), and other entities regulated by state insurance laws, such as life, disability, and long-term care insurers. It also gives the Secretary the authority to define other situations where it is appropriate to allow genetic information to be disclosed. This modification will ensure that genetic information can still be used, where appropriate, to help improve important biomedical research efforts. It also prohibits insurers from varying premiums in a group plan based on the genetic information of any individual in that group. It also contains some technical changes that protects the intent of the Kassebaum-Kassebaum and ensures that the patient-doctor relationship is not undermined.

Q: REPRESENTATIVES OF SOME DRUG COMPANIES SUCH AS THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS ASSOCIATIONS (PhRMA) THAT DO BIOMEDICAL RESEARCH ARE CONCERNED THAT THIS LEGISLATION WOULD PREVENT RESEARCHERS FROM GETTING ACCESS TO MUCH-NEEDED GENETIC INFORMATION. WILL THIS LEGISLATION UNDERMINE OUR PROGRESS IN THIS AREA?

A: Absolutely not. We want to make sure that this legislation does not undermine these important research efforts. In fact, part of the reason why the President is forwarding legislation to the Hill to improve on the Slaughter-Snowe legislation is that he wants to make sure that we have clarified the underlying bill to ensure that efforts bolster -- not harm -- the efforts of biomedical researchers.

Researchers like Dr. Francis Collins of the National Institute of Health's Human Genome Project are some of the strongest supporters of the President's efforts. Fear of genetic discrimination by potential research subjects has been cited as the biggest impediment to research in these fields. By removing this fear, the Administration will greatly reduce the number of potential research participants who presently shy away from participating in studies.

Q: AREN'T MANY STATES TAKING ACTION ON THIS ISSUE? WHY DO WE NEED FEDERAL LEGISLATION?

A: While nineteen states have taken action in this area and many more have proposed legislation this year, state legislation is insufficient to solve this problem. The variability among state bills could lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans. Moreover, the Employer Retirement Income Security Act (ERISA) exempts private sector employer-sponsored health plans that provide benefits through self-funded arrangements from state insurance laws. Thus, even if states enact legislation restricting the use of genetic information nearly one-half of the American population, would not be protected.

For the most part, health insurance plans do not have formal guidelines about coverage of genetic tests, instead making decisions to cover based on individual considerations. A Task Force on Genetic Testing survey of HMOs found that some, but not most, do cover predictive testing for breast and colon cancer in asymptomatic people. Kaiser Permanente and Blue Cross/Blue Shield have conducted in-House technology assessments of the BRCA1/2 tests and both have formulated policies for covering BRCA1/2 testing under certain conditions.

Q: WON'T THE GENETIC SCREENING ISSUE BE ADDRESSED BY THE HHS SECRETARY WHEN SHE RELEASES HER STATUTORILY REQUIRED REPORT ON PRIVACY ISSUES LATER THIS YEAR? ISN'T THE WORK BY MEMBERS INTERESTED IN PRIVACY, DISCLOSURE AND CONFIDENTIALITY ISSUES GOING TO ADDRESS THIS PROBLEM?

A: Scientific experts from the NIH feel strongly that the genetic information challenge raises a host of issues that merit immediate and separate attention. While there may be some overlap on these efforts, we believe this to be the best way to most comprehensively and effectively address this issue.

The patient confidentiality issues that HHS and the Congress are looking at separate and apart from the genetic information issue relate generally to diseases that individuals already have. In contrast, predilection and susceptibility to disease may raise different issues. Moreover, genetic information not only applies to one's own medical history, but to those of future generations as well.

These are all complicated and very unique matters that require very careful and deliberate consideration. They also merit separate legislation at least at the beginning of the legislative process.

Statements of Support for the President's Action on Genetic Discrimination

"I am very pleased to express my commitment to working with President Clinton and my colleagues in the Senate to develop bipartisan legislation designed to protect each and every one of us from being unfairly discriminated against on the basis of our genetic make-up."

-- Senator Jim Jeffords,
Chair, Senate Labor and
Human Resources Committee

"In my role as chairman of the Subcommittee on Public Health and Safety, I strongly support the intent of legislation which would prohibit discrimination in health insurance against healthy individuals and their families based on genetic information."

-- Senator Bill Frist
Chair, Subcommittee on Public
Health and Safety, Labor and Human
Resources Committee

"We owe a debt of gratitude to President Clinton, Vice President Gore, Secretary Shalala, and Dr. Collins for their hard work and leadership on bringing this issue to the public's attention, and I am so pleased that the Administration has pledged to fight for passage of this important legislation."

-- Representative Louise Slaughter

"On behalf of more than 400 organizations and 51,000 individuals who are members of the National Breast Cancer Coalition, I want to thank you for your leadership in support of legislation to protect women and their families from insurance discrimination on the basis of predisposition to disease.

As we have said many times in the past, you have shown time and again that you have the vision and the courage to take on the tough issues in breast cancer, to do the right thing rather than espouse the simple or popular position."

-- National Breast Cancer Coalition

"The Women's Legal Defense Fund applauds you for taking the lead on yet another issue of tremendous importance to women and their families -- prohibiting genetic discrimination in health insurance."

-- Women's Legal Defense Fund

"The Hereditary Susceptibility Working Group of the National Action Plan on Breast Cancer applauds your leadership and support of legislation to prohibit health insurance discrimination based on genetic information. We are very gratified that your personal commitment will bring this issue to the attention of the American public. While women can survive breast cancer, they cannot survive without health insurance."

--National Action Plan on Breast Cancer

"The issue of genetic nondiscrimination is not just about Jewish women, or even about breast cancer. As scientists race to map the human genome, this issue is sure to affect everyone. [...] Hadassah strongly applauds your endorsement of this historic legislation."

-- Hadassah,
The Women's Zionist
Movement of America

"We are deeply grateful to you for championing this important issue."

--Virginia Breast Cancer Foundation

"The Genome Action Coalition, comprised of more than 115 organizations, foundations, and corporations, would like to congratulate you and thank you for the extraordinary leadership you have shown with regard to the difficult issues which come about as a result of the progress of the Human Genome Project."

-- The Genome Action Coalition

"On behalf of the trustees and scientists of the Hereditary Disease Foundation, I wish to express our deep appreciation for your support of policies to prevent health insurance discrimination based on genetic information."

-- Hereditary Disease Foundation

"Your support [...] would help provide the protection against the misuse of genetic information that causes our families with genetic disorders to continue to be so vulnerable."

-- Alliance of Genetic Support Groups

"As the parent of a young adult with an incurable genetic disorder and as the past president of The Alliance of Genetic Support Groups, I am writing to thank you for speaking out against genetic discrimination."

-- Jayne Mackta,
Past President,
Alliance of Genetic Support Groups

"It is so important that you, as the leader of our fine nation, support this legislation so that an individual can not be discriminated against because they have a disease like Tuberos Sclerosis Complex, cystic fibrosis, Huntington's Disease, or any one of the genetic disorders."

-- National Tuberos Sclerosis Association

"This is an especially important issue for those at risk for Huntington's Disease, who often must live in fear not only of having an inherited disease, but also of losing their jobs and their health benefits when they are in need of them most."

-- Huntington's Disease Society of America

"We are thrilled with your support of legislation preventing genetic discrimination in health insurance. [...] We feel it is obscene for insurance companies to deny coverage to people like us merely because science has now provided a way to know about our genetic defects."

-- A-T Children's Project

"Your support of this legislation to prohibit genetic discrimination is very much needed to give the proposal the necessary momentum to gather votes and pass Congress. We need the protection this legislation can provide and appreciate all the help you can bring to resolve this problem."

-- Sickle Cell Service

"I am writing to applaud your announcement of support for legislation which would protect consumers from health insurance discrimination on the basis of genetic information. [...] These safeguards are crucial to keep scientific advances from becoming cruelly misused in our society."

-- American Nurses Association

"The American Academy of Pediatrics applauds your action on the issue of genetic screening. Your dedicated leadership on this issue is critical to protecting those children vulnerable to genetic discrimination."

-- American Academy of Pediatrics

"The Center for Patient Advocacy strongly supports your efforts to protect American patients from genetic discrimination. [...] With your leadership and active support we are confident that the patients of today and those of tomorrow benefit from the medical technology that advances in genetics make possible. We, at the Center for Patient Advocacy, applaud your efforts in behalf of all American patients."

-- Center for Patient Advocacy

Clinton to Support Legislation Guarding Against Gene-Test Bias

Inherited Risk for Disease Has Kept Some From Getting Insured

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 [this 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 winning 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.

Neil 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

PREVENTING INSURANCE DISCRIMINATION BASED ON GENETIC INFORMATION

HC -
Genetic
screening

In his commencement address at Morgan State University today, the President highlighted the great potential and possible perils of recent advances in genetic research. To address widespread concerns about potential abuses, the President Clinton called upon Congress to pass bipartisan legislation that would prohibit insurance companies from using genetic information to determine premium rates or eligibility for health plans.

ADVANCES IN SCIENCE: POTENTIALS AND PERILS

Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. Tests for genetic predisposition to certain diseases and conditions -- such as Huntington's disease and certain types of breast cancer -- are already available and more genetic tests are on the horizon. But genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. We know that genetic information has been used to discriminate against people in the past. In the early 1970's, health insurance coverage and jobs were denied to many African-Americans who were identified as carriers of sickle-cell anemia. Studies have shown that many Americans are extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family.

ADDITIONAL PROTECTIONS NEEDED

The new legislation will build on the important anti-discrimination insurance laws in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It would strengthen HIPAA by ensuring that in all cases genetic information will not be inappropriately used or disclosed by health plans. This would not only apply to health plans covered under ERISA but also provides blanket protections for all Americans who purchase individual policies.

More than a dozen states have already enacted laws to restrict the use of genetic information in health insurance and at least thirty-one others have introduced legislation in 1997. However, state legislation is insufficient to solve this problem. The variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

BUILDING ON THE EXISTING BIPARTISAN LEGISLATION

Several bills have been introduced in this Congress, which prohibit health plans from requesting or using genetic information as a basis to deny health care coverage or raise premiums. The President believes that the bipartisan legislation introduced by Rep. Louise Slaughter, H.R. 306, represents a strong foundation for this much-needed reform. The Slaughter bill contains strict protections against disclosure of an individual's genetic information by health plans. The President looks forward to working with Rep. Slaughter and other members in both parties to pass legislation on this important issue in this Congress.

QUESTIONS AND ANSWERS ON GENETIC TESTING

Q: DIDN'T WE ALREADY TAKE CARE OF THIS PROBLEM IN THE KASSEBAUM-KENNEDY HEALTH REFORM LEGISLATION?

A: The Kassebaum-Kennedy legislation did take important steps to prevent health insurers from discriminating on the basis of genetic information. However, this legislation builds on these provisions in three important areas: (1) prevents insurers in the individual market from discriminating on the basis of genetic information (2) assures the premiums setting is in no way based on genetic information both in the group and individual market; and (3) prevents insurance from disclosing genetic information.

- **Access in the Individual Market.** The Kassebaum-Kennedy law says that employers may not use genetic information as a pre-existing condition unless the illness associated with the pre-existing condition has already been diagnosed. In that case, the health plan could deny health care coverage for a maximum of twelve months.

However, Kassebaum-Kennedy did not address the issue of genetic information for Americans who are part of the individual insurance market. This legislation would take the next step by protecting Americans who have an health insurance in the individual market from being denied health care coverage based on their genetic information.

- **Affordability in the Individual and the Group Market.** The Kassebaum-Kennedy legislation did not address the issue of affordability in the insurance market. Thus it does not prevent insurers from increasing group premium rates based on knowledge about genetic information. (It would prevent health plans from charging an individual higher premiums based on their genetic information).

This new legislation would prevent health plans from setting premium rates based on genetic information, both in group health plans and in the individual market.

- **Disclosing Genetic Information.** This new legislation would also prevent health plans from releasing genetic information. If genetic information from health plans were accessible, it would make it much easier for other parties (probably employers and other non-health insurers) to misuse this information.

Q: AREN'T LOTS OF STATES TAKING ACTION ON THIS ISSUE. WHY DO WE NEED FEDERAL LEGISLATION?

A: More than a dozen states have taken action in this area and 31 more have proposed legislation. others have introduced legislation in 1997. However, state legislation is insufficient to solve this problem. The variability among state bills will lead to a lack of

uniformity across the nation as to whether and how genetic information may be used by health plans. Moreover, Employer Retirement Income Security Act (ERISA) exempts self-funded plans from state insurance laws. Thus even if states enact legislation to build on Kassebaum-Kennedy legislation, a large fraction of the population in self-funded plans would not be protected.

Q: IS THERE ANY EVIDENCE THAT INSURANCE COMPANIES ARE DISCRIMINATING AGAINST PEOPLE WITH A GENETIC PREDISPOSITION TO A DISEASE?

A: Medical researchers and physicians have reported that people are refusing to get genetic testing or to participate in medical research because they fear that this information could be used against them or a member of their family. We know that genetic information has been used to discriminate against people in the past. In the early 1970's, health insurance coverage and jobs were denied to many African-Americans who were identified as carriers of sickle-cell anemia. We also know that a leading reason women refuse genetic testing for breast cancer is because they fear that insurance companies may deny health care coverage for either themselves or members of their families or charge excessively high premiums. Moreover, 22 percent of people who live in families where someone has a genetic disorder report that they have been discriminated against by an insurance plan. (Lapham et al., Science, Oct 1996).

Q: HOW WAS GENETIC TESTING USED IN THE 1970s TO DISCRIMINATE AGAINST AFRICAN-AMERICANS?

A: Genetic testing was used both by employers and health insurance plans to discriminate against African-Americans who had one or two altered copies of the sickle cell gene. There were newborn screening programs, pre-employment tests done, and other widespread screening done to test for this genetic disorder. However, most people mistakenly believed that if an individual had at least one altered gene, they would likely develop sickle cell anemia. In fact, both of the genes must be altered to be vulnerable to this disorder.

Q: THERE ARE LOTS OF BILLS OUT ON THE HILL ON THIS ISSUE. WHY DOES THE PRESIDENT LIKE THE ONE INTRODUCED BY REPRESENTATIVE SLAUGHTER?

A: The Slaughter Bill is based on the joint recommendations made by the National Institutes of Health's Working Group on Ethical, Legal, Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) to address the issue of genetic discrimination and health insurance. It addresses all of the central issues: using genetic information to deny or limit any coverage; establishing premium payments based on genetic information or an individual's request for genetic information; and disclosure of genetic information.

Q: HOW MUCH WOULD THIS LEGISLATION COST?

A: We do not have any formal estimates on how much this legislation would cost. However, states who have enacted legislation in this area have not experienced any major costs associated with this.

Q: HOW MANY AMERICANS WOULD BE AFFECTED BY THIS LEGISLATION?

A: This legislation would protect all Americans from having to pay higher premiums based on genetic information and from having their genetic information disclosed.

Genetic Screening Protection Legislation Would:

- 1) Prohibit insurers and other health plans from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility for insurance.
- 2) Prohibit health plans from establishing differential rates or premium payments for individual insurance policies or group-wide plans based on genetic information.
- 3) Prohibit health plans from requesting or requiring collection or disclosure of genetic information.
- 4) Prohibit health plans or other holders of genetic information from releasing genetic information without prior written authorization of the individual.