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 <u>not</u>: (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. 89) 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 others 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.
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> **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.
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> **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 feasiblity 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 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 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 Tuberous Sclerosis Complex, cystic fibrosis, Huntington's Disease, or any one of the genetic disorders."

-- National Tuberous 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 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 include 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. That 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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  -- 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.

THE FOLLOWING GROUPS HAVE ENDORSED H.R. 306, THE GENETIC INFORMATION NONDISCRIMINATION IN HEALTH INSURANCE ACT OF 1997

Alliance for Aging Research
Alzheimer's Association
American Academy of Family Physicians
American Academy of Neurology
American Academy of Pediatrics
American Cancer Society
American Heart Association
American Medical Women's Association
American Nurses Association
American Public Health Association
Amyotrophic Lateral Sclerosis Association
Association of Women's Health, Obstetric and Neonatal Nurses
Cardiac Arrhythmia Research and Education Foundation
Center for Patient Advocacy
Coalition for Heritable Disorders of Connective Tissue
Cooley's Anemia Foundation
Council for Responsible Genetics
Cystic Fibrosis Foundation
Dysautonomia Foundation
Dystonia Medical Research Foundation
Epilepsy Foundation of America
Hemochromatosis Foundation, Inc.
International Patient Advocacy Association
Jeffrey Modell Foundation
Leadership Conference of National Jewish Women's Organizations, which includes:
- American Jewish Congress
- Amit Women
- B'nai B'rith
- Emunah Women of America
- Hadassah
- Jewish Labor Committee
- Jewish War Veterans
- Jewish Women International
- Na'amat USA
- National Council of Jewish Women, Inc.
- National Jewish Community Relations Advisory Council
- Union of American Hebrew Congregations
- Women's American ORT
- United Synagogue of Conservative Judaism

Leukemia Society of America
March of Dimes
National Breast Cancer Coalition
National Hemophilia Foundation
National Incontinentia Pigmenti Foundation
National Industries for the Blind
National Marfan Foundation
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National Organization for Rare Disorders
National Osteoporosis Foundation
National Ovarian Cancer Coalition
National Tuberous Sclerosis Association
National Women's Health Network
National Women's Law Center
Osteogenesis Imperfecta Foundation
Public Citizen
Sjogren's Syndrome Foundation
Spina Bifida Association of America
Spondylitis Association of America
Sturg-Weber Foundation
Tourette Syndrome Foundation
Wilson's Disease Foundation
Women's Bar Association
Women's Legal Defense Fund

COSPONSORS OF H.R. 306, THE GENETIC INFORMATION NONDISCRIMINATION IN HEALTH INSURANCE ACT
(Total 109)

Rep. Neil Abercrombie
Rep. Gary Ackerman
Rep. Spencer Bachus
Rep. John Baldacci
Rep. Tom Barrett
Rep. Howard Berman
Rep. Sanford Bishop
Rep. David Bonior
Rep. Rick Boucher
Rep. Corrine Brown
Rep. George Brown
Rep. Benjamin Cardin
Rep. Julia Carson
Rep. Donna Christian-Green
Rep. Eva Clayton
Rep. John Conyers
Rep. Bill Coyne
Rep. Pat Danner
Rep. Danny Davis
Rep. Peter DeFazio
Rep. Diana DeGette
Rep. William Delahunt
Rep. Rosa DeLauro
Rep. Ron Dellums
Rep. Anna Eshoo
Rep. Lane Evans
Rep. Eni Faleomavaega
Rep. Chaka Fattah
Rep. Vic Fazio
Rep. Bob Filner
Rep. Tom Foglietta
Rep. Mark Foley
Rep. Jon Fox
Rep. Barney Frank
Rep. Martin Frost
Rep. Elizabeth Furse
Rep. Sam Gejdenson
Rep. Henry Gonzalez
Rep. Gene Green
Rep. Luis Gutierrez
Rep. Alcee Hastings
Rep. Bill Hefner
Rep. Earl Hilliard
Rep. Maurice Hinchey
Rep. Tim Holden
Rep. Steve Horn
Rep. Jesse Jackson, Jr.
Rep. Sheila Jackson-Lee
Rep. Nancy Johnson
Rep. Joe Kennedy
Rep. Dale Kildee
Rep. John LaFalce
Rep. Nick Lampson
Rep. John Lewis
Rep. Frank LoBiondo
Rep. Zoe Lofgren
Rep. Nita Lowey
Rep. Carolyn Maloney
Rep. Thomas Manton
Rep. Edward Markey
Rep. Matthew Martinez
Rep. Robert Matsui
Rep. Carolyn McCarthy
Rep. Jim McDermott
Rep. John McHugh
Rep. James McGovern
Rep. Cynthia McKinney
Rep. Marty Meehan
Rep. Carrie Meek
Rep. David Minge
Rep. Patsy Mink
Rep. James Moran
Rep. Connie Morella
Rep. Jerrold Nadler
Rep. Richard Neal
Rep. Eleanor Holmes Norton
Rep. James Oberstar
Rep. John Olver
Rep. Frank Pallone
Rep. Bill Pascrell
Rep. Ed Pastor
Rep. Donald Payne
Rep. Nancy Pelosi
Rep. John Edward Porter
Rep. Lynn Rivers
Rep. Marge Roukema
Rep. Lucille Roybal-Allard
Rep. Bobby Rush
Rep. Loretta Sanchez
Rep. Bernie Sanders
Rep. Charlie Schumer
Rep. Jose Serrano
Rep. Christopher Smith
Rep. Pete Stark
Rep. Louis Stokes
Rep. Bob Stump
Rep. Ellen Tauscher
Rep. Bennie Thompson
Rep. Karen Thurman
Rep. John Tierney
Rep. Esteban Torres
Rep. Edolphus Towns
Rep. Jim Traficant
Rep. Maxine Waters
Rep. Mel Watt
Rep. Henry Waxman
Rep. Lynn Woolsey
Rep. Albert Wynn
Rep. Sidney Yates

Jeffords
Domenici → Too much research process – in the statue

Sarah's copy.

File Genetics NHGRI

Comparison of Genetic Information Non-Discrimination Bills in the 105th Congress

Several bills dealing with genetic information and discrimination in the health insurance and/or employment context have been introduced in the 105th Congress. This chart summarizes the major provisions in each bill.

	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Title	Administration's Health Insurance Proposal	"Genetic Information Nondiscrimination in Health Insurance Act of 1997"	"Genetic Information Health Insurance Non-discrimination Act of 1997"	"Children's National Security Act"	Genetic Protection in Insurance Coverage Act	"Genetic Privacy & Non-discrimination Act of 1997"	"Genetic Confidentiality and Non-discrimination Act of 1997"	Genetic Non-discrimination in the Workplace Act	"Genetic Justice Act"/ "Genetic Employment Protection Act of 1997"	Administration's Workplace Proposal

→ Daschle/Dodd amendment

en lieu of Snowe

→ Stearns

→ House strategy can for hearings

Daschle/Dodd amendment

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*Indicates the original comparison prepared by the Women's Legal Defense Fund (August 26, 1997)
#Indicates an addendum prepared by the National Human Genome Research Institute (February 1998)

	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Original Co-Sponsors	N/A	**House:** Abercrombie, Ackerman, Barrett (WI), Brown (FL), Brown (CA), Clayton, Danner, DeFazio, Dellums, Eshoo, Evans, Gejdenson, Gonzalez, Green, Hilliard, Hinchey, Jackson-Lee (TX), Kennedy (MA), Kildee, LaFalce, Lewis (GA), Lofgren, Lowey, Maloney (NY), McDermott, Meek (FL), Morella, Nadler, Payne, Pelosi, Rivers, Sanders, Serrano, Smith (NJ), Stark, Thurman, Towns, Waters, Waxman, DeLauro, Matsui, Watt (NC), Roybal-Allard		Clayton, DeGette, Hooley (OR), Jackson-Lee (TX), Lofgren, Lowey, McKinney, Maloney (NY), Millender-McDonald, Mink (HI), Norton, Slaughter, Waters, Woolsey	None	Armey, Bishop, Brown (OH), Canady (FL), Davis (VA), DeFazio, Duncan, Faleomavaega, Farr (CA), Foley, Fowler, Gekas, Gillmor, Gilman, Gonzalez, Green, Herger, Hyde, Johnson (CT), Kennedy (MA), Lofgren, McCollum, McHugh, McKinney, Nadler, Oberstar, Oxley, Sensenbrenner, Shadegg, Smith (NJ), Stump, Taylor (NC), Traficant, Upton, Waxman, Weldon (FL), Woolsey	Jeffords, Dodd ↓ still Dem. only	None	**House:** Lazio	N/A
Date Introduced	July 14, 1997	January 7, 1997 (House) January 21, 1997 (Senate)	January 7, 1997	May 22, 1997	July 22, 1997	July 17, 1997	March 11, 1997	July 22, 1997	July 22, 1997 (Senate) July 25, 1997 (House)	January 20, 1998

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Committee	N/A	**House:** Commerce, Ways and Means, Education and the Workforce **Senate:** Labor and Human Resources	Commerce, Education and the Workforce	Commerce, Ways and Means, Education and the Workforce, Judiciary, Transportation and Infrastructure, Banking and Financial Services, Budget	Commerce, Education and the Workforce	Commerce, Government Reform and Oversight, Education and the Workforce, Veterans' Affairs	Labor and Human Resources	Education and the Workforce	**Senate:** Labor and Human Resources **House:** Education and the Workforce	N/A
Defines genetic information	Yes. Defined as "Information about genes, gene products or inherited characteristics that may derive from the individual or a family member."	Defined as "information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of the individual."	Defined as "information about genes, gene products, or inherited characteristics that may derive from an individual or a blood-relative of the individual."	Defined as "information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of the individual."	Yes. Defined as "Information about genes, gene products or inherited characteris-tics that may derive from an individual or a family member."	Defined as "information about the genes of the individual or a member of the individual's family or about any gene products or inherited characteristics that may derive from the individual or a member of the individual's family."	Defined as "information from a human DNA sample about molecular genotype, information from mutation analysis, or information about nucleotide sequence of a gene."	No	Defined as "information (including information regarding carrier status and information derived from a laboratory test that identifies mutations in specific genes or chromosomes, a physical medical examination, a family history, and a direct analysis of genes or chromosomes) about a gene, gene product, or inherited characteristic that derives from the individual or a family member of the individual."	No

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Defines genetic test	Defined as "the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes.	No	Defined as "a test for determining the presence or absence of genetic characteristics in an individual."	No	Defined as "a test for determining the presence of absence of genetic characteristics in an individual, including tests of nucleic acids such as DNA, RNA and mitochon-drial DNA, chromosomes or proteins in order to diagnose a genetic characteristic.	Defined as "a test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids such as DNA, RNA and mitochondrial DNA, chromosomes or proteins in order to diagnose a genetic characteristic."	No	No	Not specifically defined, but included in the definition of "genetic services," which is defined as "genetic evaluation, genetic testing, genetic counseling, and related services."	No
Defines employer/ employee	N/A	No	No	No	N/A	As defined by section 701 of the Civil Rights Act of 1964.	"Employer" defined as under section 3(5) of ERISA.	No	As defined by section 701 of the Civil Rights Act of 1964.	Not specifically defined, employer/but applies to public employee and private-sector employers, unions and labor management groups that conduct joint apprenticeship and other training programs. Employment agencies and licensing agencies that issue licenses, certificates and other credentials required to engage in various professions and occupations.

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Defines group health plan	No	No	No	No	No	Group health plan/Health insurance issuer/Health insurance coverage as defined in section 733 of ERISA.	No. See definition below of "insurer."	N/A	N/A	N/A
Defines insurer	Yes. Defined as "insurance provider refers to an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans where fully insured or self-funded."	No	No	No	Yes. Defined as "an insurance company, health care service contractor, fraternal benefit organization, insurance agent third party administrator, insurance support organization or other person subject to regulation under state insurance laws. Includes self-funded health plans and health plans regulated under ERISA."	No	Defined as "an insurance company, insurance service, or insurance organization" (including HMO) licensed and regulated by state law. **Does not include a "group health plan."**	N/A	N/A	N/A

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
HEALTH INSURANCE DISCRIMINATION PROHIBITIONS	Yes. Insurers should be prohibited from varying rates charged to a group based on *presymptomatic* genetic information and from releasing genetic information for non-treatment purposes without prior authorization. Insurers in the individual market should be prohibited from requesting or requiring genetic information except where the information relates to a disease or condition for which the individual has been positively diagnosed; from using genetic information in the absence of a diagnosis to deny, limit or vary coverage or to set rates; and from requiring individuals to undergo testing.	Yes. Plan/issuer may not "deny, cancel, or refuse to renew such benefits or such coverage, or vary the premiums, terms, or conditions for such benefits or such coverage, for any participant or beneficiary under the plan--(1) on the basis of genetic information; or (2) on the basis that the participant or beneficiary has requested or received genetic services."	Only expands "genetic information" provision of HIPAA nondiscrimination section by inserting "or a request for, or receipt of, genetic information or a genetic test" after "genetic information."	Yes. Plan/issuer may not "deny, cancel, or refuse to renew such benefits or such coverage, or vary the premiums, terms, or conditions for such benefits or such coverage, for any participant or beneficiary under the plan--(1) on the basis of genetic information; or (2) on the basis that the participant or beneficiary has requested or received genetic services."	Yes. On the basis of genetic information, insurers should be prohibited from: refusing to enroll; determining a rate; offering or providing different terms, conditions or benefits; or otherwise consider genetic information in the provision of insurance coverage or benefits.	Yes. Plan/issuer "may not use genetic information to reject, deny, limit, cancel, refuse to renew, establish differential rates or premium payments for, or otherwise affect benefits . . . ."	Yes. Insurer shall not "1) terminate, restrict, limit, refuse to renew, or otherwise apply conditions to the coverage of an individual or family member under the health policy or plan involved, or restrict the sale of the health policy or plan to an individual or family member; 2) deny coverage or exclude an individual or family under the health policy or plan; or 3) impose a rider that excludes coverage for certain benefits or services under the health policy or plan for an individual/family member; 4) establish differentials in premium rates or cost-sharing for coverage under health policy or plan for an individual/family member; or 5) otherwise discriminate against an individual or family member in the provision of health insurance coverage; on the basis of any molecular genetic information about a healthy individual or a healthy family member, or on the basis of a request for or receipt of genetic services by an individual/family member."	N/A	No	N/A

PHOTOCOPY PRESERVATION

	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Amends HIPAA "nondiscrimination" provision	Yes. Expands nondiscrimination to rates charged to a group.	No	Yes. Expands "genetic information" provision of HIPAA nondiscrimination section by inserting "or a request for, or receipt of, genetic information or a genetic test" after "genetic information."	No	Yes. Cannot determine a rate based on genetic information.	Yes. Expands "genetic information" provision of HIPAA non-discrimination section by inserting "or a request for, or receipt of, genetic information or a genetic test" after "genetic information."	No	N/A	N/A	N/A
Applies to group plans	Yes. Amends ERISA	Yes--amends ERISA.	Yes--amends ERISA.	Yes--amends ERISA.	Yes	Yes--amends ERISA (also applies to programs administered by the VA).	Applies to "insurers" (see definition section above) but not to "group health plans." Insured ERISA plans would be covered but not self-insured ERISA plans.	N/A	N/A	N/A

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Prohibits plans from varying premiums on the basis of genetic information in the group market	Yes. Insurers shall not adjust premium or contribution rates on the basis of presymptomatic genetic information or a request for or receipt of genetic services. Stem gutter adjusting premium rate	Probably. States that plan/issuer "may not . . . vary the premiums, terms, or conditions" on the basis of genetic information. Presumably this would restrict premium differentials within a group as well as premiums charged to an entire group.	Only to the extent that HIPAA provides this protection. HIPAA prohibits premium differentials within a group; HIPAA does not restrict the premium charged to the entire group.	Probably. States that plan/issuer "may not . . . vary the premiums, terms, or conditions" on the basis of genetic information. Presumably this would restrict premium differentials within a group as well as premiums charged to an entire group.	Yes. Insurers cannot determine rates on basis of genetic information.	Probably. Plan/issuer may not use genetic information to "establish differential rates or premium payments for, or otherwise affect benefits provided . . . ." Presumably this would restrict premium differentials within a group as well as premiums charged to an entire group.	Yes. Insurer shall not "establish differentials in premium rates or cost-sharing for coverage under health policy or plan for an individual or family member."	N/A	N/A	N/A
Applies to individual coverage	Yes. Expands HIPAA protections to the individual market.	Yes	The bill does not contain a nondiscrimination ban applicable to insurers in the individual market. Provisions relating to collection and disclosure of genetic information apply to insurers in the individual market (see below).	Yes	Yes	Yes	Yes	N/A	N/A	N/A

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Prohibits plans from varying premiums on the basis of genetic information in the individual market	Yes	Yes	No	Yes	Yes	Yes	Yes	N/A	N/A	N/A
Prohibits plans from requiring people to disclose genetic information	Yes, but in individual market, insurers can request genetic information relating to a disease or condition which has been positively diagnosed.	Yes	Yes	Yes	Yes	Not explicitly. Plan/issuer may not use genetic information to discriminate against employees, but there is no specific language prohibiting plans from requiring people to disclose.	Yes	N/A	N/A	N/A
Prohibits plans from requiring people to take genetic tests	Yes	No mention of the taking of a genetic test, but plan is prohibited from requiring people to disclose genetic information (see above).	Yes	No mention of the taking of a genetic test, but plan is prohibited from requiring people to disclose genetic information (see above).	Yes	No	Yes	N/A	N/A	N/A

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Requires written authorization before plans can disclose genetic information	Yes. Authorization required for any entity that is a member of the same controlled group; any other insurer; the MIB; any plan sponsor; or any other person the Secretary may specify in regulations.	Yes. Required for each disclosure and must include identification of person to whom disclosure would be made.	Yes. Description of the information, to whom, and purpose required for each disclosure.	Yes. Required for each disclosure and must include identification of person to whom disclosure would be made.	No	Yes. Description of the information, to whom, and purpose.	Yes. Requires signed, dated, identification of person authorized to make disclosure; description of the specific information to be disclosed; identification of person to whom disclosing; description of purpose of disclosure; expiration date of authorization; revocation/ amendment statement. The bill also states: "A general authorization for the release of medical records shall not be construed to be an authorization for disclosure of genetic information about the molecular genotype of an individual with respect to any genetic trait."	N/A	N/A	N/A

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Exceptions to written authorization	Yes. For treatment purposes and claims payment or benefit coordination.	No	Yes--if authorized under certain criminal laws; required by court order; for testing paternity; for purpose of providing genetic information to blood relatives for a medical diagnosis; for identifying a body.	No	N/A	Yes---if authorized under certain criminal laws; required by specific court order; authorized under law for establishing paternity; for identifying a body.	Yes. Information can be disclosed "to the extent reasonable in the exercise of judgment for professional medical consultation for the direct benefit of a patient," or as otherwise required by federal or state law. Section 204 of the bill also includes extensive procedures relating to compulsory disclosure of genetic information in court proceedings brought against people who "store" genetic information in "clinical records." This may include health plans and employers if they "store" genetic information in "clinical records."	N/A	N/A	N/A

PHOTOCOPY
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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Creates private cause of action by individual for damages	Yes	Yes. Plan/issuer "may in the court's discretion be liable . . . for compensatory, consequential, and punitive damages."	No	Yes. Plan/issuer "may in the court's discretion be liable . . . for compensatory, consequential, and punitive damages."	No	No	No	N/A	N/A	N/A
Authorizes Attorney General to pursue civil penalties/injunctive relief	No	No	No	No	No	No	Yes. AG may bring action to restrain a person violating or about to violate provisions of the Act via TRO or preliminary/ permanent injunction. If person knew/should have known violating Act, court can require civil penalty of not more than $50,000 for each violation and may require reasonable costs, including atty fees.	N/A	N/A	N/A
Requires insurers to provide applicants/enrollees with an understandable, written statement of their rights	No	No	No	No	No	No	Yes	N/A	N/A	N/A

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
EMPLOYMENT DISCRIMINATION PROHIBITIONS	N/A	No	No	No	N/A	Yes. Employer may not "attempt to acquire, or use the genetic information of an employee or applicant for employment or require a genetic test of an employee or applicant for employment for the purpose of distinguishing among employees or applicants for employment or for the purpose of discriminating against or restricting any right or benefit otherwise due or available to an employee or applicant for employment .."	Yes. Employer shall not "request, require, or use the genetic information" of an employee/potential employee for the purpose of restricting any right or benefit otherwise due.	No. Restricts access to genetic information, but does not have discrimina-tion provisions.	Yes. Employer shall not: "1) fail or refuse to hire or to discharge any individual, or otherwise to discriminate against any individual with respect to the compensation, terms, conditions, or privileges of employment of the individual . . .; or 2) limit, segregate, or classify the employees . . ." because of "genetic information with respect to the individual, including an inquiry by the individual regarding genetic services." Bill also has similar sections regarding labor organizations, employment agencies, and training programs. In addition, an employer shall not "3) request or require the collection for the employer or disclosure to the employer of genetic information . . . ." except under certain circumstances (see below for exceptions).	Yes. 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.

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	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Exceptions	N/A	N/A	N/A	N/A	N/A	Yes. If genetic information or genetic test is "job-related and consistent with business necessity, or is required under Federal or State law."	Yes. Employer "may request or require or use" the genetic information of an employee for the purpose of: "(1) permitting a genetically susceptible employee to avoid occupational exposure to substances with a mutagenic or teratogenic effect; or (2) determining a genotype that is otherwise directly related to the work and is consistent with business necessity."	N/A	Yes. Employer may "request or require collection . . . of genetic information" if: "1) the employer made the request or requirement after making an offer of employment; 2) the information is job-related for the position in question and consistent with business necessity; and 3) the knowing and voluntary written consent of the individual has been obtained for the request or requirement, and the collection or disclosure."	Yes. (1) Employer shuld be permitted to monitor employees for the effects of a particular substance found in the workplace. Infored consent required. (2) The statutory authority of a federal agency or contractor to promulgate regulations, enforce workplace safety and health laws, or conduct occupational or other health research should not be limited. (3) An employer should be able to disclose genetic information for research and other purposes with the written, informed consent of the individual.

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PRESERVATION

	#Administration's Health Insurance Proposal December 17, 1997	*H.R. 306/S.89 Slaughter/ Snowe	*H.R. 328 Solomon	*H.R. 1726 Furse (Same as H.R. 306)	#H.R. 2216 J. Kennedy	*H.R. 2198 Stearns	*S. 422 Domenici	#H.R. 2215 J. Kennedy	*S. 1045/H.R. 2275 Daschle/ Lowey	#Administration's Workplace Proposal January 20, 1998
Confidentiality provision	N/A	N/A	N/A	N/A	N/A	Yes. Employer shall not "1) allow access to genetic info of employees . . .;" (see exceptions below).	No	Yes. No employer may obtain from any source genetic information about an employee unless authorized as follows: authorization is in writing, signed by the individual and dated on the date of signature. The authorization is not on a form used for any other purpose. The employer authorized to receive the information must be specifically named in the authorization. The employer must provide the employee with a written statement of the uses which the employer intends for such genetic information.	Yes. If an employer/labor organization/ employment agency has genetic information, it "shall maintain the information on separate forms and in separate medical files, and treat the information as a confidential medical record . . . " (see exceptions below).	Yes. Employers should not obtain or disclose genetic information about employees or potential employees under most circumstances.

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Exceptions to confidentiality provision	N/A	N/A	N/A	N/A	N/A	Yes. Employer can "allow access to genetic information . . . to persons whose duties and responsibilities in connection with the employer require access to such information for purposes consistent with subsection (a) . . . " (subsection (a) includes determinations of job-relatedness and business necessity). It is unclear if provision requiring "prior, written, and informed consent of the employee" applies here.	N/A	None	Yes. If employee provides "knowing and voluntary written consent," employer may 1) inform supervisor regarding necessary restriction of work/duties of, or a necessary accommodation for, the employee; 2) inform first aid/safety personnel; and 3) provide relevant info to government official investigating compliance with this Act, on request.	Yes. Exceptions for: (1) Genetic testing and use of genetic information to monitor employees for effects of a particular workplace substance. (2) Statutory authority of a federal agency to conduct occupational research. (3) For research and other purposes with the written informed consent of the individual.

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	N/A	N/A	N/A	N/A	The bill does not have a clear prohibition on disclosure of genetic information by employers.	Yes. "A person may disclose genetic information characterized from the DNA sample of an individual only with the written authorization of the individual." Written authorization requires signed, dated, identification of person authorized to make disclosure; description of the specific information to be disclosed; identification of person to whom disclosing; description of purpose of disclosure; expiration date of authorization; revocation/ amendment statement.	No specific requirement for authorization, but provides for a penalty if employer discloses without authorization.	Yes. Written authorization required for release of information under confidentiality provision (see above). Otherwise, disclosure other than to employee (at the employee's request) is prohibited.	Yes. See above

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Exceptions to written authorization	N/A	N/A	N/A	N/A	N/A	See above.	Yes. Information can be disclosed "to the extent reasonable in the exercise of judgment for professional medical consultation for the direct benefit of a patient," or as otherwise required by federal or state law. Section 204 of the bill also includes extensive procedures relating to compulsory disclosure of genetic information in court proceedings brought against people who "store" genetic information in "clinical records." This may include health plans and employers if they "store" genetic information in "clinical records."	No. See above	No	No

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Creates private cause of action by individual for damages	N/A	N/A	N/A	N/A	N/A	Enforcement through sections 705-09 of Civil Rights Act of 1964, so employee must exhaust administrative remedies before filing suit. These sections of Title VII do not provide for damages--only equitable relief (i.e., backpay, reinstatement, injunctive relief, attorneys fees and costs).	Yes. Liable for actual damages sustained as a result of the violation or $50,000, whichever is greater. If violation resulted in profit/monetary gain, treble damages. If successful action, costs and reasonable atty fees as determined by the court. **Bill also states: "may be enforced in accordance with title VII."**	Yes. Civil action for actual damages and equitable relief.	Yes. Employee may bring action in federal or state court. Court may award any appropriate legal or equitable relief.	Yes. Private lawsuit in federal or state court.
Statute of limitations	N/A	N/A	N/A	N/A	N/A	Enforced through sections 705-09 of Civil Rights Act of 1964, which requires that charges be filed within 180-300 days of the alleged violation.	Yes. 6 years after date alleged violation was/should have been discovered. If disabled (i.e. minor, incapacity b/c mental illness) tolling is 10 years after disability is removed. **Bill also states: "may be enforced in accordance with title VII," which has a different statute of limitations.** (See Stearns)	No	No specific provision in bill, so state law would generally apply (average 2-3 years).	No

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Authorizes Attorney General to pursue civil penalties/injunctive relief	N/A	N/A	N/A	N/A	N/A	Enforcement through sections 705-09 of Civil Rights Act of 1964, which provides for action by the Attorney General in limited circumstances.	Yes. AG may bring action to restrain a person violating or about to violate provisions of the Act via TRO or preliminary/permanent injunction. If person knew/should have known they were violating Act, court can require civil penalty of not more than $50,000 for each violation and may require reasonable costs, including atty fees. **Bill also states: "may be enforced in accordance with title VII," which provides for actions by the AG in limited circumstances.**	No	No	Recommends relief through EEOC, DOL or other appropriate federal agency.

PHOTOCOPY PRESERVATION

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.

PREVENTING INSURANCE DISCRIMINATION BASED ON GENETIC INFORMATION

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 <u>all</u> 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.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release February 8, 2000

REMARKS BY THE PRESIDENT
ON GENETIC DISCRIMINATION

American Association for the Advancement of Science
Washington. D.C.

12:40 P.M. EST

THE PRESIDENT: Thank you very much, and good afternoon. I want to begin by thanking all the people at AAAS for having us here today -- my longtime friend, Dr. Shirley Malcolm, thank you. And thank you, Dr. Richard Nicholson. I thank Dr. Francis Collins -- what a remarkable statement he made.

I was thinking when he said that line that I'm beating to death now that we're all genetically 99.9 percent the same, that the one-tenth of 1 percent difference between him and me is all the intellectual capacity for the sciences. (Laughter.) Regrettably. (Laughter.) That's a great thing for people who care about the future of the human genome.

I'm delighted to be joined here by several members of our administration, and by three members of Congress, showing that this is a bipartisan issue. It's an American issue. I thank Representative Louise Slaughter from New York, who was with me yesterday talking to me about this; and Representative Fred Upton from Michigan; and Representative and Dr. Greg Ganske from Iowa. Thank you all for being here. We appreciate you very much and your concern for this.

I thank again all the people in the administration who worked on this -- my Science Advisor, Dr. Neal Lane, and all the people from OPM and the EEOC and others.

This is really a happy day for me. For years, in our administration, I was a sort of political front person, and now we've got the first election in a quarter-century that I can't be a part of. And people are always coming to me saying, oh, this must be a real downer for you, you know, that the Vice President and Hillary, they're out there 7:00 a.m. in the morning hitting all these coffee shops, you must be -- (laughter) -- how are you dealing with this terrible deprivation? (Laughter.)

And I went out to Cal Tech the other day to talk about my science and technology budget, and I said, well, I'm using this opportunity to get in touch with my inner nerd -- (laughter) -- and to really sort of deal with these things that I have repressed all these years, that I'm really trying to get into this.

We're laughing about this. But, you know, it is truly astonishing that we are all privileged enough to be alive at this moment in history, and to be, some of us, even a small part of this remarkable explosion in human discovery; to contemplate not only what it might mean for us and our contemporaries, in terms of lengthening our lives and improving the quality of them, and improving the reach of our understanding of what is going on, both within our bodies and in the far reaches of space, but what particularly it will mean for the whole

structure of life for our children and grandchildren.

And I am profoundly grateful to all of you who have been involved, and who will be involved, in that march of human advance in any way. That quest for knowledge has defined what the AAAS has done for, now, more than 150 years.

We are here today, as the previous speakers have said, to recognize that this extraordinary march of human understanding imposes on us profound responsibilities, to make sure that the age of discovery can continue to reflect our most cherished values. And I want to talk just a little about that in somewhat more detail than Dr. Collins did.

First and foremost, we must protect our citizens' privacy -- the bulwark of personal liberty, the safeguard of individual creativity. More than 100 years ago now, Justice Brandeis recognized that technological advances would require us to be ever-vigilant in protecting what he said was civilization's most valued right, the fundamental right to privacy. New conditions, he said, would often require us to define anew the exact nature and extent of such protection.

And, indeed, much of the 20th century jurisprudence of the Supreme Court has dealt with that continuing challenge in various contexts. So, once again, Justice Brandeis has proved prophetic for a new century.

Today, powerful ways of technological change threaten to erode our sacred walls of privacy in ways we could not have envisioned a generation ago -- not just the ways, by the way, we're discussing here today. Will you ever have a private telephone conversation on a cell phone again? Can you even go in your own home and know that the conversation is private if you become important enough for people to put devices in your walls? What is the nature of privacy in the 21st century and how can we continue to protect it?

But, clearly, people's medical records, their financial records and their genetic records are among the most important things that we have to protect. Last year we proposed rules to protect the sanctity of medical records; we'll finalize them this year. Soon I will send legislation to complete the job we started in protecting citizen's financial records. Today, we move forward to try to make sure we do what we can to protect, in an important way, genetic privacy.

Clearly, there is no more exciting frontier in modern scientific research than genome research. Dr. Collins did a good job of telling us why. And when this human genome project is completed, we can now only barely imagine, I believe, the full implications of what we will learn for the detection, treatment and prevention of serious diseases. It will transform medical care more profoundly than anything since the discovery of antibiotics and the polio vaccine, I believe, far more profoundly than that.

But it will also impose upon us new responsibilities and, I would argue, only some of which we now know -- only some of which we now know -- to ensure that the new discoveries do not pry open the protective doors of privacy.

The fear of misuse of private genetic information is already very widespread in our nation. Americans are genuinely worried that their genetic information will not be kept secret, that this information will be used against them. As a result, they're often reluctant to take advantage of new breakthroughs in genetic testing -- making a point I think we cannot make too often -- if we do not protect the right to privacy, we may actually impede the reach of these breakthroughs in the

lives of ordinary people, which would be a profound tragedy.

A Pennsylvania study, for example, showed that nearly a third of women at high risk for inherited forms of breast cancer refused to be tested to determine whether they carry either of the two known breast cancer genes because they feared discrimination based on the results. That is simply wrong. We must not allow advances in genetics to become the basis of discrimination against any individual or any group. We must never allow these discoveries to change the basic belief upon which our government, our society, and our system of ethics is founded --that all of us are created equal, entitled to equal treatment under the law.

The executive order I will sign in just a couple of minutes will be the first executive order of the 21st century to help meet this great 21st century challenge. It prohibits the federal government and its agencies from using genetic testing in any employment decision. It prevents federal employers from requesting or requiring that employees undergo genetic tests of any kind. It strictly forbids employers from using genetic information to classify employees in such a way that deprives them of advancement opportunities, such as promotion for overseas posts.

By signing this executive order, my goal is to set an example and pose a challenge for every employer in America, because I believe no employer should ever review your genetic records along with your resume.

Because, by executive order, I can only do so much, we also need congressional action this year. In 1996, the Congress passed, and I signed, the Kassebaum-Kennedy bill, the health insurance portability law which made it illegal for group health insurers to deny coverage to any individual based on genetic information. That was an important first step, but we must go further. Now I ask Congress to pass the Genetic Non-Discrimination in Health Insurance and Employment Act introduced in the Senate by Senator Daschle and in the House by Congresswoman Louise Slaughter, who is with us today. (Applause.)

What this legislation does is to extend the employment protections contained in the executive order that I will sign today to all private sector employees as well, and to ensure that people in all health plans, not just group plans, will have the full confidence that the fruits of genetic research will be used solely to improve their care and never to deny them care.

There is something else we should do right away -- we must make absolutely sure that we do not allow the race for genetic cures to undermine vital patient protections.

Like many Americans, I have been extremely concerned about reports that some families involved in trials of experimental gene therapies have not been fully informed of the risks, and that some scientists have failed to report serious side-effects from these trials. I support the recent action by FDA and NIH to enforce reporting in patient safety requirements.

Today I'm asking Secretary Shalala to instruct FDA and NIH to accelerate their review of gene therapy guidelines and regulations. I want to know how we can better ensure that this information about the trials is shared with the public. I want to know whether we need to strengthen requirements on informed consent. If we don't have full confidence in these trials people won't participate, and then the true promise of genetic medicine will be put on hold.

We cannot allow our remarkable progress in genomic research to be undermined by concerns over the privacy of genetic data or the safety of gene therapies. Instead, we must do whatever it takes to address

these legitimate concerns. We know if we do, the positive possibilities are absolutely endless.

I said this the other day, but I would like to reiterate -- I think maybe I am so excited about this because of my age. I was in the generation of children who were the first treated with the polio vaccine. And for those of you who are much younger than me, you can't imagine what it was like for our parents to see the literal terror in our parent's eyes when we were children, paralyzed with fear that somehow we would be afflicted by what was then called infantile paralysis; and the sense of hope, the eagerness, the sort of nail-biting anticipation, when we learned about the Salk vaccine, and all of us were lined up to get our shots.

Unless you were in our generation, you cannot imagine. And the thought that every other problem that could affect the generation of my grandchildren could be visited with that level of relief and hope and exhilaration by the parents of our children's generation is something that is almost inexpressible.

We have to make the most of this. And we know, we have learned from over 200 years of experience as a nation, knocking down physical and intellectual frontiers, that we can only spread the benefits of new discoveries when we proceed in a manner that is consistent with our most ancient and cherished values. That is what this day is all about. So to all of you who have contributed to it, I thank you very, very much.

Now I would like to ask the members of Congress who are here, and members of the administration who are here who have been involved in this, to come up with me. And all I have to do is write my name. (Laughter.) That's a pretty good deal. You can write the human genome code, and I'll write my name -- (laughter) -- and that takes full account of the one-tenth of one percent difference in our genetic makeup.

Thank you very much. (Applause.)

END 12:58 P.M. EST