

1997/09/11; Secretarial Testimony; **Health** Insurance Portability and Accountability A

TESTIMONY OF
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SECRETARY
U.S. DEPARTMENT OF **HEALTH** AND HUMAN SERVICES
BEFORE
SENATE COMMITTEE ON LABOR & HUMAN RESOURCES

SEPTEMBER 11, 1997

Put back in Sarah's privacy notebook

Mr. Chairman, Senator Kennedy, distinguished members of the Committee I appreciate the opportunity to appear before you to discuss the recommendations I am today submitting to the Congress under Section 264 of the **Health** Insurance Portability and Accountability Act, (HIPAA) concerning standards for the privacy and protection of individually identifiable **health information**.

As you mentioned in your invitation letter for today's hearing, HIPAA also requires our Department to act in the areas of administrative simplification and nondiscrimination in group plan enrollment. At your request, I would like to address these issues briefly at the onset. As you know, the administrative simplification provisions of the Act require our Department to adopt a series of standards-to guide the interchange of electronic data for a number of administrative, insurance-related transactions in **health** care. We also are required to adopt standards for unique **health** identifiers for **health** care professionals, plans, employers and individuals, as well as for data security standards for data security or **health** indent for security

I am pleased to report that we've made significant progress. We will soon publish the first set of proposed rules for **health** data standards. As you know, HIPAA calls for final adoption of the standards by February 1998. The latest **information** about our efforts in this area is available on the HHS web site.

In developing our proposals for the standards, we did extensive outreach and consultation with the industry. We met with a wide variety of groups with interests in **health** data standards. And our public advisory committee in this area, the National Committee on Vital and **Health** Statistics, conducted eight full days of public hearings, which included over 130 witnesses from across the entire spectrum of the **health** community.

In addition, our Department's **Health** Care Financing Administration is working with the Departments of Labor and Treasury to review comments on an interim final regulation designed to prohibit a group plan from basing enrollment eligibility on an individual's **health** status, medical condition (physical or mental), claims experience, receipt of **health** care, medical history, genetic **information**, evidence of insurability and disability.

Mr. Chairman, I am pleased to provide to you today recommendations for federal legislation to protect the privacy of **health information**. I should note that our report is today available on the HHS web site (<http://aspe.os.dhhs.gov/admsimpo>). In developing our recommendations, we have benefited greatly from consultations with a variety of outside groups and from six days of public hearings conducted by the National Committee on Vital and **Health** Statistics. The hearing involved over 40 witnesses from across the **health** community, including **health** care professionals, plans, insurance companies, the privacy community and the public **health** and research communities.

Our recommendations represent tough choices and difficult tradeoffs. They strike a balance between the privacy needs of our citizens and the critical needs of our **health** care system and our nation. And, most important, they must

be the first--not the last-- chapter in an ongoing bipartisan dialogue about an issue that touches every single American.

Just a few weeks ago, the cover of Time Magazine read "The Death of Privacy." While our privacy certainly is in danger, to paraphrase Mark Twain, 'rumors of its death have been greatly exaggerated. If we act now, we still have a golden opportunity to safeguard our age-old right to privacy in a brave new world of computers and biology. Nowhere is that more important than with our most personal **information**, our family secrets: our medical records.

Until recently, at a Boston-based HMO, every single clinical employee could tap into patients' computer records and see detailed notes from psycho-therapy sessions. In Colorado, a medical student copied countless **health** records at night and sold them to medical malpractice attorneys looking to win easy cases. And, in a major American city, a local newspaper published **information** about a congressional candidate's attempted suicide. **Information** she thought was safe and private at a local hospital. She was wrong.

When we give a physician or **health** insurance company precious **information** about our mood or motherhood, money or medication, what happens to it? As it zips from computer to computer, from doctor to hospital, who can see it? Who protects it? What happens if they don't? It all depends on the states you live in.

Every day, our private **health information** is being shared, collected, analyzed and stored with fewer federal safeguards than our video store records. Let me be frank. The way we protect the privacy of our medical records right now is erratic at best-- dangerous at worst.

When Congress looked at the privacy threats to our credit records, our video records, and our motor vehicle records, it acted quickly to protect them. It is time to do the same with our **health** care records.

It's been 25 years since my predecessor, Secretary Elliot Richardson, set forth principles that led to the landmark Federal Privacy Act. Those 25 years have brought vast changes in our **health** care and our **health** care system.

Twenty-five years ago, our **health** care privacy was protected by our family doctor who kept hand written notes about us sealed away in a big file cabinet. We trusted our physicians to keep their file cabinets locked and their mouths shut.

Today, revolutions in our **health** care delivery system mean that instead of Marcus Welby, we must place our trust in entire networks of insurers and **health** care professionals--both public and private.

The computer and telecommunications revolutions mean that **information** no longer exists in one place. It often travels in real time across hospitals, physicians, insurers, even state lines. And, it can no longer be protected by simply locking up the office doors each night.

And, revolutions in biology mean that a whole new world of genetic tests have the potential to either help prevent disease or reveal our families' most personal secrets. Without safeguards that assure citizens that getting tested won't endanger their families' privacy or **health** insurance, we could, in turn, endanger one of the most promising areas of research our nation has ever seen.

We are at a decision point. Depending on what we do over the next months, these revolutions in **health** care, communications, and biology could bring us great promise or even greater peril. The choice is ours. For example, will **health** care **information** flow safely to improve care, cut fraud, ensure quality, and reach citizens in underserved areas? Or will it flow recklessly into the wrong hands?

The fundamental question before us is: Will our **health** records be used to heal us or reveal us? The American people want to know. As a nation, we must decide.

Today, almost 75 percent of our citizens say they are at least somewhat concerned that computerized medical records will have a negative effect on their privacy. If we don't act now, public distrust could deepen--and ultimately stop citizens from disclosing vital **information** to their doctors, getting needed treatment for mental illness or seeking genetic testing. As history has taught us, distrust, if left unchecked, can undermine and stop progress in our entire **health** care system.

The question is, what can we do? Some say we have already lost the battle. They say privacy in this new electronic world is impossible. There are others who say that consumers should not only have control over their **health** care **information**, they should have complete control. They say that Americans should even have the power to ensure that their records are kept on paper, not in computers. Both sides are wrong. We cannot turn back the hands of progress or turn our backs on public responsibilities like research or fighting fraud and abuse--and we shouldn't.

But we can and must do what Secretary Elliot Richardson envisioned in 1972. We must look ahead and balance our age-old right to be left alone with our desire to fulfill the promises of a new age in **health** care. **Health** care privacy can be safeguarded. I believe we must do it with national legislation, national education, and an on-going national conversation.

As I said earlier, we have federal laws that protect the privacy of video records, motor vehicle records, and credit records. But, when it comes to our private **health** care records, we rely on a patchwork of state laws. The patchwork of state laws does not provide Americans the privacy protections they need, particularly as our **health** **information** becomes increasingly national--crossing state boundaries. Right now, we have no federal **health** care privacy standards. We have no federal standards. We do have a national interest. Now all of us must make a national commitment.

Today I offer our recommendations for federal legislation protecting **health** care **information**. We want to work with you, Mr. Chairman, and other appropriate committees to develop a comprehensive measure to protect the privacy of medical records, to guarantee to consumers the right to inspect their records, and to punish unauthorized disclosures of personal **health** data by hospitals, insurers, **health** plans, drug companies or others.

THE PRINCIPLES

These recommendations are grounded in five key principles:

Boundaries

The first is the principle of Boundaries: With very few exceptions, **health** care **information** about a consumer should be disclosed for **health** purposes and **health** purposes only. It should be easy to use it for those purposes, and very difficult to use it for other purposes.

That means hospitals can use this **information** to provide and pay for quality care for their patients. And, subject to the requirements of other laws such as the Americans with Disabilities Act of 1990, employers could use it to provide on-site care for their employees or to administer a self-insurance plan. But, those same employers should not be able to use **information** obtained for **health** care purposes to make decisions about job hiring and firing, placements and promotions. We are recommending strong protections for Americans from the inappropriate disclosure of their medical records.

Who should be bound by this law? Anyone who provides **health** care or pays for

it, or who receives **health information** from a provider or payer, either with the authorization of the patient or as authorized explicitly by the legislation. Our physicians, our nurses, our hospitals and payers are the foundation of our **health care system**. They have been and must continue to be on the front lines in our battle to protect the privacy rights of patients.

However, our recommendations acknowledge that these providers and payers do not act alone. Whether it's an organization paid by a hospital to encode and process bills or a pharmaceutical benefit management company that provides **information** to pharmacists about what medications are covered and appropriate for their customers, there are many new actors on the **health care stage**. The numbers of service Organizations are increasing every day. Most do not have direct relationships with the patients. But, they do have access to their personal **health care information**. And, we are proposing that they too be bound by the same tough standards.

For example, we recommend that service organizations be able to do mailings to remind patients to schedule appointments for preventive care. But, they should not be able to sell the patient lists to a pharmaceutical company for a direct mailing announcing a new product.

We believe a federal privacy statute should define a range of **health care conditions and services** and protect certain demographic **information** about the patient collected during the **health care process**.

A federal privacy statute also should define "**information**" to include records held in whatever form possible--paper, electronic, or otherwise.

We believe that the privacy statute must strongly protect individuals from inappropriate disclosures, but only in cases where these disclosures are in fact inappropriate. These protections should only cover the **information** that is personally identifiable.

Our recommendation on defining "identifiability" follows the text of the administrative simplification provisions of HIPAA. For now, **information** should be considered as identifiable if there is a reasonable basis to believe that the **information** can be used to identify an individual. The potential for disclosure of a person's identity increases when there are other pieces of **information** present such as age, sex, marital status, race, ethnicity, place of residence, and occupation. A determination of what is identifiable **information** may require a case-by-case decision based on reasonableness and will certainly change as technology advances.

We must remember that although explicit identifiers (name, social security number, etc.) can be removed, the pieces of **information** remaining may still yield an identity. Sometimes common **information**-- marital status, number of children, place of residence--can become identifiable with combined with other **information**--like age and ethnicity. For example, what if you say someone is a male Korean college professor living in Akron, Ohio? He may be the only-person there to fit that description. Therefore, you may not have to identify him by name to have his identity be known. We want to insure that in these cases when the identity can be known, privacy protections are in place.

Because the recommendations would create a minimum floor of protection for all records, this report does not distinguish among types of **health care information** based on sensitivity. However, we are well aware that there are certain types of **information** that have been viewed as particularly sensitive--such as mental **health information**.

We look forward to working with Congress, advocates, and others to discuss these unique considerations. Where stronger protections for particular types of **information** may be appropriate, the stronger protections provided by other federal or state laws should remain in place. And new laws providing such special protections could be enacted.

For example, our recommendations do not include specific provisions related to genetic **information** in **health** records, Genetic **information** should be covered by the same rules. However, we recognize that the public is especially concerned about the unique properties of genetic **information**--its predictive nature, and its link to personal identity and kinship and its ability to reveal our family secrets. As you are aware, the President recently announced support for federal legislation that would limit collection and disclosure of genetic **information** and would also prohibit **health** insurers from discriminating against individuals on the basis of their genetic **information**. Because of the speedy development of genetic technologies and its history of abuse, we recommend that legislation concerning discrimination in underwriting by insurers be considered expeditiously. We look forward to continuing our work with you on this issue.

We have also elected to limit the scope of our recommendations to the **health** care system and the **information** that flows directly from it. For example, DNA results contained in a crime **information** data bank would not be included.

The Administration and Congress should continue to examine the privacy concerns created when **health information** is held and used in other settings, and recognize that further action may be required.

Security

The second principle is Security. Americans need to feel secure that when they give out personal **health care information**, they are leaving it in good hands. **Information** should not be used or given out unless either the patient authorizes it or there is a clear legal basis for doing so.

Think about all the ways that private **information** like your blood tests could become public.

People who are allowed to see it--like those at a lab--can misuse it either carelessly or intentionally. And people who shouldn't be seeing it--like marketers--can find a way to do so anyway, either because an organization doesn't have proper safeguards or they find an easy way around them.

To give Americans the security they deserve, we must develop legislation that requires those who legally receive **health information** to take real and reasonable steps to safeguard it. They must ensure that it isn't used improperly by those who have access to it, and it isn't obtained improperly by hackers or others on the outside.

What do we mean by reasonable steps? They include administrative and management techniques, education of employees, and disciplinary sanctions against employees who use **information** improperly. It also includes technical security safeguards like audit trails.

We don't believe a law can specify the details of these protections, since they must keep pace with the new threats to our privacy and the technology that can either abate or exacerbate them. But a law can--and must--require everyone who holds **health information** to have these types of safeguards to protect it.

Consumer Control

The third principle is Consumer Control. Americans should not have to trade in their privacy rights to get quality **health** care.

The principles of fair **information** practice (formulated in 1973 by the committee that Secretary Richardson appointed) included as a basic right the following:

There must be a way for an individual to find out what **information** about him is in a record and how it is used.

Americans should have the power to find out what rules protect their records, who's looking in them, what's in them, how to inspect, copy and, if necessary, correct them. They should be given clear explanations of how organizations will use their **information**, and what their rights are. Let me give you an example of why this is important. According to the Privacy Rights Clearinghouse, a California physician in private practice was having trouble getting **health** disability, and life insurance. She ordered a copy of her report from the Medical **Information** Bureau--a clearinghouse used by many insurance companies. It included **information** about her heart problems and her Alzheimer's disease. There was only one problem. None of it was true. What if she hadn't requested her records? With electronic data, mistakes can multiply--and sunlight is still the best disinfectant. Unfortunately, under the current system these types of errors are too often the case. Americans often do not have access to their own **health** records and even those who do are not always able to correct some of the most egregious errors.

With that in mind, our recommendations set forth a set of practices and procedures that would require that Americans be provided a written explanation from insurers or **health** care professionals detailing who has access to their **information**; how that **information** is kept; how they can restrict or limit access to it; how they can authorize disclosures or revoke such authorizations; and what their rights are under the proposed legislation should an improper disclosure occur.

We also recommend procedures for patients to inspect and copy their **information** and set out the very limited circumstances under which patient inspection should be properly denied.

Finally, we recommend a process for patients to seek corrections or amendments to their **health information** to resolve situations in which innocent coding errors cause patients to be charged for procedures they never receive or to be on record as having conditions or medical histories that are inaccurate.

Accountability

The fourth principle is Accountability. If you're using **information** improperly, you should be severely punished. This flows from the second principle of security. The requirement to safeguard **information** must be followed by real and severe penalties for violations. When someone's **health** care privacy has been violated, it's not enough to say it's wrong. We need to show it's wrong. We need to send the message that protecting the confidentiality of peoples' medical **information** is vitally important, and that people who violate that confidence will be held accountable.

People who knowingly disclose medical records improperly, or who misrepresent themselves to obtain **health information**, should be subject to criminal penalties. Federal legislation should include punishment for those who misuse personal **health information** and redress for people who are harmed by its misuse.

We believe offenders should be subject to criminal felony penalties (including fines and imprisonment) if they knowingly obtain or use **health care information** in violation of the standards our report outlines. This includes passing out **information** to those who shouldn't have it and obtaining it under false pretenses.

The penalties mandated in a federal privacy law should be higher when violations are for monetary gain, similar to those Congress mandated in the administrative simplification provisions of the HIPAA for misuse of personal identifiers and other violations. And, when there is a demonstrated pattern or practice of unauthorized disclosure, those committing it should be subject to civil monetary penalties.

But, in addition to punishing the perpetrators, we must give redress to the victims. We believe that any individual whose rights under the federal privacy law have been violated--whether those rights were violated negligently or knowingly--should be permitted to bring a legal action for actual damages and equitable relief. When the violation was done knowingly, attorney's fees and punitive damages should be available.

These four principles--Boundaries, Security, Consumer Control and Accountability--must be weighed against the fifth principle, Public Responsibility.

Public Responsibility

Just like our free speech rights, privacy rights can never be absolute. We have other critical--yet often competing-- interests and goals. We must balance our protections of privacy with our public responsibility to support national priorities-- public **health**, research, quality care, and our fight against **health** care fraud and abuse.

As a major payer of **health** care in this country, our Department is acutely aware of the need to use **health** records to fulfill those responsibilities.

For example, HHS auditors use **health** records to zero in on kick-backs, over-payments and other fraud--so we can bring the perpetrators to justice and the money back to taxpayers. Researchers have used **health** records to help us fight childhood leukemia and uncover the link between DES and reproductive cancers. Local public **health** agencies use **health** records to warn us of outbreaks of emerging infectious diseases.

In addition, our efforts to improve quality in our **health** care system depends on our ability to review charts to determine quality of care provided by **health** institutions and **health** professionals and to examine adverse events to see if they reflect underlying structural or practice problems. The practice of medicine itself is grounded in the review of profile cases in certain clinical domains to evaluate the quality of care provided to the patient.

In these cases, it's not always possible to ask for permission. And, in many cases, doing so would create major obstacles in our efforts to protect public **health** and fight crime. But that doesn't give us a free pass. Allowing access doesn't mean we can forget about protecting privacy. And we shouldn't.

PUBLIC RESPONSIBILITY CHOICES

Let me outline a few of the areas in which we recommend that disclosure of **health information** for particular purposes under specified conditions be permitted without patient authorization.

Public Health

Under certain circumstances, we propose to permit **health** care professionals, payers, and those receiving **information** from them to disclose **health information** without patient authorization to public **health** authorities for disease reporting, public **health** investigation, or intervention. Why is this important? Think about the recent outbreak of Ecoli O 157 in hamburger that resulted in the largest recall of meat products in history. Public **health** authorities, working with other officials, were able to identify quickly the source of the outbreak and thereby prevent thousands of other Americans from being exposed to a contaminated product.

Research

A recent consultant's report to HHS on **health** privacy and research concluded that if people don't trust the research community to protect their personal **information**, they may refuse to participate in clinical trials and they may even oppose the use of their records for all research under any circumstances.

Research which improves the **health** of all citizens must not only survive, but thrive, under strong assurances that privacy of personal **information** will be carefully protected. We must make every effort to see that this happens.

These are situations under which personal **information** should be made available to researchers without consent. These conditions should include a determination by an Institutional Review Board (IRB) that the research involves minimal risks to participants; that the absence of consent will not adversely affect the rights or welfare of participants; and that conducting the research would be impracticable if consent were required.

In addition, the researcher should be required to remove the personal identifiers and to provide the IRB with assurances that the **information** will be protected from improper use and unauthorized additional disclosures.

This recommendation is consistent with the Federal Policy for the Protection of Human Subjects and the Privacy Act-- policies that have protected research participants and research records for a quarter of a century and that have saved lives and fostered countless improvements in medical treatment.

Law-Enforcement

Law enforcement officials seek access to **health care information** for a variety of reasons, depending on the target of their investigation--from the hot pursuit of an injured fugitive in an emergency room to the review of **health care information** to determine if a crime has been committed by a hospital or insurance company.

We recommend that a federal **health** privacy law not interfere with the well-established procedures of the criminal justice system. **Information** would be disclosed without patient authorization for purposes required by State law--like the reporting of gunshot wound victims, the identification or location of an injured fugitive--or for other legitimate law enforcement purposes.

PREEMPTION

The report calls for national standards. But, it does not recommend outright or overall federal preemption of existing State legislation that is more protective of **health information**.

In HIPAA, Congress generally expressed a preference for leaving stronger State laws in place and that is the right thing to do. Although most State laws are in no way uniform or comprehensive, these recommendations concern an area already regulated by State laws. Some protections that we propose may be stronger than some existing State laws. Therefore, we recommend that Federal legislation replace State law only when the State law is less protective than the Federal law. Thus, the confidentiality protections provided would be cumulative, and the Federal legislation would provide a floor. Federal legislation should provide every American with a basic set of rights with respect to **health information**. All should be assured of a national standard of protection.

Many have argued for one law in the interests of administrative simplification. We may reach a consensus one day, after watching the rapid evolution of **health care**, in which we determine the interests of nationwide administrative simplification for **health** transactions justifies preemptive federal legislation. I am not convinced that day has arrived.

Nevertheless, the impact of leaving in place more restrictive State laws on the effective use of **health information** bears careful watching. If dual regulation impairs care or the operation of **information** and payment systems, poses risks to confidentiality because of confusion about two levels of law, or

creates uncertainty among patients about their rights and forms of redress, we may want to revisit the notion of a preemptive federal law.

As we seek to protect privacy in the **information** age, we will always be shooting at a moving target. As technology develops, and as we continue our implementation of HIPAA, there may need to be adjustments or additional legislation in the future to address emerging concerns.

CONCLUSION

Mr. Chairman, the five principles embodied in our recommendations --boundaries, security, consumer control, accountability, and public responsibility--should guide a comprehensive law that would give our nation real federal standards and our citizens real peace of mind.

They represent a practical, comprehensive and balanced strategy to protect **health care information** that is collected, shared, and used in an increasingly complex world.

At the same time, we need to build on the efforts of the American with Disabilities Act and the Kassebaum-Kennedy law to address another legal issue that has a tremendous impact on how people view their privacy: **health care discrimination**, including genetic discrimination. Because our efforts on **health care privacy** will never be enough until we give all Americans confidence that **information** in their medical records will not be used to deny them jobs or affordable **health insurance**.

Yet, as we know from past experience, national legislation alone will not inspire trust in one's rights or commitment to one's responsibilities. It's going to take education. Every single **health care professional**, every public **health official**, every pharmacist-- every single person who comes in contact with **health care records** must understand why it's important to keep them safe, how they can keep them safe, and what will happen to them if they don't.

Most of all, we must help consumers understand not just their privacy rights, but also their responsibilities to ask questions and demand answers--to become active participants in their **health care**.

We need an informed public, because, as the National Research Council recently pointed out, we need an informed public debate. An ongoing conversation.

We cannot expect to solve these problems all at once. With changes in medical practices and technology occurring every day, we need to be flexible, to change course if our strategy isn't working and meet new challenges as they arise.

Twenty-five years ago, Secretary Richardson and the Congress looked into an uncertain future and tried to chart a course on which individual rights and privacy would prevail. The result, as I mentioned, was the landmark Federal Privacy Act.

Now a similar challenge is before us. Twenty-five years from now, what will they say about the footsteps we left? Will we leave the next generation with real federal privacy standards based on fundamental principles? Will we have boundaries to ensure that, with very few exceptions, our **health care information** is used only for **health care**? Will we have assurances that our **information** is secure? Will we have control over what happens to it? Will those who violate our privacy be held accountable? And will we be able to safeguard our privacy rights while still protecting our core public responsibilities like research and public **health**?

In short will we harness these revolutions in biology, communications, and **health** care to breath new life into the trust between our patients and their doctors, between our citizens and their government, between our past and our future?

We can. We must. And, I believe, working together, we will.

Mr. Chairman, we in the Department and the Administration are eager to work with you to enact strong national privacy legislation.

Thank you again, for giving me this opportunity to testify. I look forward to answering any questions that you may have.

Draft: 3/9/99
3:45 pm

EXECUTIVE ORDER

TO PROHIBIT DISCRIMINATION IN FEDERAL EMPLOYMENT
BASED ON PROTECTED GENETIC INFORMATION

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

**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 for all its employees covered by Section 717 of Title VII of the Civil Rights Act of 1964 as amended.

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.

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 (42 U.S.C. 2000e-

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, or 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 are covered when an excess or deficiency of the metabolite indicates the presence of a mutation or mutations.
- (f) Protected genetic information.
 - (1) In general, protected genetic information means--
 - (A) information about an individual's genetic tests;
 - (B) information about genetic tests of family members of the individual; or
 - (C) information about the occurrence of a disease 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 of the individual) is not protected genetic information unless it is described in subparagraph (1).

1-202. The agencies, in discharging their responsibilities under this order, 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 the 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 or by a family member of 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 the 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 or by a family member of such employee.
- (c) The employing department or agency shall not request, require, collect or purchase protected genetic information with respect to an employee or a family member of the employee or information about a request for or the receipt of genetic services by such employee or by a family member of 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 or by a family member of an employee except --
 - (1) to the employee who is the subject of the information, at the request of that employee to whom disclosure is being made;
 - (2) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations;
 - (3) under legal compulsion of a Federal court order, except that if the 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;

- (4) to government officials investigating compliance with this Executive Order if the information is relevant to the investigation; and
 - (5) to government officials in connection with a compelling national security or law enforcement matter.
- (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 maintained separately from personnel files.

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, require, 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 or by a family member of such employee if :
- (1) the employee or family member uses genetic or health care services provided by the employer;
 - (2) the employee or family member 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 the results of the genetic services to anyone except to the employee who uses the services, and pursuant to section 1-202(d) of this order; and
 - (4) such information is not used in violation of Sections 1-202(a) or 1-202(b) of this Executive Order.
- (b) 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 informed of the specific results of the monitoring;
 - (3) the employee is informed of any other protected genetic information that may have been acquired, provided that the employee has given prior, knowing, voluntary, and written consent to such additional disclosure;
 - (4) the monitoring conforms to any genetic monitoring, regulations that may be promulgated by the Secretary of Labor; and
 - (5) 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.
- (c) This Executive Order does not limit the statutory authority of a Federal agency to (1) promulgate or enforce workplace safety and health laws and regulations or (2) conduct or sponsor occupational or other health research that is conducted in compliance with regulations at part 46 of title 45, Code of Federal Regulations, (3) collect protected genetic information as part of a lawful program, the exclusive purpose of which is to carry out identification of remains.

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 Executive Order.

1-402. Nothing in this Executive 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.) or the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), including coverage afforded to individuals under section 102 of Americans with Disabilities Act of 1990 and any other Federal statute;

(b) supersede any provision of the Privacy Act of 1974 (5 U.S.C. 552a), and actions taken under this Executive Order shall be in compliance with the Privacy Act;

(c) require specific benefits for an employee or dependent under the Federal Employees Health Benefits Program or similar program; or

(d) supersede any other statute, regulation, or rule that requires disclosure of information.

1-403. After consultation with the Secretary of the Department of Health and Human Services and the Chair of the Equal Employment Opportunity Commission, an agency may:

(a) determine that the collection of protected genetic information is required from an individual, after a conditional offer of employment is made, when the collection of such protected genetic information is job-related and consistent with business necessity within the meaning of the Rehabilitation Act;

(b) determine that the use of such protected genetic information to make an employment decision is necessary to avoid a direct threat within the meaning of the Rehabilitation Act.

1-404. 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,

E S S A Y

Michael Kinsley

Oh, My Aching Genes!

Drawing a tube of blood is just one of the many ways we unfairly judge people

MY STOCKS ARE DOING O.K., BUT MY GENE PORTFOLIO took a big hit recently. Doctors at Johns Hopkins announced that they have discovered a genetic mutation in Ashkenazi Jews that doubles the risk of colon cancer. Ashkenazi Jews are those with roots in Central and Eastern Europe. That covers most Jewish Americans, including me. Only 6% of Ashkenazi Jews are thought to carry the defective gene, but that's enough to make it, according to the *New York Times*, "the most common known cancer gene in a particular population." And colon cancer is just one disease for which Ashkenazi Jews seem to have a disproportionate genetic tendency. Breast cancer, Tay-Sachs and cystic fibrosis are others. The *Times* reports that this is the result of too much intermarriage during the Middle Ages! So tell that to your mother, Jewish boys of America.

The *Times* was comically eager to point out that other ethnic groups probably have a lesser genetic tendency to a larger number of diseases, so Ashkenazi Jews shouldn't feel that put upon. Nevertheless, both stories raised the possibility that blood tests for this genetic defect will be used by health insurers and employers to discriminate against people with the defective gene. (Why? Oh, possibly bosses may not want their workplace atmosphere soured by a lot of grumpy people who've just undergone a colonoscopy.)

Genetic research is rapidly discovering all sorts of creepy information about the future in our genes, such as who is likely to develop Alzheimer's. These predictions are widely regarded as the apple of knowledge, which we might be better off not tasting. There is a general feeling that it is wrong for a person's life chances to be determined by a test tube of blood. According to this reasoning, the only issue for public policy is what to do about it. Forbid or discourage genetic tests? Strict rules about what they may or may not be used for? We can't yet prevent Alzheimer's, but we can at least try to prevent discrimination against folks just because they have an increased probability of getting Alzheimer's.

This revulsion at fate-by-genetic-testing is understandable and admirable. It's also a bit crazy. That's because the sorting of people according to their genes goes on in all kinds of ways that don't involve drawing blood. It's not necessary to know the actual gene involved. In fact, the human condition can be thought of as one big genetic test. When a cave-

man lost his woman, or his life, to another caveman, that was a genetic test.

It would be nice to think of civilization as a long process by which such crude genetic determinism (the bigger guy wins) is replaced with finer and fairer values. But genes are barely less important today. There is, of course, the sensitive issue of intelligence. Many people think of the SAT as a genetic marker every bit as clinical as that contained in a syringe of blood. The



FRANCIS LETTER FOR TIME

folks who believe this are mistaken. But even the politically correct position—that "intelligence" is actually a bundle of different mental capabilities that people have in varying amounts, and that these capabilities can be strongly affected by environmental factors—leaves room for a large genetic component. Few Ashkenazi Jews, I suspect, would trade their genes for a random draw from the gene pool, whatever their fear of colon cancer and whatever they may have felt (and said) about Charles Murray, notorious co-author of *The Bell Curve*.

We are all undergoing genetic tests every day, and our life chances are being influenced by the results. A blood test for, say, an Alzheimer's gene is different in only two ways. First, the test is separate from its social application. By contrast, when the cavemen fought, the genetic measurements and their use as a way of ordering society were intertwined and simultaneous. Second, discrimination based on blood tests is punishing people on the basis of mere probabilities. Yet how much do these distinctions matter? If insurers and employers discriminate against people with an increased risk of getting some dreadful disease, they are making a rational assessment of probable future costs. We as a society may decide that such discrimination is unfair and outlaw it, but it is no more unfair than discriminating against a person with the disease itself.

Still, the natural feeling remains that there is something unfair about sorting and rewarding people based on the genes they were born with and have no control over. Good. That feeling should be encouraged. The proper lesson is not that there's nothing wrong with discrimination based on what a lab technician finds in a test tube of your blood. The proper lesson is that a lot of the sorting and rewarding in society works essentially the same way. And whatever upsets you about genetic testing ought to apply to matters larger than a slightly increased chance of getting colon cancer. ■

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FRANCES JEFFERSON FOR TIME

Intro

The Genome Project and Genetic Testing in general Today

State of the Research

Benefits today and in future from the research

Predictability of the Tests now and in the near future

Where's it headed?

Genetic Discrimination

General intro -- what is it?

Employment Discrimination

Genetic testing in the workplace today

who tests?

why are they testing today?

What's wrong with it?

predictability of tests

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other arguments making case to laypersons that there is something wrong with letting an employer conduct tests

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cases, examples, hypotheticals, who is worried and why

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What is prohibited today

Federal law -- ADA, OSH Act, etc..

State law

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Status of federal bills

Status of current state initiatives

Why the above isn't enough; why new federal legislation is needed

Recommendations (summary of principles doc)

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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.

File Genetics

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. ^{There is} 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 separately 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.

File Genetics

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.

Genetic Discrimination File

MEMORANDUM

March 8, 1999

TO: Chris
FR: Sarah B

RE: Outstanding Genetics Concerns

The following are the two remaining policy decisions to be made on the genetics EO that need high level discussions. What would be helpful is if you would read through them tonight and give me in the morning a sense of where you might be and what I need to do and who I need to have at the Wednesday meeting -- I assume you, HHS, Justice, Elena?, WH counsel, and OMB. But if you could give me a sense of who I need to educate, what your concerns are likely to be than I can spend all day tomorrow laying the groundwork.

I. Any Exemptions?

The first issue is whether there should be any cases in which agencies should be able to exempt themselves in any situation from this executive order. Clearly, this should be quite a tight clause if any exemptions are granted. The only reason to consider this at all is that we have a broad definition of genetics -- including the fact that we do not allow for the collection of any family related health care information. Therefore, one might envision a scenario where say NASA thought it would be useful to have family medical history (such as the fact that 14 people in your family have had heart disease) before deciding what kind of tests to do on someone going up into space. They may want to be aware of this kind of predisposition to a disease to be aware of what kind of testing this would require.

→ w/ authorization or not? why do you need requirements?

However, clearly if we are going to move in this direction at all, we would want a tightly crafted exemption. The one that EEOC is completely comfortable (although their preference is to have no exemptions) with (as is Labor) is as follows:

(1) An agency may determine after consulting with the Secretary of HHS and the Chair of EEOC, that the collection of protected genetic information is required only after a conditional employment offer is made where such collection is job related and consistent with business necessity.

(2) An agency, in consultation with HHS and EEOC may use such information to make employment decisions where necessary to avoid direct threat.

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From: Abigail C. Smith on 02/09/2000 12:12:03 PM

Record Type: Record

To: Devorah R. Adler/OPD/EOP@EOP

cc:

Subject: background briefing on genetic discrimination executive order

----- Forwarded by Abigail C. Smith/WHO/EOP on 02/09/2000 12:12 PM -----



Margaret M. Suntum
02/08/2000 02:32:07 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: background briefing on genetic discrimination executive order

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

February 8, 2000

PRESS BRIEFING BY
A SENIOR ADMINISTRATION OFFICIAL
ON GENETIC DISCRIMINATION

The Briefing Room

1:33 P.M. EST

MR. KENNEDY: A short while ago, the President signed an historic executive order to ban discrimination on the basis of genetic information by federal agencies. And here to provide additional information is a senior administration official. Thank you.

SENIOR ADMINISTRATION OFFICIAL: Good afternoon. Just a few short minutes ago, the President participated in an event at the American Association for the Advancement of Sciences to sign an executive order that would prohibit any genetic testing for the purposes of hiring, promoting or placing employees within every federal agency and department employing civilian employees. This executive order is the result of months of work with all the agencies throughout the federal government, but particularly with the National Institute of Genome Research, with Francis Collins, and the Department of Health and Human Services, as well as the EEOC and the Department of Labor, OPM and every agency that has been in any way significantly affected by this executive order.

Many of you know that this action is on the heels of concerns about, and extraordinary excitement for, the potentials of research in gene therapy. And the unmatched, probably unparalleled potentials in this area are such that the President outlined them in the State of the Union in some detail, as a matter of fact, and again today, as did Francis Collins.

The concern with this executive order and the reason, the rationale behind it is there is a growing concern within the consumer community as well as in the research community that there is an increasing concern by employees and Americans as a whole about the potential misuse of genetic testing -- so much so that those who may well benefit from genetic testing are suggesting to many people that they are hesitating to undergo genetic testing for fear that that information will be misused, both in terms of employment and in terms of health insurance.

The President has raised this issue before. In fact, he goes back to talk about the perils and potentials of biomedical research back to a Morgan State speech that Dr. Collins referenced in 1997. But in this particular action, we're moving ahead. We are hoping the Congress will do the same. Beyond the executive order, the President called on the Congress to pass legislation on Capitol Hill to ensure that all employers, not just federal employers, utilize the same principles and do not utilize genetic information for placement.

I'd like to just make a distinction, now, on this issue and how important it is -- and it's important to make this distinction. Utilizing health care information to determine whether someone can do the job is something that happens all the time, and is appropriate. What is not appropriate is to use genetic testing to determine predisposition for illness. People who have a predisposition for illness, that has in no way any bearing on their ability to perform their tasks at their jobs. And in fact, many people -- all of us in this room -- have a predisposition for some illness. There's no doubt about that. But if someone was going to be utilizing testing to make that determination, and trying to lower costs, I think most people -- and understandably, most all Americans -- would be aghast.

However, in the absence of legislation and this executive order, no such protections do exist in employment. Back in 1996, we did pass legislation in the Kassebaum-Kennedy HPA insurance reform initiative, to ban the use of these types of testing for health insurance underwriting. It applied to group insurance, but not individual insurance. So since that time a number of members, including Congressman Louise Slaughter, as well as Senator Daschle, have introduced comprehensive legislation to finish the job on the health insurance front, and to continue our work on the employment front in a way that is very consistent with the executive order the President released today.

The other issue that the President referenced is his concern about some of the reports on gene therapy trials that have occurred. And he has asked the Secretary to accelerate the NIH's and FDA's work in that regard, to make sure that we can enhance the public's confidence that we're doing everything possible to avoid any mistakes that have occurred previously, or at least have been reported previously.

But again, the focal point of this announcement was on the genetic discrimination in employment. We anticipate -- we have great hope and expectation that Congress will move and act. We had a bipartisan contingent in the event today, and we have a great deal of confidence that we'll be able to get the legislation done as well as the EO implemented.

The EO was signed. It is now formal. We will try to make copies for those who are interested in it. I think it will serve as a model for employers to contemplate for their model practices in the private sector before we get this legislation done.

And with that, why don't I stop and take any questions you may have about today's action.

Q Is it safe to say that the administration is trying to get ahead of the problem, rather than respond to a widespread problem?

SENIOR ADMINISTRATION OFFICIAL: I think that's relatively fair. Genetic testing does occur in a range of different areas. We have genetic testing for breast cancer, for colon cancer, for Huntington's Disease, for diabetes and for other diseases -- for instance, Collins referenced some others today.

Having said that, they are not widespread. They are certainly available. In terms of daily use, they're not used as much as they will be, inevitably, in the years to come. And absolutely this is a preventive action as the President and Francis Collins suggested today. We need to get ahead of this before inappropriate practice get endemic in this society and it

becomes harder to address the issue into the future.

I think what's exciting about this initiative is that the scientific and the consumer community are completely endorsing this legislation, and the executive order. And the reason why they are is that the fear of a growing lack of confidence in the public about the use of this information in inappropriate ways. And that has also an impact on the ability to attract people to participate in clinical trials in the ways that can produce advances in medical science and treatments, cures and diagnostics.

Q Were there agencies that were poised to use this kind of testing, whose programs are going to be interrupted or canceled as a result of this executive order?

SENIOR ADMINISTRATION OFFICIAL: I think what the agencies wanted to make certain was that medical information could be used in appropriate ways to determine ability to work in their current task -- when we made the breakthrough in terms of his executive order, when we made that point of demarkation on the issue of predisposition for illnesses that may or may not exist.

In terms of -- I do not know of any agency who had planned to use genetic testing for this purpose. But I will tell you that it is one of those issues where, not because people think that they're doing something wrong, but because they're just using another tool, that if they don't think about it, you could see it becoming a practice that is used and accepted and, before you know it, becomes a practice that people become dependent on. The President wanted to stop any such practice from occurring now and into the future, and he's done that with today's action.

Q Are there other medical privacy issues that you would expect the President to address through executive action in the months ahead?

SENIOR ADMINISTRATION OFFICIAL: Well, we have to finalize the privacy reg, which we anticipate in the next couple of months. We have had an extraordinary response from the private and public sectors on the draft regulation. We will move ahead on that -- March-April time frame I think is what we're looking for. I'll get back to you on the exact dates, but it's around the spring time frame. Genetic discrimination we'll be pushing the Congress to move legislatively this year. We hope it could be certainly before this summer.

I think an orientation to privacy and I think some people look at some of the issues of patient quality and they look at medical errors and some of those initiatives, as well as patient protections. They get wrapped in some of these broader issues of quality protections, consumer information, consumer

protections. They all will be high priorities for us this year. I do think, clearly, the patients' bill of rights will be a priority and we think we can get that done this year. Medical errors I anticipate we'll be talking about in the upcoming weeks, in response to the President's request from late last year. So this is going to be a continuation of a high priority for the President.

Q Are you aware of any public or private employer who's adopted a policy like the one the President adopted today?

SENIOR ADMINISTRATION OFFICIAL: Actually, Robert, I do not know. We are going to be working -- we were talking last night of working with the private sector and the employer community to highlight model employers in this regard, to illustrate the commitment of the employer community in these areas. We have absolutely every confidence that there are people who would be very strongly behind such activities. We also are concerned that there may well be some who are not as committed. That's why the only way you ensure these protections are in place will be to pass federal legislation, and that's what we're going to be doing.

Q When you said it's all civilian employees, does that mean that the Pentagon, all the military people at the Pentagon, are not covered by the order? And are there other agencies that are considered military?

SENIOR ADMINISTRATION OFFICIAL: All civilian employees are covered. That's 2.8 million employees. That does not include DOD. All the reference -- there is no specific exemption for DOD in this executive order. The reason is that every time we do executive orders on these types of initiatives in federal law -- and, in fact, going back from the beginning of every executive order -- they don't explicitly cover DOD. DOD generally follows civilian practices then, and we have every anticipation that they will, and DOD has made no indication that they will not. But that's how we always do it with these executive orders -- civil rights laws.

Q Can you just clear up the number of employees covered? I think Joe said in his briefing it was 1.8 million.

SENIOR ADMINISTRATION OFFICIAL: Well, I checked that today; it's 2.8 million -- 2.78 million. I rounded it to 2.8 million.

Q Do they use any genetic testing at DOD, as far as you know?

SENIOR ADMINISTRATION OFFICIAL: I have absolutely no information what DOD is doing. I will tell you that the CIA is coming into compliance; the State Department is coming into compliance. So it would be my thought, if CIA and State

Department are, that DOD probably will have no problem in doing so, particularly in the way we've drafted this EO.

Q Does that mean they were using genetic tests at certain levels?

SENIOR ADMINISTRATION OFFICIAL: I don't have information on that, although I think a while back there may have been a case on something. But I don't know current practice at DOD that has utilized genetic testing for placement or hiring or promotion.

Q Are there specific examples of people who have been discriminated against, or had their privacy --

SENIOR ADMINISTRATION OFFICIAL: Yes. We have some -- for those of you who are interested, we have some examples that have been written up. In many cases -- and we'll give you some cites of people who have actually been counseling these people in how to deal with this situation. Actually, on both sides of this, in the one case people who have actually been discriminated, and others who decided not to seek testing because of the fear of discrimination because they know they have family histories and other such issues.

I will say that many of these people do not want to be publicly recognized. You can talk to them, but they don't want to be cited in any significant way, and the reason is that there are not federal protections and they are concerned that either their employers or insurers might discriminate against them. And this really plays into the very issue the President is trying to address today.

Q Can you explain the exception that is described in the fact sheet which says that obtaining or disclosing genetic information about employees is prohibited except when it's necessary to ensure workplace health and safety -- what that exception means?

SENIOR ADMINISTRATION OFFICIAL: I think that's an example of -- I think that was a case that there are cases in which, with informed consent, that there may be an issue, for example, where there's an environmental area in the work force that would create particular health problems to that employee. In other words, they had a genetic predisposition -- not a genetic predisposition -- they had a specific medical condition where genetic tests can show that they would be at particular risk in a particular hazardous work force -- like if you were in a nuclear plant and there was an issue about radiation. But I'm pretty certain that's right, Robert, but I'll get right back to you on that.

Q -- what kind of genetic predisposition might be in appropriate to work there?

SENIOR ADMINISTRATION OFFICIAL: They may be physically unable or less able to work in that particular environmental setting. But I will -- it's a very rare exception issue, but we will give you a specific example subsequent to this briefing.

Q And in all these instances it has to be informed consent?

SENIOR ADMINISTRATION OFFICIAL: Yes. They have to meet the privacy laws and the application of the requirements that we have in the federal legislation.

Q Can you go over the distinction between the predisposition and the actual having -- I'm a little blurry on that.

SENIOR ADMINISTRATION OFFICIAL: Yes, I think that's a very important point. If you have a medical condition where it affects your ability to perform the job, there are current laws that are -- if you can't perform the job, then you can't perform the job. That isn't discrimination.

If, on the other hand, you have a predisposition for an illness -- you may have a 20 percent greater chance, or a 30 percent greater chance, or a 40 percent greater chance to have a disease -- that does not mean that you will have a disease, and it certainly doesn't affect your ability to work at the current time in that place of work. And the very -- the real distinction that we're making here is a current condition and a predisposition for one. And we think that you have to draw the line there in order to be able to deal with these types or potential abuses that could occur in the future and are occurring today.

Q Is there any opposition to this?

SENIOR ADMINISTRATION OFFICIAL: Well, this legislation has been pending for a while, a couple years now. And it either hasn't been a priority, or there's someone opposing it. There have been in the past some insurers and some in the employer community that have opposed this legislation. I don't know what their current standing is. I hope and expect them, after today's announcement, to be more supportive. And we look forward to working with them.

There are a lot of people who do support this in both sectors, both insurance and employers. And we anticipate many of them will be our allies as we move forward in this year's Congress.

Thank you very much.

END

1:50 P.M. EST

February 9, 2000

Clinton Bans Use of Genetic Makeup in Federal Employment

Forum

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By **ROBERT PEAR**

WASHINGTON, Feb. 8 -- Setting what he hopes will be a precedent for employers nationwide, President Clinton issued an order today that prohibits federal agencies from using genetic information in any decision to hire, promote or dismiss workers.

The order will protect 2.8 million federal employees. White House officials said they knew of no other employer who had adopted such a policy.

Information about the human genome and a person's genetic makeup can transform medical care, making it easier to detect, treat and prevent disease, Mr. Clinton said. But, he added, the misuse of genetic tests can also violate personal privacy.

Several studies in scientific journals suggest that many people have been asked questions about genetic diseases on job applications, and some workers report that they have been denied jobs or dismissed from jobs because of genetic conditions in the family.

"We must not allow advances in genetics to become the basis of discrimination against any individual or any group," Mr. Clinton told the American Association for the Advancement of Science. "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 résumé."

Joe Lockhart, the White House press secretary, said Mr. Clinton's order, setting policy for the nation's largest employer, "sends a powerful message to the private sector about how they'll need to deal with the advances" in human genetics.

Scientists have developed hundreds of genetic tests that can help identify people with an increased risk of developing breast cancer, ovarian cancer, cystic fibrosis, Alzheimer's and other diseases.

In 1998, a federal appeals court found that a government laboratory in California, the Lawrence Berkeley National Laboratory, had for years conducted genetic tests on employees without their permission, and it said the practice might have violated the workers' privacy rights.

Scientists had urged President Clinton to adopt the privacy protections because of evidence that many people were reluctant to take advantage of genetic tests, or to participate in genetic research, because they feared that the results might be used against them.

Mr. Clinton said Congress should pass legislation to prevent private employers from discriminating against workers on the basis of genetic tests. Such legislation has been introduced by Senator Tom Daschle of South Dakota, the Democratic leader, and Representative Louise M. Slaughter, Democrat of New York.

The legislation would also bar insurance companies from using "predictive genetic information" to deny coverage or to set rates for insurance policies. Group health plans serving 50 or more employees are already forbidden to discriminate on the basis of genetic data, but the safeguards do not apply to people buying insurance as individuals or in small groups.

Senator Trent Lott of Mississippi, the Republican leader, said he had not studied the Daschle-Slaughter bill. "But," he said, "we have a tight schedule for this year, and I don't now have that on the schedule for consideration during this year."

White House officials distinguished between genetic information, which may indicate a predisposition to an illness or disease, and the actual medical condition or disorder.

It may sometimes be appropriate for employers to consider current illnesses that impair workers' ability to perform the essential functions of a job, the officials said, but it is not proper to consider a person's predisposition to develop such illnesses.

Wendy R. Uhlmann of the University of Michigan, who is president of the National Society of Genetic Counselors, hailed the president's action, saying: "All of us are predisposed to some type of illness, but most of us don't know what it is yet. The more protections we have in place, the better it will be for all of us."

But E. Neil Trautwein, director of employment policy at the National Association of Manufacturers, said: "We have not seen any signs that additional laws or regulations are needed to prevent employment discrimination on the basis of genetic information. Existing laws are sufficient. Employers are doing everything they can to get workers into the workplace. We are not about to start barring the door, especially in an area like this, which is fraught with the potential for litigation."

The president's order says federal agencies may not dismiss, refuse to hire or discriminate against workers because of genetic tests conducted on them or their relatives. Likewise, it says, federal

agencies may not discriminate against workers because they request or receive genetic counseling or tests.

The order has several limited exceptions. For example, a federal agency could periodically test employees, with their consent, to see if they had suffered chromosomal damage or genetic alterations because of exposure to radiation or toxic substances in the workplace.

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Clinton Targets Misuse of Gene Data

Anti-Bias Order Covers Agencies

By Justin Gillis
 Washington Post Staff Writer
 Wednesday, February 9, 2000; Page A19

Seeking to allay deep public fears that advances in gene science could lead to discrimination, President Clinton today barred federal agencies from using genetic information to discriminate against employees. He called on Congress to pass a law applying the same rule to private employers.

Clinton praised researchers who are racing to unravel the human genetic code, saying the knowledge they are uncovering will become the foundation of medical progress. But he said that same progress poses a new challenge.

"The fear of misuse of private genetic information is already very widespread in our nation," Clinton said in a speech yesterday at the American Association for the Advancement of Science. "Americans are genuinely worried that their genetic information will not be kept secret, that this information will be used against them."

The fear centers on the possible use employers and insurers might make of genetic tests showing that people are at risk of developing a disease or passing the disease gene on to their offspring. Every person carries genes that may dispose him or her toward some ailments, including common diseases of aging such as cancer and heart attacks. A few people carry genes that virtually guarantee they will contract a serious disorder during their working lives.

Few such gene tests have come into wide commercial use, and only a smattering of discriminatory incidents have been reported around the country, but privacy advocates fear that could change as more tests are developed.

Congress has already barred insurers writing large group policies from using genetic tests as a basis for discrimination. But that does not apply to some types of insurance, and there are no national rules regulating what private employers can do with gene tests.

About 30 states have passed laws banning genetic discrimination in insurance, and a handful have extended the policy to employment.

Not everyone who tracks the issue is convinced the country is on the verge of a wave of discrimination. Philip Reilly, an expert on genetic issues at the Eunice Kennedy Shriver Center in Waltham, Mass., said in years of studying the issue he has yet to see a clear-cut case of discrimination. "There is extremely little evidence to support this as a

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realistic threat," he said.

Still, there is wide agreement that the fear of discrimination, if not the reality of it, is altering people's behavior. One study said many women with a family history of breast cancer were reluctant to have genetic tests that could help them safeguard their health because they feared the results would fall into the wrong hands.

Clinton made clear yesterday that he was not trying to discourage genetic tests. To the contrary, he said, banning discrimination would actually make people more likely to consent to such tests.

Sharing a stage with Francis Collins--director of the National Human Genome Research Institute, the agency that is unraveling the genetic code--Clinton emphasized his support for the new biology. He recounted the time, in his youth, when the nation deployed Jonas Salk's vaccine against polio, with parents watching in "nail-biting anticipation" as science removed a huge fear from their lives. He predicted similar progress in the new century against other scourges.

A bill pending in Congress would ban genetic discrimination by private employers. Clinton, who has spoken repeatedly on the subject of genetic privacy since 1997, offered his explicit support today for that bill. Before an audience that included biologists, doctors and a few members of Congress, he signed an executive order barring federal agencies from using genetic records in their employment decisions.

The order covers about 2.8 million federal civilian workers.

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

Clinton also called on the Food and Drug Administration and the National Institutes of Health to hasten a review they have undertaken of gene therapy tests, a controversial field of medicine that was roiled recently by the disclosure of unreported deaths and other adverse reactions in clinical trials.

"I want to know how we can better ensure that this information about the trials is shared with the public," Clinton said. "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."

Staff writer Charles Babington contributed to this report.

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S. 1322/H.R. 2457
The Genetic Nondiscrimination in Health Insurance
and Employment Act of 1999

* Indicates provisions also in S.326, the GOP bill; provisions without asterisk are unique to S.1322/H.R. 2457

TITLE I. PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION

Applies to four areas of health insurance:

1. Self-insured or other health insurance plans governed by the Employee Retirement Income Security Act of 1974.*
2. Group health insurance plans governed by the Public Health Service Act.*
3. Individual insurance policies governed by the Public Health Service Act.*
4. Medigap insurance policies governed by the Social Security Act.

The protections outlined below are applied to all four areas.

Discrimination

- Prohibits health plans or health insurance issuers from restricting enrollment based on predictive genetic information or information about genetic services.*
- Prohibits health plans or health insurance issuers from adjusting premium or contribution rates for individuals or groups based on predictive genetic information or information about genetic services.*

Genetic Testing

- Prohibits health plans or health insurance issuers from requesting or requiring an individual to undergo genetic testing. A health care professional treating a patient may suggest that a patient undergo a genetic test.

Collection of Predictive Genetic Information

- Prohibits health plans or health insurance issuers from requesting*, requiring*, collecting*, or purchasing predictive genetic information or information about genetic services. (Exception for payment of claims in strictly limited circumstances.)
GOP bill allows requests for diagnosis, treatment, and payment. No limitation on

circumstance where request for payment purposes is allowed.

Disclosure of Predictive Genetic Information

- Prohibits disclosure of predictive genetic information or information about genetic services to:
 - Health plans or health insurance issuers (except for payment for health care under strictly limited circumstances).
 - Employers.
 - The Medical Information Bureau, or other entities that collect or disseminate insurance information.
 - Other persons the Secretary of Labor or Health and Human Services may specify in regulations.

Enforcement

- Individual may bring private right of action in state or federal court. The court may award any appropriate legal or equitable relief.
- Secretary of Department of Health and Human Services or Secretary of Labor may bring an action in federal court for civil monetary penalties of up to \$50,000 for first violation, up to \$100,000 for subsequent violations.

Relationship to Other Laws

- This Act would not supersede any more protective state law on the confidentiality of genetic information or prohibiting discrimination on the basis of genetic information.

Definitions of Predictive Genetic Information and Genetic Test

- Predictive genetic information is defined as information about an individual's own genetic tests and information about genetic tests, diseases, or disorders of an individual's family members. Predictive genetic information does not include information about an individual's current health status, but predictive genetic information is protected regardless of health status.*
GOP definition only protects genetic information in the absence of symptoms, clinical signs, or a diagnosis.
- Definition of genetic test includes analysis of DNA, RNA, chromosomes, proteins, and metabolites to detect genotypes, mutations, or chromosomal changes. The definition was developed from language created by the Task Force on Genetic Testing convened by the NIH-DOE Working Group on the Ethical, Legal, and Social Implications of Human Genome Research.*
GOP definition only considers genetic tests in asymptomatic or undiagnosed individuals to be genetic tests. Test must be for the purpose of predicting risk; excludes genetic

information revealed inadvertently.

TITLE II. PROHIBITION OF EMPLOYMENT DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION

Definitions:

- The definitions of genetic test and predictive genetic information are the same as those in Title I. Definition of employer and employee are from the Civil Rights Act.
- Genetic monitoring is defined as periodic examination to detect any damage to genetic material which might occur as a result of exposure to toxic substances in the workplace.

Discrimination (Applies to Employers, Employment Agencies, Labor Organizations, and Training Programs)

- Predictive genetic information or information about genetic services may not be used as a basis for:
 - Hiring, discharging, compensation, terms, or privileges of employment
 - Limiting, segregating, or classifying individuals
 - Representation by or referral for employment by an employment agency
 - Exclusion, expulsion from membership or other discrimination in a labor organization
 - Discrimination in admission to or employment by any training program

Collection of Predictive Genetic Information

- Predictive genetic information may not be requested or required by an employment agency, labor organization or training program.
- An employer may request genetic information only:
 - For monitoring of effects of toxic compound in the workplace, if employee has provided prior written authorization, the employee is informed of the results, the monitoring conforms to regulations that the Secretary of Labor may promulgate, and the employer only receives the results in aggregate.
 - If genetic services are directly provided by the employer with employee consent, and only the employee receives the results of the services.

Maintenance and Disclosure of Information

- Any predictive genetic information in the possession of an employer must be kept as a confidential part of the employee's medical record.
- Predictive genetic information may be disclosed only:
 - to the employee at his or her request

- to an occupational safety or public health researcher under 45CFR46 (the "Common Rule")
- under legal compulsion of a Federal court order
- to government officials for investigation of compliance with this Act.

Enforcement

- Individual may bring private right of action or class action in state or federal court. The court may award any appropriate legal or equitable relief. Action may be brought under the Equal Employment Opportunity Commission.

Relationship to Other Laws

- This Act is not intended to limit rights or protections under the Americans with Disabilities Act of 1990 or the Rehabilitation Act of 1973.
- This Act would not supersede any more protective state or federal law on the confidentiality of genetic information or prohibiting discrimination on the basis of genetic information.
- This Act does not apply to the Armed Forces Repository of Specimen Samples for the Identification of Remains
- The Act does not limit the statutory or regulatory authority of the Occupational Safety and Health Administration and the Mine Safety and Health Administration.

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February 8, 2000

Clinton Seeks Gene Therapy Review

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Filed at 5:33 p.m. EST

By The Associated Press

WASHINGTON (AP) -- President Clinton ordered an expedited review Tuesday of guidelines for gene therapy research in the wake of reports that some researchers failed to explain carefully enough to patients the risks involved.

"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," Clinton said.

The September death of an 18-year-old patient in Pennsylvania triggered a government investigation, the suspension of eight gene therapy trials in that state and a Senate hearing last week. Beth Israel hospital in Boston shut down a gene therapy program this week.

The president asked Health and Human Services Secretary Donna Shalala to instruct the Food and Drug Administration and the National Institutes of Health to "accelerate their review of gene therapy and guidelines."

"I want to know how we can better ensure that this information about the trials is shared with the public," Clinton said. "I want to know whether we need to strengthen requirements on informed consent."

Gene therapy attempts to repair or replace abnormal genes in seriously ill patients by transferring normal genes into the body. Dozens of human experiments have been conducted in the past decade, but there has been no clear-cut success.

Clinton discussed the gene therapy research at an event where he announced his order barring federal agencies from discriminating against employees on the basis of genetic tests.

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PRESIDENT CLINTON TAKES HISTORIC ACTION TO BAN GENETIC DISCRIMINATION IN THE FEDERAL WORKPLACE

February 8, 2000

Today, President Clinton will sign an executive order that prohibits every civilian Federal Department and agency from using genetic information in any hiring or promotion action. This historic action will prevent critical information from genetic tests used to help predict, prevent, and treat diseases being used against them by their employer. At an event at the American Association for the Advancement of Science, the President will endorse the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, introduced by Senator Daschle and Congresswoman Slaughter, that will extend these employment protections to the private sector and finish the job begun with the Health Insurance Portability and Accountability Act to help extend protections to individuals purchasing health insurance. Finally, the President will also state his strong concerns about recent troubling reports about inappropriate use of gene therapies and will ask the Secretary of Health and Human Services to instruct FDA and NIH to expedite their review of gene therapy guidelines and regulations.

AMERICANS FEAR THAT THEIR GENETIC INFORMATION WILL BE MISUSED.

Progress in the field of genetics has increased the ability of researchers and health care providers to detect and prevent health disorders; however, it can also be misused to discriminate against or stigmatize individuals. Some employers may seek to use genetic tests to discriminate against workers – even those who have not yet or who may never show signs of illness – because they want to avoid increased costs associated with workers who are genetically predisposed to particular ailments.

- **Genetic discrimination is real.** In a 1996 study published in *Science*, 15 percent of individuals at risk of developing a genetic condition said that they had been asked questions about genetic diseases on job applications. Thirteen percent of the respondents reported that they or another family member had been denied a job or fired from a job because of a genetic condition in the family.
- **Fear of discrimination is widespread.** The confidentiality of genetic test results is a major concern for the public. A 1997 study by the National Center for Genome Resources found that 63 percent of people would not take genetic tests if employers could access the results – and that almost 50 percent of people believe that most employers will ask employees to take genetic tests in the future.

PREVENTING GENETIC DISCRIMINATION IN THE WORKPLACE. Today, President Clinton will sign an executive order that prohibits every agency in the Federal government from using genetic testing in any hiring or promotion action. This executive order, endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance, will:

- **Prohibit Federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits.** Employers would not be able to request or require employees to undergo genetic tests in order to evaluate an employee's ability to perform his or her job.

- **Prohibit Federal employers from using protected genetic information to classify employees in a manner that deprives them of advancement opportunities.** Employers would not be able to deny employees promotions or overseas posts because of a genetic predisposition for certain illnesses.
- **Provide strong privacy protections to any genetic information used for medical treatment and research.** Under the EO, obtaining or disclosing protected genetic information about employees or potential employees is prohibited, except when the collection or disclosure of genetic information by employers is necessary to provide medical treatment to employees, ensure workplace health and safety, and to provide researchers access to data. However, when genetic information about employees is obtained, it will be subject to Federal and state privacy protections.

PRESIDENT CALLS ON CONGRESS TO PROTECT THE PRIVATE GENETIC INFORMATION OF ALL AMERICANS. Today, President Clinton will endorse the Genetic Nondiscrimination in Health Insurance & Employment Act of 1999, introduced by Senator Daschle and Congresswoman Slaughter. This bill would extend the protections for genetic information included in the President's executive order to the private sector. In 1996, the President signed the Health Insurance Portability and Accountability Act (HIPAA), which prevents group health insurers from using genetic information to deny individuals health insurance benefits. The Daschle-Slaughter legislation finishes the job begun by HIPAA and ensures that genetic information used to help predict, prevent, and treat diseases will not also be used to discriminate against Americans seeking employment, promotion, or health insurance.

AT THE PRESIDENT'S REQUEST, HHS ACCELERATES THEIR REVIEW OF PATIENT PROTECTIONS IN GENE THERAPY. Today, President Clinton will also address recent reports on lapses in gene therapy clinical trials – specifically that researchers failed to comply with federal regulations requiring the reporting of any serious illness or death and that patients may have been misinformed about the risks associated with their participation in the trials. At the President's request, the Secretary of Health and Human Services will instruct FDA and NIH to expedite their review of gene therapy guidelines and regulations – to determine whether the current informed consent requirements need to be strengthened, and to ensure that information about these trials is shared with the public.

BUILDING ON THE CLINTON-GORE ADMINISTRATION'S STRONG COMMITMENT TO PROTECTING PRIVATE GENETIC INFORMATION. Since 1997, the President and Vice President have called for legislation that will guarantee that Americans who are self-employed or otherwise buy health insurance themselves will not lose or be denied that health insurance because of genetic information. Under the Clinton-Gore Administration, the Human Genome Research Project has made swift progress, and is on schedule to finish a draft of the human genome by April of 2000. The President today will make clear that while these advances promise great benefits, they also carry potential perils. Today's actions are part of the Administration's longstanding effort to ensure that we harness scientific advances to our most cherished values.

THE WHITE HOUSE
WASHINGTON

February 7, 2000

GENETIC DISCRIMINATION EVENT

DATE: February 8, 2000
LOCATION: American Association for the Advancement of
Science, Washington, D.C.
BRIEFING TIME: 11:25am – 11:45am
EVENT TIME: 12:05pm – 12:50pm
FROM: Bruce Reed, Chris Jennings

I. PURPOSE

To sign an executive order that prohibits every civilian Federal Department and agency from using genetic information in any hiring or promotion action.

II. BACKGROUND

Today, you will sign an executive order that prohibits every civilian Federal Department and agency from using genetic information in any hiring or promotion action. This historic action will prevent the critical information from genetic tests used to help predict, prevent, and treat diseases being used against them by their employer. At an event at the American Association for the Advancement of Science, you will endorse the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, introduced by Senator Daschle and Congresswoman Slaughter, that will extend these employment protections to the private sector and finish the job begun with the Health Insurance Portability and Accountability Act to help extend protections to individuals purchasing health insurance. Finally, you will also state your strong concerns about recent troubling reports about inappropriate use of gene therapies and will ask the Secretary of Health and Human Services to instruct FDA and NIH to expedite their review of gene therapy guidelines and regulations.

AMERICANS FEAR THAT THEIR GENETIC INFORMATION WILL BE MISUSED. Progress in the field of genetics has increased the ability of researchers and health care providers to detect and prevent health disorders; however, it can also be misused to discriminate against or stigmatize individuals.

- **Genetic discrimination is real.** In a 1996 study published in *Science*, 15 percent of individuals at risk of developing a genetic condition said that they had been asked questions about genetic diseases on job applications. Thirteen percent of the respondents reported that they or another family member had been denied a job or fired from a job because of a genetic condition in the family.
- **Americans do not want employers to access private genetic information.** Some employers may seek to use genetic tests to discriminate against workers – even those who have not yet or who may never show signs of illness – because they fear increased costs associated with hiring workers likely to take sick leave, resign, or retire early for health reasons, file for workers' compensation, or use health care benefits excessively. A 1999 survey found that 95 percent of respondents believed that employers should not be able to obtain access to employees' genetic records or DNA without permission.
- **Fear of discrimination is widespread.** The confidentiality of genetic test results is a major concern for the public. A 1997 study by the National Center for Genome Resources found that 63 percent of people would not take genetic tests if employers could access the results – and that almost 50 percent of people believe that most employers will ask employees to take genetic tests in the future.

PREVENTING GENETIC DISCRIMINATION IN THE WORKPLACE. Today, you will sign an executive order that prohibits every agency in the Federal government from using genetic testing in any hiring or promotion action. This executive order, endorsed by the American Medical Association, the American College of Medical Genetics, the National Society of Genetic Counselors, and the Genetic Alliance, will:

- **Prohibit Federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits.** Employers would not be able to request or require employees to undergo genetic tests in order to evaluate an employee's ability to perform his or her job.
- **Prohibit Federal employers from using protected genetic information to classify employees in a manner that deprives them of advancement opportunities.** Employers would not be able to deny employees promotions or overseas posts because of a genetic predisposition for certain illnesses.
- **Provide strong privacy protections to any genetic information used for medical treatment and research.** Under the EO, obtaining or disclosing protected genetic information about employees or potential employees is prohibited, except when the collection or disclosure of genetic information by employers is necessary to provide medical treatment to employees, ensure workplace health and safety, and to provide researchers access to data. However, when genetic information about employees is obtained, it will be subject to Federal and state privacy protections.

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CALL ON CONGRESS TO ACT NOW TO PROTECT THE PRIVATE GENETIC INFORMATION OF ALL AMERICANS. Today, you will endorse the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999, introduced by Senator Daschle and Congresswoman Slaughter, that will extend the protections for genetic information included in the President's executive order to the private sector. This legislation finishes the job that HIPAA began and ensures that genetic information used to help predict, prevent, and treat diseases will not be used to discriminate against Americans seeking employment, being evaluated for a promotion, or purchasing health insurance.

REQUEST THAT HHS ACCELERATES THEIR REVIEW OF PATIENT PROTECTIONS IN GENE THERAPY CLINICAL TRIALS. Today, you will express your concern at the recent discovery that researchers failed to comply with Federal regulations requiring the reporting of any serious illness or death of patients in gene therapy clinical trials, and reports that patients may have been misinformed about the risks associated with their participation. You will ask the Secretary of Health and Human Services to instruct FDA and NIH to expedite their review of gene therapy guidelines and regulations to determine whether the current requirements to provide trial participants with informed consent need to be strengthened and develop new ways to ensure that information about these trials is shared with the public.

III. PARTICIPANTS

Briefing Participants:

Bruce Reed

Chris Jennings

Loretta Ucelli

Lowell Weiss

Greeters:

Richard Nicholson, Executive Officer, American Association for the Advancement of
Science

Robert Zayas, Building Manager

Members of Cabinet In Attendance:

Secretary Donna Shalala

Director Janice LaChance, OPM

Ida Castro, Equal Employment Opportunity Commission

File: "Genetic
Screening"

POTENTIAL GENETIC SCREENING EVENTS

Event in conjunction with announcement on new gene discovery. Apparently, there is a new gene discovery on a well-known late adulthood disease that is potentially being announced in the next month in Science magazine. *Science* has not decided when they will publish this gene, although there is fairly good chance they will publish it in late June or early July. They will be able to notify us between two and three weeks before publication. When they do publish, the Human Genome Institute plans to do a press conference on the discovery. This event -- could highlight the discovery and then emphasize that as we make these new breakthroughs on genetics, we should enact legislation to ensure that this genetic information is not used to discriminate against people. (Even if we do not want to use this to highlight the genetic screening legislation, we may want to consider some possible POTUS involvement).

Event with the Society of the Advancement of Women's Research. This group is holding their annual awards event on June 24th, where they will give awards in the areas such as basic research, clinical research, and public policy. We could issue our report and announce our support for genetic screening legislation at that event. This event would obviously emphasize women's concerns about genetic screening in breast cancer.

Event with The Genome Action Plan. The Genome Action Plan, which consists of groups in a number of different areas including breast cancer, people with disabilities, etc. is willing to design an event with us in order to highlight our report and support legislation on genetic discrimination. This event has the advantage of including a number of groups -- rather than just one -- that are impacted by this legislation. We are having discussions with them regarding options, including some type of awards event. We will get back to you with the specifics.