

File Genetic Screening
DRAFT: 9/26/97

GENETIC INFORMATION IN THE WORKPLACE
RECOMMENDATIONS

I. Coverage

- A. Employers engaged in an industry affecting commerce.
- B. Joint labor-management committees controlling apprenticeship or other training or retraining, including on-the-job training programs.
- C. Employment agencies regularly undertaking, with or without compensation, to procure employees for an employer or to procure for employees opportunities to work for an employer.
- D. Labor organizations engaged in an industry affecting commerce.
- E. Licensing agencies.
- F. Federal, state and local governments in their capacity as employers.¹ [IS THIS NEEDED ?]

II. Prohibited practices and activities of covered entities

- A. May not require or request a genetic test or access to genetic information of any person as a condition of employment, compensation, terms, conditions or privileges of employment, license, membership, etc.
- B. May not use genetic information, or a request by the individual for genetic services, as a basis for refusing to hire, for discharging or for discriminating against any individual, or for denying any employment benefit that otherwise would be available.
or eliminating ?
- C. May not use genetic information, or a request for genetic services, to limit, segregate or classify employees in any way that would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect the status of the individual as an employee.

¹This outline does not specify each covered entity to which a particular requirement or obligation shall apply. This simply is a drafting approach adopted for convenience only. The legislation will apply the prohibitions and requirements to each covered entity, as appropriate, based on the nature of the role such entities perform in connection with workplace activities.

Genetic screening

- D. May not collect, purchase or otherwise obtain genetic information of an employee, applicant for employment or prospective employee, and as appropriate an individual, member or applicant for membership. [Is this provision necessary? overbroad?]
- E. May not disclose genetic information of an individual unless the individual (or legal representative) specifically authorizes the disclosure in writing, and the written authorization identifies the information being disclosed, the purpose of the disclosure and the person or entity to whom the disclosure is being made.
- F. May not rely on a previous disclosure, inadvertent or otherwise, as justification for a subsequent disclosure -- confidentiality is not lost because a disclosure has been made.
- G. May not maintain genetic information in general personnel files; such information must be maintained on separate forms, in separate medical files and must be treated as confidential medical records.

III. Exemptions

- A. Genetic monitoring may be permitted provided that (1) such monitoring is conducted as part of a written plan; (2) the employee has authorized such monitoring, in writing, for the effects of a particular substance in the workplace; (3) the program administrator informs the individual of the specific results of the monitoring; (4) except where the employee has to be reassigned for medical reasons, the program administrator provides the employer with the results of monitoring, only in aggregated terms that do not disclose the identity of a specific individual; and (5) the results are used to identify, evaluate and control adverse environmental exposures in the workplace.

To qualify under the genetic monitoring exemption, the genetic monitoring must be performed by a competent person, and upon a determination that continued exposure to the workplace substance has caused genetic damage, the written monitoring plan must provide for reassignment of the employee to a job without harmful exposure, with no loss in earnings, benefits or seniority, or for permanent removal, with pay for an appropriate period of time, if reassignment is not a medically acceptable alternative or if such a job is not available.

B: This Act does not limit the statutory authority of a Federal agency to promulgate or enforce workplace safety and health laws and regulations with respect to obtaining and using genetic information or to obtain access to genetic information.

C Covered entity may disclose genetic information upon the written authorization of the individual or under legal compulsion (e.g., a court order, grand jury directive or subpoena, or specific Federal statutory provision), but if the court order, etc., was secured without knowledge of the individual, the covered entity must provide the individual with adequate notice to challenge the court order, etc., unless the court order, etc., also imposes confidentiality as, for example, in a criminal investigation. **[MK: NEED APPROPRIATE LANGUAGE TO COVER CONFIDENTIAL INVESTIGATIONS, ETC. FROM DOJ]**

D Research

(1) Covered entity may disclose aggregated genetic information for research purposes and for investigations under the relevant laws (e.g., this proposed law and the OSH Act) provided that all personal identifiers are removed before disclosure. **[IS THIS NEEDED GIVEN E AND F ?]**

(2) A covered entity may disclose genetic information to researchers, provided that: (a) the information is obtained or disclosed as part of an occupational disease study approved by an institutional review board (IRB); (b) the study is operated in accordance with the federal Common Rule for the Protection of Human Subjects (except with respect to specimens where identifiers are destroyed), and (c) IRB requirements are met for any direct or indirect disclosure of identifiers or identities, including such disclosures in reports of research.

(3) A covered entity may disclose individually identifiable genetic information in medical records to researchers conducting an IRB approved occupational disease study, without obtaining individual informed consent, where an IRB determines that the research: (a) involves minimal risk; (b) would be infeasible to conduct without individually identifiable information, and (c) would not adversely affect the rights and welfare of the subjects.

E. DO WE NEED TO DEAL WITH BERYLIUM-TYPE AGREEMENTS HERE?

IV. Enforcement

A. Injunctive actions in the proper Federal district court by the Government or the individual are authorized. Such courts may issue temporary or permanent restraining orders and injunctions to require compliance with the law, including

employment, reinstatement, promotion, back pay, benefits, seniority relief and other appropriate relief. In addition, such courts, in their discretion, may award compensatory, consequential, and punitive damages, and may allow the prevailing party, except the Government, reasonable costs, including attorney's fees.

B. Private actions may be brought, by the individual affected by the violation, in a state court of competent jurisdiction as well. Such courts may award the same injunctive and make whole relief that is available in paragraph A.

Private v. GP
a

C. Authority of the Government.

1. To issue rules and regulations, including record keeping regulations.
2. To conduct investigations and inspections, including investigations of complaints filed by individuals under the law, and applicable regulations authorized in paragraph 1 above.
3. To issue subpoenas, in connection with investigations, as authorized under 15 U.S.C. 49 and 50.

D. Additional protections for the individual.

1. The individual who believes his or her rights under the law have been violated may file a complaint with the Government for investigation and resolution.
2. The individual may not waive the rights and procedures of the law by contract or otherwise.

V

Miscellaneous

1. Genetic information is information about genes, gene products, or inherited characteristics, that may derive from the individual or a family member.
2. Genetic services means health services provided to obtain, assess, and interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

3. The authorization given by an individual to obtain, use or disclose his or her genetic information, contemplates the legally effective and recognized "voluntary informed written consent" of the individual (see, for example, 45 CFR 46.116; general requirements for informed consent)

DRAFT: 9/26/97

4. ~~This law does not prohibit the genetic testing or accommodation, based on the results of the test, of an individual who provides written and informed consent to taking a genetic test and to requesting the accommodation.~~

HHS RESEARCH EXEMPTION PROPOSALS

(Replaced in preceding draft with III.B., III.D.2., and III.D. 3.)

Where does
it come from
this

1. Occupational health studies (including genetic research) may be conducted by federal and non-federal research institutions provided that the research has been approved by an institutional review board (IRB) organized and operated in a manner consistent and in accord with federal Common Rule for the Protection of Human Subjects. Researcher(s) conducting studies under this exemption may not directly or indirectly identify any individuals in any report of such research or otherwise disclose individual identities in any manner unless disclosure is made in accordance with IRB-approved procedures. An exception to the informed consent requirement of the Common Rule is permitted for IRB-approved genetic research involving anonymized biological specimens where individual identifiers have been destroyed.

2. For scientific studies into the causes and prevention of occupational disease, the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) and the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.) authorize the Secretary of Health and Human Services to access medical records, including genetic information, and to do so without securing individual informed consent. Individually identifiable genetic information in medical records may also be disclosed to researcher(s) conducting similar occupational disease studies without securing individual informed consent if such studies have been approved by an institutional review board that (a) operates in accord with the federal Common Rule for the Protection of Human Subjects and (b) has determined that the research involves minimal risk, would be impracticable to conduct without individually-identifiable information, and would not adversely affect the rights and welfare of the subjects. Researcher(s) conducting such studies may not directly or indirectly identify any individuals in any report of such research or otherwise disclose individual identities in any manner unless disclosure is made in accordance with IRB-approved procedures.

DRAFT: September 26, 1997

GENETIC PRIVACY IN THE WORKPLACE AND PROTECTION FROM DISCRIMINATION

Earlier this year DHHS issued a report w/ recommendations about how to prevent genetic health plans from discriminating on the basis of genetic discrim.

Recent advances in genetics research have made it possible to identify the genetic basis for human diseases, opening the door to ^{new} individualized prevention strategies and early detection and treatment. While these advances hold much promise ^{to improve & advance health} for the improvement of human health, genetic information can also be used unfairly to discriminate against or stigmatize individuals ^{on the job. In addition,} since some genetic traits have racial or ethnic links, such discrimination could disproportionately affect various racial or ethnic groups. American workers need the peace of mind guaranteed by federal legislation to protect them from genetic discrimination in the workplace.

However, gen. info. can lead to discrimination in the work place.

The Promise of Genetic Information

Unprecedented progress in identifying and understanding the 80,000 or so genes in the human genome provides an opportunity for scientists to develop strategies to prevent or reduce the effects of genetic disease. ^{Scientists have learned that} straightforward inherited errors in our genes are responsible for an estimated 3,000 to 4,000 diseases, including Huntington's disease, cystic fibrosis, neurofibromatosis, and Duchenne muscular dystrophy. More complex inheritance of multiple genetic errors ^{can also increase an individual's risk of developing} also plays a significant role in common disorders such as cancer, heart disease, and diabetes ^{by increasing a person's risk of developing that disorder.} For healthy people from families prone to a later-onset disease, ^{Genetic technologies, such as simple DNA tests,} increasingly are becoming available to ^{inform} people and their health care providers who might have an increased likelihood of developing that disorder and who does not. ^{The majority of diseases Americans encounter, however, do not result solely from genetic predisposition but from the interaction of genes with environmental factors, including occupation, diet, and lifestyle.}

where, for example, an individual can be denied a job or benefits at a job or lose their job because of their genetic information. These are tests for everyone.

for his or her family members and future generations, misuse of genetic information could have intergenerational affects that are far broader than any individual incident of misuse.

Genetic information has been used to discriminate in the workplace. In the early 1970s, some employers denied jobs to African-Americans who were identified to carry a gene mutation for sickle cell anemia, even though they were themselves healthy and would never develop the disease.

[?] Billings and coworkers (1991) conducted a study of genetic discrimination as a consequence of genetic testing and found 39 separate incidents of possible discrimination involving insurance or employment. Seven incidents of employment discrimination were reported. These involved the hiring, termination, promotion, and transfer of workers based on genetic testing results. In one of those cases, an individual who carried a single mutation for the metabolic disorder Gaucher disease was denied employment even though he was healthy and would never develop the disease. Another individual reported that her daughter was denied employment because she has a mild case of the neuromuscular condition Charcot-Marie-Tooth disease.

→ many of them

One of

out of how many

Fear of genetic discrimination also has been reported in the both the scientific literature and the popular press. People have hidden genetic information about themselves and avoided genetic tests that could be beneficial to them.

- A 1995 Harris poll of the general public found 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. (Harris Poll, 1995 #34)
- Fewer than 14 percent of people at risk for Huntington's disease decide to undergo genetic testing in part because of fear of discrimination in insurance or employment (Andrews 1997).
- Studies show that a leading reason women do not get new genetic tests for susceptibility to breast cancer is because they worry the results will be used to discriminate against them. — cite?



*Billings & coworkers 1991

- In another study, fear of genetic discrimination resulted in 17 percent of the participants not revealing genetic information to employers (Lapham 1996).
- An 18-year-old man, at risk for Huntington's disease because one of his parents developed it, wished to enlist in the Marines to serve in the Persian Gulf War. He believed it unlikely that he would become symptomatic during his tour of duty, but that knowledge of his risk status would disqualify him from service. He therefore answered "no" to questions regarding hereditary disorders on his application and did not include Huntington's disease in his family medical history (Geller 1996).
- An individual whose parent died of Huntington's disease chose to hide the truth. Fearing adverse consequences at work if this cause of death was known, the individual arranged for the diagnosis of asphyxiation to be reported as the cause of death to avoid mention of the disease in an obituary (Geller 1996).

individual stories should be in the record
 people seem to be afraid of discrimination
 bullets
 have an editorial
 seems a little bit
 to be a little bit
 to be a little bit

Genetic Information In the Workplace

Two types of genetic testing may occur in the workplace: genetic screening and genetic monitoring. Genetic screening is a process to examine the genetic makeup of employees or job applicants for specific *inherited characteristics*. In the workplace, genetic screening can be used in two distinct ways: 1) to detect general heritable conditions that are not associated with workplace exposures in employees or applicants, or 2) to detect the presence of genetically determined traits that render an employee susceptible, or "hyper susceptible," to a certain disease if exposed to specific environmental factors. In theory, genetic screening for occupationally relevant traits has the potential to be used to ensure appropriate worksite placement of employees susceptible to certain occupational diseases, and to ensure that employers place those "hypersusceptible" workers in the least hazardous environments. However, according to Francis Collins, Director of the National Human Genome Research Institute, there is not a single current

Should it be on before fear of discrimination? Need a context

what is the justification for the first type of screening (is this common)

a description of why this is done at all before you talk about discriminating

How common is this? Do employers know this?

example where such testing has been scientifically validated to have accurate predictive value.

The second type of testing--genetic monitoring--ascertains whether an individual's genetic material has changed over time due to workplace exposure to hazardous substances. Evidence of genetic changes in a population of workers could be used to target work areas for increased safety and health precautions, and to indicate a need to lower exposure levels for a group exposed to a previously unknown hazard. The ultimate goal of genetic monitoring is to predict the risk of disease caused by genetic damage. Although genetic changes such as chromosomal damage have been associated with exposure to some chemical mutagens or carcinogens, little research has identified which changes are predictive of subsequent disease risk. Much more research is required to establish the relationship, if any, between those changes and subsequent disease risk for affected populations and individuals.

Why not? need explanation. It can't hurt to monitor environment.

Some employers might use genetic testing of employees to monitor and reduce or eliminate adverse health effects from toxins through engineering controls or better protective equipment. Others may find genetic testing attractive because they believe it can help them avoid costs associated with workers who are at risk of health problems. Specifically, employers may seek to use genetic tests as a way to screen out workers who they fear would have lower productivity levels, cause higher insurance premiums, and would file more workers' compensation claims and lawsuits. Employers may try to select workers based on their genetic information who they believe are less likely to take sick leave, are less likely to resign or retire early for health reasons (also reducing extra costs in recruiting and training new staff), and less likely to file for worker's compensation or use health care benefits excessively.

Although there are few appropriate uses for genetic testing in the workplace, employer interest in genetic information appears to be growing.

- A 1982 survey of large businesses, private utilities and labor unions found that 1.6 percent of the 366 organizations responding were genetically testing employees (OTA 1983 Report).
- In 1989, the Office of Technology Assessment repeated a similar survey and found that

- too old?

5% of the 330 organizations responding conducted genetic screening or monitoring of its workers. (OTA 1990 Report).

- A survey of 400 firms conducted by Northwestern National Life Insurance in 1989 found that 15 percent of the companies planned to check the genetic status of prospective employees and their dependents before making employment offers (Gostin 1991, p.116).

[Genetic research into the causes and prevention of occupational disease includes studies on the effects of workplace exposures on DNA or of gene-environment interactions leading to disease risks. The findings of this research are used to understand mechanisms by which occupational diseases and injuries occur, to identify exposure-disease associations, to identify groups and individuals at high risk, and to assist qualitative and quantitative risk assessments. Research of this type will improve the ability to detect work-related disorders in their earliest stages, when prevention strategies are most effective.]

nothing more recent?

include this in discussion of gen. research w/ the text?

Real People - Real Discrimination

fears lead to discrim?
There are countless examples of where
It appears uninformed fears about genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy or the genetic condition has no effect on the ability to perform work.

- One individual was screened and learned he was a healthy carrier of a single mutation for Gaucher disease, *meaning that* in other words, he might pass this gene to children, but he would not develop Gaucher disease. He revealed this information when applying for a job and was denied the job *bc of his genetic aberration* ~~because of his carrier status??~~ even though it had no bearing on his present or future ability to perform a job (Billings 1992).

single mutation example of this?

- In another case, a 53-year-old man was interviewed for a job with an insurance company. During his first interview, he revealed that he had hemochromatosis but was

Since I have # of these examples of these polio cases
6 more you
51 to years
The President
was told
with it
has raised as this
the President

asymptomatic. During the second interview, he was told that the company was interested in hiring him but would not be able to offer him health insurance because of his genetic condition. He agreed to this condition, however, during his third interview the company representative told him that they would like to hire him, but were unable to do so because of his hemochromatosis (Geller 1996).

- One of an employee's parents ^{meaning} developed Huntington's disease -- ^{giving} the employee ^{had} a fifty percent chance of carrying the mutated gene that would cause her to develop the disease. She decided to be tested. A genetic counselor advised her to secure life and health insurance before testing, because a positive test result would probably mean loss of health insurance, ~~as well as certain illness~~. A co-worker who overheard her making arrangements to be tested reported the employee's conversations to their boss. Initially, the boss seemed empathetic and offered to help. When the employee eventually shared the news that her test results indicated that she did carry the mutated gene, she was fired from her job. In the eight-month period prior to her termination, she had received three promotions and outstanding performance reviews. Tainted by their sister's nightmare, none of her siblings is willing to undergo genetic testing for fear of losing health insurance or jobs. ^{not only women she would get this disease but would} ^{Of course, this means they ~~must~~ must live ^{circle} ^{wondering} whether they are likely to inherit ~~the~~ Huntington's disease}

Efforts to Restrict Use of Genetic Information in the Workplace

There is no scientific evidence to substantiate a relationship between unexpressed genetic factors and an individual's ability to perform his or her job. Thus, most expert recommendations prohibit or severely restrict the use of genetic testing and access to genetic information in the workplace. The American Medical Association (AMA) recommendations ^{developed} provided by the AMA's Council on Ethical and Judicial Affairs conclude that it is inappropriate to exclude workers with genetic risks for disease from the workplace because of that risk (JAMA 1991). In the future, however, the AMA Council acknowledges there may be an appropriate but limited

role for genetic testing in certain situations to protect workers who have a genetic susceptibility to occupational illness when health risks can be accurately predicted by the test.

The National Action Plan on Breast Cancer and the National Institutes of Health - Department of Energy Working Group on Ethical, Legal and Social Implications of Human Genome Research (ELSI Working Group) has drafted recommendations for state and federal policy makers to protect against genetic discrimination in the workplace. Generally, their recommendations limit the collection, disclosure, and improper use of genetic information and support strong enforcement of these limitations through governmental agencies or private right of action. An exception is made for possible situations in the future where testing is shown scientifically valid to predict occupational risk (Rothenberg 1997).

Existing Protections are Limited

As of April 1997, 15 states had enacted laws to provide protections against various forms of genetic discrimination in the workplace. There are wide variations among these state laws. Early state laws address employment discrimination against individuals with specific genetic traits or disorders, such as sickle-cell trait or the hemoglobin trait. Later laws cover broad categories of genetic traits and disorders. Some state laws prohibit compulsory genetic testing. The most comprehensive state laws regulate all genetic testing in employment decisions and the disclosure of genetic test results. ~~These state laws generally prohibit~~ employers from requiring workers and applicants to undergo genetic testing as a condition of employment. Under these more comprehensive statutes, genetic testing may be permitted when it is requested by the worker or applicant for the purpose of investigating a worker's compensation claim, or determining the worker's susceptibility to potentially toxic chemicals in the workplace, but only if the worker provides informed written consent for such testing. These laws also contain very specific restrictions governing disclosure.

The definitions of genetic information and genetic testing vary across states. For example, Texas ~~has a very narrow view that excludes some genetic testing currently undertaken.~~ *narrowly defines what genetics test can be monitored* In other states, the term genetic information includes not only the results of

such as testing by y is not included

genetic tests, but also ^{genetic?} information derived from family medical histories.

A patchwork of Federal and state laws provide limited protections against abuses in the gathering or use of genetic information.

The 1996 Health Insurance Portability and Accountability Act (HIPAA) prohibits the use of genetic information as a basis for denying or limiting health insurance coverage for members of a group plan and excludes genetic predisposition to disease from being considered a preexisting condition.

The most explicit protection against genetic discrimination in the workplace is provided under Title I of the Americans with Disabilities Act (ADA), enforced by the Equal Employment Opportunity Commission (EEOC), and similar disability antidiscrimination laws, such as Section 503 of the Rehabilitation Act of 1973, enforced by the Department of Labor. These federal laws protect workers from employment discrimination based on disabilities. EEOC enforcement guidance released in 1995 indicates that discrimination by an employer against an individual on the basis of genetic information relating to illness, disease or other disorders would constitute a violation of the ADA because the employer would be "regarding" the individual as disabled. However, the EEOC policy position reflected in this enforcement guidance has not been tested in court to date.

In addition, federal race and national origin antidiscrimination laws, such as Title VII of the Civil Rights Act of 1964, may provide a limited basis for challenging race or ethnic-linked genetic discrimination in the workplace. Because risk for some genetic disorders may be higher among certain racial or ethnic groups, members of such groups may be discriminated against by employers who presume those individuals to be at "genetically" higher disease risk. An argument could be made that genetic discrimination based on race- or ethnic-linked disease risk constitutes unlawful race or ethnicity discrimination. However, these arguments have not been well received by the courts. Further, a strong nexus between race or national origin has been established for only a few diseases.

Given the substantial gaps in state and federal protections against employment discrimination based on genetic information, comprehensive federal legislation is needed.

The need for federal protection has been recognized by the numerous bills that have been

→ New Heading?

→ does this have any implications for employers? If not, should this be included?

→ might this be strong enough shouldn't we wait & see if current laws work before enacting new ones?

have there been cases of this?

If so, we should step then as their lack of effectiveness provides the best justification for fed. act.

→ We need strong justification as to why we need new law over this

as numerous bills have been introduced
introduced in Congress with bipartisan support. Three stand-alone bills have been introduced which amend existing civil rights or fair labor laws to create ~~this worker protection~~ (S. 1045, Sen. Daschle; H.R. 2275, Rep. Lowey; H.R. 2215, Rep. Kennedy) Three additional bills have also been introduced which include worker protection against discrimination based on genetic information as part of a broader proposals addressing the use of genetic information. *which prevent workers from being disc. on basis of genetics*
(S. 422, Sen. Domenici; H.R. 2198, Rep. Stearns; H.R. 1815, Rep. McDermott).

The Need for Federal Action

This paper highlights the fundamental health, employment, and legal issues that arise from the use of genetic information in the workplace. Federal legislation that addresses these issues would supplement existing state laws to ensure that all workers are protected against discrimination in the workplace based on the use of genetic information. At the same time, it should allow the use of genetic information to protect workers from workplace hazards and preserve the ability of scientists to continue the research that is so vital to expanding the knowledge of genetics and health.

would Fed legis. be the "floor"

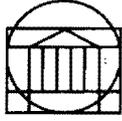
stronger state laws would remain intact right?
Such legislation should address the collection and use of genetic information by employers (and any other institutions or organizations in a position to influence employment decisions); protections from genetic discrimination based on a predisposition to a genetic disease or a genetic increased susceptibility to a toxic substance in the workplace; and protections from discrimination against workers who decline to undergo genetic testing.

[INSERT RECOMMENDATIONS]

We are discussing this at meeting 7/17/07

File
Genetic
Screening

UNIVERSITY OF VIRGINIA



HEALTH
SCIENCES
CENTER

CANCER CENTER

October 6, 1997

William Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Re: Bills S89 and HR 306

Dear Mr. President:

We are writing to express our thanks for your support of Bills S 89 and HR 306, which provide legislative protection for individuals against insurance discrimination based on genetic information. We would like to share with you our patients' struggles with difficult decisions about whether to be evaluated for inherited cancer predisposition in the absence of such protection.

By way of introduction: recently a number of genes associated with inherited cancer susceptibility have been discovered. Each gene, if pathologically altered from the normal form, increases an individual's risk to develop cancer at several specific sites. In some inherited cancer predisposition syndromes (ICPSs), the lifetime risk of malignancy may approach 80-90%. In addition, in individuals with an ICPS, the average age of tumor onset may be two decades earlier than the average age of onset of the same tumor type in individuals in the general population.

The new knowledge about inherited cancer susceptibility represents a major scientific advance that has the potential to translate into improved patient care. In the past, physicians have not been able to identify patients at genetically increased risk to develop specific types of cancer. Therefore, cancer screening and prevention efforts, including prophylactic surgery, could not be targeted intensively toward those who needed such interventions the most. In contrast, medicine now has some capacity to identify individuals with greater than average lifetime risks of specific tumors, and will continue to develop even greater capabilities as more cancer susceptibility genes are discovered. This will permit medical monitoring and the

earliest possible detection of tumors and treatment of patients at greatest risk. This becomes even more important when one considers that the youthful average age of tumor onset in genetically predisposed individuals may end life particularly early. These recent genetic discoveries have driven the establishment and very rapid growth of cancer genetic counseling services across the country.

The Cancer Genetics Clinic at the University of Virginia Health Sciences Center is such a service, whose staff evaluate patients regarding whether an ICPS is present in the patient and/or family. The evaluation occurs in two parts. The first step is an assessment of the family history of cancer to determine which ICPS, if any, is possibly present in the patient/family. The second step is DNA analysis, in which the patient's DNA undergoes laboratory testing to determine whether a pathologic change is present in a specific gene. The finding of a pathologic alteration means that the patient: is at increased risk to develop cancer at several characteristic sites; is a candidate to undergo early and intensive screening; may be a candidate for prophylactic surgeries; may wish to inform relatives that a cancer predisposition gene mutation has been identified in the family.

However, the impact on the patient's insurability of being identified as having or possibly having a pathologic form of one of these genes is potentially severe. Patients who have only their family history assessed, as well as patients proceeding with DNA testing and found to be genetically predisposed to develop cancer, may take the risk that they will lose their insurance and insurability permanently as a result of complying with their physician's recommendation to be evaluated.

Our clinic uses several informed consent documents, which the patient signs after discussion with the staff of the issues reviewed in the document. Both the Consent to Undergo Clinical Evaluation and the Consent to Undergo and Receive Results of DNA Analysis contain a statement that the patient's insurability could be permanently impacted as a result of undergoing the family history evaluation or laboratory testing. While informed consent documents always discuss the risks associated with any given evaluation or procedure, these are usually medical or occasionally psychological risks; it is unusual for such a document to list a social or financial risk. However, we feel obligated to include these matters in the documents, since there may be net harm to the patient of being identified as genetically predisposed to develop cancer if that patient then loses insurance and insurability. Our discussions with staff of other cancer genetic counseling services have informed us that many such services have also found it indicated to include discussion of insurability issues with patients.

Patients of the Cancer Genetics Clinic have had varying responses to the insurability risk aspect of undergoing evaluation. Some of our patients are well-insured under group plans and anticipate being so for the rest of their lives. These individuals, in general, have not been deterred from seeking care.

Unfortunately, other individuals referred for evaluation have declined service because of their justifiable concerns that their future insurability might be permanently affected. Some of these patients have declined assessment after reviewing the informed consent document, while others who have contacted us have refused even to make an appointment, given their awareness of the insurability impact of undergoing the evaluation. We have no way of knowing how many patients have been referred to our service but have never called us because of their concerns regarding insurability.

This means that some patients who may be at the greatest cancer risk are not informed of the increased risk to themselves and relatives of developing cancer at multiple sites, are not scheduled for early and intensive screening and/or prophylactic surgery that may improve outcome, and are not able to inform children and other relatives about the specifics of the familial risk. This is clearly unfavorable for patient care. At one level it is also self-defeating for insurers, whose financial interests are best met by the earliest possible detection of the cancers in their insurees.

Other patients, desperate to have their genetic status assessed, have proceeded with evaluation even at the risk of losing insurance and insurability. One such young patient, who is considering having her ovaries removed depending on her genetic status, has witnessed several relatives die with ovarian cancer. She informed us that she decided to proceed with genetic consultation and DNA testing because she would rather lose her insurance than die of ovarian malignancy. Americans should not have to choose between the two alternatives of: 1) receiving health care and losing insurance/insurability, or; foregoing health care and keeping insurance/insurability.

Inherited cancer predisposition is not rare. From the Virginia Tumor Registry we recently conservatively estimated the number of hereditary breast, prostate, and colorectal cancer cases in the state to be approximately 880 per year. These figures do not reflect the number of hereditary cancer cases at sites, such as the thyroid, less often affected by cancer than the breast, prostate, and colon. In addition, these figures do not show that each of these 880 individuals has relatives, some of whom will also be at increased risk to develop cancer. The incidence of ICPSs is great enough to expect that several persons with such disorders would be found in a filled Senate and House of Representatives. Furthermore, each of these individuals will have relatives, sometimes numerous, at risk for the same disorder.

None of us choose which genes we inherit. The staff of the Cancer Genetics Clinic would like to see all patients suspected of having an inherited predisposition to develop disease to be able to undergo evaluation without losing their insurance and insurability as a result of doing so. We regret very much that some individuals who wished to utilize cancer genetics assessment services declined this so that they could maintain insurance/insurability for themselves and their families.

We appreciate very much your support of Bills S 89 and HR 306 and urge that our legislators support these also.

Thank you.

Sincerely,

Susan M. Jones, M.S.
Genetic Counselor
Cancer Genetics Clinic

Susan Miesfeldt, M.D.
Director
Cancer Genetics Clinic

cc: Olympia Snowe (Senate - Maine)
Louise Slaughter (House of Representatives - New York)
Donna Shalala (Health and Human Services)
~~Christopher Jennings (Deputy Assistant to the President for Health Policy
Development)~~
William Frist (Senate - Tennessee)
Charles Robb (Senate - Virginia)
John Warner (Senate - Virginia)
Herbert Bateman (House of Representatives - Virginia)
Thomas Bliley, Jr. (House of Representatives - Virginia)
Rick Boucher (House of Representatives - Virginia)
Tom Davis (House of Representatives - Virginia)
Virgil Goode (House of Representatives - Virginia)
Bob Goodlatte (House of Representatives - Virginia)
Jim Moran (House of Representatives - Virginia)
Owen Pickett (House of Representatives - Virginia)
Bobby Scott (House of Representatives - Virginia)
Norman Sisiky (House of Representatives - Virginia)
Frank Wolf (House of Representatives - Virginia)
Francis Collins (Director, National Human Genome Research Institute, National
Institutes of Health)

MEMORANDUM

File Genetic
Screening

July 17, 1997

TO: John D. Podesta
Jacob J. Lew
Bruce Reed
Donald H. Gips
Sally Katzen
Rachel Levinson

FR: Chris Jennings

RE: PhRMA and Genetic testing

With regard to the attached letter which you received, I wanted to inform you that we have spoken with PhRMA regarding their concern that genetic discrimination could undermine important biomedical research efforts. They now understand that the President will be forwarding legislation on genetic discrimination to Capitol Hill which will build on the Slaughter-Snowe legislation. They are also aware that part of the reason why we are forwarding improved legislation is that we want to make sure that we have clarified the underlying bill to ensure that efforts bolster -- not harm -- the efforts of biomedical researchers.

It is also important to note that researchers like Dr. Francis Collins of the National Institute of Health's Human Genome Project, who well understand the importance of genetic information for biomedical research, support the President's efforts in moving legislation to prevent genetic discrimination. They believe that there are adequate protections in the President's improved legislation for important research efforts. Dr. Collins and others have communicated this to PhRMA, and PhRMA explicitly told Dr. Collins that they are now comfortable with this initiative.

Please feel free to call me at 6-5560 with any questions.

Alan F Holmer
PRESIDENT

PhARMA

July 10, 1997

The Honorable Bruce N. Reed
Assistant to the President
for Domestic Policy
The White House
Washington, D.C. 20500

Dear Mr. Reed:

We understand that the President is likely to speak publicly again next week in support of H.R. 306, Representative Louise Slaughter's bill to prohibit health insurance discrimination based on genetic information. We urge you to recommend that the President include the following sentence in his remarks suggesting the need for a minor but important change in the bill to protect biomedical research:

"I look forward to working with Representative Slaughter to ensure that her bill does not unintentionally harm biomedical research, and subsequently to promote its passage by the Congress."

The Slaughter bill unintentionally could harm biomedical research and thereby the patients who would benefit from new treatments for disease. The bill sweepingly defines "genetic information" to include information about inherited characteristics that may "derive from" an individual or a family member. So defined, "genetic information" includes information (about, for example, gender, cholesterol levels, blood type) even if it has been anonymized and does not identify the person concerned. With respect to any application affecting biomedical research, the bill should limit its focus to genetic information that identifies a particular person. Biomedical researchers should have unimpeded access to genetic and other medical information that does not identify a particular patient.

The bill then prohibits the disclosure of any "genetic information" by health insurers. Managed care organizations are arguably insurers since they provide health insurance as well as services to their members. Many managed care organizations participate extensively in biomedical research that promotes the public health and facilitates the discovery and development of new medicines. The bill's disclosure prohibition unintentionally would impede their contribution to better public health through participation in biomedical research, even when the genetic information concerned does not identify a particular patient.

Pharmaceutical Research and Manufacturers of America

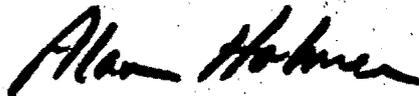
1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3420 • FAX: 202-835-3429

Mr. Reed
July 10, 1997
Page Two

The bill's provisions allowing disclosure of "genetic information" with the patient's informed consent would not cure this defect. Access to patient registries, for example, is critical to epidemiological research and studies. Obtaining informed consent to the use of data in registries – often years after the information was recorded – would not be feasible. In any event, any requirement to obtain consent in these circumstances – even when the database concerned does not identify a particular patient – would likely result in non-random selection bias in any sample of data obtained. In other words, any conclusions drawn about health outcomes under these circumstances may differ dramatically from the conclusions that would be drawn if the study were based on unlimited access to the full patient registry or other database.

While we do not take a position on this proposed legislation, we stress that its passage as currently drafted would harm biomedical research. Therefore, in any remarks on the Slaughter bill, we urge the President to stress that the bill needs to be modified to protect biomedical research. Such research continues to be crucial to promoting public health and enabling American families to live longer, healthier, happier and more productive lives.

Sincerely,



Alan F. Holmer

Identical letter to Dr. John H. Gibbons

cc: Donald H. Gips
Chris Jennings
Sally Katzen
Rachel Levinson
Jacob J. Lew
John D. Podesta
Representative Louise Slaughter



OFFICE OF THE EXECUTIVE
VICE PRESIDENT
1100-15th Street, N.W.
Suite 900
Washington, D.C. 20005

FAX

Date 7-10-97
Number of pages including cover sheet 3

*Chris -
FYI*

To: Bruce Reed

From: JUDITH H. BELLO

TEL: 456-2216

Doris Norman

FAX: 456-2878

TEL: 202-835-3431

CC: _____

FAX: 202-835-3429

REMARKS:

- Urgent
- For your review
- Reply ASAP
- Please comment

Tomorrow.

write response

MEMORANDUM

To people c'd on this

list based on g+a on

PhRMA show me ~~to~~ edit.

MEMORANDUM

July, 17 1997

TO: John D. Podesta
Jacob J. Lew
Bruce Reed
Donald H. Gips
Sally Katzen
Rachel Levinson

FR: Chris Jennings

RE: PhRMA and Genetic testing

With regard to the attached letter which you received, I wanted to inform you that we have spoken with PhRMA regarding their concern that genetic discrimination could undermine important biomedical research efforts. They now understand that the President will be forwarding legislation on genetic discrimination to Capitol Hill which will build on the Slaughter-Snowe legislation. They are also aware that part of the reason why we are forwarding improved legislation is that we want to make sure that we have clarified the underlying bill to ensure that efforts bolster -- not harm -- the efforts of biomedical researchers.

It is also important to note that researchers like Dr. Francis Collins of the National Institute of Health's Human Genome Project, who well understand the importance of genetic information for biomedical research, support the President's efforts in moving legislation to prevent genetic discrimination. They believe that there are adequate protections in the President's improved legislation for important research efforts. Dr. Collins and others have communicated this to PhRMA, and PhRMA explicitly told Dr. Collins that they are now comfortable with this initiative.

Please feel free to call me at 6-5560 with any questions.

JUL 10 '97 04:56PM PHARMA PRESIDENT P.273

Alan F. Holmer
PRESIDENT



July 10, 1997

The Honorable Bruce N. Reed
Assistant to the President
for Domestic Policy
The White House
Washington, D.C. 20500

Dear Mr. Reed:

We understand that the President is likely to speak publicly again next week in support of H.R. 306, Representative Louise Slaughter's bill to prohibit health insurance discrimination based on genetic information. We urge you to recommend that the President include the following sentence in his remarks suggesting the need for a minor but important change in the bill to protect biomedical research:

"I look forward to working with Representative Slaughter to ensure that her bill does not unintentionally harm biomedical research, and subsequently to promote its passage by the Congress."

The Slaughter bill unintentionally could harm biomedical research and thereby the patients who would benefit from new treatments for disease. The bill sweepingly defines "genetic information" to include information about inherited characteristics that may "derive from" an individual or a family member. So defined, "genetic information" includes information (about, for example, gender, cholesterol levels, blood type) even if it has been anonymized and does not identify the person concerned. With respect to any application affecting biomedical research, the bill should limit its focus to genetic information that identifies a particular person. Biomedical researchers should have unimpeded access to genetic and other medical information that does not identify a particular patient.

The bill then prohibits the disclosure of any "genetic information" by health insurers. Managed care organizations are arguably insurers since they provide health insurance as well as services to their members. Many managed care organizations participate extensively in biomedical research that promotes the public health and facilitates the discovery and development of new medicines. The bill's disclosure prohibition unintentionally would impede their contribution to better public health through participation in biomedical research, even when the genetic information concerned does not identify a particular patient.

Pharmaceutical Research and Manufacturers of America

1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3420 • FAX: 202-835-3429



Report of the Secretary to the President

HEALTH INSURANCE IN THE AGE OF GENETICS

JULY 1997

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 discrimination 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.

promise of better health because it gives researchers and clinicians critical information to work out therapies or other strategies to prevent or treat a disease.

What if we could prevent or reduce the effects of many common diseases by simple changes in lifestyle or avoidance of specific environmental substances? Many of the diseases we face--such as high blood pressure and other familiar diseases of the heart and circulatory system, diabetes, obesity, cancer, psychiatric illness, asthma, arthritis--have been difficult to study and treat because almost all involve subtle actions of several genes and the environment. Scientists are rapidly developing advanced technologies to identify each of the genes that contribute to a complex disorder and study their interactions all at once. The goal is to tease apart which disease components are genetic and which are environmental.

The slowest part of a disease-gene hunt nowadays is sorting through all the genes in the target region on a chromosome and determining which one is responsible for the disease. But this is rapidly changing. New gene maps now pinpoint the locations of more than one-fourth of all human genes, and more are developed every day.

The complete set of genetic instructions will give researchers basic information about how a human cell works as a system, or how the cells of a brain or a heart work together, or how a single fertilized cell develops into a fully formed baby. Spelling out, letter by letter, the complete genetic instructions of a human being will bring with it new technologies that make identifying DNA differences effortless compared with what we can do today. Imagine analyzing your genetic composition on a computer chip, carrying your DNA "bar code" on a small plastic card, encrypted to protect privacy, that lets health care professionals instantly know your predisposition to disease, your reactions to drugs, or your susceptibility to certain environmental exposures. All of these will become realities as we continue to make advancements in genetics.

Genetic Discrimination: A New Twist on an Old Injustice

The ability to examine our DNA for the presence of disease-related alterations opens the door to a new twist on an old injustice: "genetic" discrimination -- when people, either as groups or individuals, are treated unfairly because of the content of their DNA. The increased availability of genetic information raises concerns about who will have access to this potentially powerful information. Each of us has between 5 and 30 misspellings or alterations in our DNA; thus, we could all be targets for discrimination based on our genes. Like racism, sexism, and other forms of prejudice, genetic discrimination devalues diversity, squanders potential, and ignores achievement.

Genetic information has been used to discriminate against people in the past. In the early 1970's, some insurance companies denied coverage and some employers denied jobs to

African- Americans who were identified as carriers for sickle-cell anemia, even though they were healthy and would never develop the disease.

Of particular concern is the fear of losing or being denied health insurance because of a possible genetic predisposition to a particular disease¹. For example, a woman who carries a genetic alteration associated with breast cancer, and who has close relatives with the disease, has an increased risk of developing breast and ovarian cancer. Knowledge of this genetic status can enable women in high-risk families, together with their health care providers, to better tailor surveillance and prevention strategies. However, because of a concern that she or her children may not be able to obtain or change health insurance coverage in the future, a woman currently in this situation may avoid or delay genetic testing.

These are real concerns for too many Americans. In a recent survey of people in families with genetic disorders, 22 percent indicated they, or a member of their family, had been refused health insurance on the basis of their genetic information². The overwhelming majority of those surveyed felt that health insurers should not have access to genetic information. A 1995 Harris poll of the general public found a similar level of concern. 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 information³.

Discrimination in health insurance, and the fear of potential discrimination, threaten both society's ability to use new genetic technologies to improve human health and the ability to conduct the very research we need to understand, treat, and prevent genetic disease.

To unravel the basis of complex disorders in the large numbers of individuals they affect, scientists must analyze the DNA of many hundreds of people for each disease they study. Valid research on complex disorders will require the participation of large numbers of volunteers. But a pall of mistrust hangs over research programs because study volunteers are concerned that their genetic information will not be kept confidential and will be used by insurers to discriminate against them. Information about research participant's genetic composition must be protected from misuse.

Participants in Dr. Barbara Weber's research program on breast cancer worry a great deal about genetic discrimination⁴. She and her coworkers in Pennsylvania are trying to understand how to keep women with breast cancer gene mutations healthy by studying them closely for several years. But nearly one-third of the high-risk people Dr. Weber invites into the study refuse because they fear discrimination and/or a loss of privacy. So strong is the fear of misuse of genetic information obtained in research programs that many physician-researchers leave genetic test results out of the study medical record or warn study participants not to give the information to their private physicians. In some instances, patients and/or their providers may be forced to tell outright lies about genetic test results.

In genetic testing studies at the NIH, nearly 32 percent of eligible people offered a test for breast cancer risk decline to take it. The overwhelming majority of those who refuse cite concerns about health insurance discrimination and loss of privacy as the reason.

In an ongoing study, researchers are assessing individuals who have already had cancer and their families. Because individuals who have had cancer have already been categorized as a high risk by insurers, participants in this study are somewhat less concerned about the potential for health insurance discrimination. The vast majority of individuals invited to have genetic testing as a part of the research project have agreed to be tested. Those who have opted not to be tested state that knowledge of how this information might be used was a determining factor.

The Need for Legislation

In 1995, the National Action Plan on Breast Cancer (NAPBC, coordinated by the US Public Health Service Office on Women's Health) and the NIH-DOE Working Group on Ethical, Legal and Social Implications of Human Genome Research (ELSI Working Group) tackled the issue of genetic discrimination and health insurance. This effort built on the ELSI Working Group's long standing interest in the privacy and fair use of genetic information and the NAPBC's mandate to address priority issues related to breast cancer. The following recommendations⁵ were published and made available to state and federal policy makers:

- ▶ Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment or contribution requirements.
- ▶ Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information, or an individual's request for genetic services.
- ▶ Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.
- ▶ Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

In developing these recommendations, the NAPBC and ELSI Working Group developed the following definitions: "Genetic information" refers to information about genes, gene products or inherited characteristics that may derive from the individual or a family member.

The term "insurance provider" refers to an insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully insured or self-funded.

These recommendations would prevent insurers from having *access* to genetic information, from being able to *misuse* this information, and from *disclosing* it to others.

State Initiatives

Today, 19 states have enacted laws to restrict the use of genetic information in health insurance. These range from very narrow prohibitions in earlier legislation (e.g., Alabama in 1982 prohibited insurers from denying coverage because an applicant had sickle cell anemia) to fairly comprehensive prohibitions with strong privacy protections in more recent legislation (e.g., Wisconsin in 1991, New Jersey in 1996, and California in 1994, 1995, and 1996)⁶. Since January of this year, at least 31 states have introduced legislation to prohibit genetic discrimination in insurance⁷. The large volume of legislative activity at the state level is a positive indication of the level of concern about this important issue.

A law passed in Arizona this year prohibits health and disability insurers from rejecting an application or determining rates, terms or conditions on the basis of a genetic condition and prohibits requiring the performance of a genetic test without written informed consent. Governor Symington signed the bill into law in spite of threats by the insurance industry to leave the state.

The Illinois Legislature passed the Genetic Information Privacy Act in May, 1997. The Act is currently pending approval by the governor. The Act prohibits insurers from seeking genetic information derived from genetic testing and from using genetic testing information for nontherapeutic purposes. This bill was originally introduced by Representative Moffitt at the request of an ovarian cancer survivor whose mother and grandmother had died of ovarian cancer. This constituent wanted to be tested for BRCA1 in order to help her daughters and granddaughters. Her doctor warned, however, that if she tested positive, she and members of her family could lose health care coverage. Based on that threat, she chose not to be tested. (She has since been tested anonymously and tested negative.)

Why State Law Is Not Enough

The current patchwork of state legislative approaches does not provide a comprehensive solution to genetic discrimination in health insurance.

First, private sector employer-sponsored health plans that provide benefits for employees and their dependents through self-funded arrangements are generally exempt from state insurance laws pursuant to the Employee Retirement Income Security Act (ERISA) preemption. Thus, even if states enacted legislation modeled on the NAPBC-ELSI Working Group recommendations, approximately 125 million people, nearly one-half of all Americans, covered by such self-funded plans would not be protected.

Second, with the exception of a few states, these laws focus narrowly on genetic tests rather than more broadly on genetic information generated by family history, physical examination, or the medical record. Although insurers are prohibited from using the results of a chemical test of DNA, or the protein product of a gene, they may still use other physical/physiological (phenotype) indicators, pattern of inheritance of genetic characteristics, or even a request for genetic testing as the basis for discrimination. Thus, meaningful protection against genetic discrimination requires that insurers be prohibited from using all information about genes, gene products, or inherited characteristics to deny or limit health insurance coverage.

HIPAA: Significant Steps But Serious Gaps

In 1996, Congress enacted a law, called The Health Insurance Portability and Accountability Act (HIPAA), which took a significant step toward expanding access to health insurance. But HIPAA doesn't go far enough. Americans are still unprotected by federal law against insurance rate hikes based on genetic information and against unauthorized people or institutions having access to the genetic information contained in their medical records. HIPAA includes genetic information among the factors that may not be used to deny or limit insurance coverage for members of a group plan. Further, HIPAA explicitly excludes genetic information from being considered a preexisting condition in the absence of a diagnosis of the condition related to such information. The law specifically uses the broad, inclusive definition of genetic information recommended by the NAPBC-ELSI Working Group. Finally, HIPAA prohibits insurers from charging one individual a higher premium than any other "similarly situated" individual in the group.

These steps towards preventing discrimination based on genetics are significant, but HIPAA left several serious gaps that can now be closed by Administration-supported legislation. First, the protections in HIPAA do not extend to the individual health insurance market. Thus, individuals seeking coverage outside of the group market may still be denied access to coverage and may be charged exorbitant premiums based on genetic information. While only approximately 5 percent of Americans obtain health insurance outside the group market today, many of us will, at some point in our lifetime, purchase individual health insurance coverage. Because genetic information persists for a lifetime and may be transmitted through generations, people who are now in group plans are concerned about whether information about their genes

may, at some point later in their life, disallow them from being able to purchase health insurance outside of the group market.

Second, while HIPAA prohibits insurers from treating individuals within a group differently from one another, it leaves open the possibility that all individuals within a group could be charged a higher premium based on the genetic information of one or more members of the group.

Finally, HIPAA does nothing to limit an insurer's access to or release of genetic information. No federal law prohibits an insurer from demanding access to genetic information contained in medical records or family history or requiring that an individual submit to a genetic test. In fact, an insurer can demand that an individual undergo genetic testing as a condition of coverage. Further, there are no restrictions on an insurers' release of genetic information to others. For example, at present, an insurer may release genetic information, and other health-related information, to the Medical Information Bureau which makes information available to other insurers who can then use it to discriminate. Because genetic information is personal, powerful, and potentially predictive, it can be used to stigmatize and discriminate against people. Genetic information must be private.

Congressional Initiatives

Congressional interest in securing health insurance protection for genetic information is strong and bipartisan. Senator Hatfield and Representative Stearns introduced the first bill on genetic discrimination in health insurance and employment in November 1995. Twelve bills addressing genetic information access and/or use were introduced in the 104th Congress. Many of these bills are being reintroduced in the current Congress.

Representative Solomon (R-NY) introduced H.R. 328, Genetic Information Health Insurance Nondiscrimination Act of 1996. This bill was rewritten to close the "loopholes" in HIPAA by addressing discrimination in the individual health insurance market, but it does not prohibit rate increases in the group health insurance market.

Genetic Confidentiality and Nondiscrimination Act of 1997 (S. 422) introduced by Senator Domenici (R-NM) is a broad bill that seeks to address privacy and fair use of genetic information in many settings. The bill includes a title that would prohibit health insurers from using genetic information that follows the NAPBC-ELSI Working Group recommendations. However, this bill refers only to "any molecular genetic information about a healthy individual or a healthy family member..." rather than the broader definition of genetic information that includes family history.

The Genetic Information Nondiscrimination in Health Insurance Act of 1997 (H.R. 306) introduced by Representative Slaughter (D-NY) most closely tracks the recommendations made

by the NAPBC-ELSI Working Group. This bill successfully closes the "loopholes" in HIPAA by prohibiting rate increases in the group health insurance market based on genetic information, prohibiting the use of genetic information in the individual health insurance market, and placing restrictions on the collection and disclosure of genetic information by insurers. As of July 1, 1997, H.R. 306 had 132 co-sponsors and 67 supporting groups. The Senate companion bill, The Genetic Information Nondiscrimination in Health Insurance Act of 1997 (S. 89), was introduced by Senator Snowe (R-ME).

Recommendations for Federal Legislation

On May 18, 1997, President Clinton, in his commencement address at Morgan State University, urged "Congress to pass bipartisan legislation to prohibit insurance companies from using genetic information to determine the premium rate or eligibility of Americans for health insurance."

The Administration is proposing that Congress pass a law to ensure that the discoveries made possible by the Human Genome Project are used to improve the health of Americans and not used by health insurers to discriminate against individuals, families, or groups. The Administration recommends that the law build on the effort begun under HIPAA and encompass the NAPBC-ELSI Working Group's recommendations that seek to prevent health insurers from having access to genetic information, from being able to misuse this information, and from disclosing genetic information to others.

The bill should build on HIPAA and extend protection to insurance applicants and participants in four ways. It should --

- ▶ Explicitly prohibit health insurers from varying the rate charged to a group based on genetic information pertaining to one or more group members. This would expand the prohibition in HIPAA against using genetic information to vary the premium rates of an individual in a group plan.
- ▶ Prohibit insurers in the individual market from requesting or requiring genetic information from an individual, except where the information relates to a disease or condition for which the individual or dependent has been positively diagnosed, and prohibiting insurers from requiring individuals to undergo genetic testing.
- ▶ Prohibit insurers in the individual market from using genetic information in the absence of a diagnosis of disease to deny, limit or vary coverage or to set rates.
- ▶ Protect the privacy and confidentiality of genetic information by prohibiting insurers from releasing this information for nontreatment purposes without the prior authorization of the individual. This would impose restrictions on the disclosure of genetic information to

other insurers, to plan sponsors, and to other entities regulated by State insurance laws including life, disability, and long-term care insurers. It would also prohibit insurers from releasing genetic information to the Medical Information Bureau or any other entity that collects, compiles, or disseminates insurance information.

HIPAA does acknowledge that protections concerning access to and release of health information, including genetic information, were not provided in the law itself and directs the Department of Health and Human Services (DHHS) to develop recommendations to protect the privacy of health information. Currently, DHHS is preparing recommendations on privacy protections for all individually identifiable health information, including genetic information, as required by HIPAA. Congress may in the future enact legislation that would provide protections for personally identifiable health information in general. However, the public feels especially concerned about the unique properties of genetic information -- its predictive nature, its fundamental linkage to personal identity and kinship ties, its history of abuse, and the speed of development of genetic technologies. Therefore, it is important to move forward with legislation prohibiting health insurance discrimination and restricting health insurers' use and dissemination of genetic information.

Conclusion

The technology of genetic testing offers great promise for better health. However, genetic tests and genetic information can also be used to deny coverage or increase premiums. The Administration strongly supports efforts to protect individuals from misuse of genetic information by health insurers, while permitting providers and others who can positively use such information to continue to use genetic information in ways that will enhance the treatment and care of individuals.

We now have the opportunity to ensure that our social policy keeps pace with the scientific advances made possible through biomedical research. The American people and the Congress support protections against genetic discrimination in health insurance. Supporting the principles put forth by the NAPBC-ELSI Working Group could ensure that increasing knowledge about ourselves and our genetic heritage is used to benefit Americans, to improve their health and well-being, and not to stigmatize or discriminate against them. This is an issue that ultimately will concern all of us. The universal principles of fairness and justice compel an urgent solution to this growing problem.

References

1. Geller, Lisa N. et al, *Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis*, Science and Engineering Ethics, Vol. 2, 71-88 (1996)
2. Lapham, E. Virginia et al, *Genetic Discrimination: Perspectives of Consumers*, Science, Vol. 274, 621-24 (October 25, 1996)
3. Harris Poll, 1995 #34
4. Kolata, Gina, *Advent of Testing for Breast Cancer Genes Leads to Fears of Disclosure and Discrimination*, New York Times, C1 (Feb 4, 1997)

Cowley, Geoffrey, *Flink the Test and Lose Your Insurance*, Newsweek, 48-50 (Dec 23, 1996)
5. Hudson, Kathy et al, *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, Science, Vol. 270, 391-93 (October 20, 1995)
6. Rothenberg, Karen H., *Genetic Information and Health Insurance: State Legislative Approaches*, Journal of Law, Medicine and Ethics, Vol. 23:4, 312-19 (Winter 1995)
7. Barbara Fuller, J.D., National Action Plan on Breast Cancer, unpublished data

file:
"Genetic
Screening"



FAX Transmittal Sheet

DATE: June 6, 1997

TO: Chris Jennings

ORGANIZATION: _____

TELEPHONE: _____

FAX: 65557

FROM: RACHEL E. LEVINSON

TELEPHONE: (202) 456-6137

FAX: (202) 456-6027

NUMBER OF PAGES, INCLUDING COVER PAGE: 4

SPECIAL INSTRUCTIONS: **FYI - Heads up**

Bio**BIOTECHNOLOGY
INDUSTRY
ORGANIZATION****News Release**

1625 K Street, N.W. · Suite 1100 · Washington, D.C. 20006 · (202) 857-0244 · FAX: (202) 857-0237

FOR IMMEDIATE RELEASE

June 8, 1997

CONTACT:Eric Christensen
Megan Matthews
(713) 654-1234**International Biotechnology Community Supports Genetic Privacy****BIO Seeks White House Support**

WASHINGTON, D.C.-----Eleven international biotechnology organizations have endorsed the Biotechnology Industry Organization's (BIO) policy statement regarding genetic privacy, calling for strong protections against the misuse of personal medical information including data derived from genetic diagnostic tests.

"This is an unprecedented expression of concern by a global industry for the genetic privacy of every individual," said BIO President Carl B. Feldbaum. "It is our intention and strong expectation that this endorsement of genetic privacy contribute to the rights and well-being of individuals all over the world. BIO intends to seek even broader international consensus," Feldbaum said, "in our continuing efforts to gain legislative support for genetic privacy here and abroad. It is obvious to the U.S. biotechnology industry that while our new diagnostics will bring health benefits to individuals worldwide, any potential misuse -- to discriminate or stigmatize -- should be prohibited wherever our products are sold.

"Also, BIO has informed President Clinton through White House staff of this global statement and will enlist White House as well as congressional support. Recall that in his commencement speech at Morgan State University on May 19, President Clinton said that 'none of our discoveries (from science) should be used to label or discriminate against any group or individual.'

(more)

BIO/Privacy

Page 2

"Clinton added that 'genetic testing has the potential to identify hidden inherited tendencies toward disease and spur early treatment. But that information could also be used, for example, by insurance companies and others to discriminate against and stigmatize people.'

"We wholeheartedly agree," said Feldbaum.

On September 18, 1996, the BIO Board of Directors approved a policy statement regarding genetic privacy on behalf of BIO's 720 member companies, state organizations and educational institutions. The statement stresses that individuals must be treated with respect in the way their personal medical and genetic information is acquired and used. It points out that genetic testing provides important opportunities to improve human health.

These tests can be used to diagnose the presence of disease. Equally, they can provide information that can be used to reduce the risk of future disease and enable earlier and more effective treatment if and when disease occurs. These tests can advise doctors that patients may need changes in their diet or more exercise. The statement also highlights the need to protect the privacy of, and safeguard against misuse of, all personal medical information, regardless of the method by which it is obtained.

A number of legislative proposals designed to protect against genetic discrimination have already been introduced in the U.S. Congress and several state legislatures. Senator Pete Domenici (R-NM) currently has a genetic privacy bill, but its scope of protection needs to be broadened to include all medical information, not just genetic information, Feldbaum pointed out.

(more)

BIO/Privacy
Page 3

"So much of what our industry does is dedicated to improving the quality of life for all people. It is only natural that we speak out in favor of protection for the rights of each person, particularly when the application of biotechnology is involved," said Feldbaum.

The 11 international organizations that expressed their official support for BIO's policy statement regarding genetic privacy are: the Advanced Biotechnology Center (Italy), the All India Biotech Association, the Australian Biotech Association, the Belgian BioIndustries Association, the Biominas Foundation (Brazil), the Genetic Engineering Biotechnology Research Institute (Egypt), the Hong Kong Institute of Biotechnology Ltd., the Mexican Association of Biotechnology Firms, the Mongolian Biotechnology Association, the National Steering Committee for Biotechnology (Israel), and the New Zealand Biotechnology Association.

The Biotechnology Industry Organization (BIO) represents over 720 biotechnology companies, academic institutions, and state biotechnology centers in 47 states and more than 20 nations. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.

###