



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
OFFICE OF HEALTH LEGISLATION**

**HHH Bldg, Room 405H
200 Independence Avenue, SW
Washington, D.C. 20201**

PHONE: 690-7450

FAX: 690-8425

FROM: SEE BELOW

TO: SEE BELOW

HOLLY BODE

NAME

Chris Jennings

SHARON CLARKIN

OFFICE

SEAN DONOHUE

ROOM

PHYLLIS HENDERSON

PHONE

DOUG HUSSEY

FAX

456-5557

GREGORY JONES

DATE

ANDREA LEVARIO

PAGES

(INCLUDING COVER)

JUDY LEWIS

*Health Care & Genetic Discrim. - CMB
passback (Pellicci)*

COLLEEN MEIMAN

ROGER MCCLUNG

REMARKS

MARC SMOLONSKY

DEBRA SPEIGHT

CARL TAYLOR

*Tressury is not thrilled! and Bob said that
Labor will comment in a similar way.
I agreed with Bob that I would send this
on to you. Would you talk to Rich and
Gary about where we go from here.
Thanks
Judy*

OFFICE OF MANAGEMENT AND BUDGET

*Legislative Reference Division
Labor-Welfare-Personnel Branch*

Telecopier Transmittal Sheet



SPECIAL

FROM: Bob Pellicci -- 395-4871

DATE: 6/3

TIME: 1:30 p.m.

Pages sent (including transmittal sheet): 7

COMMENTS:

*Per our conversation - Treasury
Dept comments on genetic information
draft bill.*

TO:

Thayer Nelson, HHS

PLEASE CALL THE PERSON(S) NAMED ABOVE FOR IMMEDIATE PICK-UP.

**TREASURY COMMENTS RE HHS DRAFT BILL
GENETIC INFORMATION NONDISCRIMINATION IN HEALTH INSURANCE**

Comments from the Office of Tax Policy:

The proposal is premature at this time because certain major features of the proposal could potentially be included in an existing regulation project under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Further, there are several technical problems in the proposal that would need substantial time to resolve and would be better addressed in coordination among all three agencies (HCFA, Labor and Treasury) that are charged with implementation of similar nondiscrimination prohibitions in HIPAA.

Comments from the IRS:

This memorandum contains some preliminary comments on the draft of the "Genetic Information Nondiscrimination in Health Insurance Act of 1997," HHS-23-A, which we received yesterday. For the reasons stated below, we believe the bill has significant defects and is not ready for public release at this time.

Apart from the specific comments, the Service objects strongly to the procedure followed in drafting and circulating this bill. This bill, although it originated with HHS, contains significant amendments to the Internal Revenue Code. Despite this, neither the IRS nor the Office of Tax Policy was consulted or involved in drafting the bill and we have now been given less than 24 hours to review it. This lack of consultation is particularly unjustifiable given that the bill amends provisions added by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). The Service and the Office of Tax Policy have been working closely with HHS on task forces to develop regulations under HIPAA and these task forces, which typically meet several times a week, offered ample opportunity for consultation on related legislation.

Because the IRS has not been involved in any way in the

- 2 -

drafting of this bill, and because we have been given less than 24 hours for review, these comments are only preliminary and we reserve the right to revise and supplement them later. Moreover, due to the brief review period afforded us, we are only providing the most significant comments at this time.

Our specific comments include the following:

1) The proposed amendments to ERISA section 702(b)(1), Public Health Service Act ("PHSA") section 2702(b)(1), and Code section 9802(b)(1) would prohibit the adjustment of premium rates for groups on the basis of genetic information. This would involve a major intervention by the federal government in the regulation of rate-setting by insurance companies, an area we understand has been traditionally reserved for state regulation. The general HIPAA nondiscrimination provisions that the Genetic Information bill would amend carefully avoided such federal involvement. Moreover, this provision is contradicted by the disclaimer in subparagraph (b)(2) of the respective statutes that nothing in subparagraph (b)(1) is to be construed to restrict the amount that an employer may be charged for coverage under a group health plan.

2) The new subparagraph 9802(c)(2)(B) to be added to the Internal Revenue Code, as well as the parallel provisions that would be added to ERISA and the PHSA, restricts the disclosure of genetic information by hospitals, physicians, and other medical care providers. This would substantially expand the regulated entities under HIPAA, which at present applies only to plans and issuers. While we express no view on whether this is appropriate

in ERISA or the PHSA, it clearly is not appropriate in the Internal Revenue Code since the Service has no enforcement mechanism against providers.

3) The bill applies the genetic information nondiscrimination requirements under the Code to both plans and issuers. The existing group market nondiscrimination provisions of HIPAA in the Code apply only to plans, not to issuers. Treasury has no enforcement authority against noncomplying issuers, so the references to issuers should be deleted in the Code provisions.

4) The new subparagraph (c)(3)(B) to be added to the respective statutes provides exceptions to the new prohibitions added by the Bill. Clause (ii) of that subparagraph permits plans and issuers to request or require genetic information from other plans or issuers and from providers under certain circumstances. We have two concerns with this provision. First, it is not clear to us how plans or issuers can require the disclosure of requested genetic information from other plans or issuers. Second, the exception does not protect providers who may be replying to a request or requirement by a plan or issuer for the genetic information (thus the Bill would protect the requester but not the responder).

5) The Bill would add a new section 2752 to the PHSA. In form, section 2752 would apply the genetic information nondiscrimination requirements of the group market to issuers in the individual market and then would add some exceptions to the

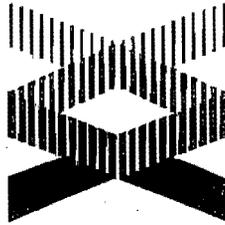
group market rules. It appears, however, that the exceptions virtually swallow the genetic information restrictions purportedly added by section 2752, so that those restrictions would be mostly or wholly illusory. We question what section 2752 was intended to accomplish and why it was drafted as it was

6) We also have numerous comments of a more technical nature, but we have not had time to tabulate and forward them.

On a more fundamental level, we have some question as to whether legislation is required at all in this area. HIPAA already prohibits discrimination on the basis of genetic information and many of the provisions in the statute relating to restrictions on group health plans and providers likely could be adopted in regulations under these existing statutory provisions. We believe more consideration should be given to the need for this legislation.

In summary, we have serious concerns about the substance of several key provisions in the bill and object strongly to the lack of consultation and abbreviated review period for a bill that amends the Internal Revenue Code. We believe the bill should not be released to the public at this time.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE, NIH



FAX TRANSMITTAL SHEET

TO: Sarah Bianchi, White House

FAX NUMBER: 202-456-5557

FROM: Kathy Hudson, Ph.D.
Assistant Director, Office of Policy Coordination

DATE: June 4, 1997

of pages including cover sheet: 5

Return FAX number: (301) 402-2218

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

Comments:

Ayle Dennis - 202-546-4732

DRAFT LETTER: JUNE 2, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

As members of The Genome Action Coalition (TGAC), we are writing with regard to your recent speech at Morgan State University concerning the role of science in American society. TGAC unites more than 100 organizations, foundations and companies in support of the success of the Human Genome Project.

The issues of genetic nondiscrimination and medical records privacy are critical for the ultimate success of the Project and you are to be commended for bringing these complex and controversial matters before the American public in a clear and understandable manner.

TGAC supports your call for bipartisan legislation to prevent health insurers from using genetic information to discriminate against future or present policyholders. Last year, we strongly supported the provision in the Kennedy-Kassebaum legislation that you signed into law that prohibited such activity with regard to group plans. Extending those provisions to all other forms of health plans is a step that we can also support.

We have taken the liberty of enclosing a set of principles that TGAC has adopted with regard to these critical issues. Please know that The Genome Action Coalition stands ready to work with you and your administration in the furtherance of scientific research leading to the curing of disease.

Sincerely,

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

Enclosure

06/02/97 MON 12:09 FAX 202 546 5051

→→→ MEGAN SEXAUER

☑003

On behalf of:

The Genome Action Coalition
Manic-Depressive Illness Foundation

MEMBERSHIP LIST

Alliance for Aging Research
 Alliance of Genetic Support Groups
 Alpha 1 National Association
 Alzheimer's Association
 American Association of Retired Persons
 American College of Medical Genetics
 American Diabetes Association
 American Foundation for Suicide Prevention
 American Jewish Congress
 American Liver Foundation
 American Sickle Cell Anemia Association
 American Society of Human Genetics*
 The Arc
 Arizona Consortium for Children with Chronic
 Illness
 A-T Children's Project
 Autism Society of America
 Baylor College of Medicine Human Genome
 Center
 Beckwith-Wiedemann Support Network
 Boystown National Research Hospital
 Cardiac Arrhythmias Research & Education
 Foundation
 Charcot-Marie-Tooth Association
 Coalition for the Prevention of Sudden Cardiac
 Death
 Coalition of Heritable Disorders of Connective
 Tissue
 Consortium of Social Science Associations
 Cooley's Anemia Foundation
 Cystic Fibrosis Foundation*
 Depression & Related Affective Disorders
 Association
 Dysautonomia Foundation, Inc.
 Dystonia Medical Research Foundation
 Ehlers-Danlos National Foundation
 Fancouli Anemia Research Fund, Inc.
 Foundation for Biomedical Research
 Foundation for Ichthyosis and Related Skin
 Types
 Gilda Radner Familial Ovarian Cancer Registry
 Genentech, Inc.*
 Genzyme Corp.*
 Guillain Barre Syndrome Foundation
 International
 Hemochromatosis Foundation, Inc.
 Hereditary Cancer Institute - Creighton
 University
 Hereditary Disease Foundation
 Hoffmann-LaRoche, Inc.
 Huntington's Disease Society of America
 Inherited High Cholesterol Foundation
 International Joseph Diseases Foundation
 International Patient Advocacy Association
 International Rett Syndrome Association
 International Tremor Foundation
 Iron Overload Diseases Association
 The Jeffrey Modell Foundation*
 Knox County Advocates for Special Kids
 Learning Disabilities Association of America
 Lexicon Genetics, Inc.
 Lowe Syndrome Association
 Manic Depressive Illness Foundation*
 March of Dimes Birth Defects Foundation*
 Merck & Co., Inc.*
 Mitochondrial Disorders Foundation of America
 Mize Informatics Foundation
 The MPS Society, Inc.
 MUMS National Parent to Parent Network
 Myositis Association of America, Inc.
 Myriad Genetics Laboratories, Inc.
 National Alliance for the Mentally Ill
 National Alopecia Areata Foundation
 National Ataxia Foundation
 National Center for Chromosome Inversions
 National Center for Learning Disabilities Inc.
 National Depressive & Manic-Depressive
 Association
 National Down Syndrome Society
 National Gaucher Foundation
 National Hemophilia Foundation*
 National Incontinentia Pigmenti Foundation
 National Marfan Foundation
 National Mental Health Association
 National MPS Society - Great Lakes Region
 National Multiple Sclerosis Society
 National Neurofibromatosis Foundation
 National Niemann-Pick Disease Foundation
 National Organization for Rare Disorders
 National Psoriasis Foundation
 National Society of Genetic Counselors*
 National Tay-Sachs & Allied Diseases
 Association
 National Tuberous Sclerosis Association
 National Vitiligo Foundation
 Neurofibromatosis, Inc.
 Novartis
 Orton Dyslexia Society
 Osteogenesis Imperfecta Foundation
 Parkinson's Disease Foundation
 Pfizer Inc*
 Pharmaceutical Research and Manufacturers of
 America
 Pituitary Tumor Network Association
 Purine Research Society
 Research!America
 Roswell Park Cancer Institute -Clinical Genetics
 Services
 Sjogren's Syndrome Foundation
 SmithKline Beecham*
 Society of Gynecologic Oncologists
 Spondylitis Association of America

06/02/97 MON 12:10 FAX 202 546 5051

MEGAN SEXAUER

005

Sturge-Weber Foundation
Sudden Arrhythmia Death Syndromes
Foundation
United Parkinson Foundation
Vejo-Cardio-Facial Syndrome Educational
Foundation
VHT Family Alliance
Williams Syndrome Association
Wilson's Disease Association

* Steering Committee

06-02-97

President Clinton's Challenge to Develop an AIDS Vaccine Does Not Undermine But Rather Builds on His Strong Record on AIDS Research, Treatment, and Prevention

President Clinton's announcement to increase efforts to develop an AIDS vaccine in no way undermines his commitment to funding AIDS prevention and treatment. Developing a successful vaccine is the only way to stop this epidemic that is killing millions of people around the world each year. The President believes that we also must increase our commitment to investing in treatment for people with HIV/AIDS and improve our prevention efforts. Since he took office, funding for all AIDS investments has increased in research, treatment, and prevention each year. Since President Clinton took office, he has:

- **Increased Ryan White by 168 percent.** The President's FY 1998 Budget proposes to spend \$1 billion on Ryan White, an 168 percent increase over the FY 1993 Budget, to help our hardest hit cities, States, and local clinics provide medical and support services for people with AIDS.
- **Accelerated Federal Medicaid spending on HIV/AIDS.** Federal Medicaid spending on AIDS/HIV treatment has increased 53 percent since FY 1993, spending \$2 billion in FY 1997. At least 50 percent of people with AIDS and more than 90 percent of children with AIDS are covered by Medicaid, making Medicaid the largest single payor of direct medical services for people living with AIDS. Currently, approximately 100,000 Medicaid beneficiaries are HIV positive.
- **Increased funding for State AIDS Drug Assistance Programs (ADAP).** As soon as the Food and Drug Administration began approving Protease Inhibitors in early 1996, the Administration proposed two budget amendments -- \$52 million in FY 1996 and \$65 million in FY 1997 -- to increase funding for ADAP which provides access to medicine for people with HIV who are not covered by Medicaid but do not have access to private health care coverage. The President's FY 1998 budget proposes \$167 million for ADAP.
- **Ensured that Medicaid covers Protease Inhibitors.** Under the President's leadership, the Health Care Financing Administration has advised all States that they are required to cover Protease Inhibitors and encouraged them to ensure that appropriate nutritional services are provided to persons living with HIV/AIDS.
- **Doubled funding for Housing for People with AIDS.** Without stable housing a person living with HIV has diminished access to care and services. It is estimated that up to 50 percent of people living with HIV and AIDS are or will be at risk of becoming homeless during the course of their illness. The President has proposed \$200 million for HOPWA, more than 100 percent of what was spent in FY 1993.
- **Increased commitment to CDC prevention programs by 27 percent.** The President's FY 1998 Budget proposes \$634 million for CDC prevention efforts, a 27 percent increase over the FY 1993 Budget. CDC works with states and communities to provide the information and tools needed to design and implement effective local prevention programs.

File ~~Genome Act~~
Genetic Screening

SCHEDULE REQUEST PROPOSAL

6/9/97

_____ ACCEPT

_____ REGRET

_____ PENDING

TO: Stephanie Streett
Deputy Assistant to the President &
Director of Scheduling

FROM: Bruce Reed, Assistant to the President for Domestic Policy

REQUEST: Event with The Genome Action Plan to highlight our support of legislation prohibiting insurance companies from discriminating against people based on their genetic information.

PURPOSE: To highlight our support for legislation prohibiting insurers from using genetic screening information to discriminate or underwrite, to release a new HHS report on the potentials and perils of genetic information, to announce the news that women's groups and the National Genome Action Plan are supporting the President on this initiative and to emphasize the importance of this legislation to women's groups who are concerned about the potential for women who may be discriminated against because of genetic information, particularly women with breast cancer.

BACKGROUND: This event would be held at the National Academy of Sciences with the National Action Plan on Breast Cancer, the National Breast Cancer Coalition and The Genome Action Plan, a broad coalition consisting of over 100 groups, including AARP, the National Alliance for the Mentally Ill, Parkinson's Disease Foundation, the American College of Gynecologists and Obstetricians, and the March of Dimes

The event would highlight the potential and perils of new information from the Human Genome Project that enables us to identify potential genetic disorders. In particular, it would highlight the need for legislation to protect Americans from genetic discrimination.

PREVIOUS PARTICIPATION: None

DATE AND TIME: Late June

DURATION: 1 hour

LOCATION: National Academy of Sciences

OUTLINE OF EVENTS: Members from one or two of the groups involved in The Genome Action Plan speaks, including a breast cancer group; a victim of genetic discrimination; Dr. Collins, the director of the Human Genome Project; Rep. Louise Slaughter (the sponsor of the legislation we are supporting) and introduces the President; and the President delivers remarks and announces the release of the HHS genetic information report.

REMARKS REQUIRED: Prepared by speech writing.

FIRST LADY'S ATTENDANCE: Not required.

VICE PRESIDENT'S ATTENDANCE: Not required.

SECOND LADY'S ATTENDANCE: Not required.

RECOMMENDED BY: Bruce Reed, Chris Jennings

CONTACT: Chris Jennings, 456-5560

ORIGIN OF PROPOSAL: Domestic Policy Council. To follow-up on the commitment to this issue that the President announced at Morgan State last month.

Addendum: The New York Times Magazine is doing a story on genetic screening in the next month or so. If we can give the journalist a date for an event fairly soon, the journalist will wait to run the story, and the President can get credit as a leader on this issue.



Cavarocchi ■ Ruscio ■ Associates
317 Massachusetts Avenue, NE, First Floor
Washington, D.C. 20002
(202) 546-4732; FAX (202) 546-5051

FAX COVER SHEET

Date: 6-6-97

To: Sara Bianchi

From: Lyle Dennis

Message: If you need to reach me over
the weekend re: the Genome Action Coalition
event we discussed, my home number



My keeper is

Lyle

Number of pages including cover sheet 1

no time before 30th.

FACSIMILE (FAX) COVER SHEET

**The Genome Action Coalition
317 Massachusetts Avenue, N.E., Suite 100
Washington, D.C. 20002
(202) 546-4732
FAX telephone (202) 546-5051**

Date: 6-5-97

To: Sara Bianchi

From: Lyle Dennis

Message: _____

Number of pages being sent, including this cover sheet: 4

KETCHUM PUBLIC RELATIONS
W O R L D W I D E

Fax: 202-835-8891

Date: 6/5/97

Time: 12:30

TO: CHARIS JENNINGS

FROM: TERRY KLEDNER

FAX: (202) 456-5557

TOTAL # OF PAGES INCLUDING COVER SHEET: 6

IF FAX TRANSMITTAL IS INCOMPLETE, PLEASE CONTACT ME AT: (202) 835-8811

MESSAGE

Note: The information contained in this facsimile is confidential and is intended only for the use of the individual or entity to whom it is addressed. If you are not the intended recipient or the person responsible for delivering it to the intended recipient, do not use or disclose this facsimile. If you have received this facsimile in error, please notify us immediately by telephone (202) 835-8800 and return the original via the U.S. Postal Service to 1201 Connecticut Avenue, Suite 300, Washington, DC 20036. Thank you.

Atlanta•Chicago•Dallas•Los Angeles•Miami•New York•Pittsburgh•San Francisco•Washington, DC

KETCHUM PUBLIC RELATIONS

W O R L D W I D E

JERRY D. KLEPNER

SENIOR VICE PRESIDENT

MEMORANDUM

June 5, 1997

TO: Chris Jennings
From: Jerry Klepner
Re: Slaughter Bill

Per our discussion yesterday with regard to H.R. 306, the Genetic Information Nondiscrimination in Health Insurance Act of 1997, I am forwarding to you a memorandum prepared for David Beier detailing concerns with the bill.

The memorandum highlights two major problems affecting research. The definition of "genetic information" and the prohibition on its use would apply to the majority of facts in a standard medical history or hospital intake form (e.g. gender, race, height, weight, and family history questions relating to heart disease and diabetes.) In addition, information about inherited characteristics "which derives from" an individual or family member meets the definition, whether or not the information actually identifies the person. In effect, medical records that do not have personal identifiers and are coded with a case number could be considered protected genetic information under the bill if the coded data included information about "inherited characteristics that may derive from an individual" or family member. The impact of the bill's prohibition on the use of "genetic information" in gathering necessary information for medical/research purposes is obvious.

Secondly, as explained on page 5 of the memorandum, we are very concerned with the requirement that "insurers may not disclose genetic information about a participant, beneficiary or applicant to anyone without specific prior consent from the individual authorizing disclosure to a particular person". This prohibition would have a direct adverse impact on epidemiological and pharmaco-economic research relying on data in patient registries or undertaken in collaboration with managed care organizations that have access to a comprehensive record of a patient's medical history. Obtaining consent from individuals' at the time of analysis—often long after the information has been recorded—is virtually impossible. More importantly, researchers at the Mayo Institute have found that if a specific consent requirement is imposed, the sample selection bias that results is not random. In effect, the disclosure prohibition could force all research into clinical trials and make it impossible for manufacturers and others to collaborate with respected institutions such as the Mayo Clinic for purposes of using their extensive database to conduct outcomes research.

Cc: David Beier

MEMORANDUM

May 21, 1997

TO: David Beier
FROM: Donna A. Boswell
RE: H.R. 306, Genetic Information Nondiscrimination in Health Insurance Act of 1997 (Rep. Slaughter)

This memorandum is in response to your request for an analysis of Representative Slaughter's bill, the Genetic Information Nondiscrimination in Health Insurance Act of 1997. The bill states that its purpose is--

"to prohibit discrimination against individuals and their family members on the basis of genetic information, or a request for genetic services."

This purpose is essentially the same as that expressed by President Clinton in his May 18, 1997 commencement address to Morgan State University. In that speech, President Clinton noted the fact that genetic information could be used "by insurance companies and others" to "discriminate against and stigmatize people." He concluded, "I urge Congress to pass bipartisan legislation to prohibit insurance companies from using genetic screening information to determine the premium rates or eligibility of Americans for health insurance."

The bill makes virtually identical amendments to the Employee Retirement Income Security Act of 1974, the Public Health Service Act, and the Internal Revenue Code of 1986, in the same sections that were amended or added by the Health Insurance Portability and Accountability Act ("HIPAA"). By using the terminology established under HIPAA, the Slaughter bill would ensure that the same provisions apply to all health benefits programs, whether offered by self-insuring employers, group plans purchased by employers or unions in the group health market, and insurance products offered in the individual.¹ The bill also adds the same anti-discrimination provisions to the Social Security Act to prohibit the use of genetic information by those who issue MediGap policies. Each of the four new statutory regimes explicitly provides an opportunity for a beneficiary or enrollee to bring a civil action seeking "compensatory, consequential, and punitive damages" from those who violate the new prohibitions.

¹ For simplicity and because the new requirements are identical, this memorandum uses the term "insurer" to refer to all of the entities to whom the prohibitions apply under all four sets of new federal laws. These may include, employers or other plan sponsors offering group health plans; companies that sell group health products; companies that sell individual health benefits products; church and school plans; as well as companies offering MediGap products.

Definitions

They keystone in understanding the bill's potentially significant impact on researchers and providers is its definitions. In addition to imposing requirements and prohibitions on virtually all entities that provide health care benefits, whether through insurance or otherwise, the pivotal term for all of the bill's provisions is "genetic information," which is defined as follows:

"The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member of the individual." (italics added)

Under this definition, virtually every piece of information on an application for health insurance as well as the majority of the facts in a standard medical history or a hospital intake form would be considered "genetic information." For example, gender is clearly an inherited characteristic, as is race, and in some sense, even height, weight, eye color, cholesterol and blood pressure levels are "inherited characteristics." Certainly, the commonplace questions regarding one's family history of heart disease, diabetes, and so forth, fall within the scope of this definition. Indeed, genomic science continues to make rapid progress in uncovering genetic elements in individuals' susceptibility to virtually every disease and condition, as well as individuals' responsiveness various treatments. Very shortly, the simple fact that one has a particular set of symptoms or has recovered from a particular disease will meet the definition of "genetic information" under this bill.

Perhaps more important for researchers is the fact that information about inherited characteristics which "derives from" an individual or family member meets the definition, *whether or not the information actually identifies the person*. Thus, as a technical matter, medical records that have been stripped of personal identifiers and coded with a case number before entry into a database could be considered to be protected genetic information under this bill, so long as the coded data included information about "inherited characteristics that may derive from an individual" or family member.

Prohibitions

The bill includes four prohibitions that apply to insurers' use of either (A) genetic information or (B) the fact that an individual has requested or received genetic services:

1. Insurers may not "deny, cancel, or refuse to renew" benefits or coverage on the basis of either (A) or (B);
2. Insurers may not "vary the premiums, terms, or conditions for benefits or coverage" on the basis of either (A) or (B);

3. Insurers may not "request or require" a participant or applicant for coverage to disclose genetic information;² and
4. Insurers may not disclose genetic information about a participant, beneficiary or applicant to anyone without specific prior consent from the individual authorizing disclosure to a particular person.³

Implications

Prohibitions number one and two pose significant new limitations on entities that issue and/or pay for health care benefits. Item one is a guaranteed issue and renewal provision that arguably expands upon the requirements included in the Health Insurance Portability and Accountability Act in that this is an absolute prohibition, while HIPAA imposes limitations based on periods of prior coverage.

Item two essentially is a prohibition on medical underwriting on the basis of "genetic information." This issue was not addressed in the Health Insurance Portability and Accountability Act.⁴ The regulation of insurance rates traditionally has been a matter subject to state authority. In effect, this bill may be interpreted as preempting state rate-setting authority, as least with respect to rates that reflect "genetic information" -- which under this bill would include inherited characteristics such as gender, an individual's personal health history of any disease that may be inherited, such as heart disease, high blood pressure, diabetes, and so forth. As science continues to identify the genetic factors underlying individuals' susceptibility to diseases and conditions, and as attorneys push the limits of the prohibition on variation in individuals'

² MediGap issuers are not subject to the prohibition on requesting genetic information from individuals.

³ MediGap issuers are not subject to the prohibition on disclosure of genetic information.

⁴ Technically, the bill would make it impermissible "to vary the premiums, terms, or conditions for such benefits or such coverage, for any participant or beneficiary under the plan on the basis of genetic information; or on the basis that the participant or beneficiary has requested or received genetic services." On its face, this requirement appears to parallel the HIPAA requirement that a group health plan cannot charge different participants and beneficiaries in the same plan different premiums -- but the Slaughter bill does not make it explicit that for purposes of this prohibition, the individual's premium is being compared to that for other participants in the same plan. As discussed above, "genetic information" is defined as information about inherited characteristics derived from individuals, it is not limited to information that identifies the individuals from whom it derives. Accordingly, if a group policy is experience-rated by the issuer, based on the prevalence in the group of diseases that have a genetic component, the proportion of males and females, and so forth, the issuer arguably has "varied the premium" paid by every participant in the plan based on genetic information. Therefore, under the Slaughter bill, every beneficiary of a group health plan premiums are higher than some community-rated norm may have a claim for damages against the issuer.

premiums, this provision promises to go a long way toward becoming a federal requirement for community rating of premiums for various forms of health care benefits coverage.

Prohibition number three promises to increase the administrative cost and complexity of health care providers' record-keeping responsibilities. In today's managed care environment, many administrative efficiencies and improvements in the quality of health care result from providers' ability to use consolidated medical history records rather than starting anew by taking a medical history from each patient upon each office visit or hospitalization. Because prohibition number three prohibits insurers from asking individuals to disclose genetic information, managed care companies will be prohibited from obtaining the information required to maintain a comprehensive medical record for use by participating providers. Moreover, to the extent that providers form provider sponsored organizations offering coordinated care products, it is likely that they will bring themselves within the scope of the bill's prohibition on obtaining such information. If enforced, this could create an absurdity in which a hospital or group practice employee could not ask questions concerning a patient's medical history. As such, this provision could become a significant legal impediment to provider organizations' ability to provide quality health care.

Because the prohibition on disclosure of genetic information does not apply to providers, an insurer might assemble such information from the records of their participating providers. (Insurers likewise are prohibited only from obtaining genetic information from individuals, not from providers.) Once assembled, however, prohibition number four arguably would not permit the managed care company to disclose any such record containing genetic information to the individual's doctor or hospital for purposes of rendering health care to the individual without specific prior consent of the individual for each disclosure. You also may be aware that providers on their own behalf have been attempting to develop systems for maintaining comprehensive medical records in the interest of improving patient care and avoiding unnecessary duplication of diagnostics, prescription drug duplication and interactions, and so forth. The bill's prohibition on disclosure does not apply to providers, but it certainly means that providers will have to be careful that their partners in these information ventures are not entities that would be subject to this new prohibition.⁶ Moreover, as providers offer various managed care products through provider-sponsored organizations, they may come within one of the

⁶ A legal conundrum also is created by the situation in which a physician is an employee of a managed care company, or a hospital is the owner of a managed care company. Because the MCO is prohibited from obtaining genetic information, it could be argued that the employees or agents (i.e., physicians and nurses) likewise are prohibited from asking questions about genetic information. Litigation-shy managed care companies could end up requiring physicians to practice medicine based on incomplete and misleading medical histories if certain fundamental questions cannot be asked of individuals. It should be noted that as providers form managed care entities to more fully participate in the group health market, the potential impact of this absurd situation is likely to multiply.

categories of insurers or plans subject to the disclosure prohibition, bringing down this disclosure prohibition on themselves, as discussed above.

Prohibition four also is the one that will have a direct adverse impact on health research. As you know, unlike clinical trials which use a formal, focused research vehicle to make a powerful, if limited, demonstration of the safety and effectiveness of a new product, most pharmaco-economic research and research concerning patient outcomes is undertaken in collaboration with managed care organizations or providers that have access to more comprehensive records of a patient's medical history and responsiveness to particular health care interventions. Likewise, epidemiology research and studies relying on data in patient registries are critically dependent on the use of information developed in the course of ordinary episodes of health care. Under the Slaughter bill, any insurer's "disclosure" of these records (which, under the bill's definitions, would include disclosures of genetic information "derived from" the individual but that does not identify the individual) would be prohibited without obtaining separate, prior written consent for each disclosure. Obtaining such consent from individuals at the time the analysis is proposed -- often long after the information has been recorded -- is virtually impossible and arguably is an unwarranted intrusion on the individual's privacy.

Perhaps more importantly, researchers at the Mayo Clinic have used their rich database of medical records to examine the feasibility and consequences of interposing an informed consent requirement. Their analyses demonstrate that if a specific consent requirement were imposed, the sample selection bias that results is not random. This selection bias leads researchers to draw conclusions that differ dramatically from the conclusions reached when they perform the same analyses on Mayo's full, anonymized database of medical records. It follows that under the Slaughter bill, analysis of medical records where specific consent is imposed cannot readily be used to draw valid conclusions regarding patient outcomes. In effect, research would be pushed back to using the clinical trial vehicle which, while powerful for some purposes, is not useful for epidemiology and outcomes studies and is very costly. The disclosure prohibition likely would make it impossible for manufacturers and others to collaborate with respected institutions such as the Mayo Clinic -- which may, to the extent that they form provider sponsored organizations, fall within the act's prohibitions -- for purposes of using their rich databases to conduct much-needed outcomes research.

I hope this analysis is useful. Please let me know if you have questions or would like to follow up.

Total Pages: _____

LRM ID: MDH75

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Friday, May 30, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below
FROM: *Conna Powers for*
Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pallicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: HHS Draft Bill on Genetic Information Nondiscrimination in Health Insurance Act of 1997

DEADLINE: Noon Tuesday, June 3, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: We understand that the Vice President may announce the attached HHS draft bill at an event scheduled for Saturday, June 7th. For this reason, this deadline is firm.

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A BILL

To prohibit discrimination against individuals and their family members on the basis of genetic information, or a request for genetic services.

1 *Be it enacted by the Senate and House of Representatives of*
2 *the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Genetic Information
5 Nondiscrimination in Health Insurance Act of 1997".

6 **SEC. 2. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF**
7 **1974.**

8 (a) PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE
9 BASIS OF REQUEST FOR OR RECEIPT OF GENETIC SERVICES.—

10 (1) NO ENROLLMENT RESTRICTION FOR GENETIC
11 SERVICES.—Section 702(a)(1)(F) of the Employee Retirement
12 Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is
13 amended by inserting before the period "or request for or
14 receipt of genetic services".

15 (2) NO DISCRIMINATION IN GROUP RATE BASED ON GENETIC
16 INFORMATION.—Section 702(b)(1) of such Act (29 U.S.C.
17 1182(b)(1)) is amended—

18 (A) by striking "may not require any individual"
19 and inserting "may not—

20 (A) require any individual";

21 (B) by moving the remainder of the paragraph two
22 ems to the right;

2

1 (C) by striking the period and adding "; or"; and

2 (D) by adding at the end the following new

3 subparagraph:

4 " (B) adjust premium or contribution rates for a
5 group of the individuals in a group on the basis of
6 genetic information concerning or a request for or
7 receipt of genetic services by any member of such group
8 or a covered dependent of such member. "

9 (b) LIMITATION ON COLLECTION AND DISCLOSURE OF GENETIC
10 INFORMATION.--Section 702 of such Act (29 U.S.C. 1182) is amended
11 by adding after subsection (b) the following new subsection:

12 "(c) WITH RESPECT TO COLLECTION AND DISCLOSURE OF GENETIC
13 INFORMATION.--

14 "(1) COLLECTION.--Except as provided in paragraph (3), a
15 group health plan, or a health insurance issuer offering
16 health insurance coverage in connection with a group health
17 plan, shall not request or require disclosure of genetic
18 information concerning an individual who is a participant or
19 beneficiary (or an applicant for coverage as a participant
20 or beneficiary).

21 "(2) DISCLOSURE.--Except as provided in paragraph (3)--

22 "(A) a group health plan, or a health insurance
23 issuer offering health insurance coverage in connection
24 with a group health plan, shall not disclose genetic
25 information about an individual who is a participant or
26 beneficiary (or an applicant for coverage as a

1 participant or beneficiary) to any other health plan or
2 health insurance issuer or to the plan sponsor or plan
3 administrator; and

4 " (B) a physician, hospital, or other person that
5 provides health care items or services to an individual
6 shall not disclose genetic information about such
7 individual to any group health plan, or health
8 insurance issuer offering health insurance coverage in
9 connection with a group health plan.

10 "(3) EXCEPTIONS.-

11 "(A) The provisions of paragraphs (1) and (2)
12 shall not apply to a request by or disclosure to a
13 health plan or issuer that provides reasonable
14 assurances that it provides health insurance coverage
15 to such individual and requires such information for
16 payment of claims or coordination of benefits.

17 "(B) Notwithstanding paragraphs (1) and (2), a
18 health plan or issuer that provides health care items
19 and services and provides reasonable assurances that it
20 requires such information for diagnosis or treatment of
21 such individual may-

22 (i) request (but not require) disclosure of
23 such information by the individual; and

24 (ii) request or require such information from
25 another health plan, or health insurance issuer,
26 or provider of health care items and services.

4

1 "(C) The provisions of paragraphs (1) and (2)
2 shall not apply if the individual, or the individual's
3 legal representative, provides prior written
4 authorization of such disclosure."

5 (e) DEFINITIONS. Section 706(d) of such Act (29 U.S.C.
6 1191b(d)) is amended by adding at the end the following new
7 paragraphs:

8 "(5) FAMILY MEMBER.—The term 'family member' means,
9 with respect to an individual, a spouse or adopted child of
10 that individual, or another individual related by blood to
11 that individual or to a spouse or adopted child of that
12 individual.

13 "(6) GENETIC INFORMATION.—The term 'genetic
14 information' means information about genes, gene products,
15 or inherited characteristics that may derive from an
16 individual or a family member.

17 "(7) GENETIC SERVICES.—The term 'genetic services'
18 means health services provided to obtain, assess, and
19 interpret genetic information for diagnostic and therapeutic
20 purposes, and for genetic education and counselling."

21 (d) EFFECTIVE DATE.—The amendments made by this section
22 shall apply with respect to group health plans and group health
23 insurance coverage for plan years beginning after 1 year after
24 the date of the enactment of this Act.

25 **SEC. 3. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.**

26 (a) AMENDMENTS RELATING TO THE GROUP MARKET.—

1 (1) PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON
2 THE BASIS OF REQUEST FOR OR RECEIPT OF GENETIC SERVICES.—

3 (A) NO ENROLLMENT RESTRICTION FOR GENETIC
4 SERVICES.—Section 2702(a)(1)(F) of the Public Health
5 Service Act (42 U.S.C. 300gg-1(a)(1)(F)) is amended by
6 inserting before the period "or request for or receipt
7 of genetic services".

8 (B) NO DISCRIMINATION IN GROUP RATE BASED ON
9 GENETIC INFORMATION.—Section 2702(b)(1) of such Act (42
10 U.S.C. 300gg-1(b)(1)) is amended

11 (i) by striking "may not require any
12 individual" and inserting "may not—

13 (A) require any individual";

14 (ii) by moving the remainder of the paragraph
15 two ems to the right;

16 (iii) by striking the period and adding "
17 or"; and

18 (iv) by adding at the end the following new
19 subparagraph:

20 "(B) adjust premium or contribution rates for a
21 group or the individuals in a group on the basis of
22 genetic information concerning or a request for or
23 receipt of genetic services by any member of such group
24 or a covered dependent of such member."

25 (2) LIMITATION ON COLLECTION AND DISCLOSURE OF GENETIC
26 INFORMATION.—Section 2702 of such Act (42 U.S.C. 300gg-1) is

6

1 amended by adding after subsection (b) the following new
2 subsection:

3 "(c) WITH RESPECT TO COLLECTION AND DISCLOSURE OF GENETIC
4 INFORMATION.

5 "(1) COLLECTION. Except as provided in paragraph (3), a
6 group health plan, or a health insurance issuer offering
7 health insurance coverage in connection with a group health
8 plan, shall not request or require disclosure of genetic
9 information concerning an individual who is a participant or
10 beneficiary (or an applicant for coverage as a participant
11 or beneficiary).

12 "(2) DISCLOSURE.—Except as provided in paragraph (3)—

13 "(A) a group health plan, or a health insurance
14 issuer offering health insurance coverage in connection
15 with a group health plan, shall not disclose genetic
16 information about an individual who is a participant or
17 beneficiary (or an applicant for coverage as a
18 participant or beneficiary) to any other health plan or
19 health insurance issuer or to the plan sponsor or plan
20 administrator; and

21 "(B) a physician, hospital, or other person that
22 provides health care items or services to an individual
23 shall not disclose genetic information about such
24 individual to any group health plan, or health
25 insurance issuer offering health insurance coverage in
26 connection with a group health plan.

1 "(3) EXCEPTIONS.--

2 " (A) The provisions of paragraphs (1) and (2)
3 shall not apply to a request by or disclosure to a
4 health plan or issuer that provides reasonable
5 assurances that it provides health insurance coverage
6 to such individual and requires such information for
7 payment of claims or coordination of benefits.

8 " (B) Notwithstanding paragraphs (1) and (2), a
9 health plan or issuer that provides health care items
10 and services and provides reasonable assurances that it
11 requires such information for diagnosis or treatment of
12 such individual may--

13 (i) request (but not require) disclosure of
14 such information by the individual; and

15 (ii) request or require such information from
16 another health plan, or health insurance issuer,
17 or provider of health care items and services.

18 " (C) The provisions of paragraphs (1) and (2)
19 shall not apply if the individual, or the individual's
20 legal representative, provides prior written
21 authorization of such disclosure."

22 (3) DEFINITIONS.--Section 2791(d) of such Act (42 U.S.C.
23 300gg-91(d)) is amended by adding at the end the following
24 new paragraphs:

25 "(15) FAMILY MEMBER.--The term 'family member' means,
26 with respect to an individual, a spouse or adopted child of

1 that individual, or another individual related by blood to
2 that individual or to a spouse or adopted child of that
3 individual.

4 "(16) GENETIC INFORMATION.—The term 'genetic
5 information' means information about genes, gene products,
6 or inherited characteristics that may derive from an
7 individual or a family member.

8 "(17) GENETIC SERVICES.—The term 'genetic services'
9 means health services provided to obtain, assess, and
10 interpret genetic information for diagnostic and therapeutic
11 purposes, and for genetic education and counselling."

12 (b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—Subpart
13 3—Other Requirements of part B of title XXVII of such Act is
14 amended by inserting after section 2751 (42 U.S.C. 300gg-51) the
15 following new section:

16 "SEC. 2752. PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON
17 THE BASIS OF GENETIC INFORMATION.

18 "(a) IN GENERAL.—Except as provided in subsection (b), the
19 prohibitions of—

20 "(1) discrimination based on genetic information or
21 request for or receipt of genetic services, and

22 "(2) collection of genetic information by a health
23 insurance issuer, or disclosure of genetic information by or
24 to such an issuer,

25 shall apply to a health insurance issuer offering coverage in the
26 individual market to the same extent as they apply pursuant to

1 section 2702 to a health insurance issuer subject to section
2 2702.

3 "(b) EXCEPTION.—The provisions of subsection (a) shall not
4 prevent a health insurance issuer subject to subsection (a) from—

5 "(1) requesting or requiring disclosure of genetic
6 information about an individual who is a participant or
7 beneficiary (or an applicant for coverage as a participant
8 or beneficiary) relating to a disease or condition for which
9 the individual has been positively diagnosed or has received
10 treatment at any time;

11 "(2) requesting an individual, as a condition for
12 initial enrollment, to undergo a physical examination or
13 related tests to determine whether the individual has a
14 disease or condition; or

15 "(3) using information specified in paragraph (1) or
16 the results of an examination or test specified in paragraph
17 (2) to deny or vary the terms and conditions of health
18 insurance benefits or coverage."

19 (c) AMENDMENT CONCERNING MEDIGAP.—Section 2791(c)(4) of such
20 Act (42 U.S.C. 300gg-91(c)(4)) is amended by inserting "except
21 for purposes of sections 2702(a)(1)(F), 2702(c), and 2752" after
22 "Social Security Act)".

23 (d) TECHNICAL AMENDMENT.—Title XXVII of such Act is amended
24 in the subpart heading following section 2744 (42 U.S.C. 300gg-
25 44) by striking "Subpart 3" and inserting "Subpart 2".

26 (e) EFFECTIVE DATE.—The amendments made by subsections (a)

10

1 through (d) shall apply with respect to

2 (1) group health plans and group health insurance
3 coverage for plan years beginning, and

4 (2) health insurance available or in effect in the
5 individual market,

6 after 1 year after the date of enactment of this Act.

7 **SEC. 4. AMENDMENTS TO INTERNAL REVENUE CODE OF 1986.**

8 (a) **PROHIBITION OF HEALTH INSURANCE DISCRIMINATION ON THE**
9 **BASIS OF REQUEST FOR OR RECEIPT OF GENETIC SERVICES.-**

10 (1) **NO ENROLLMENT RESTRICTION FOR GENETIC**
11 **SERVICES.-**Section 9802(a)(1)(F) of the Internal Revenue Code
12 of 1986 is amended by inserting before the period "or
13 request for or receipt of genetic services".

14 (2) **NO DISCRIMINATION IN GROUP RATE BASED ON GENETIC**
15 **INFORMATION.-**Section 9802(b)(1) of such Code is amended

16 (A) by striking "may not require any individual"
17 and inserting "may not-

18 (A) require any individual";

19 (B) by moving the remainder of the paragraph two
20 ems to the right;

21 (C) by striking the period and adding "; or"; and

22 (D) by adding at the end the following new/
23 subparagraph:

24 "(B) adjust premium or contribution rates for a
25 group or the individuals in a group on the basis of
26 genetic information concerning or a request for or

11

1 receipt of genetic services by any member of such group
2 or a covered dependent of such member."

3 (b) LIMITATION ON COLLECTION AND DISCLOSURE OF GENETIC
4 INFORMATION.--Section 9802 of such Code is amended by adding after
5 subsection (b) the following new subsection:

6 "(c) WITH RESPECT TO COLLECTION AND DISCLOSURE OF GENETIC
7 INFORMATION.--

8 "(1) COLLECTION.--Except as provided in paragraph (3), a
9 group health plan, or a health insurance issuer offering
10 health insurance coverage in connection with a group health
11 plan, shall not request or require disclosure of genetic
12 information concerning an individual who is a participant or
13 beneficiary (or an applicant for coverage as a participant
14 or beneficiary).

15 "(2) DISCLOSURE.--Except as provided in paragraph (3)--

16 "(A) a group health plan, or a health insurance
17 issuer offering health insurance coverage in connection
18 with a group health plan, shall not disclose genetic
19 information about an individual who is a participant or
20 beneficiary (or an applicant for coverage as a
21 participant or beneficiary) to any other health plan or
22 health insurance issuer or to the plan sponsor or plan
23 administrator; and

24 "(B) a physician, hospital, or other person that
25 provides health care items or services to an individual
26 shall not disclose genetic information about such

12

1 individual to any group health plan, or health
2 insurance issuer offering health insurance coverage in
3 connection with a group health plan.

4 "(3) EXCEPTIONS.--

5 " (A) The provisions of paragraphs (1) and (2)
6 shall not apply to a request by or disclosure to a
7 health plan or issuer that provides reasonable
8 assurances that it provides health insurance coverage
9 to such individual and requires such information for
10 payment of claims or coordination of benefits.

11 " (B) Notwithstanding paragraphs (1) and (2), a
12 health plan or issuer that provides health care items
13 and services and provides reasonable assurances that it
14 requires such information for diagnosis or treatment of
15 such individual may--

16 (i) request (but not require) disclosure of
17 such information by the individual; and

18 (ii) request or require such information from
19 another health plan, or health insurance issuer,
20 or provider of health care items and services.

21 " (C) The provisions of paragraphs (1) and (2)
22 shall not apply if the individual, or the individual's
23 legal representative, provides prior written
24 authorization of such disclosure."

25 (c) DEFINITIONS.--Section 9805(d) of such Code is amended by
26 adding at the end the following new paragraphs:

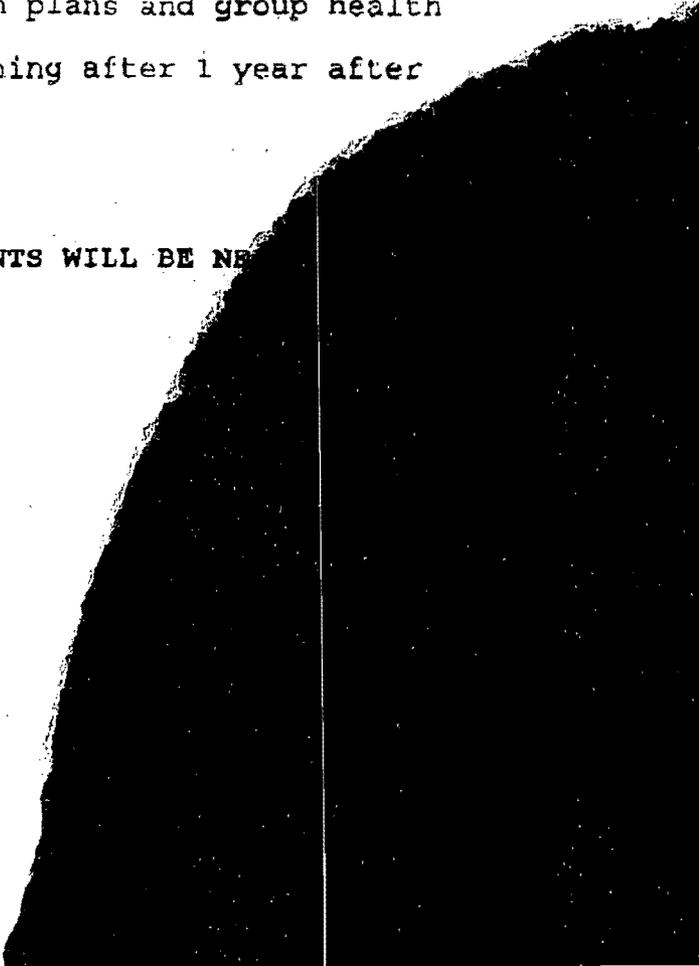
1 "(6) FAMILY MEMBER.—The term 'family member' means,
2 with respect to an individual, a spouse or adopted child of
3 that individual, or another individual related by blood to
4 that individual or to a spouse or adopted child of that
5 individual.

6 "(7) GENETIC INFORMATION.—The term 'genetic
7 information' means information about genes, gene products,
8 or inherited characteristics that may derive from an
9 individual or a family member.

10 "(8) GENETIC SERVICES.—The term 'genetic services'
11 means health services provided to obtain, assess, and
12 interpret genetic information for diagnostic and therapeutic
13 purposes, and for genetic education and counselling."

14 (d) EFFECTIVE DATE.—The amendments made by this section
15 shall apply with respect to group health plans and group health
16 insurance coverage for plan years beginning after 1 year after
17 the date of the enactment of this Act.

18
19 [NOTE: TECHNICAL AND CONFORMING AMENDMENTS WILL BE NE





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Congresswoman Slaughter, thank you for the privilege of being here to give voice to countless numbers of American who have been discriminated against by health insurers because of their genotype. These people will understandably not come forward to tell their own stories because of the highly sensitive nature of their experiences, yet they deserve the opportunity to have their stories heard. What happened to them can only be told anonymously through someone else's voice. As former Director of the first federally funded study of discrimination based on genotype, and not phenotype, I am able to communicate their stories, as they were reported to me, on this very important occasion. Unless the nation is made fully aware of not only the broad range in which genetic discrimination presently exists, but its significant impact on the lives of those affected, protection is not likely.

The personal accounts I will relate all describe the experiences of individuals who have a genetic diagnosis for well known disorders but are asymptomatic. One of the most frequent disorders is hereditary hemochromatosis.

Hereditary hemochromatosis (HC) is an autosomal recessive condition which affects roughly 3 of every 1000 Caucasian Americans and is one of the most frequent

genetic disorder. Individuals if treated are at no greater morbidity or mortality risk than the general population, yet they have been excluded from insurance because of pre-existing condition clauses, rated as if they have secondary disease, and denied coverage for the very treatments that prevent serious secondary disease.

Consider the following stories- all true. The names, of course, have been changed.

Jane X, a young midwestern woman in her late 20's, was approved for full standard health insurance as a dependent on her husband's small group policy, while simultaneously undergoing a diagnostic workup. Four months later she was diagnosed and informed that the policy was rescinded. She was pregnant at the time. Tim Y, of South Carolina, was accepted for independent standard coverage, but dropped 9 months later when diagnosed, also on the basis of pre-existing condition. Bill P, in Pennsylvania, is able to keep his insurance but the insurer refuses to pay for phlebotomy treatments unless provided as a hospital inpatient in which case significant unneeded hospital charges are paid. Were Bill able to have his treatments covered by going to a local bloodbank the costs involved would be greatly lower. Linda W, in Colorado, tried unsuccessfully to obtain health insurance for six years subsequent to her controlled HC diagnosis. Although, insurers covered the cost of her treatments, her rates have risen dramatically- 38% increase the first two years, 45% increase the next, 65% increase the next and finally a 74.5% increase. At this point, Linda was required to begin spending her life savings to pay for her health insurance. When she attempted to switch to less expensive insurers she was

refused each time. Milton A, in Texas, was diagnosed while covered under a group policy. He dropped his policy to get more favorable coverage under his wife's policy. When she switched jobs, he tried to renew his former policy but was rejected due to HC.

Older but non-retired individuals have similarly been refused long term or supplementary health insurance. At 63, ten years after having been diagnosed with HC and in excellent health having successfully treated it, Mary C. was refused nursing home insurance due to her controlled HC diagnosis. Robert T. was refused group disability coverage due to his "blood condition". The rejection letter stated that the company does not take substandard risks, even though it is a group policy. Jim O., at the age of 58 and diagnosed with HC, wanted to start his own business. When inquiring about the feasibility of obtaining health insurance independently, he was refused by several carriers on grounds of his HC. He gave up his dream of owning a business. At the time of his interview, he wanted to take advantage of an early retirement program, but was fearful of insurance exclusion so didn't.

In all of these cases letters from people's physicians stating that HC does not constitute a health risk and that prognosis was excellent were insufficient to reverse adverse decisions. I'd like to add that although the blood of a person with HC contains no safety risks, Red Cross and affiliated blood banks refuse to accept their blood because in their case the donation is considered to be motivated by self-interest rather than altruism. This occurs even in the face of periodic supply shortages.

Porphyria is autosomal dominant inborn error of metabolism resulting in different

enzyme defects which can result in the production of abnormal metabolites. Because environmental factors play a major role in the clinical expression of all forms of the disease, many gene carriers stay asymptomatic for years or NEVER become symptomatic. Though particular types are more prevalent in specific populations, the incidence in the US is estimated to be 5 to 10 per 10,000. Kathy L has a family history of porphyria, and believes that she once had a very mild episode though the clinical event was termed an incidental finding, and no treatment was indicated. When she applied for insurance through her employer she was informed that because the group was less than 25 people, each employee would have to apply individually. Insurers found that she had been tested and although results did not rule out or confirm a diagnosis, Kathy was refused insurance. Although her physician assisted her in challenging the exclusion, arguing that Kathy did not have porphyria, she was offered insurance only after complying with a 12 month waiting period for pre-existing condition.

Huntington Disease is an autosomal dominant condition with offspring of an affected parent having 50% of inheriting the deleterious gene. Wayne C. in Colorado, was repeatedly refused health insurance based on his family history of Huntington Disease, even though he may never become ill. Paula S., was denied private supplemental long term care insurance unless she agreed to undergo genetic testing to determine if she did not have the gene. The company did not agree to pay for testing, and Paula did not want to undergo testing because she believed the test to be unreliable and inconclusive. In addition, she didn't want the burden of

knowing the results.

Phenylketonuria (PKU) is an autosomal recessive disorder resulting from a deficient enzyme. Newborn screening is widely done because dietary treatment prevents the accumulation of the deficient enzyme and inevitable mental retardation. Yet, dietary treatments are frequently not covered by insurers. Moreover, many infants with PKU have been refused health insurance due to pre-existing condition.

In many cases discrimination extends beyond the individual to their relatives. Family members, without genetic diagnoses, have experienced exclusions based on their affected relative. Jerry M, of Kentucky, worked for a small company of 5 employees in the midwest. When the company renegotiated its benefit package she was informed that she was ineligible for insurance due to her husband's HC- even though he was successfully treated. Similarly, Ron S. was informed by his large and self-insured employer that he was ineligible for health insurance because of his wife's HC diagnosis. Ron recalled the company's policy stating that it could bar any employee or their dependent from group insurance. In Massachusetts, a family of 4 was refused health insurance by an HMO because one of the two children in the family had PKU. In California, a family of 3 was refused health insurance through the husband's employer because their son was diagnosed with Hurler syndrome.

I would like to add a few words about individuals with symptomatic genetic disease. Mucopolysaccharidoses, (MPS) are autosomal recessive conditions comprising a heterogeneous group of storage diseases resulting from an enzyme deficiency. Most of the particular forms are lethal with life expectancy roughly 13 years. Because of

the poor prognosis and expected, though not certain, time of degeneration, insurers have cancelled coverage for quality of life sustaining treatments. When Judy H and her husband, in California, switched insurers the physical, verbal and auditory treatments that their child, diagnosed with Hurler's (one of the MPSs), had been receiving were cancelled due the insurers determination of poor prognosis. Lack of access to treatments speeded up the degeneration. Similarly, a child with San Fillipo disease (another of the MPSs), was deemed ineligible for hospitalization because, "he would die from his illness".

These stories illustrate the broad range of situations in which individuals may experience genetic discrimination in health insurance. It is important to recognize that each of these individuals is white, college educated and middle class. Equally important is the fact that I have spoken about only five of several thousand known disorders. Given the increased availability and use of genetic tests the potential for genetic discrimination is likely to increase. Moreover, in as much as each of us likely carries 5-7 mutated genes, we are all at risk for genetic discrimination.

The impacts of these discriminatory experiences, are frequently catastrophic for the individuals involved. They are also exceedingly significant for the country as a whole since genetic discrimination threatens to create an underclass of uninsurables. This is an outcome which many consider morally repugnant.

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WHIP-AT-LARGE



CONGRESS OF THE UNITED STATES

LOUISE M. SLAUGHTER
28TH DISTRICT, NEW YORK

February 4, 1997

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3120 FEDERAL BUILDING
100 STATE STREET
ROCHESTER, NY 14614
716/232-4850
TTY 716/454-4805

Dear Colleague:

This article from today's *New York Times* highlights once again Americans' very real fear of genetic discrimination in health insurance. It tells the story of a woman whose insurance company refused to pay for her prophylactic double mastectomy because she tested positive for the BRCA1 breast cancer gene. After the woman paid for the surgery herself, a biopsy on the removed tissue revealed a cancerous tumor that had been missed by mammograms.

Please join me in cosponsoring H.R. 306, the Genetic Information Nondiscrimination in Health Insurance Act to end this practice once and for all. While the Kassebaum-Kennedy health reform package took important steps toward banning genetic discrimination in health insurance, many loopholes remain. My legislation would provide comprehensive protection for all Americans against this practice.

Congress can and should act to end genetic discrimination by health insurers. For more information or to sign on as a cosponsor, please contact me or Cindy Pellegrini of my staff at 5-3615.

Sincerely,

Louise M. Slaughter
Member of Congress

Advent of Testing for Breast Cancer Genes Leads to Fears of Disclosure and Discrimination

By GINA KOLATA

DR. BARBARA WEBER is still reeling from the experience of a patient who told her insurance company that she had a mutated gene that could cause breast cancer.

The woman had been tested for the mutation at Dr. Weber's clinic at the University of Pennsylvania, and Dr. Weber told her the results. Since some

studies indicate that women with the mutated gene have a 90 percent chance of developing breast cancer, the woman wanted both of her breasts removed right away. Before she had the operation, she submitted a claim to her insurance company. Dr. Weber said, not disclosing that she had had the genetic test but reporting a strong family history of breast cancer.

The company turned her down, Dr. Weber said, on the ground that it did not pay for preventive medicine. So, at the woman's request, Dr. Weber submitted the woman's genetic test results. At that point, Dr. Weber said, the company told the woman that it would not pay for the surgery because she had a

Weber said, when pathologists examined the woman's breast tissue, they found a cancerous tumor that had been missed by mammograms.

It is cases like this and fears of similar treatment that are convincing some women and researchers that it might be too dangerous to genetic testing results on medical charts and clinical records, where privacy cannot be assured.

Women worry that insurers will raise their rates, or refuse to insure them, that employers will not hire them or promote them, and even their friends and family members might treat them differently if they knew that they were tainted with a deadly gene.

Fears of genetic testing have been expressed by some people for several years, starting with tests for rare genetic diseases like Huntington's. But



Gene Wilkinson for The New York Times

preexisting condition — a genetic defect — when she took out her health policy.

"It was absolutely unbelievable," Dr. Weber said. She said that the woman, who did not return telephone calls requesting an interview, had the surgery anyway. Afterward, Dr.

Dr. Barbara L. Weber says patients who get gene testing are refusing to enroll in studies for fear of discrimination.

recent discovery of two genes that can cause breast and ovarian cancer when mutated has made the issue more pressing.

Not only is breast cancer the disease that women fear the most, but the mutations, in genes known as BRCA1 and BRCA2, are relatively common in Ashkenazi Jewish populations (of Eastern European descent), affecting as many as 1 in 50 women.

In addition, many women who are not Jewish but have a strong family history of breast or ovarian cancer also inherited mutated genes. In the past year, several commercial laboratories have begun offering tests for breast cancer gene mutations; major medical centers across the country have set up their own testing programs.

Some legal experts say the fears of discrimination may be exaggerated. Federal legislation t



will go into effect on July 1 addresses part of the issue, focusing on people who are covered under group medical plans. The law states that if an individual was in such a plan for at least 12 months and had a genetic condition diagnosed in the past 6 months, a new insurer cannot use that genetic information to deny or limit coverage.

Alexander Morgan Capron, an ethicist and law professor at the University of Southern California, said insurers could charge people with genetic conditions more for insurance. But, Mr. Capron added, 20 states including New Jersey, have recently passed laws preventing health maintenance organizations and health insurance companies from charging people more because they have a gene mutation. In addition, the Americans With Disabilities Act prevents employers from discriminating against people who have disease-causing genetic mutations. Employers who insure their employees are exempt from the state laws, Mr. Capron said.

Richard Coorsh, a spokesman for the Health Insurance Association of America, said that people's fears that insurance companies would discriminate against them might be overblown. Many people are insured through their employers as part of large groups, and they would be covered even if they did have a cancer-causing gene.

But Mr. Coorsh said that those who change jobs or lose their jobs and have to seek insurance as individuals "will probably end up having to pay a lot more money" for health insurance if they test positive for a cancer gene. There have been few systematic studies to assess how real the risk of genetic discrimination is, but one survey, published in October in the *Journal of Science*, showed that the fear, at least, is widespread.

The study, by Dr. E. Virginia Lapham of the Georgetown University School of Medicine and her colleagues, involved 332 people who be-

longed to support groups for families with a variety of genetic disorders. Of them, 25 percent believed they were denied life insurance because of their disorder, 22 percent thought they were denied health insurance, and 13 percent believed they were not hired for a job or that they lost a job because of the disorder.

Whether or not these suspicions are justified, they are having an effect. Some researchers at major medical centers are worried enough to work under a cloak of secrecy. They test for the breast-cancer gene is under the aegis of a research program, which allows doctors to keep the results secret, coded and encased in locked files.

Some researchers advise women who are tested not to tell even their private doctor of their test results if the doctor insists on putting all relevant information in a woman's medical record. Some doctors agree not to write down test results, relying instead on their memories.

At treatment centers, which, unlike research centers, are not permitted to hide test results, some women have used aliases to protect their privacy.

"If we ever needed proof that the system is broken, this is it," said Dr. Francis Collins, director of the National Center for Human Genome Research in Bethesda, Md. "The system forces people to take drastic steps to protect themselves. It is putting a terrible burden on patients."

Doctors, too, are placed in an untenable situation, Dr. Collins said. "You are forced sometimes to have interactions with insurance agents or with other physicians or with H.M.O.'s where you would have to pretend you don't have the information," Dr. Collins said. "It's a very strange dilemma — to choose between patient confidentiality and telling the truth."

It is, said Dr. Thomas Murray, the director of the Center for Biomedical Ethics at Case Western Reserve University in Cleveland, "a classic ethical quandary," and one with no obvious solution.

Moreover, some cancer researchers note, there is a legitimate reason why insurers and employers might want to avoid people with genes that can cause cancers: the insurers because of the extra cost of treating them and the employers because of the extra insurance cost and because of lost productivity.

"I'm not sure you can totally blame insurance companies or employers," said Dr. C. Kent Osborne, a cancer researcher at the University of Texas in San Antonio. "It's a bigger problem than that. It's something we have to deal with as a society."

In the meantime, doctors and patients are trying to act expediently.

Dr. Funmi Olopade, who directs the breast cancer genetic testing program at the University of Chicago, was interviewed just after an appointment with a 25-year-old woman, who came to learn her test results. The woman was found to have a genetic mutation that can cause breast and ovarian cancer. The university keeps these records secret. But, Dr. Olopade said, the woman asked her if she could tell her private doctor of her test and what it disclosed.

Dr. Olopade suggested that the young woman start by asking her doctor if he felt he had to put everything he knew about a patient into the medical records. If so, Dr. Olopade said, the woman might not want to tell.

And with good reason, said Dr. Mark Siegler, who directs the ethics program at the University of Chicago. More than a decade ago, before the proliferation of electronic records, before the merging of health maintenance organizations that both pay for and care for patients, he investigated the complaint of a woman who had come to the hospital for elective gall bladder surgery and had said that too many people were looking at her medical records.

"I started to ask how many people had legitimate access to her chart," Dr. Siegler said. "I stopped counting at 75." He concluded, he said, "that confidentiality really didn't exist." That is even more true today, he added.

Some doctors, like Dr. John Glick, the director of the University of Pennsylvania's cancer center, say they will not put genetic testing information in a woman's medical records if she asks that it be kept out. Instead, Dr. Glick said, he simply remembers what the woman said about her test results.

Other doctors refuse to go along with such requests. One woman, who tested positive for the breast cancer gene at the University of Pennsylvania, said her private doctor told her it would be dishonest not to include the test result in her medical records. So, the woman said, "I asked that my medical records be closed and I changed doctors."

The woman said she was worried about health insurance. "The company my husband works for just got bought out, so things aren't as steady as they used to be," she said. "You can survive breast cancer, but you can't survive if you don't have insurance."

Dr. Henry Lynch, who directs the

Some doctors won't put results of genetic tests in a woman's records.

cancer center at Creighton University in Omaha, tests women for the breast cancer gene as part of a research program in which he can keep the results secret, and as part of a clinical program, where he cannot. But some women in his clinical program use aliases. Others pay for tests out of their own pockets, hoping to keep the information out of the hands of their insurance companies.

Dr. Weber said that she was confronting a new ramification of women's fears of discrimination. Women who were tested as part of her research program are refusing to participate in long-term studies that would assess their risk of developing cancer and the success of interventions, like frequent mammograms, or hormone treatments, or surgery to remove their breasts or ovaries.

The women, Dr. Weber said, fear that it would be a red flag on their medical records to participate in the study. Their mammogram results and any biopsies, for example, would have to be sent to the university's research program.

The only possibility of learning if there is a way to prevent cancer in women who are genetically predisposed, Dr. Weber said, is to do long-term studies. If no one will participate, she said, what is the point in testing women to see if they have the cancer genes?