

**Congress of the United States**  
**Washington, DC 20515**

December 5, 2008

The Honorable Henry Paulson  
US Department of the Treasury  
1500 Pennsylvania Avenue, NW  
Washington, DC 20220

The Honorable Elaine Chao  
US Department of Labor  
Frances Perkins Building,  
200 Constitution Ave., NW  
Washington, DC 20210

The Honorable Michael Leavitt  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: REQUEST FOR INFORMATION REGARDING SECTIONS 101 THROUGH 104  
OF THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008**

Dear Secretary Paulson, Secretary Chao, and Secretary Leavitt:

As authors of the Genetic Information Nondiscrimination Act (GINA), we appreciate having the opportunity to comment about Title I of the bill to clarify any ambiguities of our intentions and to help guide drafting of the regulations. We championed this legislation for many years, with the primary intention of protecting individuals from being discriminated against in health insurance and employment settings because of their genetic information.

There are currently over 15,500 recognized genetic disorders affecting 13 million Americans, and every one of us is estimated to be genetically predisposed to between 5 and 50 serious disorders. Because none of us has perfect genes, GINA is designed to protect all of us who have bad genes, but may never get the disease.

We believed that establishing these protections will allay individuals' concerns about the potential for discrimination; encourage individuals to take advantage of genetic testing, new technologies, and new therapies; and increase participation in genetic research. Moreover, enactment of GINA will now allow us to realize the tremendous potential of genetic research and transform the way our country provides health care.

### **A. Comments regarding economic analysis, paperwork reduction act and regulatory flexibility act**

Prior to passing GINA in the House of Representatives, we asked the Congressional Budget Office to score the bill. In its scoring, CBO stated that it estimates the bill would increase the number of individuals who obtain health insurance by about 600 people per year, nearly all of whom would obtain insurance in the individual market. Furthermore, GINA would affect federal revenues because the premiums paid by some of those newly insured individuals would be tax-deductible. As such, CBO estimated GINA would reduce revenues by less than \$500,000 in each year from 2008 through 2017, by \$1 million over the 2008-2012 period, and by \$2 million over the 2008-2017 period. Although GINA would apply to Medicare supplemental insurance, which could affect direct spending for Medicare, CBO estimated there would be no significant effect on direct spending. To access the CBO score, go to:  
<http://www.cbo.gov/ftpdocs/80xx/doc8001/hr493.pdf>

Because GINA had a small cost associated with it, according to the "pay-as-you-go" rules in the U.S. House of Representatives, we were required to offset its costs. We did this by increasing penalties for violations of child labor laws.

### **B. Comments regarding regulatory guidance**

Title I of GINA applies to employer-sponsored group health plans, health insurance issuers in the group and individual markets, Medigap insurance, and state and local non-federal governmental plans.

#### Section 101 – ERISA

The Employee Retirement and Security Act (ERISA) currently prohibits a group health plan or health insurance issuer offering coverage in connection with a group health plan from discriminating against an individual in the group in setting eligibility, premium, or contribution amounts based on the individual's genetic information.

This legislation clarifies that genetic information includes "information about a request for or a receipt of genetic services by an individual or family member of such individual."

While current law protected individuals in a group from being charged premiums or contributions that are higher than the premiums or contributions for similarly situated individuals, this protection did not extend to the group as a whole. Thus, this section prohibits a health insurance issuer offering health coverage in connection with a group health plan from adjusting premium or contribution amounts for a group on the basis of genetic information concerning an individual in the group or a family member of the individual.

#### Section 102 – the Public Health Service Act

We made an important change, via amendment, to the section of the Public Health Service Act dealing with the individual health insurance market (sections 2753(a), 2753(b), and 2753(c)).

Under GINA, we brought prohibitions in the individual market in line with prohibitions in group health plans. Specifically, under GINA both group health plans and individual market health plans are prohibited from using genetic information for three things: 1) determining eligibility; 2)

charging an individual a higher premium; and 3) adding a rider or amendment to a premium (for example, if a person tests positive for the BRAC-1 gene then gets insurance, the insurer cannot say it will cover everything but breast cancer because that is a preexisting condition).

*1) Section 2753(a)—Prohibition on genetic information as a condition of eligibility.* A health insurance issuer in the individual market may not establish rules for eligibility (including continued eligibility) for an individual to enroll for coverage based on genetic information (including information about a request for or receipt of genetic services by an individual or family member of such individual).

*2) Section 2753(b)—Prohibition on genetic information in setting premium rates.* A health insurance issuer in the individual market shall not adjust the premium or contribution amounts for an individual on the basis of such individual's genetic information (including information about a request for or receipt of genetic services).

*3) Section 2753(c).—Prohibition on genetic information as preexisting condition.* A health insurance issuer in the individual market shall not impose any preexisting condition exclusion for an individual on the basis of such individual's genetic information (including information about a request for or receipt of genetic services).

#### Section 103 - the Internal Revenue Code

During consideration of the House bill, the Ways and Means Committee added section 103 to allow the Secretary of the Treasury to seek penalties for violation of GINA. Specifically, the law enforces prohibitions on adjusting premiums or contribution amounts, as well as requesting or requiring genetic testing, through the use of an excise tax on group health plans that fail to comply with these rules. This same enforcement mechanism is used under present law with respect to similar health care provisions, including provisions relating to mental health parity, limitations on pre-existing condition exclusions, the prohibition on discrimination based on health status, and the rules relating to benefits for mothers and newborns.

#### Section 104 - Medigap

This section prohibits an issuer of a Medicare supplemental policy from denying or conditioning the issuance of a policy, discriminating in the price of the policy, or applying pre-existing condition exclusions to the policy on the basis of genetic information. Section 104 also prohibits an issuer of a Medicare supplemental policy from requesting or requiring genetic testing and restricts an issuer's collection of genetic information.

#### Title I – in general

##### Genetic tests and manifested disease

In section 101(a)(3)(B) and subsequent relevant sections in Title I, we added a rule of construction clarifying permissions and prohibitions on the underwriting of an individual and family member with a manifested disease.

The definition of genetic test is important here because it states that a genetic test does not include a disease that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved. This definition clarifies that in order to

be considered “manifested” the disease has to have signs (other than a genetic test) and symptoms beyond a genetic marker that would allow the disease to be detected by a health care provider. Regulations should specify that “manifestation” should be linked to the presence of “signs” (other than a genetic test) and “symptoms” of the disease, disorder, or pathological condition.

Regulations should specify that a genetic test result is not, by itself, enough to diagnose a manifested disease. If it were, any genetic test result could be declared a “diagnosis” of future disease that has not actually manifested itself in a detectable way -- gutting the protections afforded by GINA and undermining Congressional intent. There is legal precedent for ensuring that a test result cannot by itself be used as the basis of making a diagnosis. HIPAA states “Genetic information shall not be treated as a condition described in subsection (a)(1) [a pre-existing condition] in the absence of a diagnosis of the condition related to such information.”

Under GINA, the manifestation of a disease in family members of an individual also constitutes genetic information about the individual. Health insurers are not allowed to discriminate against the relatives of a person with a manifested disease based on this family history, even if they are dependents on the original individual’s health plan or members of the same group health plan. Further, the genetic information of an individual with a manifested disease is protected under GINA and cannot be used for underwriting.

At the same time, during negotiations on GINA, health insurers had argued that the bill could create a situation where an insurer could not use manifested disease for legitimate underwriting purposes, because it would also be genetic information of a family member. An example is where two brothers were both insured by the same company, and brother #1 had a child with a genetic disease. Insurers were concerned that even though they were underwriting based on the manifested disease, they might be considered to be using the genetic information of a family member to discriminate against brother #2. The insurers were concerned that they would need to resort to community rating practices.

Although we believe that the government has a responsibility to ensure accessible, affordable, quality health care to all Americans, the issue of how to prevent health insurers from underwriting based on a manifested disease was beyond the scope of this bill, which instead focused on ensuring protections for one's genetic information only. Therefore, to clarify our intentions, we added a rule of construction specifying that the prohibition against underwriting based on genetic information of an individual or family member does not preclude an insurer from underwriting based on a manifested disease of an individual or family member, and that manifested disease of one individual cannot also be used as genetic information of another individual. At the same time, we took caution to protect the prohibition on health insurers requesting, requiring or purchasing an individual's genetic information for purposes of determining enrollment eligibility or for underwriting. The regulations should reflect a narrow interpretation of the rule of construction and ensure that the prohibition on requesting, requiring, and purchasing an individual's genetic information remains intact.

#### Definition of a family member

We modified the definition of family member to reflect how existing law defines a dependent. We referred to the US code on this definition, which includes spouse, dependent child, and a child being placed for adoption. We also limited the definition to extend to fourth-degree relatives of an individual. Our intention was to protect, in the most expansive way possible, an individual's family history by broadly defining family members.

#### Restrictions on health plans providing information

Title I of GINA prohibits group health plans, health insurance issuers in the group and individual market, and issuers of Medicare supplemental policies from requesting or requiring an individual to take a genetic test. Insurers and plan sponsors may not ask prospective enrollees for information about genetic testing, genetic services, or family history in initial enrollment or medical underwriting questionnaires. Regulations should specify that group health plans and group and individual health insurance issuers are not allowed to ask for, seek, or obtain genetic information about applicants before they enroll in coverage.

Overly broad requests for health information that are likely to also gather some genetic information should be prohibited. To avoid this, regulators should develop model language for insurers and issuers to inform people that they should not reveal genetic information. Furthermore, regulations should require plans and insurers to notify the enrollee if information was inadvertently collected. Such a requirement would encourage plans and insurers not to collect such information in the first place. In addition, health plans and health insurance issuers should regularly report to the agencies instances of incidental collection of genetic information. This will inform oversight and compliance audit efforts by regulators.

Regulations should specify that GINA does not prohibit a plan or issuer from providing information to enrolled or covered individuals about genetic testing. For example, a plan may send written information about carrier screening or cancer predisposition genetic testing to all covered individuals or to subgroups based on appropriate demographic factors. However, regulations should specify that plans and issuers may not contact patients directly to request or require that they take a genetic test.

The rules of construction do allow a health care provider providing health care services to an individual to request that an individual undergo a genetic test. The rule of construction was crafted so as to not interfere with a physician's ability to deliver health care services to his patient. The intent is to protect individuals from health insurers asking or forcing individuals to take a genetic test, while at the same time allowing physicians to provide quality health care for their patients when medically necessary.

#### Claims processing

Title I of GINA does allow health insurers to obtain the results of an individual's genetic test for the purposes of providing payment. Therefore, information about claims for genetic services may reveal genetic information to health insurers who thereby would obtain genetic information without violating GINA. However, the law is very clear that health insurers may only request the minimum amount of information necessary to process the claim. We believe it is critical that this limitation in the law be fully enforced, so as to deter health insurers from using this as a loophole to obtain a person's genetic information. Therefore, in enforcing GINA, regulators

should consider implementing requirements for insurers to isolate the information obtained through claims processing from the underwriting process, notify enrollees that they have received this information but will not use it, and certify to the Secretary that they will not use this information for underwriting. Regulations also should require that if an insurer makes a determination that only disclosure of a genetic test result will suffice to prove medical necessity, that determination must be in writing and must cite the specific evidence or guidelines on which it is based. Insurers should be required to report periodically the number of times they make such determinations.

#### Wellness programs

While wellness programs are not specifically mentioned in Title I, regulations implementing this title must specify that wellness programs that are part of or related to the health insurance offered by an employer must comply with Title I's prohibition on the collection or use of genetic information, including family history.

#### State preemption

The state preemption provisions in Title I of GINA are the same standards that exist for the medical privacy regulations. Specifically, a requirement under this section shall supersede any contrary provision of state law unless such provision of state law imposes requirements, standards, or implementation specifications that are more stringent than those imposed under this Title.

However, no state health insurance laws today are fully in compliance with GINA requirements; no states currently have adopted GINA's definition of genetic test; many do not include family history in the definition of genetic information; and no state definitions specifically reference genetic services. The burden rests with HHS to enforce the provisions of this law applying to the group and individual health markets when states fail to do so. Thus, when regulations are drafted, HHS should emphasize that states should take care to adopt and enforce each and every health insurance provision of GINA.

#### Public Outreach and Education

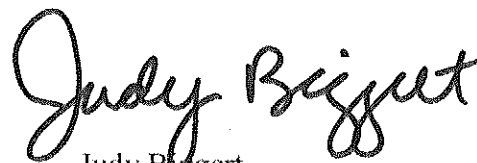
Although not specified in the legislation, we highly recommend that all of the relevant federal agencies issue guidance on notice requirements for group health plans and health insurance issuers to alert consumers to their new protections under GINA. The Secretaries of HHS and the Department of Labor also should engage in outreach to state officials to educate them about GINA's requirements and determine what assistance states may need in order to adopt and enforce these in a timely and effective manner.

Thank you for the opportunity to comment.



Louise M. Slaughter  
Member of Congress

Sincerely,



Judy Biggert  
Member of Congress