

# United States Senate

WASHINGTON, DC 20510

March 4, 2008

Senator Harry Reid  
Majority Leader  
United States Senate  
528 Hart Senate Office Building  
Washington, DC 20510

Senator Edward Kennedy, Chairman  
Senate Health, Education, Labor, and  
Pensions Committee  
317 Russell Senate Building  
Washington, DC 20510

Dear Senators Reid and Kennedy:

We hope that Congress can quickly send President Bush the Genetic Information Non-discrimination Act (GINA). Appropriately drafted legislation is an important key to unlocking the tremendous potential to save and improve lives through the exciting field of medical genomics. GINA has long been a bi-partisan vision, and we hope to see it soon become law.

As you know, different versions of GINA have already passed the Senate Health, Education, Labor, and Pensions Committee and the full House this Congress. We are very concerned with a recent draft that some suggest reflect House and Senate discussions. When crafting significant civil rights legislation, we do not believe it is appropriate to ignore both regular order and the important concerns raised in this letter and elsewhere. We believe that a few language changes—fully consistent with the longstanding intent of GINA—will secure its swift Senate passage. We believe these are common-sense issues that should be easily addressed. All Americans need to know that their genetic information will not be used against them in health care and employment decisions. We believe this protection can be finally enacted by incorporating the following changes:

First, we note that the legislative language of GINA does not reflect Senator Kennedy's intent as outlined in the HELP Committee report from April 7, 2007. The report states, "The actions of an employer, labor organization, employment agency, or joint labor-management committee when taken in its capacity as a plan sponsor, fiduciary, or plan administrator, would be governed by title I of this legislation...The Committee does not intend to extend liability under Title II, where broader remedies may be more attractive than the remedies under Title I, for violations of Title I." We note that Title I is carefully crafted to govern health plans and Title II is designed to govern employment situations—even the definitions of genetic test differ between Titles I and II. It is important to maintain the current-law distinction between employee benefit disputes, which have a separate and established remedial system, and disputes about civil rights in the employment context. Blurring this clear distinction is not only contrary to the intent of the Committee and the Congress, but would negatively impact the accessibility and affordability of health benefits by introducing new legal liability due to overlap between the two systems. We have attached legislative language that achieves the common-sense intention of the Senate HELP Committee to prohibit genetic discrimination while maintaining the integrity of the civil rights and employee benefit remedy systems.

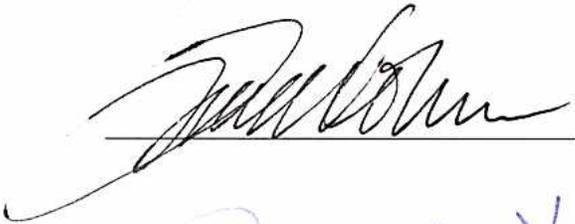
Second, the intention of GINA is not to punish employers for non-discriminatory use of their employees' genetic information. Accordingly, the current language includes an exemption for "inadvertent" collection of genetic information and several other specific exemptions. While this is an important part of crafting a workable statute, it simply is not possible to have thought of all legitimate reasons for an exemption. Case in point: even though GINA has been around for more than 12 years, an exemption for law enforcement was added (because it involves the collection of employee genetic information to prevent sample contamination during DNA analysis) right before the full House passed GINA last summer. This clearly illustrates that there may be other examples we have not yet considered. Previous labor statutes, such as the Americans with Disabilities Act, have recognized this and included business necessity exemptions. We believe that GINA should include a similar provision, and language to achieve that is attached. This is particularly important given the different definition of genetic information in Title II. As we read it genetic information includes the manifestation of diseases in a family member, which could include something as simple as flu in a child.

There are several places where the current version of the bill is not completely clear whether information about a "manifested" disease or condition is included in GINA's prohibitions. Current law generally allows employers, group health plans, health insurance issuers, and issuers of Medigap policies to request and receive information about whether an individual has a manifested disease. The current version of GINA is equivocal regarding this long-established process because some sections do and some do not clarify that information about a manifested disease is not intended to be prohibited under GINA. The agreed-upon scope of GINA has not included prohibitions on manifested diseases. We believe the final draft of GINA should provide clarity to the health insurance industry, maintain the integrity of the underwriting process, and ensure accurate premium assessments. We understand that this has been the intent of GINA, and it requires only a minor technical fix to reflect that.

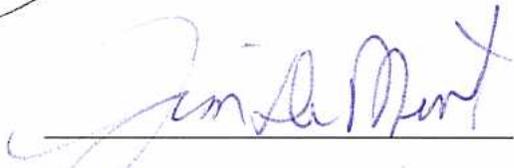
Finally, we note an important provision of the bill that passed the House. That legislation made clear that entities covered under the Health Insurance Portability and Accountability Act (HIPAA) privacy regulations, could continue to communicate medical information consistent with HIPAA and not face an inconsistent scheme under Title II of GINA. It is very important that medical information for the coordination of health care be regulated under the HIPAA construct and not an overlapping regime operated by the Equal Employment Opportunity Commission. Among other things, failure to have this provision would deter employers from providing important benefits such as personal health record services. Employer clinics would be subject to rules that would hamper and deter the promise of interoperable electronic health records. We support the language as passed by the full House on this issue.

We appreciate your attention to the details necessary to enact the Genetic Information Non-discrimination Act. This letter's list of concerns fully addresses the policy issues needed to pass GINA by unanimous consent in the Senate. We support the intent of GINA, but believe its prohibitions should not result in unintended consequences that will ultimately harm the individuals it seeks to protect. We look forward to working with you to achieve the important protections of GINA so that the American people may fully benefit from the promise of genomics and personalized medicine.

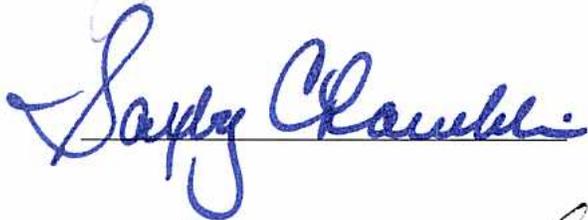
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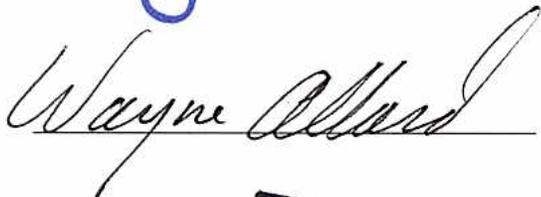
  
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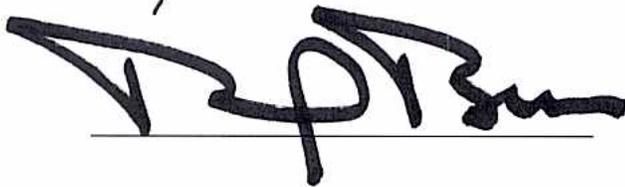
  
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## **Title I/II “Firewall”**

At the appropriate place in Title II insert:

(a) IN GENERAL.-Nothing in this title shall be construed to --

(1) [current language]

(2)(A) limit the rights or protections of an individual to bring an action under this title against an employer, employment agency, labor organization, or joint labor-management committee for a violation of this title, except as otherwise provided by this paragraph;

(B) provide for enforcement of, or penalties for violation of, any requirement or prohibition applicable to a group health plan, health insurance issuer offering group health insurance in connection with a group health plan, employer, employment agency, labor organization, or joint labor-management committee, on the basis of an act that is a violation of a requirement or prohibition the enforcement of which, or penalties for which, are provided under the amendments made by title I; or

(C) make subject to this title any actions or communications of an employer, employment agency, labor organization, or joint labor-management committee when taken in its capacity as a sponsor, fiduciary, or administrator of a group health plan;

(3) ....

## **Business Necessity Exemption**

At the appropriate places in Title II insert:

“where the request, requirement, or purchase of such genetic information is otherwise job related and consistent with business necessity.”