December 9, 2009

Hilda Solis
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Dear Secretary Solis:

I write on behalf of the University of Michigan Health Management Research Center in regard to the recent interim final regulations concerning Title I of the Genetic Information Nondiscrimination Act (GINA). We respectfully request an immediate moratorium on the implementation and enforcement of these regulations. We further request the creation of a special panel to review and understand the impact of these regulations on the use of wellness programs.

The Health Management Research Center (HMRC) is a leader in the study of the relationships between health status, economic outcomes, and quality of life. The HMRC has 30 years’ experience in the analysis of the associations between the health risks of an employee population and the health care and productivity costs to the employer. Our research has shown the importance of helping individuals maintain their low risk health status and helping organizations create healthier, more productive worksites. Given the current emphasis on the economics of health care reform, this research holds particular promise for its potential impact on curbing health care costs and promoting a culture of wellness. Furthermore, for American companies to remain globally competitive, maintaining and improving the health of their employees must be viewed as a serious economic strategy.

The HMRC supports the intent of Title I of GINA to prohibit the misuse of genetic information and family medical history. The HMRC agrees with the GINA provisions that prohibit group health plans and health insurers from increasing group premiums or contribution amounts based on genetic information and requesting or requiring individuals to undergo a genetic test. HMRC also concurs with the prohibition against requesting, requiring or purchasing genetic information prior to or in connection with enrollment in a health plan, or at any time for underwriting purposes. However, the HMRC believes the definition of “underwriting” included in the interim final regulations far exceeds Congressional intent and will have unintended consequences.

The final interim regulations broadly define “underwriting purposes” to mean rules for determining eligibility, computation of premium or contribution amounts, and application of pre-existing condition exclusions. The interim final regulations also state that a wellness program that rewards individuals for completing an HRA that requests family medical history would violate the prohibition against requesting genetic information for underwriting purposes, even if the rewards or incentives are not based on the outcome of the assessment. Finally, the interim
final regulations prohibit the use of an HRA to determine whether a participant is eligible for a disease management program if the HRA collects family medical information.

The prohibition on collecting genetic information for underwriting purposes, as currently defined, severely impacts the use of the Health Risk Appraisal (HRA). The HRA is a proven tool used to identify individuals who are at-risk for or currently managing chronic illness; in addition, the HRA is a validated research instrument that has been widely used for studies of productivity and cost-effectiveness. The use of sophisticated HRA tools enables targeted programs designed to benefit these individuals and provide services and support based on current health status. Data from the HRA have also enabled the HMRC to explore the associations between health risk and a variety of health-related and economic outcomes. It is important to recognize that these tools have been shown to improve health care status and quality and reduce health care costs.

The HMRC believes that wellness programs and the tools they use, such as HRAs, are consistent with the Administration's health care reform goals of improved quality and reduced costs. As such, the Title I GINA interim final rules directly contradict those goals and should not be permitted to move forward to implementation or enforcement without closer examination and adherence to the original Congressional intent.

Sincerely,

[Signature]

Dee W. Edington, Ph. D., Director
University of Michigan
Health Management Research Center