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Timothy Geithner
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

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

Kathleen Sebelius
Secretary
U.S. Dept. of Health and Human Services
200 Independence Avenue SW
Room 639G
Washington, DC 20201

Stuart J. Ishimaru
Acting Chairman
U.S. Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

cc: Robert Kocher, MD, Special Assistant to the President, National Economic Council, The White House
Ezekiel Emanuel, MD, Special Advisor for Health Policy, Office of the Director, Office of Management and Budget

Dear Sirs and Madams:

As a leading health management firm committed to supporting individuals to achieve better health, Alere fully supports the goal of the Genetic Information Nondiscrimination Act (GINA) to prevent improper use of genetic information in hiring practices and in the provision and pricing of health insurance. However, at a time when so much effort is focused on reforms to improve the effectiveness and efficiency of our health system, the GINA Title I interim final rule will create significant barriers to both the use of health risk assessments as well as access to wellness and chronic disease management programs. Accordingly, we ask that the departments of Health and Human Services, Labor and the Treasury delay implementation and enforcement of the Title I interim final rule and evaluate the rule's potential impact on workplace health promotion programs. In addition, we ask that the Equal Employment Opportunity Commission delay adoption of similar rules under Title II of GINA, or define "voluntary" in a way that precludes the use of non-discriminatory incentives to encourage participation in wellness programs

Family history of disease has been shown in the peer-reviewed literature to influence an individual's likelihood of developing many diseases. An individual's awareness of familial predisposition for health risks can be a potent motivator for taking action to change lifestyle behaviors and mitigate these risks. The Centers for Disease Control and Prevention and the Office of the Surgeon General have actively promoted awareness and use of family medical history in the fight against chronic disease – the GINA regulation undermines these efforts.

Incentives for completing health risk assessments and for participating in health improvement programs have consistently demonstrated positive impacts.

- A CDC-sponsored employer health and productivity management benchmarking study identified "meaningful incentives," such as insurance premium discounts for completing an HRA, as a promising practice.[i]
- Incentives can serve as powerful motivators: A $25 cash incentive can generally spur a 50 percent HRA participation rate compared with a 10 percent to 15 percent rate in programs without incentives.[ii]
- Incentives also have been shown to result in clinical improvements. For example, modest financial incentives can be effective in motivating overweight employees to lose weight.[iii]
- Research has shown a positive relationship between HRA participation rates and costs savings – an average of $212 per participant in one study.[iv]

Eliminating family medical history questions from an HRA linked to incentives significantly diminishes the effectiveness of the HRA, which Alere uses extensively in our wellness and disease management programs. The alternative, removing incentives, predictably drives down participation rates. The result: individuals who could benefit from wellness and disease management services fall through the cracks, the prevalence of chronic conditions rises, and employers experience increased health care costs and productivity losses.

GINA Title I offers two impractical options: removing questions about family medical history from the HRA, which greatly diminishes its effectiveness; or ending incentives, which drives down participation rates. A third option, establishing two health risk assessments – one with questions about family medical history and one without – adds a burdensome layer of complexity, inconveniences employees and increases health care costs. Even if they forgo incentives, employers still could not use family medical history gained through an HRA to direct employees to beneficial disease management services.

GINA Title II prohibits employment discrimination based on genetic information and restricts employers and other entities from acquiring and disclosing genetic information. Recent activity by the EEOC suggests that it is reconsidering the use and size of financial inducements in wellness programs heretofore defined as "voluntary", as well as what is considered a penalty for non-participating employees, under both the ADA as well as Title II of GINA. We share our clients' concerns that GINA Title II (and the ADA) may be interpreted by the EEOC such that a program will not be considered voluntary if an incentive is provided for participation. This will have a predictably chilling effect on the adoption and success of employer-sponsored health promotion and improvement activities, which have been shown in the literature to be effective in improving health outcomes, while improving productivity and reducing aggregate health-related costs.

We believe that public policy should support the limited use of family history information to appropriately aid individuals in identifying their risk for developing disease. Further, we believe that public policy should support the use of incentives for participation in disease management and wellness programs, to improve health outcomes and reduce health-related costs. The health and productivity of our nation's workforce will suffer if employers face barriers, such as those imposed by GINA Titles I and II, to promoting healthful lifestyles and behaviors. With open enrollment underway and the GINA regulations set to take effect Dec. 7, employers have only the narrowest window of opportunity to assess and understand the regulations and adjust programs accordingly. Given this compressed timeframe and fears about running afoul of the regulations, employers may restrict wellness and disease management activities even beyond what GINA requires, further harming these programs.

As a physician, I appreciate the importance of family medical history as an essential component of evaluating and managing a patient. GINA's restrictions on the collection of family medical history will result in fewer patients understanding their risk of disease and seeking appropriate, coordinated care from their physicians. Ending incentives to comply with GINA's restrictions on collecting genetic information will have the same result – fewer patients will seek needed care because fewer will complete health risk assessments. Impeding awareness of genetic predisposition to disease will limit the effectiveness of the medical home and other new models of care coordination for chronically ill patients.

Alere believes that health risk assessments and participation incentives are core tools in effective health promotion and health improvement programs. GINA, as currently defined, has unintended perverse impacts on health improvement programs that will hamper the ability of employers, health plans, and health management organizations to identify and engage plan members who could benefit most from these services. We urge the departments of Health and Human Services, Labor, and Treasury to take prompt action to delay implementation and enforcement of the Title I interim final rule in order to mitigate the rule's deleterious impact on workplace health

promotion programs. In addition, we urge the EEOC to delay adoption of similar rules under

Title II, and to reconsider defining "voluntary" under GINA and the ADA to preclude the use of non-discriminatory incentives to encourage participation in disease management and wellness programs.

Sincerely,

Ron Geraty, M.D.
Chief Executive Officer

[ii] Goetzel RZ, Shechter D, Ozminkowski RJ, Marmet PF, Tabrizi MJ, Roemer EC. Promising practices in employer health and productivity management efforts: findings from a benchmarking study. J Occup Environ Med. 2007 Feb;49(2):111-30.
[ii] Wellness Councils of America. Absolute Advantage, 2006;6(1).
[ii] Finkelstein EA, Linnan LA, Tate DF, Birken BE. A pilot study testing the effect of different levels of financial incentives on weight loss among overweight employees. J Occup Environ Med. 2007 Sep;49(9):981-9.
[ii] Serxner, Seth A. PhD, MPH; Gold, Daniel B. PhD; Grossmeier, Jessica J. MPH; Anderson, David R. PhD. The Relationship Between Health Promotion Program Participation and Medical Costs: A Dose Response J Occup Environ Med. 2003;45:1196-200.