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November 25, 2009

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

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

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

*Re:* *REG-123829-08, CMS-4137-IFC, RIN 1210-AB27 – Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (Vol. 74, No. 193) (October 7, 2009)*

Dear Secretaries Geithner, Sebelius and Solis:

Johnson & Johnson is a health care company that brings innovative ideas, products and services to advance the health and well-being of people around the world. Our more than 250 Johnson & Johnson companies work with partners in health care to touch the lives of over a billion people every day. Johnson & Johnson is committed to offering employees effective wellness, prevention, and disease management programs. Over the past 10 years, we have successfully reduced risk factors among employees through our programs and, in doing so, have improved the health and productivity of our workforce. Our HealthMedia, Inc., business is an industry pioneer in developing digital health coaching interventions that help organizations reduce health care costs by cost-effectively enhancing the health and wellness of their employees and members. We appreciate the opportunity to comment on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA") (the "Interim Final Rules").

Johnson & Johnson fully supports GINA's intended purpose of prohibiting discrimination on the basis of genetic information with respect to health insurance and employment. However, we

believe that the overly broad definition of "underwriting" in the Interim Final Rules far exceeds the original intent of the law and will have significant and unfortunate consequences on wellness, prevention and disease management programs, and, ultimately, health care costs. Specifically, we are concerned that the Interim Final Rules prohibit (i) the collection of family medical history as part of a valid Health Risk Assessment ("HRA") that provides an incentive or is completed during an open enrollment period, and (ii) the use of HRAs that collect family medical history to match individuals with appropriate disease management programs. We believe that rather than apply absolute prohibitions against the use of these tools, there are other appropriate ways to ensure the protections provided under GINA are realized, and we believe the Agencies should take the appropriate time to evaluate these options.

Health risk assessments and health coaching programs are powerful ways to help people understand their personal health risks, including risks related to family medical history. These important tools help motivate healthier lifestyles and drive appropriate preventive behavior. Family medical history is a vital piece of the HRA. Answers to a few key family medical history questions can provide a participant critical information about his or her health risks. For example:

- The U.S. Preventive Services Task Force recommends that people at normal risk of colorectal cancer start screening at 50 years of age. Some people with a family history of colorectal cancer are at increased risk of developing this cancer at a young age, and should begin screening before 50 years. If this information is not collected in an HRA, the participant may not be advised to speak to his or her doctor about the best time to initiate screening.

- The U.S. Preventive Services Task Force does not recommend cholesterol screening for men under 35 years old who are at low risk or for women at any age who are low risk. Family history of premature heart disease (<55 years old in first-degree male relative, <65 years old in first-degree female relative) is a major risk factor for coronary heart disease. If that is the only risk factor that a woman or young man has for coronary heart disease, the participant will not be advised to get screened for high cholesterol and they may not take advantage of interventions that could lower their risk of heart attack and stroke.

These are just a few examples of how important family medical history questions are in helping individuals receive accurate risk information and motivating healthier lifestyles and appropriate preventive behavior.

It is important to note as well that, in general, employers today neither request nor receive individually identifiable family medical history information about their employees from the third parties who administer HRAs and other health coaching programs. Common industry practice is that third parties hold this information confidential from employers.

The option presented by the Interim Final Rules of removing incentives related to the completion of HRAs that contain family history questions will significantly decrease participation in HRAs. Incentives have been a key driver in encouraging people to take an HRA and to participate in health coaching programs. 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] At Johnson & Johnson, we have offered an annual incentive for completing an HRA and typically have over 80% of our employees participate, which we believe has a positive impact on the health and wellbeing of our workforce. The rules implementing GINA should not restrict incentive programs connected with valid HRAs that include family medical history questions where the family history information is used appropriately to help individuals identify and respond to important health risks.

We believe that there are ways to ensure family medical history information is not used to discriminate in employment or health coverage, while at the same time helping people identify and address health risks through the use of HRAs and health coaching tools. Therefore, we request a delay in the implementation and enforcement of the Interim Final Rules in order for affected parties to explore ways to ensure we protect genetic information, while also encouraging healthier lifestyles through use of valid and effective wellness and prevention tools.

Please contact either of us if you have any questions or would like to discuss our concerns in more detail. Kathy Buto can be reached at 202-589-1010; Dr. Fikry Isaac can be reached at 732-524-3404.

Sincerely,

Kathy Buto
Vice President, Health Policy

Fikry W. Isaac, MD
Executive Director, Global Health Services

[i] 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; 49(2):111-30.
[ii] Hunnicutt, D; Leffelman, B. (2006). *WELCOA's 7 Benchmarks.* WELCOA's Absolute Advantage Magazine, 6(1), 2-29.

cc: Robert P. 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