Business Roundtable

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Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Attention: RIN 1210–AB27

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Ladies and Gentlemen:

In response to the request for information published in the Federal Register on October 7, 2009, the Business Roundtable ("BRT") appreciates the opportunity to comment on the interim final rules implementing Sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"). As published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Departments"), the interim final rules are of great concern to the Business Roundtable.

The Business Roundtable is an association of chief executive officers of leading U.S. companies with more than $6 trillion in annual revenues and more than 12 million employees. Member companies comprise nearly a third of the total value of the U.S. stock markets and pay more than 60 percent of all corporate income taxes paid to the federal government. Annually, BRT companies return more than $167 billion in dividends to shareholders and the economy.

OVERVIEW:

As providers of health coverage to almost 35 million Americans, BRT companies play a significant role in helping American workers and their families obtain medical care. Rising health care costs affect all of America's workers and employers, and they are an increasing burden on our State and Federal governments.

The Business Roundtable is supportive of efforts to secure meaningful health care reform that will slow the rate of health care inflation and improve patient outcomes, without disrupting the employer based system. We share policymakers' goals of expanding coverage, promoting greater efficiencies, and bending the cost curve. Efforts to reduce these costs and improve health align closely with prevention and disease management efforts. As employers and the country explore legislative, regulatory and operational solutions to achieve these goals, workplace wellness initiatives have evolved as practical solutions that improve outcomes and reduce costs.

We appreciate the intent of the Departments in drafting regulations that would "secure the protections from discrimination intended by Congress." BRT companies recognize the importance of privacy and non-discrimination protections when developing these programs for our employees. Nonetheless, we believe that the interim final rules will unnecessarily curtail successful programs, which are both coveted by employees and productive for employers. Specifically, we have serious concerns regarding the new prohibition on the practice of coupling Health Risk Assessments ("HRAs") containing family medical history questions with financial incentives. Our concerns on this matter fall into three categories:

1. Regulations are driven by inaccurate assumptions.

2. Regulations will reduce future successes in wellness and health-care cost control.

3. Delayed release of regulations imposes an unreasonable burden on employers and plan-sponsors.

To address these concerns, the Business Roundtable recommends that the regulations be revised in a manner that would allow companies to maintain these beneficial wellness programs, while fortifying existing regulations that will ensure the prevention of discrimination as intended by the GINA legislation.

CONCERNS:

1. Regulations are driven by inaccurate assumptions.

The Business Roundtable believes that every person has two responsibilities with respect to health care: to make the choices that support his or her own health — including the decisions to participate in wellness, prevention and any necessary chronic care programs — and to have health insurance coverage that, at a minimum, offers catastrophic benefits. Congress and the Administration have expressed similar commitments in their pursuit of health care reform. To help employees fulfill these responsibilities, in addition to offering comprehensive health care coverage, many BRT member companies have developed longstanding wellness programs.

Strategies involving the use of HRAs have become integral tools for identifying those in need of preventive or condition management programs, and directing them to the health services they may need. The focus of many programs has moved from maintaining general health and well-being to identifying, managing or reducing specific (and potentially costly) health risks.

In 2007, 80 percent of member companies' current program offerings included HRAs. "Targeted interventions, such as disease management (82 percent), tobacco cessation (74 percent) and weight management programs (85 percent), have become common."[1]

Many of the leading causes of disability and premature death in the United States are potentially avoidable or controllable, including most injuries, many serious acute and chronic conditions, many forms of heart disease, and some cancers. Fortunately, several important risk factors are controllable, often simply by modifying health habits. Behavioral changes at any age can improve health and productivity. The early detection of illness can simplify treatment and increase chances for a complete recovery.[2]

Wellness and disease management programs help facilitate and encourage behavior modification and early detection, leading to better health outcomes and reducing health care costs. Despite the recession and recent cutbacks in some benefit programs, companies continue to add wellness and health management programs to promote healthier behaviors among their workers.[3] There has also been a simultaneous increase in employees' use of offered wellness programs. Forty-two percent of companies surveyed reported that more employees are using the company health plan, 47 percent have seen an increased use of employee assistance programs, and 30 percent reported an increase in the number of workers filing disability claims.[4]

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[1] Business Roundtable, "Doing Well through Wellness: 2006-07 Survey of Wellness Programs at Business Roundtable Member Companies," p. 3. *Available at* http://www.businessroundtable.org/sites/default/files/BR_Doing_Well_through_Wellness_09192007.pdf. In 2007, as a 10-year follow-up to the 1997 report, "Quality Health Care Is Good Business: A Survey of Health Care Quality Initiatives by Members of The Business Roundtable," BRT's Health and Retirement Task Force surveyed member companies to learn how they use health and wellness initiatives to support the health of their employees, while addressing rising health benefit costs. In late fall 2006, BRT sent comprehensive questionnaires regarding corporate health promotion and wellness initiatives to the appropriate wellness, medical or benefits director at each member company. With an unusually high rate of responses, BRT found all but one of the 76 responding companies reported having wellness programs either fully under way or in active development.

[2] *See* Partnership for Prevention, "Healthy Workforce 2010." *Available at* http://www.prevent.org/images/stories/Files/publications/Healthy_Workforce_2010.pdf.

[3] *See* "Companies Continue to Add Wellness Programs, Watson Wyatt / National Business Group on Health Survey Finds," *HealthcareIT News*, April 15, 2009. *Available at* http://www.healthcareitnews.com/press-release/companies-continue-add-wellness-programs-watson-wyattnational-business-group-health-su.

[4] *See* National Business Group on Health (NBGH)/Watson Wyatt Worldwide, "The Health and Productivity Advantage: 2009/2010 North American Staying@Work Report." *Available at* http://www.watsonwyatt.com/research/resrender.asp?id=NA-2009-13844&page=1.

Well-conceived health and wellness programs that focus on prevention, self-care, risk factor reduction, and disease management can produce substantial benefits for employers and their employees. These strategically designed wellness programs can reduce both direct and indirect healthcare costs.[5] Beyond the financial benefits, wellness programs permit companies to differentiate themselves from competitors by increasing productivity, cutting costs, and establishing a healthier work environment valued by current and prospective employees.[6] Health and wellness programs are not only coveted by employees, they have proven successful at reducing health care costs.

2. Regulations will reduce future successes in wellness and health-care cost control.

A recent survey of more than 450 large employers identified "employees' poor health habits" as the most significant challenge in maintaining affordable benefit coverage. The survey ranked HRAs as the number one employer program and strategic response to the rising cost of health benefits during a three-year period from 2006 to 2008. Eighty-three percent of respondents specified a preference for HRAs to control the rising cost of health benefits, an 18 percentage point increase in three years.[7] One of the critical barriers to the success of HRAs was a lack of employee interest,[8] indicating the importance of incentives to encourage employee participation.

Companies have found that financial incentives are necessary to engage employees in wellness efforts. Simply offering prevention and disease management opportunities yields little return by comparison. Additionally, the permissible alternative suggested by the regulations — eliminating the family medical history questions from an HRA linked to incentives —

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[5] *See* Ronald Ozminkowski, et al. "Long-Term Impact of Johnson & Johnson's Health & Wellness Program on Health Care Utilization and Expenditures," *Journal of Occupational and Environmental Medicine*, Vol. 44, No. 1, pp. 21-29 (Jan. 2002). Johnson & Johnson has administered wellness initiatives since 1979, and the present Health and Wellness Services offering, which began in 1995, includes occupational health and wellness, employee assistance and disability management professionals. The company administers HRAs to employees and offers assistance to deal with problem areas. Benchmarks and goals aim to reduce smoking/tobacco use, high blood pressure, cholesterol and inactivity. The results of the program include: savings of more than $38 million from 1995-1999, about $9.10 - $9.43 million per year; overall savings per employee per year of $225; 90 percent participation of eligible employees (approx. 43,000) in the HRA or intervention programs; and reduction in medical utilization ($3.96 million) and administrative expenses ($5.22 million).

[6] Edelman, "Finding Wealth Through Wellness: How Engaging Employees in Preventive Care Can Reduce Healthcare Costs," Fall 2006. *Available at* http://www.edelman.com/image/insights/content/Wellness_White_Paper.pdf.

[7] National Business Group on Health and Watson Wyatt, "The One Percent Strategy: Lessons Learned from Best Performers," 2008. *Available at* http://www.watsonwyatt.com/us/research/resrender.asp?id=2008-US-0037&page=1.

[8] Luann Heinen and Helen Darling, "Addressing Obesity in the Workplace: The Role of Employers," *The Milbank Quarterly*, Vol. 87, No. 1, 2009 (pp. 101–122).

significantly diminishes the effectiveness of the HRA. This alternative, by removing incentives, will drive down participation rates, undermining the efforts of BRT companies to provide coverage to their employees and jeopardizing employee health.

Overall, HRA participants cost an average of $212 less than eligible non-participants. With the current cost sharing structures of most employer sponsored health care coverage, any reduction in health care costs benefits employees significantly. Generally, employees also shoulder a significant portion of any increased costs in health care coverage. As HRA participation has increased, cost savings have also increased. Further, although participation in either an HRA or activities alone results in savings, participation in both yields even greater benefits. The findings indicate that there is an independent benefit to each of these elements of participation, but that the sum of these elements provides a greater benefit than either of the individual elements alone.[9]

Quite simply, employers will not be able to control the cost of medical claims if they do not begin changing the demand for care driven by diabetes, heart disease, sleep apnea, depression, back and knee problems, and many other health conditions caused or exacerbated by obesity.[10] The use of an HRA plays a well-demonstrated role in changing employees' behavior in a manner that provides better health outcomes at a lower cost to the employer and the employee.

3. Delayed release of regulations imposes an unreasonable burden on employers and plan sponsors.

As enacted on May 21, 2008, GINA required the Secretary of Labor,[11] Secretary of Treasury,[12] and Secretary of Health and Human Services[13] to "issue final regulations not later than 1 year after the date of enactment," or May 21, 2009. This statutory deadline considered the significant enrollment preparation, as well as the administrative timeline that employers and plan sponsors must follow, for open enrollment and the beginning of a new plan year. Most employers finalize benefit designs mid-year (by June or July) for the following calendar year in order to complete the extensive preparation necessary before open enrollment periods in the fall. Employers must prepare plan documents (including open enrollment materials, marketing and communication materials), program software systems, and train personnel to properly administer benefits. With increasingly complex benefit designs and varying choices, this

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[9] *See* SA Serxner, *et al.* "The Relationship Between Health Promotion Program Participation and Medical costs: A Dose Response," *Journal of Occupational and Environmental Medicine* Vol. 42, No. 11, pp. 1196-200 (Nov. 2003).

[10] Heinen and Darling, "Addressing Obesity in the Workplace: The Role of Employers."

[11] Pub. L. No. 110-233, § 101(f)(1).

[12] Pub. L. No. 110-233, § 103(f)(1).

[13] Pub. L. No. 110-233, § 102(d)(1).

preparation period is critical to ensure that enrollees are properly informed about their benefits during open enrollment and that benefits are correctly administered once the plan year begins.

The GINA regulations, however, were not issued by the Departments until October 7, 2009, over four months later than the deadline required by statute. The regulations, in addition to being issued after many BRT companies began open enrollment, require plan sponsors to make significant and unanticipated changes. Because of the delayed publication of the proposed regulations, employers and plan sponsors did not (and could not) foresee the imposition of these dramatic new restrictions on wellness programs and the use of HRAs. As a result, it is unreasonable to require employers, with less than three (3) months before benefit plan years ***begin*** in most cases, to restructure benefit programs, retract and revise printed materials, eliminate incentives that employees in many cases elected to pursue, and attempt to renegotiate or cancel agreements with outside vendors. Requiring employers to take these and other necessary steps to comply with the regulations by January 1, 2010 is an unattainable requirement that imposes an undue burden on employers.

RECOMMENDATION:

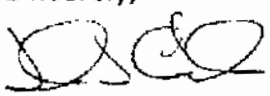
The Business Roundtable supports the original goals and intent of GINA to protect against discrimination based on genetic information. However, compliance with the new requirements imposed by the recently released regulations is unachievable by January 1, 2010, and we recommend that this effective date be revised and delayed.

In assessing GINA's goals of privacy and protection alongside the national imperative of improving wellness and controlling health care costs, we also recommend that the current proposed interim final rules be revised to more closely adhere to GINA's express legislative goals. In supporting the administration's commitment to wellness and prevention, we believe that GINA's goals of prohibiting discrimination based on genetic information can be attained with more narrowly drafted and less prescriptive regulations.

Both the Americans with Disabilities Act (ADA) and the Health Insurance Portability and Accountability Act (HIPAA), currently protect employees from discrimination based on health status and disability. In response to arguments that these laws do not adequately cover all possible scenarios, we would recommend stronger firewall requirements on the collection and sharing of health information. The Business Roundtable would appreciate the opportunity to review other options to ensure that employers are prevented from discriminating against individuals based on genetic information. Given that the majority of wellness and disease management programs are administered and coordinated by outside vendors, opportunities exist to firewall sensitive information without prohibiting programs that have realized success in improving employee health and controlling cost. Revising the effective date by 12 to 24 months would permit further study of alternative methods for strengthening privacy protections while continuing to permit beneficial wellness programs.

Thank you for the opportunity to submit comments on this important issue. The Business Roundtable is interested in working with the Departments to craft an appropriate solution. While we are committed to protecting individuals from discrimination based on genetic information, we believe that continued use of HRAs with questions regarding family medical history, in conjunction with financial incentives, is not incompatible with this commitment. We look forward to finding a solution that will permit the continued use of wellness and disease management programs that have a demonstrated ability to improve health and control cost.

Sincerely,



John J. Castellani