Worldwide Regulatory Affairs
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Global Research & Development

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To be Submitted through the Federal eRulemaking Portal

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

Dear Sir or Madam:

Pfizer appreciates the opportunity to provide these comments in response to the request for comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA"). The request was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Departments") in the *Federal Register* on October 7, 2009.

Pfizer is the world's largest research-based biopharmaceutical company. Our mission is to apply science and our global resources to improve health and well-being at every stage of life. We discover, develop, manufacture and deliver quality, safe and effective prescription medicines to help prevent and treat disease. We also partner with healthcare providers, governments and local communities around the world to expand access to our medicines and to provide better quality health care and health system support.

Consistent with its motto, "working for a healthier world," Pfizer uses wellness programs and self-reported health risk assessments ("HRAs") to encourage and optimize the health of its own workforce. Wellness programs represent a collection of tools for employers to raise awareness about health, provide relevant information and education, and encourage employees and their families to adopt healthier lifestyles. Importantly, wellness programs reduce the incidence and severity of chronic illness, and, therefore, reduce health care costs, by educating and encouraging proactive disease management. Employers often integrate their wellness initiatives with chronic disease management programs to provide a continuum of healthy lifestyle support and further contain the significant health care costs associated with chronic disease. According to a recent global survey, 77% of U.S. and Canadian employers offer wellness programs, a testament to the value and importance of these programs.[1]

In order to implement effective wellness and disease management programs, employers and others must have the ability to collect meaningful health information from employees. This

[1] Working Well: A Global Survey of Health Promotion and Workplace Wellness Strategies, Buck Consultants, November 2009.

information is aggregated and used by employers and their supply partners to make the business case for prevention, wellness and disease management, also to plan interventions and assess their effectiveness. An important benefit of HRAs is the early identification of individuals with recognizable risks for cardiovascular disease, diabetes, depression and other major chronic diseases, and the targeting of these individuals for disease management programs. Longitudinal data allows employers to monitor and measure the effectiveness of their employee health initiatives to inform decisions around strategic management of employee health plans and healthcare costs.

Typically, employers must offer financial incentives to encourage employees to complete HRAs and to participate in wellness and disease management programs. In the United States, 74% of wellness programs currently have a HRA component.[2] Over half (56%) of surveyed U.S. employers provide incentive rewards as components of their wellness programs to motivate employee participation. The most commonly rewarded activity is completion of an HRA.

Pfizer supports the intent of GINA to enable patients to benefit from the full value of genetic information by providing confidence that it cannot be used to influence decisions relating to their employment or health insurance. We understand that it is not the intent of the Departments to unduly restrict plans' use of HRAs and wellness and disease management programs, and we appreciate the regulatory examples and guidance provided by the Departments regarding some of the acceptable uses of financial incentives in conjunction with HRAs and wellness and disease management programs. However, Pfizer shares the concerns expressed by many other stakeholders that the broad regulatory definition of "underwriting" may reduce the effectiveness and impact of certain HRAs and the wellness and disease management programs they support, and may limit the impact such programs have on improving patients' health and decreasing health care costs. Accordingly, Pfizer respectfully requests that the Departments reconsider the scope of its guidance on the underwriting prohibition, and further clarify, by promulgation of additional regulatory examples or other guidance, the issues discussed below:

First, we urge the Departments to reconsider their regulatory definition of underwriting in order to permit, in limited circumstances, group health plans to offer certain financial incentives for the completion of HRAs that solicit genetic information. Plan-sponsored wellness and disease management programs serve important health improvement and cost containment roles that are wholly distinct from the underwriting process, as Congress understood that term. Congress defined underwriting as involving decisions regarding eligibility for benefits under the plan or coverage, the computation of premium or contribution amounts under the plan or coverage, the application of any pre-existing condition exclusion under the plan or coverage, or any other activity related to the creation, renewal, or replacement of a contract of health insurance or health benefits.[3]

Certain financial incentives offered for the completion of HRAs, such as de minimus cash amounts, cannot reasonably be characterized as being related to plan premiums, other cost-sharing mechanisms, health benefits, or the terms of the underlying insurance contract. Further, such incentives are necessary to ensure patient participation in programs designed to improve their health and decrease their cost sharing burdens. The policy goal of GINA — i.e., the prevention of discrimination on the basis of genetic information — is not served by impeding plans' ability to use family medical history information in a way that will financially and physiologically benefit patients.

In the event that the Departments do not revise the regulatory definition of underwriting, we ask that the Departments clarify that a group health plan may use a bifurcated HRA and offer

[2] *Id.*
[3] GINA § 101(d)(9).

financial incentives for completion of the portion of the HRA that does ***not*** request genetic information. In other words, we seek clarification that the group health plan may use a single HRA consisting of two sections: (1) one section that does not seek family medical history or other genetic information, and for which the completion may result in a financial or other incentive, and (2) a second section that does seek family medical history or other genetic information, but for which no incentive for completion is provided. The HRA would explain, in plain and clear language, that completion of the second section of the HRA is wholly voluntary, that no reward or financial incentive would be given for completing the second section, and that the individual's failure or refusal to complete the second section will not affect the financial incentive given for completion of the first section of the HRA. Such a bifurcated HRA is consistent with Example 5 in the respective regulations.[4]

Further, we ask that the Departments clarify that the prohibition on the use of financial incentives in conjunction with HRAs that request genetic information applies only with respect to wellness or disease management programs offered by group health plans, which are regulated under Title I of GINA, and not to wellness or disease management programs offered by employers which are completely distinct and independent of any health plan, and which are regulated under Title II of GINA. The Departments have indicated that the interim final rules implement sections 101 through 103 of GINA (Title I), and that compliance with these sections "is not determinative of compliance with any other provision of GINA or any other State or Federal law, including the Americans with Disabilities Act."[5] Indeed, Title II of GINA expressly permits employers to request genetic information in conjunction with a voluntary wellness program,[6] a fact that, in the Departments' view, distinguishes Titles I and II of GINA.[7] Thus, we are requesting confirmation that the Departments' prohibition on a ***health plan*** providing financial incentives for the completion of HRAs containing genetic information (including family medical history) – which could be considered an unlawful underwriting procedure -- should not be interpreted as affecting an ***employer's*** ability to effectively use such financial incentives in the context of a Title II–compliant, voluntary wellness program that involves the solicitation of family medical history.

Finally, we urge the Equal Employment Opportunity Commission ("EEOC") to clarify that employers may offer financial incentives -- that are not linked to health plan premiums, co-payments or other cost-sharing -- such as a cash reward, gift card, or in-kind gift, or other incentives such as participation in disease management programs, for the completion of HRAs that solicit genetic information and that are provided in connection with a voluntary wellness program. Employer-sponsored wellness programs that reward participation through use of such incentives are "voluntary" within the meaning of the Americans with Disabilities Act ("ADA"), as they neither require participation nor penalize non-participation in the programs.[8] These voluntary programs provide significant and cost-effective means for employees to obtain a variety of lifestyle and disease management benefits that are completely separate from and, indeed, may obviate the need for, medical services provided by a health plan. However, they cannot serve this valuable purpose without HRAs that contain the employee's complete medical history which, in any reasonable medical view, ***must*** include his or her family history.

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[4] 26 C.F.R. § 54.9802-3T(d)(3); 29 C.F.R. § 2590.702-1(d)(3); 45 C.F.R. § 146.122(d)(3).
[5] 74 Fed. Reg. 51664, 51665 (Oct. 7, 2009) (footnote 6).
[6] GINA § 202(b)(2).
[7] 74 Fed. Reg. at 51669 (footnote 12) (noting "GINA only includes an exception for wellness programs in the Title II employment provisions")
[8] *See* 74 Fed. Reg. 9056, 9062 (Mar. 2, 2009). The EEOC notes that "according to the [ADA] Enforcement Guidance, a wellness program is voluntary 'as long as an employer neither requires participation or penalizes employees who do not participate.'"

In conclusion, Pfizer is concerned that employers may suspend or discontinue use of HRAs or their disease management programs in response to the Departments' interim final rules. Any uncertainty regarding the appropriate use of incentives for the completion of HRAs by employers and health plans may have the unintended consequence of reducing participation levels in wellness and disease management programs, or otherwise rendering such programs less effective. We respectfully request that the EEOC and the Departments ensure the continued importance of employer-sponsored and plan-sponsored wellness and disease management programs. We thank you for your consideration of these comments.

Sincerely,

Lydia C. Pan, PhD
Director, Science Policy