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Department of Labor, Employee Benefits Security Administration
29 CFR Part 2590
RIN 1210-AB27

Department of Health and Human Services, Centers for Medicare & Medicaid Services
45 CFR Parts 144, 146, 148
RIN 0938-AP37

Department of the Treasury, Internal Revenue Service
26 CFR Part 54
[TD9464]
RIN 1545-BI03

The National Partnership for Women & Families, American Association of People with Disabilities, American Civil Liberties Union, Americans for Democratic Action, Asian & Pacific Islander American Health Forum, Bazelon Center for Mental Health Law, Black Women's Health Imperative, UAW, Japanese American Citizens League, Legal Momentum, NAACP, National Council of Jewish Women, National Health Law Program, and United Food & Commercial Workers are pleased to submit the following comments on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act (GINA) that were published in the Federal Register on October 7, 2009.

We are strong supporters of GINA because the law strikes an appropriate balance between promoting scientific advancement in genetic testing and protecting individuals' rights. Scientists have already identified genetic markers for various diseases and health conditions, including cancer, diabetes, Alzheimer's disease, Huntington's disease, cystic fibrosis, and potentially thousands of others. Genetic tests are currently available to identify predispositions to specific conditions, and more are expected as science advances. Although none of these tests predicts with full certainty that a condition will develop, they provide a new opportunity for individuals to know more about the potential risk of disease for themselves and their families. Once informed about their genetic status, individuals can take proactive steps to protect their health and enhance their well-being.

However, fears that health insurers will use an individual's genetic makeup to deny insurance coverage or to impose higher premiums have kept many people from benefiting from this emerging technology. Thus, GINA is a necessary protection that will allow individuals to take full advantage of the benefits of genetic testing without risking their

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health insurance or their economic security. As GINA makes clear, no individual should have to choose between the benefits of genetic testing and being able to obtain or afford health insurance. Especially in this economy, individuals need the protections of GINA so that they can maintain their economic security while seeking out the best possible health care for themselves and their families.

In crafting GINA, Congress wisely understood that proving discrimination based on genetic information could be difficult; so, in addition to prohibiting discrimination on the basis of genetic information, the law also limits when employers and health insurers can have access to this information. The decision to curtail access to genetic information follows logically from Congress's desire to prohibit discrimination on the basis of genetic information: if employers and health insurers do not have access to an individual's genetic information, they cannot use it to discriminate against that person.

We strongly support the interim final regulations published by HHS, DOL and the Department of Treasury; they should be implemented without delay. Consistent with the text, purposes and legislative history of GINA, the interim final regulations place clear limits on insurers' ability to collect genetic information and prohibit insurers from using this information for underwriting purposes. The following comments address two issues within the interim final regulations that we believe are especially critical to the full enforcement of GINA.

The Definition of "Manifest"

Pursuant to GINA, health insurers may not alter an individual's premiums based on genetic information. Insurers are permitted, however, to make such an alteration in premiums if and when the disease "manifests" itself. Of course, any such alterations must be consistent with the Americans with Disabilities Act.

According to the interim final regulations, a condition or disease is manifested when an individual has been or could be reasonably diagnosed by a health care professional with appropriate expertise in the field of medicine involved. The regulation further clarifies that a disease is not manifested if a diagnosis is based principally on genetic information. In general, we support this definition; however, we believe an additional example should be added to the regulations to make clear that it is *only* the manifestation that allows the insurer to increase premiums, not the individual accessing counseling or preventive care or acting on the basis of the results of a genetic test.

Currently, individuals may undertake a course of treatment after receiving the results of a genetic test prior to the disease manifesting itself. For example, a woman may choose to undergo BRCA testing (genetic testing for breast and ovarian cancer risk). Based on the results of that test, she may decide on a course of therapy including earlier and more frequent mammograms and preventive measures such as taking tamoxifen or having preventive surgery to remove the ovaries or breasts. However, because all of these actions would be taken prior to the "manifestation" of a condition under GINA, a health insurer should not be permitted to alter the woman's premiums based on her decision to seek counseling or undertake a course of therapy.

The Use of Health Risk Assessments and Wellness Programs

We support the use of health risk assessments (HRAs) and well designed wellness programs to improve the health status of individuals. We have serious reservations about all such programs, however, when they are linked, as many of them are, to premium adjustments or other types of rewards. HRAs that are linked to financial incentives require individuals to give up their medical privacy in order to obtain the incentive or avoid a disincentive. Similarly, wellness programs with financial incentives punish those who cannot meet the requirements of such programs, even when lack of ability to meet the program's requirements is beyond the control of the individual. For example, some individuals are simply unable to make time to attend a gym and exercise because of their work schedules and caregiving responsibilities. Other individuals live in neighborhoods that lack grocery stores or safe places to walk. For these people, wellness programs that penalize those who do not meet goals such as obtaining a certain body mass index or blood pressure target are unjust and tend to deprive those who need health care the most.

We recognize that GINA does not and will not go so far as to completely stop what we consider the inappropriate use of HRAs and wellness programs. However, GINA does provide important protections regarding HRAs and wellness programs and genetic information, and we strongly support the interim final regulations on these points.

As recognized in the proposed interim regulations, it is critical to the enforcement of GINA that HRAs and wellness programs are not permitted to incentivize the collection or dissemination of genetic information. Such incentives, whether in the forms of premium reductions or other rewards, completely undermine the protections in GINA regarding genetic information. Such programs also set up a perverse system where individuals will essentially be paid for giving up their civil rights as recognized by a federal law. We are strongly supportive of the provisions in the interim final regulations that prohibit HRAs or wellness programs that request genetic information, including family history, from offering rewards or premium differentials.

The prohibition on the collection of genetic information in HRAs or by wellness programs when a reward or premium differential is offered also comports with Congress's intent in GINA to stringently restrict the access that health insurance companies and employers have to genetic information. In limiting this access, Congress realized that the only way for employers or health insurers to discriminate against individuals based on their genetic information is if employers or health insurers somehow obtain that information. Thus, limiting the access that health insurers have to genetic information is in keeping with the purpose of GINA.

It is critical to note that the interim final regulations allow for HRAs and wellness programs to continue, as long as they respect the requirements of GINA. Thus, as made clear in the interim final regulations, HRAs may collect genetic information as long as two conditions are met. First, the HRA cannot be given prior to or in connection with the enrollment process. Second, if the HRA collects genetic information, including family history, the insurer cannot offer the individual an incentive to complete it. Similarly, the

proposed regulations do not prevent wellness programs from continuing to offer incentives as long as they do not require genetic information or family history, or, conversely, from requiring that information as long as the program is not then linked to a reward or lower premium.

We thank you for your consideration of these comments. If you have any questions, please contact Sharyn Tejani, Senior Policy Counsel, National Partnership for Women & Families, at (202) 986-2600 or stejani@nationalpartnership.org.

Sincerely,

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American Association of People with Disabilities
American Civil Liberties Union
Americans for Democratic Action
Asian & Pacific Islander American Health Forum
Bazelon Center for Mental Health Law
Black Women's Health Imperative
International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW).
Japanese American Citizens League (JACL)
Legal Momentum
NAACP
National Council of Jewish Women
National Health Law Program
United Food & Commercial Workers