



Employee Wellness Bill Could Stifle Genetics Research in Age of Big-Data Studies

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NEW YORK (GenomeWeb) – Republican legislators in the House are pushing ahead H.R. 1313, which they say aims to incentivize employees to partake in workplace wellness programs.

Leaders in the genomics field are concerned that any short-term gains the bill may have on encouraging better health and reducing costs would not be worth the crippling effects it could have on the space, particularly at a time when big data studies and data sharing are taking off.

H.R. 1313, the "Preserving Employee Wellness Programs Act," sponsored by House Committee on Education and the Workforce Chair Rep. Virginia Foxx (R-NC), states that as long as an employer-sponsored wellness program complies with a certain section under the Public Health Services Act, it will also be in line with the Americans with Disabilities Act and the Genetic Information Nondiscrimination Act. The bill would make it so employees who choose not to divulge genetic information within voluntary wellness programs would also forgo thousands of dollars in savings on the cost of their health insurance plans.

Enacted in 2008, GINA restricts health insurers and employers from asking about genetic information, except in a few limited circumstances, and from using that data to make coverage and employment decisions. Under one exception, employers can request genetic information through health risk assessments in wellness programs, but employees must give this information voluntarily and employers cannot provide discounts or rewards on the condition that they provide this data. H.R. 1313 would change that so wellness programs could base rewards on the condition that employees divulge genetic information.

This change would leave employees more vulnerable to employment discrimination based on their genetic data and could discourage them from getting tested and participating in research, say experts in the genomics field who oppose the bill. Right now, there is a lot of genetic testing occurring in disease research, to aid the development of drugs and tests, and in the context of delivering personalized medicine in cancer and rare diseases. The National Institutes of Health aims to whole-genome sequence 1 million Americans over four years within the All of Us Research Program and has promised to share test results and research findings with participants.

Last year, the Broad Institute alone sequenced more than 250,000 exomes, 65,000 genomes, and 25,000 transcriptomes. In the field, researchers are more willing to share data with each other, labs are working to resolve discrepant interpretations, and participants are increasingly demanding access to their own genetic information. But all this openness in the hopes of improving our understanding of the genomic underpinnings of disease could be quashed if people feel they are at risk of discrimination, say experts.

"There is a tremendous amount of research to be done yet in order to deliver the promises of precision health," said Jason Bobe, associate professor at Mount Sinai's Icahn School of Medicine, who is focused

on increasing participation rates in biomedical research. "Elimination of protections that facilitate broad participation in research may do more to set back our capacity for precision health over the long term compared to any short-term gains for wellness program administrators," he said.

"If [H.R. 1313] were to pass, it could harm recruitment for genetics research, such as within the All of Us program," said Derek Scholes, director of science policy at the American Society of Human Genetics. He added that the bill would also allow employers to ask employees and their family members about tests they've gotten outside of research, for example, if they've been tested for mutations in BRCA1 and BRCA2 genes that increase their risks for breast and ovarian cancers.

The ASHG has signed a letter along with more than 50 other groups asserting that H.R. 1313 would place employees at greater risk for genetic discrimination in the workplace. The architects of H.R. 1313 believe it simply reaffirms existing law under the Affordable Care Act.

Bethany Aronhalt, spokeswoman for the House Committee on Education and the Workforce, said in an e-mailed statement that groups in opposition to the bill are spreading false information about H.R. 1313 and are trying to deny employees the choice of participating in a "voluntary" program that can reduce health insurance costs and encourage healthy lifestyles. "We believe working families should be empowered with that choice, and so did the Obama administration," she said.

Sharon Terry, president of Genetic Alliance, who worked for more than a decade with other stakeholders and bipartisan members of Congress to bring about GINA's enactment, said that the groups opposing H.R. 1313 are supportive of voluntary workplace wellness programs that are in line with both the Affordable Care Act and GINA.

"GINA's Title II explicitly empowers employers to offer voluntary health and genetic services, such as through wellness programs, and employees are free to take advantage of them. That is the whole point of that section of the law!" Terry said over e-mail. "Nobody opposes it, and nothing need change for that to continue."

"It is also true that the ACA allows employers to offer wellness programs that have inducements — rewards or penalties — for employee participation or for meeting certain health targets. However, the point is that a company running such a wellness program permitted by the ACA cannot violate GINA," she continued. "Companies must comply with both laws, they cannot ignore one or the other. But that is precisely what H.R. 1313 would do. It would say that a company complying with ACA need not comply with GINA or the ADA."

The ACA allows employers to discount employees 30 percent of the total cost of the health insurance and by up to 50 percent for smoking cessation programs for meeting certain health targets. Within participation-only wellness programs where employees don't have to meet health targets, there are no limits to the incentives employers can offer. However, a 2013 [final rule](#) implementing this portion of the ACA notes that the rules prohibiting the collection of genetic information under other laws, such as GINA, still apply.

Despite significant emphasis on the word "voluntary" from Republican sponsors of H.R. 1313, the word doesn't show up in the bill or the 2013 ACA final rule on wellness programs. But the word does show up in the 2010 [final rule](#) the US Equal Employment Opportunity Commission issued on GINA, which ASHG and other groups say makes explicit that when a wellness program offers financial incentives to employees on the condition they provide genetic information it ceases to be voluntary.

"Balancing the potential benefits of health and genetic services offered to employees on a voluntary basis, including wellness programs, with the need to construe exceptions to the prohibition of acquisition of genetic information in a manner appropriately tailored to their specific purposes, we have concluded that

covered entities may offer certain kinds of financial inducements to encourage participation in health or genetic services under certain circumstances, but they may not offer an inducement for individuals to provide genetic information," the final rule states.

The EEOC further elaborated in the rule that an employer wouldn't violate GINA if it offered a financial reward for completing a health risk assessment that asked about family history or genetic information, as long as the employer made clear that the individual could decline to answer those questions and still receive the reward. Scholes further pointed out that the EEOC's rule on GINA clarifies that a voluntary wellness program is one that, "...neither requires the individual to provide genetic information nor penalizes those who choose not to provide it." However, if H.R. 1313 is enacted, wellness programs would no longer be required to comply with this aspect of GINA, he said.

Further adding to this debate about the extent to which employers can offer inducements in the context of voluntary wellness programs, last year the EEOC issued another [final rule](#) stating that an employer can offer financial incentives to an employee's spouse for providing health-related information within a wellness program, reasoning there is little risk that this data could be used to determine the genetic risk factors of an employee.

The final rule was a victory for employers groups, which have lobbied the government to clarify whether they can legally offer financial incentives for providing health and genetic data that can improve wellness programs, reduce costs and encourage employees to live healthier. Many groups, including the ASHG, felt that the EEOC erred in its interpretation and weakened protections under GINA for individuals and families. The AARP has even sued the EEOC over these final rules.

The architects of H.R. 1313 believe that its provisions would better align existing regulations with the aims of the ACA and reduce legal uncertainty for employers. Furthermore, they highlight that H.R. 1313 wouldn't alter portions of GINA that make it illegal for employers to use genetic information to make employment-related decisions. But critics of the bill say it puts people at risk for discrimination that's hard to prove.

"The reason why GINA was written the way it was is because it's very difficult to demonstrate genetic discrimination, but much easier to prevent access to the information and prevent discrimination that way," Scholes said. "If you don't have access to the information, you can't use it for any purpose."

Some of those that have signed the letter against H.R. 1313 are disease-centered groups, patient advocacy organizations, and entities that represent genetics professionals and create guidelines for the field, including the American College of Medical Genetics and Genomics, Association for Molecular Pathology, Genetic Alliance, Global Genes—Allies in Rare Disease, FORCE: Facing Our Risk for Cancer Empowered, and Susan G. Komen. Several of these signees have historically banded together in support of GINA, and [deflected past efforts](#) by employers and the wellness industry to carve out exceptions to the law that was 13 years in the making.

GINA has roots in the early days of the Human Genome Project. "There was this understanding that if we were to see the full promise of what is now called precision medicine, we needed to make sure that people felt safe from genetic discrimination from insurers and employers," Scholes said.

However, there are gaps in the law. For example, GINA doesn't restrict life insurance firms from asking for or using genetic information in actuarial decisions. These gaps already give people pause in getting genetic testing in the context of their care and in research.

Within the BabySeq Project, for example, investigators are enrolling 240 healthy newborns at Brigham and Women's Hospital and 240 newborns at the neonatal intensive care unit at Boston Children's Hospital. These newborns are randomized to an arm that receives genomic sequencing and conventional newborn screening, or to a control arm that receives just the standard screening. The study, which is exploring the

benefits and risks of genomic screening at birth, has an enrollment rate of 8 percent. The second most common reason why parents decline participation is fear of genetic discrimination for their child.

In consenting parents for this study, BabySeq investigators discuss some of the pluses and minuses of taking part in research — how they might learn something that might benefit their child's health but that this data will also go into the baby's medical record, which then could be discoverable by insurance companies. "People weigh this very carefully," said Robert Green, a geneticist at Brigham and Women's Hospital who is leading BabySeq with Alan Beggs at Boston Children's Hospital. "They are reassured by the protections we tell them about, and they are frightened when protections are missing."

Green participated last week in a two-day [NIH workshop](#) to discuss the challenges of returning genetic testing results within the All of Us Research program. At that meeting, Laura Beskow of Duke University said that in interviews with 60 thought leaders about hypothetical research involving 1 million participants, only 17 percent identified return of genetic information as a potential benefit, while more than half of interviewees identified receiving genetic information as a potential confidentiality risk. Patients Beskow surveyed also expressed concerns about the gaps in GINA.

"Rates of participation in organized health research are already very low," reflected Bobe, who also attended the NIH workshops. "Without protections against discrimination, my fear is that participation in research becomes a luxury that many cannot afford."

H.R. 1313 could further exacerbate people's fears about discrimination and ultimately bring research efforts like BabySeq to "a grinding halt," Green worried. "What if we had 1 percent, or half a percent, or nobody at all wanted to participate in a \$6 million federally funded research program to understand the clinical utility of sequencing?" he posited.

And these concerns can also spill onto the commercial side and discourage individuals from getting genetic testing that they need for medical care, he said. It could even dampen the public's growing enthusiasm for recreational genetic testing through firms like 23andMe, which genotyped its millionth customer two years ago. "This whole thing just adds uncertainty and fear," Green said.

Genetic testing firms are also exploring employer-backed wellness and prevention programs as a source of revenue, and it's unclear how H.R. 1313 would impact this relatively nascent space. For example, Newtopia uses genetic testing, as well as personality and lifestyle assessments, to encourage people to make positive behavioral and nutritional changes. In an interview last year, Newtopia CEO Jeff Ruby said the company is focused on using intrinsic motivators, rather than financial incentives.

Color Genomics is another company that is [partnering with employer groups](#) to subsidize the cost of genetic testing for hereditary cancer risks. Employees who work at companies that have signed on to Color's benefits program pay around \$100 (and sometimes nothing) for a genetic test that analyzes 30 cancer-associated genes, including BRCA1 and BRCA2, and costs around \$250.

Katie Stanton, former head of media at Twitter and chief marketing officer at Color, believes H.R. 1313 would create "troubling loopholes" that erode protections under GINA and the ADA. "These laws ensure that people can be proactive about their health, without fear of discrimination," said Stanton. "At Color, we believe that personal health data belongs to our customers and we're fully committed to protecting their privacy."

While H.R. 1313 may be good for employers and the \$6 billion workplace wellness industry, leaders in the genetic testing field urged legislators to also consider the potentially disastrous impact of the bill on the genetics industry, which has had a significant impact on the US economy. President Barack Obama said in his 2013 State of the Union Address that every dollar invested in the \$3 billion HGP returned \$140 back to the US economy. According to another estimate, genomics research between 1988 and 2012 had an

economic impact of \$965 billion, and in 2012 alone, genome sequencing-related industries created \$19 billion in personal income and supported 152,000 jobs.

"This is disadvantageous to certain kinds of progress, and certain technical advances that are good for business and the Republican agenda, which aren't going to be encouraged by a rolling back of this particular kind of regulation," Green said. "It would frighten people who would otherwise be excited about investing in these companies and purchasing these products."

Legislators in the House Committee on Education and the Workforce voted along party lines and passed H.R. 1313 last week, and have referred it to the Ways and Means and Energy and Commerce Committees. According to sources knowledgeable of the process, there may be an effort to include this bill as part of a package of healthcare-related items that will go to the House floor soon.

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