

**Comments of Anna Slomovic, PhD
Regarding Amendments to Regulations under the Genetic Information
Nondiscrimination Act**

Delivered via the Federal Rulemaking Portal at <http://www.regulations.gov>

U.S. Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

Re: RIN 3046-AB02

I appreciate the opportunity to submit comments on the Equal Employment Opportunity Commission's proposed amend the regulations implementing Title II of the Genetic Information Nondiscrimination Act of 2008 as they relate to employer wellness programs. The proposal appears in the Federal Register of October 30, 2015 at <https://www.federalregister.gov/articles/2015/10/30/2015-27734/genetic-information-nondiscrimination-act-of-2008>.

I am a consultant and a scholar, affiliated with George Washington University's Cyber Security Policy and Research Institute (CSPRI). For 15 years prior to returning to consulting and research, I served in various corporate positions, including positions as Chief Privacy Officer (CPO) of companies ranging in size from start-up to Fortune 500. One of these organizations was a nation-wide specialty health plan with 25 million members; another was a consumer-facing online health education and services company. As CPO I was responsible for privacy of both consumer and employee data. I have also served on federal and state-level work groups and commissions dealing with electronic health information. You can find additional information about my background on my website, www.annaslomovic.com. These comments reflect my own views and not the views of George Washington University, CSPRI, or any member of the university's faculty or staff.

For the past two years, I have been doing research on privacy in U.S. workplace wellness programs. The output of this research is a scholarly publication¹ and a series of short articles on specific issues that I published on my blog and elsewhere. I base my comments on this research and on my earlier research of privacy issues in genetic data.

Employer-sponsored wellness programs are at the intersection between rising healthcare costs and growing availability of fine-grained individual health data.

¹ Anna Slomovic, "eHealth and Privacy in U.S. Employer Wellness Programs," *Under Observation - The Interplay between eHealth and Surveillance*, Ronald Leenes, Nadezhda Purtova, Samantha Adams (eds.), Springer, Forthcoming. Available at SSRN: <http://ssrn.com/abstract=2613452>

Research continues on whether wellness programs improve health or reduce healthcare costs.² Regardless of the findings of this research, increasing employee participation in wellness programs through financial incentives and non-financial “engagement” techniques increases the amount of personal health information collected, analyzed, used and disclosed in the employment-related context. As more people participate in wellness programs, wellness vendors collect health and lifestyle data about more people and more data about each person. At least one wellness program³ already collects genetic data and claims to offer nutritional advice on the basis of genetic testing.

The sequencing of the human genome and the current research on the microbiome have raised the possibility that scientists will be able to develop new diagnostics and new therapies tailored to individual genetic make-up. This work has triggered a veritable gold rush by companies offering genetic testing as a basis for everything from beauty creams⁴ to disease prediction. It is not surprising that wellness vendors are interested as well.

I support the Commission in its goal to ensure that wellness programs do not create an avenue for genetic discrimination in the workplace. I suggest improvements to the Proposed Rule in several areas so that it can further protect employees from discrimination and improve privacy protections for all wellness program participants.

1. ***The Commission should restrict the collection of genetic information by a workplace wellness program to the minimum necessary to directly support the specific wellness activities, interventions, and advice provided through the program.*** The Commission should strengthen the definition of wellness programs as “reasonably designed to promote health or prevent disease” in order to prevent employers and their vendors from collecting health and genetic data in hope of finding some correlation in the data at some unspecified future time. Genetic data collected under a “reasonably designed” wellness program should be required to meet two conditions. First, there should be scientifically valid evidence that the data can be used to diagnose or prevent a specific disease or condition. Second, the wellness program must address that disease or condition using the collected data to provide recommendations. Simply providing follow-up and advice, as noted in the Proposed Rule, is not sufficient if that follow-up and advice is not based on the results of analyzing genetic data collected in the program. For example, if a wellness program collects genetic

² See, for example, Soeren Mattke et al., “Workplace Wellness Programs: Services Offered, Participation and Effectiveness,” Research Report RR724, RAND Corporation, Santa Monica, CA, 2014.

³ <http://geneticprivacynetwork.org/2015/04/28/genetic-testing-moves-into-world-of-employee-health/>

⁴ See, for example, <http://www.skinshift.com/v/vspfiles/templates/210/Science-Behind-SKINSHIFT.asp>

data for obesity management, it should be required to show that there is a scientifically demonstrated link between obesity and the genetic tests being performed by the program, and that program recommendations vary depending on the genetic profile of each individual. It should not be sufficient for the program to provide general nutrition advice as follow-up.

2. ***The Commission should prohibit workplace wellness programs from accessing genetic information from other sources, such as patient claims data and medical records data.*** As genetic research advances, an increasing number of health research and treatment programs use genetic testing. The Precision Medicine Initiative at the National Institutes of Health is only one example. Permitting workplace wellness programs to obtain access to genetic information from medical claims or medical records introduces the risk that individuals will refuse to participate in genetic testing and research because of concerns that the information will find its way to the employer, its wellness vendor, the vendor's business partners, and marketers. When individuals participate in genetic testing for health treatment or for altruistic advancement of research, they should not worry about use of their genetic data for secondary purposes unrelated to the original purposes.
3. ***The Commission should prohibit derivation or inference of predisposition to illness and disability from non-health data.*** The Proposed Rule covers programs only if they include genetic testing or direct inquiries about genetic information. This approach is a mistake. It does not consider a wellness vendor's ability to discover genetic information through the use of current and developing machine learning and inference technology without asking program participants to provide such information or to undergo a medical exam. As noted in a recent article published in *Science*, machine learning and related tools can be used to infer health and disability predispositions from non-health data.⁵ Wellness programs inferring information about health, lifestyle, and predisposition to illness and disability must comply with the same rules as programs that make direct inquiries and conduct testing directly on participants. The inferences made through machine learning and other analytic techniques must be subject to the same privacy protections as health and genetic data obtained through direct inquiries, genetic tests and medical records.
4. ***In view of current and developing technology, the Commission should prohibit the sale or other "sharing" of genetic data and of genetic data bundled with other health data, even if the genetic data or the bundle is de-identified.*** The Proposed Rule does not address whether genetic information may be sold or disclosed if it is de-identified or otherwise anonymized. In most cases, de-identified information is not subject to privacy protections, but there are two specific concern about genetic data. First, it is now possible to re-identify supposedly anonymous genetic data. In fact, some researchers urge their

⁵ Eric Horvitz and Deirdre Mulligan, "Data, Privacy and the Greater Good," *Science*, 17 JULY 2015 • Vol. 349, Issue 6245, July 17, 2015, pp. 253-255.

colleagues not to suggest that genetic data can be made or will remain anonymous.⁶

Second, genetic data may be put to uses that individuals find objectionable, even if the data is anonymized. An example of this is the case of the Havasupai Indians in Arizona. Researchers collected their genetic data to look for a genetic cause of high prevalence of diabetes in the tribe. They later used the data in population migration studies that challenged the tribe's founding mythology and in studies about inbreeding and mental illness. The tribe found these additional uses deeply offensive. Arizona State University scientists claimed that they were doing "good science" and that broad consent obtained at the time of sample collection permitting them to use the data in this way; the Havasupai claimed that had they known how the data would be used, they would have refused to provide it.⁷ In this case, it did not matter whether individual identity was tied to the data. The subject of the research was offensive. The Havasupai sued the university and won.

People who participate in wellness programs may not wish to support genetic research in various areas, such as abortion or eugenics, even if their genetic data is anonymized. They should not be required to choose between the possibility that their data will be used or sold for purposes they find objectionable and paying more for health insurance.

5. ***The Commission should reevaluate its proposal for apportioning of incentive between employee and spouse because the current proposal could lead to or exacerbate family tensions.*** As shown by the example in the Proposed Rule, there can be a larger incentive for spousal participation than for employee's participation because the cost of family coverage can be more than double the cost of employee-only coverage. If a spouse refused to take a Health Risk Assessment (HRA) or participate in a wellness program in general, the employee paying for the plan would pay a penalty larger than the one s/he would pay for his or her own refusal. This kind of apportionment is likely to cause problems in marriages that are already under strain or in cases where an employee provides health coverage to an estranged spouse. Even in cases where both employee and spouse receive equal incentives for activities related to a health factor and the remaining incentive is tied to participation, there can be tensions if a spouse is not interested in participating in the wellness program. The Commission should appoint an independent multidisciplinary panel of experts to examine whether incentives should be apportioned between spouses and if so, how this can be

⁶ Researchers can no longer guarantee anonymity of genomic data. See, for example, Erika Check Hayden, "The genome hacker: Yaniv Erlich shows how research participants can be identified from 'anonymous' DNA," *Nature*, May 8, 2013, available at <http://www.nature.com/news/privacy-protections-the-genome-hacker-1.12940>

⁷ Amy Harmon, "Indian Tribe Wins Fight To Limit Research of Its DNA," *The New York Times*, April 21, 2010, available at <http://www.nytimes.com/2010/04/22/us/22dna.html?pagewanted=all&r=0>.

accomplished in various circumstances without additional burden to employees and their families.

6. ***The Commission should clarify that the prohibition on inducement for children's health information extends to adult children between ages 18 and 26.*** It would not be surprising if some employers wanted to include in wellness programs adult children covered under an employee's family health plan. Since adult children can provide informed consent, the Commission should affirmatively prohibit employers from asking them for health history or genetic data because employees' genetic data can be derived from that of their biological children.
7. ***Privacy provisions within the Proposed Rule need to be significantly strengthened.*** Collection of genetic data poses significant privacy risks because it includes information about an individual and about the individual's family. When we talk about genetic testing, we need to talk about two components: the genetic profile or set of genetic test results, and biospecimens (e.g., blood, saliva or other cells) that contain genetic information.

Specifically,

- a. ***If wellness programs perform genetic testing, they should have policies and procedures that address disclosures of test results to family members of the tested individual.*** Genetic data can show physical characteristics and predispositions to disease for the person being tested as well as for that person's biological relatives. This raises privacy and ethical issues because the predictive power of genetic data touches not only the tested individual but others in the family.

Ethicists disagree whether there is an affirmative obligation to notify people or their families when genetic testing finds a predisposition to a disease. If a disease can be prevented or treated, family members could benefit from the knowledge. However, not everyone wants to know what their future might hold. Some people prefer not to know that they have a marker for a disease that they may never get, particularly if the disease has no treatment or cure. Genetic testing needs to be designed in a way that can provide information to family members who want to know the results while allowing others to exercise their "right not to know." Wellness programs that perform genetic testing should have policies and procedures addressing these issues, and should be required to explain these policies and procedures to individuals before performing genetic tests.
- b. ***If the Commission permits wellness programs to collect biospecimens for genetic analysis, it should require these specimens to be destroyed immediately after completion of testing.*** The preservation and retention of biospecimens present additional privacy concerns. Test labs that retain samples can re-analyze them not only to repeat the original tests, but for any other information contained in the samples. This can be

particularly tempting as genetic science advances, new links are found between genes and disease, and new testing methods become available. Medical ethicists debate whether additional analysis requires express consent. Some say that the benefits of new discoveries should outweigh individual control. Others point out that people are reluctant to have genetic testing precisely because they worry about additional uses of the specimens. Someone willing to have a test related to obesity may not be willing to allow the use of her biospecimen or genetic information for other purposes, even in de-identified form.

- c. ***Programs that perform genetic testing should provide notices to individuals with sufficient information to enable individuals to understand what data is collected as part of the program, whether or not it is collected directly from the individual, and all uses of that data.*** In addition to covering genetic data, notices should clearly describe all the sources of data collected and used by the program, including any data not collected directly from the individual. The notice should also disclose the use of public data and non-health consumer data. Notices should also describe the use of analytic algorithms in combining and analyzing the data.
- d. ***Individuals should have the right to request destruction of all their genetic data and any samples retained by the wellness program*** if they decide to stop participating in the program or leave their employer. De-identification of retained data or samples should not be permitted as an alternative.

8. Comments on specific questions raised by the Commission.

- The Commission asks if an acceptable alternative to inducements for spouses to provide information about past and present health status is provision of a physician statement that the spouse's medical risks are under active treatment. This approach might result in additional healthcare costs and in conflicts between employees, their spouses, and their physicians.⁸ Nevertheless, it might be an acceptable alternative for those who can find a physician who shares their view of health management. If offered, this alternative should be limited to a certification by a physician selected by the spouse. It should not require spouses or their physicians to provide the data that the wellness program would otherwise have collected.
- The Commission asks if authorization requirements should apply only to programs that offer more than *de minimis* inducements to spouses. Authorization requirements should apply to all wellness programs. As noted in my paper cited above, wellness programs now use techniques, such as gamification and social influencing that do not involve the use of financial incentives. These techniques induce, pressure, or manipulate individuals into participation in wellness programs and into providing data to these

⁸ See, for example, Matt Lamkin, "Healthcare Reform, Wellness Programs and the Erosion of Informed Consent," 101 Ky. L.J. 435 (2012-2013).

- programs. Authorization and all other privacy requirements should apply to all wellness programs, regardless of whether they offer financial incentives and regardless of size or type of such incentives.
- The Commission asks which best practices or procedural safeguards ensure that employer-sponsored wellness programs promote health or prevent disease and do not shift costs to employees with spouses who have health impairments or stigmatized conditions. As I noted above, wellness programs should be based on scientifically valid evidence demonstrating that the data they collect can actually diagnose or prevent a specific disease or condition. Second, wellness programs must address those diseases or conditions and base their recommendations on the collected data. The Rule should not allow programs to provide generic advice unrelated to the specific data collected and tests performed. Finally, wellness programs should have in place policies and procedures about the way they might generate, use or disclose data about stigmatizing conditions of the spouse or the employee or other members of the family.

I thank the Commission for the opportunity to provide these comments. I would be happy to discuss the comments or my research with Commission staff.

Respectfully submitted,

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