For reprint orders, please contact:
reprints@futuremedicine.com

Genetic nondiscrimination legislation: a critical prerequisite for pharmacogenomics data sharing

Russ B Altman[1†], Neal Benowitz[2], David Gurwitz[3], Jeantine Lunshof[4], Mary Relling[5], Jatinder Lamba[5], Eric Wieben[6], Sean Mooney[7], Kathleen Giacomini[2], Scott Weiss[8], Julie A Johnson[9], Howard McLeod[10], David Flockhart[7], Richard Weinshilboum[6], Alan R Shuldiner[11], Dan Roden[12], Ronald M Krauss[13] & Mark Ratain[14]

[†]Author for correspondence
[1]Stanford University, Department of Genetics and Bioengineering, Clark S172, Stanford, CA 94305-5444, USA
E-mail: Russ.Altman@stanford.edu
[2]University of California, San Francisco
[3]Tel-Aviv University
[4]VU University Medical Center
[5]St Jude Children's Research Hospital
[6]Mayo Clinic
[7]Indiana University School of Medicine
[8]Harvard Medical School
[9]University of Florida
[10]University of North Carolina
[11]University of Maryland
[12]Vanderbilt School of Medicine
[13]Children's Hospital Oakland Research Institute
[14]University of Chicago

On 31st January 2007, the US Senate Health, Education, Labor and Pensions Committee approved the Genetic Information Nondiscrimination Act (GINA) by a vote of 19:2. It was unanimously approved by the US Congress Committee on Education and Labor 2 weeks later. This legislation, aimed at preventing genetic discrimination in employment and insurance [1], will be imperative for protecting altruistic individuals who volunteer for genetic research [2]. There is an emerging consensus among researchers that genetic data must be accessible to individual research participants upon their request [3], while not putting them at risk with respect to their employment, insurance and additional personal aspects [4]. The GINA balances individual freedoms and privacy rights with societal needs for affordable and more effective healthcare and helps to pave the way for more personalized medicine [5]. Indeed, genetic information can be used to improve healthcare, in particular with regard to reducing the alarming rates of adverse drug reactions, which led to 6.7% of all US hospital admissions during 2004–2005 [6], consistent with earlier studies in the UK [7]. Increased use of individual genetic information about drug-metabolizing and drug-target gene alleles as part of healthcare treatment decisions may substantially reduce such morbidity [8]. However, building up the required knowledge depends on the analysis of large individual genotype/phenotype data sets from patient cohorts and requires open data sharing so that large, meaningful and less biased data sets are available to researchers [9]. Lack of open data sharing, in particular between the private and public sectors, hinders our ability to assemble large aggregated data sets [9]. A key obstacle for data sharing is concern about depositing data sets from individual study participants into public databases; some researchers fear they will be held responsible in cases where the data are re-identified (using computational data-mining techniques) and subsequently used (by employers or insurers) to discriminate against study participants. We therefore believe that legislation that offers protection to individuals or groups who share genetic information – against both re-identification and discrimination – is essential for efforts to move genomic medicine into practice. Legislation barring discrimination or stigmatization based on genetic information has been proposed for years, but enactment has become particularly urgent in view of rapidly falling genotyping costs [10], the scope of ongoing genome-wide association studies [11] and the increasing availability of comprehensive personal data in the public domain [4]. We therefore strongly support the current efforts to establish a solid legal framework as a primary means to protect individuals against misuse of their genetic information and as an essential tool for allowing open data sharing in pharmacogenomics.

Bibliography

1. GINA, aGAIN. *Nat Genet.* 39, 133 (2007).
2. Kohane IS, Altman RB: Health-information altruists – a potentially critical resource. *N. Engl. J. Med.* 353, 2074–2077 (2005).
3. Knoppers BM, Joly Y, Simard J, Durocher F: The emergence of an ethical duty to disclose genetic research results: international perspectives. *Eur. J. Hum. Genet.* 14, 1170–1178 (2006).
4. Lin Z, Owen AB, Altman RB: Genetics. Genomic research and human subject privacy. *Science* 305, 183 (2004).
5. Lunshof JE: Personalized medicine: how much can we afford? A bioethics perspective. *Personalized Med.* 2, 43–47 (2005).
6. Budnitz DS, Pollock DA, Weidenbach KN, Mendelsohn AB, Schroeder TJ, Annest JL: National surveillance of emergency department visits for outpatient adverse drug events. *JAMA* 296, 1858–1866 (2006).
7. Pirmohamed M, James S, Meakin S *et al.*: Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. *Br. Med. J.* 329, 15–19 (2004).
8. Collins FS, Green ED, Guttmacher AE, Guyer MS: US National Human Genome Research Institute: a vision for the future of genomics research. *Nature* 422, 835–847 (2003).
9. Gurwitz D, Lunshof JE, Altman RB: A call for the creation of personalized medicine databases. *Nat. Rev. Drug Discov.* 5, 23–26 (2006).
10. Service RF: Gene sequencing. The race for the $1000 genome. *Science* 311, 1544–1546 (2006).
11. Sladek R, Rocheleau G, Rung J *et al.*: A genome-wide association study identifies novel risk loci for Type 2 diabetes. *Nature* 445, 881–885 (2007).

future medicine part of fsg