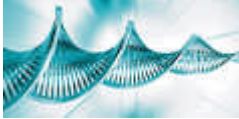


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## Global Life Sciences and Public Health Preparedness Report

May 28, 2008

### Genetic Information Nondiscrimination Act (GINA) Signed into Law: Key Milestone in Advancement of Personalized Medicine.

An important milestone in the advancement of personalized medicine was achieved on May 21, 2008 when President Bush signed into law the Genetic Information Nondiscrimination Act (GINA) of 2008. GINA is landmark legislation that will provide Federal protections against insurance and employment discrimination based on an individual's genetic information. The House voted 414-1 and the Senate 95-0. Many researchers and scientific leaders have supported GINA, believing that consumers' fear of misuse of genetic information has been an impediment to incorporating our increasing understanding of the human genome into health care practices.

The new law is intended to protect against genetic discrimination by:

- Prohibiting group health insurance plans and issuers offering coverage in group or individual markets from basing eligibility determinations or adjusting premiums or contributions on the basis of an individual's genetic information. Insurance companies cannot request, require or purchase the results of genetic tests, and they are prohibited from disclosing personal genetic information.
- Prohibiting issuers of Medigap policies from adjusting pricing or conditioning eligibility on the basis of genetic information. They cannot request, require, or purchase the results of genetic tests, or disclose genetic information.
- Prohibiting employers from firing, refusing to hire, or otherwise discriminating with respect to compensation, terms, conditions or privileges of employment. Employers may not request, require or purchase genetic information, and they are also prohibited from disclosing personal genetic information. Similar provisions apply to employment agencies and labor organizations.

More and more tests are being developed to identify genetic differences that affect our health, and these tests will likely become a routine part of health care in the future. There is the potential for health care providers to use information about each person's DNA to develop more individualized ways of detecting, treating and preventing disease. However, without protections on the use of this information, such information could be used to discriminate against people. The bill's lead sponsor in the House, Rep. Louise Slaughter (D-NY) stated, "Today marks the beginning of a new era in health care. Americans can finally take advantage of the tremendous potential of genetic research without the fear that their own genetic information will be used against them." Joann Baughman, PhD, Executive Vice President of the American Society of Human Genetics commented, "Once this legislation has taken effect, clinicians will

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be able to order genetic tests for patients and their families in a manner that ensures the full realization of the advantages of personalized medicine, while also easing patients' concerns about the risk of genetic discrimination by insurance companies and employers based on this data."

### **Personalized Medicine and Advances in Human Health**

Personalized medicine uses our advancing understanding of the human genome and molecular analysis to better understand and manage an individual's disease or predisposition toward a disease. It has the potential to enhance health outcomes by providing advanced tools and information for physicians and patients in disease management and prevention. For example, individualized screening can help lead to more precise diagnosis or disease, more effective selection and dosing of biopharmaceuticals, and better prediction of which individuals and sub-populations are at risk of disease, thereby allowing for earlier medical and non-medical interventions. Advanced understanding of the genetic basis of disease and enhanced use of biomarkers can also increase the effectiveness of the drug discovery process.

### **MLA's Life Sciences and Public Health Preparedness Practice**

McKenna Long & Aldridge LLP has further expanded our Life Sciences and Public Health Preparedness practice with the addition of the Personalized Medicine industry focus. Personalized medicine is poised to transform health care over the next several decades through innovative diagnostics, research tools, biomarkers, and targeted therapies. However, like many life science innovations, the path to progress involves a range of public policy issues and opportunities. The actions of the many government and non-government stakeholders in regulatory policies, reimbursement policies, provider and payer acceptance, and the development and implementation of sound incentives will affect the personalized medicine landscape. Opportunities will emerge to better target the delivery of medical interventions, rescue "failed" products on the shelves of pharmaceutical companies, and design clinical trials based on genetically relevant populations. Personalized medicine also creates an emerging market for the development and application of sophisticated, yet clinically meaningful diagnostic tools that will accompany these specialized therapeutics.

[1] Sharon Terry, "President Bush Signs Landmark Genetic Nondiscrimination Information Act into Law," Coalition for Genetic Fairness, 21 May 2008.

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