

This article first appeared in the August 11th issue of the *Indianapolis Business Journal*

Passage of Genetic Information Nondiscrimination Act Opens Door to DNA Age in Medicine

By Dave C. Bromund

The promise of personalized medicine - genetic tests that allow more informed and individualized health care decisions - has been blocked in recent times as patients struggle with the fear that those same genetic test results could bring genetic discrimination in the form of cancelled health insurance coverage or even the catastrophe of job loss.

In 1997, Indiana enacted a state law protecting genetic screening or testing and prohibiting health insurers from considering any information obtained from such testing in a manner adverse to the applicant. Adverse actions include cancelling, refusing to issue or renew health coverage. But, the law fails to protect Hoosiers uniformly outside of Indiana because not all states have a similar law.

In May 2008, Congress and the President leveled the playing field by enacting the Genetic Information Nondiscrimination Act of 2008 (GINA), which provides solid protections across the entire country for genetic privacy. GINA stops the improper use of genetic information in health insurance and employment. GINA prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future. GINA also bars employers from using individuals' genetic information when making hiring, firing, compensation and promotion decisions.

Like many other non-discrimination laws, an employee who believes that he or she has suffered genetic discrimination may file a charge with the federal Equal Employment Opportunity Commission (EEOC) and can litigate in federal court to recover damages, including back pay, front pay and other equitable relief. To manage that

risk, employers should take advantage of GINA's 18-month delayed effective date to prepare. Employers should look for the EEOC to publish detailed regulations implementing GINA in the coming months. Employers should review and update their policies and procedures to cover genetic discrimination and make certain that documents soliciting medical information from employees specifically exclude genetic information. Employers should consider GINA-focused training sessions to educate managers.

For individuals, GINA should reduce the fear of genetic discrimination in health coverage and employment. Importantly, GINA does not protect against genetic discrimination for life insurance coverage. So, individuals should review the adequacy of their life insurance needs and purchase additional coverage before undertaking genetic tests.

Prior to passage of GINA, treating physicians regularly warned patients of the economic risks associated with certain genetic tests. Many individuals would forgo testing entirely or order and pay for genetic test directly in an "underground" direct-to-consumer market to bypass disclosure to any third parties, including their own physician. With GINA's protections, that genetic information can be used legitimately for medical advances and personalized treatments without the threat of misuse.

GINA also may help life science scientists and companies working to discover and market diagnostic tests based on individual genetic information. Simply put, the era of personalized medicine, future scientific discoveries and preventative care can now be fully realized without fear of genetic discrimination. Geneticists should now have less trouble recruiting research participants whose discrimination fears are reduced. And, participants who have previously paid for tests with cash to avoid submitting insurance claims may find wider health plan coverage of genetic tests. As a result, the pace of discovery for life saving treatments and cures should increase.

Life science companies may develop new genetic tests that could help physicians better identify drugs most likely to work in their patients. While this may sharply reduce the market for so-called blockbuster drugs, there will be a better chance that those who

take the drug will have a positive outcome. Genentech used this strategy to great clinical success and financial reward with its breast cancer drug, Herceptin. Generally, a biomarker is a protein or chemical found in the bloodstream that acts as an indicator to assess if a patient has a possible disease or disorder. In the case of Herceptin, the particular biomarker identifies patients likely to benefit from this drug. Genentech has stated that it plans to use a biomarker test to help target the right patients for every future compound in its research program.

In a related governmental policy endorsement of personalized medicine, last month the Food and Drug Administration (FDA) advised physicians to use a genetic screening test before prescribing a drug widely used for HIV/ AIDS. FDA stated the screening test will protect patients with a particular variation in an immune system gene from a severe allergic reaction to GlaxoSmithKline's drug abacavir sold under the name Ziagen. FDA has previously recommended similar genetic screening tests for several other drugs such as the blood thinner warfarin.

Even health insurers should benefit from GINA and the long run promise of personalized medicine. For example, if a genetic test can reveal whether a patient's form of cancer will respond to an expensive, new biologic drug treatment regimen, the treatment can be tailored to the individual's genetic makeup and prescribed only for those individuals who can benefit. The cost of treatment for those who would not benefit could be avoided. Patients for whom the treatment will not work, can avoid the expense, uncertainty and risk of the current hit-or-miss series of drug treatments to find the right drug.

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