

“Good times, bad times, you know I’ve had my share...”

Led Zeppelin, 1969

The last two weeks of May 2008 will not soon be forgotten by the employees of the National Human Genome Research Institute (NHGRI) or the larger genetics community. In that brief interval we celebrated both the passage of the Genetic Information Nondiscrimination Act (GINA), and mourned the news of the impending departure of the only director the NHGRI has known – Francis Collins, M.D., Ph.D. As an observer might surmise, these landmark events were not independent, and only time will tell which will have a more lasting effect on the future of genomics in health care in the United States.

Passage of GINA on May 21, 2008 ushers in what Senator Kennedy called “...the first civil rights bill of the new century of the life sciences.” U.S. citizens are now afforded nation-wide protection from discrimination based on their genetic heritage. Specifically GINA prohibits discrimination in eligibility for or underwriting of health insurance and employment decisions based on an asymptomatic individual’s family history or genetic information. It covers all Americans save those in the military, and was crafted in response to the very real threat that employers and insurers might use genetic information to limit an individual’s future opportunities. Numerous studies have demonstrated that this threat prevented at-risk individuals from seeking needed genetic testing, and had a chilling effect on the willingness of individuals to participate in clinical research. In contrast to the protections GINA provides regarding health insurance and employment, the law does not prevent the use of genetic information in decisions regarding life, long term care or disability insurance. Importantly, GINA will not supplant stronger discrimination protections afforded by some states; rather it provides a floor of protection in all states. The rulemaking for the legislation – a process which determines how such legislation is operationalized – is now underway. Practically, the health insurance provisions will not take effect for 12 months from passage; the employment legislation will not take effect for 18 months. For more specifics on the legislation see the NHGRI’s website at www.genome.gov/24519851.

The passage of GINA marks the end of an epic 13 year struggle of many stakeholders, including the NHGRI, to ensure protections against genetic discrimination. A review of the tortuous path to passage provides an excellent lesson in just how problematic achieving a legislative fix to a health care system issue can be (see <http://www.genome.gov/11510239>). A version of GINA was first introduced in the 104th Congress in 1995, and over time has had marked levels of bi-partisan support, yet failed to achieve passage until this year. Well-funded and persistent opposition to the legislation came largely from employer groups, with some lesser degree of opposition from the health insurance industry. Those in opposition voiced concerns that the legislation would result in a bonanza for plaintiff attorneys pursuing wrongful termination suits and the like, and that the law could get in the way of standard medical practices. For several years, the legislation successfully made it through the Senate by a

wide margin, but failed to progress in the House for a vote. More recently, the legislation was passed 420-3 by the House, only to be blocked in the Senate for a year – and nearly forever - by a single Senator. Intense negotiation and effective leadership on this issue ultimately prevailed and a negotiated bill ultimately passed unanimously in the Senate and then by a 414-1 margin in the House, hardly reflective of the difficulty associated with getting passed both chambers. On May 21, 2008 the bill was signed into law by President George W. Bush who remarked “I want to thank the members of Congress who've joined us as I sign the Genetic Information Nondiscrimination Act, a piece of legislation which prohibits health insurers and employers from discriminating on the basis of genetic information. In other words, it protects our citizens from having genetic information misused, and this bill does so without undermining the basic premise of the insurance industry.”

Passage of GINA can be credited to extensive efforts by literally hundreds of scientists, patients, lawyers, health care providers, and legislators spanning a decade. However, Francis Collins’ reasoned arguments that the American public should not have the fruits of the Human Genome Project used against them were of singular importance. The accomplishment of the protections GINA affords serve as a testimony to the good one individual can create in a system that to many seems hopelessly mired in competing interests. Passage of GINA has provided the perfect bookend for Francis Collins’ 15 year tenure at NHGRI, as he was initially brought to the NIH to lead the Human Genome Project – the core activity on which the NHGRI was founded and which led to the need for protection from genetic discrimination. Over the intervening 15 years he has expertly presided over what is arguably the most remarkable period of biomedical discovery mankind has experienced – one that continues to evolve. The NHGRI, NIH, and Dr. Collins are each embarking on the next stages of discovery regarding genetics and genomics – stages that promise to significantly and irrevocably alter how we view health, illness, and the human condition.