

## **Genomics and Personalized Medicine Act (S.976)**

### **Senator Obama's Introductory Remarks**

**March 23, 2007**

Mr. President, I rise today joined by my colleague Senator Richard Burr, to reintroduce the Genomics and Personalized Medicine Act of 2007. This bill will expand and accelerate scientific advancement in the field of genomics, which is already beginning to change the paradigm of medical practice as we know it, and has profound implications for health and health care in this nation.

The “miracles of medicine” have been demonstrated since early man. Many of the traditional medicines used today, such as aspirin and morphine, are derivatives of plants ancient people used to treat illnesses and injuries centuries ago. Since those ancient times, our knowledge of medicine and disease has expanded tremendously. Today, modern breakthroughs in the fields of genetics and genomics have uncovered another layer of complexity in the way we treat and prevent disease.

Over the past decade, we have unlocked many of the mysteries about DNA and RNA, their structure, and how their code is translated into the proteins that make up the tissues and organs of the human body. Researchers have also made discoveries about the various functions of DNA such as replication, genetic recombination and regulation, just to name a few, and have developed the necessary technologies to do all of this work.

This knowledge isn't just sitting in books on the shelf nor is it confined to the work benches of laboratories. We have used these research findings to pinpoint the causes of many diseases, such as sickle cell anemia, cystic fibrosis, and chronic myelogenous leukemia. Moreover, scientists have translated this genetic knowledge into several treatments and therapies prompting a bridge between the laboratory bench and the patient's bedside.

We've made so many achievements and come a long way in our understanding and application of genetics knowledge. And yet, we are just beginning to realize the full potential of this science to predict the onset of disease, diagnose earlier, and develop therapies that can treat or cure Americans from so many afflictions.

Just 4 years ago, scientists at the National Institutes of Health and the Department of Energy reached another major landmark, with the completion of the sequencing of the entire human genome, our genetic blueprint described by many as the Holy Grail of biology and hailed as one of the greatest scientific achievements to date.

The completion of the Human Genome Project has paved the way for a more sophisticated understanding of disease causation. The HGP has expanded focus from the science of genetics, which refers to the study of single genes, to include genomics, which describes the study of all the genes in an individual, as well as the interactions of those

genes with each other. The role environmental factors play in promoting disease and the potential influence they have at the genetic level is also an area of interest.

We know that all human beings are 99.9 percent identical in genetic makeup, but differences in the remaining 0.1 percent hold important clues about the causes of disease and response to drugs. Simply put, the study of genomics will help us learn why some people get sick and others do not, and use this information to better prevent and treat disease.

The relatively new field of genomics is key to the practice of personalized medicine. Personalized medicine is the use of genomic and molecular data to better target the delivery of health care, facilitate the discovery and clinical testing of new products, and help determine a patient's predisposition to a particular disease or condition. Personalized medicine represents a revolutionary and exciting change in the fundamental approach and practice of medicine

Pharmacogenomics, or the study of how genes affect a person's response to drugs, is a critical component of personalized medicine. Currently, so-called blockbuster drugs are typically effective in only 40 to 60 percent of patients who take them. Other studies have found that up to 15 percent of hospitalized patients experience a serious adverse drug reaction, causing an estimated 100,000 deaths each year. Pharmacogenomics has the potential to dramatically increase the effectiveness and safety of drugs, both of which are major health care concerns.

We have a growing number of examples of how pharmacogenomics research has helped to save lives. For example, the chemotherapy Purinethol is a lifesaver for kids with leukemia, but in some cases, patients suffer severe, sometimes fatal, side effects. In the 1990's, researchers identified the gene variant that prevents affected patients from properly breaking down Purinethol, allowing doctors to screen patients and adjust dosages for safer use of the drug.

Herceptin, another example, is a breast cancer drug that initially failed in clinical trials. However, researchers discovered that 1 in 4 breast cancers have too many copies of a certain gene, which helps cells grow, divide and repair themselves. Extra copies of this gene cause uncontrolled and rapid growth resulting in tumor formation. As it turns out, Herceptin is an effective drug for patients with this type of cancer, with significantly improved survival for affected women. Herceptin offers a clear illustration of the power of personalized medicine and highlights the importance of incorporating genetic analysis in the development and application of new therapies.

Realizing the promise of personalized medicine will require continued Federal leadership and agency collaboration; expansion and acceleration of genomics research; a capable genomics workforce; incentives to encourage development of genomic tests and therapies; and greater attention to the quality of genetic tests, direct-to-consumer advertising and use of personal genomic information.

The Genomics and Personalized Medicine Act of 2007 will address many of these issues. The bill requires the Secretary of the Department of Health and Human Services to establish the Genomics and Personalized Medicine Interagency Working Group to expand and accelerate genomics research through enhanced communication, collaboration and integration of relevant activities.

Genetic and genomics research will be expanded, to increase the collection of data that will advance both fields, through the support of the biobanking initiative aimed at increasing and improving genomic screening tools, diagnostics and therapeutics. The Secretary will also establish a national distributed database so data finding can be shared.

This bill requests that the Secretary support efforts to improve the adequacy of genetics and genomics training through modernized curricula and review of relevant certifications, and by identifying alternative education options such as distance or on-line learning programs. In addition, the Secretary will promote initiatives to increase the integration of genetics and genomics into all aspects of medical and public health practice, with specific focus on training and guideline development for providers without expertise or experience in the field of genomics.

This bill also requests the National Academies of Science to formally study the development of companion diagnostic tests and to provide expert guidance about the level of incentives and potential approaches to really move this area forward.

Last but not least, the bill focuses on the safety, efficacy and availability of information about genetic tests, including pharmacogenetic and pharmacogenomics tests. The Secretary will contract with the Institute of Medicine to conduct a study and make recommendations regarding Federal oversight and regulation of genetic tests. After this study is complete, the Secretary will develop a decision matrix to help determine which types of tests require review and the level of review needed for such tests as well as the responsible agency. The Secretary will also establish a specialty area for molecular and biochemical genetics tests at CMS and direct a review by the CDC of direct-to-consumer marketing practices.

In conclusion, we stand at this new and expansive frontier of personalized medicine we must explore and test the hypotheses and innovations in the area of genomics that can protect and promote our health. Genomics holds unparalleled promise for public health and for medicine, and the Genomics and Personalized Medicine Act of 2007 will help us to fulfill this promise. I urge my colleagues to support me in passing this critical legislation.