



UNITED STATES SENATOR • ILLINOIS

**BARACK OBAMA**



## **The Genomics and Personalized Medicine Act of 2006**

*Opening the Door to the Next Generation of Medicine*

Genomics has the potential to revolutionize the practice of medicine, but despite significant scientific advances, very few genomics-based tests or treatments have reached consumers. Senator Obama introduced the Genomics and Personalized Medicine Act to overcome the scientific barriers, adverse market pressures, and regulatory obstacles that have stood in the way of better medicine.

### **Genomics and Personalized Medicine**

Scientists are only beginning to understand how our genetic makeup affects our propensity for disease or how we will respond to medicine. Today, the typical “blockbuster” drug is effective in only 40 to 60 percent of patients prescribed them. Meanwhile, serious adverse drug reactions impact 2.2 million people and kill an estimated 100,000 a year in this country.

Genomics could eventually help predict which Americans will get sick, diagnose illness earlier, and screen patients to determine which drugs will be effective and safe. Doctors may eventually apply this science to personalize drug treatment to an individual patient’s genetic makeup significantly improving health care outcomes and quality. Drug manufacturers, meanwhile, will be able to better anticipate which new medicines will work, speeding up drug discovery.

### **Examples of Genomic Medicine**

The chemotherapy Purinethol is a lifesaver for kids with leukemia, but in 11 percent of 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 is a blockbuster breast cancer drug that initially failed in clinical trials. However, researchers later discovered that a genetic difference present in some breast cancers made the drug very effective in up to 30 percent of cases. Today, doctors combine a genetic test with Herceptin, with significantly improved survival for women with this type of cancer. Similar research advances have improved dosing of blood thinners like coumadin and have sped the development of leukemia drugs like Gleevec.

### **Potential Unrealized**

In 1984, as scientists were beginning to identify gene variants associated with diseases, an official at the American Cancer Society predicted, "This is the biggest single breakthrough in cancer research of all time." In 2001, as Dr. Francis Collins, the head of the Human Genome Project, raced to decode our DNA, he said, “Genomic medicine holds the ultimate promise of revolutionizing the diagnosis and treatment of many illnesses.” Years later, the genomics revolution in medicine has not yet happened. Relatively few drugs or tests based on genomics research have reached the market.

### **Hurdles to New Drugs**

There are numerous scientific hurdles to innovation. Humans have tens of thousands of genes that interact in extremely complex ways. It is both expensive and time consuming to identify and understand these interactions, and how they help cause disease and affect drug response. Drug trials have only begun to keep track of patient genetic information, and biobanks – the databases that link genetic data with medical outcomes – are split up among many academic centers and drug companies.

There are market pressures that may impede progress as well. Identifying which patients will respond favorably to drugs potentially means that fewer patients will utilize these drugs. While enabling the development of new and better-tailored drugs, personalized medicine may limit the market share of blockbuster drugs.

Finally, outdated government regulations have also been a factor. The Food and Drug Administration (FDA) only set up a system for evaluating genomic drug products last year. Pairing diagnostic test and drug development can complicate and slow drug approval. While some genetic tests face minimal regulatory requirements by the Centers for Medicare & Medicaid Services (CMS), others have to clear the FDA regulatory approval process, at great time and financial expense.

### **The Genomics and Personalized Medicine Act of 2006**

#### **Sponsoring Research**

The bill sets aside \$150 million to sponsor research on genomics. It enables a national biobanking initiative and sets up a system to pool and synthesize genomic data from local sources. This act establishes an interagency task force to accelerate the translation of research into medical practice. Finally, the legislation invests in the next generation genomics workforce by encouraging the recruitment and retention of genomic professionals, and promotes the integration of genomics across all clinical and public health disciplines.

#### **Encouraging Innovation**

The legislation provides a 100 percent tax credit for the development of companion diagnostic tests that can improve the effectiveness or safety of certain drugs. In addition, the National Academies will conduct a study to determine what additional incentives are needed, and how they should be structured.

#### **Modernizing the FDA and CMS**

The bill requires that FDA and CMS study and update regulatory processes to assure the quality of genomic tests through improved oversight and regulation.

#### **Protecting Consumers**

The legislation protects consumers by reaffirming Congress' commitment to stopping genetic discrimination and protecting genetic privacy. In addition, direct-to-consumer marketing of genetic tests would receive greater scrutiny and regulation.