

August 22, 2006

Senator Obama introduces Genomics and Personalized Medicine Act of 2006

by Mollie Roth

On August 4, 2006, Senator Barack Obama (D-IL), the junior senator from Illinois, introduced a bill entitled the “Genomics and Personalized Medicine Act of 2006” (S.3822), the stated purpose of which is to “improve access to and appropriate utilization of valid, reliable, and accurate molecular genetic tests by all populations, thus helping to secure the promise of personalized medicine for all Americans.” This legislation has the potential to provide significant incentives to the industry to expand and accelerate pharmacogenomic research efforts, with the intent of speeding up the approval process for new drugs and providing additional companion diagnostic tests. In addition, the creation of a national biobank of genetic information will give more researchers access to a broader array of genetic data, which could break the bottleneck for new innovations. Finally, this legislation may force current industry players into new and unexpected alliances, thereby reshaping the process in which pharmacogenomic products are brought to market.

Background of pharmacogenomics

With the successful sequencing of the human genome in 2003, a new era of genetic-based research into the cause and effect of different disease states arrived. One of the most important concepts to result from that event was pharmacogenomics, or the study of how genes affect the way individuals respond to drugs. This technique uses markers in individual patients’ genetic codes to pinpoint a patient’s susceptibility to a disease, measure an individual patient’s ability to metabolize drugs, and identify those individuals who may suffer an adverse reaction from the use of a drug. Pharmacogenomics, often referred to as personalized medicine, is poised to revolutionize how medicine is practiced. No longer will medicine focus, as it has historically, on symptomatic disease management and empirical drug-prescribing regimens; it will move forward to a new era of individualized medicine. In this new world, pre-symptomatic disease management will become the new standard — it will be possible to measure an individual’s susceptibility to different diseases, provide prescription drug regimens tailored to an individual’s specific genetic make-up, and altogether avoid prescribing drugs likely to cause an adverse reaction.



NIXON PEABODY LLP
ATTORNEYS AT LAW

In the United States, it is currently estimated that 50 percent of individuals fail to respond to drug therapies as initially prescribed. Further, adverse drug reactions (ADRs) are responsible for approximately 100,000 drug-related deaths and 2.2 million hospitalizations per year, representing a cost of roughly \$100 billion.

Pharmacogenomic discoveries have the potential to speed up the drug approval process by stratifying the patient population necessary to conduct clinical trials, and to reduce ADRs by identifying individuals likely to experience them before a drug is prescribed.

In addition, pharmacogenomics shows great promise in identifying individual patients' abilities to metabolize a drug, which would eliminate potentially fatal overdosing and ineffective underdosing, thereby increasing patient response rates to drug therapies.

The significance of the bill

Senator Obama's bill recognizes the enormous potential of pharmacogenomics 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." Ultimately, this would "increase the efficacy and safety of drugs and reduce healthcare costs." The potential for pharmacogenomics to develop more effective, safer medications and dosing regimens for individual patients, as well as to speed up the drug approval process, will lower health-care costs and potentially provide new life for drugs previously removed from the market.

The five sections of the bill address the "Establishment of a Genomics and Personalized Medicine Interagency Working Group," "Expansion and Acceleration of Genetic and Genomics Research," "Genomics Workforce and Training," "Realizing the Potential of Personalized Medicine," and "Sense of the Senate Regarding Genetic Non-Discrimination and Privacy."

I. Genomics and Personalized Medicine Interagency Working Group

This bill provides for the establishment of a Genomics and Personalized Medicine Interagency Working Group ("IWG") within the Department of Health and Human Services, to expand and accelerate genomics research by enhancing communication about current and proposed research; and identifying areas of need and opportunity and facilitating collaboration, coordination, and integration of activities within federal agencies and among their public and private partners. The purpose of the IWG, with an initial federal appropriation of \$5 million, would be to translate the findings from genetic and genomic research into clinical and public health applications, and to provide a biennial report to Congress and the public on its progress. The IWG would include members from more than 10 government agencies, including the NIH, CDC, and FDA, as well as individuals from the Office of Minority Health, Centers for Medicare & Medicaid Services, Veterans Health Administration, and Department of Energy.

II. Expansion and Acceleration of Genetic and Genomics Research

This title provides for the expansion and acceleration of genetic and genomic research to advance the field of personalized medicine, with a prioritized focus on those conditions with substantial public health impact, population-based studies,

comprehensive studies of clinical utility, and methods to enhance use and provision of such diagnostics.

One of the most important provisions of this section is the creation of a national Biobanking Research Initiative (“BRI”), which would support the collection of evidence and ensure diverse representation of individuals in data collection, to allow statistically significant analyses of population subgroups. Pursuant to this goal, a national biobank would be created to serve as a repository for the integration of genomic data to facilitate the pooled analysis and synthesis of such data. Such a biobank, already established in several other countries, would contain extensive DNA samples available to researchers throughout the United States, thereby allowing for retroactive studies to determine genetic markers responsible for specific disease states. To date, this shortage of research materials may well have been a limiting factor in the further development of pharmacogenomic products.

Under the BRI, a grant program would also be established for creating local or regional biobanking initiatives that would assist in the development of uniform standards and guidelines for the collection, submission, and storage of such data and policies to safeguard the privacy of such information, and would address issues in ownership of genomic samples. These initiatives would also determine appropriate procedures for industry access to biobank data and the submission of data generated from such samples to the FDA as part of the drug- and device-approval process. A second grant program directed at eligible institutions would seek to develop or expand biobanking initiatives to further “advance the application of genomics to the practice of medicine and to increase the understanding of the genetic causes of disease.”

An area of great potential conflict with respect to pharmacogenomics are issues of race and ethnicity, and the need to ensure that access to these technologies is provided to all Americans and that new devices are not abandoned because they are only applicable to a smaller, ethnic cohort. To that end, this section also seeks to expand and intensify efforts to increase knowledge about the interaction between genetics and the environment, and the impact of that interaction on the treatment of diseases common in racial and ethnic minorities.

III. Genomics Workforce and Training

This section recognizes the immense strides taken in this new field of science and the fact that genomic education for health-care providers has, in many instances, lagged behind current knowledge. To rectify that situation, this title provides for technical and financial support, with an initial federal appropriation of \$10 million, designed to improve the quality of genomic training for health-care professionals; support and increase efforts to recruit and retain diverse health professionals in the genomics workforce; and develop a plan to incorporate genomic training into the health profession.

IV. Realizing the Potential of Personalized Medicine

This section provides a tax credit to eligible taxpayers for qualified research expenses incurred in the development of qualified companion diagnostic tests designed to provide

information useful for increasing the safety or effectiveness of a drug. Eligible taxpayers include anyone requested to develop a qualified companion diagnostic test in connection with a drug for which an application has been submitted under §501(b)(1) of the Federal Food, Drug, and Cosmetic Act.

The question of the optimal business model to take advantage of this new science has been an area of intense speculation and discussion amongst the pharmaceutical companies, biotechs, pharmacy benefit managers, venture capitalists, and consulting firms. Initiatives and mandates under this title may well create the types of new alliances the players have contemplated, as well as new ones not yet considered. The National Research Council of the National Academy of Sciences, through \$10 million in federal appropriations, will undertake a study to recommend incentives to encourage 1) *co-development* of companion diagnostic tests by drug sponsors, 2) development of companion diagnostics for already-approved drugs by the drug sponsor, and 3) development of companion diagnostics by device companies *not affiliated with* the drug sponsor. Further, the Secretary of Health and Human services has been empowered to *require* 1) the *co-development* of a companion diagnostic test by the drug sponsor, after the filing an investigational new drug application (INDA) or a new drug application (NDA), to address safety concerns; 2) the development of a companion diagnostic if Phase IV (post-marketing) data demonstrate significant concerns regarding safety or efficacy; and 3) re-labeling the drug to require a validated companion diagnostic when evidence of improved outcomes has been established in practice or with respect to significant safety concerns.

To improve federal oversight and regulation of genetic tests, this section also provides for the creation of a “decision matrix” that would determine 1) how best to classify genetic tests, 2) which types of tests need review and the appropriate level of such review, and 3) which agency should have oversight over such tests deemed to require review.

Two additional aspects of this section may have the potential to increase products liability litigation relating to pharmacogenomics and potentially undercut a key defense: the learned intermediary defense, which states that the fault lies not with the pharmaceutical manufacturer but with ineffective information provided by the learned intermediary, or physician. A requirement that the Food and Drug Administration (“FDA”) develop or expand ADR reporting systems to include any reports arising from use of companion diagnostics may well give rise to increased litigation pertaining to such adverse effects. Further, funding provided under this title for expanded efforts to educate the public about pharmacogenomics, with additional research to be conducted by the Centers for Disease Control (“CDC”) to assess the impact of direct-to-consumer (“DTC”) marketing for genetic diagnostic tests, may well lead to a weakening of the learned intermediary defense if courts find, as a few have with respect to DTC marketing in the traditional pharmaceutical market, that such advertisements obviate the role of the learned intermediary.

V. Sense of the Senate Regarding Genetic Non-Discrimination and Privacy

This section addresses the privacy issues inherent in this area of research, including the need for protections against genetic discrimination, for pharmacogenomics to achieve success in reducing health-care costs.

We welcome your questions and comments. For more information, please contact

Joseph Leghorn	<u>jleghorn@nixonpeabody.com</u>	617-345-1114
Vivian Quinn	<u>vquinn@nixonpeabody.com</u>	716-853-8134
Samuel Goldblatt	<u>sgoldblatt@nixonpeabody.com</u>	716-853-8121
Fred Kelly	<u>fkelly@nixonpeabody.com</u>	617-345-1319
Joseph Ortego	<u>jortego@nixonpeabody.com</u>	516-832-7564
Mollie Roth	<u>mroth@nixonpeabody.com</u>	617-345-1141
J. Christopher Allen, Jr.	<u>callen@nixonpeabody.com</u>	617-345-1261
Benjamin Dwyer	<u>bdwyer@nixonpeabody.com</u>	716-853-8122
Tracey Ehlers	<u>tehlers@nixonpeabody.com</u>	716-853-8125
Elizabeth Brophy	<u>ebrophy@nixonpeabody.com</u>	716-848-8207
Tavares Brewington	<u>tbrewington@nixonpeabody.com</u>	617-345-6171