

July 30, 2007

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The Honorable Barack Obama  
United States Senate  
Senate Hart Office Building  
Suite 713  
Washington, DC 20510

Dear Senator Obama:

The Personalized Medicine Coalition (PMC) recognizes your leadership and applauds your efforts to advance personalized medicine. We support the purpose of S. 976, the *Genomics and Personalized Medicine Act of 2007* (GPMA), believe it can be improved, and look forward to working with you to create a more accommodating landscape for personalized medicine.

The PMC represents academic, industrial, patient, provider, and payer communities and seeks to advance the understanding and adoption of personalized medicine products for the benefit of patients. As we know, personalized medicine—tailoring medical care to fit the genomic and molecular profile of an individual—represents an innovative new paradigm that promises better health care delivered at potentially lower systemic costs and requires changing traditional health care infrastructure, including its business models, reimbursement policies, and regulatory oversight. GPMA clearly demonstrates how public policy can promote a new era in medicine and healthcare delivery.

Interagency Working Group. The PMC supports Section Four of GPMA which creates the Genomics and Personalized Medicine Interagency Working Group (IWC), whose goal it is to coordinate interagency efforts to promote personalized medicine. The PMC's *Personalized Medicine Landscape Analysis* found that many proponents of personalized medicine believe that HHS could benefit from such coordination. The IWG would therefore be a timely and useful addition to the Department of Health and Human Services and HHS may further benefit by designating a national coordinator for personalized health care.

Biobanking. Section Five of GPMA, the National Biobanking Initiative, seeks to advance the field of genomics and personalized medicine by establishing a biobanking database. We agree that biobanking will facilitate the advancement of personalized medicine by giving researchers the necessary tools to develop the underlying science, and therefore, advocate the highest possible funding for this section.

Education. We applaud and strongly support Section Six of GPMA, entitled *Genomics Workforce and Training*, which aims to improve genetics and genomics training for medical professionals by directing the Secretary of Health and Human Services to collaborate with medical professional societies and accreditation bodies to integrate genetics and genomics into all aspects of clinical and public health practice. The PMC recognizes the need for a workforce that is better educated in these areas and is developing a privately-funded personalized medicine continuing education curriculum. Because an educated workforce is so critical, the PMC supports increasing the proposed funding level for Section Six.

Incentives. Section Seven of GPMA authorizes a National Academy of Sciences Study designed to recommend business incentives to “encourage co-development of companion diagnostic testing by a drug sponsor; development of companion diagnostic testing for already-approved drugs by a drug sponsor; and companion diagnostic test development by device companies that are not affiliated with the drug sponsor.” We need thoughtful business models to hasten the adoption of personalized medicine.

We are, as you know, developing a list of public policy incentives for personalized medicine that, we believe, will accelerate the adoption of personalized medicine. They include:

- reimbursement for development costs for combination diagnostic-drug products;
- designating federal funds for the development of companion diagnostics;
- an abbreviated, accelerated, or separate FDA approval process for companion products; and
- accelerated evaluation for acceptance of personalized medicine products to the General Service Administration.

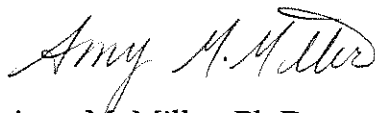
We welcome the opportunity to discuss these with you, and also to contribute to the National Academy of Sciences study.

Reimbursement. Personalized medicine is an emerging paradigm dependent on innovative diagnostic tools. Current coding and payment systems for *in vitro* diagnostics inadequately reflect the technological, clinical, and health economic impact of novel tests. Molecular tests, those that assess changes at the DNA, RNA and protein levels, unlike many other, more conventional diagnostics, typically require the services of a highly specialized laboratory specialist, and often a clinical geneticist, or a genetic counselor. PMC supports the development and implementation of a value-based payment system for diagnostics that better recognizes the actual costs of development and performance of these tests as well as the clinical and economic benefits of improved patient outcomes. With fair and value-based reimbursement, they are more likely to be developed and commercialized.

Funding. We believe that investments in personalized medicine are investments in the future of health care. Those investments will provide payers and patients with improved health outcomes and promote efficiency. Therefore we urge adequate appropriations for GPMA.

The PMC supports government policy that will help accelerate the rapid advances in science and technology underlining personalized medicine, and aligns the interests of sometimes competing stakeholders. To that end, we look forward to working with you to improve and enact S. 976, the Genomics and Personalized Medicine Act of 2007.

Sincerely yours,



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