

*Executive Director*

**Edward Abrahams, Ph.D.**

*President & Chairman*

**Wayne A. Rosenkrans, Jr., Ph.D.**  
AstraZeneca Pharmaceuticals

*Vice Chair*

**Mara G. Aspinall**  
Genzyme Corporation

*Treasurer*

**Brett J. Davis**  
IBM Corporation

*Secretary*

**Patrick Terry**  
Genomic Health, Inc.

*Past President & Chair*

**J. Brian Munroe**

*Board of Directors*

**Joanne Armstrong, M.D., M.P.H.**  
Actna

**Randy Burkholder**  
PhRMA

**Geoffrey S. Ginsburg, M.D., Ph.D.**  
Center for Genomic Medicine  
Institute for Genome Sciences & Policy  
Duke University

**Paul Landauer**  
Abbott Molecular Inc.

**Joseph D. McInerney, MA, MS**  
NCHPEG

**Gualberto Rúaño, M.D., Ph.D.**  
Genomas, Inc..

**Nancy Simonian, M.D.**  
Millennium Pharmaceuticals, Inc.

**Denny Van Liew**  
Pfizer Inc.

**Robert Wells**  
Affymetrix, Inc.

**Phyllis Whiteley, Ph.D.**  
Perlegen Sciences, Inc.

November 16, 2007

Senator Max Baucus  
Chair  
Senate Finance Committee  
Hart Senate Office Building  
SH-511  
Washington DC 20510

Dear Senator Baucus,

The Personalized Medicine Coalition (PMC) is writing in regards to proposed legislation to expand the government's role in comparative effectiveness research (CER). The PMC, representing a broad spectrum of academic, industrial, patient, provider and payer communities, seeks to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients. The emerging science of personalized medicine holds great potential to improve the quality and value of care received by patients.

PMC strongly supports efforts to expand the evidence base for health care decision-making. At the same time, we urge you to ensure that legislation expanding the government's role in comparative effectiveness research supports, rather than impedes, the implementation of personalized medicine in health care, that is the tailoring of medical care to the individual based on genomic, molecular, and other clinical information.

During our recent conference entitled *21<sup>st</sup> Century Medicine, Personalized and Evidence-based* we found that stakeholders agree that for government CER programs to support the emergence of personalized medicine, legislation should include the following principles:

- Broad stakeholder representation, including those with expertise in personalized medicine, from the public and private sectors, and opportunities for input during key stages of project development, such as priority setting, definition of research questions, and results communication.
- Open and transparent development of policies and strategies through processes that encourage a shared vision and promote public trust.
- Payment and coverage policies that reflect the emergence of personalized health care by encouraging physicians and patients to choose the optimal approaches to preventing, diagnosing, and treating disease for that individual.
- The scope of CER analysis should include evaluation of approaches to health care delivery and care management that foster effective application of personalized health care, including health information technology.
- Proposals for government CER should ensure that research and the communication of research results account for different patterns of responses attributable to genetic and other factors and explain risk-benefit trade-offs.



Personalized medicine holds great potential to improve quality and value in health care by empowering patients and physicians with information to make optimal treatment choices. Yet personalized medicine requires personalized evidence. PMC believes one of the biggest challenges in comparative effectiveness research is translating this into policy. Traditional CER research and analysis usually reflects a “one size fits all” mindset (e.g. what is the best treatment or service for a broad population). Factors that are unique to a subset of individuals are very important to patients, but often are ignored or minimized in the way results of CER are communicated. Policy-makers should support CER approaches that recognize and communicate differences in response based on genetic variation and other individualizing factors to support adoption of clinically beneficial personalized medicine technologies.

PMC also believes that to support the timely, appropriate adoption of high-value personalized medicine technologies, proposals to expand government CER must place equal weight on the range of medical interventions and the broader health system factors affecting the use of these interventions. The scope of CER proposals must focus on the totality of the healthcare delivery system, including approaches to care management, delivery, and benefit design, to empower clinicians and patients to make more appropriate decisions that support personalized, evidence-based care giving. Research also should be encouraged to identify policies that support or discourage personalized therapy.

In advance of the conference mentioned earlier, we commissioned an issues brief on personalizing the evidence base. Please find it enclosed along with our membership list. We hope that the issues brief better illustrates the promises and challenges of personalized medicine and CER.

Thank you for your consideration this subject and we would appreciate the opportunity to discuss this further and answer any questions that you may have as you consider this important issue. If you have any questions regarding these comments, please contact me or Dr. Amy Miller, Public Policy Director, (202) 589-1770, [AMiller@PersonalizedMedicineCoalition.org](mailto:AMiller@PersonalizedMedicineCoalition.org).

Sincerely,

A handwritten signature in black ink that reads 'Edward Abrahams'.

Edward Abrahams  
Executive Director

Enclosures