

## **PMC Comments: Secretary's Advisory Committee on Genetics, Health and Society Draft Report on Pharmacogenomics**

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Dear Dr. Tuckson,

The following comments are submitted on behalf of the Personalized Medicine Coalition (PMC). The PMC represents a broad spectrum of academic, industrial, patient, provider, and payer communities that seek to advance the understanding and adoption of personalized medicine concepts and products for the benefit of patients. We thank the Advisory Committee for the opportunity to actively engage in this process, and applaud its work in this arena.

We congratulate the Advisory Committee for drafting this thoughtful review of important issues in the future of health care related to the emergence of pharmacogenomics. A few specific comments follow.

*Public Education.* We agree with the Advisory Committee that the public needs to be educated and, as noted in the report, the PMC is dedicated to public education on all topics related to personalized medicine including PGx. The PMC currently is writing a proposal for the development of a national model for a medical education program in pharmacogenomics.

*Resources.* As the field develops, federal entities responsible for advancing PGx should be funded appropriately. The report highlights the importance of basic and translational PGx research programs at the National Institutes of Health (NIH). PMC supports full-funding of the NIH and encourages the NIH to increase its efforts in understanding the genetic basis of disease. The Critical Path Initiative also facilitates co-development of Dx/PGx products. PMC strongly endorses greater funding of the Critical Path Initiative, which has enormous potential to improve health care in the future.

*Reimbursement.* As the report clearly outlines, federal payers have a leading role in the adoption of PGx as the largest single health care payer in the United States. Third party coverage and reimbursement are essential to ensure appropriate access to personalized medicine products and services, and payer coverage and payment decisions should make use of the best available evidence. In situations where payers seek additional evidence, they should work collaboratively with innovators to ensure that evidence requirements are appropriate and do not create barriers to patient access to new personalized medicine technologies. In addition, we recommend that the report be broadened to suggest coverage and adequate reimbursement of the costs of the relevant pharmaceutical and the validated diagnostic test as well.

The report suggests that adding prevention, as a Medicare benefit category would expand payer coverage and PMC supports the development of new policies and legislation to expand payer coverage and reimbursement of PGx and services focused on disease prevention.

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*Health Information Technology (HIT).* The PMC strongly supports the creation of a national health information network that enables the interoperable exchange of electronic health records securely among stakeholders in the healthcare system. Such a system will improve health outcomes and increase efficiency in health care research. As the report notes, widespread adoption of electronic health records will empower patients and physicians with the information they need to make optimal treatment decisions. PMC suggests that as the infrastructure develops, it should take into account the unique needs of the basic, clinical, and translational research communities. Providing the research community with secure, consented clinical outcomes information will enable HIT to accelerate new personalized medicine breakthroughs into practice.

*Collaboration.* PMC appreciates the Committee's recognition of the importance of public-private collaborations to advance the field of pharmacogenomics, and the recognition of the role the PMC can play in advancing the field. We suggest that the report be revised to recognize some of the recent collaborations that have been established, such as the FDA/C-Path Institute Predictive Tox and Molecular Assays and Targeted Therapeutics consortia. These and other initiatives are directly using large-scale electronic health records to identify putative biomarkers for genomic analysis including the C-Path Institute/University of Utah/Intermountain Healthcare cardiovascular safety project.

In addition, the Foundation for the National Institutes of Health (FNIH), the FDA, the NIH, and the Pharmaceutical Research and Manufacturers of America (PhRMA) recently announced the launch of The Biomarkers Consortium, a public/private research partnership. The consortium will discover, develop, and qualify new biological markers to support new drug development, preventative medicine, and medical diagnostics. Results from consortium projects will be broadly available to researchers worldwide.

We hope that as policy develops, the PMC will become a partner in the process of integrating the promise of pharmacogenomics into healthcare. The PMC has the power to convene stakeholders who can speak to these issues in a clear and constructive way. We hope also to help produce sound policy that addresses the needs of patients, providers, manufactures of both pharmaceuticals and diagnostics, as well as the federal agencies that oversee them.

Thank you for your consideration.

Respectfully submitted,



Amy M. Miller, Ph.D.  
Public Policy Director