

March 21, 2007

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The Honorable Michael O. Leavitt  
Secretary of Health and Human Services  
U.S. Department of Health and Human Services  
Hubert Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Leavitt:

We deeply appreciate your interest in and commitment to improving health care through the capabilities offered by molecular technologies. We believe that much can be done if you embrace the vision of personalized medicine's capacity to create a new paradigm encompassing less-costly research, better and safer therapies for patients, and enhanced health care value by reducing trial and error medicine.

Examples of personalized medicine can most often be found today in some academic medical centers, in small NIH translational research efforts, in pockets of the FDA, and in start-up or small biotech or diagnostic companies. At the same time, we are starting to see larger, more mature companies develop new business models around personalized medicine, but not without some difficulty in achieving commercial success.

**It is unlikely that without government leadership and intervention that this evolution will quickly deliver personalized medicine's promise of safer and more efficacious therapies, better health, and conceivably lower systemic costs.** While the Personalized Medicine Coalition has begun the task of bringing together all the multiple constituencies and stakeholders needed to advance personalized medicine, without the organizing power of the government it will be difficult to achieve the promise that many envision.

We recommend that you start now by taking action within HHS, by working with us collaboratively going forward, and, especially, by engaging all Americans in this endeavor.

We will be prepared to elaborate more fully in our meeting with you, but initially we would propose that you:

- **Engage the appropriate HHS agencies:**
  - Support personalized medicine across all relevant HHS agencies and create an interagency task force on personalized medicine, reporting to you;

- Re-engage and fund FDA efforts in personalized medicine, especially those defined in the Critical Path;
  - Fund relevant research and large-scale translational initiatives at NIH; and
  - Fund personalized medicine efforts at AHRQ and CMS, including the creation of a strategy to incentivize preventive, predictive, and personalized health care.
- **Support the enactment of the Genetic Information Nondiscrimination Act (GINA).**
- **Develop and put in place a health information technology (HIT) infrastructure to improve the quality and efficiency of health care.** The PMC looks forward to developing with HHS a public private partnership to accelerate the incorporation of personalized health care into health delivery systems through the inclusion of medical genetic test and family history information into electronic health records.
- **Convene a Summit Meeting on “Leveraging Multi-Sector Capabilities to Accelerate the Adoption of Personalized Medicine.”** Such a meeting could stimulate a dialogue between HHS and the community of those who are most advanced in – and supportive of – personalized medicine approaches. Topics could include the full range of barriers, new models, and suggested policy changes and actions that can accelerate personalized health care. The summit could be designed to maximize interactions, including facilitation of discussions around key topics, and a dialogue with you and your staff that could form a foundation for a comprehensive HHS Report on Personalized Medicine that may have lasting significance.

The Personalized Medicine Coalition, the only non-profit organization focused exclusively on personalized medicine that represents all stakeholders in this arena, is proud to offer its full support to you in this endeavor. We would be pleased to assist you in any way to prepare for this event, including co-sponsoring it.

Once again, we applaud and support your efforts, and look forward to being of assistance in every way possible.

Respectfully,

Edward Abrahams  
Executive Director

Wayne Rosenkrans  
President and Chairman