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November 3, 2009

The Honorable Nancy Pelosi  
H-232  
United States Capitol  
Washington, D.C. 20515

The Honorable Steny Hoyer  
H-107  
United States Capitol  
Washington, D.C. 20515

Dear Speaker Pelosi and Majority Leader Hoyer:

The Personalized Medicine Coalition (PMC) supports the inclusion in health reform legislation of comparative effectiveness research (CER) policies that recognize and promote personalized medicine. PMC believes that CER has the potential to advance science and help patients and their doctors make better choices about the medical options available to them.

We applaud you for recognizing the critical role that personalized medicine must play in any CER initiative. The provisions on CER included in H.R. 3962, the “Affordable Health Care for America Act,” are a marked improvement over the language in earlier versions of the House health reform legislation. By recognizing that molecular and genetic sub-typing should be incorporated in CER, the new language will help prevent CER from unintentionally locking medicine into an approach that is rapidly becoming obsolete: using the same therapies for all patients without considering variations in patient responses to them.

We urge you to take additional steps to ensure that the promise of personalized medicine is fully realized. The importance and complexity of aligning CER with PM is underscored by a report PMC released last week: *Comparative Effectiveness Research and Personalized Medicine: From Contradiction to Synergy*. As the report notes, if personalized medicine and comparative effectiveness research are aligned they can optimize the quality of patient care and decrease systemic costs. Done right, comparative effectiveness research can help realize the goals of healthcare reform by getting the right therapy to the right patient, the first time.

To accomplish this goal, PMC strongly prefers the approach to CER in Congressman Schrader’s “Comparative Effectiveness Research Act” (H.R. 2502). If the bill incorporates specific language on genetics and molecular medicine, it will ensure that CER is fully aligned with personalized medicine. That is why PMC endorses the “Patient-Centered Outcomes Research Act” (S. 1213), introduced by Senators Max Baucus and Kent Conrad and adopted by the Senate Finance Committee. As health reform legislation advances to the House floor and to conference with the Senate, we urge Congress to include CER provisions consistent with these two bills.

Specifically, we believe that CER should:

- Improve the quality of the science generated from CER by incorporating new information and technological innovations into its studies, reviewing and updating evidence as necessary, and outlining what future research will be necessary to address perceived gaps;
- Incorporate research on patient preferences in the scope of work, including patient quality of life and physician choice;
- Expand the research agenda to include primary research on molecularly-informed trials;
- Define potential differences to include genetic and molecular sub-typing;
- Create an independent research methods committee that includes experts in molecular diagnostics;
- Incorporate research on benefit design and information communication; and
- Include quality of life in the definition of value in the methods section.

Most importantly, PMC contends that an independent entity to oversee CER will protect science and patients from political influence, and thereby alleviate concerns about government coming between them and the care they need. By creating an independent institute with diverse representation on its board, Congress can ensure that CER takes advantage of the knowledge and perspectives of a wide range of experts and scientists as well as patients, providers, and government officials.

At the same time, PMC supports a strong, balanced role for government officials and public research within an independent, patient-centered research program, thereby facilitating larger public policy goals and taking advantage of the existing research infrastructure. We believe that H.R. 2502 and S. 1213 achieve this important balance.

CER that helps improve our understanding of differences in patient response can do more to improve health outcomes and contain costs than any other policy recommendation under consideration. We look forward to working with you to develop a CER policy that will advance personalized, evidence-based medicine as part of healthcare reform.

Sincerely yours,



Edward Abrahams  
Executive Director