Personalized Medicine Coalition

January 16, 2009

The Honorable David Obey
United States House of Representatives
2314 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Obey:

We are writing to urge you to alter the text of the comparative effectiveness provision in the *American Recovery and Reinvestment Act of 2009* to address a potentially significant generalization – one that could harm patients, stall innovation and damage efforts to achieve meaningful healthcare reform.

As it stands today, many flaws in our health care system can be traced back to our reliance on a one-size-fits-all approach as the standard of care. We offer drugs to broad populations of patients, knowing they will work for only half, and sometimes fewer than that. The treatment that is deemed to help the most patients, on average, is considered the "best" for all.

"Personalized medicine" provides the opportunity to effectively segment populations through a better understanding of genetic differences and the molecular underpinnings of disease, thereby increasing the effectiveness and safety of many therapies. In essence, it is about assuring the right treatment for the right patient at the right time – which must be the ultimate goal of comparative effectiveness as well.

Unfortunately, the Comparative Effectiveness Research provisions of the *American Recovery and Reinvestment Act of 2009* are written in such a way as to result in one-size-fits-all comparative clinical trials that do not incorporate the targeting of therapies to improve their relative effectiveness based on appropriate segmentation of patients. Targeting health care improves quality and efficiency, adherence to therapies, and systemically saves money.

The evolution in the treatment of breast cancer offers strong evidence of the importance of evaluating the relative effectiveness of medications on a sub-population basis. The commonly used generic breast cancer treatment tamoxifen, for example, was originally found (using the standard approach for comparative effectiveness) to be less effective when compared with the non-generic aromatase inhibitors (AIs). However, scientists discovered that individuals with a particular biomarker did not benefit *at all* from tamoxifin. When those people were removed from the analysis, the two drugs demonstrated equivalent efficacy for most people, thus saving the system money while assuring that AIs were also available for those women who do not respond to tamoxifin.

Not coincidentally, we've seen a better than 30% increase in survival rates for women with metastatic breast cancer since the introduction of targeted therapies in the 1990s.

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We urge Congress to recognize that some therapies may be meaningfully targeted for distinct sub-populations and adjust the language of the comparative effectiveness research provisions accordingly. In particular, we ask that you broaden membership in the Coordinating Council to include representatives of relevant health care sectors, including personalized medicine; require open and transparent procedures to encourage consensus and build credibility; and ensure that research and communication of results accounts for different patterns of responses attributable to genetic and other factors -- thereby avoiding inappropriately generalized, "one-size-fits-all" policy decisions.

The Personalized Medicine Coalition, 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.

Thank you for considering our perspective.

Sincerely,

Edward Abrahams, Ph.D.
Executive Director