April 15, 2008

Peter R. Orszag, Ph.D.
Director
Congressional Budget Office
Ford House Office Building, 4th Floor
Second and D Streets, SW
Washington, DC 20515

Dear Dr. Orszag,

As an international organization of health care researchers and policy makers from various settings including academia, research organizations, industry, health plans and payers, we welcome the report of the Congressional Budget Office (CBO) on the use of comparative effectiveness data in the evaluation of medical therapies\(^1\). On behalf of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and its more than 4,100 members from 96 countries, we offer our perspective on establishing a comparative effectiveness program for the United States that will lead to better health outcomes and value nationwide and request your guidance on how we can contribute to the future dialogue on the subject.

Healthcare spending in the United States currently accounts for 16% of the gross domestic product (GDP). Despite the significant increase in spending versus other developed countries, such as Australia, Canada, Germany, and Great Britain (where spending ranges from 7-10% of GDP), there is little evidence of improved health outcomes in this country\(^2,3\). A formal comparative effectiveness center will provide an opportunity for clinical effectiveness and observational data to complement currently available information from selective clinical trials in controlled environments. Collectively, as noted in the CBO Report, these data can enable clinicians to improve performance, consumers to make more informed decisions, and payers to set medical policies that improve quality and value.

However, we note that there is an active debate about whether cost should form part of comparative effectiveness assessments. The science that allows for the consideration of effectiveness balanced against cost between drug therapies is “pharmacoeconomics”; however, the principles underlying such analysis applies to studies comparing diagnostics, medical devices, genetic testing, and other areas of health and medicine. So that our clinicians, consumers and payers can be fully informed, we therefore believe that comparative effectiveness research should explicitly inform considerations of cost-effectiveness. Comparative effectiveness should therefore focus both on clinical outcomes, and on other important measures of effectiveness such as patient-reported outcomes, including health-related quality of life, patient satisfaction, activities of daily living, and work productivity. If we appropriately execute comparative effectiveness studies, then the cost-effectiveness analyses that are conducted also will improve based on a more accurate denominator. We recognize the diversity across the United States (U.S.) in health care budgets, practice patterns, and cost levels, and we acknowledge and recognize the necessary flexibility in the interpretation of comparative effectiveness and cost-effectiveness by health plans, employers, government payers, and policy makers.

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Our membership’s expertise in outcomes research, economics, and health policy can assist in the discussion of these important issues. For example, more discussion is needed regarding scientific methods of incorporating economic factors in assessments in order to provide relevant information for decision makers in the U.S. context. Moreover, since the Health Care Comparative Effectiveness Research Trust Fund is proposed to be financed by issuers of health insurance policies, it would be ironic if information on the economic impact of such decisions were not available to them.

The definition and use of comparative effectiveness data will be important to how the outputs of such a center are perceived. Clinical effectiveness data from randomized clinical trials, retrospective and prospective observational data, and other sources and modes of study can be used to determine the comparative effectiveness of alternative health care technologies. When balanced against cost considerations by patients, payers, providers, and society as a whole, it provides the foundation for informed health care decisions. Our membership represents countries such as the United Kingdom, Canada, Germany, and Australia, where comparative effectiveness and cost-effectiveness information is integrated in the health care decision making process. We can learn from their experiences.

In testimony before the United State Senate Budget Committee in June, 2007, you advocated for comparative effectiveness research, with specific emphasis on the associated consideration of costs, as the most promising method for controlling rising health care costs and delivering better value in the United States. As an organization, ISPOR concurs with you and your recommendation and welcomes the opportunity for its membership to support the continued efforts of comparative effectiveness in the allocation of scarce resources to health care for all Americans.

If you have any questions or would like more information about ISPOR or discuss this issue with ISPOR leadership, please contact Marilyn Dix Smith, Ph.D., ISPOR Executive Director at mdsmith@ispor.org or 609-219-0773 ext 17.

Sincerely,

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