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January 26, 2009

The Honorable Tom Harkin  
United States Senate  
Washington, DC 20510

Re: *"American Recovery and Reinvestment Act of 2009"*

Dear Senator Harkin:

On behalf of the patients we represent, National Patient Advocate Foundation (NPAF) would like to bring to your attention provisions included in the *"American Recovery and Reinvestment Act of 2009"* addressing comparative effectiveness research. While the stimulus bill addresses many critical healthcare issues, NPAF is concerned that the provisions related to comparative effectiveness research will have harmful long-term consequences on patient care and access.

NPAF is a non-profit organization dedicated to improving access to healthcare services through policy reform. Our mission of creating avenues of patient access through improved access to, and reimbursement for, evolving therapies, therapeutic agents, and devices is influenced by the experience of patients who receive case management services from our companion organization, Patient Advocate Foundation (PAF). Last year, PAF received more than 7.5 million inquiries from patients throughout the United States seeking information and assistance for access to care issues resulting from diagnoses of a chronic, debilitating or life-threatening disease. Of those, 45,870 became full patient cases involving communications made by PAF staff on behalf of a patient in order to reach positive resolution.

The *"American Recovery and Reinvestment Act of 2009"* includes \$1.1 billion in new funding for comparative effectiveness research. NPAF supports comparative effectiveness research and believes it should be used as a tool between providers and their patients to determine the best course of action in treatment. However, NPAF is concerned that the Federal Coordinating Council established in the stimulus bill does not include roles for patient representatives. NPAF strongly believes that the Federal Coordinating Council must consist of all relevant stakeholders, including patient and consumer groups, government, providers, insurers and manufacturers of drugs and medical devices. These stakeholders should be involved in every step of the process, from setting the research agenda, and developing study methodology, to the translation and dissemination of findings. Other health agencies, such as FDA and CMS routinely appoint patient representatives to their scientific research panels and we encourage the committees considering this legislation to continue this established model.

In addition, NPAF is concerned that report language included in the House version implies that comparative effectiveness research may be used to make cost-effectiveness decisions. The report language states, "by knowing what works best and presenting this information

more broadly to patients and healthcare professionals, those items, procedures, and interventions that are most effective to prevent, control, and treat health conditions will be utilized, while those that are found to be less effective and in some cases, more expensive, will no longer be prescribed.” NPAF would like to emphasize our support for comparative effectiveness research for the purpose of improving the quality, safety and delivery of care; however, NPAF does not support using this research to limit access, deny treatment or reimbursement.

Many European countries have already developed a system for comparative effectiveness research but many of these countries impose cost-effectiveness analysis in ways which ultimately deny patients access to more expensive drugs. In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) conducts research and develops guidelines for the country’s National Health System (NHS). In the last several years, NICE has instituted certain coverage decisions based on cost-effectiveness that severely impacts patient access to appropriate care. As recent as January 2009, Ministers in the Welsh Assembly overturned a NICE decision that prohibited kidney cancer patients from accessing drugs such as Sutent, Avastin, Nexavar and Torisel, all of which have been proven to effectively treat kidney cancer. In the United States, it is common practice for these drugs to be prescribed to a kidney cancer patient. Advancing comparative effectiveness research in the U.S. can be a positive tool for patients and providers, only when it focuses on clinical comparative effectiveness.

NPAF urges you to consider these issues in the context of the economic stimulus package. If you have any questions or if we may provide you with additional information please feel free to contact me or Grayson Fowler at 202-347-8009.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Nancy Davenport-Ennis". The signature is written in a cursive style and is positioned above the printed name.

Nancy Davenport-Ennis  
President & CEO