United States Senate

WASHINGTON, DC 20510

November 9, 2010

Via Electronic Transmission

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20001

Dear Secretary Sebelius:

As Chairman of the Senate Special Committee on Aging and Ranking Member of the Senate Committee on Finance, respectively, it is our duty to ensure that Americans have access to affordable prescription medication. It is in this interest that we have worked together to examine various operations and activities of the pharmaceutical industry, including payments made to physicians for consulting activities, presentations and speeches, participation in Continuing Medical Education and conferences, and research.

As you know, the Physician Payments Sunshine Act requires drug and medical device manufacturers to disclose to the Department of Health and Human Services (the Department) anything of value given to physicians, such as payments, gifts, honoraria or travel above certain minimum thresholds. Companies would also be required to report additional information, including the name of the physician, the value and date of the payment of gift, and its purpose. This information would be collected by the Department beginning on March 31, 2012 and then made available to the public starting on September 30, 2013.

To prepare for compliance with the new legislation, some companies, manufacturers, universities and even the National Institutes of Health (NIH) have developed individual policies to increase disclosure on the nature of relationships between doctors and pharmaceutical companies or medical device makers. While we believe these initial actions are a promising beginning, we are concerned that the variation in individual disclosure policies is creating confusion within the industry and the public. For example, both academic institutions and manufacturers are releasing payment data about the same transactions, but with different levels of precision addressing different time periods. As a result, the information appears to conflict and is therefore difficult for the public to use. Prompt federal guidance is urgently needed to ensure the same information is disclosed in the same way, and is meaningful.

We need to ensure a smooth path toward increasing disclosure, eliminating conflicts, and ultimately providing patients with the tools they need to make informed health choices. To that end, we urge the Department to promptly designate an agency that will oversee the creation and operation of the database. Ideally, this agency will have the vision and dedication to ensure that this database is complete, easy to find and use, and enhances the integrity of the American health care system.

So that we may better monitor this process, we also request that you provide a briefing to the staff of the Finance and Aging Committees allowing them an opportunity to participate in the Department's decision-making on issues including, but not be limited to: who is responsible for implementation; who is accountable for insuring that the database is operational in a timely manner; and what is the timeline the Department is following to implement the disclosure and publication requirements contained in PPACA.

Thank you for your prompt attention to this important matter. We look forward to the Department providing the briefing before the end of the year. If you have any questions, please feel free to contact Debra Whitman of the Aging Committee at 202-224-5364 or Debra_Whitman@aging.senate.gov or Christopher Armstrong of the Finance Committee Staff at (202) 224-4515 or Chris_Armstrong@finance-rep.senate.gov. All formal correspondence should be sent electronically in PDF format to Jean_Doyle@aging.senate.gov and Brian_Downey@finance-rep.senate.gov or via facsimile to (202) 224-9926 and (202) 228-2131.

Sincerely,

Charles E. Grassley Ranking Member

Committee on Finance

Herb Kohl Chairman

Senate Special Committee on Aging