United States Senate

WASHINGTON, DC 20510

February 9, 2012

Jeffrey Zients
Acting Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Mr. Jeffrey Zients,

As Chairman of the Special Committee on Aging, Ranking Member of the Senate Judiciary Committee, and Member of the Senate Health, Education, Pension, and Labor (HELP) Committee, we take seriously our responsibilities to oversee the safety of medical devices that are used by, and implanted into, millions of Americans on a daily basis. At the Special Committee on Aging's hearing on medical device safety last April, witnesses testified to post-market surveillance activities for medical devices at the Food and Drug Administration (FDA) and its Center for Devices and Radiological Health (CDRH). Clear gaps in the post-market surveillance system of medical devices were identified at the hearing.

A post-market surveillance initiative that can help fill these gaps, the Unique Device Identifier (UDI), was authorized by section 226 of the Food and Drug Administration Amendments Act of 2007, P.L. 110-85. At the Special Committee on Aging's hearing, FDA testified that "key infrastructure improvements, such as…the establishment of the Unique Device Identification (UDI) system, and the incorporation of UDI into health-related electronic records, will have a profound and positive impact of the nation's ability to adequately monitor medical devices in the post-market period."

We introduced the bipartisan Medical Device Patient Safety Act (S. 1995), which is aimed at bolstering and improving post-market safety of medical devices and as such, we are fully committed to ensuring that FDA has the data it needs to protect the public health, better track problems when device malfunctions occur, and improve the recall process of faulty medical devices. Due to our strong desire for a robust post-market environment, we are very concerned with the delayed implementation of the UDI.

On July 11, 2011, the Office of Management and Budget (OMB) received a proposed rule to develop the UDI system (RIN: 0910-AG31). It is our understanding that, under Executive Order 12866, OMB has 90 days to make a decision on the rule, or receive a 30 day extension.

To help us better understand the delay, please provide us with a current comprehensive status report on the UDI rule at OMB. Please include the timeline to when OMB expects to release the UDI rule, whether extensions of review time were granted, and cause(s) of the delay. We would

also appreciate detailed information on any other related, updated information concerning other CDRH post-market surveillance and safety initiatives.

We look forward to working together to enhance post-market safety of medical devices and establishing a functional UDI system. We respectfully request that OMB provide this information to our offices by no later than close of business on March 1, 2012. You may contact Sarah Levin in Senator Kohl's office (sarah_levin@aging.senate.gov, 202-224-5364), Erika Smith in Senator Grassley's office (Erika_smith@judiciary-rep.senate.gov, 202-224-0675) or Rachel Pryor in Senator Blumenthal's office (Rachel_pryor@blumenthal.senate.gov or 202-224-2823) with any questions concerning this request.

Sincerely,

Herb Kohl
U.S. Senator

Charles Grassley
U.S. Senator

Richard Blumenthal
U.S. Senator