United States Senate
WASHINGTON, DC 20510

March 8, 2016

Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Andy Slavitt,
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Robert Califf, MD, MACC,
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Secretary Burwell, Acting Commissioner Slavitt, and Commissioner Califf,

We are writing to inquire about the progress the Department of Health and Human Services (HHS), Center for Medicare and Medicaid Services (CMS), and Food and Drug Administration (FDA) have made on the addition of the unique device identifier (UDI) of medical devices to health insurance claims forms in order to improve post market surveillance and curb waste in the Medicare program.

Congress has recognized that a tracking system for medical devices is a critical tool to better detect adverse events, facilitate product recalls and enable robust post market surveillance. In 2007, Congress required the FDA to create the UDI system and then in 2012 required that the Sentinel Initiative—a large electronic database comprised of primarily insurance claims data designed to evaluate the safety of drugs and biologics—be expanded to medical devices. Active post-market surveillance of medical devices can help to track product safety and performance, which is critical to public health and safety.

To reap the numerous benefits that UDI can provide, it must be incorporated into electronic health data sources – including insurance claims. We wrote to CMS Administrator Marilyn Tavenner on December 22, 2014 asking how the addition of UDI on the insurance claims form could improve patient safety and evaluation of medical devices, and what actions CMS planned

to take to make this important update. CMS replied at the time, and has continued to express, opposition to adding UDI to the claims form solely because of the technological challenges associated with the change.

In addition to the patient safety benefits that the inclusion of UDI in claims can provide, inclusion may also help to protect the integrity of the Medicare program. We are enclosing a letter from the Office of Inspector General in response to our request for feedback on a study they are conducting that outlines the costs that Medicare incurred due to recalled or poorly performing devices. Their preliminary findings indicate that recalls of defective products have likely resulted in millions of claims for monitoring, replacement and follow up care at significant costs. Inclusion of UDI in claims would allow for faster identification of poorly performing and recalled devices, and ensure that hospitals, device manufacturers, and CMS are all receiving proper reimbursement.

Continued opposition by CMS is contrary to the statements made by Secretary Burwell on the record for the HELP Committee. It is also contrary to recent comments from Commissioner Califf and CMS officials in the enclosed *Wall Street Journal* article that the addition of UDI in claims is a priority for the FDA in their efforts to establish a national evaluation system for medical devices and that CMS is "generally supportive" of placing UDI on claims.

Although the next version of the claims form is not scheduled to be implemented until approximately 2021, the window to make changes is rapidly closing. Given the importance of this issue, we hope you will ensure that CMS works collaboratively with FDA and other stakeholders to ensure that the next update of the claims form will incorporate UDIs.

If you have any questions, please do not hesitate to contact Remy Brim in Senator Warren's office and Karen Summar in Senator Grassley's office. Thank you.

Sincerely,

Elizabeth Warren
U.S. Senator

Charles E. Grassley
U.S. Senator