Congress of the United States
Washington, DC 20515

April 25th, 2013

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

As co-chairs of the New Democrat Health Care Task Force, we are writing to inquire on the status of the U.S. Food and Drug Administration (FDA) final regulations to establish a unique device identifier (UDI) system and database. We are concerned about recent public comments from FDA officials that suggest that the agency will not finalize the regulations by the statutory deadline—May 7. As a result, patients, clinicians and hospitals will have to wait longer for improvements in postmarketing surveillance and medical device recalls.

As members of the New Democrat Coalition's Health Care Task Force, we are committed to harnessing technological, scientific, and medical innovation to achieve the promise of a 21st century health care system. Adopting policies that foster innovation and hasten the adoption of new discoveries and best practices will improve the efficiency of our system and better the health of all Americans. Part of that work includes supporting the development of a national, interoperable health IT system to encourage information sharing across multiple providers—a goal that requires a more accurate tracking of the devices used in patient care.

Congress has repeatedly passed legislation to establish a UDI system. An effective UDI system will improve postmarket surveillance and facilitate medical device recalls—two chief FDA concerns. Once UDIs are included in health care databases, researchers and the FDA will be able to more rapidly detect problems with medical devices. Similarly, device tracking will ensure more efficient device recalls by assisting manufacturers, providers, hospitals, and patients to more quickly identify and remedy faulty products. In a 2011 study, the Government Accountability Office found that more than half of medical device recalls conclude without all products either corrected or removed from the market.

There is also evidence that a UDI system could help generate health care savings. The California Department of Health Care Services (DHCS) conducted a pilot study to identify Medicaid savings by tracking medical supplies dispensed by retail pharmacies and durable medical equipment providers. The DHCS identified $30 million in savings through improved rebate collection, but the agency estimates that additional benefits include improved detection of fraud and abuse, enhancing the quality of claim reports, allowing the development of fee schedules based on actual market rates, among other advantages.

In the Food and Drug Administration Amendments Act of 2007, Congress instructed the Secretary of Health and Human Services to issue regulations creating a UDI system for medical devices. The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law by President Obama last July, requires the promulgation of final UDI regulations within six months of the close of the public comment period on the proposed rule. The FDA issued proposed regulations in July and closed the comments period on November 7, 2012. Therefore, the statutory deadline for the release of a final UDI rule—May 7—is quickly approaching. While the FDA met its first FDASIA deadline by issuing a proposed rule well before the December 2012 requirement for its release, the agency—based on public comments—appears poised to miss the May deadline for the rule's finalization.

Drug Administration Safety and Innovation Act (FDASIA), signed into law by President Obama last July, requires the promulgation of final UDI regulations within six months of the close of the public comment period on the proposed rule. The FDA issued proposed regulations in July and closed the comments period on November 7, 2012. Therefore, the statutory deadline for the release of a final UDI rule—May 7—is quickly approaching. While the FDA met its first FDASIA deadline by issuing a proposed rule well before the December 2012 requirement for its release, the agency—based on public comments—appears poised to miss the May deadline for the rule's finalization.

The benefits of a UDI system can only be achievable after the FDA releases a final UDI rule, which will enable manufacturers to begin including unique identifiers on medical device packaging and, where appropriate, on the product itself.

Lengthy delays in releasing final regulations may postpone the Centers for Medicare and Medicaid Services' (CMS) and the Office of the National Coordinator for Health Information Technology's (ONC) consideration of policies to facilitate UDI capture—such as in electronic health records (EHR) or claims forms. CMS and ONC are preparing rulemaking to establish new EHR standards and criteria to provide incentives—known as Stage 3 meaningful use objectives—for clinicians and hospitals to utilize electronic records. Until the FDA finalizes the UDI rule, CMS and ONC cannot include device tracking as part of these important regulations.

A UDI system will be the cornerstone to achieving several improvements in medical device safety. We urge the FDA to meet the statutory deadline for finalizing the UDI rule, which will enhance medical device tracking and, ultimately, improve patient care. We look forward to an update on the FDA's progress finalizing the UDI regulations. Thank you for your attention to this matter.

Sincerely,

Allyson Y. Schwartz
Member of Congress

Bill Owens
Member of Congress

Kurt Schrader
Member of Congress