United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

December 21, 2010

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We write to express our support for efforts to ensure that the 510(k) medical device regulatory pathway is well-functioning and predictable, while fostering innovation and ensuring patient safety. We are concerned, however, that a number of recommendations included in a recent Food and Drug Administration (FDA) report could undermine these efforts.

On August 3 the FDA Center for Devices and Radiological Health (CDRH or the Center) released for comment two preliminary reports, which recommended several proposals that were intended to foster medical device innovation, enhance regulatory predictability and improve patient safety. Shortly thereafter, Center Director Jeff Shuren advised Health, Education, Labor, and Pensions Committee staff that the Center would implement noncontroversial recommendations, while any more controversial recommendations would be referred to the Institute of Medicine - and ultimately, Congress - for further evaluation.

Based on our review of the reports and discussions with stakeholders, we are concerned that several of the recommendations are controversial and have the potential to disrupt the current regulatory balance under the 510(k) pathway, jeopardizing patients' timely access to new treatments and cures. In particular, we believe that the recommendations regarding rescission authority; split and multiple predicates; intended use and indications for use; splitting Class II; and the treatment of proprietary information, including trade secrets could have significant unintended adverse consequences on the existing regulatory process.

It is important for Congress and the full range of stakeholders to know the specifics of the FDA's recommendations and assess their full impact. We also recognize that the cumulative effect of the changes proposed by the Agency could be quite significant. In order to facilitate the committee of jurisdiction's oversight of these ongoing

developments, we respectfully request copies of all internal planning documents regarding the development of timelines, project milestones and notice-and-comment procedures that will be used to implement any proposals, as well as change-management plans for the overall project. Kindly provide this information by Friday, January 21. If you have any questions, please contact Keith Flanagan of Ranking Member Enzi's HELP Committee staff at (202) 224-6732.

Sincerely,

Michael B. Enzi
US Senator

Lamar Alexander
US Senator

Richard Burr
US Senator

Johnny Isakson
US Senator

John McCain
US Senator

Orrin G. Hatch
US Senator

Lisa Murkowski
US Senator

Tom Coburn, M.D.
US Senator

Pat Roberts
US Senator

Cc: Jeff Shuren, Jeanne Ireland