Congress of the United States Washington, DC 20515

October 12, 2010

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

Dear Commissioner Hamburg:

We are writing as part of an ongoing dialogue the Food and Drug Administration (FDA) FDA began last month when it recommended changes to the 510(k) process. As you know, 510(k) is the pathway to market for more than 90% of the medical devices sold in the United States. Maintaining a well-functioning, efficient system that both fosters innovation and ensures patient safety is our goal. We believe this balance must be achieved if patients are to continue having timely access to new treatments and cures, and if the U.S. medical technology industry is to maintain its global leadership.

At present, FDA is soliciting public comment on a list of recommendations published in the Federal Register on August 3rd. We welcome the commitment you made in a briefing with staff for the Energy and Commerce Committee and Health, Education, Labor and Pensions Committee on August 4, 2010 to focus first on the recommendations that have consensus among interested parties, and then to solicit additional input from stakeholders, including our Committee, where the recommendations prove to be controversial.

Since the release of the recommendations, we believe at least five proposals fall into this latter category and should be considered controversial. Specifically, proposals involving Rescission Authority, Split and Multiple Predicates, Clarifying Intended Use and Indications for Use, Mandatory Pre-Market Inspections and Mandatory Clinical Information for a subset of Class II devices, and Proprietary Information all have the potential to disrupt the device review process. Depending on how FDA implements these recommendations, they could prevent companies from using important evidence in product applications, delay the introduction of innovative new therapies, increase the cost and time associated with new product development, and potentially upset the delicate balance that exists between providing information to the public and protecting intellectual property.

We do not necessarily oppose these recommendations, but more transparency from FDA is needed. Without knowing greater specifics of each proposal, it is difficult to adequately assess their full impact. We ask that you take the following steps as you contemplate changes in these highlighted areas in order to provide greater detail:

First, please provide us with a more detailed work schedule for implementing the recommendations of August 3rd.

Second, as you indicated in the Committee briefing, changes can come in multiple forms, including guidance documents, rulemaking, and statutory change. For the five areas identified above, please provide your views on which components of each area could be done through guidance documents, rulemaking, or statutory change.

Third, please release more details on the proposals listed above, and ensure that adequate and appropriate public comment is solicited before moving forward.

Finally, we ask that you provide the Committee with an analysis of the economic impact of the recommendations on the domestic medical device industry.

We appreciate your continued efforts to keep us, the Committee, the public, and the medical technology community informed and engaged as you refine the medical device application process. It is vital to patient safety, job creation, and the U.S. economy that this process work effectively and efficiently. We look forward to working with you to achieve those goals.

Sincerely,

Rep. Baron P. Hill (IN-09)	Rep. Joe Barton (TX-06)
Rep. Jim Matheson (UT-02)	Rep. Fred Upton (MI-06)
Rep. John Barrow (LA-03)	Rep. John Shimkus (IL-19)
Bin Mung	Jan PAHS
Rep. Christopher S. Murphy (CT/05)	Rep. Joseph R. Pitts (PA-16)
Rep. Zack Space (OH-18)	Rep. Mike Rogers (MI-08)
Rep. Jerry McNerney (CA-11)	Rep. Michael C. Burgess (TX-26)