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# United States Senate

WASHINGTON, DC 20510-1401

January 7, 2011

Margaret A. Hamburg, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20903

Dear Commissioner Hamburg:

I write to you early in this New Year regarding pending proposals to modify the Food and Drug Administration's 510(k) medical device regulatory process. I am pleased to have the opportunity to highlight concerns expressed to me in recent months by medical device manufacturers from my state. I request your careful attention to a letter I have enclosed which I received from Danelle Miller, President of the Indiana Medical Device Manufacturers Council (IMDMC). As you will read, this letter both underscores the considerable importance of this industry within Indiana and touches on a number of industry concerns regarding specific recommendations generated by the FDA Center for Devices and Radiological Health. As an addendum to this letter, I have also enclosed official IMDMC comments submitted previously to the FDA.

It is my understanding that a number of my Senate colleagues, including the entire minority membership of the Senate Health, Education, Labor and Pensions Committee, have also written to you to express reservations or suggestions on certain 510(k) reform recommendations under consideration. I am grateful for your agency's efforts to ensure the continued safety of medical devices in this country, which includes taking into consideration the constructive input of all stakeholder groups and the potential that additional layers of regulatory requirements on device manufacturers could have unintended, negative effects on innovation and emergent life-saving technologies.

Any update you are able to provide on this important topic would be most welcome. Thank you for your attention to the materials I have provided and the important perspective they present.

Sincerely,



Richard G. Lugar  
United States Senator

RGL/aca  
Enclosures