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COMMERCE, SCIENCE, AND TRANSPORTATION
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SMALL BUSINESS

United States Senate
WASHINGTON, DC 20510–2102

April 13, 2011

The Honorable Margaret Ann Hamburg
Commissioner, Food and Drug Administration
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Commissioner Hamburg:

I appreciate your efforts to reform the 510(k) medical device clearance process to provide more predictability, transparency, and stability to medical device manufacturers while maintaining the strong patient safeguards that citizens expect. I understand that the FDA is deferring the implementation of several recommendations until the Institute of Medicine (IOM) has completed their review. However, I am concerned that some of the recommendations that the FDA has forwarded to the Institute of Medicine (IOM) could be disruptive to the medical device industry and could have a chilling effect on growth, jobs, and patient access to medical innovation.

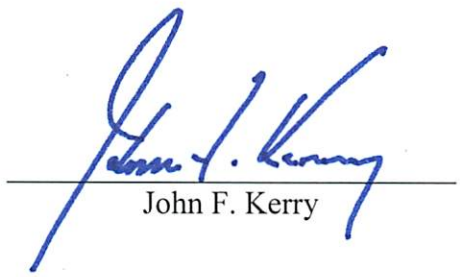
As you know, President Obama issued an Executive Order in January aimed at creating a 21st century regulatory system that protects the public while promoting economic growth, innovation, competitiveness, and job creation. The Executive Order said our regulatory system must promote predictability, reduce uncertainty, and rely on the most innovative and least burdensome tools for achieving regulatory ends.

Patient safety continues to be my highest priority, and I couldn't agree more that our regulatory framework must strike the right balance when it comes to increasing efficiency and transparency in the process. However, the medical device industry in my state has expressed concern that some of the recommendations would result in continued delays in 510(k) review times or would be unnecessarily burdensome and delay life-saving products from coming to market. Specifically, they have expressed concern that limiting the use of predicates, expanding the FDA's rescission authority, creating a new category of Class IIb devices, and changing key definitions and terms could place an additional burden on manufacturers and hinder innovation and economic growth.

I understand your agency's implementation plan defers action on these controversial recommendations until the release of the IOM's report. I have heard concerns that since the panel currently reviewing the 510(k) program at the IOM does not include representatives from the medical technology industry, they may not fully understand the impact of the proposed regulations on the industry. Given the concerns expressed, I urge you to establish a deliberative and transparent process for reviewing the IOM recommendations that ensures adequate opportunity to solicit substantive and meaningful input from all stakeholder groups before any recommendations are finalized.

I look forward to working with you on the important goal of reforming the 510(k) process in a manner that rigorously protects patient safety while maintaining our global leadership in medical technology. Thank you for your consideration of this request.

Sincerely,



John F. Kerry