Office of Advocacy
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Advocacy: the voice of small business in government

July 26, 2011

The Honorable Margaret A. Hamburg
Commissioner, U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

Dear Commissioner Hamburg:

The Office of Advocacy (Advocacy) was established by Congress under Pub. L. 94-305 to represent the views and concerns of small business before Federal agencies and Congress, and to ensure that regulatory agencies comply with the analytical provisions of the Regulatory Flexibility Act (RFA) designed to minimize economic impacts on small businesses. Advocacy is an independent office within the U.S. Small Business Administration (SBA).

I was pleased to learn of your July 15, 2011, speech in Cleveland, Ohio to businesses highlighting the Food and Drug Administration's (FDA) commitment to small medical technology companies, and of your desire to collaborate more closely with the U.S. Small Business Administration in ways to reach out to small businesses. I am writing you because, as Chief Counsel for Advocacy, small businesses often ask me to pass along their business concerns to various Federal agencies. Recently, I met with leaders of small medical device companies who voiced concern with the length of time it takes the FDA to approve new and innovative medical devices for introduction into the marketplace.

The importance of promoting medical device innovation in this country has long been of great importance to me. Prior to joining Advocacy I worked in venture capital providing seed and early stage funding to entrepreneurs; some of whom developed innovative medical technology devices and treatments. Many of these entrepreneurs were driven to seek cures for illnesses that, in many cases, directly affected someone close to them. Developing a new device is a long and expensive process, but many are willing to undertake the risk. The uncertainty of the regulatory scheme, especially with respect to Premarket Approval Applications (PMA) and

the 510(k) approval process has caused many investors and entrepreneurs to close promising small businesses. Entrepreneurs understand that possible failure is a cost of doing business, but the risk is warranted when new and novel medical devices are developed helping to eradicate some of our most challenging diseases.

On June 7, 2011, I travelled to Sunnyale, California to participate in a roundtable discussion titled: Early Stage Medical Device Barriers. Medical device industry representatives lamented the costs associated with getting medical devices to market, and the difficulty they have navigating the FDA approval process which they believe puts them at a competitive disadvantage with companies that choose to launch their products in Europe. Since my participation in the roundtable, my office has reached out to numerous small medical device companies and venture capital groups in an effort to better understand the difficulties they face getting their products to market. I believe that this is an advantageous time to bring these industry concerns to your attention as the FDA is currently in the midst of its Medical Device Innovation Initiative and the 510(k) Plan of Action.

Historically, Advocacy has worked closely with the FDA as it issues rules that are expected to have a significant impact on small food and health care businesses. I am interested in learning about the FDA's activities regarding possible changes to the PMA and 510(k) processes, and developing an understanding of how those changes will impact small businesses involved in medical device manufacturing and venture capital. Lastly, I would like to meet with you to discuss areas in which Advocacy can work with the FDA in the future as it promulgates rules involving the RFA, and as the Agency explores ways to minimize the impacts of the medical device approval process on small medical device companies. Thank you for your attention to the above matters and I look forward to working with you on these issues of interest to small businesses in the near future. If you have any questions, or concerns with this letter, please feel free to contact my office at (202) 205-6533.

Sincerely yours,

Winslow Sargeant, Ph.D.
Chief Counsel for Advocacy

Cc: Jeffrey Shuren, M.D., J.D. – Director, Center for Devices and Radiological Health