



BIOMEDICAL ENGINEERING ALLIANCE & CONSORTIUM

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April 24, 2012

Senator Tom Harkin
Chairman
Senate HELP Committee

Representative Fred Upton
Chairman
House Energy & Commerce Committee

Senator Mike Enzi
Ranking Member
Senate HELP Committee

Representative Henry Waxman
Ranking Member
House Energy & Commerce Committee

Dear Chairman Harkin, Chairman Upton, Senator Enzi, and Representative Waxman:

On behalf of BEACON, the medical device trade association in Connecticut, I am writing to express support for your legislative proposals to reauthorize the medical device user fee program.

As you know, unless Congress acts to reauthorize it, the Food and Drug Administration's (FDA) authority to collect user fees under the medical device user fee program and, by reference, FDA's obligation to meet specified performance goals, will expire on September 30, 2012.

Industry and the FDA have negotiated a new user fee agreement, which is reflected in your legislation. This new user fee agreement is a good one for patients, industry and FDA. It is a substantial improvement over the current user fee agreement and lays the groundwork for significantly improved agency performance through increased accountability, more meaningful goals, important process improvements, better metrics and additional resources.

FDA is a critical partner in our associations' efforts to bring safe and effective medical devices to patients. Without a strong, effective, and efficient FDA, we cannot have a strong and competitive industry. As you may know, the medical technology industry employs 11,000 in the State of Connecticut playing an important role in our state's economy. It is important that Congress move expeditiously to pass this agreement, which will provide certainty to both the agency and industry.

We commend you for your bipartisan efforts, and are greatly encouraged by the legislation you have put forward. In addition to the underlying user fee agreement, the legislation includes a number of proposals that have been introduced with the goal of improving the FDA's operations. We are appreciative of efforts by all Members who seek to give the FDA the tools and structure it needs to succeed, and are supportive of many of the legislative reforms put forward by the committees. However, we continue to have concerns with certain provisions, and look forward to working with you to make further changes as the legislative process continues.

It is essential that the legislative process advances quickly, and we are committed to working with you to achieve reauthorization of the medical device user fee program on a timely basis.

Sincerely,

A handwritten signature in black ink on a light yellow rectangular background. The signature is cursive and reads "Joseph D. Bronzino".

Joseph D. Bronzino
Founder and President