



David E. Miller
PRESIDENT & CEO

April 23, 2012

Senator Tom Harkin
Chairman
Senate HELP Committee
Committee

Representative Fred Upton
Chairman
House Energy & Commerce

Senator Mike Enzi
Ranking Member
Senate HELP Committee
Committee

Representative Henry Waxman
Ranking Member
House Energy & Commerce

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

On behalf of the Illinois Biotechnology Industry Organization—better known worldwide as iBIO®—I am writing to express support for your legislative proposals to promptly reauthorize the medical device user fee program (MDUFA).

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 companies' 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 thousands of workers in Illinois and play an important role in our state's economy. In addition, many of our most exciting startup companies in Illinois are engaged in bringing forward innovative new medical devices. 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.

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, appearing to be 'D. Miller', followed by a horizontal line.

David Miller
President & CEO
Illinois Biotechnology Industry Organization- iBIO®