



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 Advanced Medical Technology Association (AdvaMed), 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 (MDUFA) and, by reference, FDA's obligation to meet specified performance goals, will expire on September 30, 2012.

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

This agreement is critical to the future success of the medical technology industry. Our industry directly employs more than 400,000 workers nationwide, and indirectly accounts for over two million jobs at those businesses that supply components and services to our industry. Whether a company is large or small, success in our industry comes only from innovation—the creation of diagnostics, treatments and cures that extend and enhance lives. Our industry's investment in research and development is more than twice the national average. And with \$33 billion in total exports in 2008, medical technology ranks eleventh among all manufacturing industries in gross exports. Notably, unlike virtually every other sector of U.S. manufacturing, medical technology has consistently enjoyed a

favorable balance of trade. Put simply, our industry is a major contributor to American job growth and economic success.

FDA is an essential 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. It is important that Congress move expeditiously to codify this agreement and provide certainty to both the FDA 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. Legislative reforms that do not alter or undermine the negotiated agreement between FDA and industry and seek to improve consistency and predictability in the FDA device review process hold the potential to create a legislative reauthorization package that maximizes the opportunity for success at the agency.

However, we continue to have concerns with certain provisions. In particular, we are strongly concerned by a proposal that would change the way medical devices are reclassified, changing it from a rulemaking process to an administrative order. This change would remove several steps of the current reclassification process that are important in providing basic due process protections to companies whose devices are being considered for reclassification. While we appreciate that the current reclassification procedure involves several steps, FDA has successfully reclassified devices and diagnostic products under the current process. Up-classification holds significant economic implications for the company whose product may be up-classified, and for future innovators. We believe the current process could be streamlined while still ensuring the continuation of internal governmental review of FDA's significant regulations and other basic due process protections, and encourage the consideration of alternative approaches.

We look forward to working with you as the legislative process moves forward to address any remaining concerns. Ultimately, it is essential that the 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,



Stephen J. Ubl  
President and CEO