



April 23, 2012

Senator Tom Harkin
Chairman
Health, Education, Labor and Pensions Committee
U.S. Senate

Senator Mike Enzi
Ranking Member
Health, Education, Labor, and Pensions Committee
U.S. Senate

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of LifeScience Alley, the largest state-based life sciences trade association in the U.S., and the more than 680 companies and organizations we represent, I am writing to thank you for your ongoing leadership to advance legislation that revises and extends the Food and Drug Administration (FDA) user-fee programs for medical device and prescription drugs and establishes user-fee programs for generic drugs and biosimilars.

Overall, the new user-fee agreements are a substantial improvement over the current programs and lay the groundwork for significantly improved agency performance through increased accountability, more meaningful goals, important process improvements, better metrics and additional resources. We support the committee moving forward with its user-fee package that will improve the current regulatory environment. However, there are some provisions that we believe need refinement, most notably the section outlining new procedures for the reclassification of medical devices. We look forward to working with you to address industry concerns on reclassification as the package continues to move through the legislative process.

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 agreements, 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.

FDA is a critical partner in our companies' efforts to bring safe and effective medical devices and medicines to patients. Without a strong, effective, and efficient FDA, we cannot have a strong and competitive industry. As you may know, the medical technology, biotechnology and pharmaceutical industries are a key economic driver in Minnesota and our member companies employ more than 250,000 people. Minnesota represents the most densely concentrated medical technology economy in the world. It is important that Congress move expeditiously to pass an agreement, which will provide certainty to both the agency and industry.

Again, thank you for your leadership toward passage of FDA user-fee programs that will provide continued access to drugs, medical devices, and biologics that save lives and extends and improves the quality of lives of millions of patients. We look forward to working with you to achieve a final package that will help ensure the long-term health and success of Minnesota's bioscience industry and access to innovative medicines and medical devices.

Sincerely,

A handwritten signature in black ink, appearing to read 'Dale Wahlstrom', with a long horizontal flourish extending to the right.

Dale Wahlstrom
President & CEO
LifeScience Alley & The BioBusiness Alliance of Minnesota