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The Honorable Hal Rogers  
Chairman  
House Appropriations Committee  
Rayburn House Office Building, Room: 2406  
Washington, DC 20515

The Honorable Nita Lowey  
Ranking Member  
House Appropriations Committee  
Rayburn House Office Building, Room: 2365  
Washington, DC 20515

March 5, 2013

Dear Chairman Rogers and Ranking Member Lowey,

On behalf of AdvaMed, the world's largest medical technology association representing manufacturers of medical devices, diagnostic products and medical information systems, I write in support of H.R. 933, the continuing resolution to fund government operations until the end of the fiscal year on September 30, 2013.

As you know, last year the medical device industry negotiated a new Medical Device User Fee Agreement (MDUFA III) with the Food and Drug Administration (FDA), and Congress passed with bipartisan support legislation to codify this new agreement along with a number of other reforms intended to improve FDA's regulatory efficiency and predictability. Under MDUFA III, the industry agreed to pay higher fee levels to FDA in return for new performance goals and commitments that we believe create the conditions for success at the agency.

The current continuing resolution that funds the government through the end of this month contains an anomaly that prevents FDA from accessing the full amount of user fees paid by industry under MDUFA III. While companies are paying the new, higher fee levels, FDA is only able to access and spend fees up to the amounts authorized in FY 2012, threatening to leave FDA short of \$40 million in medical device user fee payments.

H.R. 933 contains language that would correct the anomaly and allow FDA to spend user fees at the levels authorized under MDUFA III. We strongly believe that FDA should have full access to the fees paid by industry, and support passage of H.R. 933 so that this issue can be resolved. By fixing this anomaly, FDA can continue on the path of implementing reforms that will help improve the efficiency and consistency of the device review process.



**AdvaMed**

Advanced Medical Technology Association

It should also be noted that under the terms of sequestration, which triggered on March 1, FDA's access to user fees will also be restricted. We look forward to working with you on a future legislative change to address that provision.

Sincerely,

Stephen J. Ubl  
President and CEO

Cc: All Members of the U.S. House of Representatives