

**Congress of the United States**  
**Washington, DC 20515**

January 7, 2014

The Honorable Chairman Hal Rogers  
Chairman  
U.S. House Committee on Appropriations  
H-305, The Capitol  
Washington, DC 20515

The Honorable Barbara A. Mikulski  
Chairwoman  
U.S. Senate Committee on Appropriations  
S-128, The Capitol  
Washington, DC 20510

The Honorable Nita Lowey  
Ranking Member  
U.S. House Committee on Appropriations  
1016 Longworth HOB  
Washington, DC 20515

The Honorable Richard C. Shelby  
Vice Chairman  
U.S. Senate Committee on Appropriations  
S-128, The Capitol  
Washington, DC 20510

Dear Chairman Rogers, Chairwoman Mikulski, Ranking Member Lowey, and Vice Chairman Shelby:

As you work to complete the Fiscal Year 2014 Omnibus Appropriations bill, we write to express our strong support for a bipartisan and bicameral provision that would release the Fiscal Year 2013 Food and Drug Administration (FDA) user fees from the sequester and return them to the agency.

As you know the FDA uniquely relies on two sources of revenue: congressionally-directed appropriations and user fees, with user fees comprising over 60 percent of the human drug review budget alone. A result of extensive negotiations between the pharmaceutical and medical device industry and the FDA, these fees are intended for specific purposes, such as the review and approval of a new medical therapy or device. Congress passed bipartisan, bicameral legislation to renew and increase FDA user fees in return for a strengthened and improved drug and device review process.

The sequestration of PDUFA, MDUFA and other medical user fees is impacting the ability of the FDA to fulfill its critical public health mission which includes bringing new medicines and technologies to patients in a timely manner. The FDA, and the human drug review program especially, relies heavily on user fees to ensure that the agency has the tools it needs to make new medicines available to patients in a more efficient, consistent and timely manner. For example, a hiring freeze due to sequestration at the FDA has prevented the agency from hiring any new scientific or medical personnel to appropriately staff the human drug review program and advancing crucial regulatory science priorities. For medical devices, as part of the most recent MDUFA agreement, the medical technology industry agreed to nearly double their user fees in order to help FDA address persistent problems with timely and predictable device reviews.

As a result of sequestration, however, the Office of Management and Budget (OMB) made an arbitrary decision to include FDA user fees in sequestered resources despite the fact that they are not government dollars and cannot contribute to reducing the deficit. User fees are 100 percent industry-paid and targeted specifically for the approval of safe and effective drugs and devices. The misguided decision by OMB to sequester them has prevented the FDA from meeting its congressionally-mandated responsibilities while putting patient safety at risk.

User fees by law cannot be diverted to the general treasury for deficit reduction and instead sit in a budgetary limbo unavailable to the FDA for human drug review or for any other purpose. In Fiscal Year 2013 sequestration prevented the FDA from accessing nearly \$85 million industry-paid user fees for the approval of new drugs and devices.

There is strong bi-partisan support in both the House and Senate for Congress to uphold the integrity of the user fee agreements and ensure that these fees be returned to their intended purpose.

We respectfully request that the Appropriations Committees pursue any opportunity to release these fees for appropriation in FY14 so that the FDA can continue to bring new medical products to patients in a safe and expeditious manner. Thank you for your consideration.

Sincerely,



Leonard Lance  
Member of Congress



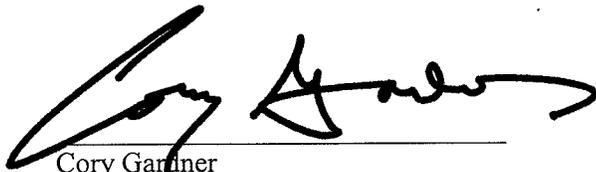
Anna G. Eshoo  
Member of Congress



Mike Rogers  
Member of Congress



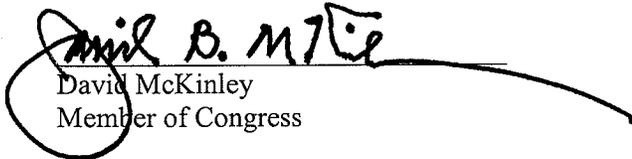
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Member of Congress



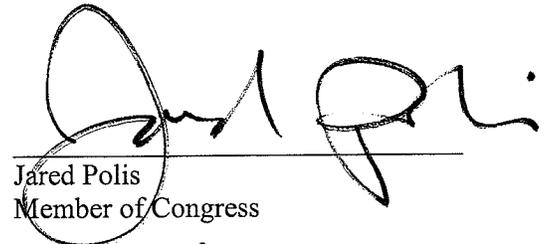
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Member of Congress



Todd Young  
Member of Congress



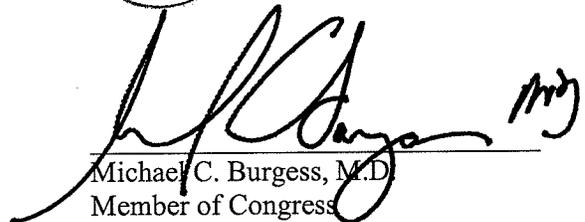
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Eddie Bernice Johnson  
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Joe Heck, D.O.  
Member of Congress

Henry C. "Hank" Johnson

Henry C. "Hank" Johnson  
Member of Congress

Doug LaMalfa

Doug LaMalfa  
Member of Congress

Tony Cárdenas

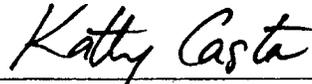
Tony Cárdenas  
Member of Congress

Gene Green

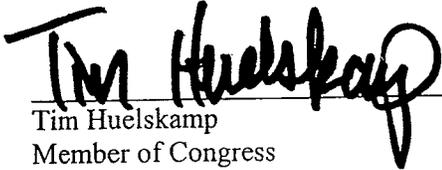
Gene Green  
Member of Congress



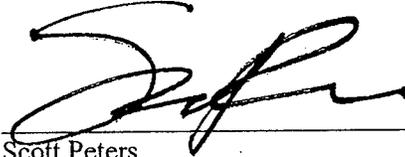
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Member of Congress



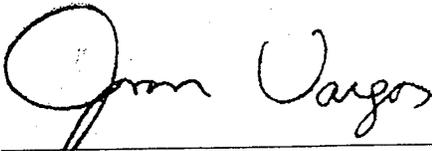
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Member of Congress



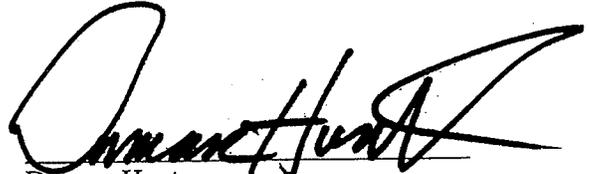
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Member of Congress



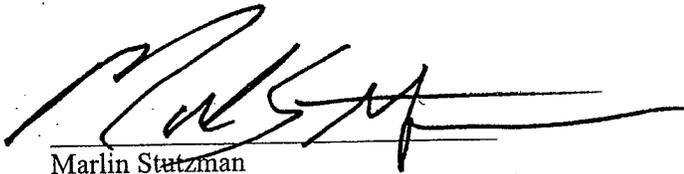
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Member of Congress



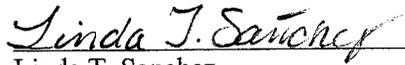
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Duncan Hunter  
Member of Congress



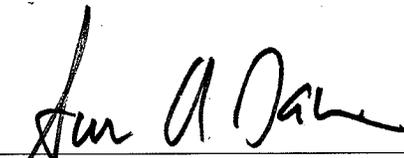
Marlin Stutzman  
Member of Congress



Linda T. Sanchez  
Member of Congress



Lois Capps  
Member of Congress



Susan Davis  
Member of Congress

Cc:

Mark Pryor, Chairman

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies  
Senate Appropriations Committee

Roy Blunt, Ranking Member

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies  
Senate Appropriations Committee

Robert Adherholt, Chairman

Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

Sam Farr, Ranking Member

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