



August 1, 2013

Mr. Jacob J. Lew, Secretary  
U.S. Department of the Treasury  
1500 Pennsylvania Avenue, N.W.  
Washington, D.C. 20220

Mrs. Sylvia Mathews Burwell, Director  
Office of Management and Budget  
725 17<sup>th</sup> Street, N.W.  
Washington, D.C. 20503

Dear Secretary Lew and Director Burwell,

We write with concerns regarding the sequestration of user fees at the Food and Drug Administration (FDA).

As you are well aware, Congress' failure to enact legislation developed by a Joint Select Committee on Deficit Reduction by January 15, 2012, to reduce the deficit by at least \$1.2 trillion triggered a series of across-the-board budget cuts that have affected nearly the entire federal government. The impact of sequestration is two-fold: agency budgets are cut across the board, and, agencies are prohibited from transferring funds within their own departments.

As you know, FDA relies on industry-financed user fees in order to have drugs and devices approved for their safety and effectiveness in a timely process. The FDA first began collecting user fees for drug applications in 1992, followed by medical devices in 2002. These fees were introduced in response to dangerously slow approval times for new drugs and devices, and have come to represent a true collaboration between the FDA and industry. Indeed, just last year legislation to renew and increase FDA user fees was enacted following nearly two years of work across the FDA, regulated industry, Congress and other stakeholders in order to strengthen and improve the review processes.

Accordingly, we find it extremely troubling that these industry-financed user fees are being sequestered. If the intent of sequestration is to limit *public* spending, withholding private monies is counterintuitive.

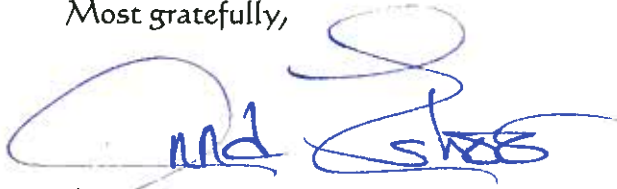
To provide transparency on this issue, we respectfully request the following information:

- Please provide documentation indicating where the sequestered FDA user fees are being held.
- Are the sequestered user fees being held for eventual use for their statutorily mandated purpose, or are they being diverted to support other federal activities?
  - If these funds have been or will be diverted to support other federal activities, please indicate which ones and describe the process for making these determinations.

- Are the sequestered user fees earning interest? If so, please provide documentation indicating the interest rate and total accrued interest.
- What will become of the sequestered user fees, including all interest accrued, if sequestration ends?

We strongly support the FDA's mission to approve safe and effective drugs and devices for patients. We fear that sequestering FDA user fees will have a negative impact on public health, the economy, jobs, and American innovation. We look forward to your timely response and thank you in advance for it.

Most gratefully,



Anna G. Eshoo  
Member of Congress



Leonard Lance  
Member of Congress



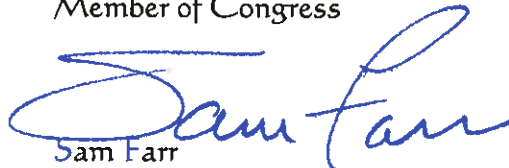
Doris Matsui  
Member of Congress



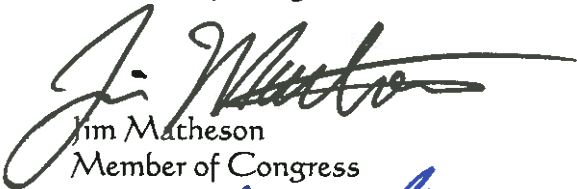
Mike Rogers  
Member of Congress



Henry Waxman  
Member of Congress



Sam Farr  
Member of Congress



Jim Matheson  
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Joe Barton  
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Jared Huffman  
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Bradley Schneider  
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Tony Cardenas  
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Eric Swalwell  
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