

Exempt FDA User Fees From Sequestration

November 14, 2013

The Honorable Paul Ryan
Chairman
House Committee on the Budget
207 Cannon House Office Building
Washington, DC 20515

The Honorable Patty Murray
Chairman
Senate Committee on the Budget
624 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairmen Ryan and Murray:

As state and regional life sciences associations representing biotechnology, pharmaceutical and medical device companies, universities, research institutions, and venture capital firms across the country, all dedicated to developing and delivering life-enhancing and life-saving products, we write to urge you to address the sequestration of FDA user fees in any upcoming budget agreement.

As you may know, in implementing the sequester, the Office of Management and Budget (OMB) inappropriately decided that both congressionally appropriated dollars and privately-paid industry user fees would be subject to sequestration. Approximately \$85 million in user fees have been sequestered in Fiscal Year 2013 alone. While we understand the need to reduce our nation's deficit, please know that sequestering these user fees will have no impact on the budget deficit because they are not taxpayer dollars. In addition, because privately-paid user fees, such as prescription drug and medical device fees, can only be used for the purpose stated in their authorizing legislation, the sequestered funds are simply sitting in an account at the Treasury Department, unused.

The sequestration of user fees is likely to delay the implementation of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), which was negotiated and enacted with the support of the FDA, industry, patient advocates, and provider groups. The bill established increased industry-paid user fees in exchange for the FDA's commitment to making critical improvements in such matters as product review and approval processes, regulatory science, product quality, and post-market safety evaluation. FDA Commissioner Margaret Hamburg has repeatedly said that the sequestration of user fees is likely to obstruct FDA's ability to fully achieve the goals and targets negotiated under FDASIA.

We recognize the fiscal challenges you face in crafting a budget agreement that must satisfy both sides of the aisle, and we commend you for your leadership. Please know that exempting FDA user fees from sequestration has strong and growing bipartisan support in both chambers and is a top priority of both industry and patient groups. Ensuring that the FDA can use the entirety of fees paid by the industry is a common sense fix that will enable the FDA to review new drugs, biologics, and medical devices in an efficient and timely manner, and achieve its mission of bringing safe, effective, and breakthrough therapies and treatments to patients in need.

Therefore, on behalf of our members, we respectfully urge you to permanently exempt Fiscal Year 2014 and future FDA user fees from sequestration in any forthcoming budget agreement.

Thank you for your consideration of our important request.


Sincerely,




Joan Koerber-Walker
President and CEO
Arizona BioIndustry Association, Inc.



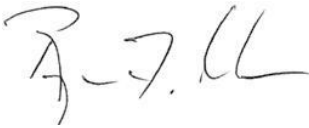
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President and CEO
BayBio (Northern California)



Joe Panetta
President and CEO
Biocom (Southern California)



Nancy K. Bryan
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Bryan Renk
Executive Director
BioForward (Wisconsin)



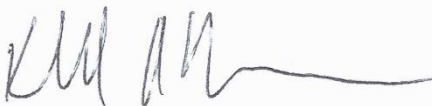
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BioNJ, Inc



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BioOhio



Claire Deselle
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Bioscience Association of Maine



Kimball Thomson
President and CEO
BioUtah



Todd Gillenwater
Senior Vice President, Public Policy
California Healthcare Institute



April Giles
President and CEO
Colorado BioScience Association



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CONNECT (San Diego)

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Florida Medical Manufacturers Consortium

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David Miller
President and CEO
Illinois Biotechnology Industry Organization

Peggy Welch
Executive Director
Indiana Medical Device Manufacturers Council

Rachel Hurley
Executive Director
Iowa Biotech Association

Angela Kreps
President and CEO
KansasBio

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Abby Trotter
Executive Director
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President and CEO
Massachusetts Biotechnology Council

Thomas J. Sommer
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MedTech (New York)



Stephen Rapundalo, PhD
President and CEO
MichBio



Samuel Taylor
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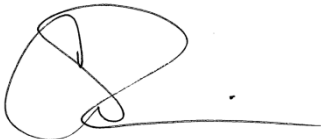
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Executive Director
South Dakota Biotech



Thomas R. Kowalski
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Texas Healthcare and Bioscience Institute



Jeffrey M. Gallagher
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Chris E. Rivera,
President and CEO
Washington Biotechnology & Biomedical
Association