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May 24, 2012

The Honorable Tom Harkin  
Chairman  
U.S. Senate Committee on Health, Education, Labor, and Pensions  
731 Hart Senate Office Building  
Washington, DC 20510

The Honorable Michael B. Enzi  
Ranking Member  
U.S. Senate Committee on Health, Education, Labor, and Pensions  
379A Russell Senate Office Building  
Washington, DC 20510

**Re: Oppose Amendment SA 2130 to the *Food and Drug Administration Safety and Innovation Act (S. 3187)***

Dear Senators Harkin and Enzi:

Public Citizen, representing more than 250,000 members and supporters nationwide, urges you and your colleagues to oppose Amendment SA 2130 to the *Food and Drug Administration Safety and Innovation Act (S. 3187)*, introduced by Senator Burr. This amendment would greatly politicize the process for negotiating user fee agreements between the Food and Drug Administration (FDA) and the drug and medical device industry, undermining the integrity of the process in ways that could threaten prescription drug and medical device safety.

The amendment introduced by Senator Burr would require that members of Congress or their designated staff be permitted to be present at any user-fee negotiation meeting conducted between the FDA and industry representatives. Attendance of members of Congress at such meeting would allow political considerations to directly and unduly influence these negotiations. With intensive lobbying of Congress by industry, such political influence would almost certainly weaken the negotiating position of the FDA and strengthen that of industry, thus tilting the negotiations in favor of industry interests, rather than the interests of protecting public health. Such circumstances would pose a danger to public health.

In light of the harmful effects this provision is likely to have upon public health and the safety of prescription drugs and medical devices, we strongly urge all Senators to oppose Amendment SA 2130.

Sincerely,

Michael A. Carome, M.D.  
Deputy Director  
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.  
Director  
Public Citizen's Health Research Group

Cc: U.S. Senators