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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 2132 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 2132 to the *Food and Drug Administration Safety and Innovation Act* (S. 3187), introduced by Senator Coburn. This amendment would weaken prescription drug and medical device safety by offering annual financial bonuses to Food and Drug Administration (FDA) scientific reviewers in exchange for speedier reviews of drugs and devices.

FDA scientific reviewers are responsible for protecting public health by ensuring the safety and effectiveness of new drugs and medical devices. The amendment introduced by Senator Coburn would undermine this critical public health mission by creating perverse incentives for agency reviewers to focus on the clock, rather than the scientific merits of an application for a new drug or device. Individual agency reviewers, aware that the potential awarding and size of annual financial bonuses is tied to faster reviews, will be more likely to take short cuts, compromise on scientific standards, and ignore potential unresolved concerns regarding safety, efficacy, and data quality. Such circumstances would threaten 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 2132.

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