AMERICANS for TAX REFORM

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COST OF GOVERNMENT CENTER

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The Honorable Tom Harkin
731 Hart Senate Office Building

The Honorable Fred Upton
2183 Rayburn House Office Building

The Honorable Mike Enzi
379A Russell Senate Office Building

The Honorable Henry Waxman
2204 Rayburn House Office Building

Dear Chairman Harkin and conferees,

As you begin negotiations to reauthorize the Food and Drug Administration (FDA) drug user fee and medical device programs we urge you to keep the ongoing battle to rein in government spending at the forefront of your mind. Specifically, we urge you not to leave any pay-fors that have already been agreed to in both bills off the table; both H.R. 5651 and S. 3187 offer innovative and important cost-savings for taxpayers.

We applaud both chambers for coupling the extension of the FDA and its user fee programs to sources of funding designed to pay for them. Through such efforts, the reauthorization bills received significant bipartisan support in both the House and the Senate. As conference commences, we encourage negotiators from both chambers and parties to work together to ensure that taxpayers receive the highest possible cost savings.

The primary difference between the House and Senate versions is the form of their pay-for mechanisms. The version passed by the House generates an estimated savings of $620 million over the next ten years by streamlining and shortening the process by which the FDA responds to citizen petitions. However, this option may be undercut by a Supreme Court ruling that overturns the President's health care law. As such, a conference report that does not also include the Senate's pay-for does not protect taxpayers from future costs down the road.

The Senate version gains savings by reforming the Risk Evaluation Mitigation Strategies (REMS) process to expedite generic drug development. The Congressional Budget Office estimates that encouraging this expansion of the generic drug market would net savings of $753 million over 10 years.

As the national debt continues to climb to $16 trillion, lawmakers should be eager to avail themselves of every possible cost-saving measure.

A combined bill would simultaneously streamline the process through which FDA responds to citizens while providing increased access to generic drugs. Simplifying how brand drug makers can release samples to generics manufacturers will increase the array of available products for Americans, bringing down healthcare costs. The combination of both pay-for mechanisms has great cost-savings potential and we urge lawmakers to include both options in the final bill.

Sincerely,

Mattie Duppler
Executive Director
Cost of Government Center