



Thomas A. Schatz
President

June 7, 2012

U.S. Senate
U.S. House of Representatives
Washington, D.C. 20515

Dear Conferee,

You will soon meet with your colleagues to reconcile the differences between S. 3187 and H.R. 5651, legislation that would reauthorize and modify the Food and Drug Administration's (FDA) prescription drug and medical device user-fee programs. On behalf of the more than one million members and supporters of the Council for Citizens Against Government Waste (CCAGW), I urge you to support these bills and adopt both the House and Senate version pay-for mechanisms.

While the House and Senate versions are similar, there are two notable differences in how each is paid for. H.R. 5651 would shorten the timeframe that the FDA has to respond to certain citizen petitions, a measure that would reduce mandatory spending by an estimated \$620 million over 10 years. However, this amount of savings is only possible if the Patient Protection and Affordable Care Act is upheld by the Supreme Court. If the bill is struck down, as we believe it should be, H.R. 5651 would in fact cost the government money. S. 3187, on the other hand, continues to generate savings regardless of the Supreme Court's determination and includes an important provision that would block drug makers covered by Risk Evaluation Mitigation Strategies (REMS) from restricting sample sales to generic-drug firms that agree to follow certain safety procedures approved by the FDA. The Congressional Budget Office estimates that this provision and others that would reduce market barriers for generics would reduce spending by \$753 million over 10 years.

Included as part of H.R. 3580, the Food and Drug Administration Amendments Act (FDAAA), which was signed into law in September 2007, REMS was established to control the distribution of drugs that have harsh side effects or pose grave health risks. While the FDAAA specifies that a REMS should not block generics from coming to market, drug manufacturers have used this rule to block the flow of drug samples to generic manufacturers, prohibiting the production of cost-saving generic alternatives and giving brand-name rivals a competitive edge. S. 3187 removes this loophole, saving consumers and taxpayers, who foot the bill for Medicare, Medicaid and similar programs, hundreds of millions of dollars.

At a time when the national debt exceeds \$15.7 trillion, members of Congress should seize every viable opportunity to save taxpayers' money. I strongly urge you to include both the House and Senate provisions that address citizens petitions and REMS in the final version of the bill in an effort to streamline and expedite the delivery of generic drugs into the marketplace, lower prices for consumers, and save taxpayers hundreds of millions of dollars. The only way that guaranteed savings can be achieved is if both cost-saving measures are implemented. All votes on S. 3187 and H.R. 5651 will be among those considered in CCAGW's 2012 *Congressional Ratings*.

Sincerely,

1301 Pennsylvania Avenue, N.W.
Suite 1075
Washington, D.C. 20004
202-467-5300