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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

BRUCE A. COHEN, *Chief Counsel and Staff Director*
KOLAN L. DAVIS, *Republican Chief Counsel and Staff Director*

October 13, 2011

The Honorable Patty Murray
Co-Chairman
Joint Select Committee on Deficit Reduction
United States Congress
Washington, DC 20510

The Honorable Jeb Hensarling
Co-Chairman
Joint Select Committee on Deficit Reduction
United States Congress
Washington, DC 20510

Dear Senator Murray and Representative Hensarling:

As the Joint Select Committee on Deficit Reduction considers measures to accomplish deficit reduction, we urge you to include our bipartisan pro-consumer legislation to remove barriers to generic drug competition, the Preserve Access to Affordable Generics Act, S. 27. Because it would increase the availability of low cost generic drugs to millions of Americans, this legislation has been scored by the Congressional Budget Office as saving the federal government over \$ 2.68 billion in reduced drug reimbursement payment in federal health programs over the next decade. The President's budget for FY 2012 estimated that adoption of our bill would save the federal government \$ 8.79 billion over the next decade.

Our bill would presume illegal so-called "pay for delay" pharmaceutical patent settlements. In these settlements, brand name pharmaceutical companies pay millions of dollars in cash or other valuable consideration to generic drug companies to settle drug patent litigation, in return for the generic drug company agreeing to withhold marketing its generic drug until the end, or shortly before, the expiration of the patent.

These pay for delay settlements deprive consumers of years of generic drug competition, while enriching both the generic drug company and the brand name manufacturer, which maintains its monopoly on the drug. However, consumers lose by paying substantially higher prices and the government loses by paying substantially higher drug reimbursement payments under Medicare and other federal health programs.

In the late 1990s, the FTC challenged several pay-for-delay agreements as being anti-competitive and shortly thereafter, the use of these agreements declined. From 2000 to 2004, patent cases continued to settle, but the settlements did not include payments to generic drug makers. Since 2005, however, three Circuit Courts of Appeal decisions have rejected these antitrust challenges, and held that the rights of patent holders make virtually any patent settlement permissible, even anti-competitive settlements, trumping antitrust law. And the effects of these court decisions were immediate - the FTC found that half of the settlements made in 2006 and 2007 between brand name and generic companies included a pay-off

from the brand name manufacturer in exchange for a promise from the generic company to delay entry into the market. These precedents have made it very difficult for the FTC to successfully challenge these pay-for-delay patent settlements. Our legislation would ensure that these anticompetitive pay-for-delay agreements are properly subject to antitrust scrutiny.

The Preserve Affordable Access to Generics Act is a balanced solution to addressing this problem. Under our legislation, these pay-for-delay agreements will be presumed illegal and the FTC will have to pursue legal action under the FTC Act to invalidate a settlement. During the proceeding, the drug companies will have the opportunity to prove to a judge by clear and convincing evidence that these agreements are pro-competitive. Significant penalties may be assessed against companies that enter into agreements which are found to be illegal. This legislation will therefore prevent anti-competitive pay-for-delay agreements while permitting settlements which truly do not harm competition.

In addition, we should stress that our bill would in no way prevent pharmaceutical patent settlements that do not contain pay for delay provisions. In FY 2010, the FTC reviewed 113 settlements agreements under the Medicare Modernization Act. Of those, 31 contained pay-for-delay provisions, of which 22 involved different drugs for a total of \$9.3 billion in U.S. sales. The 81 remaining settlements did not have a pay-for-delay provision in them. This data suggests that these cases can be settled without resorting to a pay-for delay agreement. Our legislation only targets those settlements that harm competition – pay-for-delay agreements in which cash or other valuable consideration is exchanged for delay in generic entry.

Our legislation passed the Senate Judiciary Committee with bipartisan support in both of the last two Congresses, most recently in July. By removing a significant barrier to the availability of generic drugs, this bill will reduce the federal deficit and benefit millions of consumers. We urge the Joint Select Committee to include our bill as part of any overall deficit reduction measure that you adopt.

Thank you for your consideration.



HERB KOHL

Chairman, Subcommittee on
Antitrust, Competition Policy
and Consumer Rights

Sincerely,



CHUCK GRASSLEY

Ranking Member, Committee on the
Judiciary

CC:

Senator Max Baucus
Senator John Kerry
Senator Jon Kyl
Senator Rob Portman
Senator Pat Toomey
Congressman Xavier Becerra
Congressman Dave Camp
Congressman James Clyburn
Congressman Fred Upton
Congressman Chris Van Hollen