May 17, 2012

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

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

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of our over 38 million members and all Americans who are age 50 and older, AARP urges you to capitalize on the opportunity that the Fair and Immediate Release of Generics Act ("FAIR GENERxICS Act of 2011") presents to lower drug costs for all consumers by including it in the Food and Drug Safety and Innovation Act. The bill will bring lower cost generic drugs to market sooner by preventing abuses stemming from patent settlements between generic and brand name prescription drug companies.

When the patent for a brand name drug has expired or is ruled invalid, generic manufacturers are able to bring their product to market. However, some generic and brand name drug manufacturers enter into settlement agreements that have upended the intent of the Hatch-Waxman Act – to expedite consumer access to generic medicines. These "pay-for-delay" settlements delay public access to generic drugs, costing consumers and taxpayers approximately $3.5 billion per year.

The root cause of "pay-for-delay" settlements is the Hatch-Waxman Act provision that grants a 180-day period of marketing exclusivity to the first generic manufacturer to submit an application for Food and Drug Administration approval. First-to-file generic manufacturers can agree to "park" this exclusivity as part of a patent settlement agreement, delaying market entry and effectively blocking other generic manufacturers from entering the market.

This legislation would grant shared exclusivity rights to any subsequent generic manufacturer who wins its patent case or is not sued for patent infringement by the brand pharmaceutical company, thus ending the problem of "parked" exclusivities. It would also create more certainty around litigation for brand name and generic companies by prohibiting brand name manufacturers from suing generic challengers for patent infringement outside the 45-day window provided under Hatch-Waxman.

We look forward to working with you to pass this important piece of bipartisan legislation. If you have any questions or need additional information, please do not hesitate to contact Ariel Gonzalez on our Government Affairs staff at (202) 434-3770 or agonzalez@aarp.org.

Sincerely,

Joyce Rogers
Senior Vice President
Government Affairs