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WASHINGTON – Today the U.S. Senate Judiciary Committee approved a bipartisan bill introduced by Senators Herb Kohl and Chuck Grassley to limit pay-for-delay settlements that keep lower-cost generic drugs off the market.

The Preserve Access to Affordable Generic Drugs Act would deter the brand name drug company practice of settling patent disputes by paying generic drug manufacturers in exchange for the promise that its generic version of the drug will be kept off the market. Under the bill, these anti-consumer pay-off agreements would be presumed illegal and the Federal Trade Commission would be given the authority to stop the agreements.

"Generic drugs save billions of dollars and keeping them off the market only hurts consumers and taxpayers," Kohl said. "This is an important step in making sure that there's no room in a competitive marketplace for these kinds of backroom deals."

"The wheeling and dealing between brand name and generic drug manufacturers simply lines the pockets of the manufacturers and costs taxpayers and consumers billions of dollars," Grassley said. "Our bill would end this practice of pay-for-delay and ensure that cheaper medicines can be made available sooner rather than later."

The Congressional Budget Office estimated that the bill will save the federal government – which pays approximately one-third of all prescription costs – \$2.68 billion over ten years. The President included a provision to end pay-for-delay settlements in his fiscal 2012 budget, estimated to save the federal government \$8 billion over 10 years. The Federal Trade Commission estimates that ending these settlements would save consumers who pay for prescription drugs through private insurance or on their own \$3.5 billion per year.

According to a study by the Pharmaceutical Care Management Association, health plans and consumers could save \$26.4 billion over the next five years by using the generic versions of 14 popular drugs scheduled to lose their patent protections.

Brand name drug companies and generic manufacturers routinely enter into settlement agreements to end drug patent litigation, but until 2005, none of them included pay-for-delay

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provisions. From 2000 to 2004, companies assumed such agreements violated antitrust law. But in 2005, following three courts of appeals decisions that prevented the Federal Trade Commission from taking action on behalf of consumers, pay-for-delay settlements became commonplace. In the four years after these court decisions, 63 out of 194 patent settlements had provisions in which the brand name drug company made payments to the generic manufacturer in exchange for the generic manufacturer agreeing to delay entry of generic competition.

For example, Cephalon Corporation was able to keep competition to their narcolepsy drug Provigil at bay for six years by paying \$136 million to four different competitors. Provigil sales in the U.S. at that time were more than \$3.1 billion. In another case, Bayer kept generic competition to its antibiotic Cipro off the market by paying \$400 million to three potential competitors, depriving consumers of a generic version for more than six years.

In fiscal 2010, there were a record 31 pay-for-delay settlement agreements that kept generics off the market, a 63 percent increase from 2009. This legislation passed the Judiciary Committee in late 2009 and was included in the Financial Services and General Government Appropriations bill reported out of the Senate Appropriations Committee last year. Final passage of the bill stalled when the House and Senate failed to agree on an Omnibus Appropriations package at the end of the last Congress.

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