## KOHL, GRASSLEY: STOPPING "PAY-FOR-DELAY" DEALS ESSENTIAL TO LOWERING RX DRUG COSTS

***Bipartisan effort to speed less expensive generic prescription drugs to market***

WASHINGTON, D.C. – U.S. Senators Herb Kohl and Chuck Grassley have reintroduced legislation limiting pay-for-delay settlements used to keep lower-cost generic drugs off pharmacy shelves. Under these pay-off agreements, brand name drug companies settle patent disputes by paying the generic drug manufacturer in exchange for a promise that it will keep its generic version of the drug off the market. Kohl and Grassley's "Preserve Access to Affordable Generics Act" will stop this anti-consumer practice by presuming these deals illegal, and giving the FTC the authority to stop them.

"Generic drugs save consumers and the federal government money, to the tune of billions of dollars a year. But in order to freeze out competition and delay entry of low cost generic drugs for consumers, brand-name drug companies pay-off generic manufactures to keep their products off the market. It is past time to put an end to these backroom deals and pass this bipartisan legislation," Kohl said.

"These agreements between generic and brand name pharmaceutical manufacturers are only serving to line the pockets of the companies. When people across the country are having a hard time making ends meet, this wheeling and dealing simply delays the entry of lower priced medicines into the marketplace, leaving consumers on the short end of the stick," Grassley said.

A compromise version of 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 last month.

The Federal Trade Commission has estimated that stopping these types of settlement agreements would save consumers at least $35 billion over the next ten years, and provide significant cost savings in the amount of $12 billion over ten years for the federal government, which pays approximately one-third of all prescription drug costs. A recent CBO report estimates that the federal government could save $2.68 billion over ten years, should this bill become law

Despite the FTC's opposition to pay-for-delay patent settlements, two 2005 appellate court decisions have permitted these payoffs. In the two years after these two decisions, the FTC has found nearly half of all patent settlements involved payments from the brand name from the generic manufacturer in return for an agreement by the generic to keep its drug off the market. According to a study by Pharmaceutical Care Management Association (PCMA), health plans and consumers could save $26.4 billion over the next five years by using the generic versions of 14 popular drugs that are scheduled to lose their patent protections before 2010.

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 provisions. From 2000 to 2004, companies assumed such agreements violated antitrust law. But in 2005, following three courts of appeals decisions that prevented the FTC from taking action on behalf of consumers, pay-for-delay settlements became commonplace. In the four years following 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. In 2009, there were a record 19 pay-for-delay settlement agreements that kept generics off the market.

Last Congress, Kohl served as chairman of the Senate Judiciary Subcommittee on Antitrust, Competition Policy, and Consumer Rights. Grassley is the incoming Ranking Member of the Judiciary Committee.

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