Preserve Access to Affordable Generics Act (S. 369)
Amendment #4332

The Preserve Access to Affordable Generics Act (S. 369), authored by Senator Herb Kohl (D-WI), will explicitly prohibit brand-name drug manufacturers from using pay-off agreements to keep cheaper generic equivalents off the market. This bipartisan bill is co-sponsored by Senators Chuck Grassley (R-IA), Russ Feingold (D-WI), Susan Collins (R-ME), Richard Durbin (D-IL), Byron Dorgan (D-ND), Bill Nelson (D-FL), Sherrod Brown (D-OH), Amy Klobuchar (D-MN), and Al Franken (D-MN). On October 15, 2009, a bill with the identical language passed out of the Judiciary Committee in a bi-partisan vote of 12 to 7.

"It is imperative that we pass this amendment [bill] to fight the backroom deals between brand name drug companies and generic drug companies that keep generics off the market and out of reach for consumers. The brand name drug companies win because they get rid of their competition. Generic drug companies win because they get paid without having to manufacture a product. And consumers lose because they have been robbed of a competitive marketplace." -- Senator Herb Kohl (12/10/2009)

Background

This legislation is in response to the resurgence of patent settlement agreements in which a generic firm agrees to keep its drug off the market in exchange for a payment from the brand-name pharmaceutical company. These pay-off settlements (also known as "reverse payments") delay consumer access to cost-saving generic drugs.

Settlement agreements arise in the context of patent infringement lawsuits filed against generic firms seeking to market generic versions of brand-name drugs. In the interest of promptly concluding the dispute, the parties may agree to a patent settlement setting forth terms and conditions by which the generic drug may be marketed. In some cases, patent settlement agreements can provide great benefit not only for the parties involved, by allowing them to avoid protracted litigation, but also for consumers, by speeding the entry of generic drugs that might otherwise have been deferred by the litigation.

Beginning in the late 1990's, however, these settlement agreements began to include agreements by the generic firms to stay off the market in exchange for payments from the brand-name firms. In 1999, the FTC challenged several pay-off agreements as being anti-competitive and, shortly thereafter, the use of these agreements declined. From 2000 to 2004, no patent settlements contained payments to generic companies. Unfortunately, in 2005, two appellate court decisions reversed FTC's long-standing position, and upheld settlements that include such pay-offs. The consequences of these court decisions were stark. The FTC has 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.

In 2006, the Supreme Court declined to hear an appeal from one of these decisions (the Shering-Plough case) and left in place the appellate court precedent that have undermined the FTC's ability to halt these anti-consumer settlements.

Legislation

The bill, passed by the Judiciary Committee (12 to 7) on October 15, 2009, will help prevent "pay-for-delay" patent settlements that eliminate generic drug competition and strengthen the FTC's ability to challenge such agreements in court.

The bill as originally introduced would have imposed an absolute ban on these settlements. At the request of several colleagues, the bill was changed during Judiciary Committee consideration to address their concerns that categorically banning all such settlements would reach too far. Under the compromise, pay-for-delay agreements would be presumed illegal – but the FTC would need to pursue legal action to challenge an agreement, as they currently do now. The process would work similar to how it does now. First, the drug companies, as required under the Medicare Modernization Act of 2003, must submit the final settlement agreement to the FTC and DOJ for review. The FTC, having jurisdiction over pharmaceutical antitrust issues, would then investigate the settlement agreement and decide whether it involves exchange of consideration that is not exempted by our bill (i.e. payment of something of value to the generic company to stay off of the market). If the FTC found that it did, it would initiate an action either in Federal district court or before an independent administrative law judge. Then the drug companies would have to convince a judge by clear and convincing evidence that the agreement is pro-competitive. The companies could appeal an adverse decision to the Court of Appeals. If the companies cannot show that their agreement is procompetitive, the FTC will have the authority to assess significant civil penalties.

This legislation strikes the right balance. It will deter drug companies from entering into anti-competitive and anti-consumer settlements, but it also gives them the opportunity to pursue agreements which truly do not harm competition.

Cost-Savings

Passage of this bill will end an egregious practice that costs consumers and government billions of dollars in higher drug costs, and denies us the benefits of generic drug competition. At this time when we are all trying to find ways to save costs in our health care system, this bill will go a long way by saving us billions of dollars a year.

According to estimates by the Congressional Budget Office, generic drugs save consumers between $8 and $10 billion each year. In 2007, the average retail price of a generic prescription drug was $ 34.34, while the average retail price of a brand name drug was $ 119.51. According to a 2007 study by the 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.

In June, the FTC found that by stopping these settlements in order to facilitate earlier access to generic drugs, we could save consumers $35 billion dollars. The CBO estimates that over 10 years, this legislation will reduce direct spending by $1.8 billion, increase revenue by $0.2 billion, and reduce spending subject to appropriation by $0.2 billion.