Testimony of

The Honorable Patrick Leahy

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In April, Senator Grassley and I re-introduced the Drug Competition Act of 2001 (S. 946), joined by Senators Cantwell, Durbin, Feingold, Kohl and Schumer. This bill passed the Senate by unanimous consent last November, and I hope that in this Congress it is actually enacted into law. Prescription drug prices are rapidly increasing, and are a source of considerable concern to many Americans, especially senior citizens and families. Generic drug prices can be as much as 80 percent lower than the comparable brand name version.

While the Drug Competition Act is small in terms of length, it is large in terms of impact. It will ensure that law enforcement agencies can take quick and decisive action against companies that are driven more by greed than by good sense. It gives the Federal Trade Commission and the Justice Department access to information about secret deals between drug companies that keep generic drugs off the market. This is a practice that hurts American families, particularly senior citizens, by denying them access to low-cost generic drugs, and further inflating medical costs.

I am very happy to see Chairman Muris before the Committee today, for it was the Federal Trade Commission that played such an important role in exposing the issue of drug companies paying their generic competitors - and potential competitors - not to enter the marketplace. While the FTC has sued pharmaceutical companies that have made such secret and anticompetitive deals, as the then-Director of the Bureau of Competition Molly Boast testified before the Judiciary Committee in May 2001, the antitrust enforcement agencies are only finding out about such deals by luck, or by accident.

In fact, last fall the FTC released its long-awaited report on the entry of generic drugs into the pharmaceutical marketplace - the report that we are discussing here this morning. The FTC had two recommendations to improve the current situation and to close the loopholes in the law that allow drug manufacturers to manipulate the timing of generics= introduction to the market. One of those recommendations was simply to enact our bill, as the most effective solution to the problem of Asweetheart@ deals between brand name and generic drug manufacturers that keep generic drugs off the market, thus depriving consumers of the benefits of quality drugs at lower prices. In short, this bill enjoys the unqualified endorsement of the current FTC, which follows on the support by the Clinton Administration=s FTC during the initial stages of our formulation of this bill. We can all have every confidence in the common sense approach that our bill takes to ensuring that our law enforcement agencies have the information they need to take quick action, if necessary, to protect consumers from drug companies that abuse the law.

Under current law, the first generic manufacturer that gets permission to sell a generic drug before the patent on the brand name drug expires, enjoys protection from competition for 180 days B a headstart on other generic companies. That was a good idea B but the unfortunate loophole exploited by a few is that secret deals can be made that allow the manufacturer of the generic drug to claim the 180 day grace period B to block other generic drugs from entering the market B while, at the same time, getting paid by the brand name manufacturer not to sell the generic drug.

Our legislation closes this loophole for those who want to cheat the public, but keeps the system the same for companies engaged in true competition. I think it is important for Congress not to overreact and throw out the good with the bad. Most generic companies want to take advantage of this 180 day provision and deliver quality generic drugs at much lower costs for consumers. We should not eliminate the incentive for them. Instead, we should let the FTC and Justice look at every deal that could lead to abuse, so that only the deals that are consistent with the intent of that law will be allowed to stand. The Drug Competition Act accomplishes precisely that goal, and helps ensure effective and timely access to generic pharmaceuticals that can lower the cost of prescription drugs for seniors, for families, and for all of us.

The second recommendation made in the FTC report is also of vital interest this morning, particularly given the FDA's new generic drug rule. The FTC suggests a modification of Hatch-Waxman to allow brand name drug companies to receive only one 30-month stay of FDA approval per new generic drug product to resolve patent infringement disputes. Allowing only one 30-month stay will dissuade brand name companies from filing frivolous patents with the FDA. Under current law, there is an incentive to obtain as many patents as possible for a drug, as these companies could use multiple patents to receive multiple stays of FDA approval, preventing cheaper generic drugs from reaching our local pharmacies. This issue has been dealt with extensively in the HELP Committee, and I will be a co-sponsor of the Gregg-Schumer-McCain-Kennedy bill which would limit the number of stays prescription drugs can receive.

I look forward to hearing from all of the panelists about the state of the prescription drug market and will be interested in hearing their suggestions for improving our drug patent laws. Overall, the Hatch-Waxman Act has done a superb job in speeding generic drugs to the market while protecting the patent rights of the brand name companies. Working in a bipartisan manner, we have the potential to save consumers billions in prescription drug costs by closing the few loopholes that have been discovered since the bill's passage eighteen years ago. I look forward to hearing what our witnesses have to say this morning, and I thank Senator Hatch for convening a hearing on an issue that has such an impact on the physical health and fiscal well-being of all our citizens.

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