Statement of
The Honorable Patrick Leahy
United States Senator
Vermont

January 17, 2007

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Senate Judiciary Committee
Hearing On "Paying Off Generics to Prevent Competition with Brand Name Drugs: Should It Be Prohibited?"

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This hearing today is a continuation of a longstanding, bipartisan effort by several members of this Committee to provide consumers more choices and lower-cost medicines. My focus in this hearing is on making lower-cost generic medicines available to our seniors and families, based on provisions of existing law which I think are being misused by some brand-name and generic drug companies. The fact that we have scheduled this hearing so early in this new Congress is a sign that solving this problem will be the high priority for this Committee that it deserves to be, and that consumers want it to be.

We will be examining the harmful effects of a type of collusion that limits consumer choices and that keeps consumer prices artificially high. Rarely do we have such a clear-cut opportunity as this to remove impediments that prevent competition and the marketplace from working as they should, to benefit consumers.

The basics of this issue are very simple: Congress never intended for brand-name drug companies to be able to pay off generic companies NOT to produce generic medicines. That would be a shame, harmful to consumers, and a crime.

In fact, the history and text of the Hatch-Waxman laws make it clear that the OPPOSITE of delay was the goal.

It is no secret that prescription drug prices are rising and are a source of considerable concern to many Americans, especially senior citizens and working families. In a marketplace free of manipulation, generic drug prices can be as much as 80 percent lower than the comparable brand name version.

In June of last year I sponsored a bill, introduced by Senator Kohl, and also sponsored by Senators Grassley, Schumer, Feingold and Johnson, which would have stopped these payoffs to delay access to generic medicines. Working with Senators Kohl and Grassley and with many others, we will try to enact a new version of that bill.

It is unfortunate that we even have to do this. However, as I said in June, there are still some companies driven by greed that may be keeping low-cost, life-saving generic drugs off the marketplace, off pharmacy shelves, and out of the hands of consumers, by carefully crafted anti-competitive agreements.

Since some of these deals used to be done in secret, I am glad that because of a bill that was reported out of this Committee, Congress is now aware of this problem. In 2001, I worked with Chairman Hatch and later with Senator Grassley to make sure that our law enforcement agencies – the Federal Trade Commission and the Department of Justice – at least were made aware of these secret, and potentially criminal, deals.

The New York Times and others published major investigative stories on how the manufacturer of a hypertension drug to help prevent strokes and heart attacks -- Cardizem CD -- had made deals to pay a

potential generic competitor $10 million every three months to stop it from developing a generic version of Cardizem. This led to my introduction of S. 754 – the Drug Competition Act -- which was reported out of this Committee and was finally passed as part of the Medicare Modernization Act Amendments with significant assistance from Senator Grassley.

The concept of that law is simple: It requires that if a brand-name company and a generic firm enter into an agreement that is related to the sale of either the brand named drug or its generic version, then both companies must file copies of any agreements with the FTC and the DOJ so those agencies can enforce the law. Incidentally, once the Cardizem deal was exposed and challenged, the U.S. Circuit Court held that the "the horizontal market allocation agreement . . . [was] per se illegal under the Sherman Act."

Today, Commissioner Leibowitz will testify about what the FTC has found regarding these deals between brand-name companies and generic competitors, as revealed through the provisions of the Drug Competition Act, and the harm done to the public.

I will once again strongly support an effort by Senators Kohl and Grassley to allow the FTC to do its job. Two subsequent Circuit Court decisions have undermined the Cardizem approach and relied on the general rule favoring settlements between private litigants. The problem -- with respect to deals not to compete -- is that the interests of millions of senior citizens, millions of children, and millions of others – are not taken into account. Those cases ignore the decision in Associated General in which the U. S. Supreme Court noted that "the Sherman Act was enacted to assure our customers the benefits of price competition . . . ." Note the focus is on consumers, not on whether private companies should be able to make back-room deals that harm consumers as part of a settlement of a lawsuit.

Our bipartisan bill will solve that problem by making payments by brand-name companies, to delay introduction of a generic drug, unlawful. My initial position is to follow this bright-line approach to avoid endless litigation and set forth a clear standard. I will be interested in hearing from others on possible solutions, so long as the interest of the public in accessing these life-saving medicines is paramount. That has been, and will continue to be, my top priority.