Oral Statement of Commissioner Jon Leibowitz
Hearing of the Senate Judiciary Committee
January 17, 2007

Chairman Leahy, Ranking Member Specter, and Members of the Committee, we applaud your early hearing on legislation to ensure that consumers continue to have access to low-priced generic drugs. It is critical to eliminate the pay-for-delay settlement tactics employed by the pharmaceutical industry. Simply put, companies should not be able to play "deal or no deal" at the expense of American consumers.

Mr. Chairman, I am particularly honored to return to the Committee for which I worked for so many years.

But let me start with the usual disclaimer: the written statement we submitted represents the views of the Commission; my oral testimony today reflects my own views and not necessarily the views of any other Commissioner.

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possibly earn. As a result, with these agreements, both firms are better off than they would be if they competed.

Of course, consumers are left holding the bag. Or, more precisely, footing the bill.

For the past decade, the FTC has made challenging these pharmaceutical patent settlements a bipartisan priority. In 2000 and 2001 the Commission obtained two major consent decrees involving anticompetitive payments between brands and generics. We put pharmaceutical companies "on notice" that we would consider *all* available remedies – including disgorgement of profits – against this behavior in the future.

Our actions stopped this conduct cold. And the Commission set forth rules that everyone understood: if you settle a case by paying off a generic to stay out of the market, we will not let you get away with it. As a result, to the best of our knowledge there were dozens of settlements between 2000 and 2005 – and no exclusion payments.

In 2003, the Commission ruled that a 1997 settlement with a payment from Schering Plough (the brand) to Upsher-Smith (the generic) violated the antitrust laws. The case involved a potassium supplement widely used by older Americans taking medication for high blood pressure and heart disease. The Eleventh Circuit reversed us in 2005. The Second Circuit, in a 2-1 decision in the Tamoxifen case, issued a similar holding later that year. These decisions, which essentially allow a patent holder to compensate a generic except under very limited circumstances, have dramatically altered the legal landscape – we believe, to the detriment of consumers.

Mr. Chairman, how do we know this to be accurate? Thanks to the reporting requirement that you included in the 2003 Medicare Modernization Act – Congress passed this law, presumably, because you were troubled by these agreements – the FTC reviews each and every Hatch-Waxman settlement. Tellingly, here's what the data for the last few years reveals.

For fiscal year 2004 and the early part of fiscal year 2005, *none* of the nearly twenty agreements reported between brands and generics contained both a payment from the brand and an agreement to defer generic entry (see Chart I). In other words, parties could – and did – settle patent litigation without money flowing to the generic.

But data from fiscal year 2006, which we released just this morning and reflects agreements reached *after* the Schering and Tamoxifen decisions, is far more disturbing. Half of all settlements – 14 out of 28 – involved some form of compensation to the generic and an agreement by the generic not to market its product for a period of time. Almost all of the settlements with first-filers – 9 out of 11 – involve similar restrictions.

In other words, just before *Schering* and *Tamoxifen*, there were no such payments; just after these decisions, it appears to be the new way of doing business.

These settlements with first filers are especially problematic because they may create a bottleneck for other generics that want to enter (see Chart II).

Mr. Chairman, given how profitable these agreements are for both the brands and the generics, it is not surprising that the industry has reacted so quickly to recent court decisions. After all, they do have responsibilities to their shareholders.

Nor should it be hard to predict what will happen if nothing changes. There will be more and more of these settlements with later and later entry dates. No longer wiDcDee