**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.

There is particular urgency to pharmaceutical competition issues today. Recent appellate decisions are making it difficult to challenge so-called exclusion payments; that is, patent settlements in which the brand name drug firm pays the generic to stay out of the market.

If these decisions are allowed to stand, drug companies will enter into more and more of these agreements, and prescription drug costs – which slowed in 2005 after years of precipitous growth – will likely begin to rise rapidly again. These increased costs will burden not only individual consumers but also the federal government's new Medicare drug program, state governments, and American businesses striving to compete in a global economy – like General Motors, which reports that employee health care costs add $1500 to the price of each car that rolls off its assembly line.

Mr. Chairman, as our 2006 patent settlement report released today confirms, this is not just a theoretical concern. In the past year, we have a seen a dramatic increase in these types of settlements.

When Congress enacted the Hatch-Waxman statute in 1984, you encouraged speedy introduction of generics by establishing mechanisms to challenge invalid or narrow patents on branded drugs. This statutory framework ensures that our pioneer drugs firms remain the envy of the world – and they are – while also delivering enormous consumer savings. When the first generic enters the market, it generally does so at a 20 to 30 percent discount off the brand price. Prices drop even further – by 80 percent or more – after other generic competitors go to market, usually six months later. Generic competition following successful patent challenges to just four products – Prozac, Zantac, Taxol, and Platinol – is estimated to have saved consumers more than $9 billion dollars alone.

But those benefits will be at risk – as will the Hatch-Waxman Act itself – if companies are able to settle patent litigation through arrangements in which brands can pay generics to sit it out. Sadly, the incentives to enter into such pernicious pay-for-delay agreements are substantial – because generic entry causes the branded drug firm to lose far more in sales than the lower-priced generic could ever

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 will generic companies vie to be the first to bring a drug to market; instead, they will vie to be the first to be paid not to compete.

From our perspective, we'll continue to be vigilant in looking for ways to challenge anticompetitive settlements. It is a matter of public knowledge that we're looking to bring a case that will create a clearer split in the circuits and encourage the Supreme Court to resolve this issue. But that could take years, and the outcome is uncertain.

A legislative approach could provide a swifter, more certain, and more comprehensive solution. For that reason, we strongly support legislation to prohibit these anticompetitive payments, and we strongly support the intent of the bipartisan bill introduced by Senators Kohl, Leahy, Grassley, and Schumer, which takes a bright-line approach to prohibiting these deals. Drafting such a measure is challenging, so we're happy to work with you as the bill moves forward.

Mr. Chairman, we do have enormous respect for the pharmaceutical industry, both brands and generics. Brand drug companies pursue hundreds of unsuccessful candidates for each one that comes to market – Pfizer's unexpected failure with a cholesterol lowering drug late last year is a stark reminder of the risks they face – and these companies have brought significant health benefits to consumers. For their part, generic drug companies have produced low-cost pharmaceuticals and pushed the brands to innovate even faster.

And we are not opposed to all settlements – let me briefly dispel that urban myth. And we have brought only a handful of cases involving pharmaceutical settlements – and none involving deals between 2000 and 2004 – that is, before *Schering*.

But we do not – and can not – support settlements when brands and generics resolve their disputes at the expense of consumers.

Mr. Chairman, at a time when our nation faces the challenge of rising health care costs, the antitrust laws – and the Hatch-Waxman Act – should be used to ensure innovation and lower prices. They should not be used to undermine competition and, we believe, congressional intent.

Thank you.