Oral Statement of FTC Commissioner Jon Leibowitz
Hearing of the House Subcommittee on Commerce,
Trade, and Consumer Protection,
Committee on Energy and Commerce
May 2, 2007

Chairman Rush, Chairman Dingell, Chairman Waxman, Ranking Member Stearns, and Members of the Subcommittee, thank you so much for inviting the FTC to testify. Simply put, we believe that H.R.1902 is a fundamentally sound approach to eliminate the pay-for-delay settlement tactics employed by the pharmaceutical industry that could cost American consumers (and the federal government) billions of dollars annually.

But let me start with the usual disclaimer: The written statement we submitted represents the views of the Commission; my oral testimony does not necessarily reflect the views of any other Commissioner. Mr. Chairman, I ask unanimous consent to put the Commission's written statement into the Record and to have eight minutes for my oral remarks.

There is particular urgency to pharmaceutical competition issues today. Recent appellate decisions are making it difficult to challenge so-called exclusion payments – or reverse 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 will continue to rise rapidly. Indeed, in the past year, we have seen a dramatic increase in these types of deals – from none in fiscal year 2004 to more than a dozen in FY 2006.

These increased costs will burden individual consumers. They will burden American businesses striving to compete in a global economy. And they will burden the federal government which, with the new Medicare Part D program, paid an estimated 68 billion dollars – or 32 percent – of the nation's 214 billion dollars in annual drug purchases last year.

Now, when Congress enacted the Hatch-Waxman statute in 1984, this Committee promoted the speedy introduction of generics by encouraging challenges of invalid or narrow patents on branded drugs, while providing additional protections for innovator firms [such as patent restoration]. This statutory framework ensured that our pioneer drugs companies remain the envy of the world – and they are – while also delivering enormous consumer savings.

Generic entry prior to patent expiration has played an instrumental role in helping Americans afford the medicine they need. The first generic usually enters the market at a 20 to 30 percent discount off the brand price. When other generics enter, the price can drop by 80% or more.

Indeed, according to the Generic Pharmaceutical Association's own study, 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 before the expiration of the brands' patents.

Those savings will be lost, however, if brands are given a green light to pay the generics to "sit it out."

Sadly, the incentives to enter into these "pay-for-delay" deals 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 by competing.

It's a win-win deal for the companies. But it's a lose–lose proposition for consumers, who are left footing the bill.

Over the past decade, a unanimous Commission – six Republicans, four Democrats and one independent – has made stopping these harmful settlements a bipartisan priority. In 2000 and 2001 the Commission obtained two major consent decrees preventing anticompetitive payments from brands to generics.

Our actions stopped this conduct cold. And the Commission set forth rules that everyone understood: if you settled a case by paying off a generic, we would not let you get away with it. There were dozens of settlements between 2000 and 2005 – and no exclusion payments.

Recent court decisions have changed the dynamic, though, inviting parties to enter into these anticompetitive deals. In 2003, the Commission ruled 5-0 that a 1997 settlement involving a payment from Schering Plough (the Brand) to Upsher-Smith (the generic) violated the antitrust laws. The case involved a drug widely used by older Americans. The Eleventh Circuit reversed us in 2005. Later that year, the Second Circuit, in a 2-1 decision in the Tamoxifen case, issued a similar holding. These decisions essentially allow a patent holder to compensate a generic except under very limited circumstances.

As a result, the exclusion-payment problem is almost certainly growing.

Mr. Chairman, how do we know this to be true? Thanks to the reporting requirement that this Committee included in the 2003 Medicare Modernization Act – presumably you did so because you were troubled by these agreements – the FTC reviews every Hatch-Waxman settlement.

Tellingly, here's what the data for the last few years reveal.

As you can see from the chart, for fiscal year 2004 and the early part of fiscal year 2005, *none* of the nearly 20 agreements reported between brands and generics contained both a payment from the brand and an agreement to defer generic entry.

But data from fiscal year 2006, which reflects agreements reached *after* Schering and Tamoxifen, is very disturbing. Half of all settlements – 14 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 of 11 – involved similar restrictions.

As you know, Mr. Chairman, these settlements with first filers can create a "bottleneck" that may make it impossible for other generics to enter.

In sum, just before *Schering* and *Tamoxifen*, there were no reverse payments; now it is becoming the new way of doing business.