Oral Statement of Commissioner Jon Leibowitz
Hearing of the Senate Special Committee on Aging

July 20, 2006

Chairman Smith, Ranking Member Kohl, and Members of the Committee, protecting competition in the pharmaceutical sector has been and continues to be a mainstay of our work at the FTC. Your hearing is both timely and important, and we appreciate the opportunity to testify. 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 does not necessarily represent the views of the Commission or of any other individual Commissioner.

The savings that generic drugs offer are particularly important for older Americans. Research indicates that 87 percent of persons aged 65 and older take at least one prescription drug on a regular basis. On average seniors take four different prescription drugs daily. Persons over 65 – only 13 percent of the population – account for 42 cents of every dollar spent on prescription drugs.

There is a particular urgency to pharmaceutical competition issues right now. Recent decisions by some appellate courts are making it difficult to challenge agreements that delay generic competition. If these decisions are allowed to stand, prescription drug costs – already the fastest growing segment of our nation's spending on health care – will rise even more dramatically. These increased costs will burden not only individual consumers – especially older Americans – but also the federal government's new Medicare Part D drug program; state governments trying to provide access to health care with limited public funds; and American businesses striving to compete in a global economy.

In my oral remarks this morning, I will focus primarily on what are called "exclusion payments." By this, I mean settlements of patent litigation in which the brand name drug firm pays a generic challenger to stay out of the market. I will then touch briefly on two other issues: "bottlenecks" that keep subsequent generic filers off the market and so-called "authorized generics" – that is, generics that the brand itself introduces.

Mr. Chairman, when Congress enacted the Hatch-Waxman statute in 1984, it encouraged speedy introduction of generics by establishing mechanisms to challenge invalid or narrow patents on branded drugs. This statutory framework, while ensuring that our pioneer drugs firms remain the envy of the world – and they are – has also delivered enormous consumer savings. Indeed, as a general matter, when the first generic enters the market it does so at a 20 to 30 percent discount off the brand price. Prices drop even further – perhaps by as much as 50 to 80 percent – after other generic competitors go to market, usually six months after the first generic entrant. 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.

The consumer and government savings that result from generic entry will be lost, however, if companies settle through arrangements in which they share the monopoly profits that are preserved by delay. Sadly, the incentives to enter into such pernicious settlements are substantial – because generic entry causes the branded drug firm to lose far more in sales than the lower-priced generic earns. As a

result, if the companies agree to delay entry and share profits, 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 patent settlements that delay generic entry a bipartisan priority. In the late 1990's, when we started seeing these disturbing pharmaceutical settlement payments, we acted to stop them. The Commission obtained (in 2000 and 2001) two major consents involving anticompetitive payments between brands and generics. And we put pharmaceutical companies on "notice" that we would consider *all* available remedies – including disgorgement of profits – against this conduct in the future.

Our actions stopped this conduct cold. And it set forth rules that everyone understood: if you settle a pharmaceutical patent case by paying off a generic, you will face antitrust scrutiny. As a result, to the best of our knowledge there were no such settlements between 2000 and 2004.

The Commission ruled in 2003 that a 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 and the Second Circuit, in a 2-1 decision in the Tamoxifen case, issued a similar opinion later that year. These decisions, which essentially hold that a patent holder has a right to compensate a generic except where the brand's infringement suit is a sham, have dramatically altered the legal landscape, we believe, to the detriment of consumers.

Mr. Chairman, this is not idle speculation. Thanks to the reporting requirement that Congress included in the 2003 Medicare Modernization Act – you passed this law, presumably, 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 reveals.

For fiscal year 2004 and the early part of FY05 – *none* of the nearly twenty agreements reported between brands and generics contained a payment from the brand to the generic accompanied by deferred generic entry. In other words, parties can – and did – settle patent litigation without money flowing to the generic.

In sharp contrast, though the most recent data from the first half of fiscal year 2006 – reflecting agreements *after* the Schering and Tamoxifen decisions – is far more disturbing. Seven of ten agreements between brands and generics during this period included a payment from the brand and an agreement to defer generic entry.

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.

From our perspective, we'll continue to be vigilant in looking for ways to challenge anticompetitive settlements, and I hope the Supreme Court will eventually weigh in on this problem. A legislative approach, however, could provide a swifter and more comprehensive solution. For that reason, we strongly support the intent behind the "Preserve Access to Affordable

Generics Act" (S. 3582) – the bipartisan bill introduced by Senators Kohl, Leahy, Grassley, and Schumer. Drafting such a measure is challenging, so we're happy to work with you as the bill moves forward.

Let me briefly raise two other issues. The first is yet another strategy that thwarts consumer access to generic drugs and which, we believe, undermines Congressional intent. We discuss this "bottleneck" issue in detail in our written submission – and it involves legal complexities unique to Hatch-Waxman. But translated into plain English, it boils down to this: subsequent generics are supposed to have an alternative way to enter the market when the first generic delays its own entry. Instead, because of recent case law, they're stuck in a pharmaceutical "Catch 22": the courts won't let them bring a patent challenge, and the FDA won't let them market without winning one. It's a sort of drug purgatory, one that results in considerable delays for consumers. We made a legislative recommendation to solve this problem in 2002 and it's in our written statement.

The second matter is authorized generics – a product, chemically identical to the brand drug, that the brand firm introduces as its own generic. In recent years, brand firms have increasingly begun to market authorized generic drugs at precisely the same time that the first generic entrant begins its 180-day exclusivity period. In the short run, the entry of an authorized generic may benefit consumers by creating additional competition that lowers prices. Critics assert, however, that in the long term consumers will be harmed because competition from authorized generics – and the significantly lower profits that result – will decrease the incentives of generic firms to pursue entry, especially for non-blockbuster drugs. At the Commission, we are undertaking a study to examine the competitive effects of authorized generics.

Mr. Chairman, at a time when this nation faces the challenge of ever-mounting health care costs, ensuring that seniors – and other consumers – have access to low-cost pharmaceuticals is a matter of critical concern. The FTC is committed to doing whatever we can to promote drug competition. We stand ready to assist your Committee.

Thank you.