

**J. Thomas Rosch
Commissioner, Federal Trade Commission**

Oral Statement Before the

**Subcommittee on Commerce, Trade, and Consumer Protection
Committee on Energy and Commerce
United States House of Representatives**

on

**“How Pay-For-Delay Settlements Make Consumers and the
Federal Government Pay More For Much Needed Drugs”**

March 31, 2009

Chairman Rush, Ranking Member Radanovich, and distinguished members of the Subcommittee, I am Tom Rosch, a Commissioner of the FTC. I appreciate the chance to appear before you today. The written statement we submitted today represents the views of the Commission. My oral testimony is my own and doesn't necessarily reflect the views of any other Commissioner.

There are several compelling reasons why it's imperative that Congress enact legislation in this area. Reverse payment agreements strike at the heart of the special statutory framework Congress created in the Hatch-Waxman Act. That framework was designed to balance two policy goals that are critically important to the pharmaceutical industry. Hatch-Waxman gave branded companies a longer patent life – up to five additional years from regulatory delays (brands can get additional FDA exclusivity periods for drugs that have particularly limited sales potential). The trade-off was that generic companies were given a strong incentive to challenge questionable brand patents and to start competing with the branded companies if they win – 180 days of generic exclusivity. In this way, generic companies were supposed to protect consumers from unwarranted patent monopoly pricing by branded companies.

division agreements should be permissible to settle patent litigation. For example, the Eleventh Circuit's *Schering* decision, in which the circuit court declined to follow *Palmer* or *Cardizem*, emphasized that its decision was based on "policy." But Congress is the body with the responsibility to set patent policy. In short, the courts have disturbed the balance Congress struck in Hatch-Waxman by permitting reverse payment settlement agreements, and Congress should correct that imbalance.

Congress shouldn't wait for the Supreme Court to review these erroneous judicial decisions either. There f000 Tcom0.00 0.00 0.00 rgpae

who have served the agency in the decade of enforcement here have opposed these deals. And all four of us on the current Commission strongly support your legislation to ban these anticompetitive agreements. Thank you.