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.

But reverse payment agreements frustrate the purpose of Hatch-Waxman in two ways: first, these settlements incentivize the generic to abandon the patent challenge, leaving a suspect patent intact for the entire extended patent period; second, they may incentivize the generic to challenge patents that shouldn't be challenged (in hopes of getting paid off for settlement). In other words, these anticompetitive agreements have ended up vitiating the incentives for generics to protect consumers and instead can result in generics feathering their own nests: by virtue of the reverse payment settlement agreement the brand can stop the generic's challenge and thus doesn't lose its patent monopoly even if its patent is invalid or not infringed. The generic meanwhile can get a share of the brand's monopoly profit in the form of the reverse payment. But the consumer (including the federal government) ends up being a huge loser since consumers continue to pay monopoly prices until the generic starts to compete. This is demonstrated in the pie chart on page 12 of the Commission's written remarks. A good example is our *Cephalon* case, where the CEO of the brand boasted that his deals generated an additional four billion dollars in sales. Most of the profits from those sales will come from the consumers' pockets. Now, imagine if there are 10, 15 or even more of these settlements each year.

Beyond that, on their face, reverse payment agreements are market division agreements between potential competitors (the brand and the generic). That's why the Sixth Circuit in the *Cardizem* case held that they were *per se* illegal. That is consistent with the 1990 Supreme Court *Palmer* case, which held that market division agreements between potential competitors are *per se* illegal. So reverse payment agreements not only violate the purpose of Hatch-Waxman, but also seemingly violate the *Palmer* holding.

So why am I here? Supporting Congressional legislation? Recent circuit court decisions have ignored *Palmer* and *Cardizem,* substituting their own judicial policy judgments that market

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's no reason to think the Court will set things right anytime soon. It has declined to review both *Schering* and *Tamoxifen* (which followed *Schering*), and the petition currently before the Court in *Cipro* (the most recent of these decisions) suggests that the Supreme Court defer ruling on the petition until the parties file a petition in a parallel action. More important, however, *Cipro* represents the extreme case: it holds that reverse payment settlements are, in effect, *per se legal*. Even if the Court concludes that *Cipro* is wrong and that reverse payment agreements are not *per se* legal, that still leaves open the question whether, as *Schering* and *Tamoxifen* held, the strength of the patent is a *threshold* issue that must be litigated before the public or private plaintiff can litigate the antitrust merits.

I've said publicly that litigating the strength of the patent may be one way to avoid *Schering* and *Tamoxifen*. But I'll be the first to admit that may be costly and duplicative. Hatch-Waxman contemplated that the generic would litigate the strength of the patent, not public or private plaintiffs too.

Finally, I want to emphasize that this is an area of bipartisan support at the Commission that has withstood changes in administration and changes in Chairmanship. I am a Republican. All eleven past and present Commissioners – Republicans, Democrats, and an Independent –

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.