STATEMENT OF CHAIRMAN JON LEIBOWITZ ON THE RELEASE OF THE COMMISSION'S INTERIM REPORT ON AUTHORIZED GENERICS

I commend staff for its excellent work in preparing this Interim Report. I am also grateful to Senators Rockefeller, Leahy, and Grassley and Representative Waxman for requesting the study. Providing professional, careful, and unbiased factual information and economic analysis on issues of public policy is one of the Commission's most critical roles. Here, in Chapter One, the Interim Report uses more data and provides a far more thorough analysis of pharmaceutical competition involving AGs during the 180-day marketing exclusivity period than any prior study on the topic. Chapter Two provides disturbing new evidence that increasing numbers of patent settlements involve agreements by brands not to compete with an AG in return for agreements by generics to defer entry beyond when they otherwise would enter. Although these analyses and facts do not answer every question about long-term and overall effects on competition from the use of AGs, they offer new insights and understandings of AG competition that Congress may find useful in its deliberations on this issue.

The FTC's preliminary data analysis in Chapter One shows that AG competition results in greater discounts to consumers during 180-day exclusivity than when AG competition is not present. These additional discounts are relatively modest, however. Retail prices are on average 4.2 percent lower, relative to the pre-generic brand price, as a result of AG competition during 180-day exclusivity, and wholesale prices are on average 6.5 percent lower than pre-generic entry brand prices as a result of AG competition during 180-day exclusivity.

On the other hand, AG competition substantially reduces the revenue of a single generic company in competition with that AG during 180-day exclusivity. Estimates of the average decline in this situation range from 47 to 51 percent, which could result in a generic's loss of millions in revenue. This revenue effect is so much larger than the price effect for consumers because the AG typically obtains significant market share at the expense of the single generic.

Because the impact of an authorized generic on first-filer revenue is so sizable, the ability to promise not to launch an AG is a huge bargaining chip the brand company can use in settlement negotiations with a first-filer generic. It used to be that a brand might say to a generic, "if you go away for several years, I'll give you $200 million." Now, the brand might say to the generic, "if I launch an AG, you will be penalized $200 million, so why don't you go away for a few years and I won't launch an AG." This use of AGs is not only simple, it's inexpensive – a relatively low-cost way for a brand to preserve its monopoly and its high profits along with it.

Indeed, chapter 2 confirms that such troubling agreements are becoming more common. Although Commissioner Rosch downplays the 25 percent of patent settlements with first filers that agreements involving AGs represent, in fact that percentage is significantly higher over the past few years, as this novel way to delay generic competition has evolved. More troubling, even a single such agreement is not just a

theoretical matter for a patient who needs life-saving medicine and has a very limited budget, or is one of the 47 million uninsured in the United States. An American consumer should not be denied the discounts that come with generic entry – both modest discounts during the 180-day exclusivity and much more significant, 85% price reductions thereafter, when multiple generics enter – because a brand and a generic have decided they can make more money if they substantially delay the point at which they begin to compete with each other. As I reported in my speech yesterday, a restriction on such pay-for-delay settlements would result in savings to American consumers of $35 billion or more over ten years— about $12 billion of which would be savings to the federal government.

Finally, with respect to my colleague and friend, Commissioner Rosch, I fear his statement overlooks the Hatch-Waxman context in which Congress has asked us to answer these questions. Commissioner Rosch views this exercise as a question of whether AGs lower price and expand output. But Congress did not ask for an antitrust analysis. When Congress passed Hatch-Waxman, it made a policy choice to create the 180-day marketing exclusivity period to give generics incentives to challenge brands' patents and seek to enter prior to patent expiration. In asking for this study, Congress was in essence asking, "how much do authorized generics benefit consumers?," and "how much do they undermine the incentive for generics to seek entry prior to patent expiration?" This Interim Report provides facts and analysis relevant to these questions, and the Commission will provide yet more analysis in its final report.