Statement

Of

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Hearing On

Pay to Delay: Are Patent Settlements that Delay Generic Drug Market Entry Anticompetitive?

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Mr. Chairman and Members of the Subcommittee, my name is Guy Donatiello and I am the Vice President for Intellectual Property for Endo Pharmaceuticals Inc. I am a patent attorney and have worked exclusively in the intellectual property field for more than twenty years.

Endo is a specialty pharmaceutical company engaged in the research, development, sale, and marketing of branded and generic prescription medicines in pain management, urology, endocrinology, and oncology. Endo is based in Chadds Ford, Pennsylvania and employs nearly 1,500 people throughout the United States.

Endo is a mid-sized company with $1.2 billion in sales in 2008. We are a member of PhRMA, our trade group that represents the country's leading research-based pharmaceutical and biotechnology companies which as an industry invested over $50 billion in research and development in 2008. In addition, Endo is a member of America's Specialty Medicines Companies, an informal working group of mid-sized pharmaceutical companies.

Thank you for the opportunity to testify on behalf of the biopharmaceutical industry regarding an issue of great importance to future medical innovation and patient care: patent settlements and competition in the marketplace. I hope I can provide you with a unique perspective on this issue as a representative of a mid-sized pharmaceutical company that participates in both the branded and generic markets.

Before I respond directly to the issue we are here to discuss, I would like to point out that pharmaceutical products effectively have a shorter period of useful patent life than other types of products. Pharmaceutical companies

must obtain FDA approval before marketing their products, and by the time the medicine comes to the market, there is usually far less time before patent expiration than with other products. Hatch-Waxman attempted to balance the interests of both branded and generic companies by recognizing these patent life challenges. The law made it easier for generics to come to market but also restored to branded companies some of the patent time lost during clinical research and the FDA regulatory review process.

As a mid-sized pharmaceutical company that brings to market both branded and generic medicines, patents are critical to our success in both commercial areas. On the branded side, strong patents permit Endo to innovate and bring new medicines to market to treat unmet medical needs and to compete, **on price**, with other branded products in the same therapeutic class to the benefit of patients. On the generic side, patent expirations of branded medicines permit us to bring to market medicines that will compete with generic and branded counterparts, **also on price**, to the benefit of patients.

Our ability to defend, and to challenge, patents underpins our continued success and fosters future medical innovation for tomorrow's cures. Legislation banning certain patent settlements is unnecessary and harmful. It would halt pro-consumer settlements, erode the value of patents, chill incentives for medical innovation, and reduce patient access to generic drugs.

There are current mechanisms in place to handle truly anti-competitive settlements. To be clear, current law dictates that every settlement between a brand and generic must be submitted to the FTC for review, and any settlement that is judged to be anti-competitive can be invalidated.

This judgment is a result of fact-sensitive litigation that recognizes that every case is different and every case might result in a unique compromise in settlement. Under the proposed legislation, generic companies may bring fewer patent challenges if they have fewer options to resolve litigation without the cost and risk of going to trial. The rapid increase in generic utilization has been fueled in part by the fact that branded and generic manufacturers have been able to settle some patent suits in appropriate ways without taking every case through trial and appeal.

Banning certain types of patent settlements would restrict the ability of both branded and generic companies to settle ANDA patent cases logically. As a result, it would force companies to engage in patent disputes that might otherwise be settled reasonably, quickly, and in the public interest. The parties involved could be forced to spend significant resources on litigation, diverting those resources from valuable investment in future innovation. In addition, statistics show that innovators are likely to win the majority of patent cases litigated through appeal, and these patents would bar generic entry until they expire. In contrast, a settlement might include a provision allowing the generic to come to market well before the patent expires, getting a low-cost generic into patients' hands sooner.

Under certain circumstances, the impact of banning certain patent settlements could result in companies being forced out of business. Small to mid-sized companies like Endo are particularly vulnerable because they often rely on just one or two branded products to generate revenue. These revenue-generating products are often medicines with revenues too small or markets too specialized to be profitable for larger companies to bring to market. It is the smaller companies that bring these medicines to the patients

who need them. When generic competition threatens these patented products through an ANDA filing, a patent dispute often results. Because the small branded company is so dependent on the product being disputed, losing the patent case threatens the company's very existence. Furthermore, if a generic company launches its generic product during a long and expensive litigation, it may ruin a small branded company; even though the branded company may ultimately win the litigation and compel the generic product off the market, the harm has already been done – the genie cannot be put back in the bottle.

I would like to turn to the generic drug development process to highlight another point. The development of generic drugs is not always a smooth pathway with success as a given. Despite excellent scientists, a generic company may work on a project for years and never duplicate the brand to FDA's satisfaction. By the time an ANDA is filed, significant resources are committed to the project based on an anticipated return on investment. Allowing settlements where we recoup some of our investment allows us to develop more low-cost generics for patients. Conversely, adding new barriers to settlements will increase uncertainty, sap resources, and chill investment in new generic medicines.

In short, when a small company, whether a branded manufacturer or a generic challenger, becomes involved in complex, lengthy, expensive litigation with an uncertain outcome, the continued existence of that company is threatened. Resources for future R&D are inevitably squeezed and channeled into legal fees. Patients are the real losers because access to future branded and generic medicines will be delayed or denied.

In conclusion, H.R. 1706 would add cost and uncertainty to bringing new branded and generic medicines to patients. Instead of an across-the-board ban, enforcement agencies and courts should continue to evaluate patent settlements on a case-by-case basis, examining all relevant facts including the strength of the patent and whether the settlements benefit consumers.

While it is a delicate balance, the current system works – innovation is rewarded and competition is robust. Without the ability to make full legitimate use of intellectual property rights, the innovative process that results in intense competition between and among branded and generic manufacturers will suffer, and patients will ultimately suffer. There will be fewer medicines to treat diseases. And with fewer medicines there is also less price competition.

Thank you. I would be happy to answer any questions.