Prepared Statement of William P. (Bill) Kennedy
Co-Owner
Nephron Pharmaceuticals Corporation

Hearing on H. R. 1706, the *Protecting Consumer Access to Generic Drugs Act of 2009*

Before the

US HOUSE OF REPRESENTATIVES
COMMITTEE ON THE JUDICIARY

On

June 3rd, 2009

Testimony of William P. (Bill) Kennedy, R.ph.
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Company Profile

Nephron Pharmaceuticals Corporation ("Nephron"), a family owned pharmaceutical manufacturing and sales company, has grown rapidly since it was purchased in 1991. Nephron utilizes state of the art Blow-Fill-Seal technology to manufacture sterile generic respiratory medications. Only four such facilities currently exist in the US. In spite of today's volatile economic times, Nephron is undergoing a 35 million dollar expansion to upgrade automation and technology at its Orlando, Florida manufacturing facility. Already a large employer, the company is adding specialized engineers and scientists to support its efforts to double manufacturing capacity of their life saving generic respiratory medications.

Introduction

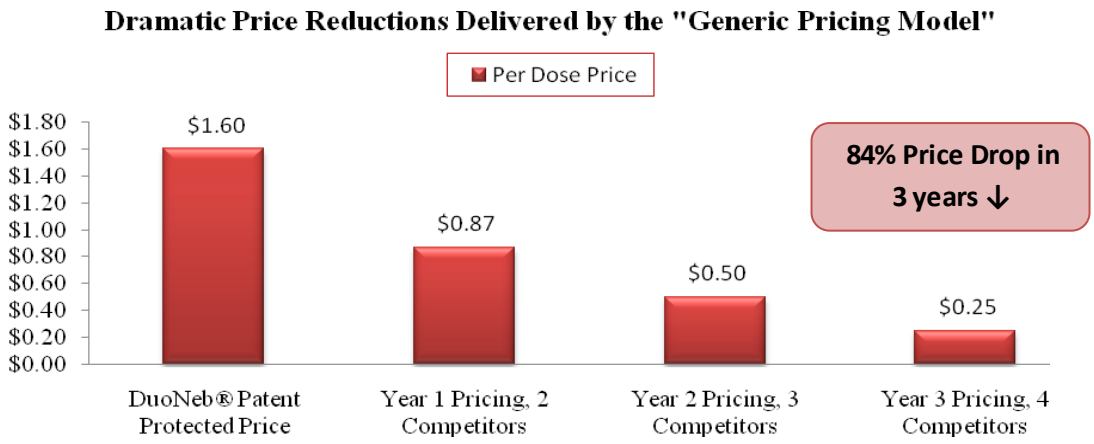
Chairman Conyers, Ranking Member Smith and Members of the Committee, thank you for allowing me to testify before you today. My remarks are in support of H.R. 1706. I am here to show you how the American consumer can save 60% of the cost of their prescribed medications, if Congress will adopt my suggestions.

My name is Bill Kennedy and I purchased Nephron in the early nineties. I am a pharmacist by trade, and have 42 years of experience in healthcare. I have personally witnessed the struggles of the elderly and poor to afford their medications. I also remember the introduction of generic drugs, offering patients affordable therapeutic equivalents. As a generic drug manufacturer, it is my business practice to deliver low cost, high quality generic drugs to our customers. In fact, it is the hallmark of our company.

Multi-source generic drugs operate in a highly price competitive arena, while single source generic drugs or "authorized generics", rarely deliver significant price savings over their branded rivals. I propose that this committee supports H.R. 1706 to restore the incentives to generic drug makers in their challenge of patents with little or no legal basis, or medical benefit to consumers. Drugs with weak patents serve only to maintain artificially high prices for the American consumer. If Congress adopts H.R. 1706, competition and government savings that benefit all constituents and tax payers will prevail, restoring the public policy rationale originally envisioned by Hatch-Waxman.

The Challenge

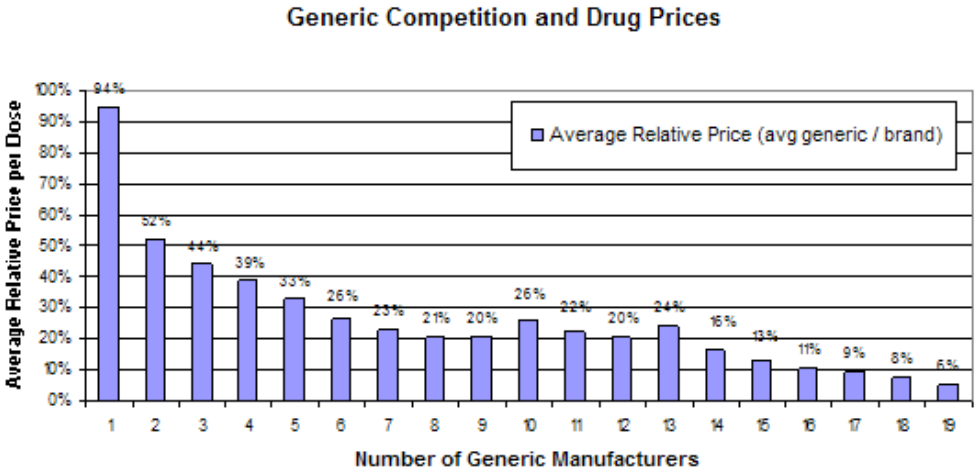
A product pricing example from Nephron's recent history shows how the price of a generic drug rapidly drops in a competitive drug market. Nephron manufactures and sells a generic version of DuoNeb®, a widely used respiratory solution. As shown in the following diagram, this product was originally priced at approximately $1.60 per dose as a single source, brand name drug. When the first authorized generic entered the market, the price dropped to approximately 0.87 cents. After the entrance of the third, fourth and fifth generic competitor, prices eroded to the current 0.25 cents range. In this case, consumers and the U.S. Government realized a cost reduction of more than 80% within three years after generic price competition began. Even though this price drop was steep and fairly rapid, this three year window could have been shortened, given the weak patent at introduction. By adopting H.R. 1706 Members of the Committee have the power to **accelerate that price drop by 2 or more years**; thus, saving billions of federal dollars and providing great benefit to the patient.



The Hatch-Waxman amendments to FDCA, include a feature called the "paragraph IV certification" filing. The filing offers generic drug manufacturers who challenge and successfully win a patent litigation case, a 180 day period to exclusively market a new generic drug before a brand drug is openly exposed to further generic competition. Filing a paragraph IV certification typically involves litigation between a patent holder and generic challenger. The 180 day exclusivity window serves as an incentive to the generic challenger to dispute a weak patent. This allows the potential winner of the challenge to recover the costs of litigation. Originally, the Hatch-Waxman amendments were intended to create additional access to generic drugs for the American consumer. In recent years, "patent settlement" agreements (sometimes referred to as "reverse settlement agreements"), between the patent holder of a drug and the first and second to file generic competitors have stifled competition. These agreements allow the brand manufacturer to continue selling its drug, at or near, the original branded price, while paying the first to file generic drug manufacturer not to distribute its product, or to offer its "authorized generic product", priced just beneath the branded drug. As a result, greatest consumer savings are delayed, and the American healthcare system, including Medicaid and Medicare, are forced to spend millions more on drugs.

If a prior party has filed a Hatch-Waxman paragraph IV certification application with the FDA, and entered into a corresponding patent settlement agreement with the patent

owner, then Nephron, as a third or fourth filer is unwilling to commit precious capital to the highly litigious process of weak patent challenges. As the law is currently written, Nephron would not receive the financial benefit of the 180 day exclusivity window, even if Nephron prevails in the weak patent challenge case. This is a disincentive for companies like Nephron to challenge weak patents and restricts price competition in the drug market. It is crucial to understand that the generic drug pricing model will not deliver significant cost savings to the consumer, until the 3rd and 4th competitor has entered the market. The FDA research presented below notes the average price drop of a dose of product from the 1st generic manufacturer to the 4th generic manufacturer is 61%.



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

[1]

The Position of Nephron Pharmaceuticals Corporation on H.R. 1706

On March 31, 2009, testimony to the Subcommittee on Commerce Trade and Consumer Protection Energy and Commerce Committee, US House Of Representatives was given regarding H.R. 1706 by some of the largest generic drug manufacturers in the world. Those large companies explained their positions eloquently, and testified drug prices fall as much as 20% when they enter the market. I am here to offer the perspective of a

[1] FDA. (2005, February1). *Generic Competition and Drug Prices.* Retrieved May 1, 2009, from www.fda.gov: http://www.fda.gov/cder/ogd/generic_competition.htm

manufacturer that may file third or fourth. With our entrance into the market…… **prices fall 60% and more!** In fact, our very existence has been charted by the ability to compete behind the first and second filers. For this reason, my recommendations to the committee, as a family owned manufacturer, differ from a large scale publicly owned one. Drug companies are engaging in a business practice using "patent settlement agreements", and Hatch-Waxman Act paragraph IV certifications, to create disincentives to generic drug manufacturers from challenging weak patents in the courts. Nephron is in opposition to collusive business practices known as "patent settlement agreements" between generic and branded drug companies and **strongly** supports H.R. 1706.

For the generic and branded pharmaceutical companies that have aligned themselves through patent settlement agreements, there is tremendous incentive to maintain the status quo due to the enormous profits generated for each day a product remains protected by a weak patent. My competitors, large generic manufacturers, often refer to their settlement agreements as "pro-consumer". This is only slightly true, because with a third or fourth competitor in the market, the generic drug pricing model takes over, allowing for pricing to reach truly "pro-consumer" levels. Weak drug patents should receive adequate review in a court venue. In court, it is the burden of potential competitors to fund the analysis and arguments, while generating new and novel approaches to the drugs they can produce. By supporting H.R. 1706, the committee will restore the original vision of Hatch-Waxman, which is to allow generic drug companies to rationally invest in challenging weak patents. Increasing the availability of generic drugs is vital to lowering costs within the U.S. healthcare system.

Nephron's Recommendation for H.R. 1706

1. Nephron recommends that the committee adopt H.R. 1706 and eliminate the practice of patent settlement agreements.

2. Nephron urges the committee to consider a major change in Hatch-Waxman, by changing the "first to file" approach to a "first to win the patent case without

settlement" approach. If Nephron were to win in court challenging a weak patent, Nephron would expect to be the sole beneficiary of the exclusivity period starting when the weak patent is knocked out, regardless of its position among other "paragraph IV" filers.

3. The "first to win" approach is likely to be time consuming, expensive and an all-or-nothing proposition. Therefore, Nephron proposes to the Committee to consider expanding the exclusivity period from 180 days to one year. A company investing in a successful challenge to a weak patent deserves to achieve a reasonable rate of return on its investment, and the expanded exclusivity period would provide more incentive and protection to the challenger. After the expiration of the one year exclusivity period, the market for the new generic drug would be open to all respective abbreviated new drug application ("ANDA") holders. Nephron believes that four to five competitors would readily enter and compete in the market place for the new generic drug one day after the expiration of the exclusivity period.

We feel the implementation of our recommendations would create an extremely competitive marketplace, and it is only with greater competition that lower prices will reach the American consumer.

Thank You, Mr. Chairman, my family and I are extremely grateful for the opportunity to speak to the committee in support of H.R. 1706, which we feel is critical in lowering costs to the American consumer. I am happy to answer any questions you may have.