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Opening Statement of U.S. Senator Amy Klobuchar As prepared for delivery

JEC Hearing: At what cost? Egregious price increases in the pharmaceutical drug industry

July 24, 2008

Thank you for attending this important hearing on rising prices of prescription drugs.

I will be introducing each panelist after opening remarks, but I'd like to thank each of them for taking the time out of their busy schedule to join us today and share their experiences and expertise.

First, I'd like to thank Danielle Foltz for her courageous effort to share her family's experience with us today. Her passionate advocacy has brought to light how decisions made in boardrooms affect families across the country.

I would also like to thank Madeline Carpenelli of the PRIME Institute, based in my home state of Minnesota, for her effort to provide context and insight into the impact of drug pricing. She has been working with Dr. Steve Schondelmeyer, who began collecting data on cases of enormous, overnight drug increases since the 1980s.

It is his work, along with Ms. Carpenelli's expertise from spending almost a decade at the Health and Human Services' Office of the Inspector General that has allowed us to examine the big picture of what these increases have done to patients with rare diseases.

And I'd like to extend special thanks to Dr. Alan Goldbloom, the CEO of Children's Hospitals and Clinics of Minnesota.

Since last July, I've worked with Children's several times in connection with the case of Abbey Taylor, the little girl who died after being seriously injured in a wading pool last summer.

This hospital is dedicated to the care of their young patients. They know how important it is for children to have access to affordable, quality health care.

That's why we're here this afternoon.

We are here because we are outraged by what some pharmaceutical companies have been doing with pricing for important medications that affect all generations. These are drugs that, because of aggressive pricing practices, have seen dramatic increases in cost. Often times, because of a limited market or other factors, the drug's price is more likely to remain at that astronomical level.

I first became aware of this issue when I received word from Children's Hospital in Minneapolis that the price for a drug called Indocin I.V. had increased substantially. It's a medication used to treat patent ductus arteriosus also called PDA, a disorder that prevents holes from healing in the hearts of premature infants.

Since its approval in the 1970s, the drug has become the most commonly-used method for treating this condition.

Two years ago, Ovation Pharmaceuticals acquired the rights to this drug from Merck. The company quickly increased the price by more than 18 times – from \$100 to \$1,875 – for three one-milligram units of the drug.

Even though it's an American company, the price they charge in the United States is now 44 times higher than what they sell it for in Canada, nothing can justify that kind of huge price disparity.

As it happens, there is only one other drug approved by the FDA for this heart problem – a formulation of intravenous Ibuprofen. Ovation is also the sole source of that drug in the United States and, not surprisingly, the price it charges for this medicine is nearly identical to what it charges for Indocin I.V.

A number of other Ovation products have seen similar drastic price increases. Drugs that – like Indocin - have been around for a long time and are the premier treatments for a number of diseases.

In a recent article in the medical journal *Pediatrics*, Dr. Alan H. Jobe of Cincinnati Children's Hospital described Ovation's pricing of its two drugs for the premature babies' heart condition as "quite extraordinary."

He wrote: "Words such as 'unconscionable,' 'unethical' and 'socially irresponsible' come to mind."

So the issue we have is that an upstart company purchases a number of drugs from another company, and even though these drugs had been on the market for years, the upstart company increases the price drastically.

But Ovation isn't the only company engaging in this disturbing trend.

Questcor Pharmaceuticals was once losing money at a rate of \$1 million a month. The company's fortunes turned around after they purchased HP Acthar from Aventis. This drug was

approved in the 1970s to treat multiple sclerosis, but it is now primarily the “gold-standard” for treating infantile spasms, a disorder that affects about 2000 families in the U.S.

Prior to Questcor’s purchase of the drug, the wholesale price of HP Acthar was about \$1600 per vial. Once in Questcor’s hands the price of the drug skyrocketed to \$23,000 per vial – that’s a 14-fold increase!

And according to the PRIME Institute, we’re hitting just the tip of the iceberg, because the problem isn’t isolated to drugs that benefit small numbers of patients.

Abbott Pharmaceuticals increased the price of Norvir, a drug used to treat AIDS. The drug was often used by other companies as an ingredient in their drug therapies. In 2003, Abbott jacked up the price of Norvir [“NORE-veer”] by 400 percent.

This was done at the same time that Abbott began marketing their new product, Kaletra, another AIDS pharmaceutical drug that included Norvir and served as a replacement for the competition’s drug therapy. The result forced patients and providers to turn to Abbott’s Kaletra instead of the formerly cost-effective alternative that used Norvir and competitor’s drugs.

Previously undisclosed documents and emails reviewed by *The Wall Street Journal* in 2007 show that Abbott’s leadership actively considered ways to promote Kaletra over Norvir.

This bar graph illustrates the drastic jump in price, an egregious increase from \$257 to \$1285.

This chart shows just a few examples of enormous drug price increases. Mustargen to treat rare cancers, 1000 percent increase! Cosmegem to treat kidney disease, 3500 percent increase!

And the price increase for Matulane is nearly off the chart with an 8000 percent increase!

This seems to be simple price gouging to me. And it not only hurts hospitals that have to purchase these expensive drugs, but also the patients who rely on them.

An elderly woman from Park Rapids, Minnesota who suffers from cutaneous T-cell lymphoma was forced to pay over \$8000 in out-of-pocket expenses for Mustargen, a drug sold by Ovation Pharmaceuticals whose single dose price increased from around \$50 to nearly \$550 after the company acquired the rights to the drug.

In March, I had the opportunity to meet the Benson family and their twin girls Anna and Sophia. Sophia suffered from PDA and needed Indocin I.V. for treatment. They were able to receive the drug through Children’s Hospital, but with such obscene price increases, it is getting more and more difficult for providers to meet such runaway costs.

What is the solution?

In America, we have a serious problem with health care inflation and runaway costs. It’s no wonder: When we have pharmaceutical companies like Ovation or Questcor increasing prices to

astronomical levels because of the lack of competition in the market, their actions are able to exploit an extremely vulnerable and captive market.

And it's not like the pharmaceutical industry is withering on the vine. This chart shows that even when compared to other Fortune 500 companies, pharmaceutical company profits are much higher.

The Orphan Drug Act was passed in 1983 to provide incentives to drug companies to develop innovative drugs for rare diseases because without incentives, drug companies may never be able to recoup research and development costs in niche markets.

What we've seen, however, is that at least a handful of drug companies have used this "status" of orphan drugs to keep increasing costs—well beyond the costs of research, development, and manufacturing. These staggeringly high prices, in turn, threaten the financial stability of middle class families relying on the drugs.

Where generic drugs have helped lower the cost of many prescription drugs on the market, generic competition is also less likely to occur for orphan drugs. According to a study published in the *RAND Journal of Economics*, the market size for a drug has to be \$32 million (in 2007 dollars adjusted for inflation) to ensure entry of a generic into the market.

When we're talking about drugs that have been around for decades and treat patient populations of only a few thousand, there is often just not enough of an incentive for a generic drug to enter the market.

Beyond hospitals and patients, a dramatic, unforeseeable increase in price for one of these drugs has a significant impact on the federal government. If the wholesale cost of a drug goes up, Medicaid or Medicare has to pay for the increase.

We are holding this hearing to uncover this practice, but also to look forward at what we can do to curb the dramatic increase of drug prices we've seen in the last few years.

I've asked the Federal Trade Commission to initiate an investigation into any potential anti-competitive conduct or consequence arising out of Ovation's market actions and dominance in the area of non-surgical treatments for PDA.

We need to ensure that the FTC continues to conduct these crucial investigations to guarantee competition—keeping costs low for consumers and encouraging innovation.

It's disturbing that our providers, hospitals and patients are being blindsided by these exorbitant price increases. Our federal government should be able to track these trends in pharmaceutical pricing. If we start to monitor this data, there is more of a paper trail, giving us enhanced ability to do something about these companies' practices.

When provided with the right information on drug prices, especially in smaller markets, doctors can be alerted of big price increases, potentially spurring generic alternatives to expensive drugs

and giving the Centers for Medicare and Medicaid Services (CMS) the tools and information to better track pricing activity in the market.

Finally, I intend to investigate whether the FDA can fast-track approval for generic drugs that would be just as safe and effective, but much less expensive, creating competition in markets with dramatic price increases.

I understand that we have a market-based economy. It's fine for companies to make money on the products they sell. But when you're dealing with the well-being of sick patients – babies and the elderly and everyone in between – there has to be special consideration.

I look forward to hearing our witnesses' thoughts on this important issue, and I hope today marks a starting point for addressing the problems that accompany such enormous price increases. Problems that have been plaguing doctors, insurance companies, Medicare and Medicaid programs, and most importantly, the patient, for far too long.

After openings, I will introduce our panelists, and we will hear their testimony.

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