Testimony of
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Madame Chairman, members of the committee, thank you for the opportunity to testify here today on this critically important issue.

My name is Dr. Alan Goldbloom; I am president and CEO of Children's Hospitals and Clinics of Minnesota. We are the 7th largest pediatric health care system in the nation and we are the largest provider of care to children with severe prematurity, cancer, heart disease, and complex surgical conditions in the Upper Midwest.

Children's of Minnesota is recognized – both nationally and internationally – for our outstanding outcomes in treating premature infants.

My testimony here today will focus on my personal experiences at Children's of Minnesota and two drugs we use in treating premature babies and a rare seizure disorder in very young infants. My testimony is not a rant against the industry as a whole, for this industry has produced extraordinary advances in health care, from which we all benefit. Rather, my concern is focused on the practices of some specialty pharmaceutical companies and the questionable pricing of some older drugs. And though my personal experiences involve two specific companies, they are in no way alone in this practice nor is it confined to only pediatric pharmaceuticals.

One condition we treat in infants is patent ductus arteriosus – or PDA. PDA affects about 3,000 infants annually and is most common in premature babies. I will explain this in very simple terms. Blood circulation changes within minutes of a baby's birth. Normally, our blood picks up oxygen in the lungs and then is pumped by the heart to bring that oxygen to the rest of our body. However, a baby doesn't breath while still in the womb. Instead, a blood vessel called the ductus arteriosus diverts blood away from the lungs, and the fetus actually gets oxygen directly from the mother via the umbilical cord. Once the baby begins to breath after birth, the ductus arteriosus normally spontaneously closes, allowing blood to flow to the newborn's lungs. However, in some babies, especially those who are premature, the ductus does not close. Often, this is a minor problem that resolves without treatment. However, in some infants it becomes serious enough to cause congestive heart failure, and to interfere significantly with breathing. When that happens, treatment is required. Last year, Children's of Minnesota treated around 110 babies for this condition.

For many years, the only way to definitively treat this condition was with surgery, a procedure in which the persistently open artery was simply tied off. However, over 30 years ago it was learned that the drug indomethacin (Indocin), when given intravenously, could often produce the same result without subjecting the baby to surgery. Indocin is now the standard initial treatment for this condition.

Until recently, Indocin has been a low cost, safe, non-surgical way to treat these infants. In fact, the cost for Indocin up until January of 2006 was just over $108 per unit. About 42 of the nation's largest free-standing children's hospitals are members of an organization called Child Health Corporation of America (CHCA), which serves as the group purchasing organization for three-quarters of those hospitals. For the members of the group purchasing organization, the collective annual cost prior to 2006 was just $136,426 nationally.

However, when the specialty pharmaceutical company Ovation bought exclusive rights to Indocin and several other drugs from pharmaceutical giant Merck in August of 2005, the price for one unit of Indocin jumped from $108 to $1,500 – a 1,278 percent increase. Yet Indocin is an old drug. It has been on the market for more than three decades, so this dramatic price increase cannot be attributed to the high cost of research and development. As purchasers, the children's hospitals have had no other options. There have been no other manufacturers of Indocin. Effectively, one company has a monopoly and can use it to price-gouge.

Madame Chairman, at this time I would like to insert into the record the article titled "Drug Pricing in Pediatrics: The Egregious Example of Indomethacin" authored by Dr. Alan Jobe of Cincinnati Children's Hospital in Cincinnati, Ohio which appeared in the Journal of The American Academy of Pediatrics in June of 2007.

On the price increase of Indocin after Ovation acquired the drug from Merck, Dr. Jobe writes "This is a rather astounding increase in price for a drug that has a stable niche market and requires no advertising, no educational expenses (all neonatologists know how to use indomethacin), and no further drug development. It is quite hard to imagine how such an increase in price could be justified." (Pediatrics, Volume 119, Number 6, June 2007, pg. 1197). Dr. Jobe also points out that the cost per milligram of Indocin is 30 to 60 times higher in the United States than other countries that

have similar health care systems with little explanation as to why this occurs except for profit motivation. The cost per milligram in the U.S. is $1,875 compared with $14 in Canada, $16 in Britain, $22 in Germany and Holland, and $11 in Australia.

The effect of this dramatic price increase in our hospital has totaled nearly 150,000 dollars in the first year of the price increase. And, according to CHCA it cost its member hospitals close to $2 million that same year – that's up from just over $136,000 just one year earlier. Like all health care providers, we struggle with the issue of increasing costs. Often we are not able to immediately recover these costs from insurers, especially when children's hospitals rely heavily on Medicaid as the single largest insurer of children in the country. Eventually, however, increased costs do get passed on, and are reflected in the premiums that individuals and businesses pay, and in the tax-supported programs like Medicaid. From our perspective, that extra $150,000 that we paid to one drug manufacturer is money we would much rather have spent on improved services for patients.

The children's hospitals who are part of the CHCA group purchasing organization represent only the tip of the iceberg when it comes to the numbers of patients and costs of Indocin in the nearly 600 neonatal intensive care units nationwide. Most of these units are not in children's hospitals, but instead are often in general and maternity hospitals where the babies are born. So the overall impact is ultimately much higher than I have quoted here.

Indocin is not the only drug Ovation has marked up in such a dramatic fashion. Three other drugs that were purchased from Merck – Cosmegen, Diuril Sodium, and Mustargen have seen price increases of 3,437 percent, 864 percent, and 979 percent respectively. Cosmegen is an agent used to treat a variety of pediatric cancers, Diuril Sodium is a diuretic used to reduce fluid overload in infants and neonates, and mustargen is used to treat brain tumors and certain lymphomas (another form of cancer).

Madame Chairman, I would like to insert into the record the following chart that shows the cost of the four drugs purchased by Ovation. As you will see, after Ovation purchased these four drugs from Merck, there was a significant price increase – by as much as 3,437 percent in the case of Cosmegen.

Brand Name	Price per unit Prior to 01/24/06	Price per unit As of 06/08/06	Percent of Increase
Cosmegen	$13.43	$475.05	3437%
Diuril Sodium	$12.36	$119.21	864%
Indocin I.V.	$108.88	$1500.00	1278%
Mustargen	$50.55	$545.28	979%

*Information provided by the Child Health Corporation of America

I would also like to insert the following chart that shows how CHCA member hospitals have been affected by the price increases in these four drugs by Ovation:

Brand Name	2005 Total purchased units	Price per unit prior to 01/24/06	2005 Total Spend	Price per unit as of 06/08/06	2006 Extended Volume
Cosmegen	5,282	$13.43	$70,937.26	$475.05	$2,509,214.10
Diuril Sodium	12,991	$12.36	$160,568.76	$119.21	$1,548,657.11
Indocin I.V.	1,253	$108.88	$136,426.64	$1,500	$1,879,500.00
Mustargen	42	$50.55	$2,123.10	$545.28	$22,901.76
Grand Total	27,195		$370,055.76		$5,960,272.97

*Information provided by the Child Health Corporation of America

Madame Chairman, the total cost increase for CHCA hospitals in one year for these four drugs alone was more than $5.5 million.

One of the best known examples of similar practice in the industry occurred when the specialty pharmaceutical company Questcor bought Acthar Gel from Aventis. Acthar Gel is used to treat infantile spasms, a rare, severe, and treatment-resistant form of seizures affecting very young infants. Acthar Gel is considered the gold standard in the treatment of IS. At Children's of Minnesota, we have one of the nation's largest, most advanced epilepsy treatment units and have used Acthar Gel nearly 50 times so far this year.

Originally approved in 1978 for multiple sclerosis, the cost of the drug has always been high. However, after Questcor bought the rights to sell Acthar Gel, the price went from a list price of $1,650 per vial to a list price of

$23,269 per vial. That's twenty three thousand, not twenty three hundred dollars. In fact, this more than 1,000 percent price increase costs CHCA hospitals more than $21 million per year.

Madame Chairman and Members of the Committee, there are many other drugs – hundreds in fact – that are priced this way – both pediatric and non-pediatric. And, even with good insurance, a twenty percent copay on Acthar Gel is more than many people's mortgage payment. What is frightening is that in this time of skyrocketing health care costs, the burden of expensive health care now affects the insured as well as the uninsured or under insured. The market for many of these drugs is quite limited, so it is unlikely that other companies will begin to produce or sell a low-volume specialty product at a reasonable cost. The resulting monopoly is resulting in windfall profit opportunities for companies like Ovation and Questcor, and they are taking full advantage.

At this time Madame Chairman I would like to place into the record an article dated April 14, 2008 by Gina Kolata that appeared in the New York Times titled "Co-Payments for Expensive Drugs Soar."

Today, the nation is in an uproar over $4 dollar a gallon gasoline. We accuse the nation's oil companies of price gouging and Members of Congress and the presidential candidates are working to find solutions to the problem. But, if you compare the most recent financials for Exxon Mobil and Questcor - you'll find that one company's profit margin is much higher – and it's not who you might think. Pharmaceuticals and specialty pharmaceuticals are the nation's most profitable industries. I want to reiterate that my testimony today is not a rant against the industry as a whole which has produced many extraordinary benefits in health care. Instead, my concern is focused on the practices I just described, in which unjustified pricing decisions are taking advantage of some of the most vulnerable members of our population, and driving health costs up unnecessarily.

Thank you for the opportunity to speak with you today.