SMALL MARKET DRUGS, BIG PRICE TAGS: ARE DRUG COMPANIES EXPLOITING PEOPLE WITH RARE DISEASE?

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SMALL MARKET DRUGS, BIG PRICE TAGS:
ARE DRUG COMPANIES EXPLOITING PEOPLE
WITH RARE DISEASE?

THURSDAY, JULY 24, 2008

CONGRESS OF THE UNITED STATES,
JOINT ECONOMIC COMMITTEE,
Washington, DC.

The Committee met at 10 a.m. in room SD–1066 of the Dirksen Senate Office Building, the Honorable Amy Klobuchar, presiding.

Senators present. Klobuchar and Schumer.

Staff present. Christina Baumgardner, Tamara Fucile, Colleen Healy, Jeff Schlagenhauf, Marcus Stanley, and Jeff Wrase.

OPENING STATEMENT OF HON. AMY KLOBuchar, A U.S.
SENATOR FROM MINNESOTA

Senator Klobuchar [presiding]. I call the hearing of the Joint Economic Committee to order. I want to thank you all for attending this important hearing on rising prices of prescription drugs.

I’m going to be introducing each panelist after opening remarks, and I also know there are some other members coming, but I’d like to thank each of you for taking your time out of your busy schedule to join us to today and to share your experiences and your expertise.

I’d first like to thank Danielle Foltz for her courageous effort to share her family’s experience. I know that her family is there in the front row, very well behaved children, I would say.

Her passionate advocacy on these drug issues has brought to light how decisions made in board rooms affect families across the country.

I would also like to thank Madeline Carpinelli of the Prime Institute—based in my home State of Minnesota—for her efforts to provide context and insight into the impact of drug pricing.

She has been working with Dr. Steve Schondelmeyer, who began collecting cases of enormous data and information on overnight drug increases since the 1980s, and thank you both for the work that you’ve done, and I’m proud to have you doing that out of the State of Minnesota.

We’re kind of a medical mecca in Minnesota, with the home of the Mayo Clinic and the University of Minnesota, and I thank you. A lot of the ideas that I’ve gotten for healthcare reform have come right from our State.

Finally, 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 have worked with Children’s Hospital on a number of issues, including this one, but for me, the most difficult and important thing was the work that we did with the Taylor family, a little girl who was severely injured and later died from a malfunctioning swimming pool, and Children’s did everything that they could for months. Sadly, she had a transplant at another hospital and it didn’t work, but the care she got there, the discussions I’ve had with her parents, and the fact that we’re able to pass a bill that inspired everyone across the country to do something differently with their swimming pools, is a tribute to her family and also to the good work of Children’s Hospital, so thank you for that.

I know firsthand. My daughter, when she was born, was sick, and Children’s Hospitals helped her and have helped so many young children across this country. And thank you, Dr. Goldbloom, and Children’s, for calling this very important issue to my attention.

We’re here today because we’re 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. Oftentimes because of a limited market or other factors, the drug price is more likely to remain at this astronomical level.

I first became aware of this issue, as I mentioned, when I received word from Children’s Hospital in Minneapolis that the price for a drug called Indocin had increased substantially.

It’s a medication used to treat patients with ductus arteriosus, also called PDA, patent ductus arteriosus, 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 drug for this type of condition.

Two years ago, Ovation Pharmaceuticals acquired the rights to this drug from Merck. This drug had been around since the 1970s, but it was in 2005 that Ovation acquired this drug.

The Company quickly increased the price by more than 18 times, from $100 to $1,875. This is it, Indocin, right here, this drug which used to be $100, sold from one pharmaceutical company to another; no more research, no changes, same drug, the price goes up 18 times.

Even though it’s an American company, the price that they charge in the United States—that Ovation now charges for this drug—is 44 times higher than they charge for it in Canada.

So here’re the facts: You’ve got a drug that was going for a hundred bucks that went up to $1,800, and then you have the fact that they’re selling it in the United States for 44 times the amount that they sell it for in Canada.

And as it happens, the only other drug approved by the FDA for this heart problem, a formulation of intravenous ibuprofen, Ovation is also the sole source for that drug in the United States, and, not surprisingly, the price that it charges for this medicine is nearly identical to what it charges for this.

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. Allen Job of Cincinnati Children’s Hospital described Ovation’s pricing of its two drugs for the premature baby’s heart condition as quite extraordinary, and he didn’t mean that in a good way.

He went on to write 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 have been on the market for years, the upstart company increases the prices drastically.

But Ovation isn’t the only company engaged in this disturbing trend, and we have a chart here that shows what’s been going on when there have been these extraordinary—to use the Doctor’s words—price increases, which are becoming more common.

[The chart, “Extraordinary Price Increases Are Becoming More Common” appears in the Submissions for the Record on page 46.]

Here, you see a number of branded drug products whose prices have more than doubled in one single price increase. In other words, you could maybe imagine a price increase going up slightly because of factors—research, things like this—but we’ve gone from 5 drugs in 1988, where the prices have more than doubled when there was a price increase, to 64 drugs in 2008.

So something’s going on, and I don’t think it’s the law of supply and demand. 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 1950s to treat multiple sclerosis, but it is now primarily the gold standard for treating infantile spasms, a disorder that affects about 2,000 families in the United States. Prior to Questcor’s purchase of the drug, the wholesale price of HP-Acthar was about $2,000 per vial; once in Questcor’s hands, the price of the drug skyrocketed to $23,000 per vial. That’s a fourteenfold 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 Pharmaceutical’s 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 by 500 percent. You can see the prices before and the prices after.

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 competitors’ drugs.

Previously undisclosed documents and e-mails reviewed by the Wall Street Journal in 2007, show that Abbott’s leadership actively considered ways to promote Kaletra over Norvir.

Now, we also have another chart here, which shows the changes and a few examples of other price increases. Mustargen, to treat cancers, a 1,000 percent increase; Cosmogen, to treat kidney dis-
ease, a 3,500 percent increase; and the price increase for Matulane, which is nearly off the chart, was a 7,999 percent increase.

[The chart entitled, “Huge Drug Price Increases,” appears in the Submissions for the Record on page 47.]

I don’t know if they went down a few pennies so they wouldn’t make 8,000 percent, but that’s what we’re talking about, Senator Schumer, a 7,999 percent increase.

This appears to me to be simple price-gouging, and I know firsthand, from this—which we’ve looked at at length, the one that we had here that came to my attention in Minneapolis, that really we have yet to get an answer about why this drug would be increased 18 times, a drug that saves little babies’ hearts.

It not only hurts the 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 cell lymphoma was forced to pay over $8,000 in out-of-pocket expenses for Mustargen, the drug sold by Ovation whose single-dose price increased from around $50 to nearly $550, after the company acquired the right for the drug.

In March, I had the opportunity to meet with the Benson family and their twins, Anna and Sophia. Sophia suffered from PDA and needed Indocin 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 these runaway costs.

Remember, this is a drug that is an alternative to much more expensive surgery.

What is the solution? Well, in America, we have a serious problem with healthcare inflation and runaway costs, and when you hear these stories, it is no wonder. When we have pharmaceutical companies like Ovation and 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.

Now, we have a chart showing how the pharmaceutical companies earned higher profits than other Fortune 500 companies, while at the same time that we saw these astronomical increases—doubling increases—of so many drugs that save children’s lives and other lives in this country.

[The chart, “Pharmaceutical Companies Earn Higher Profits Than Other Fortune 500 Firms,” appears in the Submissions for the Record on page 46.]

It is not like the pharmaceutical industry is withering on the vine. The chart shows that even when compared to these other Fortune 500 companies, pharmaceutical companies’ 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 have 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 cost of research development and manufac-
turing. No one has ever said there was a bunch of research done on this drug.

These staggeringly high prices, in turn, threaten the financial stability of middle class families in relying on these drugs. Whereas generic drugs have helped to lower the costs of many prescription drugs on the market, generic competition is also less likely to happen for orphan drugs.

According to a study published in the Rand Journal of Economics, the market size for a drug has to be about $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 a few 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, then Medicare or Medicaid has to pay the increase, so this is also about taxpayers' money.

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

I've asked the Federal Trade Commission to initiate an investigation into any potential anticompetitive 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, our hospitals, and our 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 keeping the centers for Medicare and Medicaid services, giving them the tools and information to better track pricing activity.

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 that they sell, but when you’re dealing with the wellbeing of sick patients, babies and the elderly and everyone in between, there has to be special consideration; that if the competitive market isn’t working, if it’s not allowed to work, if companies are allowed to simply jack up prices because they can, on the backs of the taxpayers and on the backs
of the middle class, on the backs of little babies like the one sitting in this front row, then we have to do something about it.

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 and insurance companies, Medicare and Medicaid programs, and most importantly, the patients that have gone on for far too long.

I would also want to mention before I turn it over to our Chairman, Senator Schumer, and then to our witnesses, that we invited Ovation to participate in this hearing, and they declined to come.

With that, Senator Schumer.

[The prepared statement of Senator Klobuchar appears in the Submissions for the Record on page 26.]

OPENING STATEMENT OF HON. CHARLES E. SCHUMER, CHAIRMAN, A U.S. SENATOR FROM NEW YORK

Chairman Schumer. Well, thank you, Senator Klobuchar. I want to thank you for your leadership on this issue and for spearheading and chairing this hearing.

I know most of my colleagues—and many of you know this—Senator Klobuchar has a unique understanding of things that hurt average folks, a unique way to solve those problems, and a unique way to relate to both the people who are hurt and those who need to change their behavior.

So she is, as I like to say, a natural, and it’s perfect for her to investigate this issue.

Now, yesterday, we had a hearing where we talked about the middle class squeeze and how American families gather on Friday nights around their kitchen tables after dinner, and they talk about the things they care about—their children, their future, their health—and, more and more, they’re talking about how the heck are we going to pay these bills?

The middle class is squeezed, and it’s not just food and gasoline and college and daycare—which it is—but it’s prescription drugs and healthcare. Today’s hearing focuses on the lack of affordability of potentially lifesaving drugs that treat rare diseases.

Imagine being a parent and having your child, who you deeply love, and you know there’s a drug out there on the market that could cure him or her, make them better, take away their pain, and it’s just so exorbitantly priced that you can’t afford it. The instinct of most people would be, they’d want to rob a bank to save the life of their child.

No one will do that, or very few—let’s hope no one—but that’s how you’d feel, where you’d want to go into the drug company, almost with a gun and go to the CEO and say, I want that drug for my child. Again, no one would do it, but that’s how you’d feel.

So, this is amazing hearing, and it’s heartfelt. And you know, we all believe in innovation, and we all believe in profitability, and we all believe in the free market system, but the prices that Senator Klobuchar showed on her chart and the dramatic increases show that something is wrong.
Something is wrong in the values of a society when a drug can go up from $60 to $6,000 and is basically taken away from families who need that drug for their children’s lives.

As I said, these drugs have gone up 100, 500, 3,000 percent, months, weeks, overnight. As Senator Klobuchar said, that’s more than inflation, more than supply and demand, more even than just reasonable profitability.

And what is our healthcare system doing when things like that happen? Again in America, what we try to do is start with the free market and use that as our basis, but it doesn’t mean the free market is always the answer, particularly when you’re dealing with areas where there is not competition.

And you know, I’ve heard about—I won’t be able to stay, but I heard about your testimony, Ms. Foltz, and the drug Acthar to treat your little son for life-threatening epileptic spasms, and you have to pay $29,000 a vial—13 times higher than the price that it had been 8 months before?

What’s the matter? What is wrong? Something, something, something is wrong with our values, our society, our system, and our government when things like that are allowed to happen.

And so I’d ask unanimous consent that my entire statement be read into the record.

[The prepared statement of Senator Schumer appears in the Submissions for the Record on page 25.]

Chairman Schumer. I’d like to make just another point. Along with Senator Klobuchar, we’ve asked the General Accounting Office to look into the issue of these price increases and see if they’re justified. We’re not going to stop; I want to assure the people here and the people who will read or listen to this hearing, that we’re going to keep at it.

One other thing that’s indirectly related. I’ve been a leader on generic drugs, and we worked in the Senate with Senators Kennedy and Clinton and Enzi and Hatch, to create a pathway for generic versions of biologic drugs, which will make a huge difference in issues like this.

I’m pleased that the National Organization for Rare Diseases touted the passage of the Pathway for Followon Biologics, in their submission for the record in this hearing—and that’s just one of many ways. Not all these drugs are susceptible to that, but that’s one way that we can help.

Generics and market competition work, and we need to build on these successes and improve our system of approval for licensing generics. The research shows that it takes at least two or three generic entrants to seriously lower drug prices and shows that generic companies are reluctant to enter the market for rare diseases, since many of these niche markets aren’t large enough to sustain more than one or two competitor drugs, and therefore, we have to go beyond generics when we look at this particular situation.

But the bottom line is, we owe it to people like Ms. Foltz and her family and the thousands and thousands and thousands of people who are in that position, and there, but for the grace of God, go you or I, and we really want to help. I want to thank, once again, Senator Klobuchar for focusing in her usual, excellent way, a spotlight on this important issue.
I apologize to the witnesses, but I wanted to be here to lend my support.

Senator Klobuchar [presiding]. Thank you very much, Senator Schumer, and thank you for leadership, particularly in the area of getting these generic drugs out, which is one way that we can put some downward pressure on prices.

But there are other ways, as well, and we want to talk about those today. First, we're going to hear from Madeline Carpinelli. Ms. Carpinelli is a research fellow with the Prime Institute, headquartered at the University of Minnesota.

Her duties include designing and implementing research projects related to pharmaceutical economics and other public policy issues.

Before joining the Prime Institute, Ms. Carpinelli served as co-Chair of the Department of Health and Human Services Drug Pricing Planning Group. In that capacity, she led a team of analysts in tracking pharmaceutical industry trends and worked on issues relating to drug pricing benchmarks and drug rebate programs.

Ms. Carpinelli.

STATEMENT OF MADELINE CARPINELLI, INSTITUTE FOR PHARMACEUTICAL RESEARCH IN MANAGEMENT AND ECONOMICS AT THE UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Ms. Carpinelli. Thank you, Senator Klobuchar, for the kind introduction and for this opportunity to present on information and insights regarding pricing trends in the pharmaceutical market.

As you said, I'm Madeline Carpinelli, and I'm a research fellow with the Prime Institute—currently. In my previous life, I was with the Office of the Inspector General, where I worked on most of the drug price reporting and compliance issues for about the last 10 years.

I also interfaced with the Department of Justice and the OIG Office of Counsel with regards to their prosecutions and investigations.

These remarks present my own findings and views, based upon my experience in studying the pharmaceutical marketplace for the last nine years, and upon my observations and ongoing work in collaboration with Dr. Steven Schondelmeyer with the Prime Institute.

Today, I will provide an overview and preliminary findings from research we have been conducting on extraordinary price increases in the pharmaceutical market.

Through our tracking of prices over time, we have become aware that certain drug products have experienced extraordinary price increases that are well beyond what would normally be expected in a competitive market.

We found hundreds of cases of extraordinary price increases for branded drug products. We also found that the incidence of such extraordinary price increases has been rising sharply in recent years, and today is much higher than it was in the 1980s and 1990s.

The Prime Institute routinely tracks price changes as part of our ongoing work, as well as for specific projects such as tracking the
annual inflation rates for the most commonly used drugs by Medicare recipients, on behalf of the AARP.

As such, we are accustomed to seeing annual price increases of between 6 and 7 percent for brand-name prescriptions—two times the rate of general inflation.

We also expect to see the prices for certain commonly used brand-name products experience price increases that are substantially higher. For example, in 2007 Ambien had an annualized price increase of 27.7 percent from 2006, not surprising since it’s one of the most commonly prescribed products.

In examining the prices of all products that have entered the market since 1987, we discovered a pattern that challenges our parameters for acceptable price increases.

In recent years, we’ve found that some less commonly used products had one-time extraordinary price increases of 100 percent or greater. This rate of inflation is unacceptable and has a tremendous impact upon patients, payers, and policymakers.

To examine and understand the magnitude of these extraordinary price jumps, the Prime Institute has been conducting a study of such price increases. Today, we’ll present the findings on our analysis with the specific focus on brand-name drugs.

To identify extraordinary price increases, we reviewed increases that were equal to or greater than 100 percent at a single point in time during 1988 to 2008. In other words, we identified those drug products whose cost doubled overnight.

Excluded from this particular analysis are those prices whose percent difference met this criteria—met or exceeded this criteria, but over time. Instead, we just looked at those that had a single point in time.

What we found was across all of the drugs, 13.5 percent have had 1 or more extraordinary price increase in the last 20 years. One in 20 of the brand, single-source products and 1 in 45 of the brand off-patent drugs had seen extraordinary price increases.

We also looked at the timing of these increases over the last 20 years. While there were a few extraordinary increases in the 1990s, the vast majority have been since the year 2000.

The number of these has been growing, especially for brand-name drugs, especially over the last 4 years. If you refer to Figure 1 in my written testimony, you’ll see this chart.

[A chart entitled “Figure 1. Extraordinary Price Increases of Drug Products: 1988 to 2008” appears in the Submissions for the Record on page 31.]

A price increase of 100 percent or more at one point in time is remarkable in its own right, but the size of some of these extraordinary price increases is staggering. For the brand single-source drug products, there were 6 price increases of more than 1,000 percent, with the largest being almost 3,500 percent.

Another 6 brand single-source drugs had an increase between 500 percent and 999 percent. One of the brand off-patent NDCs had a price increase of over 10,000 percent, and another ten had extraordinary price increases of greater than 500 percent.

This trend of price increases is not limited to just list and retail prices. There is a real financial impact on financial programs,
namely Medicare Part D, Part B, Medicaid, and the Public Health Service’s 340(b) Drug Discount Program.

While we intend to investigate this issue on a more comprehensive basis, a review of the sample of the drugs in our universe against the Medicare Part B average sales price file confirms the trend of extraordinary price increases.

For example, the average sales price reported for Acthar Gel, which we’ve heard about, in January 2007 was equal to $1,145, but by January 2008 the ASPs for Medicare-eligible patients were reimbursing providers $23,540.

The pharmaceutical market is extremely complex and vexing to most observers. There are many unique institutional and structural features to the pharmaceutical market that influence the economic behavior of drugs and drug prices.

The extent and magnitude of drug price increases seen in our preliminary study of this issue appear to indicate that the extraordinary price increases are not driven by ordinary explanations for price increases such as general inflation, cost of materials, labor and distribution, or the cost of FDA-required research for approval.

The magnitude of these extraordinary price increases is so great that these prices do not appear to be the product of an economically efficient and competitive market.

There are many reasons why these increases could potentially be explained. We have theorized on a couple of these issues.

Most of the drug products with extraordinary price increases are not among the top 100 to 500 drug products on the market. In part, these drug companies may have been able to implement these extraordinary price increases because they are low-volume drugs and they’re not often tracked or noticed in the marketplace.

This point speaks directly to Senator Klobuchar’s discussion about monitoring prices within the Department, which they do not.

Also, many of these drug products are for conditions that have a relatively small volume of demand. Some of the products have such a small market that it would not be profitable for even two competitors to survive.

Other drug products with extraordinary price increases may have been in short supply, either before or after the price increase was taken. The fact that some of these drug products are sold only through limited distribution channels, for example, specialty pharmacies, mail order pharmacies, physician dispensers, dialysis care centers, and others, may also play a factor in enabling extraordinary price increases.

The Prime Institute plans to continue research in this area to better understand and characterize the market conditions that have led to the growth of extraordinary price increases for prescription drug products.

Our research will look for patterns across firms, therapeutic categories, market conditions, intellectual property and exclusivity status, dosage forms, distribution channels, and other factors.

The continued research will also examine how these extraordinary price increases have affected private and Government drug programs, market entry and the market for drug products, and specific patient populations. Thank you very much.
Senator Klobuchar. Thank you very much, Ms. Carpinelli.

Dr. Alan Goldbloom, who is our next witness, became president and CEO of Children’s Hospitals and Clinics of Minnesota—which is the eighth largest children’s healthcare provider in the Nation—in January of 2003.

Prior to joining Children’s, Dr. Goldbloom served as executive vice president and chief operating officer of the Hospital for Sick Children in Toronto, responsible for day-to-day operations of the Hospital, as well as community initiatives and partnerships.

Dr. Goldbloom’s career is centered on a passion for providing quality care for children and strengthening pediatric medicine.

Dr. Goldbloom.

STATEMENT OF DR. ALAN L. GOLDBLOOM, M.D., CEO, CHILDREN’S HOSPITALS AND CLINICS OF MINNESOTA, MINNEAPOLIS, MN

Dr. Goldbloom. Madam Chair, thank you so much for the opportunity to testify here today. As you mentioned, I have the privilege of serving as president and CEO of Children’s Hospitals and Clinics of Minnesota and prior to that—I also have a background as a pediatrician, but I’m no longer practicing.

Children’s is the largest provider of care to children with severe prematurity, cancer, heart disease, and complex surgical conditions in the upper Midwest.

My testimony here today will focus on our experiences at Children’s with two drugs that are used in the treatment of serious conditions in infants. My testimony is not a criticism of the pharmaceutical industry as a whole, for this is an industry that has produced extraordinary advances in healthcare 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, while I will refer to two specific companies, they are in no way unique in this practice.

One condition that we treat in infants is called patent ductus arteriosus, or PDA, to which you, Madame Chairman, have already referred. This condition affects about 3,000 infants annually in the United States and is most common in very premature infants.

I’ll try to explain this in very simple, non-technical terms. A newborn baby’s blood circulation changes within moments of being born. As adults, our blood circulates to our lungs to pick up oxygen, and then gets pumped out to bring that oxygen to the rest of our bodies.

For a fetus still inside the womb, the lungs are not functioning, so the ductus arteriosus is a blood vessel that actually diverts the blood away from the lungs. The fetus gets oxygen from the mother, instead, through the umbilical cord.

Once the baby is born and the lungs begin to function, the baby takes the first breath, that ductus arteriosus normally spontaneously closes itself off; it just tightens up and shuts off so that blood does flow to the lungs.
But in some babies, especially those with prematurity, that ductus does not close; it remains open or patent, hence, patent ductus arteriosus.

And while sometimes that will resolve spontaneously, in some infants it becomes a serious enough condition to cause congestive heart failure and to interfere significantly with breathing.

When that happens, we have to treat, and last year for example, at Children’s of Minnesota, we treated about 110 babies with that condition.

For many years, the only way to treat this was through surgery. The surgeons went in and literally tied off that open blood vessel.

But over 30 years ago, it was learned that a very common drug, indomethacin—the brand name is Indocin—when given intravenously, could often produce the same result without subjecting the baby to surgery, and Indocin became the standard initial treatment for PDA.

Until recently, Indocin has been a low-cost, safe, non-surgical way to treat these babies. In fact, the cost for Indocin, up until January of 2006, was just over $100 per unit.

About 42 of the Nation’s largest freestanding children’s hospitals are members of an organization called Child Health Corporation of America, or CHCA, which serves as the group purchasing organization for three-quarters of those hospitals.

And for the members of that group purchasing organization, the collective annual cost, up until 2006, was just $136,000 nationally.

Well, things changed when the specialty pharmaceutical company, Ovation, bought exclusive rights to Indocin and several other drugs from the pharmaceutical giant, Merck, in August of 2005.

The price for one unit of Indocin jumped from $108 to $1,500, an over 1200-percent increase.

But Indocin is an old drug. It’s been on the market for over three decades, so this dramatic price increase cannot be attributed to the high cost of research and development.

As purchasers, our children’s hospitals had no other options. There have been no other manufacturers of Indocin, so effectively, one company has a monopoly and can use it to price-gouge.

The effect of this dramatic price increase in our Hospital totaled nearly $150,000 in the first year of that increase, and according to CHCA, it cost its member hospitals close to $2 million in that first year, up from $136,000 just a year earlier.

Like all healthcare providers, we struggle with the issue of increasing costs. Often, we’re 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 this 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; so from our perspective, that extra $150,000 that we pay 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 that group purchasing organization at CHCA represent only a fraction of the nearly 600 neonatal intensive care units nationwide. All of them see babies
with PDA, so the overall impact is much higher than the number I've quoted.

And 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 3400, 864, 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.

A very similar situation developed when specialty pharmaceutical company, Questcor, bought Acthar Gel from Aventis. Acthar Gel, as you have mentioned, is used to treat infantile spasms, a rare, severe, and treatment-resistant form of seizures that affects very young infants.

Acthar Gel is considered the gold standard for treatment of infantile spasms and at Children's of Minnesota, we have one of the largest epilepsy treatment units and have used Acthar Gel nearly 50 times so far this year.

This drug was originally approved in 1978 for multiple sclerosis, and its cost has always been high. However, after Questcor bought the rights to Acthar Gel, the list price rose from $1,650 per vial to $23,269 per vial. This is a 1400 percent increase, which costs the CHCA hospitals over $21 million per year.

Madam Chair, there are many other drugs, hundreds in fact, that are priced this way, both pediatric and non-pediatric, and even with good insurance, a 20-percent co-pay on something like Acthar Gel is more than many people's monthly mortgage payments.

Sadly, in this time of skyrocketing healthcare costs, the burden of expensive healthcare 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 appear to be taking full advantage.

I want to reiterate, Madam Chairman, that my testimony today is not intended as a rant against the industry as a whole, because it has produced many great benefits, but 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 very much for the opportunity to speak with you today.

[The prepared statement of Dr. Alan Goldbloom appears in the Submissions for the Record on page 33.]

Senator Klobuchar. Thank you very much, Dr. Goldbloom. We appreciate your testimony and your good work.

We now have Danielle Foltz, who became a passionate advocate for families affected by infantile spasms when her son, Trevor, who is with us today, was diagnosed with the disorder in November of 2007.

The incident sparked a passion in Ms. Foltz to help families with IS issues. Prior to 2007, Ms. Foltz worked with a nonprofit orga-
zation, BBF International, for 5 years. She lived in Tanzania, East Africa, and assisted in the oversight of the feeding center called Nema House, which helped feed impoverished children.

Ms. Foltz holds a B.A. Degree from Louisiana Baptist University.

Mrs. Foltz.

STATEMENT OF DANIELLE FOLTZ, PARENT OF YOUNG PATIENT FROM RHODE ISLAND

Ms. Foltz. Madam Chair Kobuchar, I would like to thank you for this opportunity to share our personal story today. I am Danielle Foltz, as you've already mentioned, from Rhode Island and the mother of Trevor Foltz, and I would like to share with you our journey to receive critical treatment for our son.

While I am speaking only on behalf of my own family, I would like to acknowledge the support of the Epilepsy Foundation. The Epilepsy Foundation represents the 3 million Americans who have epilepsy, and their goal is to help those individuals gain access to the medications they need, like Trevor. I know they will continue to follow this hearing and the path from here forward.

I understand that today's hearing is highly political; I get that, but for us and the 2,000 families that are going to deal with infantile spasms every year, this is personal.

How do you find the words to describe the most horrific event in your life, your personal valley of the shadow of death? Because that is exactly the feeling that clamps your heart when you are at a place where the medication needed to rescue your child is out of your reach.

For 7 1⁄2 months, we celebrated our beautiful third born, Trevor. In fact, we were packing our luggage in anticipation of returning to our ministry in Tanzania, East Africa, when we noticed him making jerky, odd movements. They resembled newborn startle reflexes.

Devastated does not begin to touch how we felt when we learned that those jerky movements were actually seizures. Trevor was having as many as 20 seizures in a single 60-second span, up to 5 times a day.

We knew it was serious when his neurologist told us to meet with him immediately following that first EEG. It was in that meeting that we were given the devastating news that our beautiful 7 1⁄2-month-old son had the rare and catastrophic disorder called infantile spasms.

All three neurologists we consulted told us the same thing: If we did not get control of his seizures immediately, Trevor's developing brain would be irreparably damaged.

We were told that the only thing between our son and a shot at a normal life was a drug called ACTH, marketed as Acthar Gel by Questcor Pharmaceuticals. Our neurologist prepared us that Trevor's treatment would be pricey. He estimated that it would be around $10,000 per vial.

As you can imagine, we went numb. We immediately notified our insurance company. The urgency of providing Trevor's treatment, was heavy and we needed to move forward as quickly as possible.

As Trevor's seizures continued to intensify, we read the information about IS online, and the sorrow of what we were up against
was emotionally overwhelming. What we did not know was that 4 months prior to Trevor’s diagnosis, Questcor Pharmaceuticals had implemented a new business model.

This business model included raising the price per vial of Acthar Gel from approximately $1,000 each, to over $30,000 per vial. And because Trevor was the first child to receive ACTH treatment after the price increase, not even our neurologist was aware of how dramatically the price had risen.

What he thought would cost us no more than $50,000, total, would now be an astounding $150,000 for the medication alone. In hindsight, we have no doubt the excessive price of this drug influenced our insurance company against originally approving it for Trevor.

My husband spent days on the phone fighting for Trevor to have coverage. We knew there was no way that we could afford this treatment ourselves. One vial of Acthar was being quoted at a minimum of $30,000, and Trevor was going to need at least 5.

We could buy a nice three-bedroom colonial in some areas of the country with that kind of money, but because we had given our lives to serve a nonprofit ministry in Tanzania, we don’t own that three-bedroom colonial. We didn’t have the house to mortgage as collateral for his treatment, which I’ve heard some families have actually been forced to do.

All of our earthly possessions were in Africa. We had nothing to liquidate to come up with this money, but to wait was not OK; we needed to save our son.

And so I was frantically looking for other options. I called the Acthar Support and Assistance Line because I had learned that Questcor offers the assurance that no child who truly needs this treatment will go without. I spoke with the call center representative and was informed that the approval process included paperwork for ourselves and Trevor’s doctors to submit.

When I asked how long the approval process would take, I was informed it would be a minimum of 3 business days. When I asked if approval was a sure thing in a case like ours, I was told, no.

At that point—I’ll be honest—my emotions got the best of me, and I informed her that I thought it was a sham, that if Questcor was really about providing a vital medication in a time of desperation, it wouldn’t take 3 business days to reach the maybe point.

When your infant’s body is being racked by 40 seizures every single day, you do not have 3 business days to play Russian Roulette, waiting for a medication that could stop his seizures and right your world again.

Those days following Trevor’s diagnosis, for our family, were the most emotionally dark that we’ve lived through. My husband and I were pretty much a puddle on the floor.

Just getting that kind of diagnosis shatters you, but then to add the guilt of realizing that you may not be able to rescue your son because you can’t afford to, it’s unimaginable, and in my mind, unacceptable.

We literally thought it was possible that our son would go without treatment, or that he would be forced to use a less effective medication that could leave him developmentally challenged forever.
I wonder how many other families are living that same nightmare right now. How many are being exploited in their desperation? For our family, finally on Wednesday, November 21, 2007, the day before Thanksgiving—after numerous emotional phone calls between my husband and our employer—we were told to move forward with the treatment.

It had already been a week since Trevor’s diagnosis, and each day without treatment was stealing our son from us. We witnessed his physical regression and the distress as his seizures became ever more violent.

We were admitted the following day and Trevor’s very first Thanksgiving was spent at Hasbro Children’s Hospital.

Because the ACTH must be injected into the thigh, a nurse was sent to teach us how to administer it for when we went home. My husband was asked, was he nervous when he gave Trevor the shot for the first time? And he replied that he was more nervous holding $5,000 in a single syringe, or worse, dropping the vial and breaking it.

I know that our family was lucky. Trevor is a miracle, and our insurance ended up covering the 6-week course that Trevor needed of ACTH. Trevor has been seizure-free since his fourth injection, and that’s why I brought him with me today.

I believe his face needs to be here, representing all the other IS faces. He is the poster child for why this drug needs to be available and affordable.

Today we’re celebrating our miracle, and we pray that Trevor will remain seizure-free, but what if he doesn’t? Are we going to have to fight for coverage again?

I’m going to leave this hearing today, and as you can imagine, I’m going to go home. I have a 3-year-old daughter waiting for me. I’ll return to my life of loving and advocating for my son, but my story is inextricably connected to the 2,000 families this year and next year and the next who will live with this horrific diagnosis.

My heart cannot help but be consumed by those families devastated by infantile spasms. Will they have access to this drug, or will they be priced out?

In fact, in preparation for my testimony today, my husband, Jonathan, researched the current price for a vial of ACTH. Unbelievably, the escalation has not plateaued. The very same vial we ended up paying $26,000 to obtain just 6 months ago, today can cost as much as $40,000.

Where does it end? I can’t pretend to understand the many layers of this issue, but what I can wrap my heart around is the terror that a young mother faces when she cannot rescue her baby, not because his treatment or his sickness is untreatable, but because she cannot financially afford the medication he needs.

And I implore you today to please consider my thoughts and to find a way to help families like mine get access to these medications. I don’t want another family to live with the nightmare of IS and not able to treat their child.

Please help these families dealing with infantile spasms get affordable access to the drug that could be their miracle, too. Thank you.
Senator Klobuchar. Well, thank you very much, Mrs. Foltz, for that moving testimony and for being willing to have your family here. As I listened to you, I could relate a little bit to this in a very small way.

When my daughter was born, she couldn't swallow, and I got kicked out of the hospital. It was when you could only stay for 24 hours, and just that feeling of trying to—having no control and trying to come back to find her and help and stand in the rooms and try to figure out what was wrong, when you really couldn't stay overnight in the hospital.

Those things were wrong. We changed that and got a 48-hour mandatory stay in Minnesota, as well as across the country for new mothers and their babies.

But I just remember that feeling that you're talking about, where you would go to any length to protect your child and someone's getting in the way for what is nothing more than greed.

Did you feel, when this was going on—did you even consider that you wouldn't pay for that drug if you had to find a way to do it?

Ms. Foltz. No, no. I mean, we thought, if worse came to worst, we'd be paying for it for the rest of our lives. I mean, he needed the medication, and we need to move forward.

The problem is, the hospital where we were only had one vial, and I'm not sure if they could access it. We were working with pharmacies and other things, but we needed the medication.

I mean, ACTH is the front-line treatment for infantile spasms, and he needed it. Obviously, he responded to it within 4 days, so we were going to do whatever it took. It was just, how were we going to do it?

Senator Klobuchar. He just moved his arms. I think he heard you.

Ms. Foltz. He hears mommy.

[Laughter.]

Senator Klobuchar. Well, when you said his name, that got a move, too.

So anyway, so your husband kept pushing on the insurance company. Did they ever say anything about that it was the price of the drug, or that's what you thought it was?

Ms. Foltz. I mean, that is total speculation. They said that because it was not FDA approved or FDA indicated for infantile spasms—which I do think is a part of the problem—that was why they officially told us they wouldn't cover it, but they refused to budge until our neurologist actually sent a letter telling them that if you don't cover this medication, this child will be mentally retarded for the rest of his life, and you'll pay millions more than what you expected to.

Senator Klobuchar. For not covering him?

Ms. Foltz. Yes.

Senator Klobuchar. And you think that made a difference?

Ms. Foltz. That absolutely is what turned the tide with our insurance company.

Senator Klobuchar. And did you have to go to the doctor and get the doctor to do it, or how did you get that done?
Ms. Foltz. She was—you know, our neurologist was amazing. She was handling everything for us. She was on the phone with the insurance company, I want to say “duking it out,” but I don’t know if that’s appropriate, but yes, she was——

Senator Klobuchar. Anything’s appropriate at this hearing. [Laughter.]

Ms. Foltz. She was duking it out for us with them, so she definitely was an advocate for us all the way through.

Senator Klobuchar. And has your son received other medical treatment for his disorder, besides the Acthar?

Ms. Foltz. Yes and no. He is not currently taking any anti-epileptic medicine, and that’s because he has been seizure-free, but with infantile spasms, babies are really in a danger zone, at least until they are school aged, until age 5.

They are at risk of developing other forms of seizures. From my understanding, infantile spasms is really a symptom of an underlying condition, and the reason why it’s so devastating is because these babies are having 40 seizures, sometimes hundreds of seizures a day, in the very essence of their development. Their little brains are developing.

So Trevor still is monitored by his neurologist. We see her every 6 months. We’re still tracking down his underlying cause, getting MRIs and EEGs. He’s going to have his sixth EEG this next week, so he still receives treatment, just not medication.

Senator Klobuchar. So the idea here is that this drug isn’t necessarily one he would have to take for a lifetime?

Ms. Foltz. No.

Senator Klobuchar. But it was needed at that moment, at that time?

Ms. Foltz. Yes.

Senator Klobuchar. To stabilize him.

Ms. Foltz. Exactly.

Senator Klobuchar. And how long did he take it?

Ms. Foltz. He took it for 5 weeks.

Senator Klobuchar. For 5 weeks. It was just for 5 weeks?

Ms. Foltz. Just for 5 weeks.

Senator Klobuchar. And how long was the delay in getting him the drug?

Ms. Foltz. It was at least 5 days, and we were actually told that if we—and part of the problem was timing. He was admitted on Thanksgiving, and no one wants to take their holiday and rescue a little baby, unless it is, in their minds, life or death, and this wasn’t considered that for them.

But, yes, it took those 5 days to get that treatment.

Senator Klobuchar. Did the treatment have any side effects, or from your perspective, it went well because then he didn’t have any spasms?

Ms. Foltz. In Trevor’s case, we had minimal side effects. He did have elevated blood pressure, which was monitored at home by a visiting nurse, and he also took blood pressure medication, but that was really the only side effect that Trevor had.

Senator Klobuchar. How is he doing now?

Ms. Foltz. You can see, he’s amazing. If he were awake, I’d let him toddle around for you.
[Laughter.]

Ms. Foltz. Yeah, he is a miracle, and he’s thriving, and he’s overcoming, and I can only imagine what is in store for his future.

Senator Klobuchar. And what advice would you give to other families who find out that they need a drug where the prices suddenly had gone up, you know, as we had some examples 8,000 times, 18 times, 1,000 times; how would you tell them to handle it?

Ms. Foltz. You know, part of the difficulty of that, is when you’re in that crisis moment, your head is not on straight. I mean, you’re not thinking what can I do? And I mean, I guess, part of my advice would be, and what benefited me the most, was getting online and joining a community of other infantile spasm parents who have direct resource to the different options out there.

And that’s where I’ve learned most of my information about infantile spasms and courses of treatment, so that would be my first piece of advice and the second is just keep fighting. You fight because your baby deserves the coverage and your baby deserves to get treatment, and don’t wait.

Senator Klobuchar. OK, thank you. Now, what’s Trevor’s brother’s name, there?

Ms. Foltz. That’s Toby.

Senator Klobuchar. Hey Toby, thank you for being so good.

All right, we’re going to ask some more questions now. They might not be quite as interesting, Toby, as the ones we asked your mom.

[Laughter.]

Senator Klobuchar. OK, well, why don’t we turn to you, Ms. Carpinelli, and talk a little bit about just the general state of this. Were you surprised by Mrs. Foltz’s story?

Ms. Carpinelli. I had the opportunity to read her online blog about it, which was fantastic and just really colorful, and it told quite a bit. And it really does speak to the personal side of this issue. I’m here to present the dry, economic side of things, and I’m glad to hear the experiences of Dr. Goldbloom and Ms. Foltz.

But this is not surprising. There have been issues with these types of products for years. It is impacting both private and public insurers very much.

I know that from previous experience that companies are going so far as to try to single out individuals that they’re covering, that have rare diseases, and trying to figure out ways to get them treatment at other places, so they don’t have to cover the cost of their drugs, because it’s raising everyone else’s per-month, per-year, or per-member costs.

These people that do have rare diseases or hemophilia, for example, are getting singled out and asked to get care at a place, such as a public health service grantee where at least they can purchase the drug at a discounted price, and maybe offer you a price break.

But for those cash payers, this is just outlandish.

Senator Klobuchar. So how do—to go back to the pharmaceutical companies—how do the prices and changes to U.S. pharmaceutical products compare to external benchmarks such as, you know, overall inflation in the economy or prices that we’ve seen in other countries?
Ms. Carpinelli. Through our research, we found that the increases for drugs is typically two to three times what the average rate of inflation looks like.

What's really interesting is that each time the price trends are examined, there are a handful that have increased substantially greater than this. But, some of these can be between 10 and 30 percent of an annual increase, and not acceptable anymore.

The economic market for pharmaceuticals is so distorted that it's OK to have a 10 to 20-percent increase, you know, from month to month or from year to year. Increases of this magnitude are just viewed as normal now.

This is not acceptable in any other market. I mean, consider the outrage over gas prices now. This isn't gas; these are drugs; these are drugs that save people's lives.

Senator Klobuchar. And what impact do you think this has on—well, I know it's 11 percent of our healthcare expenditures, pharmaceuticals are totaling about $217 billion.

Ms. Carpinelli. Right.

Senator Klobuchar. What impact does this have on Medicare and Medicaid?

Ms. Carpinelli. We at the Prime Institute are still conducting research on this issue, but are challenged by the amount of confidential data that the manufacturers possess for the Part D program and for Medicaid.

There are a lot of price components that get reported to the Government, that are based on actual sales, versus list prices. In order to get a really true assessment of that, of how it will impact Medicaid and Medicare, you have to have access to this data.

I am glad to hear that the Committee has requested further study from the GAO. They will have access to that confidential pricing information and will be able to report a much more accurate figure.

Senator Klobuchar. Very good. In your testimony, you highlighted drugs that appear to demonstrate effects related to monopoly pricing. In a normal market, you know, one would expect that the unit cost would decrease as sales increased. That's what's supposed to happen, right?

Ms. Carpinelli. Right.

Senator Klobuchar. At least that's what I learned in Economics 101.

[Laughter.]

Senator Klobuchar. Because the manufacturer can afford to offer a lower price. However, with some of these products, it seems like an increased or stable market, actually exists, but the price suddenly gets jacked up a hundred percent, a thousand percent.

Ms. Carpinelli. Right. We at the Institute like to say that each individual values their life as exponential but that does not mean that the cost for a drug should also be exponential. In other words, drug companies could not make pricing decisions on what they think the market will bear.

An individual can't compare the value of their life to how much a drug product is going to be. In essence, the prices discussed today could be what we refer to as supra-competitive prices, or prices above what can be sustained in a competitive market.
Supra-competitive prices are present when a firm has a unique position in the market with respect to intellectual property or legal status, barriers to entry, product features that offer a competitive advantage, or other factors.

The number and magnitude of these types of price increases that we’ve discussed today also raises the possibility that antitrust issues may be present. Going back to the Norvir case that you had mentioned, there are several lawsuits that Abbott is currently engaged in, for that reason, exactly.

**Senator Klobuchar.** Right, well in fact, the FTC filed a complaint against Cephalon, in response to its anticompetitive behavior for its sleep disorder treatment, Provigil. According to the FTC complaint, Cephalon is paying four generic drug makers to refrain from selling generic versions of this drug, until 2012.

**Ms. Carpinelli.** Right.

**Senator Klobuchar.** Do you know about that case?

**Ms. Carpinelli.** Not those specifics, but that doesn’t surprise me. That’s been a common reason for cases in the last years.

**Senator Klobuchar.** So they are actually paying off generic drug manufacturers, not to——

**Ms. Carpinelli.** There is some concern that there are other financial incentives to companies that are subsidiaries of other companies, that are waiting, that are kind of in cahoots with their larger parent company.

**Senator Klobuchar.** I think you mentioned the drug, PhosLo, in your testimony, and there the gradual increase, as opposed to the drastic spike in price that occurs with this particular drug. How is that drug different?

**Ms. Carpinelli.** You know, there were two drugs whose prices we examined that didn’t necessarily have a single-point-in-time increase, rather, their increase was substantial over time.

I’m not exactly sure why that drug would have been different, but instead, for PhosLo, there were four increases over a year and a half’s time of 40 percent, 40 percent, 40 percent, and 32 percent, equalling 262 percent total.

Once again, it’s the same sort of thing that we’ve discussed—that this is a product that was on the market, got bought out by another company, and then suddenly the product price spiked.

I did want to briefly mention the Orphan Drug Act. As you mentioned in your testimony, this was an Act designed to help create products in a market that wasn’t necessarily attractive.

And as part of that, manufacturers do get a lot of really great incentives. In addition to the 7-year market exclusivity, they also get a waiver from the $500,000 a year user fee from the FDA, they get grant money to do their clinical studies, and they also get tax breaks on their clinical investigations.

It’s important to note that in addition to the market exclusivity, that there are other incentives that kind of offset the costs for the development. I think this furthers your point that having orphan drug status might not necessarily be a motivation in terms of price increases.

**Senator Klobuchar.** Right. Dr. Goldbloom, a July 2008 Wall Street Journal article discussed the recent implications of rising
pharmaceutical costs in the field of oncology, where drug prices can cost more than $100,000 per year.

Many health policy experts have started to suggest that it’s time for American doctors to begin reconsidering costs when assessing treatment options.

Do you think that this is a good practice? Should cost be a consideration?

**Dr. Goldbloom.** Senator, I believe that all of us in healthcare have a responsibility to use our resources as wisely as we can. That means that decisions are never based on costs alone.

The first and most fundamental is to use evidence-based research about which treatments are best and most effective, most reliable, and cause the least risk. That’s always the number one decision.

When we have two treatments that are equivalent and one is at a lower cost, then yes, I believe we have a societal responsibility in those situations to use resources wisely.

And I believe that it’s a direct benefit to society, because the more we can spread those resources, it improves our ability to provide coverage to others; it improves our ability to provide treatment to others.

There is not an unlimited pool of resources, so the answer is, it is a factor, and it’s part of our overall responsibility. It should never be the only factor, and when there is a single lifesaving, disease-curing treatment that is available that happens to be expensive, just as we heard in the testimony of Ms. Foltz, then we have to do what is right for the patient.

**Senator Klobuchar.** OK. You, in the case of indomethacin or Indocin that we’ve been talking about, you first heard about this from your pharmacy manager; is that correct?

**Dr. Goldbloom.** That is correct.

**Senator Klobuchar.** And why was this so surprising to you when you heard about this increase?

**Dr. Goldbloom.** This was a surprise to me because I reflected back, frankly, to my own days back when I was training as a pediatrician, and that was in the early 1970s, and we were using this drug then.

So this is, to me, a very old drug; it’s been around a long time, standard treatment for a long time. I could not imagine any justification for a sudden change in the price, particularly a change of the magnitude that we’ve described here today.

There’s been no new research that I’m aware of, and the only thing that seems to have changed was the right to manufacture and sell the drug.

**Senator Klobuchar.** Did you hear anything that there might have been a shortage of the drug? That’s something we’re hearing from Ovation, that suddenly there was a shortage when they were producing it.

**Dr. Goldbloom.** I had not heard that, Madam Chair.

**Senator Klobuchar.** Did you have a shortage at your hospital of the drug, like you couldn’t obtain it?

**Dr. Goldbloom.** Not that I’m aware of.

**Senator Klobuchar.** How does your hospital offset the increased cost of drugs such as indomethacin and Acthar?
**Dr. Goldbloom.** In the first year or two, we absorbed most of that cost because we function under existing contracts with our payers, with the insurers. So when things change in the midst of a contract, we simply absorb the cost, which means that we have to reduce our spending in other services that we provide.

So, in an indirect way, it does have an impact on other services to other patients. Eventually, however, if that looks like a sustained price increase, we build it into the costs that we use as the basis for our negotiations with payers, whether insurers or whether Medicaid, which means that the costs are being passed on, either to the taxpayers or to individuals and companies.

It's costing society more when we're all trying to reduce healthcare costs.

**Senator Klobuchar.** Have the insurance companies or Medicaid—you wouldn't have Medicare at Children's Hospital—but Medicaid, the insurance companies talk to you or others about their concern about these price increases?

**Dr. Goldbloom.** They have not specifically talked about this drug, but they certainly are under tremendous pressure to minimize the annual increases in the contracts. This becomes a struggle between hospitals and insurers every time a contract is up for negotiation.

We do face significant increases year after year, some of them understandable, like when there's a brand-new drug that has been the result of great and very expensive research and development and is used, say, in the treatment of childhood cancer. We do understand some of those price increases.

But it is part of a continuing battle, if you will, in the negotiations that occur with our payers.

**Senator Klobuchar.** In your testimony, Dr. Goldbloom, you mention the Child Health Corporation of America, CHCA, which serves as a group purchasing organization for many of the country's freestanding children's hospitals. Does CHCA have any power in controlling the price of these drugs?

**Dr. Goldbloom.** Well, they do have the power of numbers, in the sense of trying to use the group purchasing volume as a means of negotiating. The problem is, when there is a single manufacturer, you lose most of your leverage.

**Senator Klobuchar.** So in other words, it might be a major drug manufacturer who cares about the fact that you're a leveraged group, a large group, and you can negotiate with them because they don't want to lose your business on other drugs?

**Dr. Goldbloom.** Correct.

**Senator Klobuchar.** And so when you have a case where someone just takes one or two drugs and jacks up the prices, they don't really care, especially if they own both of the patents for the drug?

**Dr. Goldbloom.** The negotiation becomes a take-it-or-leave-it kind of negotiation.

**Senator Klobuchar.** And then obviously, there's other hospitals that aren't in your purchasing group.

**Dr. Goldbloom.** Right.

**Senator Klobuchar.** That must be like smaller hospitals and things like that.

**Dr. Goldbloom.** Yes, that's right.
**Senator Klobuchar.** OK, all right, well, I want to thank you, Dr. Goldbloom. I wondered, did any of the three of you have anything that you wanted to add? I see Trevor is up and eating now. [Laughter.]

**Senator Klobuchar.** And he smiled. [Laughter.]

**Senator Klobuchar.** Do you have anything that you’d like to add, at all?

**Dr. Goldbloom.** I’d just like to thank you, Senator Klobuchar, for shedding light on the issue and bringing it to public attention, because I think that’s the first step in trying to find solutions to the problem.

**Senator Klobuchar.** Thank you.

**Ms. Foltz.** I definitely want to say thank you, thank you from a family that lived through this, and it’s really nice to see that you guys are paying attention and seeking to help families like mine.

**Senator Klobuchar.** Well, thank you. I do want to say that this is just the beginning. This is one hearing. I know there’s a House Hearing right now, as well, on pharmaceutical pricing, and what we’re trying to get here is to get whatever information we have, because we know that this has a ripple effect on not just the hospitals, as Dr. Goldbloom has pointed out, but on taxpayers, with Medicare and Medicaid, and then on individual families’ finances.

And this is not to say that people shouldn’t be able to make money and it’s not to say that we don’t want the market to work. We’d like the market to work because if the market was working, we probably wouldn’t be in this situation with one company owning both patents on a drug that competes with each other.

What I think we need to do when we have cases like this of just outrageous pricing, where the people that are getting ripped off are families and the citizens of this country, that we have to give the agencies that regulate this the tools they need, and if that’s not working, then we’re going to have to change the law, because this just can’t keep happening like this.

It’s just one example of many of cost overruns and problems in our healthcare system in this country. When you have a company like Ovation that can somehow make the cost decision and think it’s OK to sell this drug that saves babies’ hearts, for 44 times the amount an American company in America, than it sells it in Canada, we have a problem.

And when they can jack up the price 18 times, just because someone sold it to them, there’s a problem. And so I just want to assure you, Mrs. Foltz and Dr. Goldbloom, from a hospital perspective, and Ms. Carpinelli, from the academic research perspective, that we’re not just going to let this go.

That’s why we’ve asked the FTC to look at this, and why we’re holding, in Congress, major hearings as we go forward and gathering ideas about how to stop this from happening and help the people of this country.

So thank you very much, and our hearing is adjourned.

[Whereupon, at 11:18 a.m., the hearing was adjourned.]
I'd like to thank Senator Klobuchar for holding this important hearing, and thank our witnesses for being here today. Yesterday we talked about the Middle Class Squeeze and how American families gather around their kitchen tables and talk about how they’re going to pay these skyrocketing bills for food, gasoline, college, day care, and yes—prescription drugs and health care. Today's hearing focuses on the lack of affordability of potentially life-saving drugs that treat rare diseases.

And we're not talking about an everyday kind of un-affordability. We are talking about drugs that have gone up 100, 500, or 3,000 percent in a matter of months, weeks, or overnight. That's way more than inflation, and it far outpaces the increases families are paying for so many of their other household expenses.

Our health care system can, and usually does provide high quality care, but more and more we hear about significant problems with access and affordability hurting American patients.

While we are talking about smaller segments of our population when we discuss rare diseases, the total number of American families touched by them is quite high. NIH estimates that between 9 and 10 percent of the American population, or nearly 30 million men, women, and children, are affected by a rare disease. Approximately half of these people are children, and many of these rare diseases are present at birth.

Patients with rare diseases and their families suffer from more than their disease alone. They also have the frustrations of not being able to find information about their disease and the heartbreak of finding out that there is no treatment, or in the case of a witness we will hear from today, that the life-saving treatment she needs for her child is priced exorbitantly high.

When our panelist, Danielle Foltz, needed the drug Acthar (ACT-Thar) to treat her infant son for life-threatening epileptic spasms, she faced paying over $29,000 per vial. That’s 13 times higher than the price had been just 8 months before he was diagnosed. One might say that a brand new drug that just hit the market might be pricey because it had to recoup research and development expenditures, but Acthar has been on the market for three decades.

And the same is true for the drug Matulane (matt-you-lane), which treats Hodgkin’s Lymphoma, and cost less than $70 per dose in late 2004. Just 6 months later, the price had increased to $5,568! That’s an eight thousand percent increase. And not for a groundbreaking new drug—for a drug that was put on the market in the 1960s.

Our witnesses today are going to shine a light on practices that look uncomfortably like an abuse of the pricing power we give to drug companies. In case after case, it appears that PHARMA companies have been taking critical drugs that have been on the market for years—with the costs of their development long since paid for—and increasing prices to the very highest levels the market will bear.

Our witness from the PRIME Institute at the University of Minnesota has found over one hundred cases since 2002 where the price of single-source drugs more than doubled due to a single price increase.
Healthcare reform is on the horizon, and the appropriate pricing of drugs and all medical services should be a top priority. We all benefit from incredible innovation of pharmaceutical companies. Their success is in treating or sometimes curing diseases both severe and mundane is an important part of American competitiveness and greatness.

But the testimonies today are disturbing and show that much greater oversight and perhaps even significant action by the Congress is needed.

Along those lines, together with Senator Klobuchar I’ve asked the General Accounting Office (GAO) to look into the issue of these price increases and see if they are truly justified.

I also introduced a bill and worked to develop the Senate compromise with Chairman Kennedy and Senators Clinton, Enzi and Hatch on creation of a pathway for generic versions of biologic drugs. I am pleased that the National Organization for Rare Diseases touted the passage of a pathway for follow-on biologics in their submission for the record of this hearing. That is one clear way we can help patients with rare diseases.

Creating this pathway is an important development for American consumers, and I bet that the next Administration will work with Congress to make sure that the FDA implements this priority.

Generics and market competition works. We need to build on these successes and improve our system of approval and licensing for generics. The research shows that it usually takes at least two or three generic entrants to seriously lower drug prices. It also shows that generic companies are reluctant to enter markets for rare diseases, since many of these “niche” markets aren’t large enough to sustain more than one or two competitor drugs.

Of course we realize that there are legitimate reasons why drug companies may need to raise prices. Price increases can be a normal cost of doing business. But we can’t let the cost of doing business serve as an all-purpose excuse for excessive pricing that put important drugs out the reach of many families.

We owe it to all of America’s patients to keep a vigilant watch on this situation.

PREPARED STATEMENT OF SENATOR AMY KLOBUCHAR, PRESIDING

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 arteriosis 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. But 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* 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! Cosmegen 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 spurrying 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.
Good morning. I would like to thank Chairman Schumer for allowing Senator Klobuchar to hold this hearing to examine the skyrocketing prices of certain prescription drugs. I want to welcome our panel and thank them for testifying here today.

Evidence has been coming to light recently of potential abuses of the pricing power we give to drug companies in the United States. In case after case, it appears that some pharmaceutical companies have been taking critical drugs that have been on the market for years—with the costs of their development long since paid for—and increasing prices to the very highest levels the market will bear.

Since some of these drugs are the only available cures for life-threatening diseases, those prices can be extremely high. One of the more egregious examples is the drug company Sigma Tau, which increased the price for Matulane, a key drug for treating Hodgkin’s Lymphoma, by an amazing 8,000 percent over 6 months. The research and development costs for this drug are far in the past—Matulane has been on the market for some forty years.

These sudden and questionable price hikes are having a devastating impact on families. In 2007, Questcor Pharmaceuticals increased the price of Acthar, the best available drug for treating infantile epileptic spasms, by 1,300 percent. Acthar is a well-known drug that has been in widespread use since the 1970s. Yet because of this recent price increase, Danielle Foltz, one of our witnesses today, almost could not get life-saving treatment for her infant son.

It appears that some companies are making massive price increases for niche market drugs a critical part of their business strategy. In 2006, Ovation Pharmaceuticals increased the price of four different drugs it had recently purchased by an average of 1,640 percent.

Nor are these isolated incidents. Recent research by the PRIME Institute at the University of Minnesota has found numerous recent cases where the price of single-source drug products more than doubled due to a single price increase. What’s more, they’ve found that the incidence of these sudden price jumps increased substantially in this decade compared to the 1980s and 1990s.

The only protection our system provides against these exorbitant price increases is competition from generic alternatives. In recent years we’ve seen real progress in using generic competition to lower prices in drug markets for common diseases. We need to build on that success and improve our system of approval and licensing for generics. But research shows that generic companies are reluctant to enter markets for rare diseases, since many of these “niche” markets aren’t large enough to sustain significant competition.

Most of the drugs discussed in this hearing are in these “niche” markets for rare diseases—markets that can allow drug companies to raise prices without much competition. These drugs may be obscure, but they are critical to the patients who need them. And it’s our responsibility to make sure that access to these drugs is maintained. Going forward, Congress needs to examine ways to do this—and to address the kind of massive and unnecessary price increases that endanger access to life-enhancing drugs.

Mr. Chairman, thank you for holding this important hearing.

Prepared Statement of Madeline M. Carpinelli, Research Fellow and Stephen W. Schondelmeyer Professor and Director PRIME Institute, College of Pharmacy, University of Minnesota, Minneapolis, MN

Thank you, Chairman Schumer and other members of the Joint Economic Committee for this opportunity to provide information and insights regarding pricing trends in the pharmaceutical market.

I am Madeline Carpinelli and I serve as a Research Fellow with the PRIME Institute at the University of Minnesota. This Institute focuses its research on policy issues related to pharmaceutical economics and the distribution and management of drug expenditures at all levels in the marketplace. Prior to joining the PRIME Institute, I was a senior policy analyst at the Office of Inspector General (OIG) for HHS, where I managed a team of analysts in conducting evaluations of government expenditures.
drug price reporting and compliance issues. During my tenure at the OIG, I played a significant role in the development of the OIG’s annual Work Plan related to identification of key issues in the pharmaceutical industry such as the role of AWP, AMP and the Public Health Services’ 340B Drug Program. I also interfaced with the Department of Justice and the OIG Office of Prosecutions and Investigations.

These remarks present my own findings and views based upon my experience in studying the pharmaceutical marketplace for the past 9 years and upon my observations and ongoing work in collaboration with Dr. Stephen W. Schondelmeyer, the Director of the PRIME Institute.

Today, I will provide an overview and preliminary findings from research we have been conducting on extraordinary price increases in the pharmaceutical market. Through our tracking of drug prices over time, we have become aware that certain drug products have experienced extraordinary price increases that are well beyond what would normally be expected in a competitive market. We found hundreds of cases of extraordinary price increases for branded drug products. We also found that the incidence of such extraordinary price increases has been rising sharply in recent years, and today is much higher than it was in the 1980s and 1990s.

**TRACKING DRUG PRICES AND RELATED TRENDS**

Tracking changes in the benchmark prices of prescription drugs is important since it provides an explanation of the role of price changes in drug expenditures over time. AARP and the PRIME Institute have routinely tracked the price changes experienced by the brand name and generic prescription drugs most commonly used by Medicare recipients. These price change reports are updated quarterly and the reports can be found on the AARP website (www.AARP.org). These price trend reports have shown that a representative market basket of the most commonly used brand name drugs has experienced price increases from 2006 to 2007 that averaged 7.4 percent. For the same time period, the rate of general inflation, as measured by the Consumer Price Index for All Items, was 2.9 percent. In other words, brand name drug prices grew at more than two and one-half times the rate of general inflation.

Certain commonly used brand name drugs experience price increases that are substantially greater than other brand name drugs on average. For example, in 2007, Ambien (5 mg and 10 mg tablets) had an annualized price increase of 27.7 percent compared to the overall brand name inflation rate of 7.4 percent. Brand name prices that increase at a rate of two to three times the rate of general inflation have persisted for more than a decade. Each time the price trends are examined there are a handful of brand name prescription drugs that have price increases substantially greater than the overall brand name inflation rate. The impact of these prices growing faster than general inflation has been that prescription drugs have been growing as a share of national health expenditures and as a share of the gross domestic product.

While tracking the price changes of the most commonly used brand name and generic drugs, the prices of other drug products beyond the top 200 to 300 drugs have also been examined. In recent years, some of these less commonly used prescription drug products have had extraordinary price increases.

**EXTRAORDINARY DRUG PRICE INCREASES**

What do we mean by an extraordinary price increase? Extraordinary is a term that can be understood in contrast to the ordinary. Ordinarily brand name price increases have been two to three times the rate of general inflation and this rate of price increase has become routine. This rate of inflation is not necessarily acceptable, or even reflective of an economically efficient pharmaceutical market, but it has come to be expected in recent years. Even the fact that certain brand name drugs have price increases that are two to three times the average rate of inflation for most brand name drugs has come to be expected. Price increases of these certain brand name drugs may be 10 percent to 30 percent on an annual basis.

We should not minimize the impact that these brand name price increases have on public and private drug expenditures each year, or the concern that these price increases raise for patients, payers, and policymakers. Recently, however, there have been other prescription drug products that have had extraordinary price increases which are far beyond these already substantial price increases observed for major brand name drug products.

In order to examine, and understand, the magnitude of these extraordinary price increases, the PRIME Institute has been conducting a study of such price increases. For purposes of this study:
Extraordinary price increases are: ‘any price increase that is equal to, or greater than, 100 percent at a single point in time.’

A 100 percent increase in price means that the price of a drug has doubled overnight. In other words, a prescription that costs $100 today would cost $200 tomorrow. Other levels of price increases may well deserve the label as extraordinary price increases, but a price that more than doubles all at once is certainly extraordinary. A price increase of this magnitude could also be labeled as a supra competitive price indicating that the price is achieved through some real, or perceived, monopoly position in the market.

The benchmark prices known as AWP and WAC are set, or influenced, by the drug firm. These are publicly available prices and changes in these prices will lead to changes in expenditures of public and private drug programs. Our work on this study is ongoing, but we have preliminary descriptive data on the extent of extraordinary price increases.

The price history of each drug product, at the NDC (national drug code) level, was examined to determine the direction and amount of price change in both of the usual benchmark prices (i.e., AWP and WAC). There was a total of 35,143 NDCs that have been introduced to the market since 1987 and this set of NDCs was used as the data set for the study. More than one-half of these drug products (18,124 NDCs) were manufactured, or at least marketed, by the firm whose name is on the label. The remaining 17,019 NDCs are drug products that are sold by firms known as repackers. An examination of the role, practices, and pricing of these repackers will be the subject of a later analysis.

The drug products were grouped by their patent and exclusivity status into three broad groups: (1) brand single source drugs, (2) brand off-patent drugs, and (3) generic off-patent drugs. Price changes for brand name drug products have been the initial focus of our research. Across all drug product groups, 13.5 percent of all NDCs have had one or more extraordinary price increases in the period 1988 to 2008. One in twenty (5.3 percent) of the brand single source NDCs and one in forty-five (2.2 percent) of the brand off-patent NDCs had seen an extraordinary price increase.

The timing of when these extraordinary price increases occurred was examined over the twenty year period from 1988 to 2008. While there were a few extraordinary price increases in the decade of the 1990s, the vast majority have been seen since the year 2000. The number of extraordinary price increases has been growing, and especially for brand name single source and brand name off-patent NDCs, in the past 4 years (See Figure 1).

**Figure 1.** Extraordinary Price Increases of Drug Products: 1988 to 2008
Brand Single Source & Brand Off-Patent NDCs
(Price Increases of ≥ 100% at a Single Point in Time)

![Bar chart showing extraordinary price increases over time](chart.png)

Source: Compiled by the PIRM Institute, University of Minnesota from data found in Price Chain PC (Ontario, Illinois: Access Insight, Inc., June 4, 2008). Extraordinary price increases at a single point in time for 1988 to 2008 (preliminary data is the year indicated).

Chart data does not indicate NDCs for drug products that are an inactivated, reformulated, reconstituted, or for drug ingredients used by pharmacists for compounding prescriptions.

Data for 2008 was for January 1 through June 30. The number reported above was extrapolated by extending the experience from the first 6 months.
A price increase of 100 percent or more at one point in time is remarkable in its own right, but the size of some of these extraordinary price increases is staggering. For the brand single source drug products there were 6 price increases of more than 1,000 percent with the largest being 3,436 percent. Another 6 brand single source NDCs had an increase between 500 percent and 999 percent. One of the brand off-patent NDCs had a price increase of 10,631 percent and another 10 NDCs had extraordinary price increases of greater than 500 percent.

IMPACT OF EXTRAORDINARY DRUG PRICE INCREASES

Obviously there have been some extremely high price increases for a large and growing number of drug products. Because of the magnitude of these extraordinary price increases, it is hard to imagine that there has not been a significant impact on the market. These observations raise questions and concerns.

The questions involve asking:
- Why have these extraordinary price increases occurred?
- What market forces have led to, or allowed, these extraordinary price increases?
- What patterns are there with respect to types of drug products involved?
- What patterns are there with respect to types of drug firms involved?
- What policy issues are raised by this pricing behavior?
- What policy approaches may be appropriate to mitigate or regulate this behavior?

The concerns raised by these extraordinary price increases include:
- What is the impact Medicare Part D and Part B drug expenditures?
- What is the impact on Medicaid drug expenditures?
- What is the impact on drug expenditures in other government programs such as the Veterans Administration, the 340 B program, Indian Health Service, the active military health system, and other programs?
- What is the impact on employer and private drug benefit programs?
- What is the impact on orphan drug products?
- What is the impact on access to medications?
- What is the impact on access and affordability to vulnerable patient populations?

FACTORS DRIVING extraordinary drug price increases

The pharmaceutical market is extremely complex and vexing to most observers. There are many unique institutional and structural features to the pharmaceutical market that influence the economic behavior of drugs and drug prices. The extent and magnitude of price increases seen in our preliminary study of this issue appear to indicate that the extraordinary price increases are not driven by the ordinary explanations for price increases such as the general inflation rate of the economy, the cost of materials, labor and distribution, or the costs of FDA required research for approval.

The magnitude of these extraordinary price increases is so great that these prices do not appear to be the product of an economically efficient competitive market. In fact, these prices may well be supra competitive prices, that is, prices above what can be sustained in a competitive market. Supra competitive prices are present when a firm has a unique position in a market with respect to intellectual property, legal status, barriers to entry, product features that offer a competitive advantage, or other factors. The number and magnitude of these extraordinary price increases also raises the possibility that antitrust issues may be present. Determination of the antitrust implications would require an assessment of the specific and unique market for each drug product to determine the circumstances and market forces that enabled these extraordinary price increases to be taken and sustained.

Most of the drug products with extraordinary price increases are not among the top 100 to 500 drug products on the market. In part, these drug products may have been able to implement these extraordinary price increases because these are low volume drugs that are not often tracked or noticed in the marketplace. In a sense, these drug products and their price increases have “flown below the radar” with respect to attention being given to their pricing behavior.

Many of these drug products are for conditions that have a relatively small volume of demand. Indeed, some of these drug products are even designated as orphan drugs—meaning that they are for conditions that have a small target population. Among the drug products with extraordinary price increases are a number of products that are unusual dosage forms such as injections, gels, transdermal patches, sustained release tablets and capsules, and others. Some of these drug products may have such a small market that it would not be profitable for two competitors to survive. Other drug products with extraordinary price increases may have been in short supply either before or after the price increase was taken. The fact that some of these drug products are sold only through limited distribution channels (e.g., spe-
cialty pharmacies, mail order pharmacies, physician dispensers, dialysis care centers, and others) may also have played a factor in enabling extraordinary price increases.

The intellectual property and exclusivity status of these drug products may also have facilitated the extraordinary price increases. Among the drugs found to have these large price increases were old drugs that have a patent for a new use of the drug, thus providing a period of market exclusivity for the drug product. Other old drug products have been prepared in a new dosage form that may be the subject of a patent, thus preventing the expected generic competition that is usually seen. In other situations, certain drug firms have a large number of drug products with extraordinary price increases. This observation raises the issue of whether or not the extreme price increases are a matter of a particular corporate strategy. Firms may acquire drug products that have limited market competition, or that have high potential for monopoly power with or without intellectual property rights.

The PRIME Institute plans to continue research in this area to better understand and characterize the market conditions that have led to the growth of extraordinary price increases for prescription drug products. Our research will look for patterns across drug firms, therapeutic categories, market conditions, intellectual property and exclusivity status, dosage forms, distribution channels and other factors. The continued research will also examine how these extraordinary price increases have affected private and government drug programs, market entry and the market for drug products, and specific patient populations.

SUMMARY

Extraordinary price increases for drug products have been observed in recent years. These extraordinary price increases are price changes of more than 100 percent at a single point in time with some ranging to more than a 10,000 percent increase in price. About one in every twenty brand single source drug products (5.3 percent) has had one or more extraordinary price increases. These enormous price increases certainly affect the individual patients who are using the medication and in aggregate these large price increases expand the ever-growing expenditures of private and public drug programs. The PRIME Institute will continue to study this issue to improve our understanding of the issues involved and to identify policy alternatives to address any societal concerns that may be present.

PREPARED STATEMENT OF ALAN L. GOLDBLOOM, M.D., PRESIDENT AND CEO
CHILDREN'S HOSPITALS AND CLINICS OF MINNESOTA

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 L.S. is $1,875 compared with $14 iii 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 1 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.
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:

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

* Information provided by the Child Health Corporation of America.

Madame Chairman, the total cost increase for CHCA hospitals in 1 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.
Drug Pricing in Pediatrics: The Egregious Example of Indomethacin
Alan H. Jobe
Pediatrics 2007;119;1197-1198
DOI: 10.1542/peds.2007-0184

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://www.pediatrics.org/cgi/content/full/119/6/1197
**Drug Pricing in Pediatrics: The Egregious Example of Indomethacin**

Alan H. Jobe, MD, PhD


date

1. **Indomethacin for Closure** of a patent ductus arteriosus (PDA) in preterm infants has been the standard of care since the 1970s. Indomethacin was the first drug specifically approved for use in infants by the US Food and Drug Administration as the result of collaborations between academic pediatricians and the pharmaceutical company Merck. Indomethacin was not a new chemical entity when evaluated for PDA, and it remains today one of the most frequently used over-the-counter nonsteroidal antiinflammatory drugs. The unique aspect of indomethacin for PDA is that the drug is formulated for intravenous use. There are no other approved uses for intravenous indomethacin in the United States.

Ovation Pharmaceuticals acquired the distribution rights for indomethacin from Merck in 2006. The list price for indomethacin then increased from approximately $100 to $1875 for three 1-mg vials. 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. This concern, together with the public discussions about Medicare negotiations for drug prices, stimulated me to ask colleagues about indomethacin pricing in other countries. Hospital costs of indomethacin in available packaging and the cost per milligram of drug in US dollars are shown in Table 1 for comparative purposes. My unease about the pricing in the US was further strengthened. The price per milligram is ~30 to 60 times higher in the United States than in other countries with health care systems of similar quality. I suspect that manufacturers and distributors in these other countries are not losing money.

I also have another concern. There are a number of recent reports that indicate that ibuprofen is as effective as indomethacin for the closure of PDA in preterm infants and it may have a better safety profile.² The initial dose of ibuprofen is 10 mg/kg or 50 times the dose of 0.2 mg/kg for indomethacin. Ibuprofen is also commonly used as an over-the-counter nonsteroidal antiinflammatory drug. An intravenous formulation of ibuprofen was recently approved by the US Food and Drug Administration only for use for closure of PDA in preterm infants. Ibuprofen is less widely available for this indication worldwide, but it is ~10 times more expensive in the US than in the United Kingdom or Germany (Table 1). Ovation Pharmaceuticals is also the only source of ibuprofen for closure of PDA in the United States, and

**Table 1. Comparative Pricing**

<table>
<thead>
<tr>
<th></th>
<th>Indomethacin</th>
<th>Ibuprofen</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unit Price, mg</td>
<td>Unit Price, mg</td>
</tr>
<tr>
<td></td>
<td>(Total Cost, $)</td>
<td>(Total Cost, $)</td>
</tr>
<tr>
<td>United States</td>
<td>3 x 1 (610)</td>
<td>3 x 1 (610)</td>
</tr>
<tr>
<td>Canada</td>
<td>1.6 x 1 (177)</td>
<td>2 x 1 (354)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>1 x 1 (17)</td>
<td>4 x 1 (69)</td>
</tr>
<tr>
<td>Germany</td>
<td>3.2 x 1 (208)</td>
<td>8 x 1 (416)</td>
</tr>
<tr>
<td>Holland</td>
<td>5.4 x 1 (22)</td>
<td>7 x 1 (123)</td>
</tr>
<tr>
<td>Australia</td>
<td>3 x 1 (123)</td>
<td>5 x 1 (383)</td>
</tr>
</tbody>
</table>

*Note: Data not available for country.*

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**Footnotes:**

1. A recent article in the New England Journal of Medicine discusses the issue of drug pricing in the US.

2. The safety profile of ibuprofen is better, but it is less effective than indomethacin for the closure of PDA.

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**Abbreviation:** PDA, patent ductus arteriosus

**Downloaded from www.pediatrics.org by on October 16, 2008**
the retail price for a treatment course of three 20-mg vials is $1812. This drug does need further evaluation, but its costs are just $33 less than indomethacin. To the clinical neonatologist or pharmacist, the similar pricing of ibuprofen and indomethacin seems to be more than a coincidence. We all know that drugs are expensive in the United States and that we subsidize drug development for the rest of the world. However, it is the pricing of these two useful agents that are standard of care is quite extraneous. Words such as “unconscionable,” “unethical,” and “socially irresponsible” come to mind.

REFERENCES

GENETIC TESTS OFFER PROMISE, BUT RAISE QUESTIONS, TOO

"A growing industry is hoping to spin gold from DNA’s double helix by using ultra-sensitive genetic tests to personalize medical treatment for cancer, lupus and other diseases. . . . More than 1,000 genetic tests are available to researchers. Despite the tremendous promise of these tests, there is growing concern among researchers and patient advocates about how consistently their claims match reality. How accurate are they at finding potential genetic problems? Are different tests for different conditions equally reliable? And how tight is the connection between a genetic trait and a specific illness? Some researchers say they believe that the practical relevance of many tests has been oversold. Over the last two decades, for example, there has been a steady stream of news about researchers discovering "the gene" that links people to diabetes, Alzheimer’s, obesity, schizophrenia, depression and many other ailments. Yet most of those hard-wired gene-disease links—so many as 95 percent of them, according to one British study published in 2003—don’t hold up to closer scrutiny. Instead, follow-up studies find that if there is any measurable genetic link to these common diseases, it results from the more complex interactions of many genes with one another, as well as with the environment. According to the Human Genome Project, this state of affairs is particularly troubling, considering that a few companies have started marketing genetic tests directly to the public—sometimes claiming their kits not only test for disease, but can also customize medicine, vitamins and diet to an individual’s genetic makeup. There is no independent review or government oversight of the validity of these tests, particularly those available to consumers through their doctors. No agency yet has the formal responsibility to make sure that genetic tests can produce correct answers reliably over time, or, more important, that there is even a relationship between a particular genetic variation and a person’s health."

Noted by JL, MU
Health insurance companies are rapidly adopting a new pricing system for very expensive drugs, asking patients to pay hundreds and even thousands of dollars for prescriptions for medications that may save their lives or slow the progress of serious diseases.

With the new pricing system, insurers abandoned the traditional arrangement that has patients pay a fixed amount, like $10, $20 or $30 for a prescription, no matter what the drug’s actual cost. Instead, they are charging patients a percentage of the cost of certain high-priced drugs, usually 20 to 33 percent, which can amount to thousands of dollars a month.

The system means that the burden of expensive health care can now affect insured people, too.

No one knows how many patients are affected, but hundreds of drugs are priced this new way. They are used to treat diseases that may be fairly common, including multiple sclerosis, rheumatoid arthritis, hemophilia, hepatitis C and some cancers. There are no cheaper equivalents for these drugs, so patients are forced to pay the price or do without.

Insurers say the new system keeps everyone’s premiums down at a time when some of the most innovative and promising new treatments for conditions like cancer and rheumatoid arthritis and multiple sclerosis can cost $100,000 and more a year.

But the result is that patients may have to spend more for a drug than they pay for their mortgages, more, in some cases, than their monthly incomes.

The system, often called Tier 4, began in earnest with Medicare drug plans and spread rapidly. It is now incorporated into 86 percent of those plans. Some have even higher co-payments for certain drugs, a Tier 5.

Now Tier 4 is also showing up in insurance that people buy on their own or acquire through employers, said Dan Mendelson of Avalere Health, a research organization in Washington. It is the fastest-growing segment in private insurance, Mr. Mendelson said. Five years ago it was virtually nonexistent in private plans, he said. Now 10 percent of them have Tier 4 drug categories.

Private insurers began offering Tier 4 plans in response to employers who were looking for ways to keep costs down, said Karen Ignagni, president of America’s Health Insurance Plans, which represents most of the nation’s health insurers. When people who need Tier 4 drugs pay more for them, other subscribers in the plan pay less for their coverage.

But the new system sticks seriously ill people with huge bills, said James Robinson, a health economist at the University of California, Berkeley. “It is very unfortunate social policy,” Dr. Robinson said. “The more the sick person pays, the less the healthy person pays.”

Traditionally, the idea of insurance was to spread the costs of paying for the sick.

“This is an erosion of the traditional concept of insurance,” Mr. Mendelson said. “Those beneficiaries who bear the burden of illness are also bearing the burden of cost.”

And often, patients say, they had no idea that they would be faced with such a situation.

It happened to Robin Steinwand, 53, who has multiple sclerosis.

In January, shortly after Ms. Steinwand renewed her insurance policy with Kaiser Permanente, she went to refill her prescription for Copaxone. She had been insured with Kaiser for 17 years through her husband, a Federal employee, and had had no complaints about the coverage.

She had been taking Copaxone since multiple sclerosis was diagnosed in 2000, buying a 30 days’ supply at a time. And even though the drug costs $1,900 a month, Kaiser required only a $20 co-payment.

Not this time. When Ms. Steinwand went to pick up her prescription at a pharmacy near her home in Silver Spring, Md., the pharmacist handed her a bill for $325.

There must be a mistake, Ms. Steinwand said. So the pharmacist checked with her supervisor. The new price was correct. Kaiser’s policy had changed. Now Kaiser was charging 25 percent of the cost of the drug up to a maximum of $325 per prescription. Her annual cost would be $3,900 and unless her insurance changed or the drug dropped in price, it would go on for the rest of her life.

“I charged it, then got into my car and burst into tears,” Ms. Steinwand said.
She needed the drug, she said, because it can slow the course of her disease. And she knew she would just have to pay for it, but it would not be easy.

“It’s a tough economic time for everyone,” she said. “My son will start college in a year and a half. We are asking ourselves, can we afford a vacation? Can we continue to save for retirement and college?”

Although Kaiser advised patients of the new plan in its brochure that it sent out in the open enrollment period late last year, Ms. Steinwand did not notice it. And private insurers, Mr. Mendelson said, can legally change their coverage to one in which some drugs are Tier 4 with no advance notice.

Medicare drug plans have to notify patients but, Mr. Mendelson said, “that doesn’t mean the person will hear about it.” He added, “You don’t read all your mail.”

Some patients said they had no idea whether their plan changed or whether it always had a Tier 4. The new system came as a surprise when they found out that they needed an expensive drug.

That’s what happened to Robert W. Banning of Arlington, Va., when his doctor prescribed Sprycel for his chronic myelogenous leukemia. The drug can block the growth of cancer cells, extending lives. It is a tablet to be taken twice a day—no need for chemotherapy infusions.

Mr. Banning, 81, a retired owner of car dealerships, thought he had good insurance through AARP. But Sprycel, which he will have to take for the rest of his life, costs more than $13,500 for a 90-day supply, and Mr. Banning soon discovered that the AARP plan required him to pay more than $4,000.

Mr. Banning and his son, Robert Banning Jr., have accepted the situation. “We’re not trying to make anybody the heavy,” the father said.

So far, they have not purchased the drug. But if they do, they know that the expense would go on and on, his son said. “Somehow or other, myself and my family will do whatever it takes. You don’t put your parent on a scale.”

But Ms. Steinwand was not so sanguine. She immediately asked Kaiser why it had changed its plan.

The answer came in a letter from the Federal Office of Personnel Management, which negotiates with health insurers in the plan her husband has as a Federal employee. Kaiser classifies drugs like Copaxone as specialty drugs. They, the letter said, “are high-cost drugs used to treat relatively few people suffering from complex conditions like anemia, cancer, hemophilia, multiple sclerosis, rheumatoid arthritis and human growth hormone deficiency.”

And Kaiser, the agency added, had made a convincing argument that charging a percentage of the cost of these drugs “helped lower the rates for Federal employees.”

Ms. Steinwand can change plans at the end of the year, choosing one that allows her to pay $20 for the Copaxone, but she worries about whether that will help. “I am a little nervous,” she said. “Will the next company follow suit next year?”

But it turns out that she won’t have to worry, at least for the rest of this year. A Kaiser spokeswoman, Sandra R. Gregg, said on Friday that Kaiser had decided to suspend the change for the program involving Federal employees in the mid-Atlantic region while it reviewed the new policy. The suspension will last for the rest of the year, she said. Ms. Steinwand and others who paid the new price for their drugs will be repaid the difference between the new price and the old co-payment.

Ms. Gregg explained that Kaiser had been discussing the new pricing plan with the Office of Personnel Management over the previous few days because patients had been raising questions about it. That led to the decision to suspend the changed pricing system.

“Letters will go out next week,” Ms. Gregg said.

But some with the new plans say they have no way out.

Julie Bass, who lives near Orlando, Fla., has metastatic breast cancer, lives on Social Security disability payments, and because she is disabled, is covered by insurance through a Medicare H.M.O. Ms. Bass, 52, said she had no alternatives to her H.M.O. She said she could not afford a regular Medicare plan, which has co-payments of 20 percent for such things as emergency care, outpatient surgery and scans. That left her with a choice of two Medicare H.M.O’s that operate in her region. But of the two H.M.O’s, her doctors accept only Wellcare.

Now, she said, one drug her doctor may prescribe to control her cancer is Tykerb. But her insurer, Wellcare, classifies it as Tier 4, and she knows she cannot afford it.

Wellcare declined to say what Tykerb might cost, but its list price according to a standard source, Red Book, is $3,480 for 150 tablets, which may last a patient 21 days. Wellcare requires patients to pay a third of the cost of its Tier 4 drugs.
“For everybody in my position with metastatic breast cancer, there are times when you are stable and can go off treatment,” Ms. Bass said. “But if we are progressing, we have to be on treatment, or we will die.”

“People’s eyes need to be opened,” she said. “They need to understand that these drugs are very costly, and there are a lot of people out there who are struggling with these costs.”

This article has been revised to reflect the following correction:

Correction: April 15, 2008

An article on Monday about a large increase in insurance co-payments for high-priced drugs misstated the way the multiple sclerosis drug Copaxone is administered. It is injected, not taken in pill form.

PREPARED STATEMENT OF DANIELLE FOLTZ, PARENT OF YOUNG PATIENT FROM RHODE ISLAND

Chairman Schumer, Vice Chair Maloney, Senator Klobuchar and members of the distinguished panel. I am Danielle Foltz of Rhode Island and the mother of Trevor Foltz. I want to thank you for this opportunity to speak today about our family’s experience with Infantile Spasms and our journey to receive critically needed treatment for our son.

While I am speaking only on behalf of my own family, I would also like to acknowledge the support of the Epilepsy Foundation. The Epilepsy Foundation represents the 3 million Americans who have epilepsy and their goal is to help those individuals get access to the care they need. I know they will continue to follow this hearing and the path from here forward. Thank you.

I understand that today’s hearing is highly political. But for us—and the two thousand families devastated by the diagnosis of Infantile Spasms each year—it’s personal.

How do you find the words to describe the most horrific event of your life; your personal valley of the shadow of death? Because that is exactly the feeling that clamps your heart when you are at a place where the medication needed to rescue your child is unattainable.

For 7½ months we celebrated our beautiful third born, Trevor. In fact, we were packing luggage in anticipation of returning to our non-profit ministry & home in Tanzania, East Africa when we noticed the jerky, odd movements Trevor suddenly started making. It resembled a newborn startle reflex.

Devastated does not touch how we felt when we learned that those jerky movements were actually seizures! Trevor was having as many as 20 seizures in a 60 second span; up to 5 times a day. We knew it was serious when the neurologist told us to meet with him immediately following Trevor’s first EEG.

In that meeting we were given the devastating news. Our beautiful 7½ month old son had the rare & catastrophic disorder called Infantile Spasms.

All three neurologists we consulted told us the same thing. If we did not get his seizures under control immediately Trevor’s developing brain would be irreparably damaged. We were told the only thing between our son and a shot at a normal life was a drug called ACTH, marketed as Acthar gel by Questcor Pharmaceuticals.

Our neurologist prepared us that Trevor’s treatment would be pricey. He estimated around $10,000 per vial. We went numb.

We immediately notified our insurance company. The urgency of providing Trevor’s treatment was heavy and we needed to move forward as quickly as possible. As Trevor’s seizures intensified we read the information about IS online and the sorrow of what we were up against was emotionally overwhelming.

What we didn’t know was that 4 months prior to Trevor’s diagnosis, Questcor Pharmaceuticals had implemented a new business model. This business model included raising the price per vial of Acthar Gel from approximately $1000 each to over $30,000 a vial. And because Trevor was the first child to require ACTH treatment after the price increase, not even our neurologist was aware of just how dramatically the price had risen. What he thought would cost no more than $50,000 total would now be an astounding $150,000 for the medication alone!

In hindsight, we have no doubt the excessive price of this drug influenced the insurance company against originally approving it for Trevor.

My husband spent days on the phone fighting for Trevor to have coverage. We knew there was no way we could afford to pay for his treatment ourselves. One vial of Acthar was being quoted at a minimum of $30,000. And Trevor needed 5 vials. We could buy a nice 3 bedroom colonial is some areas of the country with that kind of money! But because we had given our lives to serve a non-profit ministry in Tan-
zania, we don’t own that 3 bedroom colonial. We didn’t have a house to mortgage as collateral for his treatment—which I’ve heard some families have been forced to do. All of our earthly possessions were in Africa. We had nothing to liquidate to come up with the money. But to wait was not OK. We needed to save our son NOW. And so I was frantically looking for other options. Any options.
I called the Acthar support & assistance line because I read that Questcor offers the assurance that no child who truly needs this treatment will go without. I spoke with a call center representative and was informed that the approval process included paper-work for ourselves & Trevor’s doctors to submit. When I asked how long the approval process would take I was informed it would be a minimum of 3 business days. When I asked if approval was a sure thing in a case like ours—I was told “no”. At that point, my emotions got the best of me, and I informed her that I thought it was a sham! That if Questcor was really about providing a vital medication in a time of desperate need it wouldn’t take three business days just to get a maybe!

When your infant’s body is being wracked by forty plus seizures daily—you do not have THREE business days to play Russian Roulette waiting for a medication that could stop his seizures and right the world again!

Those days following Trevor’s diagnosis were the most emotionally dark in our family’s life. My husband & I were pretty much a puddle on the floor. Just getting that kind of a diagnosis shatters you, but then to add the guilt of knowing that you may not be able to rescue your son because you can’t afford to? It’s unimaginable and unacceptable.

We literally thought it was possible that our son would go without treatment. Or that he would be forced to use a less effective medication that could leave him developmentally challenged forever. I wonder how many families are living that same nightmare right now? How many are being exploited in their hour of desperation?

Finally, on Wednesday November 21st 2007, the day before Thanksgiving, after numerous emotional phone calls between my husband & our employer we were told to move forward with the treatment. It had already been 1 day shy of a week since Trevor’s diagnosis. And each day without treatment was stealing our son. We witnessed his physical regression and distress as the seizures became more violent.

We were admitted the following day. Trevor’s first Thanksgiving was spent at Hasbro Children’s Hospital.

Because ACTH must be injected into the thigh, a nurse had to teach us how to administer it once we went home. When she asked my husband if he was nervous about giving Trevor his shot for the first time, he answered that he was more nervous about holding $5000 in a single syringe. Or worse, dropping the vial!

I know that we were lucky. Our insurance ended up covering Trevor’s 6 week course of ACTH; which has proven to be his miracle drug. Trevor has been seizure free since his fourth injection. Trevor is the poster child for why this drug needs to be available & affordable! Today we are celebrating our amazing miracle boy! We pray that Trevor will continue to be seizure free. But what if his spasms return? Will we again have to fight for ACTH?

I will leave this hearing today and go home. I’ll return to my life of loving & advocating for my son. But my story is in-ex-tricably connected to the 2000 families this year- and the next- and the next—who will live this horrific diagnosis. What about them? My heart cannot help but be consumed for the other families that will be devastated by Infantile Spasms this year. Will they have access to this drug? Or will ACTH not even be an option for their child because they are priced out of the drug they desperately need?

In fact, in preparation for this testimony today my husband researched the current price of a vial of ACTH. Unbelievably, the escalation has not plateau-ed! The very same vial we ended up paying $26,000 to obtain 6 months ago, today can cost as much as $40,000. Where does it end? I’m not going to pretend that I understand the many layers of this issue. But what I can wrap my heart around is the terror a mom faces when she cannot rescue her baby. Not because his sickness is untreatable but because financially she cannot access the medication he needs!

I implore you today to please consider my thoughts and to find a way to help families like mine get access to the medications they need. Please help families dealing with Infantile Spasms get affordable access to the drug that can give them a miracle too.
The National Organization for Rare Disorders (NORD) appreciates the opportunity to provide input on a topic that is extremely important to our primary constituents—the nearly 30 million Americans affected by rare diseases. NORD is widely recognized as the primary public policy advocate for individuals and families affected by rare diseases in the United States. It was formed in 1983 by leaders of patient organizations for specific rare diseases who, at that time, were providing advocacy for enactment of the Orphan Drug Act.

Today, NORD is a unique federation of voluntary health organizations and individuals committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. It provides grants and fellowships for clinical research on rare diseases. Each year, millions of Americans visit its Web site or call its information center to obtain information about rare diseases and referrals to patient organizations. Through its Patient Assistance Programs, NORD provides millions of dollars worth of free medication to uninsured or underinsured patients each year, along with co-pay and premium assistance for patients who qualify on the basis of financial need. Through its Washington, DC, office, NORD also provides a voice for all Americans affected by rare diseases on important public policy issues of interest to the rare disease community. It is in that role that we come to you today.

THE ORPHAN DRUG ACT OF 1983

Two months ago, more than 500 people gathered in Union Station here in Washington, DC, to celebrate the 25th anniversary of the Orphan Drug Act of 1983 (ODA), legislation that has improved the lives of millions of Americans and far exceeded original expectations for its impact. Those present at the anniversary celebration in May included leaders of patient organizations, academic researchers from universities and teaching hospitals, staff of the National Institutes of Health (NIH) and Food and Drug Administration (FDA), physicians and other medical professionals, and representatives of health-related industries, including pharmaceutical and biotechnology companies.

The extraordinary piece of legislation that brought this diverse community together—the Orphan Drug Act—provides financial incentives that make it possible for pharmaceutical and biotechnology companies to invest in the development of treatments for small patient populations. In the decade leading up to 1983, only 10 drugs were developed by industry for diseases that today would be classified as “orphan” or rare diseases.

In the years since the law was passed in 1983, nearly 330 therapies for rare diseases have been approved for marketing by the FDA, and the FDA has estimated that 11 to 12 million Americans now have treatments for their rare diseases as a result of the ODA.

WHAT IS A RARE DISEASE?

The definition used today by NIH, FDA, and our organization is that any disease affecting fewer than 200,000 Americans is considered rare. NIH estimates there are between 6,000 and 7,000 diseases that fit this description, including hemophilia, Tay Sachs disease, ALS or Lou Gehrig’s disease, and cystic fibrosis. In addition to these diseases, which have become fairly well known in the U.S. today, there are thousands whose names would not be recognized by the average American but which are equally devastating to the individuals and families affected by them. Many rare diseases, such as Menkes disease, Castleman disease, and Lowe syndrome, are named for the physicians who first identified them. Some are named for their signs and symptoms, or for the hospital where they were first identified.

NIH estimates that between 9 and 10 percent of the American population, or nearly 30 million men, women, and children, are affected by a rare disease. Approximately half of these people are children, and many rare diseases are present at birth.

Research in recent years, including in the National Human Genome Research Project, has confirmed that many rare diseases have a genetic component. It is estimated that this is the case for 80 to 90 percent of rare diseases. For that reason, early diagnosis and identification of any possible risks for other offspring can be extremely important for families.

Unfortunately, getting an accurate diagnosis of a rare disease often requires several years. A study commissioned by the Federal Government in 1989, the report of the National Commission on Orphan Diseases, identified length of time required
to get a diagnosis as a serious problem affecting millions of Americans with rare
diseases. At that time, it took from five to 7 years on average for many people with
rare diseases to obtain a diagnosis. A small study done by our organization in 2003
in partnership with Sarah Lawrence College found that these numbers had, unfortu-
nately, not changed greatly over the years.
Furthermore, most rare diseases have no treatment today. If we accept FDA’s es-
timate that 11 to 12 million Americans have a treatment developed since 1983, that
leaves nearly 20 million Americans who have no drug or biologic to treat their rare
disease. For those people, it is extremely important to know that there is at least
some hope that a treatment will be developed in the future.
One of the most heart-wrenching tasks our staff members have to do . . . and
they have to do it frequently . . . is to tell someone newly diagnosed with a rare
disease that there is no treatment for his or her disease and that, at this time, no one
in the U.S. is doing research to develop a possible future treatment.

What are the incentives provided by the Orphan Drug Act?
- Seven years of marketing exclusivity
- Exclusivity that can be broken only if another product for the same indication
  is proven to be clinically/scientifically superior to the existing “orphan” product
- 50 percent tax credit for clinical trial expenses
- Exemption from application user fees
- Opportunities to apply for grant funding for certain clinical testing expenses
- Assistance in clinical research study design
- Under certain circumstances, exemption from annual facility and product user
  fees
Recognizing that it costs millions of dollars to bring a new therapy to market
today, we are left with the stark reality that without these incentives, industry
would not be able to justify involvement in development of products for small popu-
lations. This was the case before 1983, and it would be a simple fact of economics
today if the Orphan Drug Act did not exist.

NORD understands the concerns of this committee regarding the high cost of
some orphan drugs and biologics. We share those concerns. However, we also wit-
ness firsthand every single day the positive impact on the lives of Americans of
progress made since 1983 in the development of drugs, biologics, and medical de-
vices for rare diseases. Any action that would have a chilling effect on that process,
now or in the future, would be inherently wrong and would result in a very vocal
reaction from the patient community. We would strongly oppose any action that
would reverse the effects of the Orphan Drug Act and negatively impact the willing-
ness and, in truth, the ability of industry to continue to invest in research and de-
velopment related to products for small patient populations.

In cooperation with all stakeholders, and this includes government regulatory ex-
erts from FDA, NIH officials, academic researchers, medical economists, industry
and—especially—patient organizations and the patient/family community, we have
pledged to work tirelessly to craft a balanced solution to the pricing of orphan prod-
ucts. We agree wholeheartedly that it is an issue that must be addressed. However,
this is a complex issue that requires serious discussion in which all stakeholders
are included.

Intellectually, the rare disease community understands why many orphan drugs
are so expensive. The reasons include:
- Small patient populations
- Geographically dispersed patient populations (Clinical trials must be inter-
national in many cases.)
- Limited funding (The small seed-money grants provided by NORD and other
  patient organizations attract proposals from highly qualified researchers and ex-
  cellent universities and teaching hospitals because there are so few other sources of
  funding for rare diseases.)
- Few researchers. (Understandably, most scientists are attracted to fields where
  it will not be so difficult to obtain research funding.)

It is estimated that between 80 and 90 percent of rare disease patients are treat-
ed “off-label” today because there are not FDA-approved drugs or biologics specif-
cally for their disease. As the cost of healthcare continues to rise, insurers, both
public and private, are increasingly refusing to reimburse for off-label therapies.
Every day, we receive phone calls and emails at NORD from patients or family
members struggling to obtain needed drugs or biologics for which a private insur-
ance company, Medicare or Medicaid is refusing coverage. For this reason, and to
ensure that treatments continue to meet accepted standards of safety and efficacy
in the U.S., companies must continue to be incentivized to conduct clinical trials.
Some of the other related issues that must be included in a full and complete discussion of orphan drug pricing include:

- The development of follow-on (generic) biologics and establishment of an unambiguous and transparent regulatory pathway at FDA that will encourage competition, stimulate innovation, and provide patients with access to biologics that cost less
- Allowing the FDA the flexibility and authority to determine on a case-by-case basis what it needs to approve follow-on biologics
- Providing a clear and timely resolution to patent disputes while prohibiting frivolous lawsuits that restrict access to follow-on biologics and delay competition in the marketplace
- Decoupling litigation between the innovator and generic manufacturer, and the review and approval of the follow-on biologic application at the FDA
- Guaranteeing predictability to allow scientifically proven, safe, and effective follow-on biologics to enter the marketplace
- Ensuring that the 7 years of marketing exclusivity provided by the Orphan Drug Act continues to encourage the development of new, life-saving drugs and biologics for the treatment of rare diseases

In addition, the Orphan Products Research Grants Program administered by the FDA needs to be adequately funded. Legislation adopted in 2002 provided for increased funding for that program, but to date significant funding increases have not been authorized.

Also, the Office of Rare Diseases (ORD) at the National Institutes of Health must be adequately funded. This office, while small in numbers of staff and dollars, has brought new hope to millions of Americans through its efforts on behalf of rare disease patients and patient organizations. In recent years, of specific note, is the success the ORD has had in encouraging cooperative efforts among the NIH institutes in research on rare diseases, which frequently are multi-organ or multi-system diseases.

CONCLUSION

Again, we must reiterate that any action that would have a chilling effect on the clinical research and development of orphan drugs, biologics and humanitarian use devices, now or in the future, would be inherently wrong and would result in a very vocal reaction from the patient community. We would strongly oppose any action that would reverse the effects of the Orphan Drug Act and negatively impact the willingness and, in truth, the ability of industry to continue to invest in research and development related to products for small patient populations.

This coming fall, NORD plans to begin working with all stakeholders, and this includes government regulatory experts from FDA, NIH officials, academic researchers, medical economists, industry and—especially—patient organizations, and the patient/family community, to address the cost of drugs and biologics marketed to treat very small patient populations. We are committed to work tirelessly to craft a balanced solution to the pricing of orphan products. We agree wholeheartedly that it is an issue that must be addressed. However, this is a complex issue that requires serious discussion in which all stakeholders are included.

The National Organization for Rare Disorders advocates for people affected by rare diseases because they have the same right that other Americans have to believe in a better future... to believe that their lives are important... and to have faith that in due time medical researchers will seek safe, effective treatments for their diseases rather than putting their efforts into duplicating blockbuster drugs for large patient populations.

We represent patients and their families. The entire history of our organization has been dedicated to providing a voice for, and representation of, the patient/family community in all matters related to rare diseases. And, ultimately, patients and families are the ones who stand to be most affected by any action taken as a result of this hearing. We feel strongly that their needs must be kept foremost in mind and that this complex issue deserves serious discussion and a serious search for solutions rather than a rush to judgment and speedy resolution.

Respectfully Submitted,

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Rare Hodgkins Lymphoma Drug Price Increases 7999%

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Source: JGZ. Democratic staff calculations from IMS Health and Tufts Health Plan. June 2009