Statement of Senator Charles E. Schumer
Chairman, Joint Economic Committee
Hearing: "At What Cost? Egregious Price increases in the Pharmaceutical Drug Industry"
July 24, 2008
(As prepared for delivery)

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 eight 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 Hodgkins Lymphoma, and cost less than $70 per dose in late 2004. Just six 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.

Witnesses:

Madeline Carpinelli, Institute for Pharmaceutical Research in Management and Economics at the University of Minnesota

Alan Goldbloom, CEO of Minnesota Children's Hospital

Danielle Foltz, Parent of young patient from Rhode Island