Testimony on:

Drug Shortages: Why They Happen and What They Mean

United States Senate

Committee on Finance

Patrick Cobb, MD

Frontier Cancer Center and Blood Institute

Billings, Montana

December 7, 2011

Chairman Baucus, Ranking member Hatch, and members of the Committee, thank you for giving me an opportunity this morning to talk to you regarding the impact of the drug shortage crisis on cancer patients throughout the United States.

I have been a private practice oncologist in Billings, Montana for more than 16 years. Every day patients come to my office asking a simple but critical question: "Can you help me?" For most of my career the answer has generally been "Yes." That is, until recently.

The current shortage of generic chemotherapy drugs has significantly limited our treatment options and, in many cases, have made treatments much more expensive. I want to share the stories of two patients to illustrate the problems we're facing.

Jerry is the father of two young children who came to the emergency room complaining that his nose wouldn't stop bleeding. The workup ultimately showed he had acute leukemia, a deadly disease but one that is very curable with chemotherapy. The standard treatment involves a generic drug called cytarabine, but that drug is in very short supply. We were able to find enough cytarabine to get Jerry through his first cycle of treatment. The problem is that now his condition demands a significantly higher dose of cytarabine, and we are not sure we will be able to find enough drug to complete treatment.

What do I tell Jerry, his wife, his parents, his kids? "Well, Jerry, with proper treatment you have a good chance of surviving this leukemia, but I don't know if we can find enough cytarabine. We might have to consider an alternative treatment, but one that doesn't have the same track record of cure." As you can imagine, this is not a conversation any physician should have to have with a cancer patient.

Another patient, Donna, a senior covered by Medicare, was recently diagnosed with colon cancer. She had surgery that removed the tumor, but the cancer had spread to three lymph nodes, putting her at increased risk that the cancer would return. By giving her chemotherapy post-operatively we decrease the chance of cancer recurrence and significantly improve the chances she'll be around to watch her granddaughter graduate from high school in three years.

Donna's chemotherapy regimen includes leucovorin, a generic drug that costs Medicare $35 and Donna's copayment is $9 for each treatment. Unfortunately, leucovorin is another drug in short supply. Because we can't find leucovorin, I have to use Fusilev, a brand-name drug. The problem is that Fusilev is significantly more expensive for Medicare and Donna — It costs Medicare over $24,000 more and Donna an extra $6,000 for the 12 cycles of treatment.

What do I tell Donna? "I'm sorry, but I have to substitute a drug that is going to cost you an extra $500 for each cycle of treatment, even though you won't get any better results."

I speak with oncologists from across the country on a regular basis and I can assure you that these patients' stories are not unique to Montana — this is a national crisis. Cancer treatment is being delayed, changed, and in cases even stopped on a regular basis.

When I'm faced with a cancer patient, I have to determine the origin of the disease before I can implement treatment. In analyzing the drug shortages, it is clear to me that the root cause is economics. It can be tracked back to the way Medicare Part B reimbursement was changed in the Medicare Modernization Act of 2003. Although I agree with the intent to better balance payments for cancer drugs and services, there have been unintended consequences.

The first consequence has been the closing of cancer clinics and the consolidation of clinics into the more expensive hospital setting due to Medicare reimbursement cuts to both drugs and services. In relation to drugs, you have to understand that the Medicare reimbursement system based on ASP, which is the average sales price of a drug, is price controlled. We have cases where the drug actually costs more than Medicare reimbursement.

The next consequence of the MMA is the drug shortage crisis due to a consolidating market of generic manufacturers. This is a result of a substantial drop in ASPs. At first blush, falling prices should look like a good thing for Medicare and patients. The problem is that there are now few manufacturers apparently willing to produce sterile injectable cancer drugs for what can be less than a dollar ASP per vial. Any manufacturing, regulatory, or quality problem is now magnified and leads to shortages when there are so few producers.

We have to treat the underlying cause of drug shortages, not just the symptoms. The drug shortage problem is a direct consequence of the reimbursement system that was set up by the MMA — it must be changed. It is critical that Congress move quickly to modify the Medicare reimbursement system, certainly not cut ASP reimbursement any further as some propose, and to create appropriate incentives for manufacturers. The lives of cancer patients hang in the balance.

Thank you for listening.