



Short-Supply Prescription Drugs: Shining a Light on the Gray Market
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Chairman Rockefeller and members of the Committee, my name is David Mayhaus and I am the Chief Pharmacy Director at Cincinnati Children's Hospital Medical Center. I am grateful for the opportunity to speak to you today not only on behalf of Cincinnati Children's, but also as a member of the Executive Committee for the Children's Hospital Association Pharmacy Forum. My goal today is to describe the process Cincinnati Children's uses for managing drugs when they reach critical shortage and how these issues have impacted our pharmacy operations over the past five years.

Cincinnati Children's was recently ranked third in the nation among all Honor Roll hospitals in U.S. News and World Report's Best Children's Hospitals ranking. Our institution is ranked in the top 10 for all of the pediatric specialties ranked. On the research side, Cincinnati Children's is one of the top two pediatric recipients of grants from the National Institutes of Health. In FY 2011 there were over 1 million patient encounters at Cincinnati Children's from 48 states and over 50 countries. Cincinnati Children's operates over 570 registered beds including a Heart Institute, a Perinatal Institute and a Cancer and Blood Disease Institute. Cincinnati Children's division of pharmacy is a large facility which dispenses approximately 7,500 doses per day. When there is a sudden drug shortage crisis the impact can be felt through our entire system.

Our division of pharmacy consists of 150 FTEs. Three of these FTE are pharmacy buyers. These buyers are responsible for managing the inventory of approximately 2800 line items of drugs. Over the past several years, more and more time has been dedicated to management of medications that are in short supply. Over time I have seen it grow to the point where today our buyers spend 30% of their day just dealing with drug shortages and trying to prevent Cincinnati Children's from experiencing a crisis. In addition to our drug buyers; clinical pharmacists and directors spend an inordinate portion of their time monitoring drug supply which can range from modification of therapy, to alternative medications. Our pharmacists have contacted manufacturers, wholesalers and alternative suppliers to get what we need. As Chief Pharmacy Director approximately 10 percent of my time

is also dedicated to these issues including what I am doing today, appealing to you to assure adequate supply of medications for our patients.

Today at CCHMC there are currently 30 drugs being actively managed on a daily basis and approximately an additional 70 where there have been concerns about shortage in the recent past. The buyers who report to me check our primary wholesaler on a daily basis for the 30 drugs on the critical list. We meet informally several times a day as a group and discuss where we are and possible mitigation plans. As a pediatric institution, it is vitally important to continually monitor the drug shortage market and react quickly to the changes.

There are several mechanisms to determine new and ongoing drug shortages. The 3 most important are the American Society of Health-System Pharmacists (ASHP) web site, The FDA web site and the Children Hospital's Association's pharmacy directors and buyers list serve. Other less helpful mechanisms are the primary wholesaler and manufacturer notifications. It is the experience of Cincinnati Children's that these last two tend to be delayed in their announcement of shortages. For these reasons we applaud the Senate for their passage of the Senate Bill 3187, the FDA user fee legislation, which will create an early-warning notice system that will give providers like myself more timely notice ahead of a critical shortage.

Everything we do is in the best interest of our pediatric patients. Once a drug is determined in shortage, our clinical pharmacists identify our utilization pattern and an estimate for days supply is developed. If the anticipated length of the shortage exceeds our current supply, we meet to develop a mitigation plan which could include purchase from the gray market in extreme circumstances. Our goal at this point is to extend the amount of inventory until the drug is released to the market. Work also begins at this stage with the impacted medical divisions to explore if various safe alternatives in treatment exist. Mitigation plans could include: reducing the dosing guidelines within medical staff approval for the affected drug, changing the current distribution from readily available to pharmacy dispensed therefore maximizing product or changing to a similar drug in the pharmaceutical class. None of these decisions would be made without complete and thorough consultation with the medical team.

The vast majority of the drugs purchased from Cincinnati Children's are from two primary wholesale companies. At the point all inventory of the affected drug has been exhausted, regular wholesalers have no product and the mitigation plan has run its course, Cincinnati Children's has in the past looked to alternative wholesalers for product. Let me be clear, Cincinnati Children's only use these alternative wholesalers as a last resort when it is determined that the absence of the drug could cause harm to our patients.

In those situations where Cincinnati Children's decides to purchase a drug from an alternative wholesaler, we follow extensive due diligence procedures including checking the prescription drug pedigree.

Over the past 12 months Cincinnati Children's has purchased only 9 out of 2,800 different line item drugs from these alternative wholesalers. As a medical team it was determined that all of these drugs were critical and in fact three of them are drugs used to maintain life support during a code. Cincinnati Children's believes running out of stock of these drugs is not an option and would have had the potential to cause significant harm to our patients.

Critical chemotherapy drugs have been frequently reported to be in short supply. One specific example is approximately 18-24 months ago the institution needed to purchase a very important chemotherapy (Cytarabine) that was in short supply. Cytarabine is used to treat Acute Lymphoblastic Leukemia (ALL) and is the drug that our number three ranked oncology division firmly believes has the most efficacy for treatment. After careful consideration and the due diligence described above and because there is no treatment alternative for this particular drug, Cincinnati Children's did in fact purchase this drug from alternative wholesalers. Because of the purchase, we did not run out of this important drug and all patients received the appropriate dose.

It is a daily reality that the buyers in our division receive e-mails and phone calls from alternative wholesalers. It is our experience that the call activity increases when a new or critical drug goes into a shortage situation. The prices vary from wholesaler to wholesaler. Cincinnati Children's has had the experience of the price changing rapidly, even between phone calls, within the same alternative wholesaler depending on the market activity and the critical nature of the drug. These business practices are not the normal procedure for our primary wholesaler or for any other activity within the practice of pharmacy. As you can surmise, it is also a fact that in all of our purchases through alternative wholesalers, Cincinnati Children's paid substantially more than our normal contracted price. In some cases this price exceeded 35 times more than normal pricing.

Finally, on behalf of my colleagues at the other children's hospitals across the country, I would like to conclude by thanking this Committee for its efforts to gain a full understanding of the complexity of these issues. As Cincinnati Children's has seen over the past five years the fragile nature of the pharmaceutical supply chain does have a direct correlation to treatment for patients. At Cincinnati Children's safety is paramount and there is nothing more important to the institution than making sure a child gets the right care, in the appropriate setting with the very best quality and competence that can be delivered.

Thank you for allowing me to share our experiences with you today and I will be happy to respond to questions.