Senate Special Committee on Aging

Hearing on: "Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines"

December 9, 2015

Oral Statement for the Record
Submitted by Erin R. Fox, PharmD
Director, Drug Information Service

Good afternoon and thank you Chairman Collins, Ranking Member McCaskill, and distinguished Members of the Committee for holding this hearing. My name is Erin Fox, and I am Director of Drug Information at University of Utah Health Care. I am here today to provide perspective on how sudden price increases of off-patent drugs have impacted our health system.

University of Utah Health Care is the only academic medical center in Utah and in a region that spans over 10% of the continental United States, including Idaho, Wyoming, Montana, much of Nevada, and western Colorado. The Drug Information Service is nationally recognized for providing all drug shortage content for the public website of the American Society of Health-System Pharmacists (www.ashp.org/shortage). As part of my role at our organization, I work to help manage drug shortages, assist with developing our drug budgets, and lead and guide medication use policy.

Our organization has been adversely impacted by recent price increases of medications we have used for years. Two key examples are nitroprusside and isoproterenol. These are critical medications used to treat very sick patients. Nitroprusside is particularly important for patients with severe high blood pressure or heart failure. Isoproterenol can be potentially life-saving for patients with very slow heart rates in emergency situations.

In 2013, University of Utah Health Care paid approximately $50 a vial for nitroprusside and isoproterenol, which were sold by Hospira. Marathon purchased these products from Hospira in 2014, and raised the price of nitroprusside to about $215 and

isoproterenol to about $440. In 2015, Valeant purchased these drugs from Marathon, and prices increased again – nitroprusside went from $215 to about $650, and isoproterenol went from $440 to about $2700. When we became aware of these new price increases, we calculated the potential impact to our inpatient pharmacy budget and discovered that if we continued to purchase the same amount of each drug, it would cost our organization just over 1.6 million dollars more for isoproterenol and approximately $290,000 more for nitroprusside compared to what we paid the previous year.

Recognizing that this type of arbitrary and unpredictable inflation is not sustainable in our hospitals, especially when we receive capitated payments for most of our patients, we began exploring how we could minimize costs without impacting patient care. We started by educating our physicians on the drug price increases and developing cost-reduction strategies. One of the key strategies we used was to remove isoproterenol from our approximate 100 crash carts, which we store throughout our system to ensure essential emergency medications are available in case of a critical emergency or cardiac arrest, often described as a “code.” Our physicians reported that they rarely used isoproterenol, but that the medication can be very important in managing an emergency where a patient’s heart rate is extremely low. With that in mind, our physicians decided that, instead of stocking isoproterenol in crash carts, we would only stock isoproterenol in the pharmacy back-up boxes that our pharmacists bring to the “codes.” In this way, the physicians could still have access to a critically important

medication, but we wouldn't face the full burden of 1.6 million dollars for just one medication.

Unlike isoproterenol, we have not found a way to drastically reduce use of nitroprusside, a drug that is critically important for some patients. For now, we are working on educating our physicians on the higher costs associated with nitroprusside, and are providing suggestions for alternatives when it makes sense, but most of the time, the use of nitroprusside is clinically appropriate and there are no good alternatives.

We have put reasonable strategies in place to protect against extreme increases in medications costs, but our physicians are extraordinarily frustrated by having to make decisions about whether to use these critically important but extremely expensive medications in emergency situations, especially when they have been using these drugs for years.

Nitroprusside was approved in 1974, and while FDA approved two Abbreviated New Drug Applications for generic products, nitroprusside is currently a single-source product sold by Valeant as Nitropress®. Isoproterenol was approved in 1956, and while generic products were once available, isoproterenol is also now a single-source product and is sold by Valeant as Isuprel®. Although Valeant sells these products, Valeant does not manufacture them – Hospira manufactures them on a contract basis. The Valeant packaging doesn't disclose that Hospira manufactures these products because, unfortunately, United States' labeling laws do not require transparency as to which

company manufactures a medication or the country of origin. Under 21 C.F.R. § 201.1(a) (2015), a medication label is only required to list the "name and place of business of the manufacturer, packer, or distributor." The end result is that hospitals are purchasing the same drug they used to purchase for about $50, but at a much higher price – the only difference is the label.

Why doesn't the free market fix this market failure? Why are there no generic competitors? I believe the reason is the same as the reason behind the ongoing drug shortages problem – namely, the supply chain for generic injectable off-patent drugs is incredibly fragile. Most of the injections used by hospitals every day are manufactured by three or fewer companies, and those companies are at capacity and cannot manufacture sufficient product to alleviate a shortage. Additionally, many manufacturers of injectable generics continue to work through quality and manufacturing problems that have slowed or halted production. The system of contract manufacturing where one company makes a product for another company to label is particularly problematic, because there is no required transparency. In the case of Isuprel® and Nitropress®, Valeant is not manufacturing these products.

Some have suggested that overseas production may help with shortages, but it may not be an answer as FDA continues to find quality problems at foreign manufacturing facilities, with the Office of Manufacturing Quality issuing 16 Warning Letters to date in 2015 due to poor manufacturing quality. These Warning Letters outline serious quality problems at the manufacturing sites, yet the specific products are not disclosed to

clinicians or the public. This lack of transparency leaves clinicians who would like to purchase medications based on a record of good quality, unable to do so.

Our organization works hard to provide the highest quality of care at the lowest cost. For the sixth year in a row, University of Utah Health Care was recognized for quality leadership, and our organization continues to be ranked in the top 10 of all academic medical centers. In order to provide this high quality care at the lowest cost, our leadership team is tasked with closely reviewing our budget. We work hard to predict potential inflation for medications and also to predict new drug approvals that will increase our budget. What we cannot predict are older, off-patent medications with exponential price increases. It is impossible to predict double or triple digit price increases. Our ability to provide high quality clinical care to our patients suffers with unpredictable costs.

When medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage. Hospitals are unfortunately well versed in managing critical drug shortages and can use a variety of strategies to minimize patient impact. These strategies can include limiting stocking to only critical areas, using alternatives whenever appropriate, and rationing product for the most critical patients. These management strategies are effective only if some product remains available. Additionally, these strategies take an inordinate amount of time to implement. Many hospitals devote full-time staff just for drug shortage

management. If prices for off-patent injectable drugs continue to rise at unpredictable rates, hospitals may be forced to devote additional manpower just for cost avoidance to be able to maintain current levels of care.

Thank you once again for holding this hearing and for the opportunity to appear before you to discuss how unpredictable price increases of off-patent drugs have impacted University of Utah Health Care. I look forward to learning more about potential solutions to this problem and offer my service if I can be of any assistance. I welcome any questions you may have.