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ON

Examining the Increase in Drug Shortages

**BEFORE THE COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON HEALTH**

U.S. HOUSE OF REPRESENTATIVES

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Good morning Chairman Pitts, Ranking Member Pallone and distinguished Members of the Committee. My name is Mike Alkire and I serve as chief operating officer for the Premier healthcare alliance. I am pleased to be here today on behalf of the more than 2,500 U.S. hospitals and 77,000 other care sites that are members of the Premier healthcare alliance to testify on the pressing issue of our nation's drug shortages. Premier is a performance improvement alliance that is using the power of collaboration to lead the transformation to high quality, cost-effective care. Not-for-profit hospitals created Premier as a way to better serve their patients by overcoming the challenges posed by our fragmented healthcare system. Through the Premier alliance, hospitals, suppliers and the government are united to meet our healthcare system's greatest challenge – advancing quality patient care while controlling costs.

First, I would like to thank you for calling this hearing and for the Committee's strong leadership in addressing the critical problem of shortages in the drug supply. The record shortage of drugs we are currently experiencing has had an adverse effect on the health and safety of communities across the country, and is a contributing factor to rising healthcare costs. Today, I will discuss what several analyses conducted by Premier have revealed about the scope of the shortage problem and its financial and human toll on our nation. I will also offer some initial thoughts about what the Committee, the Food and Drug Administration (FDA) and others can do to address this important issue.

Premier is owned by not-for-profit hospitals, health systems and other providers, and our mission is to improve the health of communities. We operate a leading healthcare purchasing network and maintain the nation's most comprehensive repository of clinical, financial and outcomes information. We are a leader in helping deliver measurable improvements in care and have worked through large-scale hospital collaboratives with organizations including the Centers for Medicare & Medicaid Services to improve hospital performance.

A key component of our alliance is the Premier Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety and increased knowledge sharing with other healthcare professionals. Sourcing committees made up of clinical experts from our member hospitals help evaluate current and emerging pharmaceuticals for contracting.

Premier offers a field team of highly qualified pharmacists to help our members enhance their use of medications. Our field experts provide clinically appropriate savings strategies that reduce overall costs and enhance the safe use of medication therapy, analyze high-volume, high-cost drugs and benchmark prescription practices that can help other hospitals improve the performance.

Premier's role in the supply chain is aggregating the buying power of our hospitals to provide the economies of scale necessary to secure the best pricing on drugs for hospitals and other providers. As part of this, we look at appropriate product utilization and comparative effectiveness to help providers get the most effective product at the optimal price. We then negotiate a separate contract with distributors to stock and move the drugs to providers. These are separate contracts, but are both equally important in the supply chain process. Premier monitors to the extent possible how distributors perform in terms of stocking and supplying products and, also to the extent feasible, monitors manufacturers in terms of issues with the FDA, pricing and ability to meet supply demands. Additionally, Premier often acts in a support role for our member facilities, providing guidance on issues of importance to them.

Premier's findings on drug shortages

Our healthcare system has experienced an alarming increase in the number of reported drug shortages for a range of products vital to treatment. More than 45,000 different prescription drug products are on the market today, originating from about 1,400 different manufacturers. Each year, the U.S. experiences a shortage of some number of these products, but the frequency and

impact of drug shortages has risen to critical levels, more than tripling since 2005 and affecting all segments of healthcare. According to the University of Utah's Drug Information Service, the current list of shortages is already the longest in a decade at 180 products. Shortages are getting so severe that it is expected that more than 211 products will be unavailable by the end of the year. Many of these medicines are essential to patient care, and include those used in chemotherapy, sedation to conduct surgeries and emergency treatments for heart attack patients.

Faced with these escalating shortages, Premier set out to better understand the extent of shortages, how they are impacting our hospitals and other care sites' ability to access the drugs needed for patient care, and to identify potential strategies to mitigate the problem. In March, Premier conducted a survey of 311 pharmacy experts representing 228 hospitals, as well as infusion, oncology and surgery centers, outpatient and retail pharmacies and long-term care facilities. The survey revealed that over the course of a six-month period (July-December 2010):

- More than 240 drugs were either in short supply or completely unavailable in 2010.
- Over 400 generic equivalents were back-ordered for more than five days.
- Many of the drugs noted as back orders in 2010 have remained unavailable or in short supply in 2011.
- This represents a dramatic increase in drug shortages over the last five years.

The American Hospital Association (AHA) also conducted a recent survey that affirms Premier's findings. The AHA survey showed that 99.5 percent of hospitals reported experiencing one or

more drug shortage in the last six months, and nearly half of the hospitals reported 21 or more drug shortages.

Impact on patient care

A shortage in the supply of a prescription drug can have serious implications for patient care. In the hospital setting, a shortage may result in the delay of medical procedures. Substitution of therapeutic or similar medications, if available, may lead to medication errors and preventable adverse events especially when prescribers are not as familiar with the alternative products' dosing and potential for adverse interactions with other drugs. Some second or third choice products also may be less clinically effective. And in some cases, concerns arise about the reliability of the source of the drugs, which may be outside the U.S., and whether they have been properly handled throughout the chain of custody.

In evaluating the threat of drug shortages to patient safety, Premier's survey found:

- 89 percent of hospitals experienced shortages that had the potential to cause a medication safety issue or an error in patient care, and 53 percent suggested this occurred more than six times. We see this, for example, when drugs are not available and therefore cannot be used to treat the patient's condition, or when a physician has to use a drug as a substitute that has a different dosing parameter that is unfamiliar in the clinical setting.
- 80 percent of hospitals experienced shortages that resulted in a delay or cancellation of a patient care intervention, and 34 percent suggested this occurred more than six times.

Examples of these incidences include chemotherapy delays or cancelations due to unavailable oncology drugs and delays in surgery due to lack of anesthesia agents.

Financial impact of drug shortages

The growing problem of drug shortages is also extremely costly to hospitals and to the healthcare system as a whole. Premier's survey found that 98 percent of hospitals experienced shortages that resulted in an increase in costs; 88 percent suggested this occurred more than six times; and 41 percent suggested this occurred more than 21 times. Steps needed to respond to shortages can divert important resources away from improving care. The cost in time and money can be especially high when hospitals and other providers face shortages in drugs that are needed to respond to new treatment guidelines and to treat victims of natural and other catastrophes where disease outbreaks, for example, threaten large numbers of people.

Premier's ability to analyze the expansive pharmaceutical supply chain data of our members has enabled us to provide financial impact snapshots of drug shortages. Combined with results from other organizations' analyses on drug shortages, these findings suggest that **shortages could cost U.S. hospitals at least \$415 million annually** through the purchase of more expensive generic or therapeutic substitutes and additional labor costs.

- According to Premier's analysis, the annual financial impact of drug shortages on *Premier alliance members alone* where generic alternatives are available exceeds **\$78 million**. More than \$66 million (or 85 percent) of the impact is felt by Premier's 2,500 hospital members, with the remaining amount within Premier's non-acute care sites. The highest areas of cost

are infectious disease (\$22.5 million), surgery (\$12 million), oncology (\$10.5 million), and cardiovascular therapies (\$8.5 million).

- Extrapolating nationwide from the analysis findings, Premier found drug shortages cost *all U.S. hospitals* at least \$200 million annually through the purchase of more expensive generic or therapeutic substitutes. This is a conservative estimate and excludes drugs purchased on the “gray market,” or with therapeutic alternatives. Premier conducted a separate analysis on the dramatic impact on pricing that the gray market has, which I will review later in my testimony. Our research also does not include indirect costs such as added labor needed to manage shortages and secure alternative supplies.
- A survey conducted by the American Society of Health-System Pharmacists and the University of Michigan Health System addressed this area and found that the labor costs and time required to manage shortages translates to an estimated annual impact of \$216 million nationally.

Premier’s gray market analysis

We might hope that in this time of crisis, people would band together and do everything they could to help patients get the drugs they need, when they need them. Rather, we have seen numerous “gray market” vendors taking advantage of the shortage situation, attempting to sell shortage products at exorbitant prices to enrich themselves. These vendors are attempting to

capitalize on the desperation of pharmacy directors and buyers who are finding it increasingly difficult to secure a sufficient supply of the drugs needed to meet all of their patient care needs.

The gray market, also known as a parallel market, is a supply channel that is unofficial, unauthorized or unintended by the original manufacturer. In markets where the products are scarce or in short supply, gray markets evolve to sell the item at any price the market will bear.

Over the last year, Premier has received many requests from our alliance member hospitals, asking for assistance with the growing trend of price gouging efforts by these gray market vendors and understanding the pedigree of a drug purchased from the gray market. In response, Premier developed a series of recommendations to help our members and providers nationwide avoid gray market vendors and identify safe buying opportunities. I will touch on these recommendations further in a few moments.

Along with the recommendations, we also did some research on this situation. Over a two-month period, Premier members turned over 1,745 unsolicited sales offers from gray market vendors. The offers came in the form of marketing emails and fliers. All offered to sell shortage drugs, and sometimes excluded price or the code needed to properly identify and track the drug. Of these offers, the 636 that contained both the price and the proper drug identification number were analyzed and compared to Premier's standard contracted prices for these medicines.

The results were appalling.

The average markup being offered to hospitals by these gray market vendors is 650 percent, and many others were far higher. In fact, **the highest markup was more than 4,500 percent**. In this case a drug used to treat high blood pressure, which normally sells for \$25.90, was being offered at \$1,200 – a staggering increase. Forty-five percent of the offers were marked up at least 1,000 percent above normal price. And, over a quarter of them were marked up at least 2,000 percent above normal price.

In other cases, offered markups were as high as 4,000 percent for chemotherapy medicines to treat leukemia and non-Hodgkin's lymphoma and 3,100 percent for medicines to help cancer patients retain bone marrow. We saw similar markups for medicines for sedation during surgeries; to dilate veins and prevent brain or heart spasms; and to prevent damage during a heart attack.

Considering the nation's budget crisis and our skyrocketing healthcare bill, these markups are nothing more than profiteering at the expense of patients and providers who are struggling to afford vital medicines needed for patient care. Price gouging in healthcare is so troubling to us because it is taking advantage of some of our most vulnerable citizens: the grandmothers who need chemotherapy to survive; the father who goes to the hospital for a heart attack; and the children suffering from leukemia.

Safety concerns with the gray market

Not only are pharmacies and patients being asked to pay the price gouger's premium, but in some cases, they cannot be sure that the medication is safe or even authentic. When price

gougers emerge with products, it begs several questions. Where and how are they getting medicines that no one else can? And how can the integrity of these drugs be ascertained?

When a gray market vendor enters the market, it is not unheard of for a drug to be bought and sold four or five times in the same day. You can imagine if a product changes hands that many times, the price is going to increase with each sales transaction.

Premier's response to the drug shortage situation

As I mentioned, members of Premier have asked us to help them cope with the drug shortage situation and, in particular, help them ensure safe purchases.

Premier believes that new measures and accelerated efforts are needed to address situations with prescription drug shortages and is helping members navigate the ongoing situation. We are working aggressively to diminish shortage-related costs to member hospitals. Our expansive supply chain data repository provides unique opportunities to source drugs from suppliers that demonstrate the ability to safely meet member market demands.

Specifically, Premier is:

- **Working with manufacturers:** We are working closely with manufacturers to determine their manufacturing capabilities at the front end when contracting to determine if they can

supply the market. Premier looks for alternatives if manufacturer's capabilities cannot meet demand.

- **Maintaining a hospital communication network:** Premier has instituted an early warning system in which hospitals notify Premier of drug access problems, even before they are posted on the FDA website. Once notified of a drug shortage, we determine if it is a local or national problem and regularly communicate this information to the FDA to make them aware of what is being shorted. Premier provides guidelines to hospitals on what steps to take to help reduce financial and quality impact of drug shortages. And, in collaboration with our members, we have developed toolkits, programs and professional advisories to help members manage drug shortages.
- **Creating longer term contracts:** Premier is seeking contracts that are longer in duration to enhance a stable market.

Premier has taken a firm position that hospital pharmacies should avoid the gray market, and stick to purchasing from known organizations. To help our members and providers nationwide source safe and effective drugs, Premier pharmacy staff developed recommendations, including the following best practices that should be followed whenever purchases are made outside a hospital's known, established primary distributor:

- Ask for and confirm receipt of a drug pedigree that records the products' chain of custody.

- Confirm with State Board of Pharmacy or Department of Health that the seller is appropriately licensed and not subject to any current investigations.
- Verify with the product manufacturer that the distributor is an authorized distributor of record (ADR).
- Keep records of sellers you have refused to do business with and reasons why, and confirm the distributor is a Verified-Accredited Wholesale Distributor (VAWD) through the National Boards of Pharmacy. VAWD ensures a higher level of assurance due to this accreditation.

Though these recommendations are intended to protect our members and the patients they serve from unintended harm, even if they are followed, they do not guarantee that all selected sellers will be legitimate. We do, however, feel strongly that they will help.

Recommendations to address the drug shortage crisis

Lastly, I would like to suggest some ideas to address the drug shortage crisis. While the Premier healthcare alliance is employing the measures I described to ensure better preparation for a drug shortage and processes to deal with it, private sector initiatives can only go so far in addressing the problem.

We ask the Committee and the FDA to consider:

- Shortening the approval process for medically necessary generic drugs that appear to be in shortage.
- Encouraging the FDA Drug Shortage Program staff to broadly engage members of the healthcare community in discussions determining whether a drug is “medically necessary. The objective here is to assist with prioritizing which drugs are critically necessary for treatment and may also be at risk for drug shortage due to insufficient manufacturing capacity. A first step in this effort could be creating a workgroup to guide FDA’s decisions on designating a drug as medically necessary.
- Enabling more flexibility in regulations that apply to quotas to registered manufacturers of controlled substances. The Drug Enforcement Agency (DEA) currently limits the amount of active ingredients manufacturers may purchase for controlled substances, thus limiting the ability of manufacturers to ramp up production when another supplier exits the market. Flexibility should be afforded to allow the DEA to expeditiously modify or transfer these quotas among manufacturers when one ceases production of a drug containing a controlled substance.
- Creating a fast track approval of new Active Pharmaceutical Ingredient (API) suppliers for medically necessary drugs in shortage.

- Working with manufacturers to slow the trend of acquiring the bulk of the raw materials used in pharmaceuticals outside of the U.S. For raw materials overseas, the manufacturers should be required to inspect the facility from which they are purchasing.
- Requiring manufacturers to provide the FDA notification of planned discontinuation or interruption in the manufacture of drugs as soon as practicable after determining the current production will not meet average historic demand. This will allow FDA time to work with remaining manufacturers to increase production.
- Creating a stakeholder committee to advise FDA on market conditions.

Premier will continue to look at the data on drug shortages and talk to our hospital members, manufactures and others to identify potential solutions. To this end, Premier is a member of a multi-stakeholder workgroup that emerged from last year's FDA/stakeholder summit to seek solutions.

In closing, I would again like to thank the Committee for the opportunity to share what we have learned about the scope of drug shortages and the alarming impact it has on the safety and health of our communities, as well as its part in driving up healthcare costs. The Premier healthcare alliance appreciates the Committee's recognition of the urgency in which this problem needs to be addressed, and we stand ready to help Congress find achievable ways to ensure a safe, reliable drug supply.