

## Buyer beware: Drug shortages and the gray market

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### **Background**

For more than a year our healthcare system has experienced an alarming increase in the number of reported drug shortages for a range of products vital to treatment. The University of Utah Drug Information Service reported a record high of 180 drug shortages over the first half of 2011 (January 1-July 31). This follows a [Premier healthcare alliance analysis](#) showing more than 240 drugs were either in short supply or completely unavailable, and more than 400 generic varieties were back-ordered for five or more days from July 1 -December 31, 2010. Both reports forecast that the number of drug shortages will continue to increase, and the industry could experience more than 360 drugs in short supply in 2011, the highest count in recorded history. The majority of drugs in short supply are needed for sedation, emergency care and chemotherapy.

Drug shortages present a danger to public health, and have a number of adverse effects on the overall quality of healthcare. Consider the following:

- Healthcare system pharmacy departments, where budgets are already stretched, **struggle daily to obtain an adequate supply of critical and life-saving drugs** that patients need.
- Healthcare providers desperately try to obtain drugs that are needed to treat patients in areas such as cancer treatment and surgery, and **may postpone planned procedures** if a drug is unavailable.
- Hospital administrators are concerned, wondering how they can run an oncology center or a surgery suite **if the medications needed to provide treatment are not available**.
- Hospital financial officers are concerned about the pharmacy drug budget, as **drug shortages create higher than expected expenses** that far exceed payor reimbursement levels.
- Physicians are concerned that **substitution of similar medications, if available, may lead to errors and adverse events**, especially if prescribers are unfamiliar with the alternative products' dosing and potential interactions with other drugs.
- Patients are often not aware or cannot understand how a drug vital to their treatment is not available. They are frightened that their **healthcare outcome could be threatened** by the lack of a critical drug.

The crisis has caused healthcare providers to expend critical resources to obtain needed drug replacements, while advocacy groups call for investigations and legislation to ameliorate the crisis.

### **The gray market**

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 may evolve to sell the item at any price the market will bear. In other circumstances, when commodities are already being sold at high margins, a gray market may develop to compete with the innovator's product, but at a lower price.

Often, in a shortage situation, gray market vendors offer to sell shortage products, typically at exorbitant prices. Capitalizing 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, these profiteers may be the only available source of supply.

### **Research on incidence of gray market offers**

In April 2011, Premier healthcare alliance membership asked its Pharmacy support team to review the incidence of gray market offers and suggest guidelines to member pharmacy departments on best practices for handling such offers. Premier surveyed all of its acute-care membership, requesting examples of unauthorized offers to sell products in short supply. The call for gray market offers was

**1,745** recorded gray market offers to providers,  
average markup of **650** percent.

posted in the Premier Pharmacy Weekly Update in the last week of April 2011. Examples of specific national drug codes (NDCs) and their selling prices were tabulated and compared using Premier base contract prices.

Over a two-week period at the beginning of 2011 the following data was recorded.

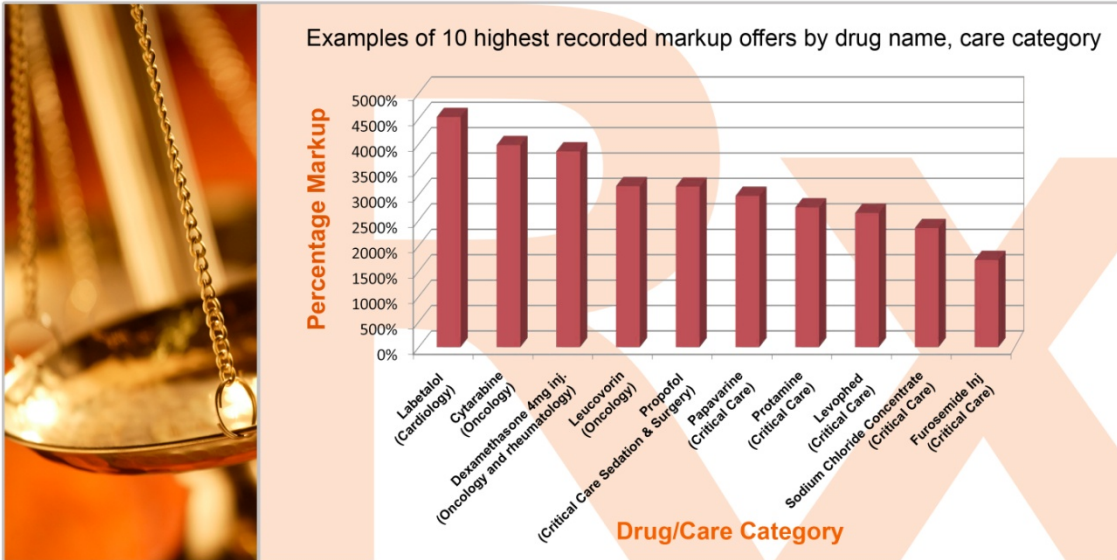
- 1,745 examples of gray market offers were recorded from 42 acute care hospitals.
- All drugs offered were manufacturer back-ordered or unavailable drugs.
- 636 examples with both NDCs and prices offered.
- 310 different generic drugs that could be matched to Premier contract price.
- 18 gray market vendors were recorded.

The markup percent was calculated for all examples that contained both offered price and NDC of the product.

The average markup was 650 percent, but even higher prices were seen in certain critical care areas. The highest markups seen in the 10 manufacturer back-ordered drugs are summarized below:

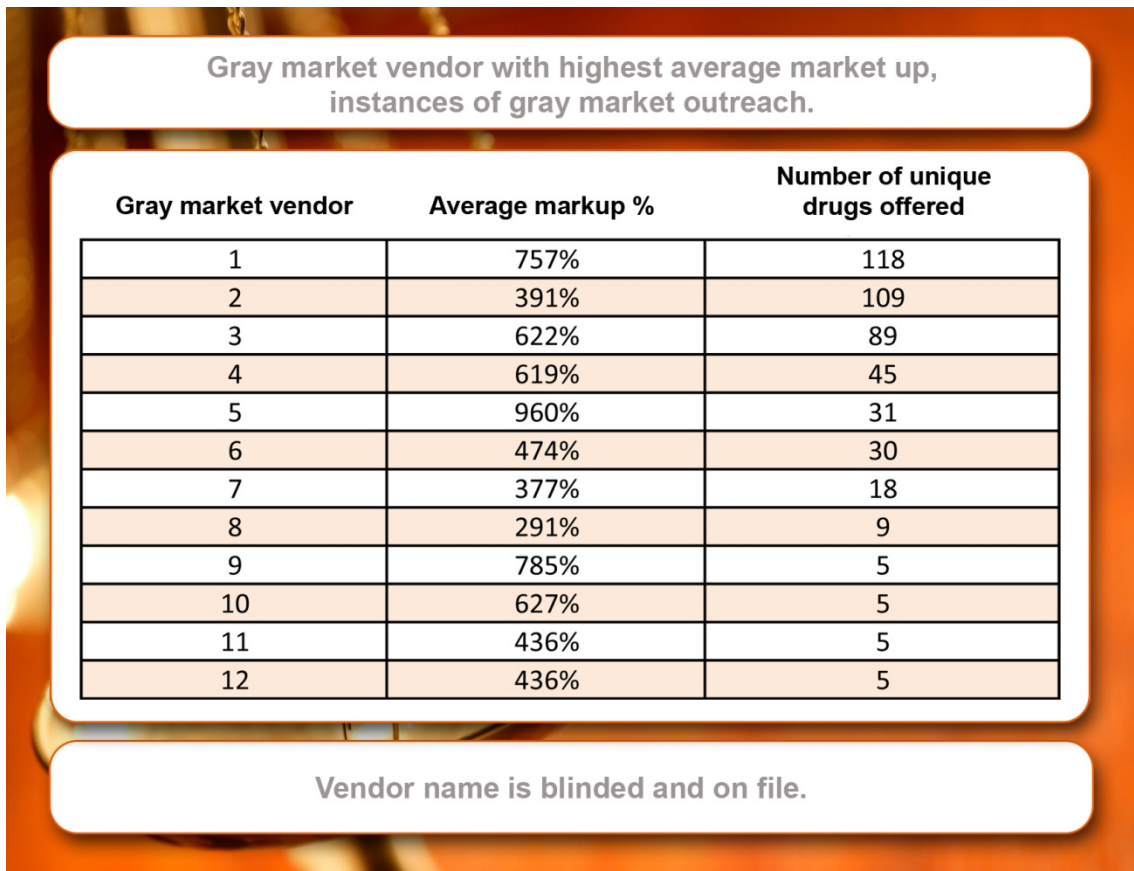
- Labetalol (cardiology) – 4,533 percent
- Cytarabine (oncology) – 3,980 percent
- Dexamethasone 4mg inj. (oncology and rheumatology) – 3,857 percent
- Leucovorin (oncology) – 3,170 percent
- Propofol (critical care sedation and surgery) – 3,161 percent
- Papavarine (critical care) – 2,979 percent
- Protamine (critical care) – 2,752 percent
- Levophed(critical care) – 2,642 percent
- Sodium Chloride Concentrate (critical care) – 2,350 percent
- Furosemide Inj. (critical care) – 1,721 percent

**Largest markup offers for drugs needed to treat critically ill.**



The marketing offers were often in the form of emails and fliers that contained language such as: “We only have 20 of this drug left and quantities are going fast.” All of the top 10 offers to sell products involved drugs in short supply or those that were completely back-ordered by their manufacturers. All were drugs specifically indicated for critically ill patients.

The price percentage markup and number of agents offered by each gray market vendor varied. The following chart shows the variation of offers.



The price often varied according to the date of the product being offered and the quantity available. When quantity decreased, demand increased and so did the price. There were three sources that offered no selling price on their marketing emails. They instead asked customers to call for price quotes.

In the case of pharmaceuticals, as opposed to commodities, the gray market doesn't just represent a cost concern. There are also myriad safety issues that need to be factored in. The pharmaceutical supply chain is highly regulated, and the distribution of medications is tightly controlled, with strict standards for storage and handling, as well as requirements to record the product's chain of custody from manufacturer, to distributor, to pharmacy.

So, when vendors emerge with products that the manufacturer and reputable drug distributors can't supply, it begs several questions: Where and how are these organizations getting the drugs when other sources cannot supply the drug? How can the integrity of these drugs be ascertained? Is this practice legal? Is it best practice – or even acceptable – for providers to purchase from these markets? More often than not, the answer is no.

A [CNN Money.com article](#) in May 2011 told of situations where a drug was traced from a drug warehouse and shipment thefts led to negative patient outcomes. The stolen drugs got back into the supply chain through a gray market source, which then provided the drug to a pharmacy to fill prescriptions. Earlier in 2009, consumers reported to the FDA that their insulin was not controlling blood sugar levels. Upon investigation, it was found that the patients were using stolen insulin. It is thought that the insulin was not stored or handled properly by the gray market, and lost its potency<sup>1</sup>. Other documented cases have found gray market vendors selling counterfeit or diluted medications<sup>2</sup>.

But stolen, counterfeit or mishandled drugs can be very difficult to spot. In fact, the FDA notes that fake medicines are being produced using sophisticated new technologies that may be difficult even for the original manufacturers to detect<sup>3</sup>. Compounding the problem, gray market vendors have also deployed sophisticated tricks to impersonate legitimate, licensed distributors when offering to sell products.

In times of shortage, pharmacies may have no choice but to purchase from companies that are not among their traditional contracted suppliers. Most of the time, these suppliers are legitimate companies. But hiding in their midst are gray market impersonators.

In order to avoid an unwitting purchase from the gray market, pharmacies must take additional steps and perform due diligence to ensure that the products are genuine, safe and handled appropriately, in accordance with all state and federal laws.

Following are key issues for purchasers to consider during all such buying processes.

### **Drug integrity, handling and storage**

The question of drug integrity and the appropriate handling and storage of product must be considered as the pharmacy community responds to this challenge. Drugs often have narrow ranges of temperature and climate conditions required for maintaining efficacy, and only a well-controlled supply chain channel can meet these requirements. Many regulations for handling drugs are therefore in place to safeguard

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<sup>1</sup><http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf>

<sup>2</sup> <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108483.htm>

<sup>3</sup> <http://www.fda.gov/Drugs/DrugSafety/ucm173255.htm>

patients and ensure positive outcomes. Improper handling and storage of drugs may cause inadequate or even harmful results.

Drugs from any unknown channels should be reviewed for appropriate handling by looking for legitimate exchange of product between points of sale to and from licensed distributors and buyers. This is the best way for purchasers to avoid the gray market, and ensure that products purchased are safe and legitimate.

### **Pedigrees**

A drug pedigree is the record of transactions from the manufacturer origin through to the dispensing pharmacy (pedigrees are to include dates, names and addresses of all parties involved in a transaction, as well as specifics about the drug being transferred, including lot number). Many states have enacted legislation requiring distributors to supply a pedigree documenting each product's chain of custody through the supply chain, either in hard copy or an electronic version. If a distributor has a broad geographic service area encompassing one of these states, a pedigree should be supplied.

Prior to purchase from a new supplier, a suggested best practice is for a pharmacy to confirm that a pedigree (hard copy or electronic) will be supplied prior to or upon purchase from the distributor, and that each listed transaction is bona-fide and can be authenticated. Authentication can be achieved by simply verifying that the product was sold by the manufacturer or manufacturer's approved distributor of record, and then to any other participants in the supply chain. Keep in mind that pedigrees (particularly those in paper form) can be counterfeited, so authentication is an important step to take to verify authenticity.

### **Verified-Accredited Wholesale Distributor accreditation**

Establishing that the distributor is a Verified-Accredited Wholesale Distributor (VAWD) also is an important step. This designation identifies companies that have an accreditation for pharmaceutical wholesale distribution by the National Boards of Pharmacy (NABP). VAWD plays a role in preventing counterfeit drugs from entering the U.S. drug supply chain. The certification includes verification of the following:

- Verifies wholesaler and designated representative licensing
- Screen applicant against NABP's clearinghouse for disciplinary or other actions
- Performs criminal and financial checks
- Reviews policies and procedures for compliance with VAWD criteria
- Includes site survey (survey follows collection of all documentation of policies and procedures)

States such as Indiana, North Dakota and Wyoming require this accreditation to obtain a license to sell prescription drugs. Additional suppliers that have been accredited by NABP can be viewed [here](#).

## **How to ensure safe, reliable purchases**

In an effort to provide hospitals and health systems nationwide with guidance, Premier developed a series of eight actions that should be taken to ensure a safe, reliable purchase<sup>4</sup> Following these best practices should help hospital pharmacies avoid the gray market and conduct business only with legitimate, licensed suppliers.

### **Recommendations for healthcare providers to ensure safe, reliable purchases<sup>4</sup>**

1. **Understand risks.** Fully understand the risks that the gray market can pose to your patients and the facility, including the possibility that supplied drugs may be counterfeit, stolen, diverted, mishandled and/or adulterated. Engage with your legal and risk management departments locally to better comprehend the differences between a legal and an illegal operation.
2. **Develop and communicate policy for purchasing decisions.** Develop a policy for how your pharmacy department will decide which distributors and suppliers to do business with. Communicate the policy and process for any exceptions to administration, medical staff, nursing, pharmacy staff, purchasing department, etc.
3. **Consider and document exceptions to policy.** Carefully consider and document exceptions that may be allowed to your existing policy, such as emergency loans from other hospitals or purchases from sources outside of normal suppliers/distributors.
4. **Confirm receipt of drug pedigree with all appropriate information.** Confirm that a pedigree (hard copy or electronic) will be supplied prior to or upon purchase and that each of its listed transactions are bona-fide and can be authenticated and tracked back to the manufacturer or manufacturer's approved distributor of record.
5. **Confirm wholesaler, distributor and supplier licensure with authorities.** At a minimum, supplies should only be purchased after pharmacists confirm with the State Board of Pharmacy or Department of Health that the distributor is appropriately licensed as a wholesale distributor of pharmaceuticals. The drug's manufacturer also will be able to verify whether the distributor is an authorized distributor of record (ADR). Purchases from non-ADRs should be subject to additional scrutiny, such as verification from the NABP website that the distributor is VAWD accredited.
6. **Keep records of suspect organizations.** Keep records of any vendors you have refused to do business with and reasons for those decisions to provide pharmacy staff with a resource to check prior to making purchases.
7. **Compare and scrutinize purchases. Don't use drug if there are concerns.** Whenever a purchase is made from a new supplier, compare and scrutinize the package, label (font, color, size) and contents. If the product label appears to have been altered, doesn't appear consistent with earlier purchases, has residue left near the label and/or content appears to be different, question its authenticity. Also, listen to patients who often can detect similar abnormalities.
8. **Consider reporting any suspect suppliers to all appropriate authorities/organizations.** Consider reporting suspect suppliers that may be trafficking in counterfeit, stolen, diverted and/or adulterated product to your State Board of Pharmacy, the FDA's [MedWatch reporting site](#), and any applicable local, state or federal law enforcement authorities. Similarly, consider reporting any violations of state or federal pedigree laws to both the FDA and state authorities.

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<sup>4</sup> When considering the use of an unauthorized supplier, hospitals should, at a minimum, follow these purchasing guidelines. These recommendations are intended to protect the hospital, as well as the patients consuming medications, from unintended harm. However, it should still be noted that even if these guidelines are followed, it can't be guaranteed that all sellers will be legitimate.



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## References and resources

1. "Drug shortages cost U.S. care providers at least \$200 million annually, pose patient safety risks, research suggests." Premier healthcare alliance website. [www.premierinc.com](http://www.premierinc.com).
2. "What is Parallel Market?" The Gray Blog. [http://espinosaiplaw.com/wordpress/?page\\_id=5](http://espinosaiplaw.com/wordpress/?page_id=5).
3. "Drug Theft Goes Big." Fortune on CNNMoney.com. <http://features.blogs.fortune.cnn.com/2011/03/31/drug-theft-goes-big/>.
4. The FDA MedWatch Reporting Site. Food and Drug Administration. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm>.
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6. "Tips for Pharmacists in Detecting Counterfeit Medications." Current Concepts in Pharmacy Management – Summer 2011. By Marv Shepherd, PhD. [http://www.ccpharm.com/01\\_counterfeit\\_meds.php](http://www.ccpharm.com/01_counterfeit_meds.php)

### **About the Premier healthcare alliance, Malcolm Baldrige National Quality Award recipient**

Premier is a performance improvement alliance of more than 2,500 U.S. hospitals and 75,000-plus other healthcare sites using the power of collaboration to lead the transformation to high quality, cost-effective care. Owned by hospitals, health systems and other providers, Premier maintains the nation's most comprehensive repository of clinical, financial and outcomes information and operates a leading healthcare purchasing network. A world leader in helping deliver measurable improvements in care, Premier has worked with the Centers for Medicare & Medicaid Services and the United Kingdom's National Health Service North West to improve hospital performance. Headquartered in Charlotte, N.C., Premier also has an office in Washington. <http://www.premierinc.com>. Stay connected with Premier on [Facebook](#), [Twitter](#) and [YouTube](#).