FDA Drug Shortages Workshop

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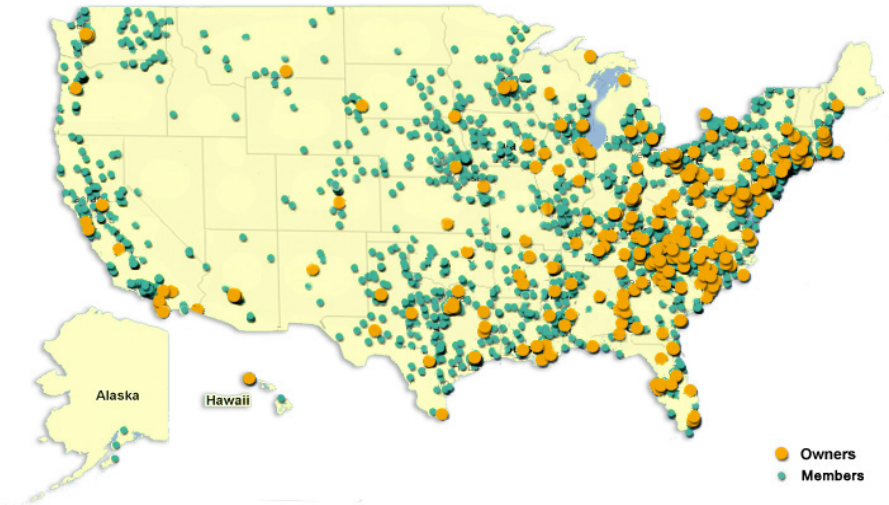
Premier healthcare alliance



- Over 2,500 hospitals, more than 75,000 non-acute sites
- Using the power of collaboration to improve the health of communities
- Nation's largest clinical/operational/supply chain comparative databases
- 2010 member validated savings of $1.4 billion
- Safety, Diversity and Environmentally Preferred Purchasing programs
- $36 billion in annual group purchasing volume
- 2006 recipient of Malcolm Baldrige National Quality Award
- Four-time recipient of Ethisphere's Most Ethical Companies award.

Cost Reduction
Group Purchasing & Supply Chain Improvement, Labor Management

Quality Improvement
Quality Measurement & Benchmarking, Safety Surveillance

Risk Mitigation
Liability, Benefits & Risk Management

Execution Engine
Comprehensive, accelerated approach to improving financial, operational and clinical performance.

Premier Drug Shortage Survey

- 311 respondents – Pharmacy Directors and Pharmacy Supply Chain Professionals
- From July 2010 – December 2010:
  - More than 240 drugs were either in short supply or completely unavailable
  - Over 400 generic equivalents were backordered for greater than five days
  - Many of the drugs noted as back orders in 2010 have remained unavailable or in short supply in 2011
- Based on Premier research of drugs with generic alternatives that were backordered

** Excludes drugs purchased on "gray market" or with therapeutic alternatives*

Threat of drug shortages to patient safety

- 89% experienced shortage that may have affected patient care
  - Over 50% suggested occurrence 6+ times
- 80% experienced shortage that resulted in a delay or cancellation of a patient care intervention
  - 30% suggested occurrence 6+ times

- Premier estimates drug shortages cost hospitals $415 million annually through purchase of more expensive substitutes and additional labor costs
  - The annual financial impact of drug shortages on *Premier alliance members* exceeds $76.5 million*
  - Extrapolated nationwide, Premier found drug shortages cost *U.S. hospitals* at least $200 million, excluding labor costs to manage shortages
  - Drug shortages translates to $216 million in *labor costs* and time required to manage shortages**

** Excludes drugs purchased on "gray market" or with therapeutic alternatives*

*** American Society of Health-System Pharmacists and the University of Michigan Health System*

What is Premier doing to address drug shortages?

- Determining scope of problem
  - Drug shortage and grey market survey/analyses
- Working closely with manufacturers to determine their manufacturing capabilities
  - At front end when contracting with manufacturers
  - Can they supply the market?
  - Look for alternatives if capabilities can't meet demand
- Maintaining hospital communication network
  - Early warning system: hospitals notify Premier of drug access problems (typically *before* posted on FDA site)
  - Premier determines if it is a local or national problem and often notifies FDA
  - Premier provides guidelines to hospitals on what steps to take to help reduce financial and quality impact of drug shortages
- Creating longer term contracts to enhance stable market

Premier's gray market analysis

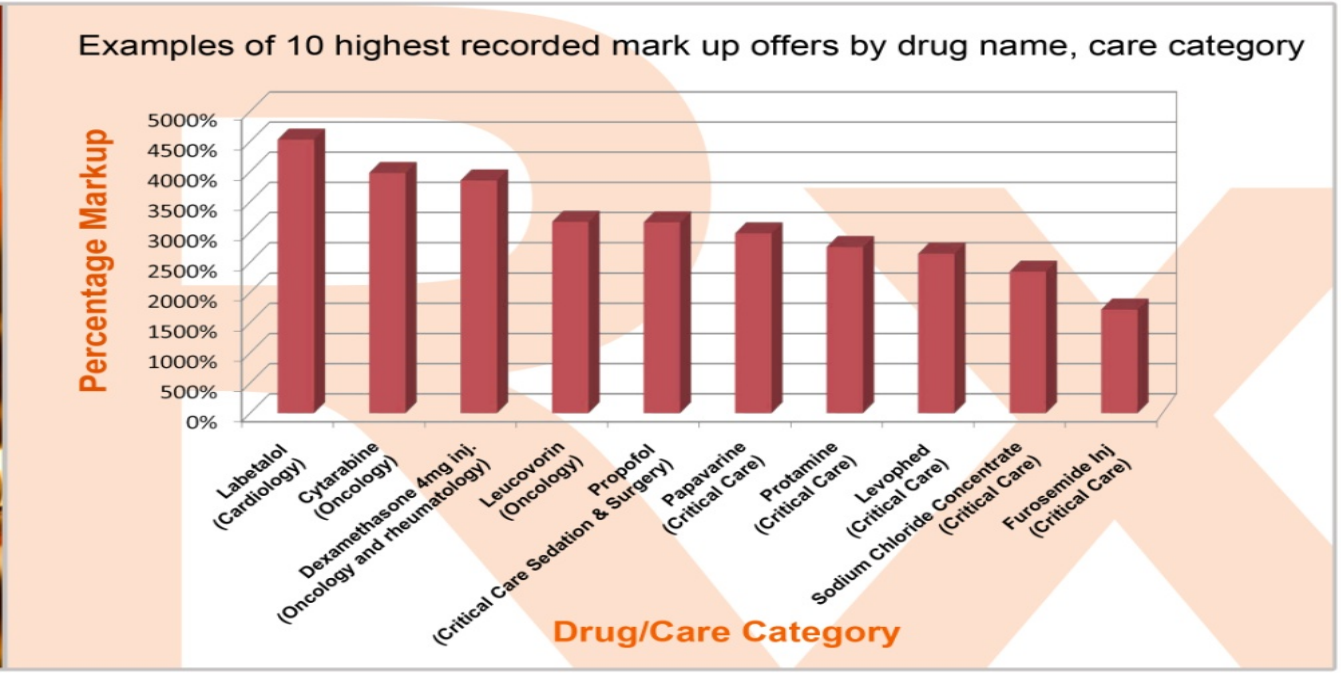
Premier analyzed 636 unsolicited sales offers from gray market vendors:

- Average markup was 650%
- Highest markup was more than 4,500%
- 45% were marked up at least 1,000%
- More than 25% were marked up at least 2,000%

A drug used to treat high blood pressure, which normally sells for $25.90, was being offered at $1,200 – a staggering increase

Premier grey market analysis

- Highest mark-ups seen with drugs needed to treat critically ill patients in the following care categories: Critical care sedation and surgery, emergency care, chemotherapy and to fight infectious disease.



Recommendations to address the drug shortage crisis

- Speed approval process for medically necessary generic drugs that appear to be in shortage
- Encourage FDA Drug Shortage Program staff to broadly engage members of the healthcare community in discussions determining whether a drug is “medically necessary”
- Grant DEA flexibility to adjust API quotas
- Create fast track approval of new API suppliers for medically necessary drugs in shortage
- Work with manufacturers to slow trend of acquiring raw materials outside the U.S.
- Require manufacturers to notify FDA of planned discontinuation or interruption in manufacturing
- Establish an “early warning” point of contact at FDA