

October 2011

## The Impact of Drug Shortages in Health Care

*The ongoing shortage of prescription drugs in the United States is costing hospitals at least \$200 million annually and increasing the chances of medical errors for patients<sup>1</sup>. At least 15 deaths in the past 15 months have been blamed on shortages of life-saving medications<sup>2</sup>. Shortages of drugs used for chemotherapy and emergency care have become a national health care crisis.*

Drug shortages can be created by a lack of available raw materials (80% of our raw materials come from foreign markets<sup>3</sup>), contamination in the manufacturing process, and consolidation of the pharmaceutical industry. Other reasons include production problems in plants, poor inventory management, surges in market demand, or even changes in the Food and Drug Administration (FDA) testing requirements.

### Regulatory Causes of Drug Shortages

#### The FDA Unapproved Drug Initiative

- A 2006 FDA initiative requires manufacturers to submit New Drug applications for drugs marketed before the enactment of the Food, Drug, and Cosmetic Act of 1938 – when the pre-market testing of drugs was authorized.
- The goal of the initiative is to prove the safety and efficacy of drugs that were introduced in the market prior to FDA's current approval processes.
- Some manufacturers have argued that it is easier and cheaper to stop making a drug than to submit a new application.
- Many of the products marketed before 1938 are generic drugs, like opioids and pain killers, which have been used for decades by hospitals but were never authorized by the FDA.

#### The Drug Enforcement Agency (DEA)

The DEA issues quotas for controlled substances (i.e., opioids and pain killers) that can delay or inhibit manufacturers from increasing their drug production.

Current drug shortages are voluntarily reported by pharmacies on the FDA website but there is no legal requirement to do so. The FDA encourages manufacturers to notify the agency of any drug shortages but has no legal power to demand it.

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<sup>1</sup> The Premier Healthcare Alliance. *Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance analysis*. March 2011.

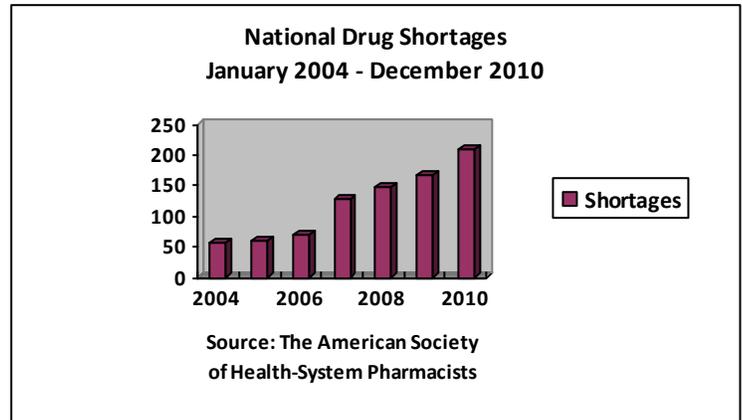
<sup>2</sup> Rush, Brittany. *AP Impact: Hospital Drug Shortages Deadly, Costly*. Bioethics International. 26 Sept. 2011. Web. 28 Sept. 2011.

<sup>3</sup> The Premier Healthcare Alliance. March 2011.

## National Drug Shortages

According to the American Society of Health-System Pharmacists, the number of drugs in short supply has more than tripled since 2004, jumping from 58 drug products in 2004 to 210 in 2010. So far this year, there have been 201 drug shortages. This trend is expected to continue unless immediate policy changes are made.

It is estimated that by the end of 2011, the drugs declared in short supply could reach up to 300 – a record number<sup>4</sup>.



## What is the Impact on the Cost of Health?

### Labor Costs

The hours spent managing shortages have tripled over the years and so have hospital costs. A survey conducted by the American Society of Health-System Pharmacists to 353 hospital pharmacy directors of hospitals across the nation revealed:

- The time pharmacists spend managing drug shortages has increased from 3 hours a week in 2004 to 9 hours a week in 2011- creating an annual labor cost of \$216 million for all health systems nationwide.
- 32% of hospitals have reallocated existing staff to allow time for managing shortages.

Findings from different organizations suggest that drug shortages could cost U.S. hospitals at least \$415 million annually through the purchase of more expensive drug substitutes and additional labor costs<sup>5</sup>.

### The Gray Market

Drug shortages are forcing hospitals to buy from outside pharmacies or "gray market" drug distributors that charge as much as 335% more than the normal market price. The FDA has allowed unapproved drugs to be imported from Europe to fill the gap but these sources are highly expensive and also unsafe.

In April 2011, the Premier Healthcare Alliance totaled the gray market sales offers made to its acute-care membership over a two-week period at the beginning of 2011. Out of a total of 1,745 sales offers, Premier found that 650% was the highest markup<sup>6</sup>.

Labetalol, a generic drug used to treat high blood pressure, normally priced at \$25.90 per dose, was costing \$1,200 per dose.

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<sup>4</sup> American Society of Health-System Pharmacists. *Drug Shortages Harming Patients, Increasing Costs to Hospitals*. July 2011.

<sup>5</sup> The Premier Healthcare Alliance. *Testimony of Mike Alkire before the Committee on Energy and Subcommittee on Health*. U.S. House of Representatives. September 23, 2011.

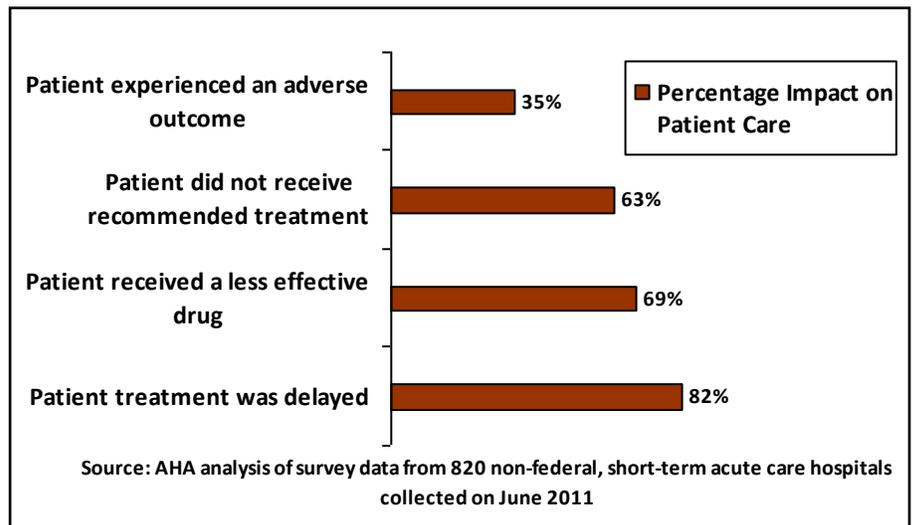
<sup>6</sup> The Premier Healthcare Alliance. *Buyer Beware: Drug Shortages and the Gray Market*. August, 2011.

# What is the Impact on Patient Safety?

## Medical Errors

A national survey of more than 1,000 providers conducted in 2010 identified at least 1,000 errors and adverse patient outcomes due to drugs shortages<sup>7</sup>. These errors are happening because nurses are unfamiliar with the alternative drugs and can sometimes use the wrong dosage.

Obtaining alternative drugs in the gray market can generate severe risks for patients as well. The guidelines for handling and manufacturing these drugs are often lax, so they can easily be stolen and then sold back to pharmacies. They might be either adulterated or have quality issues as a result of sustaining heat and not being stored properly during the theft.



In 2009, the FDA learned of a case where a patient taking insulin went into convulsions and another in which the insulin was not controlling blood sugar levels. Upon investigation, it was found that the insulin was stolen<sup>8</sup>.

## Delayed Treatment

Drug shortages can force physicians to delay treatment for patients. This can be very dangerous for patients who need immediate, life-saving treatments, such as cancer patients and those undergoing surgery.

A survey conducted in June 2011 found that 99.5% of the 820 hospitals who responded had one or more drug shortages in the last six months<sup>9</sup>.

The survey also found that 78% of the hospitals nationwide were rationing drugs in short supply. In some instances, this led to patients waking up in the middle of a surgery because of lack of sufficient anesthesia.

Drug shortages are also jeopardizing the development of new treatments that could help patients. According to the Department of Health and Human Services, more than 300 clinical studies paid for by the National Cancer Institute involve a drug that is in short supply<sup>10</sup>.

<sup>7</sup> Institute for Safe Medication Practices. *National Survey on Drug Shortages Reveals Serious Impact on Patient Safety*. September 2010.

<sup>8</sup> Katherine Eban. *Drug Theft Goes Big*. March 2011

<sup>9</sup> American Hospital Association. *AHA Survey on Drug Shortages*. July 2011.

<sup>10</sup> United States Department of Health and Human Services. *Examining the Increase in Drug Shortages: Statement before Committee on Energy and Commerce, Subcommittee on Health*. September 23, 2011.

# What has been done to address drug shortages?

## Congress: Bill S.296 – Preserving Access to Life-Saving Medications

- A bill proposed in February 2011 by Senator Amy Klobuchar (D-MN) and Senator Bob Casey (D-PA) would give the FDA the power to demand that drug makers give at least six months' notice before discontinuing any prescription drug.
- S.296 is currently in the first step of the legislative process. It was referred to the Committee on Health, Labor, Education, and Pensions.

On October 5, 2011, Congressman Elijah Cummings (D-MD) announced an investigation relating to "gray market" drug companies that sell drugs in critically short supply for exorbitant prices. As part of the investigation, Cummings also announced the creation of a tipline with information about price gouging and speculation in drugs that are in critically short supply. The tipline is available at: <http://democrats.oversight.house.gov/><sup>11</sup>

## The Food and Drug Administration

- Communicates all drug shortages reported from their manufacturers by posting them on the FDA website.
- Works with manufacturers to try to ramp up their production.
- Finds foreign companies that are willing to import the drug during the shortage.
- Expedites review of new production lines or raw materials when there is a shortage.

## The Department of Health and Human Services (HHS)

The HHS has engaged important stakeholders, including legislators, hospitals, and pharmaceutical manufacturers, to hear their views on the issue of drug shortages.

*Florida Hospital is actively monitoring the issue and is taking all reasonable measures to minimize the impact of any of these problems on our patients.*

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<sup>11</sup> Committee on Oversight and Government Reform, October 5, 2011.