



Tags: [prescriptions](#), [health care](#), [hospitals](#), [national/world](#)

- [Comment Now](#)
- [Email](#)
- [Print](#)
- [Report a typo](#)
-
-
-
-
-
-
-

 Associated Press

TRENTON, N.J. (AP) - September 23, 2011 (WPVI) -- A severe shortage of drugs for chemotherapy, infections and other serious ailments is endangering patients and forcing hospitals to buy life-saving medications from secondary suppliers at huge markups because they can't get them any other way.

Related Content

[More: Send a Breaking News alert](#)

[More: Report a typo](#)

[More: Sign up for 6abc Newsletters](#)

[More: See more Action News slideshows](#)

An Associated Press review of industry reports and interviews with nearly two dozen experts found at least 15 deaths in the past 15 months blamed on the shortages, either because the right drug wasn't available or because of dosing errors or other problems in administering or preparing alternative medications.

The shortages, mainly involving widely-used generic injected drugs that ordinarily are cheap, have been delaying surgeries and cancer treatments, leaving patients in unnecessary pain and forcing hospitals to give less effective treatments. That's resulted in complications and longer hospital stays.

Just over half of the 549 U.S. hospitals responding to a survey this summer by the Institute for Safe Medication Practices, a patient safety group, said they had purchased one or more prescription drugs from so-called "gray market vendors"- companies other than their normal wholesalers. Most also said they've had to do so more often of late, and 7 percent reported side effects or other problems.

Hospital pharmacists "are really looking at this as a crisis. They are scrambling to find drugs," said Joseph Hill of the American Society of Health-System Pharmacists.

A hearing on the issue was set for Friday before the health subcommittee of the House Energy and Commerce Committee. The Food and Drug Administration is holding a meeting Monday with medical and consumer groups, researchers and industry representatives to discuss the shortages and strategies to fight them.

The FDA says the primary cause of the shortages is production shutdowns because of manufacturing problems, such as contamination and metal particles that get into medicine.

Other reasons:

- Companies abandoning the injected generic drug market because the profit margins are slim. Producing these sterile medicines is far more complicated and expensive than stamping out pills, and it can take about three weeks to produce a batch. Making things worse, companies don't have to notify customers or the FDA that they've stopped making a medicine. That means neither FDA nor competitors can fill the gap in time.
- Only a half-dozen companies make the vast majority of injected generics. Even if other companies wanted to begin making a generic drug in short supply, they're discouraged by the lengthy, expensive process of setting up new manufacturing lines and getting FDA approval.
- Theft of prescription drugs from warehouses or during shipment.
- Secondary, "gray market" vendors who buy scarce drugs from small regional wholesalers, pharmacies or other sources and then market them to hospitals, often at many times the normal price. These sellers may not be licensed, authorized distributors.

Hospitals that buy scarce medicines from the "gray market" are taking a gamble.

The drugs may be stolen and hospitals can't always tell whether a medicine was properly refrigerated - as required for many injectable drugs - or whether it's past the expiration date, said Michael R. Cohen, a pharmacist and president of the institute. Either way, the active ingredient might have degraded and the drug might not work well or could harm the patient, he said.

Cohen attributes at least 15 recent deaths to drug shortages based on reports by medical personnel, but says many deaths and injuries go unreported.

In the worst known case, Alabama's public health department this spring reported nine deaths and 10 patients harmed due to bacterial contamination of a hand-mixed batch of liquid nutrition given via feeding tubes because the sterile pre-mixed liquid wasn't available.

So far this year, 210 drugs have been added to the list of drugs in short supply, one less than the total for all of last year, according to the University of Utah Drug Information Service, which tracks the shortages. That's triple the roughly 70 a year from 2003 to 2006, when shortages began to climb steadily.

"The shortages aren't resolving. They're piling up on top of existing ones," said Erin Fox, a pharmacist who manages the service. She said at least 55 drugs from shortages before this year are still unavailable or scarce.

The average price markup on drugs sold by secondary distributors was 650 percent, according to an Aug. 16 report by the Premier Healthcare Alliance, a group that helps U.S. hospitals and other health providers improve their patient care and finances. The report is based on an analysis of 636 unsolicited sales offers that were faxed and emailed to hospitals from secondary distributors in April and May.

Virtually every offer was for at least double the normal price, the survey found. The drugs with the highest markups were for critically ill patients needing anesthesia or other medicines for surgery or for emergency care, cancer, infectious diseases and pain management.

In an extreme case, one vendor was offering a generic drug for dangerously high blood pressure, normally priced at \$25.90 per dose, for \$1,200.

So far, hospitals have been absorbing the extra costs, but they'll soon have to start passing them on to insurers and patients, according to the American Hospital Association.

Hospitals sometimes have to cave in to save patients, according to Cohen and several hospital pharmacy directors.

The FDA says it must uphold quality standards but also works hard to prevent shortages.

"When FDA detects a contaminant, whether it be shards of glass or metal particles or an infectious agent, we have to take action to protect the public," said Dr. Peter Lurie, a senior adviser in the FDA commissioner's office.

When the agency orders a production shutdown, it urges other manufacturers to boost their output and expedites any approvals needed, said Valerie Jensen, associate director of FDA's drug shortage program. When raw materials used to make drugs are in short supply, the FDA tries to find new sources.

The agency averted 38 shortages last year, Jensen added.

Legislation pending in the House and Senate would increase penalties for drug thefts from warehouses and tractor-trailers. Another proposal, which has bipartisan support, would require drug manufacturers anticipating a shortage to immediately notify the FDA.

Sen. Amy Klobuchar, D.-Minn., the primary sponsor of the Senate version of the notification bill, said other solutions being considered include better tracking of medicine shipments, mandatory accreditation of distributors, stockpiling of key drugs and allowing routine imports of prescription drugs from countries such as Canada.

Distributors that supply about 90 percent of prescription drugs to hospitals buy direct from drug manufacturers and deliver only to customers with appropriate licenses, said John Parker, a spokesman for the Healthcare Distribution Management Association. He said HDMA members don't participate in the "gray market" but would not comment further.

The pitches hospitals get from the secondary distributors generally say they have small batches of specific drugs that are hard or impossible to find. "Are you enjoying this crazy 'roller coaster ride' of

pharmaceutical shortages? ... I utilize over 60 vendors to locate and procure needed pharmaceuticals to assist when you have shortage needs," one reads.

Several distributors who sent hospitals solicitations for scarce drugs didn't return calls from the AP. One representative said he wasn't authorized to discuss the issue.

One company, Novis Pharmaceuticals, defended the higher prices, saying secondary distributors have to charge far more because they don't get the big rebates manufacturers give primary distributors. They also have high costs to locate and transport batches of scarce drugs, although the company, which mainly distributes blood plasma, would not disclose its profit margin.

It's illegal for companies to create a monopoly or collude to create a medicine shortage and raise prices, and there's no evidence of that. There's no federal law against price-gouging on prescription drugs, according to the FDA, but it does urge pharmacists to report cases to its Office of Criminal Investigation. An agency spokeswoman said she could not discuss whether any cases are being investigated.

The top three wholesalers say they try to alleviate problems by working with drug manufacturers, updating hospitals on shortages and rationing scarce supplies by giving their regular hospital customers a portion of their normal order. McKesson Corp. and Cardinal Health Inc. say they halt sales to any smaller distributors found to be diverting drugs or otherwise breaking rules. AmerisourceBergen Corp. does background checks on customers.

The hospital association and other groups urge hospitals not to buy from unaccredited vendors, to insist on documentation of the drug's source if they must, and to report price gouging to state authorities. But only three states - Kentucky, Maine and Texas - have price-gouging laws that specifically cover medicines.

"Something has to be done here," said pharmacist Michael O'Neal, head of drug procurement for Vanderbilt University Medical Center in Nashville, which has had to purchase medicines from secondary suppliers about 70 times over the past two years.

"This is unethical," he said. "We're talking about people's lives."

Summary of state price-gouging laws:

<http://www.ncsl.org/default.aspx?tabid=14434>

Institute for Safe Medication Practices consumer site:

<http://www.consumermedsafety.org/>

(Copyright ©2011 WPVI-TV/DT. All Rights Reserved.)

[Get more National/World »](#)

Tags:

[prescriptions](#), [health care](#), [hospitals](#), [national/world](#)