

2011 Medication Shortages Set New Record

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TRENTON, N.J. (AP) — The number of new prescription drug shortages in 2011 shot up to 267, well above the prior record and about four times the number of medication shortages in the middle of the last decade.

Figures just released by the University of Utah Drug Information Service, which tracks national drug shortages, show there were 56 more newly reported drug shortages in the U.S. last year than in 2010, when there were 211. By contrast, there were only 58 drug shortages reported in 2004.

As the drug shortages worsen, so does their impact on patient care, particularly in hospitals. The inability to get crucial medicines has disrupted chemotherapy, surgery and care for patients with infections and pain. At least 15 deaths since 2010 have been blamed on the shortages, which have set a record high in each of the last five years.

"At the beginning of the year, we were on a pace of about a shortage every day," Erin R. Fox, manager of the service, told The Associated Press. "Luckily, that pace has definitely diminished."

She noted the Food and Drug Administration has said it has prevented more than 100 new shortages in 2011. That's partly because of an executive order President Obama issued on Oct. 31 to address the shortages, with provisions requiring more manufacturers to report potential shortages in advance to the FDA.

But Fox is still worried because many of the current shortages won't be resolved anytime soon, based on reports from several key manufacturers that have had to shut down production because of contamination or other quality problems. For some medicines, there may be only one other manufacturer, which doesn't have the capacity to fill the gap immediately or completely.

In addition, Fox said some of the more recently reported shortages are very difficult for hospital pharmacists and other staff to manage. She noted new shortages of sedatives widely used in surgery, including Valium, Versed and lorazepam. Another big problem is the recent shortage of the opioid painkiller fentanyl.

"It is used like water in hospitals, for everything from moms giving birth and ICU patients to the ER," Fox said.

Her service provides hospitals with lists of alternative drugs to those in short supply, but for some medicines the alternatives also are hard to find, and switching to an unfamiliar drug can result in dosage errors.

Most of the drugs in short supply are sterile injected drugs that are the workhorses

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of hospitals and are normally inexpensive because they've long been available as generics.

The FDA says the main reason for the shortages is manufacturing deficiencies leading to production shutdowns. Other reasons include companies ending production of some drugs with tiny profit margins, consolidation in the generic drug industry and limited supplies of some ingredients.

Besides disrupting patient care, the shortages have delayed clinical trials comparing experimental drugs to older ones and have led to unprecedented price gouging, with hospitals sometimes having to pay outrageous markups for scarce drugs. In one case that's among those under investigation by Congress, a vendor outside the normal supply chain offered to sell a hospital a vial of a cancer drug that normally costs about \$12 for more than \$990.

The FDA and several members of Congress have been holding hearings since September to identify reasons for and possible solutions to the shortages.

"I hope that we won't have another record-breaking year" in 2012, Fox said. "But I'm not optimistic."

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