

## Fear in US as drug shortages mount

September 4 2011, by Jean-Louis Santini

Shortages of vital drugs, particularly cancer-fighting medication, have raised concerns in the United States, where regulators often have to race to try to find replacements.

A recent report by the <u>Federal Drug Administration</u> (FDA) found that the number of important treatments that are difficult or impossible to find nearly tripled from 61 to 178 between 2005 and 2010.

Most of the rare medications are for hospital use, including sterile injections, intravenous treatments, <u>anesthetics</u> and antibiotics. The products include both name-brand and generic drugs.

"FDA hears from patients and also from <u>healthcare professionals</u> and organizations about the terrible impact the shortages have had," spokeswoman Shelly Burgess said.

"We continue to do all we can under our current authority to address shortages when they occur."

The FDA's efforts are hindered, however, because it cannot force private <u>pharmaceutical companies</u> to produce certain drugs or even require them to notify the agency when they plan to discontinue one, Burgess said.

In 2010 it was able to avert 38 shortages, mainly by persuading other manufacturers to produce the drugs or helping to resolve production issues.



But a survey of 820 hospitals carried out in June by the American Hospital Association found that almost all had run out of an important drug over the past six months.

Eighty-percent said they had to delay patient treatments because of <u>drug</u> scarcity, and 70 percent said they administered less effective treatments.

"We really need to take a very careful look at what is going on. I have never seen anything like this and I have been a <u>pharmacist</u> for over 40 years," says Mike Cohen, a pharmacist at the non-profit Safe <u>Medical Practices</u>.

The group recently surveyed 1,800 <u>health professionals</u> and found that a third of doctors and a fifth of pharmacists were aware of adverse reactions in their patients -- including deaths -- because of <u>drug shortages</u>.

Cynthia Reilly of the American Society of Health System Pharmacists says the "dramatic increase" in shortages is in part due to "quality issues."

"In a lot of instances the manufacturer is either having problems with the production lines or perhaps they found particular products in vials so they have to do a recall," she said.

Reilly fears the shortages will worsen as the pharmaceutical industry continues to consolidate, and as more companies stop producing generic drugs because they are less profitable.

"A few years ago five companies were making a similar product. Now there is only one or two... There are not a lot of companies to fill the gap," she said.



She and other advocates believe new legislation to allow the FDA to force companies to alert it six months in advance of closing a production line would be helpful, as it would give the agency more time to find a substitute.

Two bills with broad support are currently under discussion in Congress.

Another problem is the so-called "gray market," whereby distributors scoop up rare drugs and then charge hospitals exorbitant rates for them. Some drugs can fetch up to 1,000 times the normal price.

"We tell our members to contact their state attorney general. Unfortunately there is opportunity for unscrupulous behavior," Reilly said.

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