Look beyond drug makers to avoid tragedies like meningitis outbreak, expert says

October 17 2012, by Elizabeth K. Gardner

(Medical Xpress)—A Purdue University medication safety expert said it is important to look at the larger system surrounding medication use, as well as the facilities where drugs are made to avoid tragedies like the meningitis outbreak that has claimed 15 lives.

"No one condones making a bad product, but we also need to examine the quality assurance process of the larger medication-use system that doesn't catch it," said John B. Hertig, medication safety project manager for the Purdue College of Pharmacy's Center for Medication Safety Advancement. "It is a failure of the larger system and practices that allow a harmful product to make it through numerous hands and be administered to a patient. A system-wide view is the most effective in improving overall patient safety."

The broader pharmaceutical system can be thought of as a stack of slices of Swiss cheese, Hertig said. Each step in the system, from manufacture to shipping and receiving to treatment, has holes where a mistake could go undetected. It is only when the holes in each piece line up that a mistake can make it all the way through to a patient, he said.

The Centers for Disease Control and Prevention recently linked a meningitis outbreak that spans 15 states to possibly tainted steroid injections that were made in a Massachusetts facility. The CDC on Monday (Oct. 15) reported 212 people have been infected and 14,000 may have received the injections.

The outbreak raises questions about the oversight of such facilities, called compounding pharmacies, which create customized medication solutions for patients for whom manufactured drugs won't work or are not available, Hertig said.

"In the midst of tragedy our emotions run high and we can get caught up in putting all of the blame on an individual," he said. "We certainly shouldn't tolerate gross negligence, but we also need to take a step back and look at the bigger picture. Even after the individuals responsible for a particular incident have been held accountable, unaddressed flaws in the system will continue to produce negative consequences."

Hertig also is concerned that over-regulation of compounding pharmacies could have the unintended consequence of adding significant costs to the facilities, raising the prices of such treatments and shrinking a critical source of pharmaceuticals.

There have been 200 instances of harmful side effects or illnesses caused by treatments involving 71 compounded products reported to the Food and Drug Administration since 1990, Hertig said.

"It is important to note that these cases represent a very small fraction of the total number of compounded medications dispensed, and without these pharmacies many patients would not have access to much-needed therapies," he said. "Greater regulation may be part of the solution, but enacting increasingly complicated legislation could inhibit compounding pharmacies to the detriment of patient care."

Provided by Purdue University

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