SOUTHWESTERN NEWS

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# EXPERT CALLS FOR DOCTORS, PHARMACISTS TO REPORT ALL ADVERSE EFFECTS FROM NEW DRUGS TO CURTAIL LIVER INJURIES

DALLAS – July 31, 2003 – Physicians and pharmacists should be more proactive in reporting adverse drug reactions that result in liver damage after medications are approved by the Food and Drug Administration, writes a researcher at UT Southwestern Medical Center at Dallas.

In a review article published in today's issue of *The New England Journal of Medicine*, UT Southwestern professor Dr. William M. Lee, whose liver research has been published extensively, details the importance of continuing to monitor new drugs for liver-damaging side effects.

Drug-induced liver injury, although rare, is the most common reason for withdrawing approved drugs from the market and accounts for more than 50 percent of all acute liver failure cases in the United States. It is estimated that fewer than 10 percent of these adverse drug reactions are reported, potentially delaying identification of a problem.

Dr. Lee said case reports detailing the toxic effects that appear in the first years after a drug is approved, as well as more consistent monitoring, could help the FDA determine which new agents require closer scrutiny.

"It is important to report these because no one knows if some untoward event is happening, possibly all over the country, if everyone thinks their case is the only one," said Dr. Lee, professor of internal medicine and holder of the Meredith Mosle Distinguished Professorship in Liver Disease. "It is the aggregate experience that allows us to determine how frequently a drug reaction is occurring."

Drug reactions cannot always be detected before a medicine wins FDA approval

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because those reactions may happen too infrequently to be detected during clinical trials, he said. Liver reactions to medications can be expected to occur in less than 1 in 10,000 patients exposed, while most late-stage drug testing usually involves about 3,000 patients.

After a drug is approved and widely prescribed, a much larger and more diverse group of patients is exposed to the medicine. Patients sometimes have other health conditions that put them at a higher risk for liver injury than those who participated in the trial. That group could include those with renal or heart failure, with HIV or AIDS, and pregnant women, the elderly or children. Also, patients may be taking larger doses or be on the medication longer than those who participated in clinical trials.

Physicians should talk to their patients regularly about other medications they may be using and foods in their diets to make sure drug combinations won't injure the liver. Many deaths could be prevented if drugs are discontinued at the first sign of adverse reaction, Dr. Lee said.

"The condition is reversible often if it is caught early, but patients that believe they should continue to take the medication and are not concerned when they turn yellow, get in big trouble for obvious reasons," he said. "The damage keeps on going."

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