

# Los Angeles Times

## Reported adverse reactions to drugs on rise

By Thomas H. Maugh II, Los Angeles Times, Sept 11, 2007

The number of serious adverse events and deaths attributed to prescription medications has nearly tripled since the Food and Drug Administration (FDA) initiated a system in 1998 to make it easier to report significant side effects, researchers said Monday. Twenty percent of drugs accounted for 87.1 percent of adverse effects, and the biggest offenders were painkillers and drugs that modify the immune system to treat arthritis, according to the report in the Archives of Internal Medicine.

A fourth of the increase could be attributed to a boost in prescriptions and another 15 percent to the introduction of new biotechnology drugs since 1998, but the rest of the increase could not be explained, said drug-safety expert Thomas Moore of the Institute for Safe Medication Practices in Huntingdon Valley, Pa.

"The clear finding is that we are losing ground in terms of drug safety, and that ought to be of great concern," said Moore, who led the study. The report is expected to add momentum to reform the federal government's monitoring of prescription drugs. The report said the dramatic rise in so-called "adverse events" reported to the FDA point out myriad problems with the government's monitoring of drugs before approval and after they are on the market. The study looked at "serious adverse events," which are events that result in death or serious injuries including birth defects, disability and hospitalization.

The report suggested that the FDA and the health-care system, including doctors, hospitals and other caregivers, are lacking in their ability to manage medications. Insulin, for example, was among the top drugs cited for causing disability or other "serious outcomes." Although specific reasons for adverse events were not disclosed, the report's lead author said mismanagement of the medication can cause low blood sugar, which can also lead to balance issues, accidents and unconsciousness. "There is plenty of blame to go around," Moore said. "This is a direct set of data that shows that the system is failing and it is getting worse. We are in denial about drug safety."

Both the FDA and a trade group representing drugmakers agreed that the number of reported adverse events had been increasing, but they attributed much of the rise to an increase in reporting. Moore and his colleagues analyzed all of the serious adverse-event drug reports submitted to the FDA through its Adverse Event Reporting System, commonly known as MedWatch reports. Physicians and the public submit reports to the FDA or to drugmakers, which are then required to forward them to the FDA.