Adverse drug events reported to FDA appear to have increased markedly

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The number of serious adverse drug events reported to the U.S. Food and Drug Administration (FDA) more than doubled between 1998 and 2005, as did deaths associated with adverse drug events, according to a report in the September 10 issue of Archives of Internal Medicine, one of the JAMA/Archives journals.

A serious adverse drug event, as defined by the FDA, means an adverse event that resulted in death, a birth defect, disability, hospitalization, or was life-threatening or required intervention to prevent harm, according to background information in the article. Such events are voluntarily reported to the FDA through its Adverse Event Reporting System (AERS) and known as “MedWatch” reports. The reports come to the FDA directly or through drug manufacturers, who are then required to forward them.

Thomas J. Moore, A.B., of the Institute for Safe Medication Practices, Huntingdon Valley, Penn., and colleagues analyzed serious adverse drug events reported to the FDA through AERS from 1998 through 2005.

During this period, a total of 467,809 serious adverse events were reported. The annual number of reports increased 2.6-fold between 1998 and 2005, from 34,966 to 89,842. The number of fatal adverse drug events increased from 5,519 to 15,107 in the same time frame, a 2.7-fold increase.

“The overall relative increase was four times faster than the growth in

total U.S. outpatient prescriptions, which grew in the same period from 2.7 billion to 3.8 billion," the authors write.

A total of 1,489 drugs were associated with adverse events, but a subset of 51 drugs that each had 500 or more reports in any year accounted for 203,957 or 43.6 percent of the total adverse event reports in the study.

"Contrary to our expectations, drugs related to safety withdrawals were a modest share of all reported events and declined in importance over time," the authors write. In the subset of 51 drugs with 500 or more reports in a year, the percentage of reported events associated with drugs related to safety withdrawals declined from 26 percent in 1999 to less than 1 percent in 2005. "Among the most frequently reported drugs associated with fatal events, we observed a disproportionate contribution of pain medications and drugs that modify the immune system."

"These data show a marked increase in reported deaths and serious injuries associated with drug therapy over the study period," they conclude. "The results highlight the importance of this public health problem and illustrate the need for improved systems to manage the risks of prescription drugs."

Source: JAMA and Archives Journals