FDA data: serious adverse drug events have more than doubled since '98

by Ven_Griva

It is a statistic that is showing an alarming trend.

The number of serious adverse drug events reported to the U.S. Food and Drug Administration has more than doubled between 1998 and 2005, as did deaths linked to such events, reports the Sept. 10 issue of Archives of Internal Medicine.

The FDA defines a serious adverse drug event as one resulting in death, birth defect, disability, hospitalization, or one that is life-threatening or requires intervention to prevent harm.

Serious adverse events are voluntarily reported to the FDA through its Adverse Event Reporting System. They are known as MedWatch reports and come to the FDA directly or through drug manufacturers, which are required to forward them.

Thomas J. Moore of the Institute for Safe Medication Practices and colleagues analyzed serious adverse drug events reported to the FDA through the Adverse Event Reporting System from 1998 through 2005.

In that time, 467,809 serious adverse events were reported. The yearly number of reports increased almost 260 percent between 1998 and 2005, from 34,966 to 89,842. The number of fatal drug events went up from 5,519 to 15,107 in that same time, a 270 percent 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.

Nearly 1,500 drugs were linked to serious adverse events, but a subset of 51 drugs that each had 500 or more reports in any year accounted for almost half 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. "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."

The Institute for Safe Medication Practices is the only nonprofit organization in the United States devoted entirely to medication error prevention and safe medication use. The institute has more than 30 years of experience in helping health care professionals keep patients safe and continues to lead efforts to improve the medication use process.

Moore is a senior scientist and drug safety and policy expert at the institute. He has spent more than a decade as a researcher, writer and lecturer on the risks and benefits of prescription drugs.

More information about the Adverse Event Warning System can be found online at www.fda.gov/cder/aers/default.htm.

DRUG WARNING

A new analysis by scientists at the Wake Forest University School of Medicine has added to growing evidence that the diabetes drug rosiglitazone significantly increases the risk of cardiovascular disease and heart attack.

The analysis was reported Sept. 12 in the Journal of the American Medical Association and was the first to evaluate how long-term use of rosiglitazone, which is marketed under the brand name Avandia, affects risk of heart attacks, heart failure and mortality. The analysis involved studies that followed patients for at least one year.

"The public health impact of potential harm with rosiglitazone is substantial," said Dr. Sonal Singh, lead author and an assistant professor of internal medicine at Wake Forest. "Regulatory agencies should urgently evaluate whether this drug should remain on the market."

Singh said an estimated 3.5 million people in the United States take Avandia. He said that while caution should be taken in estimating event rates based on the analysis, the findings suggest that the drug might be responsible for more than 4,000 excess heart attacks and 9,000 excess cases of heart failure a year.

On May 27, the U.S. Food and Drug Administration required that rosiglitazone and another drug in the same

class carry the agency's toughest "black-box" warning because of an increased risk of heart failure. The agency is evaluating whether a warning about heart attack risk should also be included for rosiglitazone.

Patients who are taking Avandia, especially those who are known to have underlying heart disease or who are at high risk of heart attack, should talk to their doctor about this new information as they evaluate the available treatment options for their type 2 diabetes, the USDA recommended in May.

The researchers pooled data from four studies that randomly assigned participants with type 2 diabetes or impaired glucose tolerance to receive Avandia or either another type of diabetes drug or a placebo, an inactive drug.

Based on the analysis, the researchers estimate that for every 220 diabetic patients treated with Avandia for one year, one will have a heart attack linked to the drug. And there would be one case of heart failure for every 30 people taking the drug for one year.

"There is no need for physicians, health plans or patients to wait for regulatory action," said Dr. Curt Furberg, co-author of the report. "On the contrary, they should take prompt action and restrict the use of Avandia, especially since safer alternatives are available."

Avandia is manufactured by GlaxoSmithKline, which is based in Research Triangle Park, N.C. Avandia received regulatory approval in 1999 and at that time no serious adverse events were recognized. However, since approval, Avandia has been linked to heart failure, vision loss, heart attacks and bone fractures in women.

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