

Serious Adverse Drug Events Reported to the Food and Drug Administration, 1998-2005

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Background The US Food and Drug Administration has operated the Adverse Event Reporting System since 1998. It collects all voluntary reports of adverse drug events submitted directly to the agency or through drug manufacturers.

Methods Using extracts published for research use, we analyzed all serious adverse drug events and medication errors in the United States reported to the Food and Drug Administration from 1998 through 2005.

Results From 1998 through 2005, reported serious adverse drug events increased 2.6-fold from 34 966 to 89 842, and fatal adverse drug events increased 2.7-fold from 5519 to 15 107. Reported serious events increased 4 times faster than the total number of outpatient prescriptions during the period. In a subset of drugs with 500 or more cases reported in any year, drugs related to safety withdrawals accounted for 26% of reported events in that group in 1999, declining to less than 1% in 2005. For 13 new biotechnology products, reported serious events grew 15.8-fold, from 580 reported in 1998 to 9181 in 2005. The increase was influenced by relatively few drugs: 298 of the 1489 drugs identified (20%) accounted for 407 394 of the 467 809 events (87%).

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

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