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GAO

Report to Congressional Requesters

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ADVERSE DRUG EVENTS

The Magnitude of Health Risk Is Uncertain Because of Limited Incidence Data



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drug is first available to consumers, it can be quickly prescribed to hundreds of thousands of patients who are far more heterogeneous than the patients studied in the clinical trials. Further, physicians often prescribe new drugs to patients who have not responded to older medications; thus, the initial recipients of a drug are more likely to be especially ill and unlike the patients studied in the clinical trials.

FDA's current postmarketing data collection systems for approved drugs are intended to compensate for the limitations of information from clinical trials by detecting the existence of previously unidentified ADEs. However, because FDA's Adverse Event Reporting System (AERS) relies on voluntary reports from physicians, pharmacists, patients, and others, it can uncover instances of problems but it cannot determine their incidence.¹⁰ The same intrinsic limitation applies to the incident reporting systems that many hospitals have established to monitor adverse events, including ADEs. All such systems based on spontaneous reporting detect only a fraction of the total number of adverse events (Cullen and others, 1995). FDA's AERS includes an estimated 1 to 10 percent of adverse events (Goldman and others, 1996). In addition, the adverse events that are reported are unlikely to be representative of the much larger number of unreported events. For example, there is evidence that ADEs are reported more often to FDA if they involve a newly released drug or one sold by a company that has a relatively large postmarketing surveillance program (Baum and others, 1994). Consequently, any estimate of ADE incidence based on a spontaneous reporting system such as AERS would necessarily incorporate the biases of the data, undercounting some types of adverse events and overcounting others.

FDA, recognizing the limitations of its spontaneous reporting system, augments the data in AERS with information from other sources. If "signals" from AERS reports suggest new adverse events or an unexpectedly large number of known ADEs, FDA can gather additional information from several health maintenance organizations that have cooperative agreements with the agency to use their databases of member medical and pharmacy records to investigate issues of ADE causation and incidence. However, these databases sometimes do not have enough

¹⁰Health care providers and patients are not obligated to report suspected ADEs to FDA. However, they are encouraged to report events either directly to AERS or to the drug's manufacturer, and the manufacturers are required to forward all adverse event reports they receive to FDA.

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