The Challenge to Improve Patient Safety:

FDA Logs Over 350,000 Reports of Adverse Events Annually

"To Err is Human," acknowledged the title of an Institute of Medicine report in November 1999. Its message, however, was an urgent call on our nation to minimize the exorbitant toll of medical errors by building a safer health-care system.

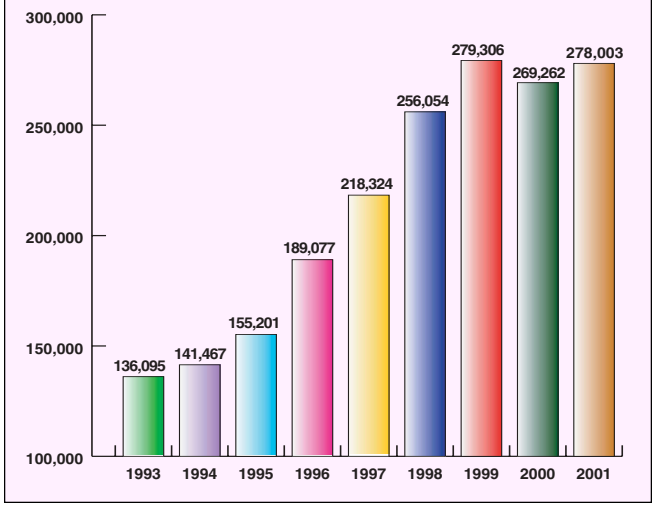
The consequences of misused or unsafe medical products are shocking: According to recent studies, adverse events associated with drugs are the single leading contributor to preventable patient injury, and may cost the lives of up to **100,000 Americans**, account for more than **3 million** hospital admissions, and increase the nation's hospitalization bill by up to **$17 billion** each year. Drug-linked injuries outside the hospital are estimated to inflate the annual health-care bill by an additional **$76.6 billion**.

The FDA, which each year receives hundreds of thousands of reports about adverse events associated with the products it regulates, makes major efforts to reduce this enormous toll. Here are some of the actions the agency is taking to improve the management of medical risks:

- Enhancing the **collection and analysis of adverse event reports** involving drugs, vaccines, medical devices and food products. Serious problems prompt corrective measures, including warnings and alerts for consumers, physicians and patients; limitations on the products' use; and, if necessary, call for their withdrawal from the market.
- Implementing a new regulation requiring all manufacturers of blood and blood components to report to the FDA any event associated with the testing, processing, packing, labeling, storage, or holding for distribution of a blood or blood component in which the safety, purity, or potency of a distributed product may be affected.
- Proposing to reorganize and clarify the scientific information in **drug labeling** to make it more easily accessible by physicians, and thereby help prevent errors in prescribing.
- Working with industry to **reduce medication errors** caused by look-alike or sound-alike product names and confusing packaging configurations.
- **Expanding outreach** to health-care providers and the public on safe use of products.

For more information, please call 301-827-3219 or visit the FDA Web site at *www.fda.gov/medwatch*.

Adverse Events Associated with Drug and Biologic Products Reported to FDA — 1993-2001



Adverse Events Reporting Goes Global

The FDA's analysts frequently consult with their counterparts abroad about drugs that cause serious side effects. This exchange of information will soon become global. As part of the FDA-pioneered international harmonization of drug standards, regulators and the pharmaceutical industries in the United States, European Union and Japan have created a special medical dictionary for adverse event reporting, and are developing electronic standards for secure transmission of all regulatory information.

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FOOD AND DRUG ADMINISTRATION
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Rockville, MD 20857

Publication No. FS 01-9
FDA Web site: *www.fda.gov*
Revised: February 2002