

FDA'S SAFE USE INITIATIVE: Collaborating to Reduce Preventable Harm From Medications

On 11/04/09, the FDA announced the "Safe Use Initiative." Through this initiative, FDA officials will collaborate with health care professionals and other stakeholders to identify drugs, drug classes, and therapeutic situations that are associated with preventable adverse events. Additionally, the FDA plans to develop population-based national estimates of preventable errors for specific drugs and therapies, solicit input through a public meeting series, and work with stakeholders to develop safe-use initiative programs.

According to the FDA, an estimated 1.5 million preventable adverse drug events occur within the health care system each year. Misuse of prescription drugs also results in 4 million visits to Emergency Departments, physicians' offices, and outpatient care facilities—in addition to 100,000 hospitalizations annually. The director of the FDA's Center for Drug Evaluation and Research, says errors are a result of prescribers' lack of information at the "point of care, or by patients or consumers at the point of use, as well as by procedural and process errors"—for example, dispensing the wrong drug or wrong dose of a drug.

Despite efforts by all parties, each year medications cause hundreds of thousands of injuries and deaths. Adverse events from drug use result in more than 4 million visits to emergency departments, doctors' offices, or other outpatient settings annually and 117,000 hospitalizations each year. A report on long-term care facilities projected nearly 10 adverse drug events per month for every 100 residents. There is also a high incidence of adverse drug events in hospitals; reports range from just over 2 events per 100 admissions to more than 6 adverse drug events per 100 admissions.

Although the initiative is still in early stages of development, the FDA plans to implement a small number of drug prevention interventions in the first year of the program.