



Prescribed Drugs' Toll Is Among

Deadliest



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More than 2 million Americans become seriously ill every year because of toxic reactions to correctly prescribed medicines taken properly, and 106,000 die from those reactions, a new study concludes. That surprisingly high number makes drug side effects at least the sixth, and perhaps even the fourth, most common cause of death in this country.

The analysis, the largest and most complete of its kind, suggests that one in 15 hospital patients in the United States can expect to suffer from a serious reaction to prescription or over-the-counter medicine, and about 5 percent of these will die as a result.

If the findings are accurate, then the number of people dying each year from drug side effects may be exceeded only by the numbers of people dying from heart disease, cancer and stroke, and may be greater than the number dying from lung disease, pneumonia or diabetes.

Experts said the study, which appears in today's issue

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of the Journal of the American Medical Association, is stronger than previous ones because it looks only at cases in which drugs were taken correctly. Previous hints of similarly high side-effect rates had been attributed in large part to people getting the wrong medicines or taking them in the wrong doses.

Only one-quarter of the reactions were due to patients being allergic to the drug in question. In theory, those reactions could be avoided by more carefully asking people about known allergies. The rest of the side effects were classified as inevitable, bound to affect a certain percentage of the population for unknown reasons.

Pharmaceutical manufacturers, drug regulators and the researchers themselves warned against overreacting to the numbers, noting that the study made no effort to measure the benefits of the same medicines — an equally important part of the cost-benefit calculation that determines the overall usefulness of a drug.

"We're not saying, 'Stop taking drugs,' " said Bruce H. Pomeranz, the University of Toronto neurophysiologist who initiated the study. For example, he said, blood thinners may cause fatal bleeding in some but also save countless lives by preventing heart attacks.

Pomeranz called for additional research to determine which drugs are most problematic and which patients are most at risk — information that the current analysis did not try to gather. Meanwhile, he said, hospitals

should set up improved systems for tracking adverse reactions as they occur, and for reporting them to federal regulators so medicine labels can be updated and physicians and consumers can be better informed about the relative risks and benefits of their medicines.

Michael Friedman, acting commissioner of the Food and Drug Administration, said the agency in recent years has implemented new systems for preventing, identifying and keeping track of adverse drug reactions. A nationwide electronic network now allows doctors to report adverse reactions easily over computer lines. And a growing number of pharmacies are using an FDA-supported system that automatically prints out side-effect warnings and other information for consumers when they pick up their medications.

"The important message is not to be afraid of your medication but to be respectful of the possibility of side effects," Friedman said. "More people are using medications today than ever before, and for more serious and extreme conditions than ever before. There are real benefits these patients achieve with these medications, but every one has a side effect."

The Pharmaceutical Research and Manufacturers Association, a Washington-based trade association, yesterday released a brief statement urging consumers not to take the findings "out of context."

Alan Holmer, the group's president, said in an

interview that side effects were inevitable given the increased potency and effectiveness of modern drugs. "Drugs are powerful substances and affect different people differently," he said. "They cannot be made completely safe for all patients in all circumstances."

According to Pomeranz, however, who conducted the study with Toronto colleagues Jason Lazarou and Paul N. Corey, the problem is bigger than had been recognized before and is deserving of more serious attention than has been accorded.

Pomeranz and his colleagues re-analyzed data from four previous studies designed to spot adverse drug reactions, both those that occurred in the hospitals and those that happened at home and resulted in hospitalization.

By combining each study's results in a single statistical analysis, a method known as meta-analysis, the researchers sought to come to firmer conclusions than could be attained with any of the studies alone.

The team threw out all cases of prescription error, overdose, drug abuse and bad reactions in which the link to a drug was deemed uncertain, then analyzed the remaining adverse reactions in 39 hospitals. Based on the total number of patients in the hospitals, it concluded that serious adverse reactions (defined as those that required or prolonged hospitalization, were permanently disabling or resulted in death) struck 6.7 percent of patients and killed 0.32 percent.

Extrapolating from the 1994 U.S. hospital patient population, the team calculated that 2.2 million were affected nationwide, and between 76,000 and 137,000 died. If the smaller number is accurate, drug reactions are the sixth-ranking cause of death in this country; if the larger number is accurate, they rank fourth.

Some experts noted that the study focused mostly on teaching hospitals, which tend to treat more seriously ill and heavily prescribed patients and so could bias the results toward higher adverse reaction rates. But Pomeranz said results from the non-teaching hospitals in the study were the same and that if anything, the results were conservative.

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