Reference 8: Nearly 1/3 of drugs have safety events

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Nearly a third of FDA-approved drugs had problems, study finds

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Among 222 FDA-approved novel therapeutics, there were 123 postmarket safety events. Bextra was among those taken off the market.

STORY HIGHLIGHTS

Seventy-one novel therapeutics approved from 2001 to 2010 had postmarket safety events

3 were withdrawn, 61 got boxed warnings, 59 required safety communications

Experts say study shows the benefits of monitoring drug safety

(CNN) —
Patients might think the US Food and Drug Administration's stamp of approval means that a product is the last word on safety, but about a third of the drugs the FDA approved between 2001 and 2010 were involved in some kind of safety event after reaching the market, according to a study published Tuesday in the Journal of the American Medical Association.

The authors found that in that time, 222 novel therapeutics were approved, and there were 123 postmarket safety events involving 71 products that required FDA action.

Manufacturers needed to add 61 boxed warnings, also commonly called a black box warning, to call attention to serious or life-threatening risks.

In 59 cases, some kind of communication had to warn users about a product's safety.

Three therapeutics were withdrawn from the market.

Drugs used to treat mental illness and drugs that went through an accelerated approval process had a higher number of "events," the study found.

"The key message with all new drugs and technology is that there is an ongoing learning process that will continue through the lifetime of the drug," said author Dr. Nicholas S. Downing, an author of the study and a resident physician of internal medicine at Brigham and Women's Hospital in Boston.

As the study notes, the majority of these drugs were trialed in 1,000 or fewer patients to get FDA approval. When drugs are used under real-world circumstances in a wider patient population, problems can happen, Downing said, and so scientists need to continuously test the drugs to make sure they work with a wide range of variables.

"Aspirin has been around for hundreds of years. We generally know how it works, for example, but there are still countless new studies coming out, and we learn more about it all the time," he said.

Although the percentage of safety events may sound high, Downing adds that it is "reassuring" that the system works well enough to catch these problems.

The FDA does perform postmarket monitoring to identify new safety information that may impact product labeling.

"In general, the FDA does not comment on specific studies, but evaluates them as part of the body of evidence to further our understanding about a particular issue and assist in our mission to protect public health," the agency said in an emailed statement. "The FDA is reviewing the findings of the paper."

David Gortler, a drug safety expert and former FDA official who was not involved in the research, said it is important to note that a lot of the medications in the study are niche drugs used for specialty-type diseases. Blockbuster-type drugs used by many people, such as a cholesterol medication, would typically be tested on a much larger population before approval.

"There is nothing to be alarmed about with this," Gortler said. He often notes that drugs will work differently in a person who weighs 200 pounds, for instance, versus someone who is 125 pounds. Race, gender, ethnicity and other health problems all can affect how a drug works.

"We may all be human beings, but drugs react differently in all of us, so you are going to see issues. This is to be expected," Gortler said.

This study comes as the Trump administration has vowed to "slash restraints" on drug development and has promised that the FDA drug approval process will speed up.

President Donald Trump mentioned this priority in his first address to a joint session of Congress in January.

There have been previous efforts to speed drug approval. In 1988, the FDA formalized its “fast track” designation, and in 1992, the agency created the “accelerated approval” process to allow drugs to go ahead with even earlier-stage data if they are intended to treat a life-threatening or serious illness.

On average, it takes about 12 years to get a drug from the research phase to patient. Only five in 5,000 drugs in preclinical testing make it to human trials, and only one in five is ever approved for human use.

A 2015 independent analysis of drugs approved using the accelerated processing time found that the trend toward faster approval “is being driven by drugs that are not first in class and thus potentially are less innovative.”

Other studies have showed that some drugs approved using this quicker process had a large number of adverse events that required additional warning labels.

Downing said the new study is a good argument for continuous monitoring of the safety of drugs “throughout their life cycle.”