Safety events common for pharmaceuticals and biologics after FDA approval

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Among more than 200 new pharmaceuticals and biologics approved by the U.S. Food and Drug Administration from 2001 through 2010, nearly a third were affected by a postmarket safety event such as issuance of a boxed warning or safety communication, according to a study published by *JAMA*.

The majority of pivotal trials that form the basis for FDA approval for therapeutics (pharmaceuticals and biologics) enroll fewer than 1,000 patients with follow-up of six months or less, which may make it challenging to identify uncommon or long-term serious safety risks.

These risks may only become evident when new therapeutics are used in much larger patient populations and for longer durations in the postmarket period. Postmarket safety events can change how these therapeutics are used in clinical practice and inform patient and clinician decision making.

Joseph S. Ross, M.D., M.H.S., of the Yale University School of Medicine, New Haven, Conn., and colleagues examined safety events (a composite of withdrawals due to safety concerns, FDA issuance of incremental boxed warnings added in the postmarket period, and FDA issuance of safety communications) for all novel therapeutics approved by the FDA between January 2001 and December 2010 (followed-up through February 2017).

During this time period, the FDA approved 222 novel therapeutics (183

pharmaceuticals and 39 biologics). There were 123 new postmarket safety events (3 withdrawals, 61 boxed warnings, and 59 safety communications) during a median follow-up period of 11.7 years, affecting 32 percent of the novel therapeutics. The median time from approval to first postmarket safety event was 4.2 years, and the proportion of novel therapeutics affected by a postmarket safety event at 10 years was 31 percent. Postmarket safety events were significantly more frequent among biologics, therapeutics indicated for the treatment of psychiatric disease, those receiving accelerated approval, and those with near-regulatory deadline approval. Events were significantly less frequent among those with regulatory review times less than 200 days.

The authors write that these findings should be interpreted cautiously but can be used to inform ongoing surveillance efforts.

Limitations of the study are noted in the article.

"The high frequency of postmarket safety events highlights the need for continuous monitoring of the safety of novel therapeutics throughout their life cycle," the researchers write.

More information: *JAMA* (2017). jamanetwork.com/journals/jama/….1001/jama.2017.5150

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