Boxed warnings are common in novel therapeutics

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(HealthDay)—Boxed warnings are common on recent drug approvals, and many occur years after approval, according to a research letter published online Aug. 15 in *JAMA Internal Medicine*.

Christine M. Cheng, Pharm.D., from First Databank Inc. in San Francisco, and colleagues determined the frequency of premarket and postmarket boxed warnings and safety-related withdrawals for novel therapeutics approved from 1996 to 2012. Patterns were examined based on drug type and approval year.

The researchers identified 522 novel therapeutics approved during the study period, of which 441 were pharmacological and 81 biological products. Of these, 180 had ever received a boxed warning (136

pharmacological and 44 biological products). There were 89 postmarket warnings in total and 11 withdrawals, 81 percent of which occurred after 2004. Premarket warnings were more common among biological (31 percent) than pharmacological (22 percent; odds ratio, 2.0) products. Drugs approved after 2004 versus before 2004 were more likely to have premarket warnings (36 versus 18 percent; odds ratio, 2.4). The median time from approval to first boxed warning or withdrawal was 4.2 years, and was shorter for drugs with premarket warnings versus those without (2.3 versus 4.9 years; P

"Clinicians should be aware of the prevalence and growing numbers of boxed warnings and the importance of continued adverse event reporting for identifying new safety concerns," the authors write.

One author is employed by First Databank, a commercial drug knowledge vendor.

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Editorial