

Studies Used to Approve ADHD Drugs Did Not Address Long-Term Safety



Studies used to approve drugs to treat attention-deficit hyperactivity disorder (ADHD) did not address long-term safety, according to new research.

Drug manufacturer clinical trials conducted for drugs such as Ritalin and Adderall showed they alleviated ADHD symptoms, but few were designed to look at the drugs' long-term safety, The *Boston Globe* reports.

The Boston Children's Hospital researchers say this doesn't mean the drugs are unsafe.

The investigators looked at 32 clinical trials on the 20 ADHD drugs approved by the Food and Drug Administration (FDA). Only five of the studies focused on drug safety. Each drug was given to an average of 75 patients before receiving FDA approval.

The studies lasted an average of just four weeks. The FDA asked for six follow-up safety studies to look at long-term safety risks, but only two were conducted.

An expert group on drug development, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, recommends that drugs intended for chronic use in non-life-threatening conditions (such as ADHD) should be tested in a minimum of 300 to 600 patients for at least six months, in 100 patients for at least one year, and in 1,500 patients total before receiving approval.

The findings appear in the journal *PLOS One*.

"This is a wake-up call for what's lacking in the drug approval process and what we want to see in the future," said study co-author Dr. Kenneth Mandl. "Our findings are particularly troubling since these drugs are so widely used and used for years, not weeks."

Approximately 11 percent of children ages 4 to 17 have been diagnosed with ADHD, according to the Centers for Disease Control and Prevention. About 6 percent of children in this age group take

Studies Used to Approve ADHD Drugs Did Not Address Long-Term Safety

ADHD medication.