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PROFESSION

Cough medicine abuse prompts FDA to consider restrictions

The agency may require suppressants containing dextromethorphan to be stored behind pharmacy counters.

By KEVIN B. O'REILLY, amednews staff. Posted Sept. 13, 2010.

An advisory committee to the Food and Drug Administration is considering whether to recommend measures to make it more difficult for teenagers and others to abuse dextromethorphan, an ingredient in more than 100 over-the-counter cough and cold remedies.

Emergency department visits associated with recreational use of OTC cough medicines containing dextromethorphan rose 73% from 4,634 in 2004 to nearly 8,000 in 2008, according to data released by the FDA as part of a report to its Drug Safety and Risk Management Advisory Committee before a Sept. 14 meeting.

Clinical studies have shown that at eight to 20 times the maximum OTC dose, dextromethorphan causes euphoria and dysphoria in users. The FDA said abuse can cause irregular heartbeat, brain damage, seizures and loss of consciousness.

The Drug Enforcement Administration has requested the FDA's opinion on whether to make dextromethorphan available as a scheduled drug by prescription only. Experts consider it unlikely that the FDA will go in that direction, but cough syrups could join products containing pseudoephedrine behind the pharmacy counter and require a signature and photo identification for purchase.

"Dextromethorphan-containing medicines are a safe and needed treatment, and scheduling OTC medicines containing dextromethorphan is not the right solution to address potential abuse," said Elizabeth Funderburk, a spokeswoman for the Consumer Healthcare Products Assn., which represents OTC manufacturers and distributors.

Funderburk said the association has been working since 2003 to educate parents and teens about the risks of abusing cough medicine. Those efforts have resulted in an increase in parent-teen talks about the issue and a greater perception among teens that recreational cough medicine use is dangerous, she said.

Last year, the trade group launched a website, "Stop Medicine Abuse," devoted to the issue.

This content was published online only.

ADDITIONAL INFORMATION:

WEBLINK

Consumer Healthcare Products Assn. advice on preventing teen cough medicine abuse (www.stopmedicineabuse.org)

Report to the FDA Drug Safety and Risk Management Advisory Committee on evaluating and scheduling recommendations for dextromethorphan (www.fda.gov/downloads/advisorycommittees/drugs/ucm224446.pdf)

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