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FDA orders lowering pain reliever in Vicodin

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Associated Press

Washington— Federal health regulators are limiting a key ingredient found in Vicodin, Percocet and other prescription painkillers that have been linked to thousands of cases of liver damage each year.

The Food and Drug Administration said today it will cap the amount of acetaminophen in the drugs at 325 milligrams per capsule.

Acetaminophen is a ubiquitous pain reliever found in Tylenol, Nyquil and thousands of other medicines used to treat headaches, muscle aches and sore throats. The ingredient is also used at larger doses in prescription combination drugs that combine it with other drugs like oxycodone.

Those products are not dangerous by themselves, but can cause toxic overdoses when patients combine them with a second acetaminophen-containing drug like Tylenol.

"The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed the current maximum dose of 4,000 milligrams within twenty-four hour period," said FDA deputy director for new drugs, Dr. Sandra Kweder.

The restrictions announced today will not affect over-the-counter products like Tylenol and Theraflu.

Acetaminophen is the leading cause of liver failure in the U.S. and sends 56,000 people to the emergency room annually. About 200 of them die and the FDA estimates 120 of those deaths are linked to prescription drugs with acetaminophen.

The FDA said it would add a boxed warning, the strongest type, to all prescription drugs containing acetaminophen. Such drugs are prescribed roughly 200 million times annually, according to FDA data.

Vicodin is marketed by Abbott Laboratories, while Percocet is marketed by Endo Pharmaceuticals. Both painkillers also are available in cheaper generic versions.

The FDA restrictions come more than a year and a half after a high-profile meeting where a panel of 37 expert physicians narrowly voted to eliminate drugs like Vicodin completely. The same panel recommended lowering the dose of acetaminophen found in over-the-counter products.

The FDA is not required to follow the group's advice, though it often does.