FDA group recommends acetaminophen liver warnings

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(AP) -- A Food and Drug Administration report released Wednesday recommends stronger warnings and dose limits on drugs containing the painkiller acetaminophen, citing an increased risk of liver injury.

The recommendation covers both prescription doses and over-the-counter medication, of which Johnson & Johnson's Tylenol is the most well-known. Acetaminophen is also widely available as a generic over-the-counter drug.

"There is extensive evidence that hepatotoxicity (liver toxicity) caused by acetaminophen use may result from lack of consumer awareness that acetaminophen can cause severe liver injury," the working group report said.

The outside advisers will meet in June to discuss the report's findings. The recommendations include enhanced public information efforts, stronger labels warning of liver side effects, and dose limitations.

"Consumers may not be aware that acetaminophen is present in many over-the-counter combination products, so they may unknowingly exceed the recommended acetaminophen dose if they take more than one acetaminophen product without knowing that both contain acetaminophen," the report said.

The recommendations also call for limiting the maximum adult daily dose to no more than 3,250 milligrams. The current recommendation

stands at 4,000 milligrams per day. Other recommendations include limiting tablet strength for immediate release formulations and limiting options in liquid formulations for children.

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