FDA Reevaluating Safety of Pain Medications Following Multiple Studies Showing Major Harm

By: Jonathan Benson, Natural News

A U.S. Food and Drug Administration (FDA) advisory panel has rejected a petition filed by Bayer HealthCare to have its over-the-counter (OTC) pain medication Aleve (naproxen) declared to be safer for the heart than competing alternatives like Advil and Motrin (ibuprofen). According to reports, the drug giant tried but failed to take advantage of ongoing investigations into the safety of OTC pain drugs, which are increasingly being linked to heart attacks and strokes, by pushing for Aleve to be rebranded as a safer alternative.

But the evidence was severely lacking, according to information relayed by *USA Today*, and Bayer was ultimately denied asylum for its pain medication, which makes sense, because it is more than likely just as dangerous as ibuprofen when it comes to heart health. A host of new research, in fact, implicates virtually all non-steroidal anti-inflammatory drugs (NSAIDs) with increasing the risk of gastrointestinal bleeding, liver damage, heart attack and erectile dysfunction, among many other conditions.

The FDA convened the panel after research out of Oxford University that was published last year seemed to suggest that naproxen might somehow be safer than its counterparts. But the information contained in the study was incongruous and questionable at best, as it combined data sets from hundreds of unrelated studies to make this claim, as well as lumped together data on prescription and non-prescription use of the drugs -- the study was essentially undertaken with the goal of making naproxen look superior to the competition.

"The Oxford analysis is difficult to interpret because it combines information from hundreds of unrelated studies," explains Associated Press (AP) Health Writer Matthew Perrone. "While this approach is useful in getting a broad view of rare events -- such as heart attacks -- it is not considered the strongest form of medical evidence."

NSAIDs can cause major heart damage after just a few days of use, says study

Though the FDA is not required to form policy based on the recommendations of its advisory panels, the agency almost always does, which has left naproxen supporters like Professor Michael Farkouh from the Icahn School of Medicine at Mount Sinai reeling. He recently expressed to *USA Today* his belief that the FDA could somehow "save lives" if it recommended naproxen over other common pain medications.

But not everyone agrees with this assessment, including Elliott Antman, president-elect of the American Heart Association (AHA). He explained to reporters that a scientific consensus cannot be reached based on the available science, which fails to show any significant safety risk variance among currently approved NSAIDs.

"While there is a scientific rationale to believe that naproxen is safer than the other commonly used NSAIDs, the available data from clinical trials and observational studies is not compelling enough to make a definitive statement," Antman is quoted as saying. "The vote by the Advisory Committee reflects that uncertainty."

New research out of Denmark further muddies the waters, revealing that the short-term heart risks associated with NSAIDs are far more serious than health authorities have led us all to believe. Based on their assessment, which the FDA advisory panel considered prior to voting against naproxen's reclassification, heart problems caused by the use of NSAIDs can manifest in a matter of just a few days.

"I think advice to clinicians needs to be that these events can occur from the start of therapy," stated panel member Linda Tyler, a professor of pharmacy practice at the University of Utah College of Pharmacy, as quoted by *USA Today*.

Sources for this article include:

http://www.usatoday.com

http://www.kfoxtv.com