

# FDA to heighten alerts for heart risk from NSAID painkillers

By Gil Ross — July 10, 2015



[1]In 2005, the FDA required a boxed warning on NSAIDs,

stating that the drugs may cause an increased risk of heart attack and stroke. Now, subsequent to a expert panel review conducted last year, the [FDA has determined that NSAIDs](#) [2] cause an increased risk and will require the prescription drugs to so warn. (The over-the-counter drugs are under a different regulatory paradigm and the agency has requested their makers to change their Drug Facts consumer-friendly package inserts).

NSAIDs are used by millions of Americans, and include the common painkillers Aleve, Motrin IB, Celebrex, and Advil. Generic names include naprosyn, ibuprofen, diclofenac, among others. Aspirin, while also technically an NSAID, does not have the adverse CVD effect of the other members of this class; in fact, many of us are taking aspirin daily at various doses to prevent heart events, and there is no reason for that to change.

In 2004, the blockbuster anti-inflammatory, pain-relieving drug Vioxx was linked to a significantly elevated risk of CVD events: heart attack and stroke. Merck was found to have held back some disturbing studies to get the drug approved in 2002, and the new revelations propelled the company to withdraw the drug from the market, a multi-million dollar event. How many people were harmed will never be determined.

The next year, after further studies found that several other drugs in the NSAID class were also associated with a CVD risk, the FDA slapped a boxed warning (sometimes known as a black-box warning) on the prescription NSAIDs, saying that these drugs may cause an increased risk of heart attack and stroke.

The FDA warns that the effect on heart risk can occur early on, and increases with both the length of use and the dose. It varies from drug to drug, but there are no data available at this time to discern which are more or less risky. Anyone with a history of CVD or at higher risk of these conditions should discuss taking NSAIDs with their doctor before starting such treatment, or if taking one now, should probably consult regarding continuing use. The risk is actually quite low for people with neither history of or risk factors for CVD, but all should be aware of it.

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**Links**

[1] <http://acsh.org/wp-content/uploads/2015/04/TheFDA.jpg>

[2] <http://www.fda.gov/forconsumers/consumerupdates/ucm453610.htm>