

# FDA Issues New Heart Attack, Stroke Risk Warnings for NSAIDs

BY JEFF EVANS

The Food and Drug Administration has taken new action to strengthen existing warning labels about the increased risk of heart attack or stroke with the use of prescription and over-the-counter nonaspirin nonsteroidal anti-inflammatory drugs.

In a recent drug safety communication, the agency did not provide the exact language that will be used on NSAID

labels but said that they “will be revised to reflect” information describing that:


- ▶ Increased risk of heart attack or stroke can occur as early as the first weeks of using an NSAID.
- ▶ The risk may increase with longer use and at higher doses of the NSAID.
- ▶ The drugs can increase the risk of heart attack or stroke even in patients without heart disease or risk factors for heart disease, but patients with heart disease or risk factors for it have a greater

likelihood of heart attack or stroke following NSAID use.

- ▶ Treatment with NSAIDs following a first heart attack increases the risk of death in the first year after the heart attack, compared with patients who were not treated with NSAIDs after their first heart attack.
- ▶ NSAID use increases the risk of heart failure.

The new wording will also note that although newer information may

suggest that the risk for heart attack or stroke is not the same for all NSAIDs, it “is not sufficient for us to determine that the risk of any particular NSAID is definitely higher or lower than that of any other particular NSAID.”

The update to NSAID labels goes against the recommendations given by panel members from a joint meeting of the FDA’s Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee in February 2014 in which they said that the evidence about potentially new cardiovascular risks with NSAIDs that had been presented to them over the 2-day meeting was not sufficient to change labeling. The panelists also voted that there were not enough data to suggest that naproxen presented a substantially lower risk of cardiovascular events than did either ibuprofen or selective NSAIDs, such as cyclooxygenase-2 inhibitors. 

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## Caring *for consumers*

### More Isn't Always Better

*Barney Spivack, MD, CMD, a post-acute and long-term care medical director and physician, talks about why some cancer screenings may not be advised for elders.*

Although many tests, treatments, and interventions are useful and appropriate for frail elderly people, some screenings may not provide sufficient value, and they may subject individuals to unnecessary inconvenience, discomfort, and possible harm.

Patients in the post-acute and long-term care setting may have many chronic illnesses and health problems, limited mobility and cognitive loss, and life expectancies of less than 10 years. Studies about the impact of screenings for breast, colorectal, and prostate cancer in older adults in general, especially in PA/LTC residents, suggest that benefits of these screenings are limited.

While it's true that these screenings may help detect cancers before they spread, they are not without risks. For example, mammograms expose women to radiation and may cause discomfort. This test isn't perfect — false negatives, as well as false positives, are common. Some women may be subjected to additional tests, including biopsies, and the stress that accompanies these. Cost is another factor; working up false positive mammogram results can cost thousands of dollars.

Prostate cancer is usually slow-growing, and most nursing home residents will die of something else before cancer spreads beyond the prostate. The possible risks of prostate screenings include pain, bleeding, and infection associated with biopsies, as well as the mental stress and anxiety associated with false-positive test results. It also is important to note that this test doesn't always produce an accurate result.

The most common screening test for colorectal cancer, the colonoscopy, lets the doctor see the entire colon and rectum and remove abnormal tissue, such as polyps, and take samples for biopsies. However, the test might not detect all small polyps and cancers. Additionally, it involves several risks. For instance, it requires complete colon cleansing beforehand; and this means temporary diet, fluid, and medication changes.

These can cause discomfort and other problems for older adults. At the same time, sedation is almost always needed, and this can be risky. Complications of the test also may include internal bleeding, cramping, bloating, and perforation.

Of course, all screening and care decisions should involve conversations with the individual's physician and other practitioners. These should include discussions about personal preferences, current illnesses, life expectancy, and health care goals. However, for most nursing home residents, experts generally discourage these screenings.

#### ▶ Questions To Ask Your Practitioner

- What is my loved one's or my risk of having/getting various types of cancer?
- What lifestyle changes can my loved one or I make now to limit these risks?
- What are the benefits/risks of various cancer screenings for my loved one or me personally?
- What cancer screenings are likely to be of greatest benefit for my loved one or me, given personal health, life expectancy, and other issues?

#### ▶ What You Can Do

- Make lifestyle changes to reduce your cancer risk, including not smoking, eating healthy, and staying physically active.
- Discuss the risks and benefits of various screenings and tests with your trusted practitioner.
- Complete an advance directive, physician order for life-sustaining treatment (POLST) form, or other document to outline your care preferences.

#### ▶ For More Information:

- Colon Cancer Screening: Weighing the Options: <http://mayocl.in/1nqvNYY>
- The Pros and Cons of Screening for Three Cancers: <http://bit.ly/1NEAGXE>
- Mammography's Limits, Seldom Understood: <http://nyti.ms/1gXjGBf>
- Prostate Cancer Screening: Should You Get a PSA Test?: <http://mayocl.in/1nLo31h>

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## Coding Errors Cost Millions in Overpayments

BY ALICIA GALLEGOS

Coding mistakes made on behalf of physicians and other health providers led to more than \$35 million in Medicare overpayments for outpatient drugs, according to results from an audit by the Department of Health & Human Services Office of Inspector General (OIG).

Medicare contractors in 13 jurisdictions overpaid Medicare Part B providers by \$35.8 million between July 2009 and June 2012. Erroneous codes and incorrect units of service submitted on behalf of those providers were the top reasons for the overpayments, according to the OIG report.

The medications most frequently overpaid because of incorrect units of service were adenosine, rituximab, infliximab, leuprolide acetate, and bortezomib.

Other common billing mistakes by physicians that resulted in overpayments included insufficient documentation about patient services; billing for outpatient drugs in which payment was already included in that of a primary procedure; incorrect use of Healthcare Common Procedure Coding System codes; and billing Medicare for noncovered outpatient drugs. As of May 4, the Centers for Medicare & Medicaid Services had recovered 63% of the overpayments found in the OIG audit, according to the report. 

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