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March 2008: Higher Doses Of Celebrex Are Associated With Heart Attack And Stroke Risks

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FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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Lower, More Popular Dose Presumed To Be Safe, But Definitive Study Results Will Not Be Available For Few More Years

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On March 31, 2008, at the American College of Cardiology's annual meeting, a recent analysis of several studies involving Pfizer Inc.'s arthritis drug Celebrex was presented. In short, it showed that only higher doses of Celebrex are associated with an increased risk of heart attacks and strokes.

That same day the medical journal *Circulation* published (online before print) an article by Scott D. Solomon, director of noninvasive cardiology at Brigham and Women's Hospital in Boston, and colleagues about this latest data analysis concerning the safety of Celebrex, "[Cardiovascular Risk of Celecoxib in 6 Randomized Placebo-Controlled Trials. The Cross Trial Safety Analysis](#)".

From the abstract for this medical journal article about the side effects associated with high dose Celebrex (celecoxib):

Conclusions—We observed evidence of differential cardiovascular risk as a function of celecoxib dose regimen and baseline cardiovascular risk. By further clarifying the extent of celecoxib-related cardiovascular risk, these findings may help guide treatment decisions for patients who derive clinical benefit from selective cyclooxygenase-2 inhibition.

The significance of this *Circulation* article as well as the American College of Cardiology (ACC) presentation in Chicago is explained by *Wall Street Journal* reporter Jennifer Corbett Dooren in her March 31, 2008 article, "[Higher Doses of Pfizer's Celebrex Are Linked to Heart, Stroke Risks](#)":

The analysis, supported by the National Cancer Institute, broadly shows patients receiving the highest dose of Celebrex of 400

milligrams twice daily had a nearly three times higher risk of heart attacks and strokes than patients not taking the drug. Patients taking a lower dose of Celebrex, 400 milligrams once daily, had a 10% higher risk of a cardiovascular event....

[This is] an analysis of six studies that lasted for at least three years comparing patients taking Celebrex to those taking placebo. The combined analysis involved 7,950 patients.

The analysis showed Celebrex was associated with an increased risk for a combined study endpoint of cardiovascular death, myocardial infarction (heart attack), stroke, heart failure or thromboembolic event, or events related to blood clots, compared to patients not taking the drug. The risk was not affected by aspirin use.

For some contextual information we turn to a *Bloomberg* article, "[Pfizer's Celebrex at High Doses May Raise Heart Attack Risk](#)", by Shannon Pettypiece:

Most arthritis patients take a total of 200 milligrams or less of Celebrex a day. The study didn't examine risk for those lower doses, Solomon said.

Celebrex belongs to a category of drugs called Cox-2 inhibitors, which includes Merck's Vioxx and Pfizer's Bextra. Merck withdrew Vioxx in September 2004 after a company-sponsored study found the rate of heart attacks and strokes among people who took Vioxx for at least 18 months was 15 per 1,000 patients, about double the rate for those given a placebo.

Pfizer later removed Bextra and said Celebrex should remain on the market because there was no data showing a risk at the most commonly prescribed doses.

The study presented today examined the highest doses. The study that supported the removal of Vioxx looked at the most commonly prescribed dose, Solomon said. There is no data available showing whether Celebrex carries a heart risk at the lower doses....

A more definitive assessment on the risks of Celebrex won't come until 2010 or 2011, when a \$100 million study of 20,000 patients comparing Celebrex with the pain pills ibuprofen and naproxen is expected to be completed.

In light of what we heard reported at the March 2008 ACC meeting in Chicago about how some negative study results about Vytorin and Zetia were seemingly delayed, or withheld, by Merck and Schering-Plough, it makes me a bit uneasy that we must wait for several more years before learning whether or not the lower, more popular dose of Celebrex is safe for use.

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