[The FDA's Vioxx shennanigans are parallel to the CDC's hiding of thimerosal's adverse effects by means of deliberate data-dilution and by willing collusion by the IOM, FDA, and AAP. -Teresa]

FDA report links Vioxx to 27,785 heart attacks, deaths Agency releases study, had been warned of risk before

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http://www.baltimoresun.com/news/health/bal-bz.merck03nov03,1,948633.story
<http://www.baltimoresun.com/news/health/bal-bz.merck03nov03,1,948633.story?coll=bal-health-headlines>

WA$$$HINGTON - Merck & Co. Inc.'s recalled Vioxx painkiller may have contributed to 27,785 heart attacks and deaths from 1999 through 2003 because of the drug's effects on the cardiovascular system, U.S. regulators said in a report published online yesterday.

Vioxx caused more heart attacks and deaths from sudden cardiac arrest than would have occurred if patients taking Vioxx were on Pfizer Inc.'s
Celebrex, Food and Drug Administration researcher David J. Graham concluded after analyzing 1.4 million patient records.

Merck's announcement of the Vioxx withdrawal, the biggest drug recall ever, wiped out almost $27 billion of the stock's market value Sept. 30.

The Wall Street Journal reported Graham's estimate of deaths and heart
attacks Oct. 6. The agency posted the findings online yesterday.

Merck withdrew Vioxx because of a three-year company study showing that patients taking it for more than 18 months faced twice the risk of a heart attack as those taking a placebo.

The FDA and researchers for Kaiser, the largest U.S. nonprofit insurer with 8 million members, had presented the report's preliminary findings in August at a conference in France.

The study was based on an analysis of the records of 1.4 million Kaiser members in California. Graham compared the incidence of heart attacks and sudden cardiac death for patients taking Vioxx with those on Celebrex.

Based on 92.8 million U.S. prescriptions for Vioxx, also known as rofecoxib, from 1999 to 2003, Graham estimated that 27,785 more patients taking the Merck product may have had heart attacks or sudden cardiac death than among those on Celebrex, made by Pfizer Inc. of New York, the world's biggest drugmaker.

'Widespread exposure'

"The population impact of rofecoxib's increased risk is great because of the widespread exposure to the drug," said Graham, the FDA's associate director for science in the office of drug safety, in a report dated Sept. 30.

"This illustrates the effect that even a relatively small increase in risk can have if you're dealing with a serious outcome that is not

rare
in the general population" such as heart attacks and sudden cardiac death.

About 20 million people in the United States tried the drug since its 1999 introduction, according to Merck, the No. 2 U.S. drugmaker.

"In general, there is no reliable way to measure the actual use of Vioxx
in the population, and therefore no reliable way to estimate the actual
events," said Chris Loder, a Merck spokesman. "Because heart attacks and
strokes occur in the general population, one cannot say that if someone
had an event while taking Vioxx, that Vioxx caused it."

Sought halt

Graham also had said in the report that Vioxx use should be halted.

"Prior to today, my conclusions regarding rofecoxib were that high-dose
use of the drug should be ended and that lower- dose rofecoxib should not be used by physicians or patients," Graham said.

"If lower-dose rofecoxib remained on the market, physicians and patients
needed to understand that risk [of heart attacks and sudden cardiac death] was substantially increased and that there were safer alternatives."

Two congressional committees are questioning the FDA's actions to ensure
the safety of Vioxx.

The New England Journal of Medicine released a letter Oct. 6 from the Cleveland Clinic's chairman of cardiovascular medicine, Dr. Eric J. Topol, saying Merck and the FDA ignored earlier studies showing that Vioxx was linked to elevated risk of heart disease.

The FDA, which had told Merck in 2002 to include warnings about the heart risks on the Vioxx label, never required the company to conduct additional safety studies or curtail its marketing, Topol wrote.

"We are in a situation where there seems to be no end to negative reaction for Merck, even if the news has been previously reported," said
analyst Ira Loss of Washington Analysis in Washington, which advises institutional investors.

Merck's shares fell $1.48, or 5.2 percent, to close at $26.80 yesterday
on the New York Stock Exchange. The stock has plunged 42 percent this year.

On Monday, Merck's shares fell 9.7 percent after The Wall Street Journal
reported that the drugmaker tried for years to stop safety concerns from
hurting Vioxx sales. The report was based on internal Merck documents and marketing materials.

Alabama attorney Andrew Birchfield said yesterday that he turned over company documents and statements obtained in litigation to U.S. Senate
investigators probing the recall.

Liability exposure

Investors were trying to estimate the hit Merck may take from lawsuits

over Vioxx. The company said Oct. 21 that it had about $630 million in
product liability insurance and hadn't established reserves for Vioxx
litigation. Merck reported that more than 300 lawsuits had been filed by
Oct. 15.

Standard & Poor's said Monday that it may downgrade Merck's triple-A
rating on corporate credit and senior unsecured debt because of
"increasing concern about the magnitude of possible litigation."