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From the Los Angeles Times

**PREVIEW / FEB. 6-12**

## **Vioxx Data Omissions May Affect Lawsuits**

From Associated Press

February 6, 2006

A top medical journal's criticism of a study cited in Vioxx lawsuits is expected to play a part in the retrial of the first federal Vioxx lawsuit.

The disclosure that some negative data were omitted from the study could make manufacturer Merck & Co. look as if it's hiding something, legal experts say.

That is what attorneys for Evelyn Irvin Plunkett, whose husband died after taking the drug for a month, say they can prove in the trial starting today.

The first federal trial — held in Houston in the wake of Hurricane Katrina — ended with a deadlock. Two jurors said the split was 8 to 1 in favor of Merck's contention that taking Vioxx had nothing to do with the death of Richard "Dickie" Irvin.

The day those deliberations began, the New England Journal of Medicine published criticism — one step short of retracting the study — accusing its authors of withholding and deleting relevant data.

The information alone is "damaging although not shattering," but its implications could be devastating, Northwestern University law professor Ronald Allen said.

Vioxx was a \$2.5-billion-a-year seller when Merck pulled it from the market in September 2004 because a study found that taking it for 18 months doubled the risk of heart attacks.

An earlier study known as VIGOR, published by the journal in 2000, is being cited in allegations that Merck held back information about the risk of heart attacks.

The journal's critique noted that its editors learned that the authors had deleted information about three additional heart attacks not reported in the original study but reported to the Food and Drug Administration. That would have changed a section about side effects, showing that Vioxx patients had five times as many attacks as those on the pain reliever naproxen, rather than four times as many — and that patients not considered high-risk were having heart attacks, it said.

"Taken together, these inaccuracies and deletions call into question the integrity of the data," the journal said.

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