Medical 'ghostwriting' assailed

Vioxx reports raise research concerns

By Lindsey Tanner
Associated Press

CHICAGO — Two new reports involving the painkiller Vioxx raise fresh concerns about how drug companies influence the interpretation and publication of medical research.

The reports claim Merck & Co. frequently paid academic scientists to take credit for research articles prepared by company-hired medical writers, a practice called ghostwriting.

The reports also contend Merck tried to minimize deaths in two studies that showed that the now-withdrawn Vioxx didn't work in treating or preventing Alzheimer's disease.

Merck called the reports in today's Journal of the American Medical Association false and misleading. Five writers of the articles were paid consultants to people who sued Merck over Vioxx's heart and stroke risks; the sixth testified about Merck and Vioxx's heart risks before a Senate panel. Merck says those connections make the reports themselves biased.

Although Merck is singled out, the practices are not uncommon, according to JAMA's editors.

In an editorial, they urge strict reforms, including cracking down on ghostwriting and requiring all authors to spell out their specific roles.

Dr. Catherine DeAngelis, JAMA's editor in chief, said the magazine already has those policies but many other journals do not.

The practices outlined in JAMA can lead editors to publish biased research that can result in doctors' giving patients improper and even harmful treatment, she said.

Drug studies involve several steps, including designing and performing the research, analyzing the results and writing them up for submission to a medical journal. Pharmaceutical companies sometimes pay for a study but have independent scientists perform all those steps. Sometimes companies and their own scientists are involved in some or all the steps, and those were the studies scrutinized in the JAMA reports.

The articles are based on reviews of company documents from court cases over Vioxx, which was pulled in 2004 because of its heart and stroke risks. Last November Merck agreed to pay $4.85 billion to settle thousands of lawsuits.

One JAMA report says internal company data showed in 2001 that Vioxx patients in two Alzheimer's studies had a higher death rate than patients on dummy pills.

Merck didn't publicize that "in a timely fashion" and gave federal regulators information that downplayed the deaths, the report said.

But Jim Fitzpatrick, a Merck attorney, said "it's completely not true" that Merck tried to minimize those deaths. He said a Merck analysis found the excess deaths were not related to Vioxx.

Spending scrutiny planned

For years, the nation's largest drug and medical-device manufacturers have courted doctors with consulting fees, free trips to exotic locales and sponsorships of the educational conferences that physicians attend.

Now, under the threat of regulation by Congress, the two industries are promising to be more forthright about their spending.

A dozen of the nation's leading drug and device makers have told Sen. Charles Grassley, R-Iowa, that they have plans or are working on plans to publicly disclose grants to outside groups. The details will be provided on each company's Web sites.

Watchdog groups say the companies are trying to derail legislation that would require public disclosure of their giving.