

Drugs in the News 3/11/09 – More Cutting Edge Pharmacotherapeutics

Below is an article published in this morning's *Wall Street Journal* about the fabrication of positive results of at least 21 published research articles involving Vioxx, Bextra, Celebrex, Neurontin, and Lyrica by an anesthesiologist and pain "expert" from the Baystate Medical Center, Springfield, MA.

Baystate is a 653-bed academic teaching hospital that serves as the Western Campus of Tufts University School of Medicine and advertizes on its Web that it is recognized for quality care. The hospital sounds like it would be a perfect site for APPE rotations for pharmacy students could observe cutting edge pharmacotherapeutics in the clinical setting.

So much for science the Lyrica combination is on preprinted post-op orders at some hospitals.

The anesthesiologist dubbed the "Medical Madoff" by Scientific American is recognized for encouraging prescribers to combine the use of painkillers like Celebrex and Lyrica for patients undergoing common procedures such as knee and hip replacements.

Among the many disturbing aspects of this episode is that investigators may be heading down dead ends based on the positive results of these 21 retracted articles.

If anyone would like the list of the 21 retracted papers please just let me know.

Best,

MARCH 11, 2009

Top Pain Scientist Fabricated Data in Studies, Hospital Says

By [KEITH J. WINSTEIN](#) and [DAVID ARMSTRONG](#)

A prominent Massachusetts anesthesiologist allegedly fabricated 21 medical studies that claimed to show benefits from painkillers like Vioxx and Celebrex, according to the hospital where he worked.

Baystate Medical Center, Springfield, Mass., said that its former chief of acute pain, Scott S. Reuben, had faked data used in the studies, which were published in several anesthesiology journals between 1996 and 2008.

The anesthesiologist allegedly faked data in 21 studies on the use of various painkillers, including Vioxx.

The hospital has asked the medical journals to retract the 21 studies, some of which reported favorable results from the use of painkillers like [Pfizer Inc.'s Bextra](#) and [Merck & Co.'s Vioxx](#) -- both since withdrawn -- as well as Pfizer's Celebrex and Lyrica. Dr. Reuben's research work also claimed positive findings for [Wyeth's](#) antidepressant Effexor XR as a pain killer. And he wrote to the Food and Drug Administration,

urging the agency not to restrict the use of many of the painkillers he studied, citing his own data on their safety and effectiveness.

"Dr. Reuben deeply regrets that this happened," said the doctor's attorney, Ingrid Martin. "Dr. Reuben cooperated fully with the peer review committee. There were extenuating circumstances that the committee fairly and justly considered." She declined to explain the extenuating circumstances. Dr. Reuben didn't respond to requests for comment sent through Ms. Martin and left at his former office.

The retractions, first reported in Anesthesiology News, have caused anesthesiologists to reconsider the use of certain practices adopted as a result of Dr. Reuben's research, doctors said. His work is considered important in encouraging doctors to combine the use of painkillers like Celebrex and Lyrica for patients undergoing common procedures such as knee and hip replacements.

Last month, the journal Anesthesia & Analgesia retracted 10 of Dr. Reuben's studies and posted a list of the 11 published in other journals on its Web site. The journal Anesthesiology said it has retracted three of Dr. Reuben's articles.

Dr. Reuben had been a paid speaker on behalf of Pfizer's medicines, and it paid for some of his research. "It is very disappointing to learn about Dr. Scott Reuben's alleged actions," Pfizer said in a statement. "When we decided to support Dr. Reuben's research, he worked for a credible academic medical center and appeared to be a reputable investigator."

Wyeth said it isn't aware of any financial relationship between the company and Dr. Reuben.

An FDA spokeswoman said late Tuesday she wasn't aware of the matter. Merck had no immediate comment.

Hal Jenson, the chief academic officer at Baystate Medical, said a routine audit last spring flagged discrepancies in Dr. Reuben's work. That led to a larger investigation in which Dr. Reuben cooperated, Dr. Jenson said. "The conclusions are not in dispute," he added.

Dr. Reuben is on an indefinite leave from his post at Baystate, the hospital said. He no longer holds an appointment as a professor at Tufts University's medical school, according to the university.

Baystate concluded that "Dr. Reuben was solely responsible for the fabrication of data," Dr. Jenson said.

Jeffrey Kroin, who co-wrote four papers with Dr. Reuben, said he was dumbfounded to receive a letter earlier this year from Baystate, retracting the studies.

"We analyzed it and made figures and graphs, and sent it back, and wrote papers, and everything seemed fine," said Dr. Kroin of Rush University Medical Center in Chicago. "If someone has a good reputation, has 10 years of papers and has a very high position within their medical school, generally you assume they have a lot of integrity."

Jacques E. Chelly, the head of acute interventional postoperative pain service at the University of Pittsburgh Medical Center, said he was "shocked" by the news of the retractions. Dr. Reuben "was very well respected," Dr. Chelly said.

He added that the situation has prompted his hospital to review the protocols it uses to treat patients for pain, because Dr. Reuben's work was so influential in establishing them. He said the hospital was now conducting its own study to verify the efficacy of drugs that Dr. Reuben claimed were effective painkillers.

In an editorial in the journal *Anesthesiology*, editor James C. Eisenach warned that "these retractions clearly raise the possibility that we might be heading in wrong directions or toward blind ends in attempts to improve pain therapy."

The retracted studies aren't expected to affect the drugs' regulatory status because Dr. Reuben's studies weren't part of the packages that manufacturers submitted to the FDA or European authorities.

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