

# SCIENTIFIC AMERICAN

## A Medical Madoff: Anesthesiologist Faked Data in 21 Studies

A pioneering anesthesiologist has been implicated in a massive research fraud that has altered the way millions of patients are treated for pain during and after orthopedic surgeries

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Over the past 12 years, anesthesiologist Scott Reuben revolutionized the way physicians provide pain relief to patients undergoing orthopedic surgery for everything from torn ligaments to worn-out hips. Now, the profession is in shambles after an investigation revealed that at least 21 of Reuben's papers were [pure fiction](#), and that the pain drugs he touted in them may have slowed postoperative healing.

"We are talking about millions of patients worldwide, where postoperative pain management has been affected by the research findings of Dr. Reuben," says Steven Shafer, editor in chief of the journal *Anesthesia & Analgesia*, which published 10 of Reuben's fraudulent papers.

Paul White, another editor at the journal, estimates that Reuben's studies led to the sale of billions of dollars worth of the potentially dangerous drugs known as COX2 inhibitors, Pfizer's Celebrex (celecoxib) and Merck's [Vioxx](#) (rofecoxib), for applications whose therapeutic benefits are now in question. Reuben was a member of Pfizer's speaker's bureau and received five independent research grants from the company. The editors do not believe patients were significantly harmed by the short-term use of these COX2 inhibitors for pain management but they say it's possible the therapy may have prolonged recovery periods.

Baystate Medical Center in Springfield, Mass., began investigating Reuben's findings last May after its chief academic officer, Hal Jenson, discovered during a routine audit that Reuben had not received approval from the hospital's review board to conduct two of his studies. Reuben "violated the trust of Baystate, the community and science," Jenson says. The story of the investigation was [first reported by \*Anesthesiology News\*](#) late last month.

Reuben, 50, has been stripped of his research and educational duties and has been on medical leave since May. He received his medical degree from the State University of New York at Buffalo School of Medicine & Biomedical Sciences in 1985 and did his residency at the Mount Sinai Medical Center in New York City. In 1991, he joined Baystate, which serves as the western campus for Tufts University School of Medicine, and has worked as a staff [anesthesiologist](#) and the director of acute pain management.

His lawyer, Ingrid Martin of Dwyer & Collora, LLP, in Boston, told *ScientificAmerican.com* that Reuben has cooperated with the investigation and that he "deeply regrets that all of this happened." She added that "with the [investigating] committee's guidance, he is taking steps to ensure this never happens again." She declined to answer any further questions, and Reuben did not respond to an e-mail request for comment.

Beginning in 2000, Reuben, in his now-discredited research, attempted to convince [orthopedic](#) surgeons to shift from the first generation of nonsteroidal anti-inflammatory drugs (NSAIDs) to the newer, [proprietary](#) COX2 inhibitors, such as Vioxx, Celebrex, and Pfizer's Bextra (valdecoxib). He claimed that using such drugs in combination with the Pfizer anticonvulsant Neurontin (gabapentin), and later Lyrica (pregabalin), prior to and during surgery could be effective in decreasing postoperative [pain](#) and reduce the use of addictive painkillers, such as [morphine](#), during recovery. A 2007 editorial in *Anesthesia & Analgesia* stated that Reuben had been at the "forefront of redesigning pain management protocols" through his "carefully planned" and "meticulously documented" studies.

Many orthopedic surgeons, however, were slow to adopt COX2 inhibitors due to animal studies that showed short-term use might [hinder bone healing](#). Then, in 2004, Vioxx and Bextra were pulled from the market because of their link to an increased risk of heart attacks and strokes, leaving Pfizer's Celebrex as the only COX2 inhibitor available. Celebrex [sales plunged 40 percent](#) after a study that same year suggesting that it, too, posed a heart attack risk. Despite this, Reuben continued to present "findings" in research funded by Pfizer that trumpeted Celebrex's alleged benefits and downplayed its potential negative side effects.

He apparently hoped to erase doubts by persuading orthopedic surgeons to co-author papers with him based on his bogus data. In 2005 he and Evan Ekman, an orthopedic surgeon at Southern Orthopaedic Sports Medicine in Columbia, S.C., published a study on the use of Celebrex to control pain in back surgery patients. "The short-term administration of celecoxib," they wrote in the paper published in *The Journal of Bone and Joint Surgery*, "results in no significant deleterious effect on bone or ligament healing or cardiovascular outcomes."

Three years later, Reuben's career would begin to unravel as Ekman began to suspect foul play. In addition to collaborating with Reuben on the now-retracted Celebrex study, Ekman agreed to review a Reuben manuscript on surgery on the anterior cruciate ligament (ACL) in the knee. But when he asked the anesthesiologist for the name of the orthopedic surgeon on the study, Reuben ceased communication with him.

Then, last year, Ekman was invited by Pfizer to give a talk. While there, he was handed a version of the very manuscript Reuben had asked him to review, which had subsequently been published in *Anesthesia & Analgesia*. To his surprise, and horror, he was listed as a co-author: Reuben had forged his signature on the submission form, Ekman says.

By then, Editor in Chief Shafer had already put several Reuben manuscripts on hold after learning that Baystate had initiated a probe into the validity of his research. The investigation later identified 21 articles based on patient data that had been partially or completely doctored. Although Pfizer funded Reuben's research between 2002 and 2007, Baystate has no records of those payments and says that the research funds could have been paid directly to Reuben. Such an arrangement would be "highly unusual," Shafer notes. "It's just a little frustrating," Baystate spokesperson Jane Albert says. "I don't know how many dollars went to Dr. Reuben or his group."

Pfizer spokesperson Sally Beatty insists the grants were properly disbursed to Baystate in accordance with Pfizer policy. "Pfizer is not familiar with the records retention policies of Baystate Medical Center," she says, "However, independent investigator-initiated research grant agreements were executed between Pfizer and Baystate Medical Center." Beatty was unable to provide information on the dollar amount of the grants, but editor White says they typically range between \$10,000 to \$100,000.

The question is: Why did it take 12 years before a "routine audit" revealed Reuben's widespread data fabrication? "Baystate publishes about 200 [studies] every year, and of those [articles], the audit rate might only be 5 percent," Baystate's Jenson says, acknowledging that ultimately "Baystate is responsible" for making sure that research done there is properly conducted and reported. He says that the hospital has been trying to strengthen its oversight program over "the past few years" and that it is in the process of applying for accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in Washington, D.C., which provides an independent evaluation of an organization's ethical standards and oversight. The lack of accreditation is not unusual because the nonprofit program was not established until 2001 and only recently has grown to include 159 hospitals, academic institutions and other organizations.

In hindsight, *Anesthesia & Analgesia* editors Shafer and White admit that it should have been a "red flag" that Reuben's studies were consistently favorable to the drugs he studied. White, who has also received drug company educational grants, says that [such funding](#) comes with "subtle pressure" to give the companies the results they want. For now, at least, neither the [drug companies](#) nor Reuben's co-authors are officially sharing in the blame, but that's expected to change. "There's a lot of responsibility to pass around," White says, "It's all being focused on Scott Reuben, but the reality is there are many other responsible parties."