

Fraudulent Conduct That Takes Lives

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By James J. Neal

In recent years, surgical instrument companies working through surgeons with concealed equity interests in devices, have created new procedures, to promote the sale of equipment. Corporations have created demand for new surgical procedures "through massive advertising campaigns to convince the public of [their] necessity.

Leading surgical researchers, with equity interests have fabricated surgical research to demonstrate the safety and efficacy of new procedures with device costs of \$2,000-\$5,000 per operation. One sales rep described his companies' philosophy as "dollars per procedure." Although the device industry has generated tens of billions of dollars in revenue using these tactics, serious surgical morbidity from many new device dependent operations has multiplied.

Treating MD's and patients need law enforcement's assistance in deterring fabricated research data published by research surgeons with concealed equity interests in expensive medical devices, and new drugs. The question raised in this analysis is whether fraudulent medical research is taking lives, and if so, how many.

A third client clinically tests new medical devices for many instrument companies. A fourth client, a former Chief Medical Officer at the Devices Division of the FDA has found over 1,000 misreported device malfunctions. This report is about what law enforcement has not done - but can do to deter deaths and injuries from what Clients #1 and #2 refer to as "the medical mafia."

The third client, a prominent surgeon, after finding that a new surgical device caused potentially fatal injuries in 3 of 18 patients - was persuaded to avoid testifying about the injuries he observed, by a company Chief Operating Officer. The device, which Client #3 told the Chief Operating Officer was a "lethal weapon," has since injured tens of thousands of patients, including an estimated 1,000-3,000 deaths.

Doctor John Guerigian, an MD biochemist who left the FDA after over 20 years says,

"They're killing people and no one's going to jail."

This document argues that some should. Fraudulent device researchers with equity interests in products, who count on law enforcements' inaction - are doing

serious harm with fabricated studies backing some of the new long stemmed devices that are "revolutionizing" surgery.

A Comforting Myth About Device and Drug Research

In 2001, Dr. Richard Horton, the Editor of Lancet, one of the world's oldest and preeminent medical journals, published his conclusion that the "notion" that drug and device research still serves medicine is a "comforting but erroneous myth."

The myth referred to by Horton is about more than questionable research choices. It's about using a portion of a 200 billion dollar plus annual revenue to pay some "leading researchers" multimillions to purchase safety data that is not valid.

This permits a company to obtain FDA approvals, and promote products based upon invalid data. There is a growing body of evidence that misleading drug and device research in the burgeoning for profit clinical medical research system is multiplying, is undeterred, is now a threat to public safety that rivals firearms in magnitude, and should be criminally prosecuted.

If fabricated and otherwise misleading research on new drugs and devices has contributed to over 100,000 deaths, as appears probable, prosecution of the most dangerous offenders must be considered. Fabricating positive drug and device research results can be extremely lucrative. Indeed, it can generate billions of dollars in sales.

Some fraud in commerce is self-policing through caveat emptor. However, the actual police are required when fraudulent medical research "backs" a new drug or device - precluding caveat emptor.

[Red Flags Weekly](#) June 8, 2002