PATIENT SAFETY BLOG

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The Going Rate for Compromising A Surgeon's Principles and Patient Safety: \$16 Million

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That's the sellout price for a spine surgeon. Give or take a few million.

Like police officers, whose thin blue line separates them from "the other," medical researchers and doctors are loath to diss their fellow professionals. But this week, the code of omerta was breached with a series of critical reports in The Spine Journal about industry-sponsored research in general and the use of a bone growth product in particular.

As noted in the New York Times, "It is extremely rare for researchers to publicly chastise colleagues, and editors of leading medical journals said they could not recall an instance in which a publication had dedicated an entire issue for such a singular purpose."

At the center of attention is Infuse, a product manufactured by Medtronic that's used in more than 100,000 spinal fusion surgeries in the U.S. each year to encourage growth of new bone so the spine

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pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) fusion "takes." The Spine Journal articles claimed that researchers subsidized by Medtronic exaggerated the benefits of Infuse and minimized the risks.

All surgical procedures and all medical products carry some element of risk, large or small.

Dumbfoundingly, some of Infuse's defenders claimed it had no risk. None. Zip. Nil. Uh-huh, and I'm vacationing next month on Jupiter.

In a joint editorial, five doctors wrote, "It harms patients to have biased and corrupted research published. It harms patients to have unaccountable special interests permeate medical research."

Objective research and the "do no harm" vow apparently have their price, and for some of the so-called "scientists" championing Infuse, it is \$12 million to \$16 million—the **median** amount collected by researchers from Medtronic. Median. That means half got *more*. Clearly, for Medtronic, corrupting science is a good investment: In the most recent fiscal year, Medtronic earned an estimated \$900 million from Infuse.

Infuse was approved by the FDA in 2002 for one type of spinal fusion, and as required, Medtronic reported complications in its use that the agency considered sufficiently significant to require the company to list them on the product label. But, as the New York Times explained, "in reporting on such studies in 13 medical journal articles published during the last decade, researchers whose studies were paid for by Medtronic maintained that Infuse's use was not tied to any complications."

In addition to its approved use, Infuse is used for other spinal procedures. The Justice Department, however, has been conducting a criminal investigation to determine whether Medtronic illegally promoted such off-label uses, which the company denies.

At this point, Medtronic's credibility, and that of the people who speak for its scientific authority, is thin.

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