Sending Deficient Hip Implants Overseas

February 27, 2012 by Patrick A. Malone

File this story under: exporting your problems.

That's what Johnson & Johnson did after the FDA said the company wasn't allowed to market its artificial hip in the U.S. because J&J's own studies showed the device was unsafe.

As recounted in the New York Times, not only did J&J pawn its questionable product off on Europeans, it continued to sell a related model in the U.S. that had been made available temporarily only because of a regulatory loophole enabling it to escape the scrutiny of a safety review. In December 2010, The Times called that device "[o]ne of the most troubled orthopedic implants of the past decade."

It's not known how many people overseas got the banished replacement hip after the FDA failed to approve it in 2009, nor how many U.S. patients got the similar implant. The two were on the market for eight years and implanted in about 93,000 patients worldwide; about one-third of them were in the U.S.

The problem for both models was the all-metal hip socket cup. These components have long been problematic, and we've written about them before, most recently here and here.

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

Citing declining sales, the DePuy orthopedic division of Johnson & Johnson began phasing out the “articular surface replacement” device known as ASR in November 2009. They were recalled formally in August 2010 because of high failure rates much earlier than their purported 15-year lifespan.

Generally, regulatory standards in other countries for approving the sale of medical devices are lower than here, so there’s no claim that Johnson & Johnson broke the law. And Britain’s Medicines and Healthcare Products Regulatory Agency told The Times that companies were not required to notify it when the FDA failed to approve a product for U.S. consumption that was used in patients there.

But what’s legal and what’s moral aren’t always the same.

But maybe J&J’s squishy moral standards are coming home to roost. As noted by The Times, the FDA rejection may exacerbate the company’s legal and financial problems surrounding the ASR. In January, J&J took a special $3 billion charge, largely to address anticipated legal and medical expenses associated with the recall. Thousands of lawsuits involving the device are pending, including some from patients crippled by metallosis, a form of poisoning by implants shedding metallic debris.

And let’s not forget that, before the recall, when complaints about the ASR were building, DePuy defended it by claiming that any failures were those of the surgeons, who didn’t properly implant the hip cup. So here we have a company that can’t cop to its own shortcomings, and, worse, ships them overseas in hopes nobody notices.

The lack of transparency in medical device approval remains a real threat to patient safety. The FDA’s process is confidential, a practice it justifies because it might include proprietary business information. But when it comes to developing a product that creates so much harm, is this a business model anyone would replicate?

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