

Hip Recall Victim Takes Stand Against FDA, Johnson & Johnson

JAN. 26, 2011 / SAN FRANCISCO / Just five months after Johnson & Johnson's subsidiary DePuy Orthopaedics recalled 93,000 defective hip implants worldwide, the FDA, as of last week, abandoned a proposal that would have required manufacturers to prove that an implanted medical device is safe before marketing it.

But a San Diego woman and former California Broadcast President and TV general manager who is living in agony, says she represents thousands of patients already affected and says the FDA needs to close the loophole allowing untested medical implants to cripple people and endanger lives. She has made it her mission to strengthen the FDA's oversight of this largely unsupervised industry and protect future hip implant recipients from the pain she has suffered.

Although DePuy sold over 30,000 ASR hip implants in the United States alone, the FDA never approved the device as safe and effective. Instead, DePuy used a loophole in the FDA regulations—known as “§510(k) clearance”—to sell the ASR hip implant without having to conduct any clinical trials to show that the hip implant is safe. If DePuy had conducted such clinical trials, the product defect likely would have been discovered before it was surgically implanted in thousands of Americans.

This year, the FDA was expected to close the §510(k) loophole and require that manufacturers prove that potentially dangerous medical devices are safe before they are implanted in people. But the FDA inexplicably abandoned these changes last week when it announced several other revisions that curry favor with medical device companies and their powerful lobbying interests. The newly-proposed regulations preserve the §510(k) loophole that allowed DePuy to sell the defective ASR hip implant to unsuspecting patients.

Lisé Markham is one of the thousands of victims of DePuy's defective hip implant. In March 2008, when DePuy sold Ms. Markham the ASR hip implant, DePuy already had received hundreds of reports that the implant had failed in other people. But DePuy sold the product anyway, and the failure of the implant caused a second painful surgery and permanent injuries to Ms. Markham. Markham, 56, stated: “Anyone who has received this implant which was marketed as one of the best implants for baby boomers, knows what this device did to their lives. You can recall a car part but you can't just recall a body part. The pain is akin to being shot and branded with a hot iron, 24/7.”

Also today, Markham filed a lawsuit against Johnson & Johnson and DePuy alleging that the company is responsible for the failure of her hip implant and the permanent injuries and damages that she has suffered. The lawsuit alleges that, based on hundreds of complaints, Johnson & Johnson was fully aware that the ASR hip implant was defective at the time that Markham was implanted with it, yet it continued to sell the implant to boost corporate profits.

Ms. Markham's lawyer, Brian Devine, is a former executive at a global manufacturer of hip implants. He stands with Ms. Markham in support of closing the §510(k) loophole. Devine said, “The §510(k) loophole allowed DePuy to sell defective hip implants that seriously injured Lisé and thousands of other people. The loophole must be closed and the FDA must be given the tools it needs to protect patients from dangerous and untested medical devices.”

ABOUT US

Lisé Markham, an entrepreneur and former broadcast television executive in San Diego, is one of the thousands of victims of Johnson & Johnson's hip implant recall. She has founded the website www.hiphelp.org to provide a resource and community for hip implant patients.

Brian Devine is a San Francisco attorney. The former Assistant General Counsel of Sulzer Medica, a global manufacturer of hip implants, Devine now uses his years of experience inside the orthopedics industry to represent Ms. Markham and several other victims of DePuy's hip implant recall.

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