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Local hospital, doctor named in lawsuit over fake surgical hardware

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The University of Maryland's Baltimore Washington Medical Center is sending letters to about 250 spinal fusion patients who received hardware from a defunct California company accused of selling fake parts.

The Glen Burnie hospital is continuing to investigate whether any counterfeit parts were used in patients and sent the letters to "address any concerns." Officials said they've found no evidence yet its patients were affected.

A number of hospitals across the country, including Baltimore Washington Medical Center, have been sued by health insurers alleging the hospitals used the fake parts and overbilled for them. The suit also named one of the hospital's spinal surgeons, Dr. Randy Davis. Local law firms are also investigating and reaching out to patients.

The parts in question were distributed by a company called Spinal Solutions LLC, which was cited in 2012 by the U.S. Food and Drug Administration for quality control problems. The following year, the company recalled parts used in lower spine fusions, specifically saying that some had been distributed in Maryland.

In announcing the recall, the FDA said inadequacies in the parts "might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization."

One local lawyer questioned why the recall didn't prompt hospitals that used the hardware to investigate earlier and notify patients there was a possibility that counterfeit hardware had been implanted.

"We've discussed this with numerous patients and all have questions about the health implications of potentially having these unapproved parts in their bodies," said Judson H. Lipowitz, who manages the injury and wrongful-death practice of Azrael, Franz, Schwab & Lipowitz.

The Towson firm and the Law Firm of Peter G. Angelos began advertising for patients after seeing stories about Spinal Solutions, which went out of business after the recall. None of the patients who've responded to Lipowitz's firm have received a letter from the hospital yet, he said, adding that sending them is a good step.

The case highlights the growing problem of counterfeit medical devices and drugs that national and international regulators have sought to stem, and raises questions about how to best protect consumers.

"Shadowy product makers are trying to worm their way into the supply chains," said James Quiggle, spokesman for the Coalition Against Insurance Fraud, an industry and consumer watchdog that has been monitoring the Spinal Solutions case.

"The junk is implanted in people and can cause permanent harm," he said. "Some luckless patients must face lifetimes of pain and disability."

Quiggle said the global problem calls for more cooperation among regulators here and overseas where many devices are made. He said hospitals also have a responsibility to police the supply chain, and one "red flag" is financial arrangements doctors have with equipment and drug makers.

Such arrangements, however, are not uncommon and hospitals have said they can lead to advances in medicine. The U.S. Centers for Medicaid and Medicare Services recently reported $6.5 billion in payments to doctors from drug and device makers for consulting, royalties and other services.

The insurers' suit alleges that doctors, including Davis at Baltimore Washington Medical Center, were given lucrative "sham" consulting contracts in exchange for bringing business to Spinal Solutions.

In the lawsuit, filed in February and unsealed in May, Davis is accused of accepting $458,962 in payments, largely in consulting fees. In return, the suit said, the hospital bought in excess of $1 million of implantable hardware from Spinal Solutions delivered by private aircraft.

The suit alleges that there were similar arrangements with doctors in California, Texas, Wisconsin and Nevada and that their hospitals were complicit. In all, it named 17 hospitals and 15 doctors as well as Spinal Solutions and other companies.

Davis, a board-certified orthopedic surgeon in the hospital's spine and neuroscience center, would not comment because of the pending lawsuit, according to Karen Lancaster, a spokeswoman for the University of Maryland Medical System, which owns the hospital.

Attorneys for the insurers who filed the suit did not respond to a request for comment.

Baltimore Washington Medical Center began a review when officials heard of the civil complaint, covering the years from 2007 to 2012, Lancaster said.

"Our review is continuing, but we have found no evidence that the alleged non-FDA approved hardware was ever received or used in spinal surgeries" at the hospital, she said. "The hardware identified in the complaint is used in a very specific type of spine surgery; only a small percentage of patients who underwent spinal surgery at [the hospital] during this time period had this specific kind of surgery."

The suit said the fake screws and rods were "insidiously co-mingled" with real products used in spinal fusion surgery.

Real FDA-approved parts are made of titanium, rather than the stainless steel used in the first generation of hardware in the 1980s, and are not likely to fail, said Dr. Paul Asdourian, regional director of the spine program at MedStar North, who is not involved in the litigation.

If the screws and rods break or dislodge during the six weeks to six months it can take bones to fuse, the bones may not heal properly. That could lead to pain and more surgery, he said.

Patients have the procedure for several problems, including a fractured spine or a painful arthritic condition.

Asdourian said the number of spinal fusions a surgeon performs varies, but might average 75 to 100 a year. Not all require implants, and some surgeons use hardware from several suppliers, he said.

But, he acknowledged, telling a fake screw from a real one could be tough.

"It depends on how good the fake is," Asdourian said. "If it's done by a good machine shop, it may be difficult to tell. I try and use reputable companies and I know my reps, but you have to trust these people. ... If I noticed the screws looked different, I'd say something. If I noticed they broke in a couple of patients, I'd question it."

The World Health Organization, which formed a task force to stem the flow of counterfeit drugs and devices in 2006, said the scope of the problem is tough to gauge, though in 2010 it estimated about 8 percent of all devices on the market were fake.

In 2012, U.S. Customs & Border Protection reported that 9 percent of all its seizures, or 2,350 packages, were counterfeit drugs and medical devices. They were worth $83 million, and more than half came from China.

The FDA recently reported that about 40 percent of finished drugs and more than half of medical devices in the United States come from overseas, and the agency has stepped up inspections of foreign facilities. In June, the agency took action against 1,050 websites to stop selling illegal, unapproved and potentially dangerous medicines and devices.

The FDA would not confirm if it plans to take further action against Spinal Solutions.

The insurers' suit alleges fakes got through because the hospitals and doctors "willfully failed to ensure the material was genuine and FDA approved."

It says this "represented an opportunity to make money, without regard as to whether surgery was necessary... and more importantly, without regard to the safety, health and well-being of patients."

Local attorneys are just gathering information for now, seeking patients who had spinal surgery at Baltimore Washington Medical Center between 2007 and 2013 and their medical records.

"Right now we are just investigating and trying to get a client base and a look at their records to see if its true," said Jay Miller, an attorney with Angelos' firm.

"The universe is unknown at this point," Lipowitz said. "There were parts commingled in the supply chain. We don't know where this ends."

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