

## Local hospital, doctor named in lawsuit over fake surgical hardware

By: Meredith Cohn, The Baltimore Sun

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

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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.

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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.