Surgeon Sued For Off-Label Device Use

PRNewswire - A manufacturer of infusion pain pumps has filed a claim against a doctor for off-label use of the device, according to court documents filed last week. According to the claim, Dr. Bruce Holladay used a pain pump manufactured by I-Flow Corporation to administer pain medication to a teenager following shoulder surgery in 2007. The teen's parents sued I-Flow in 2007 after their son developed chondrolysis, a permanent destruction of cartilage, according to the suit.
The lawsuit accused I-Flow of negligently failing to test the pump before marketing it to the public; for promoting it for uses for which it had not obtained federal approval; and for failing to warn physicians about the risks of destroying shoulder cartilage. I-Flow, owned by Kimberly-Clark, filed a cross-claim against Dr. Holladay on November 8, said Robert K. Jenner, of Baltimore, one of Lucas' attorneys.
"What makes the situation all the more insidious, is that the doctor did nothing more than use the product the way the company and its sales representatives told physicians to use it," Jenner said. I-Flow and other pain pump manufacturers are embroiled in hundreds of lawsuits, Jenner noted. The company also is under investigation by the Department of Justice for promoting its devices for uses other than those approved by the U.S. Food and Drug Administration, he added.

I-Flow's basis for suing the doctor is the doctor's use of marcaine and epinephrine in the pump, according to the cross-claim. Company sales representatives recommended that Marcaine, also known as bupivacaine, and Marcaine with epinephrine, be used in I-Flow's pain pumps to reduce post-surgical pain, according to complaints filed across the country.

"Not only does epinephrine not cause chondrolysis, but I-Flow's literature and its sales representatives also told physicians that use of the pain pump with epinephrine directly in the shoulder joint was a perfectly acceptable use of their product," Jenner said. "Doctors rely on medical device manufacturers to guide them in safe use of their products. To turn around and sue a doctor for following the company's instructions is just shocking and a major violation of trust," said Ronald E. Johnson, Jr., who represents the patient's family.

According to the original complaint, researchers began presenting data in 2003 that direct infusion of pain medication into shoulder joints was linked to chondrolysis, but pain pump manufactures continued for many years to promote their pain pumps to orthopedic surgeons.

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