Fed Rejects Medtronic's Preemption Claim In Off-Label Use of Device

Business Wire

Kent L. Klaudt, lawyer at the national plaintiffs' law firm Lieff Cabraser Heimann & Bernstein, LLP, announced that U.S. District Court Judge G. Murray Snow of the District of Arizona denied in large part Medtronic's motion to dismiss a personal injury lawsuit brought by Dr. Cristina Ramirez against the company on grounds that the claims are preempted by Federal law.

"We are gratified that the Court rejected Medtronic's effort to close the doors to the courthouse on Dr. Ramirez and the many other patients that were implanted with the Infuse bone growth protein," stated Klaudt. "The Court's carefully-reasoned ruling reaffirms that manufacturers who violate federal safety laws cannot then evade state tort liability to injured patients." Dr. Ramirez, an Arizona resident, underwent a lumbar fusion procedure in March 2009 to alleviate her back pain. The surgeon used Infuse, a bio-engineered bone graft substitute, during the procedure. Dr. Ramirez began experiencing severe and ongoing pain following surgery. She had developed uncontrolled bone growth, causing nerve impingement, in the area where her surgeon implanted Infuse.

In 2002, the U.S. Food and Drug Administration approved the use of the Infuse device – which includes the bone graft substitute intended to be inserted into a metallic spinal fusion cage – solely for the treatment of degenerative disc disease as part of a single-level, anterior lumbar interbody fusion.

The FDA had not approved Infuse for the posterior approach procedure used on Dr. Ramirez due to concerns of potential adverse effects, such as bone overgrowth, when Infuse was used in posterior procedures. Thousands of patients nationwide, however, have been implanted with Infuse during procedures involving off-label use. Off-label use of Infuse by physicians constituted nearly 90% of the $800 million in revenue that Infuse generated for Medtronic in 2011 involved off-label use by physicians.

The complaint charges that Medtronic failed to warn the FDA of severe side effects associated with use of its spinal fusion product Infuse when used for surgeries other than that originally presented to the FDA. The complaint further alleges that Medtronic aggressively promoted off-label uses of its device utilizing journal articles, advertising media, sales representatives/consultants and paid leading physicians to urge the use, purchase, and utilization of Infuse. Off-label promotion of prescription drugs and medical devices violates Federal law.

Medtronic asserted that the complaint should be dismissed because the Infuse device was approved by the FDA. As such, Medtronic argued, any claims against a medical device manufacturer under state law for fraud, negligence, design defect,

and failure to warn of dangers were preempted because they conflict with the FDA's approval of the design and label of the device.

The Court created a bright-line rule distinguishing cases in which the manufacturer in question, although aware of the off-label use, complies with federal regulations applicable to the device from cases where the core of the claim is that the plaintiff was injured due to an off-label use tied to the manufacturer's promotion of such uses. As the Court explained, the rationale for the preemption of state law claims regarding an FDA-approved medical device "vanishes when the plaintiff brings a claim against a manufacturer that arises out of a use that has not be reviewed by the FDA but has been promoted by the manufacturer." (Order, p. 16.) The Court further explained: "By remaining in compliance with the federal scheme and promoting only the use anticipated by the regulations, the manufacturer has shielded itself from such state law claims. The shield drops when the manufacturer violates federal law. . . .Medtronic offers no controlling authority suggesting that the federal government's extensive regulations concerning a medical device apply to off-label use in cases in which the manufacturer promotes such uses." (Order, p. 19.) "Any medical device manufacturer that misleadingly promotes its products for uses never approved by the FDA, and then fails to report to the FDA significant adverse events associated with those non-approved uses of the device, should be held accountable for severe injuries caused by the device," added Klaudt. "That is basic fairness and creates a powerful incentive for manufacturers to properly design, test, and market their products." The Court's order was issued on August 21, 2013. A copy of the order can be found at: http://www.lieffcabraser.com/media/pnc/4/media.1564.pdf.