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REPORT

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Product Liability

New Suits Seek to Hold Pain Pump Makers Liable for Degeneration of Shoulder Cartilage

Several lawsuits have been filed recently that seek to hold pain pump manufacturers and drug companies liable for encouraging physicians to use the devices to deliver pain medication directly into shoulder joints following arthroscopic surgery, contrary to uses approved by the Food and Drug Administration.

Plaintiffs in these actions complain that defendants knew the procedure could lead to degeneration of the articular cartilage in the humeral joint—the joint where the arm and shoulder meet—resulting in a painful condition called Postarthroscopic Glenohumeral Chondrolysis (PAGCL). They allege that both the device companies and the drug makers misled doctors into believing that the procedure posed no danger to their patients.

Further, the plaintiffs say, FDA expressly turned down requests by pain pump makers to include in their labeling and promotional materials statements indicating that direct delivery of pain medication to the shoulder joint was an approved use of the devices. Nevertheless, company sales representatives encouraged doctors to use the devices in this manner and never warned them about possible complications.

Defendants' deceptive practices, plaintiffs say, resulted in life-long injuries for which they will need continuing treatment.

Pain pump makers named in the suits include Stryker Corp., Orthofix International, I-Flow Inc., and BREG Inc. Additionally, some plaintiffs are seeking to hold drug makers, such as AstraZeneca Pharmaceuticals LP, liable for promoting the use of their products in this manner.

Direct Delivery Systems. The cases involve intra-articular high volume pain pumps that deliver pain medication directly to afflicted areas through flexible plastic catheters. Physicians temporarily implant the catheters into patients following arthroscopic surgery to manage postoperative pain. The procedure complained of in the current lawsuits involved introduction of painkillers directly into the shoulder joint space.

In *Light v. Orthofix International NV*, D. Minn., No. 08-cv-00829, filed 3/21/08; *Hughes v. I-Flow Inc.*, S.D. Ind., No. 08-cv-0272, filed 2/29/08; and *McDaniel v. I-Flow Corp.*, D. Minn., No. 08-cv-00399, filed 2/14/08, plaintiffs alleged that, following shoulder surgery, their physicians attached high-volume pain pumps to the area. Through a catheter implanted under their skin, the pumps injected pain medication directly into the

shoulder joint on a continuous basis for at least 48 hours after surgery, they said.

All three patients developed PAGCL, which is characterized by narrowing of the shoulder joint, extreme pain, increased stiffness, decreased range of motion, and weakening of the joint. A 2007 study published in the *American Journal of Sports Medicine* linked PAGCL to temporary postoperative use of pain pumps. Previous studies had shown that certain painkillers, including bupivacaine and epinephrine, destroy bone tissue, or cartilage. The only treatment for PAGCL is more surgery, the complaints said.

The plaintiffs accused pain pump makers of deceiving physicians and their patients into believing that it was safe to use the drug delivery systems in this manner. "Specifically," the *Light* complaint said, "the Defendants made representations that pain pumps, including their use with continuously injected anesthetic solutions, were safe for use in the shoulder joint following surgery when they knew that such representations were false and unsubstantiated, and considered so by the U.S. Food and Drug Administration."

Drug Companies May Be Liable. Plaintiffs in two cases, *McDaniel* and *Huggins v. Stryker Corp.*, D. Or., No. CV-07-1671, *amended* complaint filed 3/15/08, added claims against the maker of the medications used in the pump. They alleged that AstraZeneca failed to disclose in its labeling for two popular pain medications, Marcaine (bupivacaine) and Sensorcaine, that the drugs had been associated with damage to articular cartilage. Moreover, plaintiffs said, it was foreseeable that the medications would be used with the pain pumps.

Neither the drug companies nor the pump companies had ever tested the devices for use in delivering painkillers directly into the joint space, nor did they warn anyone of potential dangers, plaintiffs alleged. And, given studies linking painkillers to cartilage deterioration, combining the drugs with the direct delivery pump system was "foreseeably fatal" to the shoulder cartilage, according to Robert K. Jenner, of Janet, Jenner & Suggs LLC, Baltimore, who is representing plaintiffs in *Light*, *Hughes*, and *McDaniel*.

Causes of Action. All plaintiffs alleged causes of action for negligence, failure to warn, and strict product liability. The *Light* and *McDaniel* plaintiffs added claims for negligent misrepresentation, fraud, breach of implied warranty, breach of express warranty, and loss of consortium. Only Caleb Huggins—who sued Stryker—asked for a specific amount of damages, asserting that he suffered \$4.5 million in noneconomic damages, expended \$300,000 for past medical expenses, and likely will incur \$750,000 in future medical expenses.

In the only answer filed to date, Stryker Corp. denied liability and asserted that its pain pump was neither dangerous nor defective when used in accordance with its label indications (*Huggins v. Stryker Corp.*, D. Or., No. CV-07-1671-M, answer filed 3/17/08). Among its affirmative defenses, Stryker contended that Huggins's claims are preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 321. Jenner disputed that claim, saying that the U.S. Supreme Court's recent opinion in *Riegel v. Medtronic Inc.*, U.S., No. 06-179, 2/20/08 (2 MELR 134, 2/27/08), does not apply to Class II medical devices such as

painpumps, that are not required to go through the agency's rigorous premarket approval process.

More to Come? The claims filed to date may be only the tip of the iceberg. Jenner told BNA March 26 that his firm has been contacted by thousands of individuals throughout the United States who allegedly suffered injuries as the result of pain pump use. Potentially thousands of lawsuits involving pain pumps could be filed, he said, raising the possibility of consolidation and transfer to multidistrict litigation.

In addition to cases seen in his firm already, Jenner noted that one physician who participated in the sports medicine study reported that 60 percent of his patients reported postoperative problems of the type complained of in the litigation.

Jenner added that these injuries easily could have been avoided. He noted that many cases involve young, active individuals—cheerleaders, athletes, and the like—whose lives have been changed irrevocably as a result of defendants' actions. Not only were the "therapeutic benefits of [the] shoulder surgery [rendered] worthless," as the complaint in *Huggins* alleged, these individuals now face life-long complications, he said.

Physicians involved in the cases are "furious," Jenner added, and feel that they were "duped" by the companies into delivering treatment that has led to more severe, life-long injuries for patients that they tried to help.

In addition to Jenner, the *Light* and *Hughes* plaintiffs are represented by John J. Cord, also of Janet, Jenner & Suggs LLC, Baltimore; and Greg L. Laker, Jeff S. Gibson, and Elizabeth J. Doepken, of Cohen & Malad LLP, Indianapolis. Daniel E. Gustafson and Renae D. Steiner, of Gustafson & Glueck PLLC, Minneapolis, joined the previously mentioned attorneys in representing the *McDaniel* plaintiffs.

On March 19, Dina M. Cox, of Lewis Wagner LLP, Indianapolis, filed an appearance on behalf of defendant I-Flow Inc. in the *Hughes* case.

Michael L. Williams, Leslie W. O'Leary, and Thomas B. Powers, of Williams Love O'Leary & Powers PC, Portland, Ore., and Laura B. Kalur, of Kalur Law Offices, Portland, are representing Caleb Huggins. Representing the Stryker defendants in this case are Jeffrey S. Eden, of Bullivant Houser Bailey PC, Portland, and Kevin R. Costello, Mario Horwitz, and Ralph Campillo, of Sedgwick, Detert, Moran & Arnold LLP, Los Angeles.

Full text of the *Light* complaint is at <http://op.bna.com/hl.nsf/r?Open=rriapi-7d4sei> on the Web.

Full text of the *Hughes* complaint is at <http://op.bna.com/Unsf/r?Open=mapi-7dWav> on the Web.

Full text of the *McDaniel* complaint is at <http://op.bna.com/hl.nsf/r?Open=mapi-7d9ljy> on the Web.

Full text of *Huggins's amended* complaint is at <http://op.bria.com/hl.nsf/r?Open=mapi-7d91kj> on the Web.