

Pain Pump Litigation

By Robert K. Jenner, Baltimore, MD & Ted G. Meadows, Montgomery, AL

Introduction

Anesthetic infusion devices, commonly known as "pain pumps," are medical devices that are used to manage post-operative pain. Surgeons implant these devices following surgery to deliver continuous doses of pain relief medication by way of a catheter. Depending on the device brand and recommendation of the physician, the pump delivers anesthetic pain medication directly into the operative site for a period ranging from 12 hours to a few days.

Surgeons generally recommend using pain pumps to obtain better post-operative surgical pain relief and to eliminate or reduce the amount of narcotics required. The health care staff in the operating room program the type of anesthetic used in the pain pump and the settings for the delivery of the anesthetic. After the pain pump is used, the physician, nurse, or patient can remove the catheter and discard it.

The pain pump is designed for and intended to be used with commonly used anesthetics such as bupivacaine (trade name Marcaine), lidocaine, or ropivacaine, with or without epinephrine, in volumes of 250 cc's or more, depending upon the manufacturer.

Prior to 2000, it was common for

physicians to insert the pain pump catheter directly in the muscle tissue following shoulder surgery. After 2000, doctors began inserting the catheters into the shoulder joint space (synovial space) as well as the subacromial space or rotator cuff area. This was not standard procedure, and the FDA had not cleared or approved the device for this use.

Glenohumeral Chondrolysis

Soon after, reports in the medical literature emerged, describing cases of chondrolysis in patients after shoulder surgery.¹ Glenohumeral chondrolysis is a painful and permanent condition that results from the disintegration of the cartilage covering the bones in the synovial joint. The loss of



Robert K. Jenner



Ted G. Meadows

cartilage causes severe pain, both in movement and at rest, as well as stiffness, a decreased range of motion, and a significant loss of strength. Injured patients usually require additional surgeries, including complete shoulder joint replacement.

Bupivacaine (the medication most frequently used in pain pumps) is known to be cytotoxic to bovine cartilage.² Bupivacaine administered from pain pumps is also toxic to shoulder joints in rabbits.³ The orthopedic specialists who conducted this study were alarmed by the sudden new phenomenon of shoulder chondrolysis in human patients. Their research showed that the continuous infusion of bupivacaine

in rabbits under conditions and doses comparable to those administered to humans using pain pumps causes significant impairment or death of chondrocytes (the cells found in cartilage). If the chondrocytes die, they do not regenerate. Death of chondrocytes leads to complete and permanent loss of cartilage within a few months. Based on these findings, the study's authors cautioned against the use of pain pumps in shoulder joints.

In July 2007, Drs. Brent Hanson and Charles Beck published a review of 12 of their own patients who developed chondrolysis following shoulder surgery between August 2003 and March 2005.⁴

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what would be interesting and helpful to other members. Then submit a short, concise article to us.

One of the goals for the year will be the expansion of the Section membership. If you know an AAJ member who does products liability or who wants to do products work but is not a member, encourage them to join the Section. If any member of your firm is not a member of the Section, a recommendation to join would be appreciated. The Section is a real benefit even to the attorney handling the

occasional products case. For example, we will have a "bring your file" round table discussion at the upcoming Winter and Annual Conventions.

I believe we have a bright future ahead of us. With the upcoming election, we should have a more victim-friendly Congress and hopefully a new administration in Washington that is more concerned about consumers. I encourage and look forward to hearing from any member with comments or suggestions on how to improve the Section and benefit the membership.

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All 12 patients had received pain pumps with infusions of bupivacaine and epinephrine directly into the synovial cavity. The authors noted that they had not experienced chondrolysis in any of their patients before this time frame.

Describing chondrolysis as a “devastating complication” for which there is no effective treatment, the authors found that the incidence of this condition among their patients was “startlingly high.” Of those who received pain pump therapy in the synovial space with bupivacaine and epinephrine, 63 percent developed chondrolysis.⁵ The authors emphasized the importance of this information to the orthopedic community at large and concluded:

We have identified a concerning and strong association between post arthroscopic chondrolysis and intra-articular pain pump catheter use with bupivacaine and epinephrine.... Until further investigation has been done, the author’s recommend that the use of intra-articular pain pump catheters in combination with bupivacaine with or without epinephrine be avoided in all joints with an intact cartilage surface. Furthermore, the effective treatment of chondrolysis remains elusive. We believe that further investigation of the possible association of pain pump use with chondrolysis is warranted.⁶

Drs. Hanson and Beck first presented this data publicly in March 2006, at the annual meeting of the American Academy of Orthopaedic Surgeons.⁷

The Defendants

There are three principal defendant manufacturers of anesthetic pain control infusion devices.

Stryker Corporation

Stryker Corporation is a multinational, publicly traded corporation. On its Web site, www.stryker.com, Stryker describes itself as a “global leader in medical technology that consistently delivers excep-

tional results.” Stryker has over 15,000 employees and claims to be one of the largest players in the orthopedic market.

Stryker is a Michigan corporation with its principle place of business in Michigan. According to the September 30, 2007 10Q quarterly report, Stryker had current assets of almost \$4.5 billion. Net product sales for the first nine months of 2007 were in excess of \$4 billion. According to

Thus, when Stryker obtained the rights to market McKinley’s pain pumps, it knew or should have known that there were no adequate studies to support the safety of pain pumps when used to administer bupivacaine directly, under continuous pressure to the shoulder joint space. More important, Stryker knew or should have known that the FDA had rejected this new proposed use of

“...the company was recently prosecuted for paying orthopedic surgeons hundreds of thousands—if not millions—of dollars for using its hip and knee replacement products exclusively.”

the 2006 annual 10K report, total net sales for 2006 were almost \$5.5 billion.

In October 2000, Stryker purchased the exclusive rights from McKinley Medical, LLP to sell its pain pump products in the United States, Canada, and Mexico. McKinley’s Outbound pain pump and other “substantially equivalent” pumps were FDA approved only for insertion of analgesic and other medications intravenously, intra-arterially, subcutaneously, and epidurally into the muscle, skin, or nerve tissue. Pain pumps were not approved for infusion into the synovial cavity (or “intra-articular joint space”).

In 1998, prior to licensing its product to Stryker, McKinley asked the FDA for permission to let it market its pain pumps for infusion into the synovial cavity. McKinley told the FDA that using the pain pump in this manner posed no harm to the joint space.

In response, the FDA asked McKinley for safety and efficacy studies to support this new marketing claim. Later, the FDA approved labeling indications for the pump to be used for continuous infusion of a local anesthetic “directly into the intraoperative site,” but not into the synovial cavity.

McKinley’s pain pumps.

Stryker’s marketing strategy is especially relevant and important because the company was recently prosecuted for paying orthopedic surgeons hundreds of thousands—if not millions—of dollars for using its hip and knee replacement products exclusively.⁸ Stryker engaged in this illegal scheme from at least 2002 to 2006, during the same timeframe that surgeons began using pain pumps in the shoulder joint.

Did Stryker also pay surgeons to promote its pain pumps exclusively and for unapproved uses? How much did Stryker spend on marketing and financial support to medical providers compared to expenditures on scientific studies to determine the safety of pain pumps and bupivacaine in humans? Did Stryker recruit and/or pay doctors as “consultants” to promote pain pumps to their colleagues at educational seminars? What sorts of written materials did Stryker give to consultants and sales representatives to support the safety of pain pumps in the shoulder joint? These are some of the

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important questions that Stryker, along with the other defendants, must answer.

I-Flow Corporation

I-Flow Corporation was incorporated in the State of California in July 1985. On July 30, 2001, I-Flow changed its state of incorporation to Delaware. Their corporate offices are in California.

The I-Flow family of products is focused on three primary market segments: Regional Anesthesia; Intravenous (IV) Infusion Therapy; and Oncology Infusion Services. I-Flow Corporation's acute pain kit product line includes the ON-Q® PainBuster® Post-Op Pain Relief System, the Soaker™ Catheter, and the C-bloc™ Continuous Nerve Block System. I-Flow has exclusive United States distribution rights to the ON-Q® PainBuster®, and has been selling the Company's products through its direct sales organization since January 1, 2002.

The FDA granted I-Flow permission to use the Soaker™ Catheters (2.5" and 5" versions) for pain management of large surgical incisions in November 1999 and March 2000 respectively. I-Flow's 1" and 10" Soaker Catheters were granted FDA permission for use in January 2005.

According to the 10Q quarterly report for the period ending September 30, 2007, I-Flow Corporation has current assets in excess of \$81 million. Net product sales for the first nine months of 2007 were in excess of \$8 million.

In August, 2007, I-Flow posted material on its Web site regarding the relationship between pain pumps and Chondrolysis. The Technical Bulletin, entitled *What We Know About Chondrolysis Today*, was posted under a physicians tab on the Web site. I-Flow's bulletin downplayed the relationship between pain pumps and chondrolysis. Instead, it pointed to a list of alternative causes for the disease.

While I-Flow claimed to have added a new warning regarding chondrolysis to its ON-Q® pain pump label in 2006, it remains unclear whether the company sent a "Dear Doctor" letter to surgeons

alerting them to this new warning. It also remains unclear whether the company instructed I-Flow sales representatives to make sure that health care providers knew not to insert the pain pump catheters delivering bupivacaine directly into the joint space or whether I-Flow took any steps whatsoever to warn the surgeons and protect the health and safety of the surgeon's patients.

Furthermore, I-Flow's warning did not disclose to doctors the following essential information:

- The FDA never cleared or approved the use of pain pumps to administer medications in a joint space;
- The safety of pain pumps for use in the joint space is unknown and has not been tested or otherwise established through proper studies;
- Medications commonly used in these pumps are reported to be harmful to cartilage; and
- The FDA rejected proposed requests for a new marketing indication for use of pain pumps in the synovial cavity.

In its Technical Bulletin, I-Flow placed the onus on doctors to determine whether and how to use pain pumps in their patients: "As always, the decision on how to treat the patient and what medications to administer belongs exclusively to the physician."⁹ However, by failing to disclose the four critical facts mentioned above, I-Flow effectively prevented doctors from making an educated risk/benefit analysis and avoiding unnecessary harm to their patients.

DJO Incorporated

DJO Incorporated, the manufacturer and/or distributor of the DonJoy® Pain Control Device, is a global provider of solutions for musculoskeletal and vascular health that specializes in rehabilitation and regeneration products for the non-operative orthopedic, spine, and vascular markets. DJO is a Delaware Corporation with its principle place of business in California.

According to the 10Q quarterly report ending September 30, 2007, DJO had current assets in excess of \$173 million. Net revenues for the first nine months of 2007

were in excess of \$350 million.

Causes of Action

Allegations against the manufacturers sound in basic product liability causes of action. An attorney should consider including allegations of negligence, strict liability, warranty, and failure to warn. Claims against the manufacturers may include:

- Commonly used anesthetics likely to be used in their pain pumps, such as lidocaine and marcaine, with or without epinephrine, were harmful to human and animal articular cartilage;
- Use of the pain pump in a joint space had not been approved by the FDA; in fact, this specific use was rejected by the FDA;
- Continuous injection of 250 cc's or more of such medications through a catheter directly into the shoulder joint for two days or more had not been adequately tested for safety or effectiveness;
- The risk of chondrolysis and other serious post-operative problems associated with using the pain pump as designed and instructed outweighed the possible benefits of such use.

Anticipated Defenses Preemption

Defendants will probably raise federal preemption as a defense to these suits. That defense will likely be unsuccessful. Medical device preemption was recently addressed in *Riegel v. Medtronic, Inc.*¹⁰ In *Riegel*, the Supreme Court addressed the issue of whether 21 U.S.C. § 360k(a) preempts state tort-law claims against the manufacturers of medical devices that have received pre-market approval (PMA) under the Medical Device Amendments Act (MDA). The Court, in a 7-1 decision, held that the MDA's preemption clause bars common-law claims challenging the safety or effectiveness of a medical device marketed in a form that received PMA from the FDA. That case evaluated heart devices, which are Class III medical devices approved through the PMA process.

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Pain pumps, however, are Class II medical devices and have been in use since the 1980's. Unlike Class III medical devices, pain pumps did not undergo the rigorous FDA PMA process. Because pain pumps are "substantially equivalent" to devices that already received FDA approval under the PMA process, pain pump manufacturers did not need to submit substantial safety and efficacy data on their products to the FDA prior to putting them on the market. In other

words, the pain pump manufacturers marketed and promoted their products without extensive FDA oversight and approval. Therefore, preemption should not be a viable defense in these cases.

Learned Intermediary

Likewise, learned intermediary is not a viable defense. Until surgeons were warned (and it appears that most have still not been warned), they had no way of knowing this new use of pain medicine was dangerous.

Not only were surgeons denied knowl-

edge of the dangers of using pain pumps in this manner, but they were also strongly encouraged to do so by the device companies. When the manufacturers learned of the specific adverse outcomes of using their pain pumps in this new way, they should have sounded the alarm immediately. Instead, they recklessly pushed this new use of their products to expand their market and make more profits. Because an alarm was never sounded, "Dear Doctor" letters were never sent out, and no attention was called to the problem, many surgeons unknowingly continue, to this day, to use these pumps in this perilous way.

Causation

As is the case in all medical device litigation, lack of causation is always a pled defense. Therefore, it should be noted that there are two suspected causes of chondrolysis based upon recent studies and case reports.

The first suspected cause of chondrolysis, as discussed above, is the use of a high volume pain pump. However, the second way in which shoulder damage can occur complicates the case against the pain pump manufacturers. The damage may occur through a procedure called glenohumeral thermal capsulorrhapy. A 2007 study revealed that eight patients in whom thermal energy was used during arthroscopy developed chondrolysis.¹¹ Concerns about the thermal wand, the device used during the procedure, have been raised since 2001 and the popularity of the procedure has declined since then.

The Good study actually reported that none of the patients received a pain pump after surgery. However, in the Hansen study (discussed previously), only four of the 12 shoulders had received the thermal wand procedure, leading the authors to conclude that there was a strong association between chondrolysis and the use of intra-articular pain pumps.

Conclusion

Currently, these authors know of individual pain pump cases filed in federal



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courts in Indiana, Colorado, Florida, Alabama, and Oregon. There is also a state court filing in Portland, Oregon with trial set on September 22, 2008, and one federal class action pending in Utah.

Attorneys investigating these claims should consider the following:

- Identify the manufacturer of the pain pump. The medical records should have a peel-off sticker placed by the health care provider which identifies the manufacturer of the pain pump. If not there, the records should be scoured to see if a health care provider recorded this information somewhere in the records. Often, the client's memory on this is shaky.
- Ask your client if he received any information from the doctor on the pump. Some doctors provided handouts to the patients that identify the manufacturer. These handouts were generally post-implant instructions.

- Review the medical records to determine if a thermal wand was used. If so, you may be suing more than one defendant for causing the client's shoulder problems.
- Meet with your client's physician. Unlike most pharmaceutical litigation, doctors appear all too eager to assist their patients in this litigation since their patients were irreversibly injured by these devices.
- Have your client evaluated by a vocational rehabilitation expert to determine the extent of the damage and the nature and cost of future care.
- Join AAJ's newly formed Pain Pump Litigation Group.

Robert K. Jenner, Janet, Jenner & Suggs, Woodholme Ctr., Ste. 320, 1829 Reisterstown Rd., Baltimore, MD 21208, T: 410-653-3200, RJenner@medlawlegalteam.com.
Ted G. Meadows, Beasley, Allen, Crow, Methvin, Portis & Miles, P.C., Post Office Box 4160, Montgomery, AL 36103-4160, T: 334-495-1130, ted.meadows@beasleyallen.com

Notes

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11. C. Good et al., *Glenohumeral Chondrolysis After Shoulder Arthroscopy With Thermal Capsulorrhaphy*, 23 *J. Arthroscopic and Related Surgery* 797.e1 (July 2007).



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