IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

BILL B. BROWN, JR.,	)	
	)	
Plaintiff,	)	**File No. _____**
	)	
v.	)	
	)	**COMPLAINT**
STRYKER CORPORATION and	)	**AND JURY DEMAND**
STRYKER SALES CORPORATION,	)	
	)	
Defendants.	)	

NOW COMES the Plaintiff, Bill B. Brown, Jr., by and through his attorneys, and for his Complaint and Jury Demand against the Defendants, alleges and states as follows:

INTRODUCTION

1. Pain pumps are Class II medical devices that surgeons used to manage post-operative pain. Orthopedic surgeons used pain pumps after surgery to deliver, by way of a catheter, continuous doses of pain relief anesthetic for several days directly into the shoulder.

2. The pumps first used in the 1990s had limited amounts of anesthetic, and surgeons placed the pain pump catheter in the muscle or outside the shoulder joint. Over the years, however, the manufacturers increased the anesthetic capacity of the pumps (high volume), and with the knowledge and encouragement of the pain pump manufacturers, surgeons began to insert the catheter directly into the shoulder joint space.

3. Continuous injection of these anesthetics directly into the shoulder joint can cause serious and permanent damage to the shoulder joint cartilage. The damage occurs when the anesthetic kills the chondrocytes (cartilage cells) and causes cartilage to

degenerate progressively. Patients injured by pain pumps develop a condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint. It is an irreversible, disabling, and extremely painful condition. These patients typically require additional surgeries, including complete shoulder joint replacement. As written in the medical literature, "the prognosis for these shoulders is grim."[1]

4. The pain pump companies manufactured and marketed these devices without doing a single study to determine the safety of high-volume pain pumps, or what damage could be caused when physicians placed the catheter directly into the shoulder joint space. Instead, the pain pump manufacturers encouraged orthopedic surgeons to use the pumps and anesthetics, in tandem, in an untested and dangerous manner.

5. Beginning in the late 1990s, the pain pump manufacturers sought approval from the Food and Drug Administration (FDA) for the placement of the pain pump catheter directly in the shoulder joint space (intra-articular).

6. The FDA repeatedly *rejected* applications requesting the pain pump manufacturers' specific orthopedic and intra-articular indications for use.

7. Knowing the pain pumps were not cleared for these uses, the pain pump manufacturers, nevertheless actively promoted the pain pumps for these exact off-label uses through a variety of marketing activities including direct representations made by sales representatives, catheter placement guides, ads, and presentations.

[1] Petty, D.H. *et al*., *Glenohumeral Chondrolysis After Shoulder Arthroscopy*, Am. J. Sports Med. 32:(2)509 (2004).

8. On November 13, 2009 and as updated on February 16, 2010, the FDA made clear that no infusion pump had ever been cleared by FDA to deliver intra-articular infusions of local anesthetics and should not be used for this purpose.

9. The United States Department of Justice is currently investigating at least one pain pump manufacturer for the alleged off-label promotion of its pain pumps.

10. Had the pain pump manufacturers not promoted the products off-label, end users would not have justifiably relied to patients' detriment.

11. Although the FDA *rejected* pain pump manufacturers' applications for orthopedic and intra-articular placement for lack of safety information, pain pump manufacturers chose not to advise physicians about the dangers of using their products in this manner, chose not to advise patients of these risks, chose not to tell physicians that their FDA applications were rejected, and continued to sell and market their pumps with reckless indifference – all to the detriment of thousands of patients generally, and to the detriment of Mr. Brown in particular.

12. On November 13, 2009, the FDA issued a directive in which it noted that pain pumps and the anesthetics used in them were defective for their failure to warn regarding the risk of shoulder chondrolysis and directed pain pump and anesthetic manufacturers to include such warnings. The FDA also noted that the information on dose administration was insufficient in so far as there was no information about maximum daily dose or intra-articular use with pain pumps. Further, the FDA directive confirmed that the intra-articular use of pain pumps was not and never had been approved by the FDA. Although this FDA directive was based upon reported adverse events of

chondrolysis, this information was known or knowable to the pain pump and anesthetic manufacturers.

13. Several safety signals have existed in the literature since at least 1933 and emerged within several pain pump manufacturers' internal files alerting the companies to the risks associated with intra-articular use of their pain pumps.

14. By the time of Mr. Brown's surgery, multiple scholarly studies were published demonstrating the toxic effects of pain pump anesthetics on shoulder cartilage. By at least 2003 surgeons were reporting incidents of chondrolysis after pain pump use. In late 2005 and early 2006, the pain pump industry also knew that Dr. Charles L. Beck, an orthopedic surgeon, had been reporting to the scientific community some very disturbing findings. He found a significant number of his shoulder patients developed chondrolysis following intra-articular placement of a pain pump catheter and he associated these injuries with the use of intra-articular pain pumps.

15. Had the Defendants conducted those studies that the FDA required back in the 1990s, as they were obligated to do, they would easily have determined that exposure to local anesthetics administered through pain pumps over time in the shoulder is exceedingly dangerous and contraindicated. Had they performed the appropriate tests timely, Mr. Brown's physician would not have used a pain pump in the joint space, and Mr. Brown would not have suffered the devastating effects of shoulder chondrolysis.

PARTIES

16. Plaintiff, Bill B. Brown, Jr. (hereinafter sometimes referred to as "Mr. Brown or "Plaintiff"), is a citizen of the State of New York, residing at 1192 Walton Avenue, Apartment C-4, Bronx, New York 10452.

17. Defendants, Stryker Corporation and Stryker Sales Corporation (hereinafter collectively referred to as "Stryker" or "Defendants"), are Michigan corporations with their principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. Stryker designs, manufactures, and develops pain pumps. At all times relevant hereto, Stryker was engaged in Minnesota in the testing, manufacturing, labeling, marketing, distributing, promoting and selling of infusion pain pumps.

JURISDICTION AND VENUE

18. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332. Plaintiff is a resident and citizen of the State of New York and Defendants Stryker Corporation and Stryker Sales Corporation are Michigan corporations and citizens with their principal place of business in Kalamazoo, Michigan. The parties are therefore diverse in citizenship.

19. This Court has personal jurisdiction over Defendants pursuant to M.S.A. § 543.19, in that, at all relevant times described herein, Defendants: (a) transacted business in the state of Minnesota; and/or (b) committed acts in Minnesota causing injury. Defendants are corporations maintaining sufficient minimum contacts with this judicial district to subject the corporations to personal jurisdiction here.

20. Plaintiff's claim for relief exceeds $75,000.00, exclusive of interest and costs, therefore satisfying the amount in controversy requirement.

FACTUAL ALLEGATIONS

A. Case Specific Facts

21. In April of 2006, Plaintiff, Bill B. Brown, Jr., was a 34 year old man living in Orlando, Florida when he consulted with orthopedic surgeon, Randy S. Schwartzberg, M.D., regarding a problem he was experiencing with his left shoulder. On April 4, 2006, Dr. Schwartzberg recommended surgical intervention. Mr. Brown agreed.

22. On May 24, 2006, Mr. Brown underwent arthroscopic surgery on his left shoulder for a SLAP and Bankart repair at the Orlando Regional Medical Center-Lucerne Medical Center. During surgery, Dr. Schwartzberg observed that Mr. Brown's articular cartilage on his left glenoid was in "good condition." Following surgery, Dr. Schwartzberg inserted a "pain pump," specifically a Stryker Pain Pump, PN 500-140, into Mr. Brown's shoulder joint to continuously infuse local anesthetic into the joint space. The pain pump continuously infused 100 mL of 0.5% Bupivacaine plain directly into Mr. Brown's left shoulder joint, for 48 hours or more following his surgery.

23. Initially, Mr. Brown progressed as expected. However, on October 12, 2006 Mr. Brown returned to Dr. Schwartzberg with complaints of pain, clicking and decreased range of motion of his left shoulder. Over the course of several months Dr. Schwartzberg treated Mr. Brown conservatively with a home exercise program, anti-inflammatory and pain medications as well as an injection into the shoulder.

24. After relocating to New York, Mr. Brown established care with internist Darren Esposito, M.D. of Bronx, New York in June of 2009. Still experiencing pain in his left shoulder, Dr. Esposito ordered an MRI and referred Mr. Brown to an orthopedic surgeon for an evaluation and possible treatment.

25. Mr. Brown consulted orthopedic surgeon, Stanley Liebowitz, M.D., at the Orthopaedic Specialists of Greater New York on April 12, 2010. After reviewing the September 4, 2009 MRI, Dr. Liebowitz recommended surgery.

26. On June 1, 2010, Mr. Brown underwent a second arthroscopic surgery of his left shoulder at Beth Israel Medical Center--Petrie Division in Manhattan, New York. Dr. Liebowitz's colleague at Orthopaedic Specialists, orthopedic surgeon Thomas A. Scilaris, M.D., performed the surgery. During surgery, Dr. Scilaris' inspection of the glenohumeral joint revealed "extensive grade 4 glenohumeral articulation changes essentially entire glenoid labrum and humeral head." Dr. Scilaris also observed "central grade 4 cartilaginous changes" and multiple loose bodies and cartilage.

27. A few days after surgery, Mr. Brown returned to Dr. Scilaris for a post-operative examination. Dr. Scilaris informed Mr. Brown that he suffered from "significant bone on bone destruction of the articular cartilage in the glenohumeral joint" and would require additional treatment and surgery in the future. It was also during this visit in June of 2010, that his physician informed him of the association between pain pumps and chondrolysis.

28. The continuous injection of anesthetic drugs over time directly into Mr. Brown's shoulder after his May 24, 2006 surgery subsequently caused him serious and

permanent cartilage damage. As a result, Mr. Brown suffered a narrowing of the joint space and/or a condition called "glenohumeral chondrolysis," which is the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition. Mr. Brown currently has and will continue to have difficulty doing the most basic tasks of everyday living. He will require additional surgeries, including possible shoulder transplants, insertion of an artificial shoulder and/or total shoulder replacements, as a result of the narrowing of the joint space and/or chondrolysis caused by the dangerously defective pain pump. Mr. Brown's daily life is consumed with the devastation of a destroyed shoulder and the prospects of a life of pain and medication. He will suffer lost income, loss of career options, a loss of enjoyment of life, and other damages, all of which were avoidable.

B. Stryker's Misconduct

29. Stryker misled both the medical community and the public at large, including the Plaintiff herein, by promoting its pain pumps for off-label uses that FDA had not cleared.

30. Stryker sought FDA clearance for an indication for use in intra-articular spaces and knew that the FDA refused to approve such an indication for use without a submission of data by Stryker evidencing the safety and effectiveness of such use. On June 5, 2001, FDA cleared Stryker's pain pump application, but without Stryker's request for use in the joint space.

31. Stryker received package inserts from local anesthetic manufacturers, as evidenced by an April 10, 2000 letter from Abbott, and Stryker knew that the local

anesthetics its pain pumps were designed to use had not been approved by the FDA for continuous intra-articular infusion.

32. Stryker's paid consultant, Lonnie Paulos, M.D. advised Stryker in approximately June of 2000 about what Stryker would need to do in order to establish the validity and safety of its pain pumps for orthopedic uses, including patient-controlled trials for efficacy and animal studies for safety, specifically regarding the effect on tissues following orthopedic procedures. Despite this information, Stryker did not undertake the recommended testing.

33. Stryker was informed on July 6, 2000 by its pharmaceutical company contact that it did not have FDA approval for intra-articular use of its pain pumps, and that it would be required to obtain a cumbersome IND (Investigational New Drug) study to obtain approval for intra-articular use.

34. Despite knowing that neither its pain pumps, nor the drugs in them were FDA approved for intra-articular use, Stryker promoted them for this specific indication for use.

35. Stryker disregarded FDA's repeated refusal to approve for intra-articular uses the pain pumps that it marketed by promoting the product off-label through direct representations to end users and promotional materials.

36. Stryker's own consultant Dr. Lonnie Paulos testified on August 15, 2008 that when the Pain Pump first came out, the Stryker sales reps would approach doctors in the operating room and encourage them to use the devices intraarticularly in the knee and shoulder.

37. Stryker also developed and disseminated catheter placement guides, including a spreadsheet indicating the joint space as an area for catheter placement, which was used during sales trainings to illustrate the use of the pain pump in various surgeries.

38. Stryker instructed its sales representatives in its Guide to Selling Pain Pumps to coach surgeons on catheter placement.

39. Stryker further misled both the medical community and the public at large, including the Plaintiff herein, by making false representations about the safety of its products. Stryker downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects associated with the use of its products, despite the existence of information available to Stryker that should have demonstrated that Stryker products were likely to cause serious injuries to product users.

40. Stryker actually and consciously considered whether intra-articular use of its pumps would be safe; however, Stryker conducted no testing to determine whether intra-articular use of its pumps would be safe; nor did Stryker conduct a reasonable search of the available medical literature to see whether common and foreseeably used anesthetics such as Marcaine were toxic to cartilage.

41. In January 2001, without conducting any tests or studies for safety, Stryker made a change to its Pain Pump 1 to 1.5, revision G to increase the size of the reservoir to 270cc. Stryker increased the volume of its pumps because its "customers wanted to be able to infuse more medication when using the Pain Pump."

42. Stryker's own functional specifications for its pain pump listed "medical toxicity" as a "potential company risk" which deserved "more investigation in terms of

all possible drugs intended to use and their indications for use;" yet, Stryker consciously designed its pain pump for intra-articular use without conducting any tests for safety.

43. Stryker had actual knowledge from its customer preference trials of its pain pump that there were concerns about "toxicity" and excessive flow rate that would expose Stryker to litigation.

44. Despite being aware that its pain pumps were unapproved for intra-articular uses, Stryker did not notify physicians that the safety of use of the pain pumps in a joint space was unknown, had not been studied and had not been tested by Stryker; yet, Stryker and its sales representatives promoted its pain pumps for use in the joint space. As Dr. Lonnie Paulos testified on August 15, 2008, Stryker sales reps would approach doctors in the operating room and encourage them to use the devises intraarticularly in the knee and shoulder.

45. As evidenced by internal correspondence dated October 25, 2006, with regard to PainPump 1, 85% of Stryker's business came from orthopedics.

46. Stryker made Mr. Brown and other patients like him unknowing, unwilling and unconsenting test subjects of the safety of intra-articular use of its pumps.

47. Even after Stryker was notified on February 11, 2005 and February 15, 2005 by its own orthopedic consultant of dozens of cases of cartilage injury associated with pain pump use, it did nothing except to continue marketing and sales of its pumps, for well than one year afterwards. Stryker did not enter any of these cases into Stryker's complaint database.

48. Stryker's outrageous conduct, as alleged herein and throughout this Complaint, demonstrates reckless indifference to the rights of others, including Plaintiff, Bill B. Brown, Jr.

49. Stryker was aware that its promotion of its pain pumps for intra-articular and orthopedic use was unapproved; nonetheless, Stryker acted in conscious disregard of that risk by promoting its pain pumps for those uses.

50. Stryker had a subjective and objective appreciation of the risk of harm to which Mr. Brown and others were exposed, including that its pain pumps posed a serious risk of harm to shoulder cartilage.

51. Despite known risks, in addition to promoting off-label uses, Stryker failed to warn of known and/or knowable risks in conscious disregard of the rights and safety of others, including Mr. Brown.

52. At the time of manufacture or distribution of its pain pumps, Stryker had actual knowledge that its pain pumps were defective and that there was substantial likelihood that the defect would cause injury that is the basis of this action, and Stryker willfully disregarded that knowledge in the manufacture or distribution of its pain pumps.

53. Even after Stryker was notified by its own orthopedic consultant of dozens of cases of cartilage injury associated with pain pump use, it did nothing except to continue marketing and selling its pumps, for well over one year afterwards, further corroborating a prolonged course of conduct of wanton, willful, malicious, deliberate, conscious, reckless, and flagrant disregard for the safety, rights, and interests of Mr. Brown and others like him.

54. Stryker's conduct was intentional, reckless, wanton, willful and/or outrageous, and said conduct was committed with gross negligence, deliberate disregard of, and deliberate, callous and reckless indifference to Mr. Brown's rights, interests, welfare and safety. Stryker misled both the medical community and the public at large, including Mr. Brown, by making false representations about the safety of its products. Stryker downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects associated with the use of its products despite available information demonstrating these products were likely to cause serious side effects to the users.

55. Stryker was or should have been in possession of evidence demonstrating that its products caused serious side effects. Nevertheless, it continued to market the products by providing false and misleading information with regard to safety and efficacy.

56. Stryker failed to provide warnings that would have dissuaded medical providers from using the pain pumps and anesthetics thus depriving medical providers and consumers from weighing the true risks against the benefits of using these products.

57. As a direct and proximate cause of Stryker's misconduct, Mr. Brown suffered and will continue to suffer injuries, damages, and losses as alleged herein.

STATUTE OF LIMITATIONS AND FRAUDULENT CONCEALMENT

58. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts by Stryker. Mr. Brown and his physicians

were kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Mr. Brown could not reasonably have known or become aware of the dangerous nature of and the unreasonable adverse side effects associated with the intra-articular use of infusion pain pumps with commonly used anesthetics following shoulder surgeries prior to his post-operative visit with Dr. Scilaris in June of 2010 when he was informed of the association between pain pumps and chondrolysis.

59. Because of Stryker's refusal to conduct appropriate studies to determine the safety of anesthetics on cartilage, and because of its failure to apprise physicians of information it held secretive within its companies, Mr. Brown was deprived of evidence of a causal connection between the injury and Stryker's pain pumps and their negligent acts and omissions until his post-operative visit with Dr. Scilaris following the June 2010 surgery. As such, Stryker fraudulently concealed the existence of a cause of action from Mr. Brown, as illustrated in the paragraphs that follow.

60. Stryker is and was under a continuing duty to disclose the true character, quality, and nature of its pain pumps. Because of Stryker's concealment of the true character, quality and nature of its pain pumps, Stryker is estopped from relying on any statute of limitations defense.

61. Stryker knew that its pumps were not approved for use in joints, and that its pumps were being used in the joint.

a. Stryker attempted to gain FDA approval for use of its pain pump in the joint space on March 28, 2001. At that time, Stryker indicated that it knew

that the FDA had required the original manufacturer of the predicate device for Stryker's pump to remove such an indication from its label.

b. FDA approved Stryker's pump on June 5, 2001, but without the indication for use in the joint space.

62. Undaunted, Stryker fully intended to and did market its pain pumps to orthopedic surgeons, including Mr. Brown's, for use in the joint space, despite FDA's denial of such indication.

a. As indicated in the deposition of Dr. Lonnie Paulos, Stryker fraudulently concealed the dangerous nature of its pain pumps by affirmatively telling orthopedic surgeons that pain pumps could be used in the intra-articular joint space.

b. In July 2000, Stryker met with Purdue Pharma to discuss combining Purdue Pharma's anesthetics with Stryker's pain pumps. During that meeting, Stryker informed Purdue Pharma that Stryker's pain pumps were to be used in the joint space. In response, Purdue Pharma informed Stryker that its anesthetics were not approved for intra-articular injection. Stryker fraudulently concealed this fact from consumers and the medical community when it marketed its pain pumps to orthopedic surgeons for continuous infusion of local anesthetics into the joint space.

c. Stryker continued to unlawfully market its pain pumps even after consumer preference trials indicated in October 2000 that surgeons were concerned about toxicity.

63. As early as 2001, Stryker fraudulently concealed the dangerous nature of its pain pumps by withholding the information regarding FDA's denial of the orthopedic or intra-articular indications from its sales representations, its research and development personnel, its operations management personnel, its regulatory quality personnel, its plant management personnel, its engineering personnel, its marketing personnel and its product management personnel. Stryker withheld this information knowing that its pumps were being designed and marketed for use in the joint space. For example, in 2001, Danielle Lopez, a Stryker marketing associate, retyped a spreadsheet she received upon taking her position that indicated the glenohumeral joint space as an area for catheter placement. She then used that spreadsheet during sales trainings to illustrate how to use the pain pump in various surgeries.

64. Stryker's marketing product manager knew that doctors were using the pain pump intra-articularly in 2003 and 2004, and at least some of Stryker's regulatory personnel knew that this was not a cleared indication for use.

65. On November 3, 2005, in an attempt to conceal the dangerous nature of its pain pumps from consumers and the medical community, Stryker provided false and misleading information to FDA in response to FDA's request for information about chondrolysis, in that Jennifer Hoffman, Stryker's Regulatory Affairs Representative misrepresented that there had only been 7 reported events of chondrolysis associated with the use of pain pumps when in fact, Ms. Hoffman and Stryker had known since February 2005 of as many as 30 events of chondrolysis associated with the use of pain pumps. For example,

a. In 2003, Stryker sales representative and later sales manager, Don Kelley was informed by a physician and Stryker consultant, Dr. Lonnie Paulos, of injury to a patient's joint that was associated with the patient's use of a pain pump.

b. On August 11, 2005, Dr. Charles Beck notified Stryker of 13 patients with post shoulder surgery chondrolysis with Stryker pain pumps.

c. On February 11, 2005, Dr. Paulos informed Brady Shirley, Vice President of Sales, of additional cases of chondrolysis and warned that Stryker should consider changing its label.

d. On February 15, 2005, Dr. Paulos informed Stryker that he knew of at least 30 cases of chondrolysis associated with the use of pain pumps.

66. Stryker fraudulently concealed the dangerous nature of its pain pumps from consumers and the medical community when Steven Docsa, Stryker's Clinical Monitor, affirmatively stated on March 3, 2005 that Stryker should do nothing in response to physician reports of chondrolysis and Stryker's own consultant, Dr. Paulos', suggestion that Stryker undertake an animal study to test the safety of its pumps on cartilage. Docsa took this position despite the suggestion by other personnel, including Jennifer Hoffman, that the complaints should be entered into Stryker's quality assurance system, SuPER, and despite Stryker's policies and procedures, which required that complaints, even if they did not meet FDA's reporting requirements should be entered into SuPER.

67. Stryker's policies and procedures, and federal law, required Stryker to follow-up and investigate the injuries reported by Dr. Paulos, including getting specific

information, including dates of events, the specific injury, how the product was being used, how the patient was doing, and if follow-up treatment was needed. However, Stryker failed to respond to Dr. Paulos' communications.

68. Stryker attempted to further conceal the dangerous nature of its pain pumps when on January 19, 2006 Ms. Hoffman contacted Dr. Beck regarding a study Dr. Beck was publishing regarding the association of pain pumps and chondrolysis. At that time, Ms. Hoffman asked Dr. Beck if he could emphasize that the pump were not the cause of chondrolysis. Ms. Hoffman's intent, as documented affirmatively in the communication to Dr. Beck was to deflect the cause of chondrolysis from the Stryker PainPump. Dr. Beck responded that his professional opinion was that it was the combination of volume, pressure, and medication that were implicated.

69. Stryker fraudulently concealed the dangerous nature of its pain pumps in October 2006 when Stryker sales managers failed to provide information to Stryker sales reps that was contained within a document circulated by Stryker personnel who attended two medical conventions discussing the association between chondrolysis and pain pumps. The document, or "hot sheet," noted that pain pumps were indicated for infusion only through particular routes, not including intra-articular, and advised readers to discuss this information with customers. Stryker sales managers never distributed the information to its sales reps.

70. In November 2006, Stryker prepared a form letter to doctors regarding chondrolysis, however, the letter mischaracterized the dangers of the pain pump when used in the joint space by indicating that no clinical studies directly linked the pain

pumps to chondrolysis. The letter failed to state that the FDA, for lack of safety, never would have approved such a study, as there was already extant literature suggesting that such use was unsafe. The letter also mischaracterized Stryker's pain pumps by stating that the pumps were not indicated for intra-articular delivery without stating that such use had been specifically denied by the FDA. Finally, Stryker did not send the letter out to physicians unless a physician requested it. In fact, the Stryker employees tasked with sending the letters out cannot recall whether any letters actually were sent.

71. In December 2006, Stryker held a training for new sales reps and in that meeting did not inform the new reps that pain pumps were not cleared for use in the joint space, despite the fact that Stryker knew that its representatives were present in the operating rooms, prepared the pain pumps for the surgeons, and instructed the surgeon on how to use the pump.

72. In October 2007, Stryker fraudulently concealed the dangerous nature of its pain pumps by indicating on its package insert that animal and in vitro studies suggested a relationship between local anesthetics and chondrocyte toxicity; but, then proceeded to undermine that information by stating that no clinical studies have shown such toxicity. Further, Stryker did not recall any of its existing labels.

73. To date, Stryker sales representatives are not aware of any warning from Stryker to doctors against placing the catheter in the joint space.

CAUSES OF ACTION
COUNT I -- NEGLIGENCE

74. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

75. At all times relevant to this action, Stryker had a duty to exercise reasonable care, and to comply with the existing standards of care, in its preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the pain pumps and the anesthetics used in the pumps, which Stryker introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

76. At all times relevant to this action, Stryker had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of pain pumps and the anesthetics used in the pumps.

77. At all relevant times, Stryker knew or reasonably should have known that the pain pumps were unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

a. Commonly used anesthetics likely to be used in its pain pumps, such as Marcaine with or without epinephrine, were harmful to human and animal articular cartilage when infused continuously over time;

b. Use of the pain pump to deliver local anesthetic to or near the joint space had not been cleared by the FDA, and in fact, had been specifically rejected by the FDA;

c. Continuous injection of high volumes of such medications, through a catheter, directly into the joint space, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using the pain pump as designed and instructed outweighed the possible benefits of such use.

78. Based on what Stryker knew or reasonably should have known as described above, it deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

a. In failing to conduct those tests and studies necessary to determine that the use of pain pumps directly into the shoulder was dangerous to shoulder cartilage and contraindicated for use;

b. In failing to instruct or warn the medical community that the safety of the pain pump with continuously injected anesthetic had not been established for use in the shoulder;

c. In failing to disclose to the medical community that continuous injection of commonly used anesthetics such as sensorcaine, with or without epinephrine, over two days or more, into the shoulder, may cause serious and permanent injury to the joint cartilage;

d. In failing to include a precaution against placing the catheter of the pain pump in the shoulder;

e. In failing to provide to the medical community adequate instructions for the safe use of the devices with continuously injected anesthetics;

f. In failing to disclose to the medical community that the effectiveness of pain pumps with continuously injected anesthetic was uncertain for use in the shoulder;

g. In failing to disclose to the medical community that no tests had been ever done to determine the safety of using the pain pump in the shoulder;

h. In negligently misrepresenting and failing to disclose, in the course of its business, material facts concerning the risks it pain pumps and anesthetics posed to patients, particularly those using the products for pain relief following shoulder surgery;

i. Manufacturing a product to be used with continuously injected anesthetic, designed to directly inject into the shoulder commonly used anesthetics associated with damage to articular cartilage;

j. Manufacturing a product designed to deliver, over time, dangerously high doses of anesthetic drugs directly into shoulder tissue; and

k. Promoting pain pumps and continuously injected anesthetics for use in the shoulder joint space after the FDA had considered and rejected such an indication.

79. Stryker violated statutes, rules and ordinances concerning the manufacturing, marketing, and/or testing of its pain pumps.

80. At all relevant times, Stryker knew or reasonably should have known that the anesthetics used in the pain pumps were unreasonably dangerous and defective when used as directed and designed, including but not limited to the following particulars:

a. Commonly used anesthetics likely to be used in its pain pumps, such as Marcaine with or without epinephrine, were harmful to human and animal articular cartilage when infused continuously over time;

b. Use of the pain pump to deliver local anesthetic to or near the joint space had not been cleared by the FDA, and in fact, had been specifically rejected by the FDA;

c. Continuous injection of high volumes of such medications, through a catheter, directly into the joint space, for two days or more, had not been adequately tested for safety or effectiveness; and

d. The risk of narrowing of the joint space, chondrolysis and other serious post-operative problems associated with using the pain pump as designed and instructed outweighed the possible benefits of such use.

81. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Mr. Brown that would not have occurred but for the use of the product.

82. The injuries and damages suffered by the Mr. Brown was the reasonably foreseeable result of Stryker's negligence.

83. Stryker under-reported, underestimated and downplayed the serious danger of intra-articular pain pumps.

84. Despite the fact that Stryker knew or should have known that intra-articular use of pain pumps following shoulder surgeries caused unreasonably dangerous side effects, Stryker continued to market, manufacturer, distribute and/or sell the pain pumps to consumers, including Mr. Brown.

85. Had Stryker performed those tests and studies necessary to determine that pain pumps and their anesthetics should not be used directly in the shoulder before Mr. Brown's physician used a pain pump following his surgery, as it was required to do, Mr. Brown would not have developed chondrolysis and suffered the injuries and damages described with particularity above.

86. Stryker is directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents, who include, but are not limited to, its sales representatives. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Mr. Brown.

87. Stryker knew or should have known that consumers like Mr. Brown would foreseeably suffer injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

88. As a direct and proximate cause of Stryker's negligence, Mr. Brown suffered the permanent loss of cartilage in his shoulder, resulting in severe pain and discomfort of the shoulder, loss of use and function of the shoulder and arm, and requiring additional surgical intervention. Mr. Brown will also require future medical care, including physical therapy, pain management, additional shoulder surgeries as he

ages, including but not limited to, joint and/or shoulder replacements. In addition, Mr. Brown has suffered mental distress and anguish and suffered permanent impairment of the use and function of his affected upper extremities, and other damages.

COUNT II -- NEGLIGENT MISREPRESENTATION

89. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

90. Stryker and its sales representatives, in the course of its business, negligently misrepresented and failed to disclose material facts concerning the risks that its pumps and anesthetics posed to patients, particularly those using the products for pain relief following shoulder surgery.

91. Stryker and its sales representatives made material misrepresentations and concealments to Dr. Schwartzberg when they marketed their product to him but failed to provide any warning that their pain pumps were neither cleared nor approved for orthopedic or intra-articular use, or provide any other warning to him regarding the risks to cartilage as a result of placing a pain pump into his patients' shoulder joints following shoulder surgeries.

92. Stryker knew or should have known, under the circumstances, that those misrepresentations were false.

93. Those misrepresentations and concealments by Stryker were made with the intent to advertise, market, and sell pain pumps and anesthetics off-label.

94. Stryker failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information to Mr. Brown and his physicians, and failed to comply with the existing standard of care.

95. Stryker is directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents, who include, but are not limited to, its sales representatives. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Mr. Brown.

96. Mr. Brown and his physicians justifiably relied on the misrepresentations and concealments, and as a direct and proximate result of such reliance, Mr. Brown suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT III -- FRAUD

97. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

98. Stryker blatantly and intentionally distributed false information, including but not limited to assuring the public, Mr. Brown, his physicians, hospitals, and healthcare professionals that the pain pumps and/or bupivacaine products were safe for its intended use in the shoulder joints.

99. Stryker had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as his healthcare providers.

100. Stryker and its agents and sales representatives knowingly, intentionally, directly and/or impliedly made material misrepresentations to Mr. Brown, his physicians, and to the public that pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries, such as Mr. Brown's. Plaintiff does not allege fraud on the FDA.

101. The representations by Stryker's agents and sales representatives were in fact false, as pain pumps and the anesthetics used in the pumps were not safe for human use following shoulder surgeries, and instead proximately caused narrowing of the joint space, glenohumeral chondrolysis and other injuries and/or adverse side effects.

102. Stryker was aware since at least June 5, 2001 that FDA had not cleared its pain pumps for use in the joint space because it then received approval from FDA to market the pain pumps without the specific indication for use intra-articular included.

103. Stryker was aware since at least April 10, 2000 based on a letter from Abbott Laboratories that the local anesthetics Stryker's pain pumps were designed to use had not been approved by the FDA for continuous intra-articular infusion.

104. This was confirmed on July 6, 2000 by its pharmaceutical company contact that it did not have FDA approval for intra-articular use of its pain pumps, and that it would be required to obtain a cumbersome IND (Investigational New Drug) study to obtain approval for intra-articular use.

105. Despite knowing that neither its pain pumps, nor the drugs in them were FDA approved for intra-articular use, Stryker promoted them for this specific indication for use.

106. Stryker marketed these products off-label through direct representations to end users and promotional materials.

107. Stryker's own consultant Dr. Lonnie Paulos testified on August 15, 2008 that when the Pain Pump first came out, the Stryker sales reps would approach doctors in the operating room and encourage them to use the devices intraarticularly in the knee and shoulder.

108. Stryker also developed and disseminated catheter placement guides, including a spreadsheet indicating the joint space as an area for catheter placement, which was used during sales trainings to illustrate the use of the pain pump in various surgeries.

109. Stryker instructed its sales representatives in its Guide to Selling Pain Pumps to coach surgeons on catheter placement.

110. Stryker further misled both the medical community and the public at large, including the Plaintiff herein, by making false representations about the safety of its products. Stryker downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects associated with the use of its products, despite the existence of information available to Stryker that should have demonstrated that its products were likely to cause serious injuries to product users.

111. When Stryker's agents and sales representatives made the foregoing representations they knew those representations were false, deceptive, and misleading, and they made those false representations with the intent to defraud, deceive, and mislead.

112. Mr. Brown, his physicians, and the public justifiably relied upon the foregoing misrepresentations and reasonably believed the misrepresentations to be true, and in justifiable reliance upon these misrepresentations, were induced to prescribe and use its pain pumps and the continuously injected anesthetics.

113. At the time the representations were made, Mr. Brown and/or his healthcare providers did not know the truth, with regard to the dangerous and serious health and/or safety concerns of the pain pumps.

114. Had Mr. Brown known the true facts with respect to the dangerous and serious health and/or safety concerns of the pain pumps, Mr. Brown would not have purchased, used and/or relied on Stryker's pain pumps.

115. Stryker's aforementioned conduct constitutes fraud and was committed and/or perpetrated willfully, wantonly and/or purposely on the Plaintiff.

116. Stryker is directly liable for the negligent and/or fraudulent conduct of its actual and/or ostensible employees, servants, and agents, including, but are not limited to, its sales representatives. The negligent and/or fraudulent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Mr. Brown.

117. As a result of the fraud of Stryker's agents and sales representative, Mr. Brown suffered and will continue to suffer injuries, damages and losses as alleged herein.

118. Stryker's reckless and intentional concealment from Mr. Brown and his physicians that pain pumps and the anesthetics used in the pumps were not safe for

human use following shoulder surgery, and cause narrowing of the joint space and/or glenohumeral chondrolysis, was oppressive, extreme, malicious, fraudulent, and outrageous conduct in that such conduct was and is so outrageous in character and so extreme in degree that it goes and went beyond all possible bounds of decency and is atrocious and utterly intolerable in a civilized community.

119. As a direct and proximate result of Stryker's outrageous conduct, Mr. Brown suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT IV -- STRICT PRODUCTS LIABILITY

120. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

121. Stryker placed its pain pumps into the stream of commerce.

122. Mr. Brown purchased and/or ultimately obtained a pain pump from Stryker.

123. Mr. Brown was given the pain pump as prescribed by his physicians in a manner that Stryker intended its products to be used.

124. Stryker's pain pumps were defective and unreasonably dangerous when they entered the stream of commerce such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

125. Stryker's pain pumps were defective in design and/or formulation because, when they left Stryker's hands, the foreseeable risks of use following shoulder surgery exceeded the benefits associated with the design and/or formulation.

126. The pain pumps were expected to and did reach Mr. Brown without substantial change in condition. Alternatively, the pain pumps manufactured and/or supplied by Stryker were defective in design or formulation because when they left Stryker's hands, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect.

127. The pain pumps were defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of such studies.

128. The pain pumps were defective due to inadequate pre- and post-marketing warning or instruction because, after Stryker knew or should have known of the risk of injury from its products, it failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

129. The pain pumps manufactured, distributed, tested, sold, marketed, advertised and represented defectively by Stryker were a substantial factor in bringing about Mr. Brown's injuries that would not have occurred but for the use of the product.

130. As a direct and proximate result of the defective condition of Stryker's products, Mr. Brown suffered and will continue to suffer injuries, damages, and losses as alleged herein.

COUNT V -- STRICT LIABILITY – FAILURE TO WARN

131. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:

132. Stryker manufactured pain pumps and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.

133. Stryker's products were defective due to inadequate warning and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting regarding the results.

134. Stryker's pain pumps and anesthetics were defective due to inadequate post-marketing warning or instruction because, after Stryker knew or should have known of the risk of injury from its pain pumps and anesthetics, Stryker failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

135. The defective warnings were a substantial factor in bringing about the injuries to Ms. Brown that would not have occurred but for the use of the product.

136. As a direct and proximate cause of the defective condition of Stryker's products, specifically its failure to warn and its other negligence, carelessness, and other wrongdoing and actions described herein, Mr. Brown suffered those injuries and damages as described with particularity above.

COUNT VI – BREACH OF IMPLIED WARRANTY

137. Plaintiff incorporates by reference all other paragraphs of this Amended Complaint as if fully set forth herein at length, and further alleges:

138. Stryker placed its pain pumps into the stream of commerce.

139. Mr. Brown purchased and/or ultimately obtained a pain pump from Stryker.

140. Mr. Brown was given a pain pump as prescribed by his physicians in a manner that Stryker intended its products to be used.

141. Stryker impliedly warranted that its pain pumps were of merchantable quality and safe and fit for the use for which they were intended.

142. Stryker breached its implied warranty in that its pumps were defective and unreasonably dangerous when they entered the stream of commerce such that the foreseeable risks exceeds the benefits associated with the design and/or formulation of the products.

143. Stryker breached its implied warranty in that its pain pumps were defective in design and/or formulation because when they left Stryker's hands, the foreseeable risks of use following shoulder surgery exceeded the benefits associated with the design and/or formulation.

144. The pain pumps were expected to and did reach Mr. Brown without substantial change in condition. Alternatively, the pain pumps manufactured and/or supplied by Stryker were defective in design or formulation because when they left Stryker's hands, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect.

145. The pain pumps were defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of such studies.

146. The pain pumps were defective due to inadequate pre- and post-marketing warning or instruction because, after Stryker knew or should have known of the risk of

injury from its products, it failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

147. Stryker's breach of implied warranty, including the fact that the pain pumps were manufactured, distributed, tested, sold, marketed, advertised and represented defectively by Stryker, was a substantial factor in bringing about Mr. Brown's injuries that would not have occurred but for the use of the product.

148. Stryker's breach of implied warranty with respect to its defective warnings were a substantial factor in bringing about the injuries to Mr. Brown that would not have occurred but for the use of the product.

149. Mr. Brown relied on the skill and judgment and implied warranty of Stryker that its pain pumps were of merchantable quality and safe and fit for the use for which they were intended.

150. Contrary to Stryker's implied warranty, its pain pumps were not of merchantable quality and were neither safe nor fit for the use for which they were intended, in that they had serious risks of harm and dangerous propensities when put to their intended use, and would instead cause severe injuries to users of the pain pumps, including Mr. Brown.

151. As a result of Stryker's breach of implied warranty, Mr. Brown suffered and will continue to suffer injuries, damages, and losses as alleged and described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Stryker Defendants as follows:

1. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For compensatory and other damages according to proof;

3. For punitive damages according to proof;

4. For disgorgement of profits according to proof;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest and the costs of suit; and

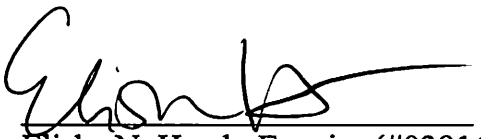
7. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a jury trial on all claims so triable in this action.

Dated: October 24, 2011

JANET, JENNER & SUGGS, LLC



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