IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOSEPH E. SASSER 1733 Noma Road Slocomb, Alabama 36375	**Case No**. _____
CHARLES G. SASSER and **DANA J. SASSER,** individually and as natural parents of **JOSEPH E. SASSER** 735 Wrights Road Slocomb, Alabama 36375	**Judge** _____
Plaintiffs,	**COMPLAINT** **JURY TRIAL DEMANDED**
v.	
I-FLOW, LLC **f/k/a I-FLOW CORPORATION** 20202 Windrow Drive Lake Forest, California 92630	
SERVE: CT Corporation System 818 West Seventh Street Los Angeles, California 90017	
Defendant.	

NOW COME the Plaintiffs, Joseph E. Sasser and his parents, Charles Sasser and Dana Sasser, individually and as natural parents of Joseph E. Sasser, by and through their attorneys, and for their Complaint against the Defendant, I-Flow, LLC, formerly known as I-Flow Corporation, allege and state 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 were first used in the 1990s by general surgeons. They used infusion pumps for chemotherapy and other intravenous fluids for patients who could not tolerate such infusions at home. In the late 1990s, however, the pain pump manufacturers recognized that the orthopedic surgery market had virtually untapped financial potential, and manufactures began developing a pump that would deliver regional anesthetics such as Marcaine for use during orthopedic surgeries.

3. Continuous injection of these anesthetics directly into any joint can cause serious and permanent damage to the cartilage contained therein. The damage occurs when the anesthetic kills the chondrocytes (cartilage cells) and causes cartilage to degenerate progressively. Patients injured by pain pumps develop a signature condition called "chondrolysis," which is the complete or nearly complete loss of cartilage in the 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 whether it was safe for physicians to dispense large volumes of anesthetics via catheters directly into the shoulder joint. 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).

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

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.

8. Had the pain pump manufacturers not promoted the products off-label, physicians would not have justifiably relied on these misrepresentations to the detriment of patients nationwide.

9. Although the FDA *rejected* pain pump manufacturers', including I-Flow's, applications for orthopedic and intra-articular placement for lack of safety information, pain pump manufacturers chose not to advise physicians and patients that the risks of placing large doses of anesthetics in the shoulder joint had never been tested; chose not to tell physicians and patients that their FDA applications were rejected; and continued to sell and market their pumps with reckless indifference to the risk – all to the detriment of thousands of patients generally, and to the detriment of Mr. Sasser in particular.

10. On November 13, 2009 and as updated on February 16, 2010, 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 the 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.

11. 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.

12. By the time of Mr. Sasser'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 that 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.

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

14. The United States Department of Justice is currently investigating at least four pain pump manufacturers for the alleged off-label promotion of its pumps.

JURISDICTION & VENUE

15. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. § 1332. Plaintiffs Joseph E. Sasser and his parents Charles and Dana Sasser are residents and citizens of the State of Alabama and Defendant I-Flow, LLC is wholly-owned by Kimberly-Clark Corporation. Kimberly-Clark Corporation is a citizen of Delaware, Texas, and Wisconsin. Kimberly-Clark Corporation is incorporated in Delaware with its principal offices located in Texas and Wisconsin. The parties are therefore diverse in citizenship.

16. This Court has personal jurisdiction over the Defendant pursuant to D.C. Code § 13-334 (a) because Defendant has enjoyed the benefit of systematic and continuous business contacts with the District of Columbia.[2] Upon information and belief, I-Flow's continuous business contacts within this jurisdiction included but was not limited to the following:

a. I-Flow used prominent Washington D.C. hospitals and doctors to endorse its products.

b. I-Flow hosted dinners at national meetings of orthopedic surgeons held in Washington, D.C. with attendance of orthopedic surgeons from all over the country, in which I-Flow promoted the intra-articular use of its pain pumps.

c. I-Flow had sales representatives marketing its products in the District of Columbia.

d. I-Flow advertised in national journals that were disseminated in the District of Columbia.

[2] See Mem. Op., *Marshall v. I-Flow, LLC*, CIV. A. 12-82 JEB, 2012 WL 1372103, at * 4-5 (D.D.C. April 20, 2012).

e. I-Flow had representatives in healthcare clinics, hospitals and physicians' offices in the District of Columba where they demonstrated to physicians how to use their pain pump products.

Thus, I-Flow has maintained sufficient minimum contacts with this judicial district to subject the corporation to general personal jurisdiction here.

17. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

18. As this Court has personal jurisdiction pursuant to D.C. Code § 13-334(a), venue is also proper here under 28 U.S.C. § 1391(a)(1).[3]

PARTIES

19. Plaintiff, Joseph E. Sasser (hereinafter sometimes referred to as "Mr. Sasser" or "Plaintiff"), is a citizen of the State of Alabama residing at 1733 Noma Road, Slocomb, Alabama, 36375.

20. Plaintiffs, Charles G. Sasser and Dana J. Sasser (hereinafter sometimes referred to as "parents"), are also citizens of the State of Alabama residing at 735 Wrights Road, Slocomb, Alabama, 36375. Charles and Dana Sasser are the natural parents of Joseph E. Sasser, who was a minor at the time of the alleged injury. Charles and Dana Sasser were, at all times relevant hereto, required to care for the needs and necessities of their minor child, Joseph E. Sasser, which included his medical care and attention.

21. Defendant, I-Flow, LLC (f/k/a I-Flow Corporation and hereinafter referred to as "I-Flow" or "Defendant") is a company organized under the laws of the State of Delaware, with its principal place of business at 20202 Windrow Drive, Lake Forest, California 92630. I-Flow

[3] See Mem. Op., *Marshall v. I-Flow, LLC*, CIV. A. 12-82 JEB, 2012 WL 1372103, at * 5 (D.D.C. April 20, 2012).

is wholly-owned by Kimberly-Clark Corporation. Kimberly-Clark Corporation is a citizen of Delaware, Texas, and Wisconsin. I-Flow designs, manufacturers, and develops pain pumps. At all times relevant hereto, I-Flow has conducted regular and sustained business in the District of Columbia by selling and distributing its products in the District of Columbia, for example:

a. I-Flow has actively sought and enjoyed profits from sales of its pain pumps to every major Washington, D.C. hospital, including George Washington University Hospital, George Washington University Medical Center, Georgetown University Hospital, Howard University Hospital, Washington Hospital Center, Walter Reed Army Medical Center and Sibley Memorial Hospital.

b. I-Flow has enjoyed the benefit of soliciting and obtaining the expert medical consulting services of prominent Washington, D.C. medical facilities and physicians, including those of George Washington University.

c. I-Flow's continental U.S. Sales are organized into 18 sales "regions," many of which encompassed several states, but I-Flow devotes an entire region to sales in Washington, D.C.

d. I-Flow has established and benefits from a partnership with the George Washington University Hospital, by which the hospital explicitly endorses I-Flow's Pain Pump on the hospital's website, including for use in orthopedics.

FACTUAL BACKGROUND

A. Case Specific Facts

22. On April 18, 2005, Plaintiff, Joseph Sasser, was a 15 year old high school student and competitive athlete living with his parents, Charles and Dana Sasser, in Slocomb, Alabama.

Mr. Sasser and his parents consulted with orthopedic surgeon, R. Bruce Hall, M.D. of Enterprise, Alabama, regarding a problem Mr. Sasser was experiencing with his right shoulder. After discussing operative and non-operative treatment options with Dr. Hall, Mr. Sasser's parents consented to surgical intervention.

23. On May 2, 2005, Mr. Sasser underwent arthroscopic surgery on his right shoulder for Bankart repair at Flowers Hospital in Dothan, Alabama. Following surgery, Dr. Hall inserted a "pain pump," specifically, an I-Flow ON-Q PainBuster, REF: PM012, LOT: 4C2811, into Mr. Sasser's shoulder for post operative pain relief. The ON-Q PainBuster continuously infused 100 ml of 0.5% Marcaine directly into Mr. Sasser's right shoulder joint for 48 hours or more following his surgery.

24. After surgery, Dr. Hall treated Mr. Sasser conservatively with physical therapy and a home exercise program.

25. Mr. Sasser initially progressed as expected; however, after a period of time, he began to experience increased pain, crepitus, grinding and decreased range of motion in his right shoulder. An MRI taken of Mr. Sasser's right shoulder on November 30, 2010 showed degenerative changes in Mr. Sasser's right shoulder joint. During this time, Mr. Sasser was an active duty service member with the United States Navy residing in Connecticut.

26. On December 8, 2010, Mr. Sasser was evaluated by orthopedic surgeon, Harlan C. Taliaferro, M.D. of Waterford, Connecticut. Dr. Taliaferro recommended surgery.

27. Mr. Sasser then relocated to North Carolina.

28. Upon relocating to North Carolina, on April 14, 2011 Mr. Sasser had an MR arthrogram taken of his right shoulder. Results from the MR arthrogram revealed extensive loss of cartilage throughout the glenohumeral joint.

29. On May 13, 2011, Mr. Sasser presented to orthopedic surgeon, Barton S. Arthur, M.D. of New Bern, North Carolina, for evaluation and possible treatment. At that time, Mr. Sasser advised Dr. Arthur of the ongoing pain and crepitus of his right shoulder. After evaluating Mr. Sasser, Dr. Arthur and Mr. Sasser discussed treatment options and Mr. Sasser agreed to arthroscopic surgery.

30. On June 9, 2011, Mr. Sasser underwent surgery at CarolinaEast Health System in New Bern. During surgery, Dr. Arthur noted "severe chondromalacia" in the right shoulder.

31. The continuous injection of anesthetic drugs over time directly into Mr. Sasser's shoulder joint after his May 2, 2005 surgery caused him serious and permanent cartilage damage. As a result, Mr. Sasser 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. Sasser currently has and will continue to have difficulty doing the most basic tasks of everyday living. He will require additional surgeries, including 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. Sasser'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.

32. In addition, Mr. Sasser's parents Charles and Dana Sasser, have incurred, and may occur in the future, expenses for the medical, surgical, therapeutic rehabilitative, and additional care and other needs and expenses for their son, Joseph. Mr. and Mrs. Sasser have suffered and will continue to suffer injuries, damages and losses as alleged herein.

B. I-Flow's Misconduct

33. I-Flow misled both the medical community and the public at large, including Mr. Sasser, his parents, and his orthopedic surgeon, by making false representations about the safety and proper use of its products. I-Flow 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.

34. I-Flow actually and consciously considered whether intra-articular use of its pumps would be safe; however, I-Flow conducted no testing to determine whether intra-articular use of its pumps would be safe; nor did I-Flow conduct a reasonable search of the available medical literature to see whether common and foreseeably used local anesthetics, such as Marcaine with or without epinephrine, were toxic to joint cartilage.

35. I-Flow 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 data showing safety and effectiveness.

36. I-Flow did not notify physicians that the safety of pain pumps in a joint space was unknown, had not been studied and had not been tested by I-Flow; yet, I-Flow and its sales representatives promoted its pain pumps for use in the joint space.

37. I-Flow made Mr. Sasser and other patients like him unknowing, unwilling and unconsenting test subjects of the safety of intra-articular use of its pumps.

38. I-Flow's outrageous conduct, as alleged herein and throughout this Complaint demonstrates reckless indifference to the rights of others, including Mr. Sasser and his parents.

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

40. I-Flow had a subjective and objective appreciation of the risk of harm to which Mr. Sasser and others were exposed, including that its pain pumps posed a serious risk of harm to shoulder cartilage.

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

42. At the time of manufacture or distribution of its pain pumps, I-Flow 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 I-Flow willfully disregarded that knowledge in the manufacture or distribution of its pain pumps.

43. Even after I-Flow was notified by its Territory Manager, Cheryle Pritchard, of several cases of cartilage injury associated with pain pump use, it did nothing except to continue marketing and selling its pumps to orthopedic surgeons for intra-articular pain relief, and even pulled down a technical bulletin that would have advised of the risks of cartilage damage associated with its pain pumps, and kept it down ten months while I-Flow executives, including then-CEO, Donald Earhart, exercised their stock options, 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. Sasser, his parents and others.

44. I-Flow'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. Sasser and his parents' rights, interests, welfare and safety. I-Flow misled both the medical community and the public at large, including Mr. Sasser and his parents, by making false representations about the safety of its products. I-Flow 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.

45. I-Flow 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.

46. I-Flow 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.

47. On May 28, 1998, the FDA approved I-Flow's PainBuster Infusion System for intraoperative use in the soft tissue or body cavity. However, for lack of safety, the FDA denied I-Flow's requests for intra-articular and orthopedic uses.

48. On August 20, 1998, I-Flow submitted a 510(k) (K982946) to the FDA seeking to expand the indications for the PainBuster Infusion Kit to include "continuous infusion of a local anesthetic directly into the intraoperative or intra-articular site for postoperative pain management."

49. On September 2, 1998, I-Flow issued a press release entitled "I-Flow Corporation (NASDAQ) Signs Letter of Understanding with Smith & Nephew, Inc. to Market I-Flow's 'PainBuster' Infusion Pain Management Kit for Orthopaedic applications," stating that I-Flow received approval in June 1998 from the U.S. Food and Drug Administration to market the

PainBuster in the United States for orthopedic surgery applications. This statement was false. In fact, I-Flow never received such approval.

50. The FDA denied I-Flow's application for intra-articular use because I-Flow failed to provide any evidence of safety to satisfy an indication for intra-articular use or for orthopedic surgery.

51. Instead, the FDA approved the PainBuster for the Revised Indications for Use (Nov. 9, 1998), as follows: "The PainBuster is intended to provide continuous infusion of a local anesthetic directly into an intraoperative (soft tissue/ body cavity) site for general surgery for postoperative pain management. Additional routes of administration include percutaneous and subcutaneous infusion."

52. The FDA did not clear the PainBuster to be marketed for intra-articular administration, nor was it approved for orthopedic surgery as I-Flow withdrew this orthopedic use indication at the FDA's request.

53. On November 11, 1998, I-Flow submitted a 510(k) (K984146) to the FDA to extend the administration set product line for its existing Paragon (intravenous) infusion system (K923875). On January 13, 1999 I-Flow submitted to the FDA a revised "Indications for Use" to be used with its Paragon Infusion Kit to include synovial infusions as an additional indication for use based on another pump manufacturer, McKinley's, inclusion of synovial cavity infusion as an indication for use. In response, the FDA denied I-Flow's submission and stated that McKinley would also be required to modify its Indications for Use Statement to remove synovial cavity infusions. On February 9, 1999, the FDA cleared I-Flow's Paragon Infusion Kit for continuous infusion into the intraoperative site and for percutaneous, subcutaneous, intramuscular and

epidural infusion as additional routes of administration. And, on March 3, 1999, the FDA sent out a correction letter to McKinley removing the synovial cavity infusion indication for use.

54. Undeterred by the FDA's denials, and in violation of the Code of Federal Regulations, as illustrated in the paragraphs that follow, I-Flow continued to promote the PainBuster for both intra-articular and orthopedic use.

55. As illustrated in the paragraphs that follow, I-Flow and its agents and sales representatives knowingly, intentionally, directly and/or impliedly made material misrepresentations to Mr. Sasser, his parents, 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. Sasser's.

56. The representations by I-Flow'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.

57. When I-Flow's agents and sales representatives made these representations that their pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries such as Mr. Sasser's, they knew those representations were false, deceptive, and misleading, and they made those false representations with the intent to defraud, deceive, and mislead. For example, on July 21, 1999, Robert Bard, the vice president of regulatory affairs for I-Flow, admitted to Kevin Sumstine of DJO, who had contracted with I-Flow to sell the PainBuster to orthopedic surgeons, that despite three attempts to secure synovial cavity use in their 510(k), the FDA had rejected this use each and every time. Thus, I-Flow marketed the

PainBuster for orthopedic use in the joint space knowing it was not approved for those purposes with the intent to defraud, deceive, and mislead physicians, including Mr. Sasser's.

58. Mr. Sasser, his parents, his physicians, and the public justifiably relied upon the misrepresentations of I-Flow's agents and representatives and reasonably believed the misrepresentations to be true, and in justifiable reliance upon these misrepresentations, were induced to prescribe and use the ON-Q PainBuster and the continuously injected anesthetics.

59. I-Flow utilized multiple marketing tools and methods to promote this off-label use that had been specifically rejected by the FDA. In fact, I-Flow engaged in full spectrum marketing of their pain pumps to orthopedic surgeons, including advertising, direct sales, promotion at industry and professional meetings, comprehensive marketing (dinner meetings, I-Flow appreciation night with ball games, cruises, etc., physician reimbursement lunches); value added programs (pens, post-it notes, and other giveaways); resource utilization (inside sales); education (in-service materials, catheter placements); incentive programs (patient challenges, support team appreciation gifts); and partnership marketing with distributors and drug companies. Many of these marketing techniques are described in I-Flow's "One-to-One Marketing Tactics" authored by Vice President of Marketing, Orlando Rodrigues, on February 5, 2004.

60. Through its promotional activities, I-Flow made representations that its pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries such as Mr. Sasser's. For example,

a. Sales representatives, including Cheryle Pritchard who testified on February 20, 2009, have testified that I-Flow trained sales staff specifically to promote orthopedic and intra-articular use;

b. I-Flow equipped its sales staff and agents with direction sheets for techniques regarding placement of the pump within the joint and used medical liaisons to give favorable presentations at conferences. For example, on October 16, 2006, I-Flow Group Marketing Director, Julie Schneider provided to a Territory Manager a PowerPoint presentation to show to an orthopedic surgeon that might serve as one of I-Flow's speakers. Two of the slides in that presentation discuss glenohumeral joint placement.

c. In fact, I-Flow prepared PowerPoint presentations for physicians to use, which included slides expressly stating that the pumps were particularly useful in shoulder and other joint surgery. One such PowerPoint was sent from I-Flow Field Sales to doctors and customers on or about May 10, 2001. Another such PowerPoint was developed by I-Flow marketing employee, Kathy Thompson, on or about November 26, 2001, and described orthopedic shoulder procedures indicating catheter placement in the joint.

d. I-Flow's marketing instructed physicians on catheter placement. For example, I-Flow developed ON-Q Catheter Placement Technique guides which specified that the pain pump catheters could be placed intra-articular (in the joint space). One such guide was developed by I-Flow on or about July 10, 2002 for a presentation by a surgeon at Green Hospital/Scripps clinic in San Diego.

e. In addition, I-Flow created marketing brochures that were available in the orthopedic surgeons' offices across the country explaining to the patient that a pain pump had been placed in the joint to provide pain relief following

surgery; and, that there was nothing that the patient needed to do; the pump worked by itself. For example, one such document was created by I-Flow on or about October 21, 2005 for use by an orthopedic physician in Brighton, Michigan.

61. The foregoing representative examples reflect a pattern and practice by I-Flow to promote pain pumps for uses other than those for which FDA had cleared.

62. When I-Flow, its agents, and sales representatives made these representations that their pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries such as Mr. Sasser's, I-Flow knew those representations were false, deceptive, and misleading, and yet it made those false representations with the intent to defraud, deceive, and mislead.

63. Robert Bard, I-Flow's Vice President of Regulatory and Legal Affairs, and Shane Noehre each had actual knowledge that the FDA had denied - on at least four separate occasions- I-Flow's application to market its pain pump for use within the joint space based on the lack of data establishing the safety of such use.

64. Roger Massengale testified on July 1, 2008 that I-Flow never studied or commissioned a study to determine the safety of its infusion pain pumps using commonly used anesthetics in the shoulder. Yet, I-Flow continued to market these products to orthopedic surgeons for that use.

65. Alan Dine confirmed in his deposition on December 16, 2008 that an efficacious and safe dosage for intra-articular administration had never been determined in any clinical study designed by I-Flow for this purpose. Yet, I-Flow continued to market its pain pumps for that use.

66. I-Flow had actual notice that patients were suffering devastating injuries to their joints when I-Flow pain pumps were used in orthopedic surgeries. For example, I-Flow first received reports of chondrolysis on July 27, 2004, when I-Flow Territory Manager, Cheryle Pritchard, reported to Alan Dine, I-Flow's Director of Clinical Research that eight college age patients had developed chondrolysis following use of a pain pump. Mr. Dine testified on December 16, 2008 that he did not to investigate these reports; indeed, he did not to follow up with Ms. Pritchard regarding these complaints, and he did not to attempt to contact the physician, Dr. James Andrews, whose patients were the subject of Ms. Pritchard's report to Mr. Dine. Ms. Pritchard's report occurred two months after an FDA officer wrote an article in the journal, *Anesthesiology*, discussing adverse events reported to the FDA that were associated with the use of pain pump systems. Yet, in violation of FDA regulations, I-Flow did nothing to investigate the circumstances surrounding this report.

67. In January 2006, an orthopedic surgeon in Montana notified I-Flow of three patients, female athletes with no history of health problems, who developed chondrolysis following the use of an I-Flow pump. That report also advised of 15 other cases of chondrolysis by another physician in Salt Lake City who attributed the cause to the pain pump, and that other surgeons had expressed concern about this same issue.

68. On March 23, 2006, I-Flow's representatives attended a presentation by Dr. Beck at the annual meeting of the American Academy of Orthopedic Surgeons. At this presentation, Drs. Hansen and Beck presented compelling medical evidence that associated chondrolysis with the continuous infusion of local anesthetic from a pain pump like the one manufactured and distributed by I-Flow. I-Flow's officers and directors, including Alan Dine, Roger Massengale, and Barbara Saint John, I-Flow's Director of Sales Training and Clinical Education, had actual

knowledge of Drs. Hansen and Beck's presentation and their research results. Following the presentation, the aforementioned officers and directors, among others, chose not to perform additional research, did not issue a warning to physicians, and chose not to send a Dear Doctor letter.

69. The March 23, 2006 presentation by Hansen and Beck prompted multiple inquiries about chondrolysis and its relationship to the use of infusion pumps. I-Flow's response to the growing number of inquiries was not concern for the safety of its customers, rather, a March 31, 2006 email exchange between Alan Dine and Barbara Saint John, shows that I-Flow's concern was to squelch the fire before it could do too much damage to I-Flow.

70. On June 27, 2006, Cheryle Pritchard again reported to I-Flow a number of chondrolysis cases from multiple surgeons, including one who had advised Ms. Pritchard that she should discourage surgeons from using the pain pump in the joint. In this same report, Ms. Pritchard stated that many, many surgeons bring this topic up to her every day.

71. In September 2006, a financial analyst for I-Flow brought to I-Flow's attention yet another incidence of chondrolysis and that the surgeon had come to the conclusion that the continuous infusion of local anesthetic into the joint was responsible for the damage.

72. Undaunted, as illustrated in the paragraphs above, I-Flow continued to provide physicians with information about placing the pain pump catheter into the joint space.

73. Roger Massengale testified on December 9, 2008 that following the Hansen and Beck presentation in March 2006 and after receiving complaints in 2006 and 2007, I-Flow engaged in no efforts to promote a study to determine the nature of this crisis and even turned away a researcher who was seeking support for such a study.

74. While I-Flow was receiving these reports of chondrolysis, I-Flow was contacted by a researcher from Stanford Medical School, Dr. Jason Dragoo, who requested 8 I-Flow pain pumps for use in an in vitro study. On July 24, 2006, Barbara Saint John responded that she would provide the pumps; however, one month later, when I-Flow realized that Dr. Dragoo wanted to study chondrolysis and not efficacy, I-Flow withdrew its support.

75. I-Flow changed its package insert in the fall of 2006 to include a warning to avoid placing the catheter into the joint; however, Roger Massengale testified that I-Flow knew at that time that the new product insert would not accompany the product until the next year. Despite this knowledge, Diana Kramer, Senior Product Director, testified on December 18, 2008 that I-Flow did not recall any pain pumps that contained the old package inserts. In addition, Barbara Saint John testified that I-Flow did not advise any physicians about the need to read the label for new safety information, or that the label had been changed.

76. I-Flow had the capacity to use vendors to reach out to all orthopedic surgeons nationally with a technical bulletin which provides information to healthcare providers regarding I-Flow's products. In the fall of 2006, I-Flow prepared a Technical Bulletin entitled, "Continuous Infusion in Restrictive Spaces: Volume and Flow Rate Selection," to include a warning.

77. On October 20, 2006, the day that the Technical Bulletin was supposed to be communicated to I-Flow's customers, the CEO of I-Flow, Donald Earhart, cancelled the distribution of the technical bulletin and requested that it be immediately removed from the website. Over the next several months, Mr. Earhart proceeded to sell millions of dollars worth of I-Flow stock.

78. Ten months later, in late August 2007, I-Flow finally issued a technical bulletin entitled "What we know about Chondrolysis Today." However, this inadequate gesture was three years after Cheryle Pritchard reported the Andrews cluster; over 1.5 years after learning of the Montana/Hansen clusters; and one year after drafting a warning on its Directions for Use.

79. I-Flow is directly liable for the negligent and/or fraudulent conduct of its actual and/or ostensible employees, servants, and agents, who include, 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. Sasser and his parents.

80. I-Flow engaged in a prolonged, wanton and malicious course of conduct, with conscious and deliberate disregard of a serious risk to the health, safety, rights and interests of Mr. Sasser and many other patients, in one or more of the following respects:

a. I-Flow knew that the FDA had repeatedly refused to clear an indication for use of I-Flow's pain pumps in the joint space, but I-Flow failed to disclose the repeated FDA rejections to the U.S. medical community;

b. I-Flow failed to undertake the necessary research, analysis and testing to determine the safety of its pain pumps within the joint space before distributing its pain pumps, knowing that the pumps would be used in this manner, and failed to disclose to the U.S. medical community that the safety of using the pain pumps within a joint space was uncertain, unknown, and unpredictable;

c. I-Flow failed to disclose to the U.S. medical community that use of the pain pumps within the joint space was an "off-label" use, which had never been approved or cleared by the FDA;

d. I-Flow failed to promptly investigate and report to the FDA once it began receiving reports of dozens of patients who had allegedly suffered injury to their cartilage following use of pain pumps within their shoulder joints, and even failed to consider such cases as complaints relating to the safety of its pain pumps;

e. I-Flow failed to disclose to its own sales force that the FDA had repeatedly rejected I-Flow's proposed indication for use of its pain pumps within the joint space. Nor did I-Flow disclose to its sales force reports it received of several patients who allegedly suffered injury to their cartilage following use of pain pumps within their shoulder joints.

f. I-Flow actively promoted the use of its pain pumps within the joint space despite knowing such use had never been cleared by FDA, and that promotion and marketing of its pain pumps for use within the joint space violated federal law;

g. I-Flow failed to warn the U.S. medical community of the known risk of serious and permanent injury to cartilage associated with the use of pain pumps within the joint space in a manner reasonably likely to meaningfully warn the U.S. medical community, for a prolonged period of time after I-Flow became aware of the existence and seriousness of the risk; and

h. I-Flow put its own profits ahead of a serious risk of harm to the health, safety, and well-being of the Plaintiffs and many others.

81. As a direct and proximate cause of I-Flow's misconduct, Mr. Sasser and his parents suffered and will continue to suffer injuries, damages, and losses as alleged herein.

STATUTE OF LIMITATIONS AND FRAUDULENT CONCEALMENT

82. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

83. Any applicable statutes of limitations have been tolled by I-Flow's fraudulent misconduct and concealment, as described in the paragraphs that follow.

84. I-Flow neglected and/or refused to conduct appropriate studies to determine the safety of anesthetics on cartilage. In addition, I-Flow failed to apprise Mr. Sasser's physicians prior to his May 2, 2005 surgery of information it held secretive within the company specifically, that its pain pumps were not approved for orthopedic use and in fact that such indications had been expressly rejected.

85. Mr. Sasser, his parents and his physician were deprived of vital information essential to the pursuit of these claims without any fault or lack of diligence on their part. Mr. Sasser and his parents could not reasonably have known, discovered or become aware of the dangerous nature of and the unreasonable adverse side effects associated with, nor establish any provable compensable damages caused by, the intra-articular use of infusion pain pumps with commonly used anesthetics following shoulder surgeries prior to August of 2009 when he viewed a television advertisement discussing the association between pain pumps and cartilage loss.

86. Neither Mr. Sasser nor his parents could have made an earlier discovery prior to August of 2009 despite reasonable diligence because of the knowing and active concealment and denial of the facts by I-Flow, as alleged herein.

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

FIRST CAUSE OF ACTION
(NEGLIGENCE AND NEGLIGENCE PER SE)

88. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

89. At all times relevant to this action, I-Flow 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 I-Flow introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

90. At all times relevant to this action, I-Flow 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.

91. At all relevant times, I-Flow knew or reasonably should have known that the pain pumps were unreasonably dangerous and defective when used as directed and as designed. A reasonably careful search and review of the scientific and medical literature, and other information, should have indicated to I-Flow that:

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.

92. I-Flow knew or reasonably should have known that the intra-articular use of pain pumps caused unreasonably dangerous risks and serious side effects of which orthopedic surgeons and consumers, including Mr. Sasser, would not be aware.

93. Based on what I-Flow knew or reasonably should have known as described above, it deviated from principles of due care, deviated from the standard of care, and was 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 its 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.

94. I-Flow violated statutes, rules and ordinances concerning the manufacturing, marketing, and/or testing of its pain pumps.

95. At all relevant times, I-Flow 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.

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

97. The injuries and damages suffered by Mr. Sasser and his parents were the reasonably foreseeable result of I-Flow's negligence.

98. I-Flow downplayed, understated and/or disregarded the serious danger of intra-articular pain pumps.

99. Despite the fact that I-Flow knew or should have known that use of intra-articular pain pumps following shoulder surgeries caused unreasonably dangerous side effects, I-Flow continued to market, manufacture, distribute and/or sell the pain pumps to consumers, including Mr. Sasser and his parents.

100. Had I-Flow performed those tests and studies necessary to determine whether the pain pumps and local anesthetics could safely be used in the joint space before Dr. Hall used a pain pump following Mr. Sasser's surgery, as it was required to do, Mr. Sasser would not have developed chondrolysis and suffered the injuries and damages described with particularity above.

101. I-Flow 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. Sasser and his parents.

102. I-Flow's actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

103. I-Flow knew or should have known that consumers such as Mr. Sasser and his parents would foreseeably suffer injury, and/or be at increased risk of suffering injury as a result of I-Flow's failure to exercise ordinary care, as set forth above.

104. As a direct and proximate cause of I-Flow's negligence, Mr. Sasser 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. Sasser 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, the costs of which his parents, Charles and Dana Sasser, may be fully or partially responsible. In addition, Mr. Sasser has suffered mental distress and anguish and has suffered permanent impairment of the use and function of his affected upper extremities, and other damages.

105. As a direct and proximate cause of I-Flow's negligence, Mr. Sasser's parents Charles and Dana Sasser, have incurred, and may occur in the future, expenses for the medical, surgical, therapeutic rehabilitative, and additional care and other needs and expenses for their son, Joseph. Mr. and Mrs. Sasser have suffered and will continue to suffer injuries, damages and losses as alleged herein.

SECOND CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

106. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

107. I-Flow and its sales representatives, in the course of selling its pain pumps for commercial gain, had a duty to use reasonable care in conveying information about its pain pumps to Mr. Sasser, his parents, his surgeon and other medical providers using its pumps.

108. I-Flow and its sales representatives, in the course of their business, breached this duty by negligently misrepresenting and failing to disclose material facts concerning the risks

that their pain pumps and anesthetics posed to patients, particularly those using the products for pain relief following shoulder surgery.

109. I-Flow and its sales representatives, in the course of their business, made material misrepresentations and concealments to Dr. Hall when they marketed their product to him by failing 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.

110. I-Flow and its sales representatives knew or should have known, under the circumstances, that those misrepresentations were false.

111. The false information supplied by I-Flow for the use of Mr. Sasser's surgeon and other medical providers using its products was that I-Flow's pain pumps were safe, effective, and would not harm or adversely affect Mr. Sasser's health when used in orthopedic surgery and/or in or near the right shoulder joint.

112. The misrepresentations and false information communicated by I-Flow for the use of Mr. Sasser, his parents, his surgeons and other medical providers using I-Flow's products were material and Mr. Sasser's surgeon and other medical providers using I-Flow's products reasonably relied in good faith on I-Flow's misrepresentations and false information, all to the detriment of Mr. Sasser and his parents.

113. The misrepresentations and concealments by I-Flow were made with the intent to advertise, market, and sell pain pumps and anesthetics off-label.

114. I-Flow sales representatives were often in the surgical suite, instructed doctors and nurses on the filling of the ON-Q PainBuster, visualized the surgeons as they placed the

ON-Q PainBuster into the shoulder joint, and interacted directly with patients when they asked patients to sign Patient Acknowledgment and Assignment of Benefits forms. I-Flow, through its sales representatives, made material misrepresentations and concealments to patients like Mr. Sasserwhen it advertised, marketed and sold its pain pumps and anesthetics to them.

115. The direct relationship between I-Flow and patients like Mr. Sasser is further evidenced by the fact that I-Flow reached out directly to patients by sending thank you letters directly to patients like Mr. Sasser following their surgeries. These letters were signed ON-Q Billing Coordinator and included ON-Q Billing Frequently Asked Questions and directed patients to contact I-Flow directly.

116. I-Flow also stocked physician's offices with brochures including telephone numbers for patients to contact I-Flow directly.

117. I-Flow failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information to Mr. Sasser, his parents and his physicians, and failed to comply with the existing standard of care.

118. I-Flow 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. Sasser and his parents.

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

THIRD CAUSE OF ACTION
(FRAUD AND DECEIT)

120. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

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

122. I-Flow and its agents and sales representatives knowingly, intentionally, directly and/or impliedly made material misrepresentations Mr. Sasser, his parents, 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. Sasser's.

123. I-Flow and its agents and representatives knowingly, intentionally, directly and/or impliedly misrepresented to Dr. Hall that the pain pumps were safe and effective for the management of post-operative intra-articular pain when placed in the joint space.

124. I-Flow and its agents and representatives knowingly, intentionally, directly and/or impliedly misrepresented to Dr. Hall that its pain pumps were FDA cleared for use in the joint space.

125. The representations by I-Flow'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.

126. When I-Flow's agents and sales representatives made these representations that their pain pumps and the anesthetics used in the pumps were safe for use following shoulder

surgeries such as Mr. Sasser's, they knew those representations were false, deceptive, and misleading, and they made those false representations with the intent to defraud, deceive, and mislead. For example, on July 21, 1999, Robert Bard, the vice president of regulatory affairs for I-Flow, admitted to Kevin Sumstine of DJO, who had contracted with I-Flow to sell the PainBuster to orthopedic surgeons, that despite three attempts to secure synovial cavity use in their 510(k), the FDA had rejected this use each and every time. Thus, I-Flow marketed the PainBuster for orthopedic use in the joint space knowing it was not approved for those purposes with the intent to defraud, deceive, and mislead physicians, including Mr. Sasser's.

127. In May of 2005, Mr. Sasser, his parents, his physicians, and the public justifiably relied upon the misrepresentations of I-Flow's agents and representatives and reasonably believed the misrepresentations to be true, and in justifiable reliance upon these misrepresentations, were induced to prescribe and use the ON-Q PainBuster and the continuously injected anesthetics.

128. Had I-Flow not misrepresented its pain pumps' uses, safety and regulatory status to Dr. Hall, he would not have used the ON-Q pain pump following Mr. Sasser's surgery.

129. By misrepresenting the regulatory status of the pain pump (e.g., that it was approved for use in the joint), its safety (e.g., that it was safe for this use), and the uses for which it could be put (e.g., in orthopedic procedures and in the joint space), I-Flow failed to exercise reasonable care in disseminating this information when first promoting the product to Dr. Hall and continuing through his use of it in Mr. Sasser's surgery.

130. At no time did I-Flow correct the misinformation provided to Dr. Hall when he began using the product or otherwise disclose to him the regulatory status/history, risks, and proper/improper uses as described herein.

131. At the time of Mr. Sasser's surgery, I-Flow was aware that orthopedic surgeons were using pain pumps intra-articularly and those sales representatives and distributors had promoted the product for those uses.

132. Had I-Flow not made express and implied false statements about the product, Dr. Hall would have made a different decision about whether or how to use the product and Mr. Sasser's injury would have been avoided.

133. I-Flow authored and approved literature, materials, and trainings about its pain pumps reasonably expecting that others would rely on it.

134. As illustrated in paragraphs 55-56 above, I-Flow engaged in a pattern and practice of promoting the products for orthopedic and intra-articular use.

135. Alan Dine confirmed in his deposition on December 16, 2008 that an efficacious and safe dosage for intra-articular administration had never been determined in any clinical study designed by I-Flow for this purpose. Yet, I-Flow continued to market its pain pumps for that use.

136. As illustrated in paragraphs 62-67 above, I-Flow had actual notice that patients were suffering devastating injuries to their joints when I-Flow pain pumps were used in orthopedic surgeries.

137. Undaunted, I-Flow continued to provide physicians with information about placing the pain pump catheter into the joint space.

138. I-Flow is directly liable for the negligent and/or fraudulent conduct of its actual and/or ostensible employees, servants, and agents, who include, 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. Sasser and his parents.

139. Mr. Sasser and his parents do not allege fraud on the FDA as no false statements made to FDA are part of Plaintiffs' claims.

140. Plaintiffs' allegations of fraud and misrepresentation are based on representations and omissions to Mr. Sasser, his parents, his physician and the public regarding the pain pump's uses, safety, and FDA clearance, not communications with the FDA in order to obtain approval for certain uses.

141. As alleged herein, I-Flow did not merely allow Dr. Hall to purchase or use the pain pumps for uses other than those for which FDA had cleared the products; rather, I-Flow misrepresented, omitted, and mislead Dr. Hall about the approved and safe uses of the product. Thus, at the time of Dr. Hall's first surgery, I-Flow caused Dr. Hall to use the product in ways other than those for which FDA had cleared the device rather than allow him to make an informed decision about off-label use.

142. As a result of the fraud and deceit of I-Flow's agents and sales representatives, Mr. Sasser and his parents suffered and will continue to suffer injuries, damages, and losses as alleged herein.

FOURTH CAUSE OF ACTION
(STRICT PRODUCT LIABILITY)

143. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

144. At all times material to these allegations, I-Flow designed, tested, manufactured, assembled, labeled, marketed, promoted, distributed and sold pain pumps, including the ON-Q PainBuster at issue in this case.

145. I-Flow placed its pain pumps into the stream of commerce.

146. Mr. Sasser and his parents purchased and/or ultimately obtained pain pumps from I-Flow.

147. Mr. Sasser was given a pain pump with anesthetic as prescribed by his physician in a manner that I-Flow intended its products to be used.

148. I-Flow 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.

149. I-Flow's pain pumps were defective in design and/or formulation because, when they left I-Flow's hands, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

150. The dangers posed by the defective condition of the pain pump, particularly that the pain pump's delivery of anesthetic solution into or near the shoulder joint space would cause destruction of the shoulder joint, were not readily recognizable by the ordinary users of the pain pump.

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

152. 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.

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

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

154. Mr. Sasser's orthopedic surgeon, Dr. Hall, did not have actual knowledge sufficient to know the danger posed by the use of I-Flow's pain pumps to continuously infuse the joint space with local anesthetics. I-Flow did not give Mr. Sasser, his parents or his orthopedic surgeon sufficient warning regarding the danger posed by the use of the pain pumps to continuously infuse the joint with local anesthetics.

155. Mr. Sasser was the type of patient which I-Flow reasonably expected would be prescribed the ON-Q PainBuster for post-operative intra-articular use.

156. I-Flow was entitled to withdraw the ON-Q PainBuster from the market at any time or provide adequate warnings to orthopedic surgeons or consumers at any time, but failed to do so in a timely and responsible manner.

157. The pain pumps manufactured, distributed, tested, sold, marketed, advertised and represented defectively by I-Flow was a substantial factor in bringing about Mr. Sasser's and his parents injuries that would not have occurred but for the use of the product.

158. As a direct and proximate result of the defective condition of I-Flow's products, Mr. Sasser and his parents suffered and will continue to suffer injuries, damages, and losses as alleged herein.

FIFTH CAUSE OF ACTION
(STRICT TORT LIABILITY -- FAILURE TO WARN)

159. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

160. I-Flow 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.

161. I-Flow's pain pumps and anesthetics were defective due to inadequate warnings and/or inadequate clinical trials, *in vivo* and *in vitro* testing and study, and inadequate reporting the results of such trials, testing and study.

162. I-Flow's pain pumps and anesthetics were further defective due to inadequate post-marketing warnings or instructions because, after I-Flow knew or in the exercise of reasonable care should have known of the risk of chondrolysis associated with its pumps when used to continuously infuse local anesthetic in joint the joint space, I-Flow failed to provide adequate post-marketing warnings that a manufacturer exercising reasonable care would have issued to the U.S. medical community and patients regarding chondrolysis. Rather, I-Flow continued to promote its pain pump as safe and effective for intra-articular use.

163. The defective warnings were a substantial factor in bringing about the injuries to Mr. Sasser and his parents that would not have occurred but for the use of the product.

164. As a direct and proximate result of the defective condition of I-Flow's pain pumps, specifically its failure to warn and its other negligence, carelessness, and other wrongdoing and actions described herein, Mr. Sasser and his parents suffered and will continue to suffer injuries, damages, and losses as alleged herein.

SIXTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY)

165. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

166. Mr. Sasser and his parents purchased and/or ultimately obtained a pain pump from I-Flow.

167. I-Flow impliedly warranted that its pain pumps were of merchantable quality and safe and fit for the use for which they were intended.

168. Mr. Sasser and his parents relied on the skill and judgment and implied warranty of I-Flow that its pain pumps were of merchantable quality and safe and fit for the use of which they were intended.

169. Contrary to I-Flow'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. Sasser.

170. As a result of I-Flow's breach of implied warranty, Mr. Sasser and his parents suffered and will continue to suffer injuries, damages, and losses as alleged herein.

SEVENTH CAUSE OF ACTION
(PUNITIVE DAMAGES)

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

172. Mr. Sasser and his parents are entitled to punitive damages because I-Flow's conduct and failure to warn manifested a flagrant disregard of the safety of persons, including Mr. Sasser, who might be harmed by its pumps.

173. I-Flow's conduct was intentional, reckless, wanton, willful and/or outrageous, and said conduct was committed with gross negligence, flagrant disregard of, and deliberate, callous and reckless indifference to Mr. Sasser and his parents' rights, interests, welfare and safety. I-Flow misled both the medical community and the public at large, including Mr. Sasser and his

parents, by making false representations about the safety of its products. I-Flow 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.

174. I-Flow 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.

175. I-Flow failed to provide warnings that would have dissuaded medical providers from using the pain pumps thus depriving medical providers and consumers from weighing the true risks against the benefits of using the pain pumps.

176. The acts complained of that form the basis for punitive damages were participated in or condoned by the officers, directors or managers of the Defendant Corporation.

177. As a direct and proximate result of these breaches, Mr. Sasser was caused to be exposed to a pain pump and anesthetic after his shoulder surgery, thereby causing the injuries described more fully herein.

178. As a result of the foregoing, Mr. Sasser and his parents are entitled to punitive damages required by justice.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant I-Flow as follows:

1. For compensatory damages in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. Economic and non-economic damages and damages for pain and suffering and loss of basic and pleasurable activities to be supported by the evidence at trial;

3. For punitive damages according to proof;

4. For disgorgement of profits;

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

Plaintiffs hereby demand a jury trial on all claims so triable in this action.

Dated: May 14, 2012

JANET, JENNER & SUGGS, LLC

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CIVIL COVER SHEET

12-776 RMC

JS-44
(Rev. 2/11 DC)

I (a) PLAINTIFFS

Joseph E. Sasser; Charles G. Sasser and Dana J. Sasser, individually and as natural parents of Joseph E. Sasser

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF (EXCEPT IN U.S. PLAINTIFF CASES) Geneva

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

Robert K. Jenner, Esq.
Elisha N. Hawk, Esq.
Janet, Jenner & Suggs, LLC
1829 Reisterstown Road, Suite 320
Baltimore, Maryland 21208; 410-653-3200

DEFENDANTS

I-Flow, LLC f/k/a I-Flow Corporation

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT (IN U.S. PLAINTIFF CASES ONLY) Orange

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

Case: 1:12-cv-00776
Assigned To : Collyer, Rosemary M.
Assign. Date : 5/14/2012
Description: PI/Malpractice

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ○ 2 U.S. Government Defendant
- ◉ 4 Diversity (Indicate Citizenship of Parties in item III)

III CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	◉ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	◉ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place a X in one category, A-N, that best represents your cause of action and one in a corresponding Nature of Suit)

○ **A.** ***Antitrust***

- ☐ 410 Antitrust

◉ **B.** ***Personal Injury/ Malpractice***

- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☒ 365 Product Liability
- ☐ 368 Asbestos Product Liability

○ **C.** ***Administrative Agency Review***

- ☐ 151 Medicare Act

Social Security:
- ☐ 861 HIA ((1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g)
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g)

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D.** ***Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E.** ***General Civil (Other)*** **OR** ○ **F.** ***Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 610 Agriculture
- ☐ 620 Other Food &Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 RR & Truck
- ☐ 650 Airline Regs
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

Other Statutes
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 900 Appeal of fee determination under equal access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus-General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus - Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights-Employment (criteria: race, gender/sex, national origin, discrimination, disability age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/PRIVACY ACT* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loans (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 730 Labor/Mgmt. Reporting & Disclosure Act ☐ 740 Labor Railway Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 444 Welfare ☐ 440 Other Civil Rights ☐ 445 American w/Disabilities-Employment ☐ 446 Americans w/Disabilities-Other	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights-Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi district Litigation ○ 7 Appeal to District Judge from Mag. Judge

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

28 U S C § 1391 Pain Pump Chondrolysis

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A CLASS ACTION UNDER F R C P 23 **DEMAND $** Over $75,000.00 Check YES only if demanded in complaint **JURY DEMAND:** YES ☒ NO ☐

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☐ If yes, please complete related case form

DATE May 14, 2012 **SIGNATURE OF ATTORNEY OF RECORD** [signature]

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44

Authority for Civil Cover Sheet

The **JS-44** civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleadings or other papers as required by law, except as provided by local rules of court This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet Consequently a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed Listed below are tips for completing the civil cover sheet These tips coincide with the Roman Numerals on the Cover Sheet

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence Use 11001 to indicate plaintiff is resident of Washington, D C , 88888 if plaintiff is resident of the United States but not of Washington, D C , and 99999 if plaintiff is outside the United States

III. CITIZENSHIP OF PRINCIPAL PARTIES This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II

IV. CASE ASSIGNMENT AND NATURE OF SUIT The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint You may select only one category You must also select one corresponding nature of suit found under the category of case

VI. CAUSE OF ACTION Cite the US Civil Statute under which you are filing and write a brief statement of the primary cause

VIII. RELATED CASES, IF ANY If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form