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10 **IN THE UNITED STATES DISTRICT COURT**
11 **FOR THE DISTRICT OF ARIZONA**

12 **LAURA E. ASHWORTH** and)
13 **JEFFREY K. ASHWORTH,**)

NO. 2:09-cv-00721-PHX-SRB

14 Plaintiffs,)

COMPLAINT AND JURY DEMAND

15 vs.)

16 **I-FLOW CORPORATION,** a)
17 Delaware Corporation,)

Related to: *Lopez v. DJO, LLC, et al.*,
Case No. CIV 08-1063-PHX-SRB

18 Defendant.)
19)
20)
21)
22)

23 Plaintiffs, by and through counsel, and for their complaint against defendant,
24 allege as follows:

25 **JURISDICTION AND PARTIES**

26 1. Plaintiffs Laura E. Ashworth and Jeffrey K. Ashworth were at all relevant
27 times residents and citizens of Maricopa County, Arizona.

28 2. Plaintiff Laura E. Ashworth underwent an initial arthroscopic surgery of
her right shoulder to repair a torn labrum on March 29, 2006 at the Arizona Orthopedic
Surgical Hospital in Chandler, Arizona. Although plaintiff's surgeon inserted a pain
pump at the end of the procedure, he placed the device in the subachromial space
(above the shoulder joint), and not directly into the intra-articular (joint) space.

1 3. Plaintiff Laura E. Ashworth re-injured her right shoulder and underwent a
2 second arthroscopic surgery on June 12, 2006 at the same facility. This time,
3 plaintiff's orthopedic surgeon implanted the catheter of an "On-Q PainBuster" pain
4 pump directly into the intra-articular space of her right shoulder. The pain pump was
5 designed, manufactured, and marketed by defendant I-Flow Corporation. It injected
6 pain relief medication directly into plaintiff's shoulder joint on a continuous basis, for up
7 to 72 hours or more following the surgery.

9 4. Defendant I-Flow Corporation ("I-Flow") is a Delaware corporation with
10 its principal place of business in California. Defendant I-Flow conducted regular and
11 sustained business in Arizona by selling and distributing its products in Arizona, as
12 described below.

14 5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332
15 because there is complete diversity of citizenship between the parties, and the amount
16 in controversy exceeds \$75,000.00, exclusive of interest and costs.

18 6. Venue in this district is appropriate under 28 U.S.C. § 1391 because a
19 substantial part of the events giving rise to this claim occurred in this district as
20 plaintiffs have at all times relevant resided in this judicial district, the pain pumps and
21 their medications were implanted and administered in this district, and plaintiffs
22 sustained injury in this district.

23 **FACTUAL BACKGROUND**

24 7. At all relevant times, defendant I-Flow designed, manufactured, and
25 distributed a product called a "pain pump," a medical device intended to deliver, via
26 catheter, continuous doses of pain relief medication directly into the shoulder joint
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1 space. The pain pump delivers anesthetic pain medication directly into the operative
2 site for 72 hours or more immediately following shoulder surgery.

3 8. The pain pumps are designed and intended to be used with commonly
4 used anesthetics such as local anesthetics with or without epinephrine, in volumes of
5 250 cc's or more, over two days or more. The continuous injection of such
6 medications at such doses over time directly into the shoulder joint, however, can
7 cause serious and permanent damage to the cartilage of the shoulder joint. Plaintiff
8 Laura E. Ashworth had a pain pump inserted post-operatively, and received
9 dangerous doses of continuously injected medication into her right shoulder joint.
10 Plaintiff, as a result, suffered narrowing of the joint space and/or a condition called
11 "chondrolysis," which is the complete or nearly complete loss of cartilage in the
12 shoulder joint, an irreversible, disabling, and extremely painful condition.
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15 9. Plaintiff Laura E. Ashworth has already undergone partial shoulder
16 replacement, and will require, additional surgery, including complete shoulder joint
17 replacement, as a result of the narrowing of the joint space and/or chondrolysis
18 caused by the dangerously defective pain pump.
19

20 10. Defendant I-Flow did not warn plaintiff Laura E. Ashworth or her surgeon
21 about the unreasonable risks and dangers of using the pain pump and anesthetic
22 medications in this manner. The surgeon used the pain pump in the manner
23 instructed and directed by defendant.
24

25 **FIRST CLAIM FOR RELIEF**

26 **(Strict Product Liability: Design Defect, Failure to Warn)**

27 11. Plaintiffs re-allege all previous paragraphs.
28

1 12. The pain pump device was unreasonably and dangerously defective
2 beyond the extent contemplated by ordinary patients with ordinary knowledge
3 regarding the devices, in one or more of the following particulars:

4 A. The labeling failed to instruct or warn the U.S. medical community that
5 the safety of the device, and the anesthetic medications used in them,
6 had not been established for use in the shoulder joint space;

7 B. The labeling failed to disclose to the U.S. medical community that
8 continuous injection of commonly used anesthetics such as bupivacaine,
9 with or without epinephrine, in volumes of at least 250 cc's, for two or
10 more days, into the shoulder joint space, may cause serious and
11 permanent injury to the joint cartilage;

12 C. The labeling failed to include a precaution against placing the catheter of
13 the pain pump in the shoulder joint space;

14 D. The labeling failed to provide to the U.S. medical community adequate
15 instructions for the safe use of the device, failing specifically to identify
16 anesthetic medications that could be safely and effectively used in the
17 shoulder joint space;

18 E. The labeling failed to disclose to the U.S. medical community that the
19 effectiveness of the device was uncertain for use in the shoulder joint
20 space;

21 F. The labeling failed to disclose to the U.S. medical community that the
22 FDA had considered the defendants' request to put this indication in the
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pain pump label, and then had rejected this precise indication for the pain pumps' use, to deliver the pain medicine directly into the joint space;

G. The products were designed to inject commonly used medications, which were associated with damage to articular cartilage, directly into the shoulder joint; and

H. When used as designed, the pain pumps delivered, over time, dangerously high doses of medication directly into shoulder tissue.

13. The product defects alleged above were substantial contributing causes of the injuries suffered by plaintiff Laura E. Ashworth. Specifically, the pain pump and local anesthetics used in it caused plaintiff to suffer the permanent loss of cartilage in her shoulder, resulting in severe pain and discomfort of the shoulder, and loss of use and function of the shoulder and arm. The use of defendant I-Flow's pain pump also rendered the therapeutic benefits of plaintiff's shoulder surgery worthless. Plaintiff has undergone surgery and will also require future medical care, including additional shoulder surgeries, as she ages, including but not limited to, shoulder replacement. In addition, plaintiff has suffered mental distress and anguish due to the permanent impairment of the use and function of her affected upper extremities.

SECOND CLAIM FOR RELIEF

(Negligence)

14. Plaintiffs re-allege all previous paragraphs.

15. At all relevant times, defendant I-Flow knew or reasonably should have know that its pain pump and the anesthetic medication used in it were unreasonably dangerous and defective when used as directed and as designed. A reasonably

1 careful search and review of the scientific and medical literature, and other
2 information, should have indicated to defendant I-Flow that:

- 3 A. Commonly used anesthetics likely to be used in its pain pumps, such as
4 bupivacaine, with or without epinephrine, were harmful to human and
5 animal articular cartilage;
- 6 B. Use of the pain pumps in the joint space had not been approved by the
7 F.D.A., and in fact had been specifically rejected by the F.D.A.;
- 8 C. Continuous injection of 250 cc's or more of such medications, through a
9 catheter, directly into the shoulder joint, for two or more days, had not
10 been adequately tested for safety or effectiveness;
- 11 D. The risk of chondrolysis and other serious post-operative problems
12 associated with using the pain pumps as designed and instructed
13 outweighed the possible benefits of such use.

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16 16. Based on what it knew or reasonably should have known as described
17 above, defendant I-Flow was negligent in one or more of the following particulars:

- 18 A. Failing to instruct or warn the U.S. medical community that the safety of
19 the device had not been established for use in the shoulder joint space;
- 20 B. Failing to disclose to the U.S. medical community that continuous
21 injection of commonly used anesthetics such as bupivacaine, with or
22 without epinephrine, in volumes of at least 250 cc's, for two or more
23 days, into the shoulder joint space, may cause serious and permanent
24 injury to the joint cartilage;

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- C. Failing to include a precaution against placing the catheter of the pain pump in the shoulder joint space;
- D. Failing to provide to the U.S. medical community adequate instructions for the safe use of the device, specifically failing to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;
- E. Failing to disclose to the U.S. medical community that the effectiveness of the device was uncertain for use in the shoulder joint space;
- F. Manufacturing a product designed to directly inject into the shoulder joint commonly used medications that were associated with damage to articular cartilage;
- G. Failing to conduct studies or otherwise investigate the potential harm to articular cartilage when exposed to the pain pumps and anesthetic medications in volumes of at least 250 cc's, for two or more days, into the shoulder joint space;
- H. Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue; and
- I. Promoting the pain pumps for use in the joint space after the FDA had considered and rejected such an indication.

17. The negligent acts and omissions alleged above were substantial contributing causes of the injuries suffered by plaintiff Laura E. Ashworth. Specifically, the pain pumps and local anesthetics used in them caused plaintiff to suffer the permanent loss of cartilage in her right shoulder, resulting in severe pain and

1 discomfort of the shoulder, and loss of use and function of the shoulder and arm. The
2 use of defendant I-Flow's pain pump also rendered the therapeutic benefits of
3 plaintiff's shoulder surgery worthless. Plaintiff has undergone partial shoulder
4 replacement surgery and will also require future medical care, including additional
5 shoulder surgeries, as she ages, including but not limited to, shoulder replacement. In
6 addition, plaintiff has suffered mental distress and anguish due to the permanent
7 impairment of the use and function of her affected upper extremities.
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9 18. The injuries suffered by plaintiff Laura E. Ashworth were the reasonably
10 foreseeable results of defendant's negligence.
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12 **DAMAGES**

13 19. Plaintiffs re-allege all previous paragraphs.

14 20. As a result of her injuries as described above, plaintiff Laura E. Ashworth
15 has suffered economic and noneconomic damages in an amount in excess of \$75,000
16 as provided by law and to be supported by the evidence at trial.
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18 **(Punitive Damages)**

19 21. Plaintiffs re-allege paragraphs 1-18 above.

20 22. Defendant I-Flow's actions, described above, were performed with
21 wanton disregard for the health and safety of plaintiff Laura E. Ashworth. Defendant's
22 actions, as described above, were performed with malice and in reckless disregard for
23 the rights of plaintiff Laura E. Ashworth, who used defendant's pain pump.
24 Defendant's failure to investigate the harms of its products has resulted in an excess
25 of hundreds of unnecessary injuries.
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- 3. Punitive damages in an amount to be determined by the jury.
- 4. Plaintiffs pray for such other and further relief as justice requires.

JURY DEMAND

Plaintiffs request trial by jury of all issues so triable.

Respectfully submitted this 8th day of April, 2009.

BEGAM, LEWIS & MARKS, P. A.

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