



STATE OF MICHIGAN
IN THE CIRCUIT COURT FOR THE COUNTY OF OAKLAND

ROBIN M. SMITH and CRAIG A. SMITH,

Wife and Husband,

PLAINTIFFS,

v.

Case No:

STRYKER CORPORATION, and

Hon.

STRYKER SALES CORPORATION,

Michigan corporations,

DEFENDANTS

MICHAEL WILLIAMS (*pro hac vice*)
LESLIE O'LEARY (*pro hac vice*)
WILLIAMS, LOVE, O'LEARY & POWERS
9755 SW Barnes Rd. Ste 450
Portland, OR 97225-6681
ATTORNEYS FOR PLAINTIFFS

LINDA MILLER ATKINSON (P23345)
ATKINSON, PETRUSKA, KOZMA & HART
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ATTORNEYS FOR PLAINTIFFS

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PLAINTIFFS' COMPLAINT
AND JURY DEMAND

There is no other pending or resolved civil action arising out of the transaction or occurrence alleged in the complaint.

LINDA MILLER ATKINSON (P23345)
ATTORNEY for PLAINTIFFS

PLAINTIFFS, ROBIN SMITH AND CRAIG SMITH, by their attorneys ATKINSON, PETRUSKA, KOZMA & HART and WILLIAMS, LOVE, O'LEARY & POWERS, for their Complaint state as follows:

I. JURISDICTION

1. This is a civil action seeking compensatory damages and exemplary damages for personal injuries arising out of the design, manufacture and sale of defective and unreasonably dangerous products within Michigan and within Oakland County.

2. Jurisdiction is conferred upon this Honorable Court and is founded upon a claim in tort and an amount in controversy in excess of \$50,000.00, exclusive of interest, costs, and attorneys' fees.

II. PARTIES

3. PLAINTIFFS, ROBIN SMITH and CRAIG SMITH are and were at all material times, wife and husband, residents of Oakland County and the State of Michigan and citizens of the United States.

4. DEFENDANT STRYKER CORPORATION ["STRYKER"] and DEFENDANT STRYKER SALES CORPORATION ["SALES"] are Michigan corporations with their principal places of business in the City of Kalamazoo, Michigan, doing regular and sustained business selling and distributing their products, including Stryker pain pumps, throughout Michigan in hospitals, including Crittenton Hospital, Rochester, Oakland County, Michigan.

5. The injuries and events giving rise to this cause of action occurred at Crittenton Hospital, in the City of Rochester, Oakland County, Michigan

6. At all relevant times, DEFENDANTS STRYKER and SALES designed, manufactured and sold a product called the Stryker “pain pump,” a medical device intended to deliver continuous doses of pain medication via catheter directly into a painful site including a post-surgical shoulder joint space. The Stryker pain pump was designed and sold by DEFENDANTS to deliver anesthetic pain medication directly into the operative site for 72 hours or more immediately following surgery including shoulder joint surgery.

7. DEFENDANTS designed, manufactured and sold their Stryker pain pump to be used with commonly available anesthetics such as bupivacaine, with or without epinephrine, in volumes of 250 cc’s or more, for two or more days, knowing that continuous injection of such medications directly into the shoulder joint, posed serious risks of permanent damage to the cartilage of the shoulder joint.

III. CAUSE OF ACTION: PRODUCT LIABILITY

8. PLAINTIFF ROBIN M. SMITH’S shoulder surgeon at Crittenton Hospital, in the City of Rochester, Michigan, after performing arthroscopic surgery upon Plaintiff’s shoulder followed instructions accompanying DEFENDANTS’ Stryker pain pump in inserting the catheter from a Stryker pain pump post-operatively into her left shoulder joint after each of two surgeries February 18, 2003 and August 13, 2003 through which Robin Smith received doses of continuously injected medication as designed and as directed by DEFENDANTS.

9. As a result of the dangerous design, manufacturing and sale of the Stryker pain pump, PLAINTIFF ROBIN SMITH suffered destruction of her left shoulder joint space and a condition called “chondrolysis,” the complete or nearly complete loss of cartilage in the shoulder joint, an irreversible, disabling, and extremely painful condition eventually requiring, first a partial prosthesis and then a total shoulder replacement on November 6, 2007.

10. DEFENDANTS did not warn PLAINTIFF ROBIN M. SMITH or her surgeon about the unreasonable risks and dangers of using the Stryker pain pump catheter directly in the shoulder joint including the risk of chondrolysis.

11. Before and during the surgical events from 2003 through 2007, the United States Food and Drug Administration ["F.D.A."] had denied DEFENDANTS' application to market its pain pumps for use in the intra-articular (joint) space including the shoulder joint, and the Stryker pain pump was never approved for use in the shoulder joint space.

12. PLAINTIFFS did not know and with reasonable diligence could not learn that the Stryker pain pumps used post-operatively in 2003 caused chondrolysis in PLAINTIFF ROBIN SMITH'S left shoulder joint until September 2007, after research was published documenting that the pain pump caused chondrolysis when the catheter was inserted into the shoulder joint.

13. The Stryker pain pump devices and the anesthetic medications used in them were unreasonably and dangerously defective when they left the hands of DEFENDANTS beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the device, in one or more of the following particulars:

- A. No warnings or instructions with the pain pump advised the U.S. medical community that the safety of the devices, and the anesthetic medications used in them, had not been established for use in the shoulder joint space;
- B. No warnings or instructions with the pain pump advised the U.S. medical community that continuous injection of commonly used anesthetics such as bupivacaine, with or without epinephrine, in volumes of at least 250 cc's, for two or more days, into the shoulder joint space, could cause serious and permanent injury to the joint cartilage;
- C. No warnings or instructions with the pain pump advised of the dangers of placing the catheter of the pain pump in the shoulder joint space;
- D. No warnings or instructions advised the U.S. medical community with adequate instructions for the safe use of the devices, failing specifically to identify

anesthetic medications that could be safely and effectively used in the shoulder joint space;

- E. No warnings or instructions disclosed to the U.S. medical community that the effectiveness of the devices was uncertain for use in the shoulder joint space;
- F. No warnings or instructions disclosed to the U.S. medical community that the F.D.A. had considered manufacturers' application for approval for the use of pain pumps to deliver the pain medicine directly into the joint space and had rejected this precise indication;
- G. As designed the pain pumps injected pain medications, known to be associated with damage to articular cartilage, directly into the shoulder joint presenting a risk of chondrolysis ; and
- H. When used as designed, the pain pumps delivered, over time, dangerously high doses of medication directly into the shoulder joint.

14. The product defects alleged above were substantial contributing causes of the injuries suffered by PLAINTIFF ROBIN M. SMITH. Specifically, the pain pump caused her to suffer the permanent loss of cartilage in her left shoulder, resulting in severe pain and discomfort of the shoulder, and loss of use and function of the shoulder and arm. The use of the Stryker pain pump also rendered the therapeutic benefits of plaintiff's shoulder surgery worthless. PLAINTIFF ROBIN M. SMITH has undergone additional surgeries, including both partial and full shoulder replacement surgeries, and will require future medical care to treat her persistent shoulder pain and disability. In addition, PLAINTIFF ROBIN M. SMITH has suffered loss of earning capacity, mental and physical pain and suffering, distress and anguish, and disfigurement all past and future due to the permanent impairment of the use and function of her affected upper extremities.

IV. CAUSE OF ACTION: NEGLIGENCE

15. PLAINTIFFS reallege and incorporate as if set forth fully here all allegations of paragraphs 1 through 14.

16. At all relevant times, DEFENDANTS knew or reasonably should have known that Stryker pain pumps with the anesthetic medications used in them were unreasonably dangerous and defective when used with a catheter to deliver pain medications into intra-articularly as designed and as directed and that:

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

17. DEFENDANTS and each of them owed users and purchasers and consumers and patients including PLAINTIFFS the duty of reasonable care in designing, marketing and selling the Stryker pain pump.

18. DEFENDANTS breached their duties to PLAINTIFFS and were negligent in one or more of the following particulars:

- A. In failing to instruct or warn the U.S. medical community that the safety of the device had not been established for use in the shoulder joint space;
- B. In failing to disclose to the U.S. medical community that continuous injection of commonly used anesthetics such as bupivacaine, with or without epinephrine, in

volumes of at least 250 cc's, for two or more days, into the shoulder joint space, may cause serious and permanent injury to the joint cartilage;

- C. In failing to include a precaution against placing the catheter of the pain pumps in the shoulder joint space;
- D. In failing to provide to the U.S. medical community adequate instructions for the safe use of the devices, specifically failing to identify anesthetic medications that could be safely and effectively used in the shoulder joint space;
- E. In failing to disclose to the U.S. medical community that the effectiveness of the devices 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. Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue.
- H. Promoting the pain pumps for use in the joint space after the F.D.A. had considered and rejected such an indication;
- I. Failing to conduct adequate testing to determine whether pain pumps filled with local anesthetics such as bupivacaine, with or without epinephrine and used in the joint space, could cause damage to articular cartilage.

19. The negligent acts and omissions alleged above were substantial contributing causes of the injuries suffered by PLAINTIFF ROBIN M. SMITH. Specifically, the pain pump caused her to suffer the permanent loss of cartilage in her left shoulder, resulting in severe pain and discomfort of the shoulder, and loss of use and function of the shoulder and arm. The use of the Stryker pain pump also rendered the therapeutic benefits of plaintiff's shoulder surgery worthless. PLAINTIFF ROBIN M. SMITH has undergone additional surgeries, including both partial and full shoulder replacement surgeries, and will require future medical care to treat her persistent shoulder pain and disability. In addition, PLAINTIFF ROBIN M. SMITH has suffered

loss of earning capacity, mental and physical pain and suffering, distress and anguish, and disfigurement all past and future due to the permanent impairment of the use and function of her affected upper extremities.

20. The injuries suffered by plaintiff Robin M. Smith were the reasonably foreseeable results of DEFENDANTS' negligence, jointly and together.

21. As a direct, foreseeable and proximate result of the injuries to his wife, Robin M. Smith, as stated above, PLAINTIFF CRAIG A. SMITH has suffered the loss of society, companionship and consortium, services and support of his spouse, past and future.

V. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Honorable Court grant the following relief:

- A. Judgment in favor of the Plaintiffs and against the Defendants in an amount in excess of twenty-five thousand dollars (\$25,000.00), which is fair, just and equitable, as and for compensatory damages, plus interest, costs and attorneys' fees;
- B. Judgment in favor of Plaintiffs and against Defendants in an amount that is fair, just and reasonable as exemplary damages to make an example of Defendants for outrageous actions marketing its pain pump for use in the joint space without approval knowing it could cause destruction of cartilage and of the joint space;
- B. Such other and further relief as this Honorable Court shall deem just, equitable, and proper in the premises.

Respectfully submitted,

ATKINSON, PETRUSKA, KOZMA & HART

BY: *Linda Miller Atkinson*

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Gaylord, MI 49734

- and -

WILLIAMS, LOVE, O'LEARY & POWERS

BY: _____

MICHAEL WILLIAMS

9755 SW Barnes Rd. Ste 450

Portland, OR 97225-6681

Dated: June 1, 2009

DEMAND FOR TRIAL BY JURY

Plaintiffs ROBIN M. SMITH and CRAIG A. SMITH, by their attorneys, ATKINSON, PETRUSKA, KOZMA & HART, and WILLIAMS, LOVE, O'LEARY & POWERS hereby demands trial by jury.

Respectfully submitted,

ATKINSON, PETRUSKA, KOZMA & HART

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- and -

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Dated: June 1, 2009