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SUPERIOR COURT OF CALIFORNIA

COUNTY OF LOS ANGELES

SCOTT ALMHJELL AND SHEILAH MARIE ALMHJELL,

Plaintiffs,

vs.

DEPUY ORTHOPAEDICS, INC., THOMAS P. SCHMALZRIED, M.D. A PROFESSIONAL CORPORATION; and DOES 1 through 20, inclusive,

Defendants.

No. BC444657

COMPLAINT FOR:

(1) STRICT PRODUCT LIABILITY,
(2) NEGLIGENCE,
(3) BREACH OF IMPLIED WARRANTIES,
(4) BREACH OF EXPRESS WARRANTY, and
(5) LOSS OF CONSORTIUM

BY FAX

JURY TRIAL DEMANDED

1. When cars are recalled, the solution is usually a quick trip to the dealership. When hip implants are recalled, the solution is not so easy. This case is about the recall and failure of an untested and unapproved hip implant that was designed, manufactured, and sold by the Defendants and implanted in Plaintiff Scott Almhjell. Mr. Almhjell's story is a tragic example of the pain, anguish, and damages that are caused when a company is motivated by greed and it continues selling a hip implant long after it realizes that the product has a defect and even long after that defect injured hundreds of other people.

PARTIES

2. Plaintiff Scott Almhjell is a citizen of the State of Arizona and resides in Scottsdale, Arizona.

3. Plaintiff Sheilah Marie Almhjell is, and at all times relevant to this Complaint was, Scott Almhjell's wife. She a citizen of the State of Arizona and resides in Scottsdale, Arizona.

4. On information and belief, Defendant DePuy Orthopaedics, Inc. ("DePuy") is a corporation organized and existing under the laws of Indiana with its primary place of business in Warsaw, Indiana. DePuy designed, manufactured, and sold the hip implant that is the subject of this lawsuit.

5. On information and belief, Defendant Thomas P. Schmalzried, M.D. A Professional Corporation ("TPS Corp.") is a corporation organized and existing under the laws of California with its primary place of business at 2200 W. Third St., #400 in Los Angeles, California. TPS Corp. designed the hip implant that is the subject of this lawsuit. TPS Corp. collects royalties for each hip implant sold, and in the last two years alone, it has collected more than $3.4 million in such royalty payments.

6. The true names and capacities of Does 1 through 20 are unknown to Plaintiffs. Plaintiffs are informed and believe and thereon allege that each of these Defendants are in some way liable for the events referred to in this Complaint and caused damage to Plaintiffs. Plaintiffs will amend this Complaint and insert the correct names and capacities of those Defendants when they are discovered.

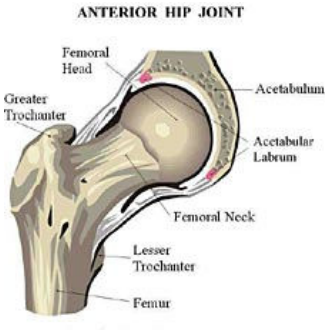
7. At all times mentioned, each of the Defendants—including DOES 1 through 20—was the representative, agent, employee, joint venturer, or alter ego of each of the other defendants and in doing the things alleged herein was acting within the scope of its authority as such.

8. DePuy, TPS Corp., and DOES 1 through 20 are collectively referred to herein as "Defendants."

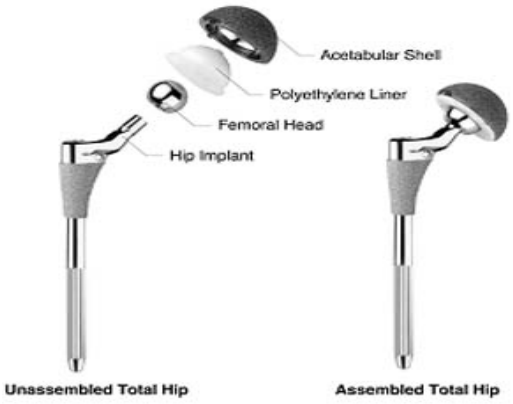
FACTUAL BACKGROUND

A. DePuy's ASR Hip Implant Has Not Been Adequately Tested or Approved By The FDA

9. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids. Over time, age and wear break down the cartilage. This forces the bone of the femur to rub directly against the bone of the acetabulum, and it causes severe pain and immobility.



10. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem (labeled as "hip implant" in the diagram to the left), (2) a femoral head, and (3) a liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.



11. The DePuy ASR hip implant that is at issue in this lawsuit has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup. The design of the DePuy ASR hip is unorthodox, it was not sufficiently tested by the Defendants, and it has never been approved by the FDA as being safe or effective.

12. The acronym "ASR" stands for "Articular Surface Replacement." ASR is a surgical procedure that is an alternative to a total hip replacement procedure. In an ASR procedure, only the articular surface of the hip (the acetabular cup and the femoral ball) are replaced. On the other hand, a total hip replacement includes not only the acetabular cup and femoral ball, but also a large piece of metal (known as a femoral stem) that is implanted deep into the patient's femur and on which the femoral ball is affixed.

13. If DePuy wanted to market its ASR Hip for use in an ASR surgery, the FDA would have required DePuy to conduct clinical trials and prove that the product is both safe

and effective. DePuy would then need to submit an application asking the FDA to approve the device, and it would be required to monitor the long-term safety and performance of the product once it was placed on the market. DePuy wanted to market its ASR Hip System in the United States, but it didn't want to go through the trouble or incur the expense of clinical trials or obtaining FDA approval.

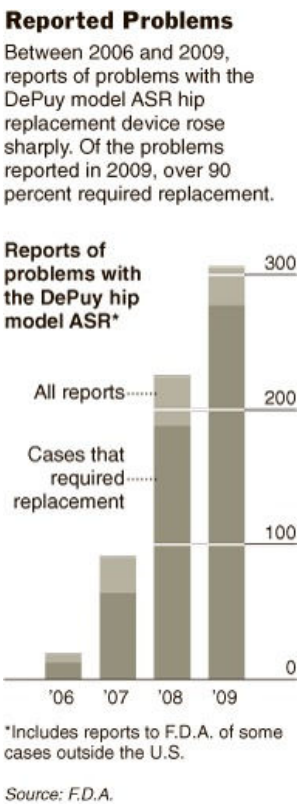
14. Instead of assuring the safety of the ASR through clinical trials, DePuy relied on a loophole in FDA regulations that allows DePuy to market its ASR Hip without conducting any clinical trials and without ever obtaining FDA approval. DePuy told the FDA that the components of the ASR Hip System would be used for total hip replacements, not for ASR surgeries. DePuy then told the FDA that its design was "substantially equivalent" to other hip products on the market. By doing so, DePuy was able to skirt the FDA regulations that would have required clinical trials and FDA approval, and it was able to put the ASR Hip System on the market in the United States ostensibly for use in an application for which it was not designed, a total hip replacement. To this day, despite being implanted in the bodies of thousands of Americans who believed that the devices are safe, DePuy's ASR Hip System has never been approved by the FDA as being safe or effective.

15. While most hip replacements use a polyethylene ***plastic*** acetabular cup, DePuy's ASR Hip System has a critical difference: it uses a ***metal*** acetabular cup. By using a metal acetabular cup and a metal femoral ball, the ASR Hip forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design for the ASR Hip, hundreds of patients—including Mr. Almhjell—have been forced to undergo surgeries to replace the failed hip implants.

B. After Hundreds of Failures, DePuy And The FDA Finally Recalled The ASR Hip

16. It wasn't long after DePuy launched the ASR hip in 2005 that reports of failures began flooding into DePuy. For example, just a few months after it began selling the ASR Hip System, in May 2006, DePuy received a complaint from a doctor who reported that the ASR acetabular cup had failed in a patient who had to undergo a revision surgery to replace the defective cup. DePuy closed its investigation of this complaint, finding that "corrective action is not indicated."

17. DePuy would go on to receive hundreds of similar complaints reporting that the ASR Hip System had failed due to premature loosening of the acetabular cup and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. As the *New York Times* chart to the right shows, by 2007 over 100 reports had been sent to DePuy. By the end of 2008, that had skyrocketed to well over 300 reports.



18. By the time DePuy sold the ASR Hip System to Scott Almhjell in February 2007, DePuy had received several complaints that the ASR hip had failed. Consequently, DePuy was fully aware that the ASR Hip System was defective and that patients already had been injured by that defect. This is confirmed by Dr. Stephen Graves, the Director of the Australian Orthopaedic Association's National Joint Replacement Registry. Dr. Graves believes that the data available to DePuy had shown for some time that the ASR had been failing early at a significantly higher rate than its competitors' devices.

19. The defect in the ASR hip appears to be design-related. Several orthopedic specialists have opined that the design of the ASR acetabular cup, which is shallower than acetabular cups made by other companies, is at the heart of the hip implant's problems. For example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles who designs hip implants said that he believed that the design of the ASR hip is prone to problems.

20. Even the surgeon who designed the ASR hip, Dr. Thomas Schmalzried, admitted that DePuy had known since at least 2008 that the ASR cup may have problems. *The New York Times* reported in March 2010 that "Dr. Schmalzried said in an interview last month that he and DePuy officials realized within the last two years that the ASR cup might be more of a challenge to implant properly than competing cups." According to Dr. Schmalzried, "The window for component position that is consistent for good, long-term clinical function is smaller for the ASR," than other cups.

21. Despite its knowledge that the ASR hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, DePuy continued selling the defective hip implant. In so doing, DePuy actively concealed the known defect from doctors and patients—including Mr. Almhjell and his doctor—and misrepresented that that the ASR Hip System was a safe and effective medical device.

22. DePuy's reason to conceal the defect in its ASR Hip System is clear. In 2009 alone, DePuy brought in more than $5.4 billion in sales. Hip implant sales are critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of Johnson & Johnson's most profitable business groups. In 2006, DePuy was faced with a critical defect in one of its hip implant systems. The last thing DePuy wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, DePuy decided that it would not issue an embarrassing recall when it learned of the

defects with its ASR Hip System in 2006. Moreover, motivated by greed rather than patient safety, DePuy did not even stop selling ASR Hip System. Instead, it continued to manufacture the hip implants and it continued to sell them to unsuspecting patients like Mr. Almhjell.

23. By early 2010, DePuy could no longer keep its secret. By then, the ASR hip had failed in 600 people, most of whom were forced to undergo a painful surgery to remove the defective ASR hip and replace it. But even after hundreds of people had been severely injured by its product, DePuy still didn't do the right thing by recalling its ASR hips.

24. In March 2010, DePuy finally began to disclose some of the alarming information about the ASR hip. It sent a letter to doctors warning them of the increased failure rate associated with the ASR Hip System. DePuy admitted that the ASR Hip System suffered from a "higher than expected revision rate," and that data compiled by the Australian National Joint Replacement Registry showed that 5.4 percent of the ASR Hips implanted had been surgically replaced after only three years and that the expected failure rate could be as high as 10 percent. The letter also stated that DePuy was planning to stop selling the ASR hip, allegedly because of "declining demand."

25. On July 17, 2010, the FDA announced a nationwide recall related to the DePuy ASR Hip System. The FDA classified this recall as a Class 2 Recall. A Class 2 Recall includes situations where exposure to a violative product could cause a situation in which use of or exposure to a violative product may cause medically reversible adverse health consequences.

26. Most recently, on August 25, 2010, DePuy confirmed that in the first five years after implant alone, 13 percent of its ASR hip implants have failed and had to be surgically removed. DePuy also confirmed that at least 90,000 people have had ASR hips implanted in their bodies, meaning that over time, at least ***11,700 people*** will have an ASR hip failure and be forced to undergo a painful surgery to remove and replace it.

C. Mr. Almhjell's ASR Hip Was Defective And Failed, Forcing Him To Undergo An Additional Painful And Risky Surgery

27. In February 2007, Mr. Almhjell underwent a surgical procedure to implant the ASR Hip in his left hip. By this time, Defendants had already received several reports that the ASR Hip has failed, but DePuy refused to disclose that information to Mr. Almhjell, his physician, or the public. It would be another ***three years*** before DePuy would finally come clean and recall the ASR Hip due to its high failure rate.

28. After his left hip surgery, around November 2009, Mr. Almhjell began suffering from persistent debilitating pain in his left hip. It became increasingly painful for him to walk, to move his leg, and to rise from the seated position. Mr. Almhjell's pain increased to such an unbearable level that, at times, he was not able to walk, and he required pain medications.

29. His left hip pain became so unbearable that his orthopedic surgeon recommended a surgery to replace it. In February 2010, Mr. Almhjell underwent a complex, risky, and painful surgery (known as a "revision surgery") to remove the failed DePuy hip implant and replace it with a new hip implant. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications. The revision surgery also required the use of four long screws into Mr. Almhjell's pelvis. These screws caused immense pain following the surgery and could lead to severe complications in the future.

30. During the revision surgery, Mr. Almhjell's surgeon found that the DePuy ASR acetabular shell was loose because it had no bone in-growth. This is a classic sign of a failure of the acetabular shell, and it is a hallmark of the defect in DePuy's ASR Hip. The fact that no bone had grown into the DePuy acetabular component over the three years that it was

implanted means that Mr. Almhjell's body was rejecting the implant due to the toxic metal particles created by the defect in the ASR Hip.

D. The Defective ASR Hip And The Defendants' Conduct Caused Permanent Injuries And Substantial Damages to Mr. and Mrs. Almhjell

31. Mr. Almhjell's recovery from the replacement surgery has been long and painful. To this day—more than six months after the revision surgery—he continues to suffer from pain and discomfort.

32. Having to go through a revision surgery subjected Mr. Almhjell to much greater risks of future complications than he had before the revision surgery. For example, several studies have found that revision surgery has a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

33. As a direct and proximate result of the failure of the defective hip system and the Defendants' wrongful conduct described in this Complaint, Mr. Almhjell sustained and continues to suffer economic damages (including medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result thereof, Plaintiffs have sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $25,000 jurisdictional minimum of this court.

34. As a direct and proximate result of the failure of the defective DePuy ASR Hip System and Defendants' wrongful conduct, Sheilah Marie Almhjell, Scott Almhjell's wife, has been and will continue to be deprived of the consortium, society, comfort, protection, and service of Scott Almhjell, thereby causing and continuing to cause Mrs. Almhjell's economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering.

FIRST CAUSE OF ACTION
(Strict Product Liability)
Against All Defendants

35. Plaintiffs incorporate by reference paragraphs 1 through 34 of this Complaint as if fully set forth here and further allege as follows:

36. Defendants designed, manufactured, promoted, distributed, marketed, and sold the DePuy ASR Hip System, including the ASR acetabular component.

37. At all times material hereto, the DePuy ASR Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was expected to reach, and did reach, prescribing physicians and consumers, including Mr. Almhjell, without substantial change in the condition in which it was sold.

38. At all times material hereto, the DePuy ASR Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

(a) When placed in the stream of commerce, the DePuy ASR Hip System contained manufacturing defects, subjecting Mr. Almhjell and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to

prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(b) When placed in the stream of commerce, the DePuy ASR Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Mr. Almhjell and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

(c) The DePuy ASR Hip System was insufficiently tested; and

(d) The DePuy ASR Hip System was not accompanied by adequate instructions and/or warnings to fully inform Mr. Almhjell or his physicians of the full nature or extent of the risks associated with its use.

39. Defendants knew or should have known of the dangers associated with the use of the DePuy ASR Hip System, as well as the defective nature of the DePuy ASR Hip System. Despite this knowledge, Defendants continued to manufacture, sell, distribute, promote and supply the DePuy ASR Hip System so as to maximize sales and profits at the expense of the public health and safety. Defendants' conduct was done in conscious disregard of the foreseeable harm caused by the DePuy ASR Hip System and in conscious disregard for the rights and safety of consumers such as Mr. Almhjell.

40. Mr. Almhjell and his doctor used the DePuy ASR Hip System as directed for its intended purpose.

41. At all times herein mentioned, the DePuy ASR Hip System was defective, and Defendants knew that it was to be used by the user without inspection for defects therein.

Moreover, neither Mr. Almhjell nor his physician knew or had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects. Neither Mr. Almhjell nor his physicians could have discovered the defects in the DePuy ASR Hip System through the reasonable exercise of care.

42. The DePuy ASR Hip System had not been materially altered or modified prior to its implantation in Mr. Almhjell.

43. As a direct and proximate result of the failure of the defective DePuy ASR Hip System, Plaintiffs suffered the injuries and damages as described herein.

SECOND CAUSE OF ACTION
(Negligence)
Against All Defendants

44. Plaintiffs incorporate by reference paragraphs 1 through 34 of this Complaint as if fully set forth here and further allege as follows:

45. At all times herein mentioned Defendants had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, and sale of the DePuy ASR Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

46. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, advertising, marketing, and sale of the DePuy ASR Hip System.

47. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Mr. Almhjell and his physicians as to the risks of the DePuy ASR Hip System.

48. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the DePuy ASR Hip System when they knew or should have known of said risks.

49. As a result of Defendants' wrongful conduct, Plaintiffs suffered injuries and damages as alleged herein.

THIRD CAUSE OF ACTION
(Breach of Implied Warranties)
Against DePuy and DOES 1 - 10

50. Plaintiffs incorporate by reference paragraphs 1 through 34 of this Complaint as if fully set forth here and further allege as follows:

51. Prior to the time that the DePuy ASR Hip System was used by Mr. Almhjell, Defendants impliedly warranted to Mr. Almhjell and his physicians that the DePuy ASR Hip System was of merchantable quality and safe and fit for the use for which it was intended.

52. Mr. Almhjell and his physician were and are unskilled in the research, design and manufacture of the DePuy ASR Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Defendants in using the DePuy ASR Hip System.

53. The DePuy ASR Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

54. Defendants, by selling, delivering and/or distributing the defective DePuy ASR Hip System to Mr. Almhjell breached the implied warranty of merchantability and fitness

and caused Mr. Almhjell to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

55. As a result of the aforementioned breach of implied warranties by Defendants, Plaintiffs suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION
(Breach of Express Warranty)
Against DePuy and DOES 1 – 10

56. Plaintiffs incorporate by reference paragraphs 1 through 34 of this Complaint as if fully set forth here and further allege as follows:

57. At all times herein mentioned, Defendants expressly warranted to Mr. Almhjell and Mr. Almhjell's physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned DePuy ASR Hip System was safe, effective, fit and proper for its intended use.

58. In utilizing the aforementioned DePuy ASR Hip System, Mr. Almhjell and his physician relied on the skill, judgment, representations and foregoing express warranties of Defendants.

59. Said warranties and representations were false in that the aforementioned DePuy ASR Hip System was not safe and was unfit for the uses for which it was intended.

60. As a result of the foregoing breach of express warranties by Defendants, Plaintiffs suffered injuries and damages as alleged herein.

FIFTH CAUSE OF ACTION
(Loss of Consortium)
Against All Defendants

61. Plaintiff Sheilah Marie Almhjell incorporates by reference paragraphs 1 through 60 of this Complaint as if fully set forth here and further alleges as follows.

62. As a direct and proximate result of the failure of the defective DePuy ASR Hip System and Defendants' wrongful conduct, Sheilah Marie Almhjell, Scott Almhjell's wife, has been and will continue to be deprived of the consortium, society, comfort, protection, and service of Scott Almhjell, thereby causing and continuing to cause Sheilah Marie Almhjell economic damages, grief, sorrow, mental anguish, emotional distress, and pain and suffering.

PRAYER FOR RELIEF

THEREFORE, Plaintiffs demand judgment for the following:

1. Past and future medical and incidental expenses, according to proof;

2. Past and future loss of earnings and/or earning capacity, according to proof;

3. Past and future general damages, according to proof;

4. Punitive and exemplary damages in an amount to be determined at trial;

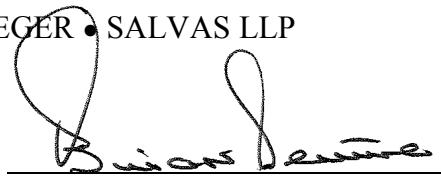
5. Prejudgment and post judgment interest;

6. Costs to bring this action; and

7. Such other and further relief as the court may deem just and proper.

DATED: August 30, 2010.

SEEGER • SALVAS LLP

By 

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