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8 SUPERIOR COURT OF CALIFORNIA
9 COUNTY OF SAN FRANCISCO
10

11 LISÉ MARKHAM,

12 Plaintiff,

13 vs.

14 DEPUY ORTHOPAEDICS, INC.,
15 JOHNSON & JOHNSON SERVICES,
INC., JOHNSON & JOHNSON, INC.,
16 THOMAS P. SCHMALZRIED, M.D. A
PROFESSIONAL CORPORATION;
17 VAIL CONSULTING LLC, SGF
MEDICAL, INC., and DOES 1 through
18 20, inclusive,

19 Defendants.
20
21

No.

COMPLAINT FOR:

- (1) **STRICT PRODUCT LIABILITY,**
- (2) **NEGLIGENCE,**
- (3) **BREACH OF IMPLIED WARRANTIES,**
- (4) **BREACH OF EXPRESS WARRANTY, and**
- (5) **BREACH OF SONG-BEVERLY CONSUMER WARRANTY ACT**

JURY TRIAL DEMANDED

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

PARTIES

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2
3 2. Plaintiff Lisé Markham is a citizen of the State of California and resides in
4 San Diego, California.

5
6 3. 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
7 business in Warsaw, Indiana. DePuy designed, manufactured, and sold the hip implant that is the
8 subject of this lawsuit.
9

10
11 4. On information and belief, Defendant Johnson & Johnson, Inc. (“J&J”) is a corporation organized and existing under the laws of New Jersey with its primary place of
12 business in New Brunswick, New Jersey. J&J designed, manufactured, and sold the hip implant
13 that is the subject of this lawsuit.
14

15
16 5. On information and belief, Defendant Johnson & Johnson Services, Inc. (“JJSI”) is a corporation organized and existing under the laws of New Jersey with its primary
17 place of business in New Brunswick, New Jersey. JJSI designed, manufactured, and sold the hip
18 implant that is the subject of this lawsuit.
19

20
21 6. 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
22 California with its primary place of business at 2200 W. Third St., #400 in Los Angeles,
23 California. TPS Corp. designed the hip implant that is the subject of this lawsuit. TPS Corp.
24 collects royalties for each hip implant sold, and in the last two years alone, it has collected more
25 than \$3.4 million in such royalty payments. In addition to designing the hip implant components
26 that were implanted in Plaintiff Lisé Markham and collecting royalties for the sale of Plaintiff’s
27 implant, TPS Corp. remained actively involved in promoting and marketing the “ASR XL
28

1 Acetabular System” (the “ASR hip implant.”) TPS Corp., by and through its shareholder,
2 director, and officer, Dr. Thomas Schmalzried, was a “product champion” for the ASR hip
3 implant. In the orthopedics community, a “product champion” uses his or her reputation as a
4 prominent orthopedic surgeon to encourage other orthopedic surgeons to use a new product. In
5 his role as a “product champion” for the ASR implant, Dr. Schmalzried, on behalf of TPS Corp.,
6 made representations to orthopedic surgeons, including Plaintiff Lisé Markham’s orthopedic
7 surgeon, that the ASR hip implant was safe and effective. Although it knew or should have
8 known about defects in the ASR hip implant at the time the ASR implant was sold to Plaintiff,
9 TPS Corp. did not disclose that information to Plaintiff or her doctors. Despite a legal duty to
10 disclose the information to Plaintiff and her doctors, TPS Corp. actively concealed mounting
11 problems with the ASR hip implant, and it instead deflected blame for the mounting failures by
12 blaming the surgical technique of the implanting orthopedic surgeon.

13
14 7. On information and belief, Defendant Vail Consulting LLC is a limited
15 liability company registered under the laws of North Carolina with its primary place of business
16 at 3474 Clay Street in San Francisco. Vail Consulting designed the hip implant that is the subject
17 of this lawsuit. Vail Consulting collects royalties for each hip implant sold, and in the last two
18 years alone, it has collected more than \$400,000 in such royalty payments. In addition to
19 designing the hip implant components that were implanted in Plaintiff Lisé Markham and
20 collecting royalties for the sale of Plaintiff’s implant, Vail Consulting remained actively involved
21 in promoting and marketing the ASR hip implant. Vail Consulting, by and through its sole
22 member, Dr. Thomas Vail, was a “product champion” for the ASR hip implant. In the
23 orthopedics community, a “product champion” uses his or her reputation as a prominent
24 orthopedic surgeon to encourage other orthopedic surgeons to use a new product. In his role as a
25 “product champion” for the ASR implant, Dr. Vail, on behalf of Vail Consulting, made
26 representations to orthopedic surgeons, including Plaintiff Lisé Markham’s orthopedic surgeon,
27 that the ASR hip implant was safe and effective. Although it knew or should have known about
28 defects in the ASR hip implant at the time the ASR implant was sold to Plaintiff, Vail Consulting

1 did not disclose that information to Plaintiff or her doctors. Despite a legal duty to disclose the
2 information to Plaintiff and her doctors, Vail Consulting actively concealed mounting problems
3 with the ASR hip implant, and it instead deflected blame for the mounting failures by blaming the
4 surgical technique of the implanting orthopedic surgeon.

5
6 8. On information and belief, Defendant SGF Medical, Inc. (“SGF”) is a
7 corporation organized and existing under the laws of California with its primary place of business
8 in San Diego, California. SGF marketed and sold the hip implant that is the subject of this
9 lawsuit.

10
11 9. The true names and capacities of Does 1 through 20 are unknown to
12 Plaintiff. Plaintiff is informed and believes and thereon alleges that each of these Defendants are
13 in some way liable for the events referred to in this Complaint and caused damage to Plaintiff.
14 Plaintiff will amend this Complaint and insert the correct names and capacities of those
15 Defendants when they are discovered.

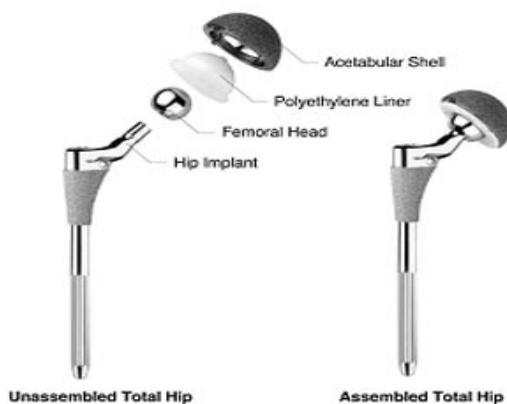
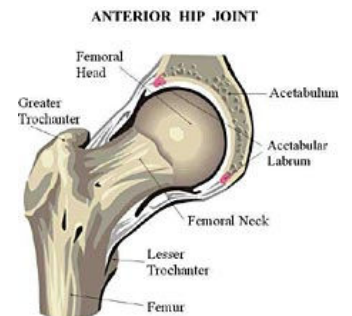
16
17 10. At all times mentioned, each of the Defendants—including DOES 1
18 through 20—was the representative, agent, employee, joint venturer, or alter ego of each of the
19 other defendants and in doing the things alleged herein was acting within the scope of its
20 authority as such.

21
22 11. DePuy, J&J, JJSI, TPS Corp., Vail Consulting, SGF, and DOES 1 through
23 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**

12. 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.



13. 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.

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



7
8 15. The acronym “ASR”
9 stands for “Articular Surface Replacement.”

10 ASR is a surgical procedure that is an alternative to a total hip replacement procedure. In an ASR
11 procedure, only the articular surface of the hip (the acetabular cup and the femoral ball) is
12 replaced. On the other hand, a total hip replacement includes not only the acetabular cup and
13 femoral ball, but also a large piece of metal (known as a femoral stem) that is implanted deep into
14 the patient’s femur and on which the femoral ball is affixed.

15
16 16. If DePuy wanted to market its ASR Hip for use in an ASR surgery, the
17 FDA would have required DePuy to conduct clinical trials and prove that the product is both safe
18 and effective. DePuy would then need to submit an application asking the FDA to approve the
19 device, and it would be required to monitor the long-term safety and performance of the product
20 once it was placed on the market. DePuy wanted to market its ASR Hip System in the United
21 States, but it didn’t want to go through the trouble or incur the expense of clinical trials or
22 obtaining FDA approval.

23
24 17. Instead of assuring the safety of the ASR through clinical trials, DePuy
25 relied on a loophole in FDA regulations—known as the §510(k) process—that allows DePuy to
26 market its ASR Hip without conducting any clinical trials and without ever obtaining FDA
27 approval. DePuy told the FDA that the components of the ASR Hip System would be used for
28 total hip replacements, not for ASR surgeries. DePuy then told the FDA that its design was

1 “substantially equivalent” to other hip products on the market. By doing so, DePuy was able to
 2 skirt the FDA regulations that would have required clinical trials and FDA approval, and it was
 3 able to put the ASR Hip System on the market in the United States ostensibly for use in an
 4 application for which it was not designed, a total hip replacement. To this day, despite being
 5 implanted in the bodies of thousands of Americans who believed that the devices are safe,
 6 DePuy’s ASR Hip System has never been approved by the FDA as being safe or effective.

7
 8 18. While most hip replacements use a polyethylene *plastic* acetabular liner,
 9 DePuy’s ASR Hip System has a critical difference: the acetabular cup includes a *metal*
 10 articulating surface. By using a metal acetabular articulating surface and a metal femoral ball, the
 11 ASR Hip forces metal to rub against metal with the full weight and pressure of the human body.
 12 Because of Defendants’ defective design for the ASR Hip, hundreds of patients—including Ms.
 13 Markham—have been forced to undergo surgeries to replace the failed hip implants and continue
 14 to do so at alarmingly high numbers compared to any other hip implant revisions.

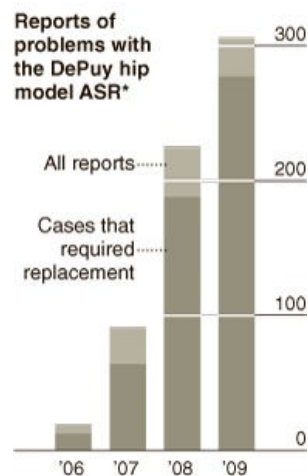
16 **B. After Hundreds of Failures, DePuy And The FDA Finally Recalled The ASR Hip**

17
 18 19. It wasn’t long after DePuy launched the ASR
 19 hip in 2005 that reports of failures began flooding into the Defendants.
 20 For example, just a few months after DePuy began selling the ASR
 21 Hip System, in May 2006, the Defendants received a complaint from a
 22 doctor who reported that the ASR acetabular cup had failed in a
 23 patient who had to undergo a revision surgery to replace the defective
 24 cup. DePuy closed its investigation of this complaint, finding that
 25 “corrective action is not indicated.”

26
 27 20. The Defendants would go on to receive
 28 hundreds of similar complaints reporting that the ASR Hip System had

Reported Problems

Between 2006 and 2009, reports of problems with the DePuy model ASR hip replacement device rose sharply. Of the problems reported in 2009, over 90 percent required replacement.



*Includes reports to F.D.A. of some cases outside the U.S.

Source: F.D.A.

1 failed due to premature loosening of the acetabular cup and that the failure had forced patients to
2 undergo painful and risky surgeries to remove and replace the failed hip component. As the *New*
3 *York Times* chart to the right shows, by 2007 over 100 reports had been sent to DePuy. By the
4 end of 2008, that had skyrocketed to well over 300 reports.

5
6 21. By the time the DePuy sold the ASR Hip System to Lisé Markham on
7 March 10, 2008, the Defendants had already received hundreds of complaints that the ASR hip
8 had failed. Consequently, the Defendants were fully aware that the ASR Hip System was
9 defective and that patients already had been injured by that defect. This is confirmed by Dr.
10 Stephen Graves, the Director of the Australian Orthopaedic Association's National Joint
11 Replacement Registry. Dr. Graves believes that the data available to the Defendants had shown
12 since as early as 2006 that the ASR had been failing at a significantly higher rate than its
13 competitors' devices.

14
15 22. The defect in the ASR hip appears to be design-related. Several orthopedic
16 specialists have opined that the design of the ASR acetabular cup, which is shallower than
17 acetabular cups made by other companies, is at the heart of the hip implant's problems. For
18 example, Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles who designs hip implants
19 said that he believed that the design of the ASR hip is prone to problems.

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

28

1 24. Despite their knowledge that the ASR hip had a defect and that it had failed
2 hundreds of times, causing hundreds of patients to undergo the agony of another surgery, the
3 Defendants continued selling the defective hip implant. In so doing, the Defendants actively
4 concealed the known defect from doctors and patients—including Ms. Markham and her doctor—
5 and misrepresented that that the ASR Hip System was a safe and effective medical device.
6

7 25. The Defendants' reason to conceal the defect in its ASR Hip System is
8 clear. In 2009 alone, DePuy brought in more than \$5.4 billion in sales. Hip implant sales are
9 critically important to DePuy's parent company, Johnson & Johnson, and DePuy is one of
10 Johnson & Johnson's most profitable business groups. Likewise, the sale of orthopedic implants
11 contributed substantially to the incomes of TPS Corp. and Vail Consulting, and SGF. TPS Corp.
12 and Vail Consulting alone received \$4 million in royalty income from DePuy in the last two
13 years, and SGF received commissions on each sale of an ASR implant. In 2006, the Defendants
14 were faced with a critical defect in the ASR hip implant system. The last thing they wanted to do
15 was to admit that these popular products had a critical defect that could cause a premature failure,
16 forcing patients to have to undergo another painful surgery. Focused on profits, and at the
17 expense of patient safety, the Defendants decided that they would not issue an embarrassing recall
18 when they learned of the defects with the ASR hip implant in 2006. Moreover, motivated by
19 greed rather than patient safety, the Defendants did not even stop selling the ASR hip implant.
20 Instead, they continued to manufacture the hip implants and they continued to sell them to
21 unsuspecting patients like Ms. Markham.
22

23 26. By early 2010, the Defendants could no longer keep their secret. By then,
24 the ASR hip had failed in 600 people, and most of them were forced to undergo a painful surgery
25 to remove the defective ASR hip and replace it. But even after hundreds of people had been
26 severely injured by its product, the Defendants still didn't do the right thing by recalling the ASR
27 hip implant.
28

1 27. In March 2010, the Defendants finally began to disclose some of the
2 alarming information about the ASR hip. DePuy sent a letter to doctors warning them of the
3 increased failure rate associated with the ASR Hip System. DePuy admitted that the ASR hip
4 implant suffered from a “higher than expected revision rate,” and that data compiled by the
5 Australian National Joint Replacement Registry showed that 5.4 percent of the ASR Hips
6 implanted had been surgically replaced after only three years and that the expected failure rate
7 could be as high as 10 percent. The letter also stated that DePuy was planning to stop selling the
8 ASR hip, allegedly because of “declining demand.” But the Defendants still did not recall the
9 defective ASR hip implants that were already on the market.

10
11 28. On July 17, 2010, the FDA announced a nationwide recall related to the
12 DePuy ASR Hip System. The FDA classified this recall as a Class 2 Recall. A Class 2 Recall
13 includes situations where exposure to a violative product could cause a situation in which use of
14 or exposure to a violative product may cause medically reversible adverse health consequences.

15
16 29. On August 25, 2010, DePuy confirmed that in the first five years after
17 implant alone, 13 percent of its ASR hip implants have failed and had to be surgically removed.
18 DePuy also confirmed that at least 90,000 people have had ASR hips implanted in their bodies,
19 meaning that at least *12,000 people* will have an ASR hip failure and be forced to undergo a
20 painful surgery to remove and replace it. This failure rate has increased since then, and some
21 hospitals estimate that 30 percent or more ASR hip implant will fail.

22
23 **C. Ms. Markham’s ASR Hip Was Defective And Failed, Forcing Her To Undergo An**
24 **Additional Painful And Risky Surgery**

25
26 30. On March 10, 2008, Ms. Markham underwent a surgical procedure to
27 implant the ASR hip implant in her right hip. By this time, Defendants had already received
28 hundreds of reports that the ASR hip implant had failed in other patients and that these patients

1 had to undergo surgeries to remove the defective products. But the Defendants actively
2 concealed that information from Ms. Markham, her physician, and the public. Instead, the
3 Defendants represented to Ms. Markham, her physician, and the public, that the ASR hip implant
4 was safe and effective, that it was thoroughly tested, and that it had a very low failure rate. It
5 would be another two and a half years before the Defendants would be forced to recall the ASR
6 hip implant due to a design defect that caused an excessively high failure rate.

7
8 31. Ms. Markham recovered quickly from her surgery in the first few weeks.
9 But then she started to notice a pain in her right hip, extending into her groin, her back, and her
10 thigh. She consulted with several doctors in various fields of medicine, including other
11 orthopedic surgeons as recommended by her doctor, to try to determine the source of the pain, but
12 her doctors were at a loss for an explanation for her pain. Her doctors recommended that she
13 undergo physical therapy, which she did, but that only made the pain worse. Her doctors also
14 recommended extensive, expensive tests from cortisone injections, x-rays, MRI's and bone scans,
15 but her pain continued and increased each day.

16
17 32. By January 2010, the pain became excruciating and unbearable. Ms.
18 Markham constantly suffered from debilitating pain, and the constant pain was punctuated with
19 spasms about five to ten times per day that felt like she was being electrocuted. This pain was
20 now accompanied by a grinding sound coming from her hip implant. Something clearly was
21 wrong with her hip implant, but her doctors could not determine what was wrong.

22
23 33. While Ms. Markham was desperately searching for the cause of her pain,
24 the Defendants were actively concealing their knowledge that the ASR hip implant was defective.
25 Defendants actively attempted to prevent Ms. Markham and her physicians from suspecting that
26 her pain was being caused by a defect in the ASR hip implant. Because of the Defendants' active
27 concealment of their knowledge about the product defect and the failures, Ms. Markham had to
28 suffer with debilitating pain while her physicians attempted to discover the cause.

1 34. On March 9, 2010, an article about DePuy’s ASR hip implant appeared in
2 the *New York Times*. In the article, journalist Barry Meier revealed shocking information about
3 DePuy’s attempt to hide a design defect in its ASR hip system that the company had known about
4 for years. The article detailed DePuy’s efforts to secretly withdraw the ASR hip implant from the
5 market, while at the same time concealing from the public the information about the known
6 defect with the product. The symptoms of failure described in the article are identical to the
7 symptoms that Ms. Markham was experiencing.

8
9 35. Once DePuy’s secret was revealed, Ms. Markham’s doctors were able to
10 determine that the source of her pain was the failure of the defective ASR hip implant. In April
11 2010, a CT scan revealed that there were shadows, called radiolucencies, around Ms. Markham’s
12 hip implant. Based on this CT scan, Ms. Markham’s doctor reached a likely diagnosis of a loose
13 hip implant. Later, on May 3, 2010, the level of cobalt metal in Ms. Markham’s bloodstream had
14 skyrocketed to 4.4 and the level of chromium had risen to 4.1. Both of these levels are more than
15 400 percent normal level, and the elevated levels of cobalt and chromium in Ms. Markham’s
16 bloodstream are now known to be caused by the failure of the DePuy ASR hip implant.

17
18 36. On May 19, 2010, Ms. Markham underwent a complex, risky, and painful
19 surgery (known as a “revision surgery”) to remove the failed DePuy hip implant and replace it
20 with a new system. Revision surgeries are generally more complex than the original hip
21 replacement surgery, often because there is a reduced amount of bone in which to place the new
22 hip implants. Revision surgeries also usually take longer than the original hip replacement
23 surgery and the revision surgery has a higher rate of complications.

24
25 37. During the revision surgery, Dr. Mark McBride found light colored fluid
26 and stained tissue in Ms. Markham’s hip joint. This fluid and stained tissue is the biologic
27 response to the toxic metal particles that are caused by a defective metal-on-metal articulating
28 surface of the DePuy ASR hip. During the revision surgery, Dr. McBride also found that the

1 DePuy ASR acetabular shell was loose because it had no bone in-growth. This is a classic sign of
2 a failure of the acetabular shell, and it is a hallmark of the defect in DePuy's ASR Hip. The
3 absence of any bone in-growth in the DePuy acetabular component over the two years that it was
4 implanted means that Ms. Markham's body was rejecting the implant due to the toxic metal
5 particles created by the defect in the ASR Hip.

6
7 **D. The Defective ASR Hip And The Defendants' Conduct Caused Permanent**
8 **Injuries And Substantial Damages to Ms. Markham**

9
10 38. Ms. Markham's medical course following the revision surgery has been
11 long and painful. To this day—more than six months after the revision surgery—she still suffers
12 from debilitating pain in her hip. Alarming, this pain is increasing as time goes on and her
13 doctors cannot find a cure for the pain. Ms. Markham's ongoing pain is likely being caused by
14 inflammation in her hip joint caused by remnants of the cobalt and chromium from the failed
15 ASR hip implant.

16
17 39. Even a month after the revision surgery, on June 21, 2010, the level of
18 chromium metal in Ms. Markham's bloodstream was still dangerously elevated at the level of 1.6
19 nanograms. It is known that exposure to high levels of cobalt and chromium can trigger a
20 hypersensitivity to metal. Consequently, the failure of the defective ASR hip implant likely
21 caused an inflammatory response which will cause Ms. Markham's body to reject every future
22 hip implant that is put into her body.

23
24 40. The levels of cobalt and chromium that were released into Ms. Markham's
25 bloodstream because of the defective ASR hip implant also can cause systemic and long-term
26 ailments such visual impairment, cardiomyopathy, cognitive impairment, auditory impairment,
27 hypothyroidism, peripheral neuropathy, and rashes. She currently suffers from osteoarthritis and
28

1 degenerative disease she did not have prior to the DePuy implant in her back, hands, and feet as a
2 result of inflammation triggered but the metal particles release in her system.

3
4 41. Having to go through a revision surgery has subjected Ms. Markham to
5 much greater risks of future complications than she had before the revision surgery. For example,
6 several studies have found that revision surgery has a much higher risk of dislocation compared
7 with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her
8 colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent
9 a revision surgery suffered from a dislocation compared with 3.9 percent of patients who
10 underwent a original hip replacement surgery. In other words, hip replacement patients who have
11 undergone a revision surgery are almost *four times more likely* to suffer from a hip dislocation
12 than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary
13 embolism, and deep infection during the first six months after elective total hip replacement.
14 *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

15
16 42. The failure of Ms. Markham's ASR hip implant caused immense personal
17 and professional loss for Ms. Markham. Because she could not bear the pain, she had to put her
18 thriving career on hold, and knows she will never be able to have her entrepreneurial career
19 resumed to get back to the level she was at prior to the failure of her hip implant. The chronic
20 pain caused by the defective ASR hip implant was also a root cause of the breakdown of her
21 marriage, which has now ended in divorce. The failure of her hip implant also negatively
22 affected both of Ms. Markham's daughters. Her daughter Lauren had to leave school part of the
23 way through the 2010-2011 year at University of Colorado to help take care of her mother. Ms.
24 Markham has lost the quality of life she once had and fears for her ability to take care of herself
25 for many potential years to come.

26
27 43. As a direct and proximate result of the failure of the defective hip system
28 and the Defendants' wrongful conduct described in this Complaint, Ms. Markham sustained and

1 continues to suffer economic damages (including past, present, and future lost income, medical
2 expenses, and hospital expenses), severe and possibly permanent injuries, pain, suffering and
3 emotional distress. As a result thereof, Plaintiff has sustained and will continue to sustain
4 damages in an amount to be proven at trial, but which will far exceed the \$25,000 jurisdictional
5 minimum of this court.

6
7 **FIRST CAUSE OF ACTION**
8 (Strict Product Liability)
9 Against All Defendants

10 44. Plaintiff incorporates by reference paragraphs 1 through 41 of this
11 Complaint as if fully set forth here and further alleges as follows:

12 45. Defendants designed, manufactured, promoted, distributed, marketed, and
13 sold the DePuy ASR Hip System, including the ASR acetabular cup that was implanted in
14 Plaintiff Lisé Markham on or about March 10, 2008.

15 46. At all times material hereto, the DePuy ASR Hip System that was
16 designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was
17 expected to reach, and did reach, prescribing physicians and consumers, including Ms. Markham
18 and Ms. Markham’s physician, without substantial change in the condition in which it was sold.

19 47. At all times material hereto, the DePuy ASR Hip System that was
20 designed, manufactured, promoted, distributed, marketed, and sold by the Defendants was in a
21 defective and unreasonably dangerous condition at the time it was placed in the stream of
22 commerce. Such condition included, but is not limited to, one or more of the following
23 particulars:
24

25
26
27 (a) When placed in the stream of commerce, the DePuy ASR Hip System
28 contained manufacturing defects, subjecting Ms. Markham and others to risks, including the risk

1 that the acetabular component would not properly grow into the bone, causing the hip system to
2 prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the
3 defective product;

4
5 (b) When placed in the stream of commerce, the DePuy ASR Hip System
6 contained unreasonably dangerous design defects and was not reasonably safe for the intended
7 use, subjecting Ms. Markham and others to risks, including the risk that the acetabular component
8 would not properly grow into the bone, causing the hip system to prematurely fail and requiring a
9 complex, risky, and painful surgery to remove and replace the defective product;

10
11 (c) The DePuy ASR Hip System was insufficiently tested; and

12
13 (d) The DePuy ASR Hip System was not accompanied by adequate
14 instructions and/or warnings to fully inform Ms. Markham or her physicians of the full nature or
15 extent of the risks associated with its use.

16
17 48. Defendants knew or should have known of the dangers associated with the
18 use of the DePuy ASR Hip System, as well as the defective nature of the DePuy ASR Hip
19 System. Despite this knowledge, Defendants continued to manufacture, sell, distribute, promote
20 and supply the DePuy ASR Hip System so as to maximize sales and profits at the expense of the
21 public health and safety. Defendants' conduct was done in conscious disregard of the foreseeable
22 harm caused by the DePuy ASR Hip System and in conscious disregard for the rights and safety
23 of consumers such as Ms. Markham.

24
25 49. Ms. Markham and her doctor used the DePuy ASR Hip System as directed
26 for its intended purpose.

27
28

1 50. At all times herein mentioned, the DePuy ASR Hip System was defective,
2 and Defendants knew that it was to be used by the user without inspection for defects therein.
3 Moreover, neither Ms. Markham nor her physician knew or had reason to know at the time of the
4 use of the subject products, of the existence of the aforementioned defects. Neither Ms. Markham
5 nor her physicians could have discovered the defects in the DePuy ASR Hip System through the
6 reasonable exercise of care.

7
8 51. The DePuy ASR Hip System had not been materially altered or modified
9 prior to its implantation in Ms. Markham.

10
11 52. As a direct and proximate result of the failure of the defective DePuy ASR
12 Hip System, Plaintiff suffered the injuries and damages as described herein.

13
14 **SECOND CAUSE OF ACTION**

15 (Negligence)

16 Against All Defendants

17 53. Plaintiff incorporates by reference paragraphs 1 through 41 of this
18 Complaint as if fully set forth here and further alleges as follows:

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

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24 55. Defendants maliciously, recklessly and/or negligently failed to exercise
25 ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and
26 sale of the DePuy ASR Hip System.

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56. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Ms. Markham and her physicians as to the risks of the DePuy ASR Hip System.

57. 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.

58. 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 Ms. Markham.

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

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

60. Plaintiff incorporates by reference paragraphs 1 through 41 of this Complaint as if fully set forth here and further alleges as follows:

61. Prior to the time that the DePuy ASR Hip System was used by Ms. Markham, Defendants impliedly warranted to Ms. Markham and her physicians that the DePuy ASR Hip System was of merchantable quality and safe and fit for the use for which it was intended.

62. Ms. Markham and her 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.

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63. 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.

64. Defendants, by selling, delivering and/or distributing the defective DePuy ASR Hip System to Ms. Markham breached the implied warranty of merchantability and fitness and caused Ms. Markham to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

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

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

66. Plaintiff incorporates by reference paragraphs 1 through 41 of this Complaint as if fully set forth here and further alleges as follows:

67. At all times herein mentioned, Defendants expressly warranted to Ms. Markham and Ms. Markham’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.

68. In utilizing the aforementioned DePuy ASR Hip System, Ms. Markham and her physician relied on the skill, judgment, representations and foregoing express warranties of Defendants.

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

3
4 70. As a result of the foregoing breach of express warranties by Defendants,
5 Plaintiff suffered injuries and damages as alleged herein.

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7 **FIFTH CAUSE OF ACTION**
8 (Breach of Song-Beverly Consumer Warranty)
9 Against DePuy and DOES 1 - 10

10 71. Plaintiff incorporates by reference paragraphs 1 through 41 of this
11 Complaint as if fully set forth here and further allege as follows.

12 72. Defendants manufactured the DePuy ASR hip implant, an “assistive
13 device” as defined by the Song-Beverly Act, for the purpose of their eventual retail sale to buyers
14 in California.

15 73. On March 10, 2008, Defendants sold to and caused to be implanted in Ms.
16 Markham the DePuy ASR hip implant.

17
18 74. Pursuant to California Civil Code section 1792, the sale to Ms. Markham
19 of the DePuy ASR hip implant was accompanied by Defendants’ implied warranty that the
20 DePuy ASR hip implant was of merchantable quality.

21
22 75. Defendants breached the implied warranty that the DePuy ASR hip implant
23 was merchantable because it was not fit for the ordinary purposes for which the goods are used.
24 Consequently, Ms. Markham did not receive merchantable goods as impliedly warranted by
25 Defendants.
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1 76. At the time of the sale of the DePuy ASR hip implant to Ms. Markham,
2 Defendants had reason to know that the DePuy ASR hip implant was required for a particular
3 purpose and that Ms. Markham and her physician were relying on Defendants' skill or judgment
4 to select or furnish suitable goods.

5
6 77. Ms. Markham and her physician relied upon Defendants' skill and
7 judgment to select or furnish suitable goods.

8
9 78. Pursuant to California Civil Code section 1792.1, the sale to Ms. Markham
10 of the DePuy ASR hip implant was accompanied by Defendants' implied warranty that the hip
11 implant was specifically fit for the particular needs of Ms. Markham.

12
13 79. Defendants breached the implied warranty that the DePuy ASR hip implant
14 was specifically fit for the particular needs of Ms. Markham because the product had a defect that
15 caused it to catastrophically fail when it was used as intended.

16
17 80. As a direct and proximate result of Defendants' breach of the implied
18 warranties described above, Plaintiff sustained significant injuries and damages as described
19 herein. Plaintiff also sustained incurred medical expenses, including the cost to replace the
20 defective DePuy ASR hip implant, and sustained significant incidental and consequential
21 damages to be proven at trial.

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23 81. Also as a direct result of Defendants' breach of the implied warranties
24 described above, Plaintiff has incurred and continue to incur attorneys' fees in an amount to be
25 proven at trial.

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PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

- 1. Past and future medical and incidental expenses, according to proof;
- 2. Past and future general damages, according to proof;
- 3. Punitive and exemplary damages in an amount to be determined at trial;
- 4. Prejudgment and post judgment interest;
- 5. Attorneys' fees pursuant to the Song-Beverly Act and Code of Civil Procedure Section 1021.5,
- 6. Costs to bring this action; and
- 7. Such other and further relief as the court may deem just and proper.

DATED: January 26, 2011.

SEEGER • SALVAS LLP

By 
 Brian J. Devine
 Attorneys for Plaintiff Lisé Markham