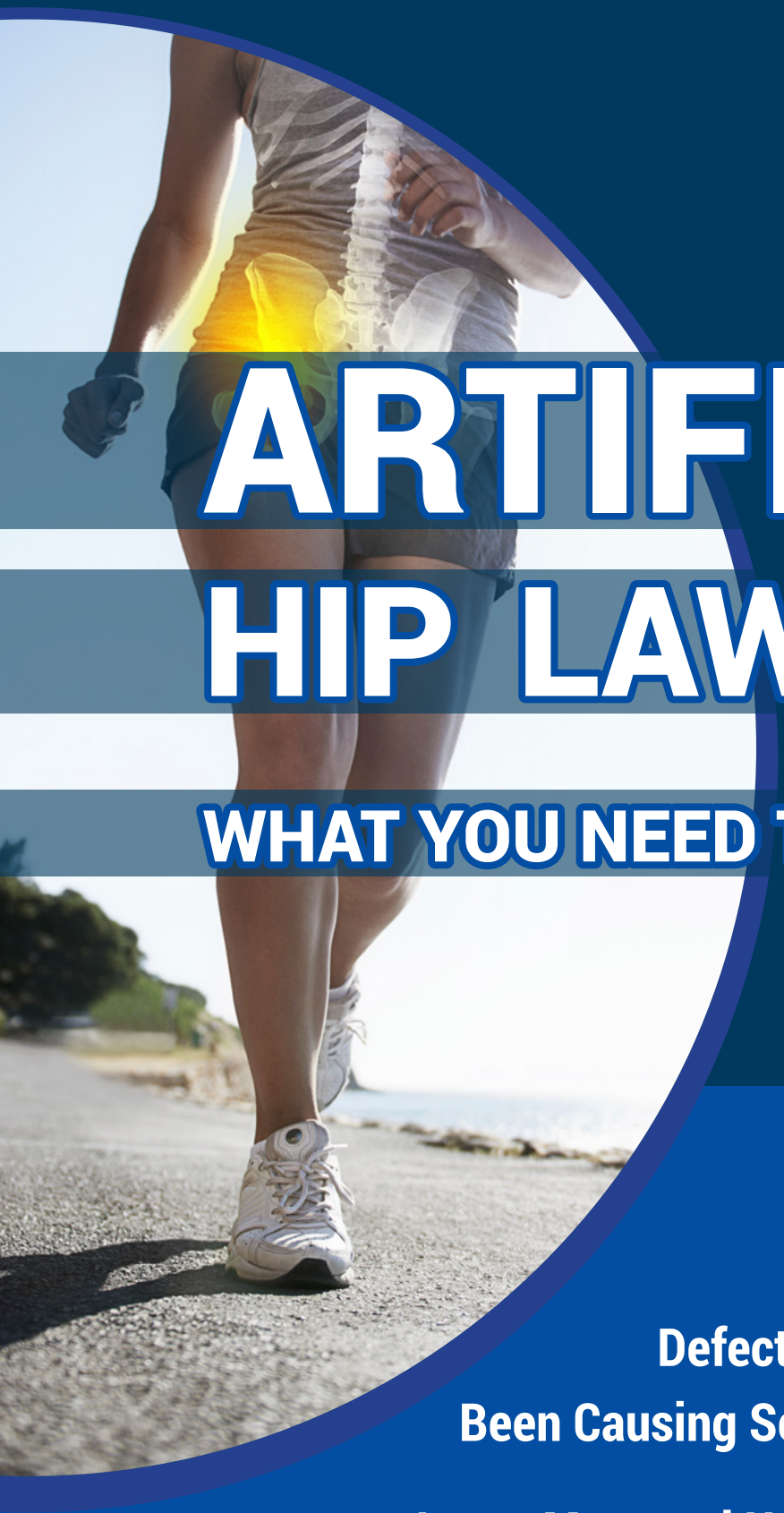


ARTIFICIAL HIP LAWSUITS

WHAT YOU NEED TO KNOW

Clay Hodges

Defective Artificial Hips Have Been Causing Serious Health Problems

Learn More and Understand Your Options

Table of Contents

INTRODUCTION

Around nine years ago I got a call from a woman who had undergone total hip replacement surgery. She had put off the surgery for years, and for obvious reasons: hip replacement surgery is one of the most invasive, painful surgeries a person can endure. But her osteoarthritis was causing increasing pain and discomfort, and she finally, reluctantly, moved forward with the surgery.

The rehabilitation was a challenge–as they all are with these surgeries–but she steadily improved and after a few months of physical therapy, she began to feel better than she did before the surgery. She began to have hope.

But then something went wrong. Pain returned, a different pain. Then the pain got worse, then it became excruciating. Her hip would suddenly lock in such a way that she could not move her leg or hip.

She was prescribed Vicodin for the pain. She took other over-the-counter medication. She tried just about anything to numb the pain and the fear and the anxiety.

She had to sleep with her feet elevated. She feared her hip would lock up while she was alone and she would be stranded. She used a walker to avoid sudden falls. Her condition was much worse than it was *before* the implant surgery. That is to say, the osteoarthritis was less painful than her condition after the hip replacement surgery.

Her surgeon eventually determined that the artificial hip component, specifically the "acetabular cup" was loose and not permanently seated in the hip cavity (the acetabulum). The cup is supposed to sit without moving in the hip.

After more than a year of misery, she had a "revision surgery" to remove the failed cup. Fortunately for my client, the revision surgery was a success.

She hired me to represent her against the manufacturer of the failed hip components. Since then I have helped many others who have had traumatic experiences following a failed hip replacement surgery. I hope it may help you.

Editorial Note: this book spends considerable time examining the Depuy Orthopaedics ASR hip failures and hip litigation, but several other companies manufactured and marketed flawed metal-on-metal artificial hips, such as Stryker, Zimmer, Wright Medical, Smith. This volume should assist you if you suffered from a failed artificial hip from any manufacturer.

CHAPTER ONE

A LITTLE HISTORY ON THE METAL-ON-METAL ARTIFICIAL HIPS

First, a little history is in order to see how an artificial hip like the Depuy ASR hip system gets to the market (and ultimately, into your body).

WHAT IS A TOTAL HIP REPLACEMENT?

A "total hip replacement" replaces the body's hip joint with an artificial one, and these artificial hips are usually made out of metal or plastics. A total hip replacement typically consists of four separate parts: (1) a stem, (2) a head, (3) a liner, and (4) a cup (called an "acetabular cup" or shell). After the surgeon hollows out the patient's femur bone, the stem is implanted. The head is a metal ball that is fixed on top of the stem. The femoral head forms the hip joint when it is placed inside the liner and the cup (the "acetabular shell").

PREMARKET APPROVAL IS DESIGNED TO PROTECT THE PUBLIC FROM UNTESTED MEDICAL PRODUCTS.

Premarket approval is a rigorous process that requires a manufacturer to submit an extensive application that includes full reports of all studies and investigations of the device's safety and effectiveness; a complete statement of the device's components and properties, and the principles of operation; a full description of the methods used in the manufacture, processing, and packing and installation of such medical device; samples or device components; and an example of the proposed labeling.

The FDA may grant premarket approval only if it finds there is reasonable assurance that the medical device is safe and effective and that any probable benefit to health from the use of the device outweighs any probable risk of injury or illness from such use.

THE DEPUY ASR ARTIFICIAL HIP DID NOT OBTAIN PREMARKET APPROVAL.

A medical device on the market prior to the effective date of the MDA—referred to as a "grandfathered" device—was not required to undergo premarket approval. This can be confusing, but a medical device marketed after the MDA's effective date may bypass the demanding premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and requires a manufacturer simply to notify the FDA under section 510(k) of the MDA of its intent to market a device like an artificial

hip at least ninety days prior to the product's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA device. The FDA may then approve the new device for sale in the United States.

THE DEPUY ASR ARTIFICIAL HIP WAS NEVER PROPERLY TESTED.

Instead of assuring the safety of the Depuy ASR Artificial Hip through clinical trials, Depuy marketed its ASR Hip without conducting any clinical trials and instead obtained FDA approval under section 510(k). In 2005, Depuy submitted a section 510(k) premarket notification of intent to market the Depuy ASR Hip.

By representing to the FDA that the Depuy ASR Hip's design was "substantially equivalent" to other hip products on the market, Depuy was able to avoid the important safety review required for premarket approval under FDA regulation including clinical trials.

In August 2005, the FDA approved the Depuy ASR Artificial Hip for sale by means of the 510(k) process; thus, the FDA did not require the Depuy ASR Hip to undergo clinical trials. This turned out to be a huge mistake. Essentially, no one, neither Depuy nor the FDA, did the hard work to make sure that the Depuy ASR Hip was safe for the public.

THE DEPUY ASR ARTIFICIAL HIP METAL-ON-METAL DESIGN

Now, let's look a little deeper into the Depuy ASR hip system, its metal-on-metal cup and ball design, and how it failed.

WHAT IS "ASR" ANYWAY?

"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 cup and the ball are replaced. On the other hand, a total hip replacement includes not only the cup and the 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 ball is attached.

To market the Depuy ASR Hip for use in ASR surgery, the FDA would have required Depuy to undergo premarket approval, which would have required Depuy to conduct clinical trials, prove that the product is both safe and effective, and monitor the long-term safety and performance of the product once it was placed on the market. This could have saved much suffering.

In essence, Depuy was able to put the Depuy ASR Hip on the market in the United States for use in a surgical procedure for which it was not designed: a total hip replacement.

THE DEPUY HIP USED A METAL-ON-METAL CUP AND BALL DESIGN.

While most hip replacements use a cup made of plastics or other materials, Depuy's ASR Hip uses a metal cup. By using a metal cup and a metal ball, the Depuy ASR Hip system forced metal to rub against metal with the full weight and pressure of the human body.

Because of the design of the Depuy ASR Hip, thousands of patients have been forced to undergo surgery to replace the failed implants. This is called a "revision surgery."

Soon after Depuy launched the Depuy ASR Hip, failures were reported. Depuy would go on to receive thousands of similar complaints reporting that the Depuy ASR Hip had failed due to loosening of the cup and that the failure had forced patients to undergo painful revision surgeries to remove and replace the failed artificial hip.

THE DEPUY ASR ARTIFICIAL HIP DESIGN FLAW THAT RESULTED IN THOUSANDS OF LAWSUITS

THE DESIGN PROBLEM WITH THE DEPUY ASR CUP.

The defect in the Depuy ASR artificial hip appears to be related to design. Orthopedic experts have stated that the ASR cup is shallower than standard cups made by other companies. Dr. Thomas Schmalzreid, a surgeon who designed the Depuy ASR Hip has stated that Depuy had known since 2008 that the Depuy

ASR cup may have design flaws. Dr. Schmalzried has said that Depuy officials realized in the first few years that the Depuy ASR cup might be more of a challenge to implant properly then competing cups. Dr. Schmalzried has stated that "the window for component position that is consistent for good, long-term clinical function is smaller for the [Depuy ASR Hip]" than other cups. That is a highly technical (and bone dry) way of explaining that the ASR cup is harder to implant properly into the hip cavity for long-term successful hip surgeries.

Despite its apparent knowledge that the Depuy ASR Hip had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo painful revision surgery, Depuy continued selling the defective hip into 2010.

OVER $5 BILLION IN SALES IN 2009 ALONE.

Depuy sold more than $5.4 billion in ASR hips in 2009 alone. Hip implant sales were vitally important to the business of Depuy's parent company, Johnson & Johnson, and Depuy has been one of Johnson & Johnson's most profitable businesses.

In 2010, Depuy began to disclose some of the more alarming problems with the Depuy ASR Hip. Depuy sent a letter to doctors warning them of the failure rate associated with the Depuy ASR Hip. Depuy admitted that the Depuy ASR Hip suffered from a "higher than expected revision rate," and that data showed that 5.4% of the Depuy ASR Hips implanted had been surgically replaced after only three years. The letter also stated that Depuy was planning to stop selling the Depuy ASR Hip because of "declining demand." Which, with all the evidence of product failures, now seems ridiculous.

On August 25, 2010, Depuy confirmed that in the first five years after implantation, approximately 13% of patients (1 in 8) who had received the ASR total hip replacement needed to have a revision surgery. ***Obviously, this is a terrible result***.

At that time, Depuy also confirmed that at least 93,000 people have had Depuy ASR hips implanted in their bodies, meaning that at least 11,700 people could eventually suffer a hip failure and be forced to undergo a painful surgery to remove and replace it.

THE AUGUST 2010 DEPUY ASR HIP RECALL

On August 26, 2010, Depuy issued a worldwide recall of its ASR XL Acetabular Hip Replacement System and Depuy ASR Hip Resurfacing System and all com-

ponents for these devices based on the higher percentage of patients who needed to undergo risky and painful revision surgery.

In the years since the recall, thousands of innocent people have been hurt, some badly by the failed ASR hip. If you underwent a hip replacement surgery in the last ten years, and have had discomfort or other unusual complications, you should arrange a visit with your surgeon and check to see if a Depuy ASR Hip was implanted in your hip.

More than 12,000 people have now filed lawsuits following injuries after implantation of the Depuy ASR Hip. As more patients suffer failures from hip replacement surgeries, this number will rise.

CHAPTER TWO

FOUR THINGS YOU NEED TO DO IF YOU BELIEVE YOUR ARTIFICIAL HIP HAS FAILED

Before I get to the four things you should do if you suspect that an artificial hip or other medical device has failed you, I must start by saying that this is one of the worst outcomes a person can endure in health care. Most people approach hip replacement surgery with great caution, as surgery is a painful and difficult and traumatic experience. Further, you have arrived at the decision to undergo surgery on the basis of a challenging and serious medical issue which requires surgery to "fix" the problem. After deciding to move forward with surgery, virtually no one expects that a medical device such as an artificial hip or knee will somehow "fail" inside your body. This result is often worse than the suffering which occurred through the underlying medical condition prompting the original implant surgery. So, at the outset, let me say that I am sorry you find yourself in this very unfortunate position. That said, you need to take action when it becomes apparent that a medical device like an artificial hip has failed:

1. START A SYMPTOMS/PAIN JOURNAL.

This is an important step you can take in protecting your rights in the face of a medical product failure. It is simple enough: when you first begin to notice sensations or pains which seem abnormal or unexpected, jot down the physical symptoms on a piece of paper or a notes app on your smart phone. The more detail the better—if the pain occurs when you sleep, note the time when the pain arrives, whether it woke you from sleep, and any other details. If you feel pain during certain activities, such as lowering yourself into your car or walking on hard surfaces, note those conditions as well. This journal may well provide critically important information for your doctors but also for your attorney as he or she prepares a settlement package or a lawsuit (or both). A person who has been injured by a medical device product failure can recover money "damages" in a category known as pain and suffering. A pain/symptoms/well-being journal can provide extremely valuable information to an attorney putting together the best case for you in the event you have a solid claim against a manufacturer for a failed medical device.

2. GATHER EVIDENCE.

Related to Item No. 1, this Item is very important in starting the process of building your legal case. Although the attorney you choose should seek out your complete medical records related to your medical device surgery and rehabilitation, it is important in the early stages to keep a file with any documentation you receive from your surgeons, your primary care doctor, your physical therapist, your pharmacist, and any other professionals who are related to your surgery or follow-up care. In addition, if appropriate, shoot video of any situations which

may shed light on your physical problems. If you have trouble getting out of bed, have your spouse or a friend take video of you attempting to get out of bed. If your hip is making a popping sound, shoot video or record audio of the pop. When gathering this evidence, try to establish the date of the video or audio, even if you have to state, "today is July 30, 2015, and I am now going to lower myself into this chair."

3. KEEP A RECORD OF ALL BILLS, OUT-OF-POCKET EXPENSES, AND TIME MISSED FROM WORK.

Keep complete records of all bills incurred and any out-of-pocket expenses you are paying for your surgery, recovery, rehabilitation, medications, etc. In some cases, manufacturers of defective medical devices have set up a procedure by which the manufacturer will pay the out-of-pocket expenses of a victim of a failed medical device (but be cautious when accepting payments from these "third-party administrators" and read all documents you sign carefully). Finally, keep detailed records of all time missed from your employment, including sick days which you were forced to spend, and days out of work for which you lost compensation.

4. MAKE AN APPOINTMENT WITH YOUR PHYSICIAN.

First and foremost, if you have a failed medical device implanted in your body, you have to get yourself back to good health. As I tell all my clients, ***your health decisions always come first***, and those are between you, your family, and your doctors, ***and do not involve any attorney***. So set an appointment with your treating physician, and let her know about the pains or discomforts or sensations you are experiencing. If the failed medical device is causing underlying problems like elevated metal levels or other bad results, you will want to have that information as soon as possible and you may need to schedule a revision surgery. But again, you need a good doctor to help you analyze your medical condition as soon as you become aware of something being "not quite right."

CHAPTER THREE

THREE OTHER THINGS YOU SHOULD DO IF YOUR ARTIFICIAL HIP HAS FAILED

In the previous chapter I set out the first four things you should do if you suspect that your artificial hip has failed you. Those were:

1. **Start a symptoms/pain journal**.
2. **Gather evidence**.
3. **Keep a record of all bills and out-of-pocket expenses incurred**.
4. **Make an appointment with your surgeon**.

In this chapter, let's look at three other actions you should take when you suspect your artificial hip (or other medical device) is failing:

1. DO YOUR RESEARCH.

For most of us, the starting point for research is the Internet. Many websites are well-researched, well-meaning, and helpful. If you have undergone a hip replacement surgery and you believe the artificial hip is failing, I would recommend starting with the U.S. Food and Drug Administration website (http://www.fda.gov/MedicalDevices/), a federal government website providing timely information on the latest recalls or problems associated with medical devices, drugs, and other products. Also, you may want to review the court website associated with the medical device you have implanted (or which has been removed in a revision surgery). For example, for the Depuy ASR cases, much of the litigation has been situated in the United States District Court for the Northern District of Ohio, with Judge David Katz presiding over discovery, pre-trial, and other issues. On this website (http://www.ohnd.uscourts.gov/home/clerk-s-office-and-court-records/multidistrict-litigation-cases/mdl-2197/) you can read about all the court orders that have been issued in the "multi-district litigation" relating to the Depuy ASR hip. Granted, it can be a slog to read court orders, but if you hang in there you can get a sense of where the litigation has gone and where it is going. Third, I recommend going to established news outlets, such as The Wall Street Journal, The New York Times, The Washington Post, and other reliable publications. The New York Times has been quite effective in reporting on failed artificial hips and knees through its news, business, and health sections. I will update these suggestions as I find helpful, reliable websites. Finally, you can always return to this website for information on failed hips, knees, and other medical devices.

2. BE CAREFUL WHEN RESEARCHING YOUR ISSUE ON THE INTERNET.

I can't stress this enough: The Internet can be a freaky place. I once saw a funny cartoon depicting a doctor handing a prescription to a patient with the caption,

"take two of these before you Google your symptoms." Indeed, within a matter of minutes on the Internet you can be reading about the worst possible outcomes in a failed hip or knee surgery, outcomes which would most likely never happen to most people who have suffered a failed medical device. Also, most people understand this but there is no requirement for truth on the Internet. People can write anything. (Of course, this rule applies to this website too; I will simply say that I am working hard to report information backed by real evidence.) If something sounds unbelievable on a website, it is probably false. I have seen at least one law firm website where the article suggested that failed artificial hip ***settlements***–not ***jury verdicts***, which are different animals–were reaching into seven figures (which is not true in nearly all cases). So again, be cautious and skeptical when conducting research on the Internet.

3. FIND THE RIGHT LAWYER.

This step is not as simple as it may sound. Many attorneys merely advertise but don't litigate or even represent the people to whom they are marketing their legal services, and other attorneys throw up a laundry list of practice areas in which they claim expertise. As with any profession, some lawyers are good and some are not very good. You will want to find an experienced attorney who practices plaintiff-side product liability and personal injury work. It is not a great idea to let your second cousin's son, who just graduated from law school and who just opened his own general practice, take on your case; it will not likely turn out well for you (or for him). Take your time with this important decision. For further information on this topic, see my chapter, "Finding the Attorney to Handle Your Failed Hip Case."

CHAPTER FOUR

RECENT JURY VERDICTS IN ARTIFICIAL HIP TRIALS

Those who have suffered from a failed artificial hip, have undergone a revision surgery (or even more than one), and now contemplate taking legal action against the manufacturer, often ask what kinds of money judgments plaintiffs have received from juries across the country. I have collected a representative sample of jury verdicts over the last few years against artificial hip manufacturers like Depuy and Zimmer. The good news for injured people is that some plaintiffs have received several million dollars from juries for their injuries. The bad news? Juries found no negligence at all by the manufacturer; in those cases, the injured person received no money at all.

I've collected a list of recent cases and their jury verdicts involved. This is not an exhaustive list, and other jury verdicts are out there, but this will give you a sense of what is going on with artificial hip cases jury trials:

Kransky v. DePuy Orthopaedics (Los Angeles Superior Court)

Jury Award: ***$8,338,236.12*** for the Plaintiff, Loren Kransky

Date of Jury Verdict: March 8, 2013

This is the case that started some of the buzz, mostly because the jury award was quite large.

The jury in this California case awarded the Plaintiff $338,236.12 in "economic damages" and $8 million in "pain and suffering" (also called non-economic) damages. The jury did not award punitive damages to Mr. Kransky.

The jury found in favor of Mr. Kransky and awarded damages for medical costs and for emotional suffering and distress. The jury did not find that Depuy acted with fraud or malice, which prevented the assessment of punitive damages.

Jurors found that the device was defective at the time of sale, and that it injured the plaintiff. Most of the jurors also found that DePuy "failed to warn" Mr. Kransky, which in product liability means that the company did not do a sufficient job in warning the consumer that the product (in this case, the artificial hip components) involved a substantial risk of injury to the plaintiff. Also, nine of twelve jurors found that DePuy was negligent.

Despite the multi-million dollar jury award, it is worth noting that Mr. Kransky's legal team sought punitive damages and other damages that would have exceeded $100,000,000.00. Some observers therefore view the jury verdict as inadequate.

Strum v. DePuy Orthopaedics (Illinois Circuit Court, Cook County)

Jury Award: ***zero***. Chicago jury found that Depuy was not responsible for the Plaintiff's injuries.

Date of Jury Verdict: April 17, 2013

After the Kransky trial and its $8.3 million dollar verdict, the Strum case out of Chicago took some of the starch out of the plaintiffs' bar. Essentially, the jury found that the hip components manufactured by Depuy Orthopaedics did not cause the injuries to the plaintiff, Carol Strum.

Ms. Strum sued DePuy and another defendant Chicago, Illinois in 2011, and alleged that the DePuy ASR femoral implant used to replace her left hip in January 2008 failed and required painful revision surgery. She also claimed that she suffered from metallosis.

Ms. Strum also argued that a Depuy executive provided an "Urgent Field Safety Notice" to medical providers in March 2010, and that DePuy issued its own notice of the recall on August 26, 2010.

Herlihy-Paoli v. DePuy Orthopaedics (Federal Court, Northern District Texas)

Jury Award: ***zero***. Jury found that Depuy was not responsible for the Plaintiff's injuries from the Depuy Pinnacle artificial hip.

Date of Jury Verdict: October 23, 2014

Kathleen Herlihy-Paoli, a Montana woman, sued Depuy Orthopaedics in federal court in Texas for injuries she suffered after her Depuy Pinnacle metal-on-metal hip implant failed.

The jury voted unanimously in favor of Depuy, and thus Ms. Herlihy-Paoli received nothing. Jurors returned the verdict after an eight-week trial. Ms. Herlihy-Paoli originally filed her case in Montana before the case was transferred to the Depuy Pinnacle Multidistrict Litigation situated in Texas. Judge Kinkeade presides over the Pinnacle MDL and also presided over Ms. Herlihy-Paoli's trial.

Ms. Herlihy-Paoli said she felt severe pain shortly after the Depuy Pinnacle hip was implanted in 2009. She also alleged that she suffered from dangerous levels of cobalt and chromium in her blood stream. Her lawsuit stated that Ms. Herlihy-Paoli's metal levels were eighty-five higher than normal.

At trial, DePuy argued that Ms. Herlihy-Paoli's injuries were not caused by product defects but instead were caused by the artificial hips being implanted improperly. Interestingly, Depuy also argued at trial that the Depuy Pinnacle implant was different from the Depuy ASR hip, which is a product that has led to thousands of lawsuits across the country.

Jurors decided Ms. Herlihy-Paoli's injuries were not caused by DePuy's failure to act as a reasonable hip implant manufacturer. The jury found that the device was not defectively designed and that Depuy's warnings about the risks of the device were not inadequate.

The following jury verdicts have been handed down in trials over failed artificial hips in 2015:

Smith v. DePuy Orthopaedics Inc., et al., (Oklahoma District Court, Tulsa County).

Jury Award: ***$2,500,000.00*** for Plaintiff Andrea Smith.

Date of Jury Verdict: ***February 12, 2015***

This case is intriguing because the Plaintiff was a woman who had the Depuy ASR artificial hips removed from ***both*** hips ("bilateral revision") less than five years after implantation.

Andrea Smith, a woman from Oklahoma, was awarded $2,500,000.00 by a jury in Oklahoma state court after DePuy ASR XL Acetabular hip systems failed in both hips and had to be removed.

The state court jury determined that there was a design defect in the ASR XL artificial hip, which caused Ms. Smith's injuries. Ms. Smith suffered from metallosis in her blood and tissue damage around both hips. She had to endure three revision surgeries before her condition stabilized.

The jury did not find that DePuy was negligent or failed to adequately warn Ms. Smith of the dangers associated with the ASR hip devices.

Ms. Smith had the original implantation surgeries in October 2006 and in February 2007. She had revision surgeries in July 2011 and in January 2012. Ms. Smith alleged that the hip devices had failed and that there was metal staining in the tissue surrounding the implants.

Ms. Smith brought suit against DePuy Orthopaedics and its related companies. She also sued her original implant physician, accusing the doctor of failing to act in a medically reasonable and proper way after DePuy announced the ASR recall in August 2010. According to the court record, Ms. Smith alleged that the physician failed to notify her that the device had been recalled or that she had elevated chromium or cobalt in her blood as a result of the failed hip implant. The case against Smith's physician was dismissed a week before the start of trial.

Warner v. Wright Medical Technology, et al., (California Superior Court, Los Angeles County.).

Jury Award: ***$4,500,000.00*** for Plaintiff Alan Warner.

Date of Jury Verdict: ***July 2, 2015***

This case is noteworthy because it ended in a verdict against Wright Medical Technology, which is a smaller company than the typical hip device companies, Depuy and Zimmer.

Just over one month ago, a California jury awarded $4,500,000.00 million to the plaintiff, Alan Warner, who alleged that Wright Medical Technology Inc.'s ***Profemur*** Hip Implant was defective.

The jury in California state court apparently reached its verdict on June 11. The jury concluded that the implant was defective; however, the jury also determined that Wright Medical was not negligent in designing the device.

The trial took two weeks.

The jury's award included $4,000,000.00 for past and future pain and suffering damages and $500,000.00 for Alan Warner's wife's loss of consortium claim. Loss of consortium is a derivative claim where a spouse or other close family member can claim (derivative) damages based on the injury to the primary plaintiff.

Mr. Warner alleged that the hip implant broke while he was walking in his home. Mr. Warner then had to undergo revision surgery.

Defendant Wright argued during trial that the surgeons who implanted Wright's medical device were to blame for Mr. Warner's injuries. The jury disagreed with Wright.

Kline, et al. v. Zimmer Inc., et al., (California Superior Court, Los Angeles County)

Jury Award: ***$9,200,000.00*** for Plaintiff Gary Kline.

Date of Jury Verdict: ***July 24, 2015***

This jury verdict is very recent, having been handed down by a California jury less than three weeks ago. The numbers are favorable to the injured plaintiff.

Gary Kline, 59, was awarded $9,200,000.00 by a California state court jury at the close of a trial against Zimmer, Inc. for its faulty Durom Cup hip implant. This verdict, as far as I can find, is the first jury verdict against Zimmer for a metal-on-metal hip failure.

The trial lasted three weeks. The jury reached its verdict on July 24, 2015 after just a few hours of deliberation.

Mr. Kline alleged that Zimmer's Durom Cup hip implant was defective and required him to undergo two hip replacement revision surgeries in fifteen months. The Plaintiff stated that the implant's failure caused him chronic pain.

The plaintiffs argued that Zimmer made changes to the device in an effort to rush the device into the United States' market.

The jury awarded $153,000.00 for medical bills, $2,600,000.00 in past non-economic pain and suffering damages, and $6,400,000.00 for future pain and suffering. Zimmer, Inc. was found completely responsible for Mr. Kline's injuries.

CHAPTER FIVE

PATIENT WITH FAILED ARTIFICIAL HIP TELLS HER PAINFUL STORY

My ordeal began in March 2008. I had my first hip replacement surgery. In April 2011, I had a second revision due to a faulty hip implant. By March 2014, I had my third hip surgery, my second revision.

From April 2011 until March 2014, I was in a very dark place. The reality of my disabled condition as a result of the faulty hip implant and second revision was more than I could manage. I was actually depressed, but could not admit it. The pain medications provided some relief, but had their own negative effects. I could not get any real answers. There was no one to offer much help or guidance. I did not know where to turn. It was a nightmare! Nagging pain and a lack of mobility were constant reminders all day—every day—that my hip surgeries had gone horribly wrong. I tried to move forward by staying in the present, putting up some semblance of a positive attitude, trying to find other ways to be active; all the while, I was desperately looking for ways to live with pain and disabilities. I just could not believe what had happened to me. I had been a very healthy, extremely active person all of my life, until now. Everything about my life as I knew it had changed.

My future did not look very promising. I have been given little hope of improvement in mobility or pain. However, I continued to do whatever rehabilitation and strengthening I could do for my hip and the rest of my body; it was a way to stay as strong as possible. I tried to strengthen my mind. Trying to stay in the present was important; I needed to just get through the day! For heaven sakes, I had four children for whom I was responsible. I tried to find ways to be grateful. I kept telling myself that things could be worse. I looked for other activities that I could do. Even though I was really angry, I tried to not let the anger consume me. It was not easy.

There was a prior history of problems with this Depuy ASR hip implant, and I understand it was removed from markets in Europe and Australia; yet the corporations and doctors continued to market the faulty device for U.S. patients. I felt they had ruined my life, and then offered no real help about how to move forward.

It is imperative that you reach out for help in some way. My physical therapist was a great resource for me, but there was only so much she could do. I went to other orthopedics for second opinions. One other doctor recommended pain management therapy that was helpful in providing some mechanical pain devices that did not involve medications. I would recommend that you get second opinions, even third and fourth evaluations. Acupuncture did provide some temporary pain relief and I went as often as I could afford. I started doing some yoga. Research and reading into your area of medical issues can provide insight and ideas and valuable information. Develop and keep a very skeptical intelligence.

Slowly, I realized that I should not live in such pain and discomfort without exhausting every other medical option and alternative. I begin my research for another doctor who might be able to help me. I found one. He saved my life.

Looking back, I realize that you often cannot think clearly in such situations. Your judgment becomes clouded by medication, pain and depression. It is vitally important to find resources, research, information and expert guidance and help. You are ultimately responsible for your own welfare and circumstances. Health care is changing. Don't expect doctors and hospitals to go out of their way to help you. Educate yourself. Listen to your own intuition. Make sure to research all procedures, techniques, cutting-edge technology and practices, doctors and hospitals. Find the best physicians and health facilities for you. Don't give up.

ARTIFICIAL HIP PATIENT STRUGGLES THROUGH FAILED IMPLANTATION SURGERY

AN ACTIVE MOTHER OF FOUR

In March 2008, I was an active, athletic, busy, single mother of four. I was fifty-four years old. I just needed a hip replacement. I was part owner of a health and racquet club and worked there part-time. The new hip replacement was supposed to allow me to resume my normal activities.

THE IMPLANTATION SURGERY

I did not tolerate the anesthesia or pain medications well, but, supposedly, the surgery went well, and I began recovery and physical therapy as scheduled and as expected. I was extremely determined and dedicated in all my therapy and exercises; however, there were problems with my recovery as time passed. I spent months and months in rehab, and I did manage to regain most of my normal routine and motion; nevertheless, I could not run with a normal gait and I could not fully extend my leg without discomfort. In follow-up appointments, the doctors advised me to "just keep trying." I resumed limited exercise activities and a somewhat normal routine, but something did not seem right.

"I HAD NO REASON TO THINK SOMETHING WAS WRONG WITH THE DEVICE"

About a year into recovery, I began to notice deterioration in my motion and some general discomfort in the hip area. My daily routine with the children and my responsibilities at home and work became increasingly difficult. I went back

into rehab, but without much relief or improvement. The physical therapists and I just could not figure out what was wrong. I had problems with some suspected tendinitis and a general ache in hip area. I also began to have more difficulty moving. Other friends who had their hips replaced were doing much better than I was. I began to have just a sick feeling that something was not right with my hip, but I had no reason to think that there was something wrong with the device, and I began to think that something was wrong with me.

THE DEPUY ASR RECALL WAS "ALMOST A RELIEF"

It was almost a relief when I received the Depuy recall letter in November 2011. I was relieved to know that I was not crazy; however, I also knew I would be facing some difficult circumstances in the near future. I contacted my doctors. The doctors ordered blood work to determine my metal levels. The results showed I had some elevated, but not severe, metal levels. My x-rays did not show any evidence of problems from the device, and the doctors recommended that I wait and just monitor my blood metal levels. However, my discomfort and limited range of motion indicated to me some injury beyond what they could see; fortunately, my physical therapist recommended that I request an immediate revision based on all her clinical observations of my condition and what she had seen in some other patients with the same hip implant. Thank heavens for my physical therapist!

FIRST REVISION SURGERY

In March 2011, I had revision surgery on my hip, my second hip surgery in three years. Everything else to date regarding my hip replacement had been a disaster. The doctors advised me, after the revision, that the device had already damaged my hip bone. It was something that the doctors just could not see through the x-rays. They said I was fortunate to have insisted upon the immediate revision.

SECOND REVISION SURGERY A SUCCESS FOR ARTIFICIAL HIP PATIENT

In this third and final part, my Client describes the agony she endured following the first revision surgery and how, in desperation, she made the decision to undergo a second revision surgery, her third hip surgery in six years.

FIRST REVISION SURGERY "EXTREMELY DIFFICULT"

My recovery from the first revision surgery had been extremely difficult; nothing like the recovery from the original implant surgery. I was on a walker for two months. I could not walk without a cane for almost six months without great discomfort. I stayed in physical therapy for a year. I would do exercises prescribed by the physical therapist and others almost every day in order to regain my strength and motion. My therapist finally released me in April 2012 without much hope for improvement. Pain relievers were required every day. I could walk, but I walked with pain and a limp. I could not remain seated for long periods without discomfort. It was difficult to travel. I could not easily bend over. Until my revision, I played tennis and played ball with my children; that was no longer possible. There are many normal movements that remain difficult or impossible for me to do. Housework and yard work are difficult to do. I was very worried about my future. How was I going to manage my life and family?

I did not want to return to my original doctor or hospital. In desperation, I sought out another orthopedist for a second opinion. He recommended a pain management group. He gave me no hope that there was anything else that could be done to improve my hip. I was devastated.

RESOLUTE IN MY REHABILITATION

I remained dedicated to daily exercises to strengthen my leg. I practiced whatever yoga postures I could do. Acupuncture gave me some short term pain relief. I went to acupuncture as often as I could afford. The pain management group was helpful. I was thankful for any progress or pain relief. It was only because I was absolutely resolute in my rehabilitation and exercise that I could walk with some strength and stamina. Pain medicine was required to get through the day, but such medications are also a toll on the body and mind and blood pressure.

I heard nothing from the original doctors or Depuy. I should have been in my doctor's office screaming from the top of my lungs for some help or relief, but I became resigned to my condition. I thought that this was the best for which I could hope; however, I slowly realized that I could not live in this condition. There had to be something else I could do. I started to research some other doctors that had been on the cutting edge of hip revisions.

HIP CONDITION WORSENED DRAMATICALLY

In August 2013, the pain and my hip condition worsened dramatically. I scheduled an appointment with a new doctor at a different hospital and practice. It

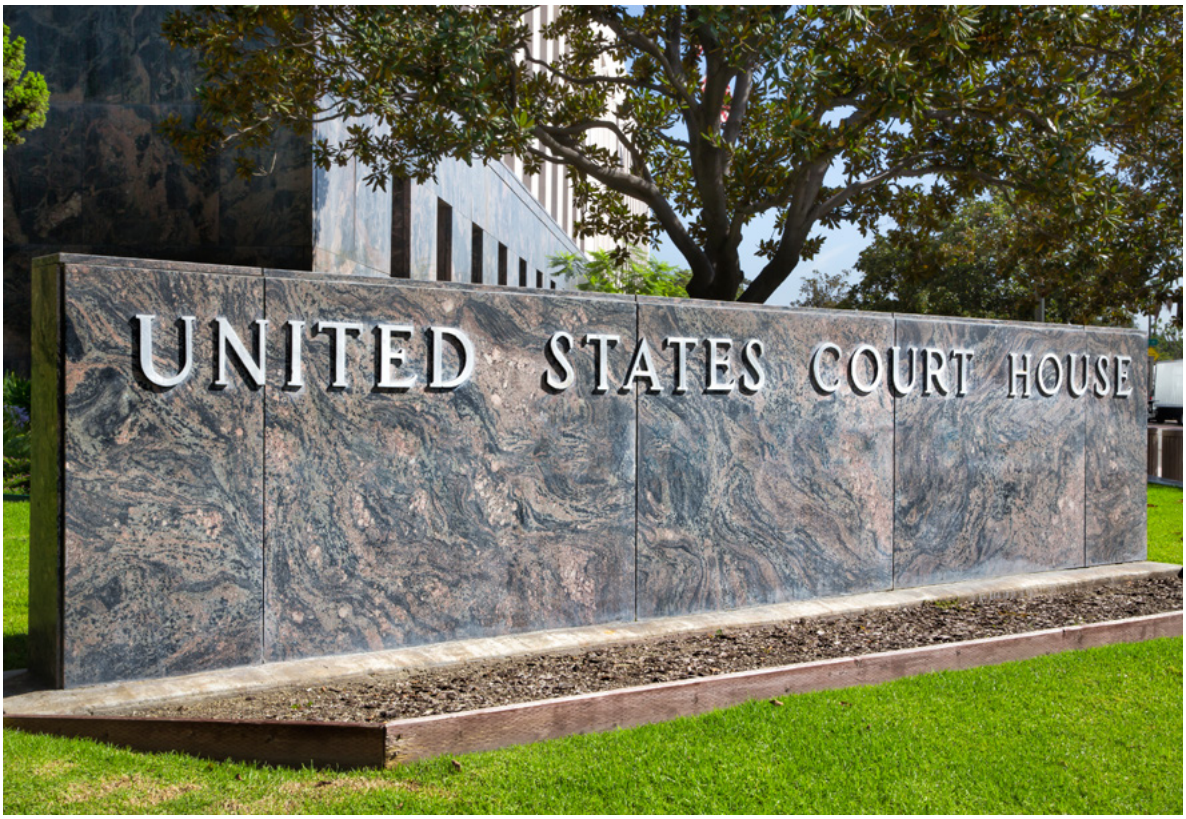
took months to get to see him, but it was worth the wait. Even though several other doctors had taken X-rays of my hip and saw no chance for improvement, my new surgeon immediately saw a problem with no bone growth into my hip implant , and he recommended a third hip surgery (and second revision surgery).

In March 2014, I had a very successful (third) hip surgery. I am very grateful to my surgeon. He saved my life.

It has taken great effort and dedication on my part to rehabilitate my hip and recover muscle strength and agility after the second revision. I work on my hip and overall conditioning every day. I will never be completely well or return to all former activities, but I can now enjoy an active and engaged life. I no longer take any medications. I am pain free.

CHAPTER SIX

MULTIDISTRICT LITIGATION: WHAT IS IT AND HOW DOES IT WORK?



All right, in this chapter we drill down a bit on a rather tedious subject: civil procedure (I know you're excited). I need to explain how your artificial hip case may start in your local state court or nearby federal court but then wind up in a federal court hundreds of miles away. It may seem random and chaotic, but with the rise in the number of failed medical devices like artificial hips, multidistrict litigation is an efficient and useful way to process thousands of lawsuits against a medical device manufacturer.

WHAT IS MULTIDISTRICT LITIGATION?

When a large number of products liability cases are filed in courts all over the country, all of which involve the failure of a single product, and which has caused similar injury to many individuals, a single court may be chosen to consolidate the cases into one "multidistrict litigation" ("MDL"). From this one court the designated federal judge will manage the discovery, hear motions, resolve pre-trial issues, possibly preside over bellwether trials, and even monitor global settlement discussion.

CONGRESS ESTABLISHED THE MDL

The United States Congress (28 U.S.C. § 1407) has authorized the federal court system to create a process to manage related, complex civil lawsuits, including medical device cases. The statute created a governing body known as the Judicial Panel on Multidistrict Litigation ("JPML"). This panel has the authority to allow the transfer of related cases to one federal judge or court for the purpose of coordinating pretrial discovery and resolving other issues prior to trial. The JPML is made up of seven federal judges based throughout the United States, all of whom are appointed by the Chief Justice of the U.S. Supreme Court. The main office for the JPML is in Washington, D.C.

In a typical MDL, once the discovery and pretrial matters have been completed, the appointed federal judge usually directs that cases be "remanded" (sent back) to the districts in which the case was originally filed, but often the case will remain with the MDL judge and the case is either settled or tried in that court.

THE CASE OF "JOE"

It usually goes something like this: a person—let's call him "Joe"—undergoes hip replacement surgery. In the following months or years, the artificial hip components inside Joe's body fail. Joe must then undergo surgery, called a "revision surgery," to remove the defective hip components and replace them with new, nondefective (is that even a word?) hip parts (not to mention all the damage

which may have occurred in the hip socket or other parts of the hip and leg). From there, Joe would learn that the original hip components were flawed or defective, and that the manufacturer was potentially negligent in one or many ways in bringing the product to market. Joe then hires an attorney, who files a lawsuit in the federal court nearest Joe's home. From there, the attorney has the option—***which is not required***—to transfer the case to the multidistrict litigation site for that specific failed medical product. In the case of the Depuy ASR hip system, the multidistrict litigation was designated to be the Northern District of Ohio in Toledo, with Judge David A. Katz serving as the presiding judge. (In the Zimmer Durom hip cases, the multidistrict litigation is "MDL 2158," in the District of New Jersey, with Judge Susan D. Wigenton presiding.)

Once Joe's case is transferred to the appropriate MDL, the case moves forward with an involved procedure consisting of sharing key information among the parties (this sharing of information is known as "discovery"). The MDL is perhaps most useful because it allows for the consolidation of key discovery. This means the parties can take hundreds of key depositions, including the many expert witnesses lined up on both sides, and share millions of pages of written discovery, then consolidate this huge amount of information in such a way that every plaintiff who joins the MDL can access the discovery and use it in their cases. This is critically important, because otherwise every single plaintiff in every single individual case, including Joe, would have to take the same depositions and request the same documents, over and over again. This inefficiency, of course, would be a nightmare, for the defendant-manufacturer but also for the individual client, like Joe.

MDL IS NOT A CLASS ACTION LAWSUIT

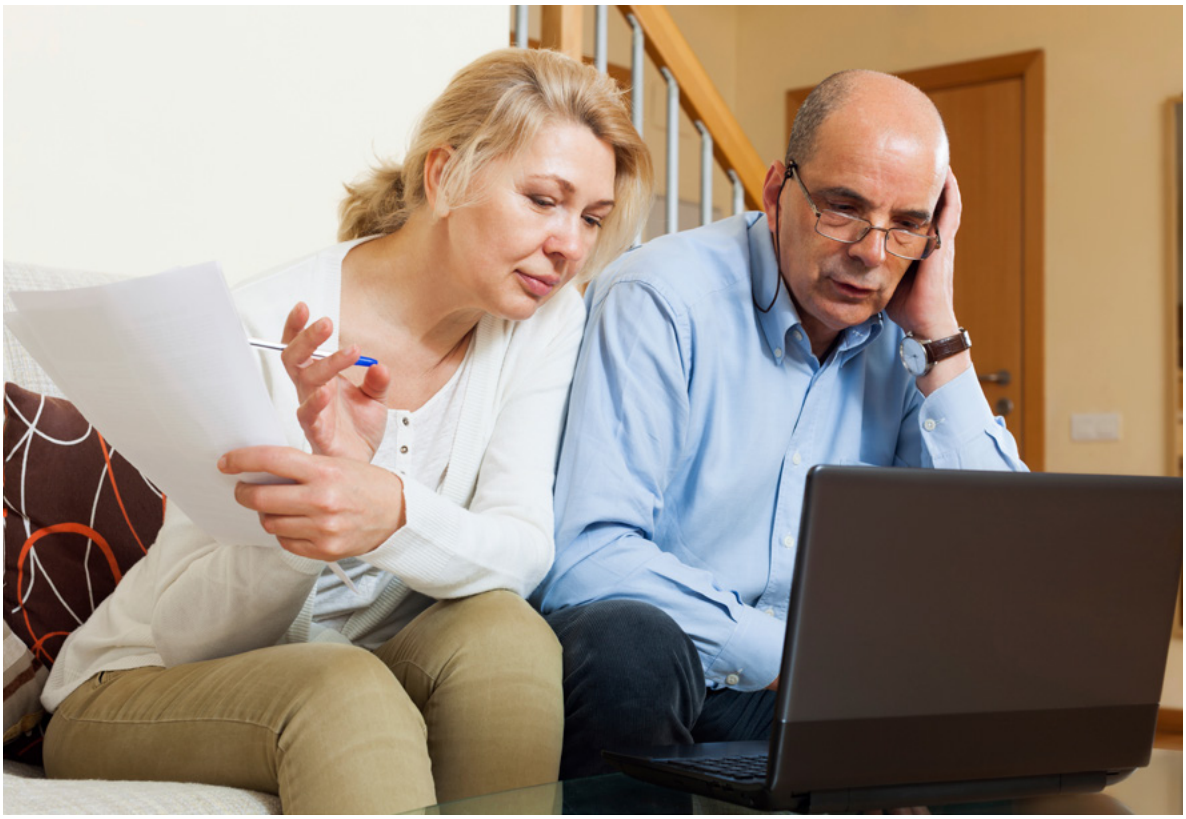
Keep in mind, "multidistrict litigation" is not a class action lawsuit. A class action is a very different animal, but with multidistrict litigation "Joe" will move through the court system with his individual case, and will eventually settle his case independently or choose to have his case tried.

MDL CLIENT HAS CONTROL OVER KEY DECISIONS

It is important to note that throughout this process, ***the client always has control over the key decisions in the case***. Joe would not be not required to join the MDL; Joe would not be required to accept a settlement, even if the plaintiffs' committee and the defendants' committee agreed to a comprehensive settlement plan; Joe can always "opt out" of settlement and have his case tried to a jury, either in the MDL or back in his home court. I will discuss comprehensive settlements and the rights of clients in a later chapter.

CHAPTER SEVEN

DEPUY ASR HIP SETTLEMENT: DO YOU OPT-IN OR SEEK A JURY TRIAL?



FIRST THINGS FIRST: YOUR MEDICAL DECISIONS

There is a big step to work through before we consider the Depuy ASR Hip Settlement. When an artificial hip fails, the hardest decision you will have to make is to choose the best course of action for your medical treatment. Some individuals will decide not to undergo revision surgery (that is, a follow-up surgery to remove the faulty artificial hip and replace it with new, non-defective hip parts); others may take a wait-and-see approach (this usually occurs when the artificial hip is not causing excessive pain and when the metal levels in the blood are not yet abnormally high); a third group may choose to undergo revision surgery as soon as possible. These individuals typically make this decision because of (1) clearly abnormal pain and discomfort (after recovery, a successful hip replacement surgery should not cause excessive pain); (2) bloodwork which reveals high metal levels in the blood (an indication that the metal-on-metal ball and cup is grinding small metal particles into the bloodstream); (3) the anxiety that accompanies the harsh news that an artificial hip inside the body has failed. In many cases, those who choose immediate revision surgery do so because of all the reasons mentioned above (and several other reasons).

Obviously, decisions relating to medical care have nothing to do with a lawsuit or with any attorney. As I tell all my clients, the ***medical decisions are always independent of the legal issues*** involved in a failed hip or knee or drug case. Find doctors you trust, understand all the options, and make the right decision—medically—for yourself.

THE NEXT DIFFICULT DECISION

Perhaps the second hardest decision you will face relating to a failed artificial hip (or knee or other medical device) is related to your legal case against the company that has sold artificial hips that have failed the public. The Depuy ASR Settlement Agreements were negotiated over a period of years among teams of defense lawyers and a plaintiffs' executive committee. You can review the broad terms of the settlement(s) here: https://www.usasrhipsettlement.com/Un-Secure/Documents.aspx.

Even if your attorney has properly filed a lawsuit against Depuy, and it is determined that you qualify for payments under the Settlement Agreement, you must ultimately decide whether to accept the settlement or reject it and move forward with your lawsuit and try your case. This is no easy decision.

WHAT HAPPENS IF YOU "OPT OUT" OF THE SETTLEMENT?

If you reject the settlement offer, your case will likely be placed on a "discovery schedule" by the judge assigned to the case. Discovery means you and your attorneys will have to share all relevant evidence relating to your case with Depuy, all other defendants, and the defense lawyers. As part of the discovery process, you will have to identify the experts who will testify at trial and support you're your claim that the artificial hip failed in your body and that the failure of the hip was caused by the negligence of Depuy Orthopaedics and Johnson & Johnson (the parent company).

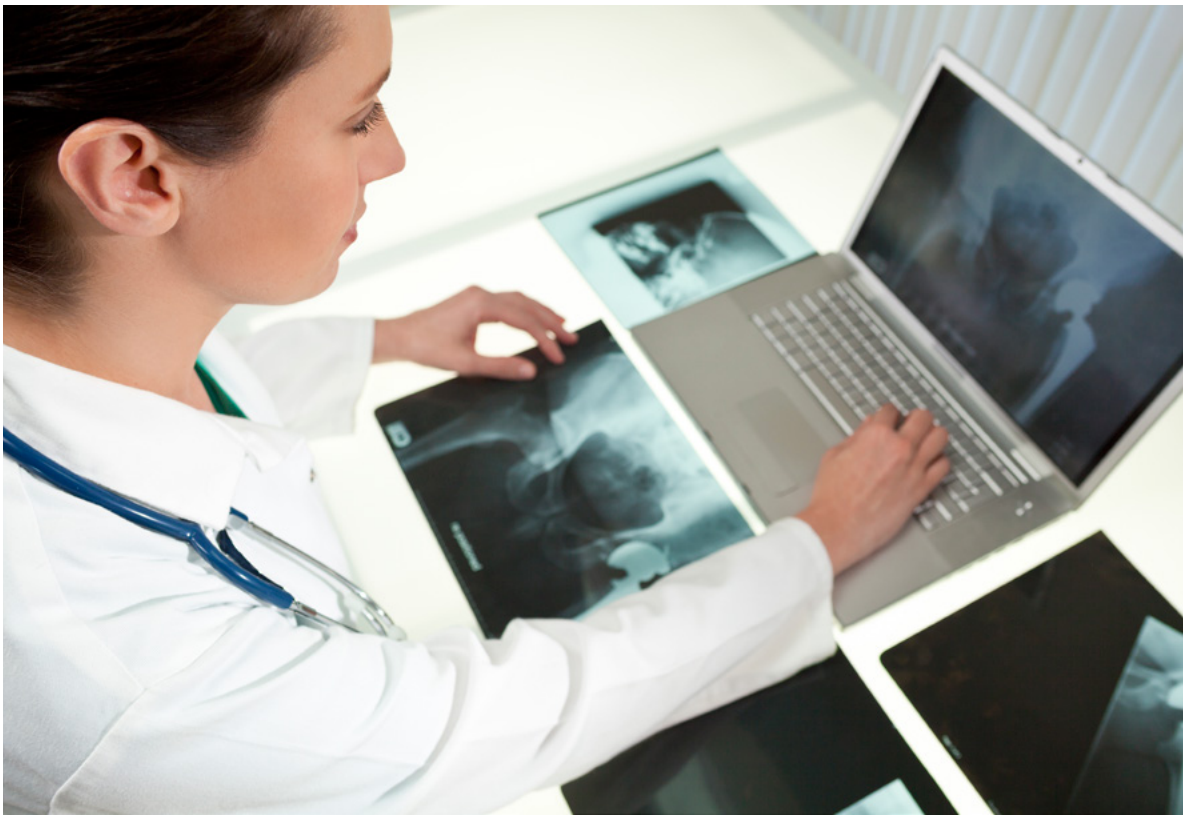
Of course, experienced defense lawyers (likely a team of them) will work hard to prepare ***a vigorous defense*** for Depuy. You should expect that the defense team will argue that Depuy was not negligent in any way and that any pain or injury you suffered was caused by other things (for example, Depuy lawyers may argue that your severe arthritis or congenital hip dysplasia caused the total hip replacement surgery to fail, and that the Depuy ASR hip parts did not cause the failure). What I'm trying to say is that, if you turn down the settlement and try your case, you will have a major fight on your hands, and Depuy will not only try to minimize the amount they have to pay, but will try to win the case outright. Which is to say, if a jury finds there was no negligence on the part of Depuy, then Depuy wins the lawsuit and you will recover no money at all.

On the other hand, if in your case the evidence of the cup's failure is particularly strong, and your suffering was extreme (some individuals have required multiple revision surgeries, or been forced to use a walker or wheelchair permanently), and your medical experts are able to clearly connect all the dots, you may reasonably decide to pursue a jury trial. The biggest upside in trying your case is that a jury may award damages that exceed the settlement figures offered in the settlement agreements.

In Chapter Eight, we will examine two Depuy ASR jury trial verdicts and analyze your options further.

CHAPTER EIGHT

DEPUY ASR HIP SETTLEMENT: FIVE KEY BENEFITS



In Chapter Seven, we began to look at some of the factors you should consider before you decide to accept a settlement from Depuy or not. Now let's dig a little deeper . . .

TWO RECENT DEPUY ASR JURY VERDICTS

As the Depuy ASR Hip Settlement was being negotiated, two cases involving the alleged failure of the Depuy ASR hip were tried to a jury, one in Los Angeles and one in Chicago. In Los Angeles, a jury awarded $8,338,000.00 to Loren Kransky, who suffered from extremely high metal levels in his blood (the jury awarded $338,000 in medical expenses and $8,000,000 in pain and suffering damages but did not award punitive damages). In Chicago several weeks after the Kransky trial, a jury found that Depuy was not negligent and that the injury to Carol Strum was more likely caused by her unique health issues, particularly her sensitivity to elevated metal levels in the blood. In the Chicago case, therefore, Ms. Strum received no money at all.

As you can see, the results of trying these kinds of cases can vary widely. Keep in mind that no two cases are alike, and these two cases were different in many ways. And although the Los Angeles case was a good result for Mr. Kransky, Depuy promptly appealed the jury verdict and thus the compensation has been postponed. That appeal is still pending.

KEY BENEFITS OF SETTLEMENT OFFER

Some individuals who have suffered through multiple hip surgeries have been dissatisfied with the terms of the Settlement Agreement. And this makes sense; after all, the pain and suffering involved with a failed artificial hip, and the misery of undergoing a painful revision surgery (or more than one) can be overwhelming. This pain and suffering–some say–should be worth much more than the amounts offered in the settlement.

I understand their frustration. While I have never had a total hip replacement, and never suffered the failure of a THR, I can easily see how someone in that position would feel that the base amounts in the Settlement Agreement just don't adequately compensate the terrible suffering.

But here's the thing: the settlement agreement offers certain ***key benefits***:

(1) a base settlement award of $250,000 (although reductions could happen based on the person's age, weight, and length of time between implant surgery and revision surgery);

(2) receipt of payment months rather than years;

(3) Depuy would pay the outstanding medical and other liens from the surgeries;

(4) an opportunity for additional money under the "extraordinary injury fund ("EIF"), referred to as Part B awards, and these amounts can be significant (***I will write about Part B awards in a later chapter***); and

(5) perhaps most importantly, you ***take the risk off the table***. The woman in Chicago who tried her case to a jury ended up with a verdict of zero. Mr. Kransky, though he won an impressive jury verdict, still has not been paid while Depuy's appeal is heard in California.

You can review the terms of the settlement agreement(s) here: https://www.usasrhipsettlement.com/Un-Secure/Documents.aspx.

WHAT SHOULD YOU DO?

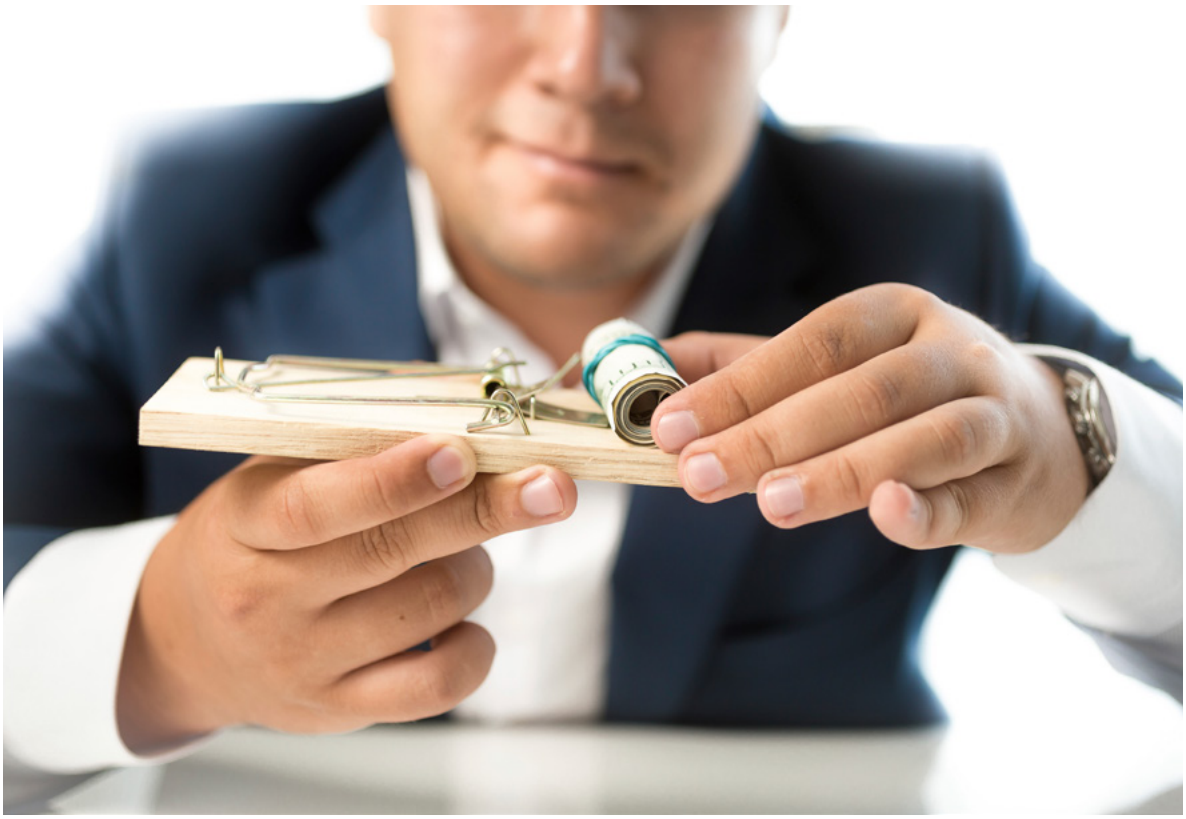
So should you opt for the settlement or decline and try your case to a jury in hopes of obtaining a bigger monetary award?

My educated answer is: I don't know.

Sorry, I suspect you may have wanted a firm answer, but there just isn't one. It sounds tired and cliched, but ***every case is different***. If your revision surgery was successful, and you are feeling better again, and you are able to exercise and sleep and perform your job without pain and discomfort, then the settlement may well be the acceptable choice for you. If your injuries are severe and ongoing and permanent, you may choose to litigate your case. The decision should only be made after a thorough analysis by your attorney of the specific details of your unique case.

CHAPTER NINE

"MEDICAL FUNDING" SERIOUS THREAT TO YOUR PRODUCT LIABILITY SETTLEMENT



I received a court filing from an artificial hip multidistrict litigation last week, and it reminded me to caution you about the ***serious financial threat*** you can face when dealing with artificial hip failures and hip litigation (and of course, other medical device failures like artificial knees and transvaginal mesh). Sadly, this threat comes from third-party companies that appear legitimate, even helpful, but mainly have a naked profit motive for getting involved in your case. These companies often cash in unfairly from all the suffering you endured from you failed artificial hip or failed medical device.

WHAT IS MEDICAL FUNDING?

Think of it as a lawsuit loan, or a loan against your future settlement recovery. Medical Funding is a medical care financial assistance "service," and occurs when a third-party company offers to pay the medical bills of a person who is injured by the negligence of others. This could be a car crash case, a failed medical device like a hip, or any other situation where the negligence of someone else caused the injury. If you accept the offer, the company will pay the medical care provider—the surgeon, the hospital, etc.—a percentage of the provider's billed charges, but usually more than the provider would have been paid by private health insurance, Medicare, or Medicaid. The company then receives an "assignment" from the medical provider that allows the company (potentially) to receive the full amount of the billed charges, which are often much higher than what the company paid for the medical care and higher than what private insurance would have paid. The third-party company will then file a medical expense "lien" on the proceeds of the person's settlement or jury award.

THIS IS HOW IT WORKS

Let's say "Andrea" had hip replacement surgery in 2010, and fourteen months later the artificial hip components failed. Her doctors advised her to undergo revision surgery, but in the past year Andrea lost her job and her health insurance. She simply could not afford the new—and necessary—revision surgery. Enter "Trust-Us Medical Funder, Inc.," a third-party medical funding company. Andrea meets with "Brad," a vice-president at Trust Us, and he explains that his company is there to help. Brad says that Trust Us will pay for Andrea's revision surgery, and will even pay for Andrea to spend three nights in a hotel near the hospital where the revision surgery is to be performed.

Andrea accepts. The revision surgery is a success. Trust Us advances costs for the medical care to the surgeon and to the hospital. A year later, Andrea's attorney

files suit against the manufacturer of the artificial hip. Her claim qualifies under the settlement agreement, and she accepts the terms of the settlement offer. However, she then learns that Trust Us has filed a medical lien for $68,000.00. This figure is larger than the amount Trust Us actually paid for Andrea's medical care. (In fact, the difference between what Trust Us paid the actual medical providers and the amount of the medical lien is the profit Trust Us stands to make by advancing the medical costs—it is the only reason Brad showed up at Andrea's house in the first place.)

MEDICAL FUNDING CAN SEVERELY REDUCE THE MONEY AN INJURED PERSON RECEIVES

In many cases, the large medical lien will be paid from the proceeds of the settlement or jury award. For example, if Andrea settles her case for $200,000.00, she may have to pay the $68,000.00 out of her share of the settlement funds. After legal fees and hard-cost expenses are paid, Andrea will be left with a net amount much less than $100,000.00, which is less than half the gross settlement amount. Let's say that Trust Us paid half of the $68,000.00 lien to actual medical providers for Andrea's care; this means that Trust Us will walk away with a cool $34,000.00 profit for advancing costs of the revision surgery. (It should come as no surprise that a backlash on medical funders has occurred, and several lawsuits have been filed against medical funding companies.)

In some master settlement agreements, the defendant-manufacturer agrees to resolve the medical liens for the injured plaintiffs, meaning that the settlement amounts to the injured person ***will not*** be reduced by the medical lien payments. In these cases, medical funding companies like Trust Us can threaten the settlement for the person or jeopardize the entire global settlement agreement. At the very least it could delay the injured person's recovery of needed funds (a speedy recovery is important for most people, but especially "Andrea," who as you'll recall lost her job through this period).

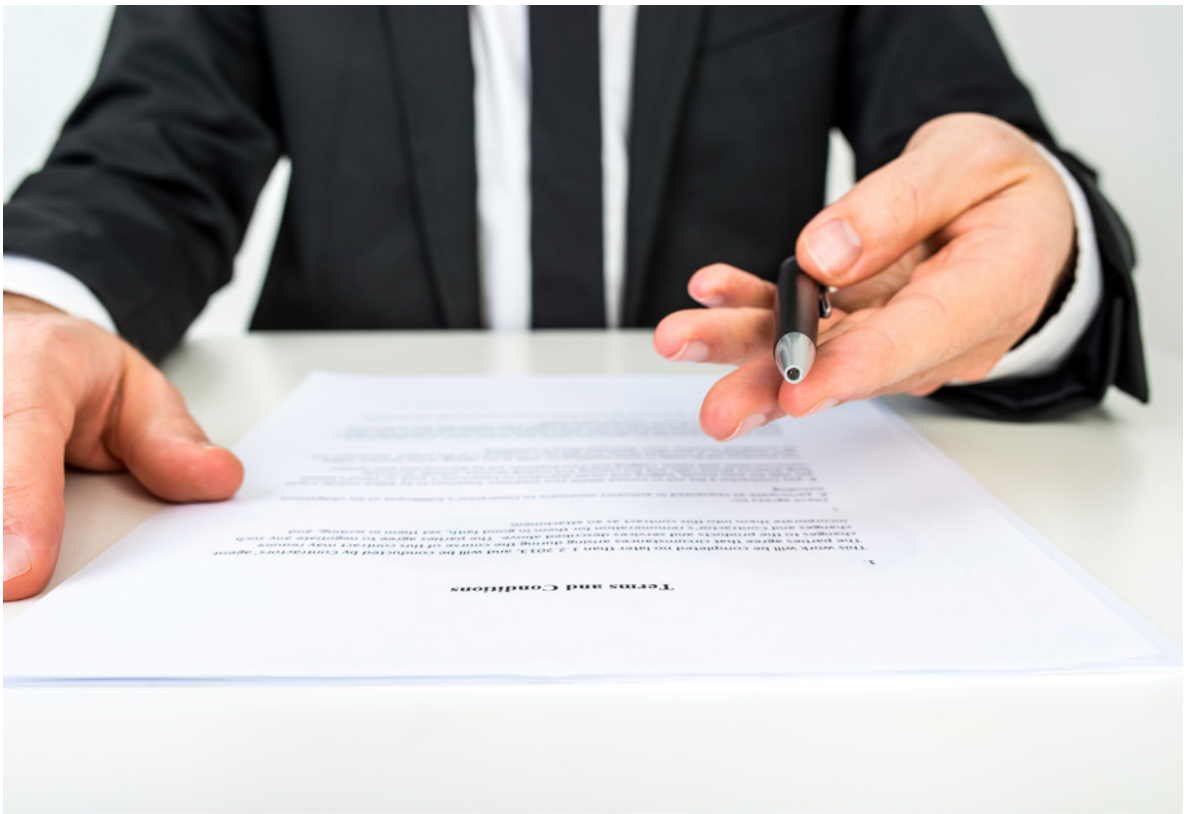
That's where last week's court document came in. In that case Depuy filed a "motion to compel" against one medical funding company, asking the court to compel the company "to produce information necessary for Depuy to review the company's lien demands." Depuy alleges that the medical funding company failed to provide key information in the litigation for Depuy to determine if the medical liens are reasonable. It is just one of many battles that take place in any failed medical product litigation, but the skirmish highlights the financial pitfalls that individuals can fall victim to when moving through a products liability case.

THE TAKEAWAY FOR YOU

The takeaway is simple: if at all possible ***do not*** engage the services of a medical funding company in your products liability case (or any personal injury case). Exhaust every other funding source possible first: private health insurance, Medicare, Medicaid, a kind and generous uncle, even a small loan. If you do not have insurance, or access to Medicare or Medicaid, and no other ability for pay for the necessary corrective surgery, and you are forced to engage the services of a medical funding company, please review the contract carefully (even two or three times), understand the terms of repayment, ask questions, and shop around.

CHAPTER TEN

DEPUY ASR HIP SETTLEMENT AGREEMENTS: WHAT IT MEANS FOR YOU



After years of litigation and negotiation among the plaintiffs and defendants, the first Depuy ASR hip settlement agreement was reached on November 19, 2013. This settlement document, with all the exhibits, was 181 pages long. The first settlement agreement required that you must have undergone revision surgery on or before August 31, 2013. A second settlement agreement was reached on March 2, 2015, which allowed participation in the settlement if you received a revision surgery after August 31, 2013 but no later than January 31, 2015. The key terms in the second settlement agreement are the same as those in the first settlement. The agreements take a long time read through, digest, and understand. In this chapter and those that follow, I am going to help you work through the settlement language.

Please note: ***The deadlines for participation in both Depuy settlement agreements have passed***. At the moment there are no settlement agreements in place in which you may enroll or participate now or in the immediate future. However, there should be new settlement agreements down the road for those of you who undergo a revision surgery after January 31, 2015. Further, you still have options if you had a revision surgery before January 31, 2015 but simply missed the deadlines for enrollment (which I discuss below). I will keep you posted if and when a third settlement agreement is reached.

For those of you who have undergone hip replacement in the past few years and believe your artificial hip may be failing, I believe it is important to understand how the settlement agreements worked, as it will certainly impact settlements for injured people in the future.

SO WHO WAS ELIGIBLE FOR THE SETTLEMENT?

To be eligible to participate in the Depuy settlement, you must:

1. Have been a "***United States patient***," which means a U.S. citizen (or legal resident) who received the Depuy ASR artificial hip as part of hip surgery that occurred in the United States;

2. Have ***had implanted*** in your body either (a) the ***Depuy ASR XL*** hip system or (b) ***ASR Hip Resurfacing*** System. Basically, you or your attorney will have to look at the surgical records, particularly the product stickers taken off the hip components when you had the first hip surgery, to determine if the artificial hip which failed in your body is one of the products for which compensation is being offered in this settlement;

3. Have undergone ***revision surgery***. This means of course that the original implant failed and had to be removed through a second surgery. According to the settlement agreement, the revision surgery cannot be caused by trauma or infection, and had to

occur more than 180 days following the first surgery. There are other qualifications, but if you check all these boxes, you are probably getting close to being eligible.

WHAT WAS REQUIRED TO REGISTER FOR THE SETTLEMENT?

Here is an interesting detail: you did not have to file a lawsuit to be eligible for participation in the settlement. You also did not have to hire an attorney to assist you through the process. But Depuy Orthopaedics did require that every person who wanted to participate in the settlement register, and this registration process was no joke: It's intricate and involved and very time-consuming. And there are reductions in the settlement amounts for those who go it alone.

For cases in which lawsuits have been filed and you have an attorney, your attorney would need to submit enrollment forms, claim forms, and required submissions for your case. If you filed a lawsuit without an attorney, by yourself, as what is called a "pro se litigant," you would need to submit all these forms as well. Finally, for people who have not yet filed a lawsuit but who otherwise qualified for the settlement, the forms would have had to be submitted as well.

Again, it is important to state again that any person who qualified and met the deadline in these settlement agreements could have participates in the settlement even if they did not file a lawsuit and even if they did not have an attorney. This path to settlement without an attorney is fraught with difficulty, but it is possible to "go it alone."

WHAT IF I QUALIFIED FOR THE SETTLEMENT BUT MISSED THE FILING DEADLINE?

Good question. The answer is that you ***still retain all your legal rights***, but (at this time at least) you are not permitted to participate in the settlements with Depuy Orthopaedics. Which is to say, you can still file a lawsuit against Depuy Orthopaedics and pursue your claim as any other injured people must do. From there, your attorney can work on a settlement with Depuy or even try your case to a jury.

Quick example: A woman gets hip surgery on August 1, 2010 with the Depuy ASR XL hip system. Three years later the Depuy hip components fail, and she undergoes revision surgery on July 15, 2014. She would not qualify for the first settlement agreement, but if she met the deadline she would qualify for the second settlement agreement. However, she does not file the registration and enrollment forms before the second settlement agreement's deadline (which was

May 1, 2015). In this case, at least until the parties involved make adjustments on their deadlines, the woman could not participate in the settlement but would be free to file a lawsuit to pursue her claims against Depuy. There may be statute of limitations issues with this hypothetical case, but this woman still seems to me to have a strong case going forward. Still, she would not be permitted to participate in the two settlements discussed above.

Note: The Depuy ASR Settlement Agreements are public documents and are the source for the information in this chapter. You can find it easily on the Internet. I have had to summarize and simplify in spots to make the terms of the agreement a bit easier to follow. I recommend that if you have a failed Depuy ASR hip, you review the entire document carefully, or at least contact a lawyer you trust and discuss the terms of the settlement and its relevance to your situation. Of course, you can also call me.

DEPUY ASR HIP SETTLEMENT AGREEMENTS: THE PART A "BASE" AWARD

There are two key areas of compensation under the Depuy ASR Hip Settlement Agreement: The Part A Base Award, and the Part B Award, which awards additional compensation under Depuy's "Extraordinary Injury Fund" ("EIF").

I remind you that although the deadlines for participation in the first two Depuy ASR settlements have passed, ***people are still filing lawsuits*** against Depuy Orthopaedics and Johnson & Johnson. More settlement agreements will likely be reached in the future, because many people who have been injured by the metal-on-metal Depuy ASR hip have not been compensated for their injuries. When those new settlement agreements are established, they will likely look much like the first two agreements. So it's helpful to review those settlement terms.

OK, so picking up where we left off in Part 1: Let's say you are a patient in the United States and that the Depuy ASR artificial hip system was implanted in your body. It failed. You then had a "revision" surgery to remove the failed hip components. Thus, you would be "eligible" to participate in the settlement. You then hired a lawyer who filed suit in federal court in your state, then properly transferred the case to the MDL in Ohio. From that point, your attorney would then submit all documentation relating to the MDL and its "Case Management Orders." To participate in the settlement, you and your attorney would need to submit all enrollment forms, claim forms, and other required submissions.

Your documentation is in order; you've met all settlement deadlines, and you signed the form electing to participate in the settlement. From this point, you

are eligible for two areas of compensation, identified in the settlement agreements as Part A and Part B awards.

PART A BASE AWARDS

This is considered the "base award." The default amount for this base award is ***$250,000.00***. You would receive this amount if you had revision surgery more than 180 days after the original implant surgery, but the revision surgery had to occur fewer than five years after the implant surgery. If you underwent revision surgery more than five years after the implant surgery, but sooner than six years, you would receive a Part A "base" amount of $225,000.00 (reduced by $25,000). Between six and seven years, you would be entitled to recover $200,000.00. Between seven years eight years: $150,000.00. Obviously, under the settlement an eligible plaintiff would be entitled to less money if a longer period of time passed between implant surgery and revision surgery. There are several reasons for this, but one reason is the rationale that artificial hips are not expected to last decades. It is customary for most artificial hips to need revision or replacement surgery after 12 to 15 years. Thus, if you were able to manage with the Depuy ASR hip system for 7 1/2 years–the rationale goes–you would have received the partial benefit of those years from the Depuy ASR hip, compared to the less fortunate patient who had to undergo a revision surgery one or two years after implantation.

"UNREPRESENTED CLAIMANTS" (THOSE WITHOUT LAWYERS)

If you do not have a lawyer you can still receive compensation from the settlement, but the numbers are reduced. The "unrepresented claimant" would be entitled to receive ***71%*** of the gross award for the Part A claim. Thus, if you your revision surgery occurred more than 180 days but less than five years from the date of the original surgery, you would receive 71% of $250,000.00, or $177,500.00. Note that this reduction is a similar amount to what many attorneys charge for representing individuals in litigation involving a contingency fee.

ADDITIONAL REDUCTIONS TO BASE AWARD

There are further reductions to the Part A base award.

Tobacco Use. If the medical records indicate you are a smoker, you will incur a reduction of 5% (e.g., this would be a $12,500.00 reduction on the $250,000.00 base amount).

ASR XL Implanted as Revision Device. If the Depuy ASR XL hip system was replaced in a revision surgery with another Depuy ASR XL hip, your Part A base award would be reduced by up to 20%. I will say that this outcome is pretty rare, as most surgeons should be leery of replacing a failed artificial hip with the exact same device, particularly with the steady drumbeat of reports identifying the Depuy ASR hip as a failing device. Also keep in mind in that case, you may have a medical malpractice action against your doctor for replacing a flawed artificial hip with the same flawed artificial hip. In addition, you may be entitled to further compensation if the second Depuy ASR hip fails.

BMI. You will lose between 10% and 20% of your base award if your **body mass index** is too high at the time of implant surgery. A BMI of 35 to 39 would yield a 10% reduction; BMI 40 to 49 would yield around 15%; BMI 50 or higher, you can be reduced up to 20%. BMI will be determined from your medical records at the time of implant surgery.

Death. If you die within five years of the revision surgery, your base award could be reduced up to 25%.

Age. If you were 70 to 85 (and older) at the time of your original implant surgery, your base award would be reduced between 4% and 15%. This reduction never made much sense to me, as a 74 year old would suffer from multiple surgeries just like a 60 year old would. I think one rationale is that hip surgeries fail more often, and not because of defective artificial hip components, in older populations.

At this point you may be thinking: ***this is harsh!*** I get it. And I agree. If you smoke, if you are a bit overweight, and your revision surgery occurred seven years after the implant surgery, your Part A base award could be $122,500, less than half of the starting figure of $250,000.00. The modest good news is that there is a provision in the agreement for a minimum Part A base award, basically a floor, and the minimums range from $150,000 down to $100,000 (depending on length of time between implant surgery and revision surgery). For unrepresented claimants, depending on reductions, the Part A base award could be as low as $71,000.00.

There is very little you can do in advance to avoid these reductions. The biggest reductions occur based on the passage of time between implant surgery and revision surgery. So if your doctor has determined that the Depuy ASR hip has failed inside your body, and you are in physical pain, or suffering from metallosis, you should not delay in scheduling your revision surgery. This is mainly for your physical well-being, but also to avoid unnecessary reductions in your settlement award. Of course, for all kinds of reasons, it is a good idea to avoid tobacco and to manage your weight.

DEPUY ASR HIP SETTLEMENT PART B "EXTRAORDINARY INJURY FUND"

Now let's look at those Part B EIF "extraordinary injuries."

BILATERAL IMPLANTS

If both of your hips, right and left, were implanted with the Depuy ASR hip, and both hips failed, requiring revision surgeries to both hips, you can recover additional compensation. Essentially, you would be entitled to recovery of two Part A base awards. If one side required revision but not the other, you would get Part A compensation on the revised hip only. Of course, if the unrevised hip subsequently failed, you would still have the right to seek compensation later on.

EIF CATEGORIES:

Covered Re-Revision Surgery—Past. This means you had to undergo two revision surgeries on the same hip. The re-revision cannot be caused by infection or "excluded trauma." A qualifying re-revision surgery would yield $150,000.00 in Part B funding. All subsequent re-revision surgeries (yes this means a third or fourth surgery on the same hip!) would entitle you to $75,000.00.

MAJOR COMPLICATIONS:

Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT). If you qualify, you would receive $30,000.00 for PE and $15,000.00 for DVT. You can only receive two awards for PE and DVT, assuming you otherwise meet the qualifications.

Dislocations. This is when the prosthetic femoral head separates from the socket (the acetabular cup). The compensation ranges from $15,000.00 for a closed reduction and $50,000.00 for an open reduction. There is a limit of three dislocations per hip.

Foot Drop. This is a condition of the foot where the front part of the foot drops as a result of damage to the "peroneal nerve." The foot can drag or go limp as the person attempts to walk. The condition must continue for 90 days after the ASR revision surgery. As with all these conditions, you must prove foot drop through the medical records and an "objective" physical examination. The compensation is $20,000.00.

Infection. Although the diagnosis must qualify based on certain factors (and there are limitations), if you suffered an infection after your revision surgery, you can recover benefits of $10,000.00 to $30,000.00, depending on severity and treatment needed.

Miscellaneous Major Complication. This is an area of compensation for a problem that resulted from a revision surgery that was not specifically listed in the Part B "matrix." This means that you suffered an unique injury that is identified in the medical records but is not one of the listed complications in the settlement agreement. The benefits would not exceed $50,000.00.

Delayed Recovery. This is a compensation category where the injury took a long time to resolve. For example, if you suffered from "foot drop" a full year after the revision surgery, you would be entitled to recover additional funds based on the severity of the injury and your age at the date of revision. Compensation for delayed recovery could also happen for an extended injury from infection, or a "miscellaneous major complication." The compensation provided in Part B ranges from $34,000.00 to $288,000.00, depending on the severity of the injury and the age of the injured person.

Myocardial Infarction. This is that big name for a heart attack. If you suffered a heart attack during the revision or re-revision surgery, you would be entitled to recover compensation under Part B ranging from $85,000.00 to $360,000.00, depending on the severity of the heart attack and your age. There are reductions to these amounts if you were a smoker or were overweight through the period.

Stroke. Compensation is awarded based on the level of the stroke and your age at the time of the stroke, from $85,000.00 to $516,000.00.

Death. If a patient died during revision or re-revision surgery, his spouse and family members would be awarded compensation. For example, the surviving spouse would receive $206,000.00, and each surviving minor child would receive $100,000.00 ($25,000.00 for all surviving adult children). There is also provision for payment of lost income resulting from the death of the patient.

Discretionary. This is a broad category of compensation for other extraordinary injuries not identified in the previous sections. Examples of this compensation area include loss of earnings, acetabular cup liner replacement, young age (50 or younger) at the time of revision surgery, and a medical condition requiring a delay of the revision surgery.

FUTURE MATRIX.

This category is intended to compensate a person who suffers a future injury that has not yet occurred. This means that even you could qualify for compensation up to two years after your revision surgery, even if, at the moment, you do not show signs of an injury. For example, if you sign on to the settlement, and at the time you qualify only for a Part A "base" award, you would receive that Part A award only. But six months later you suffer one of the categories of injury listed above (need for re-revision surgery, PE or DVT, dislocation, foot drop, infection, delayed recovery, heart attack, stroke, death, or miscellaneous injury), you would be entitled to compensation for this future extraordinary injury. Of course, there are certain reductions based on the passage of time. I just wanted to make sure you understood that you could be compensated for a future injury six months or eighteen months (up to two years) after you sign on to the settlement.

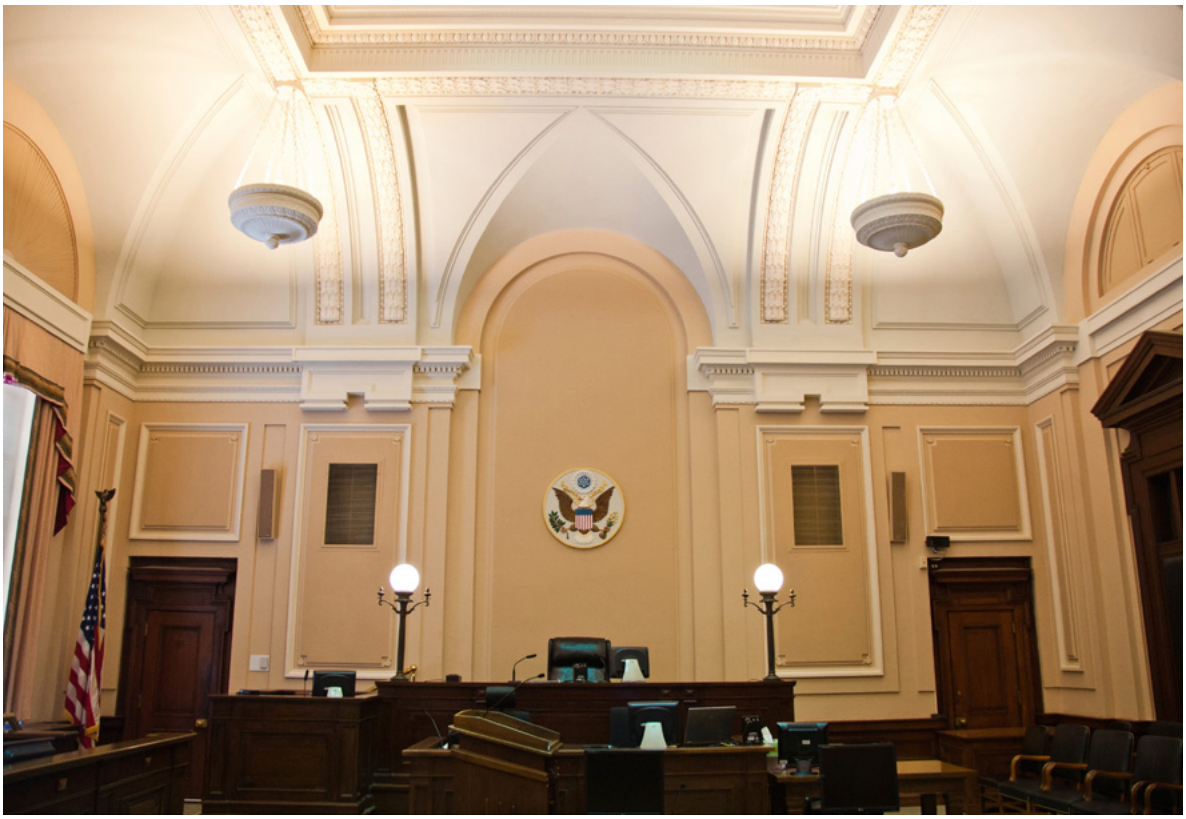
OK, so let's look at a quick hypothetical from the Part B compensation world:

Let's say you are 55, and you had revision surgery three years after the implant surgery, then a year later had to have a second revision surgery, and through that period you suffered from a "severe" case of foot drop for more than a year, you should receive a base award of $250,000.00, followed by a Part B award of $337,000.00, for a total of $587,000.00. If you lost your job or income through that period (which you could prove of course), there should be even more compensation available to you under Part B of the Depuy ASR Settlement Agreement.

Note: I had to distill many pages from the settlement agreement in this article. The Part B EIF Award "matrix" is much more complex than I have set out. It requires someone who can present your claims carefully and convincingly, with straightforward evidence from your medical and employment records.

CHAPTER ELEVEN

FINDING THE RIGHT ATTORNEY TO HANDLE YOUR FAILED HIP CASE



Let's face it, most attorneys (in fact, most everyone in any profession) sound impressive on their websites. In much the same way as people craft positive, happy versions of themselves on Facebook and Instagram, attorneys usually present a shiny version of themselves on their law firm websites. Often these websites list notable accomplishments. I don't mean to suggest that these accomplishments are unimpressive or even fabricated. What I am saying is that you must go beyond the scrubbed surface of many websites and investigate further when choosing the right attorney to represent you with your case.

1. Determine what kind of lawyer you need. Just as you wouldn't consult a cardiologist for a broken leg, you also shouldn't hire a worker's compensation lawyer to handle the failure of your artificial hip components. Look for an attorney who actively represents plaintiffs in personal injury cases, and specifically defective hip and other medical device cases. Try to avoid the generalists who appear to handle every possible case under the sun, from drafting your will to litigating your car accident case.

2. Look for an attorney with demonstrated knowledge in your specific case area. Take a good look at the information provided on the attorney's website. Does the attorney have knowledge about your medical device failures and the related litigation? Has he or she litigated cases involving defective hips or knees or other defective medical devices? Does the attorney provide recent, timely, up-to-date information on the medical device that has caused problems for you? Was the information helpful to you?

3. Review the attorney's bio. Make sure the attorney has litigation experience in this area of law. Has the lawyer handled cases such as the one you have? Is that apparent from the materials on his website? Spend some time getting to know the attorney as much as you can from the website, the attorney's blog, and any other information provided. And it never hurts to make sure the attorney attended a strong, competitive law school. Beyond that, check to see if the attorney has other noteworthy accomplishments, such as serving a judicial clerkship, which is a prestigious job offered to a small number of law school graduates. Finally, it is often (though not always) helpful for the attorney to practice in the state you live in, or at least within a day's drive; the most important advantage of this proximity is that you can meet face-to-face with your attorney when it becomes necessary.

4. Meet with the attorney you wish to hire. This is a critical step. After doing your research, call and explain your case to the firm's paralegal and arrange a time to meet in person with the attorney. If after the meeting you aren't convinced that you have found the right lawyer, or the fit simply doesn't "feel" right,

go back and start the process over. Some cases resolve rather quickly, but others can take years to resolve; it is therefore important that you choose an attorney you can work with throughout the process.

I imagine this chapter could come off as self-serving. After all, I am an attorney focused on helping people injured by defective hips and knees and other failed medical products. I believe I am a good attorney and that I can be very effective in representing you through each phase of your case. But at the end of the day, I'd rather see you take your time and find a good lawyer—even if that lawyer is not me—than for you to stumble upon an incompetent lawyer who bungles your case. I am a good lawyer, but I'm not the only one. Find a good one.

APPENDIX

DEFINITIONS

Below are common words, phrases, and names that often pop up in discussions of artificial hips, knees, and other medical devices. These definitions may assist you as you read through the articles on this site. Of course, you are always welcome to contact me directly for further explanation.

acetabular cup. A cup made of metal or ceramic or other material manufactured to sit in the body's hip cavity (acetabulum) and into which is secured the femoral ball at the top of the femoral stem. An acetabular shell sits inside the acetabular cup.

acetabulum. The hip cavity on the hip bone, where the head of the femur sits.

ASR. The acronym which stands for "Articular Surface Replacement," a surgical procedure where only the articular surface of the hip (the cup and the ball) is replaced. This metal-on-metal hip replacement system was developed and manufactured by Depuy Orthopaedics.

bellwether cases. A representative set of cases to be tried to juries. When a large number of cases are filed in courts which involve the failure of a single product (or drug), and which has caused similar injury to many individuals, a single court may be chosen to consolidate most of the cases into one "multi-district litigation." Committees of plaintiffs and defendants then choose a representative sample of those cases to be tried to a jury, which

chromium. One of the metal materials used in the construction of the metal-on-metal hip components. Evidence of chromium in the blood of patients who received the metal-on-metal hip components created a red flag for the safety of the metal-on-metal design.

cobalt. One of the metal materials used in the construction of the metal-on-metal hip components. Evidence of chromium in the blood of patients who received the metal-on-metal hip components created a red flag for the safety of the metal-on-metal design.

Depuy. A collection of companies which develops and manufactures medical products, including artificial hips and knees. Depuy, Inc. and Depuy Orthopaedics is owned by parent company, Johnson & Johnson.

Depuy ASR Cup. The metal cup manufactured by Depuy Orthopaedics which is part of the ASR XL Acetabular System.

Depuy ASR Settlement(s). So far, there have been **two** Settlement Agreements in the U.S. Depuy ASR Hip Litigation, one dated November 19, 2013 and the second dated March 2, 2015, each of which covers a different time period for the date when a person underwent revision surgery following implant of the Depuy ASR hip.

Depuy Pinnacle. A metal-on-metal hip replacement system manufactured by Depuy Orthopaedics. Like the Depuy ASR XL Acetabular System, the Pinnacle has failed an alarming number of times and required hundreds of revision surgeries.

femoral ball. Also called the femoral head, it is a metal ball that is fixed on a stem inserted into a femur as part of a hip replacement surgery.

femoral stem. The rod-like component part of an artificial hip that slips down inside the femur bone.

implantation surgery. This is the original hip replacement surgery, where the surgeon implants the artificial hip components into a patient.

MDL. Acronym for "multi-district litigation." When a large number of cases are filed in courts across the country, all of which involve the failure of a single product (or drug), and which has caused similar injury to many individuals, a single court may consolidate most of the cases into one multi-district litigation. From this one court the designated judge will manage the large caseload, hear motions, resolve disputes, preside over bellwether trials, and monitor global settlement discussion.

metallosis. The build up of metal levels in the blood and in body tissue. When a metal-on-metal artificial hip cup and ball grind together, it is believed that tiny

shavings are released into the body, elevating metal levels. This is a substantial health concerns for individuals who received metal-on-metal hip replacement components.

metal-on-metal ("MoM"). The construction of artificial hip components using metal materials, such as cobalt and chrome. The hip component manufacturers developed this hip replacement system with the hope that it would last much longer than hip components made with other materials, such as ceramic. However, the failure rate proved much higher.

revision surgery. A surgery required when a hip replacement surgery has failed. The surgeon must re-enter the hip area, secure the loose or failed components, or remove and replace the failed components.

rerevision surgery. A surgery required when a revision surgery fails. Yes, sadly this means that the person has had to undergo three surgeries to the same hip (the implantation surgery, the revision, and the rerevision). There are cases where patients have had to undergo three, four, and even five surgeries to stabilize and repair a hip. Obviously, these are among the very worst results.

Stryker. A company which develops and manufactures medical products, including artificial hips.

THA. Total Hip Arthroplasty, the medical term for a total hip replacement surgery.

total hip replacement. A total hip replacement replaces the body's hip joint with an artificial one, and these artificial hips are usually made out of metal or plastics. A total hip replacement typically consists of four separate parts: (1) a stem, (2) a head, (3) a liner, and (4) a cup (called an "acetabular cup" or shell). After the surgeon hollows out the patient's femur bone, the stem is implanted. The head is a metal ball that is fixed on top of the stem. The femoral head forms the hip joint when it is placed inside the liner and the cup (the "acetabular shell").

Zimmer. A company which develops and manufactures medical products, including artificial hips and knees.

Zimmer Durom Cup. The metal cup manufactured by Zimmer. The Durom Cup failed often and has been the subject of many lawsuits.

LEGAL DISCLAIMER

Artificial Hip Lawsuits: What You Need to Know (referred to herein as "Book") is the property of Clay Hodges. Clay Hodges holds and maintains a copyright on the contents of Book.

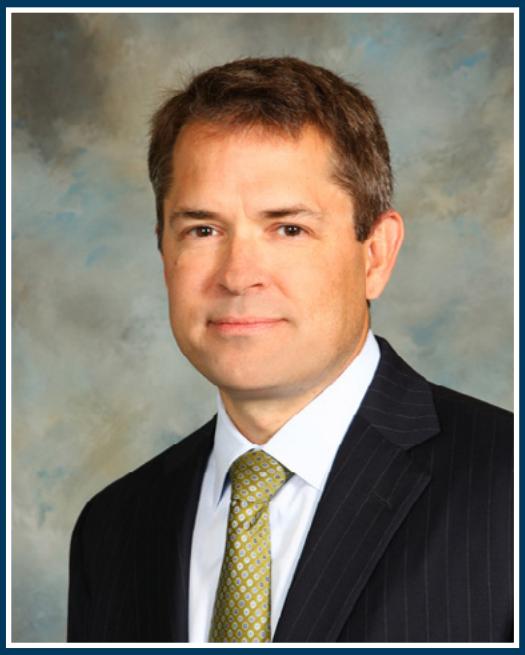
The law firm Harris Sarratt & Hodges, LLP (Firm) is not responsible for the contents of Book.

This Book is intended to provide general information on defective artificial hips and the litigation that has followed the failure of these medical devices. ***It is not intended to be and should not be considered legal advice.***

The content of this Book may not reflect current legal developments, verdicts or settlements. Clay Hodges and the Firm expressly disclaim all liability in respect to actions taken or not taken based on any or all the contents of this Book.

Photographs and other media in Book are for illustrative purposes only.

The Book and its contents are provided "as is" without warranty of any kind, expressed or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, or non-infringement.



FOR FURTHER INFORMATION

PLEASE CONTACT:

Clay Hodges
Harris Sarratt & Hodges, LLP
1620 Hillsborough Street, Suite 200
Raleigh, North Carolina 27605
(919) 546-8788

Website: www.meddevicelaw.com
Email: clayhodges@hshllp.com