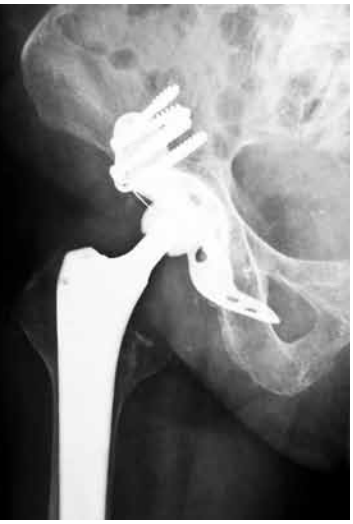
Defective Hip Implant Litigation



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The last ten years have witnessed a dramatic increase in the sale and use of artificial hip joints using cobalt and chromium metal components. Multiple manufacturers — including DePuy Orthopedics, Stryker, Wright Medical Technology, Biomet, Zimmer, and Smith & Nephew — aggressively marketed these metal-on-metal hip systems as particularly ideal for the younger and more active patient, claiming greater stability, mobility and longevity than with ceramic or plastic components.

Soon after their release, however, serious design shortfalls became apparent. Erosion and fretting from metal-on-metal wear between the ball and socket, or between other metal components, caused many hip replacement patients to suffer metal poisoning (metallosis), with associated bone and tissue necrosis, pseudotumors, disabling hip and leg pain, joint dislocations and complete implant failure. Many patients tested at toxic levels of chromium and cobalt ions in their blood, with as yet unknown long term health risks.

An unprecedented high percentage of implant recipients required revision surgeries in which the defective hips are removed and replaced. These surgeries are more demanding than the original implant surgery. They often are accompanied by significant complications, including additional bone, muscle and tissue loss, and other continued problems. The convalescence usually takes longer and is more painful. Most revision patients are left with reduced range of motion and strength, and are at increased risk of recurrent dislocations. Rather than getting the stronger and longer-lasting prosthesis they were promised, tens of thousands of metal-on-metal hip recipients have instead lost the opportunity to live their normal active lifestyles. Many more will suffer the same fate in the years to come.

Litigation

Fortunately, claims of most patients injured by these defective artificial hip joints are not preempted under *Riegel v. Medtronic, Inc.,* 552 U.S. 312 (2008) and related cases. Instead of going through the more rigorous Food and Drug Administration (FDA) premarket approval (PMA) process, most manufacturers received FDA clearance to market through the expedited 510(k) process on the asserted grounds that their new metal-on-metal hip systems were substantially similar to older models of PMA-approved hip implants. Unlike the preempted PMA process, obtaining 510(k) clearance requires no clinical testing of device safety or effectiveness and can be completed within 90 days.

Nationwide, tens of thousands of product defect claims have been filed against the various manufacturers. The majority of these claims are filed in fed-

eral court where they are consolidated for discovery and other pretrial matters by the United States Judicial Panel on Multidistrict Litigation. Currently, there are six federal multidistrict litigations (MDLs) involving five different metal hip manufacturers. Each one is assigned to a different U.S. District and judge for pretrial handling. That process typically includes coordination with various pending state court actions.

Case progress and handling varies greatly in each MDL, reflecting to some extent the date of respective product recalls, total claims filed, the manufacturer's litigation strategy and management style, and the preferred approach of the assigned judge. For example, many claims against Zimmer, related to its failed Durom Cup implants, settled early through court-sanctioned individual mediations before significant discovery was complete.

By contrast, the DePuy ASR litigation has undergone three years of intensive discovery involving over 80 million document pages and 55 depositions of corporate representatives. Two state court actions went to trial this summer against DePuy with wildly different results. An $8,300,000 verdict in California was followed by a defense verdict in Illinois. By mid-November, as a number of other ASR cases were pushing hard toward trial, DePuy agreed to a settlement of $2.475 billion, plus the medical liens, to resolve claims of ASR hip recipients who had undergone revision surgery before August 31, 2013.

Litigation will continue for the many thousands of ASR claimants who do not meet this first tier settlement criteria, or who opt out. In the Wright Medical Conserve MDL, yet another approach is being tested with bellwether mediations of representative cases. Meanwhile, the MDLs and state court actions against DePuy (Pinnacle metal-on-metal hip), Stryker (Rejuvenate and ABG II hips), Biomet (M2a Magnum hips) and other manufacturers trail behind in earlier stages of development and coordination.

The victims

The stories of our defective hip clients are compelling and strikingly similar. Seeking relief from hip pain and disability caused by osteoarthritis, they were referred to orthopedic surgeons who recommended that they undergo total hip arthroplasty, replacing both the acetabulum (hip socket) and the femoral head (ball), utilizing the latest in metal-on-metal technology with promises of greater activity and longer implant life. Based on the information provided, they consented to the surgery, often with the manufacturer's sales representative in attendance. The patients' arthritic hips were removed and a new "state-of-the-art" hip implanted. A few days post-surgery, they were discharged from the hospital to begin their home convalescence and slow recovery. At six weeks, everything typically would be progressing well and they were in less pain than they had been in years. But at some point, after months or even years, there was a significant change. They noticed a popping, began to experience a dull ache, or suffered recurrent dislocations. Many believed such symptoms were normal, until they received a letter from their doctor, often ghostwritten by the manufacturer of their implant, saying that their hip was subject to a voluntary recall and that they should come in and be checked. MRIs of the hip subsequently revealed loosening or fluid in the area of the hip implant, or blood tests documented toxic levels of chromium and cobalt ions in their blood. At first, they were advised to wait and see if their symptoms progressed. After they did progress, they were scheduled for revision surgery. Their convalescence following the second surgery was longer and more difficult than the original, and they never regained the level of comfort and function they initially experienced after the first surgery.

Our first metal-on-metal hip implant client, Steve, was 59-years-old when he developed right hip pain in 2007. He saw an orthopedic surgeon in Bend and was diagnosed with advanced degenerative arthrosis. In view of his young age and active lifestyle, the orthopedic surgeon recommended a large diameter metal-on-metal arthroplasty. In February 2008, he implanted a Zimmer Durom Cup artificial hip joint. The surgery went well and Steve enjoyed a quick recovery. Within six months, he was back to riding his bicycle and engaging in all of his other usual activities without discomfort. In early 2009, however, he started experiencing increasing right hip and groin pain. An MRI of his hip was negative and he was advised to wait and see if things improved. By June, Steve was experiencing significant swelling. An ultrasound revealed a cystic lesion in the pelvis. Subsequent CT scans led to the diagnosis of a large pseudotumor and fluid surrounding the implant. In October 2009, he underwent revision surgery

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in which the Zimmer Durom cup was removed and replaced. The pseudotumor was debrided from the vessels, tendons and other structures it had enveloped. Steve now walks with a cane and can no longer ride a bike.

Zimmer obtained FDA 510(k) clearance for sale of the Durom Cup artificial hip joint in the U.S. on March 19, 2006. In 2007, a nationally-known orthopedic surgeon consulting with Zimmer reported concerns of high implant failures. Blaming the failures on improper surgical technique, Zimmer briefly suspended sales in 2008 to revise its recommended surgical protocol, and then resumed marketing the hip. Zimmer did not permanently suspend sales of the Durom Cup until September 2010. We filed an action on Steve's behalf in June 2010 in federal district court in Eugene. After more than a year of litigation, his case settled for a confidential amount.

The future

Oregon trial lawyers represent many clients who have suffered similar disabling injuries caused by these hastily approved, heavily marketed metal-on-metal hips. Incredibly, only a few manufacturers have recalled these problem hips from the market.

Fortunately, with associated injuries and risks now well appreciated, orthopedic surgeons are giving quicker diagnosis and treatment to patients with these hip implants and are no longer implanting them. In addition, for problems related to the DePuy ASR or the Stryker Rejuvenate and ABG II models, the two respective manufacturers have voluntary programs to pay patients' out-of-pocket medical expenses, including costs for medical monitoring, revision surgeries and lost income. Unfortunately, many more thousands of patients have these implanted time bombs, and all the manufacturers continue to deny liability.

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