RECALL ! Hip Implant Failure

From 2002 to 2013, Consumer's Union found 578 recalls from six major manufacturers: Biomet, DePuy, Smith & Nephew, Stryker, Wright and Zimmer. Stryker had the most recalls by far with 231 and DePuy came in second with 150. These recalls came too late for tens of thousands of people who already received the problematic devices.

Are you experiencing complications from your hip implant?

Hip replacement devices have increased in popularity over the past two decades. Types of hip replacement devices usually fall into categories depending on what they are made of, these include ceramic-on-metal, metal-on-plastic or ceramic-on-ceramic. These new innovations in material, especially metal-on-metal designs, promised increased mobility. But, certain types of hip replacements may be more prone to failure and recall. Several joint manufacturers recalled their metal hip implants, but the recalls often come too late for tens of thousands of people who have already received these problematic devices.

Major hip replacement recalls occurred for these popular implant products:

- DePuy ASR Acetabular & Resurfacing System
- Stryker Rejuvenate and ABG II Hip Recall
- Smith & Nephew R3 Acetabular System
- Wright Conserve Plus and Profemur Z Hip Stem
- Zimmer Durom® Acetabular Component

In 2010, Depuy Orthopaedics' hip replacement recall brought attention to potentially serious injuries from these devices. The company reportedly spent $800 million on the recall. Unfortunately, people received the problematic implants before the company acted. Perhaps even more troubling is that recalls like Depuy's do not necessarily compensate injured people adequately for their pain, suffering and medical treatment.

FDA Panel Convenes Over Metal-on-Metal Hips

The FDA cleared many problematic hip replacements such as DePuy hips through a process known as the 510(k) program. Manufacturers are allowed to sell their devices as long as they can show that a "substantially equivalent" device is already on the market. Sometimes, approved products make are based on products that were later removed or recalled from the hip implant market. Because the 510(k) doesn't require rigorous safety studies and trials, it increases the chance that patients may receive faulty or less effective devices.

Since a large number of recalls involve metal-on-metal hips, the FDA called a panel meeting in June 2012 to discuss issues related to these devices. The hearing was open to the public and a number of surgeons and researchers provided data on MoM hips.

While Dr. William Rohr of Mendocino Coast District Hospital, the panel chair, said he saw no reason to continue using the implants the FDA did not call for a ban or recall. Instead, panel members called for more studies. The panel also agreed that doctors should inform patients of the problems associated with these devices.

Different Recall Classes

When the FDA issues a recall or manufacturers do voluntary recalls, they are classified into three classes by order of severity of injury that devices may cause.

- **Class I.** These recalls are the most urgent because they are the most harmful. According to the FDA, class I recalls are “a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.” More than 10 percent of the recalls in this time period were Class I.
- **Class II.** The FDA classifies these recalls as “a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.” The majority of hip recalls fall into the class II category.
- **Class III.** These recalls are the least serious and are unlikely to cause harm. The FDA did not classify any hip recalls in this category.

Recall Warnings Are Usually Too Late

Device recalls may be initiated by the Food and Drug Administration (FDA) or by a manufacturer. Unfortunately, many injuries have usually occurred by the time a manufacturer or the FDA decides to remove a device from the market. The delay is especially dangerous in Depuy’s case because an estimated 500,000 people have received all-metal hip implants in the United States.

Device manufacturers know that they are under legal duty to properly design, manufacture and test their products, as well as warn the public if a device fails, has adverse side effects or doesn’t do what it claims. That is why some manufacturers decide to voluntarily recall defective devices. But too often they are slow to respond to consumer complaints and miss the opportunity to prevent more injuries.

The FDA can also order manufacturers to recall a device. If the manufacturer refuses to cooperate and voluntarily recall the device, the FDA can get a court order forcing the manufacturer to take the device off the hip implant market.

Although the FDA is responsible for making sure that medical devices are adequately tested before they hit the market, drug and device recalls have become increasingly common in recent years. The FDA relies on manufacturer testing to approve a device. It also relies on manufacturers to continue monitoring safety and report any problems after a device hits the market. Critics complain that this type of lax regulation gives manufacturers little incentive to make safety a priority instead of focusing so heavily on marketing.

Studies by independent medical researchers sometimes bring attention to device failures that manufacturers either miss or ignore. Fortunately, consumers and health care professionals are also able to report any problems directly to the FDA. Consumers can use the MedWatch Online Voluntary Reporting Form for this purpose.

DePuy ASR Hip Recall

DePuy's 2010 recall involved the company's Articular Surface Replacement (ASR) Acetabular Hip System and ASR Hip Resurfacing System, which was sold only abroad. Like other hip devices with metal components, they were marketed as cutting-edge designs that offered better durability and more mobility than older devices made from other materials. But Depuy voluntarily recalled its hip systems after unpublished data from the U.K. joint registry revealed that metal devices are no more durable than older devices and had more problems.

In September 2011, the National Joint Registry of England and Wales published a report that DePuy's ASR acetabular implant was replaced or removed 29 percent of the time after just six years. This was compared with an overall 9.5 percent failure rate for all-metal hip implants. In January 2013, the jury in the first ASR trial heard evidence that, at the time of the recall, DePuy knew that within five years, 40 percent of its ASR implants would fail.

In addition to disappointing failure rates, all-metal hip replacement devices may also carry more health risks than older models.

Friction between the metal components can release metal shards into the body, which may result in injuries, including:

- Damage to the bone and tissue surrounding the hip joint.
- Loose implants and loss of mobility.
- Complications from metal in the bloodstream, including damage to the heart, kidneys, nervous system and thyroid.
- Severe inflammation.
- Pseudotumors.
- Infections.

Stryker Rejuvenate and ABG II Hip Recall

Approximately three years after the Rejuvenate and ABG II hip systems were first approved by the FDA, Stryker issued a voluntary recall of the devices in July 2012. The recall came after Stryker received post-market data that revealed the metal modular necks and stems of these two devices were prone to corrosion and fretting that may release excessive metal debris into body, damaging surrounding bone and tissue.

According to Stryker, the wide variety of component lengths and sizes were intended to provide surgeons more options to achieve a better fit in their patients. The neck is made of cobalt chromium and the stem is made of Stryker's proprietary titanium alloy blend designed to resist corrosion and fretting.

Just two months before the recall, Stryker issued an Urgent Field Safety Notice that warned doctors and hospitals that these two implants had an increased rate of Adverse Local Tissue Reactions (ALTRs). ALTRs are complications arising from inflammation in the tissues surrounding the implant because of metal debris released when they components rub together. These ALTRs usually end in painful and complex revision surgeries. Because stems are imbedded in the femur, they are more difficult to remove and can increase the rate of femur fracture.

Smith & Nephew R3 Acetabular System Recall

Smith & Nephew launched its R3 Acetabular System in Europe and Australia in 2007, and in the United States in 2009. In June 2012, the company issued an international recall of the metal liner that was part of its R3 system, amid reports of implant failure, loosening, pain, dislocation and metal sensitivity.

The metal liner, which created a metal-on-metal junction when it was used, was marketed as durable and wear-resistant. However, in the recall, Smith & Nephew said the metal liner had not performed as well as the company had expected.

Between 3,000 and 4,000 Americans received the metal liner option before it was recalled.

Other Problematic Hip Devices and Manufacturers

Despite the recalls, some all-metal hip devices remain on the market. Many of these implants have been linked to injuries, making additional recalls possible. Some devices have even sparked litigation.

Below are popular devices that have raised concerns in recent years. The following hip implants have been the subject of adverse event reports made to the FDA by consumers and health care professionals. Some of the devices have been recalled and taken off the hip implant market, while others have only had limited amounts recalled due to problems such as packaging errors.

Problematic Hip Implants

- DePuy Orthopaedics
- Biomet
- Centerpulse
- Corin
- Encore Orthopedics
- Exactech
- Smith & Nephew
- Stryker Orthopaedics
- Wright Medical Technology
- Zimmer Holdings

DePuy Orthopaedics

- ASR XL Acetabular System (recalled)
- ASR Hip Resurfacing System (recalled)
- AML
- Pinnacle
- Prodigy
- S-ROM
- Marathon

What to Do if Your Device is Recalled

Finding out that your medical device is faulty can be distressing. Consumers often feel reassured when a device maker announces a product recall. But a recall does not entitle a device maker to your trust.

It is important to realize that device makers face huge financial liability for dangerous products. Although they may genuinely want to do the right thing by removing the danger, they also want to stay in business. They have an interest in limiting their liability for your injuries. Sometimes that interest means that a recall may not be your best option for receiving compensation for your injuries.

If you decide to participate in the recall, there are several things you should keep in mind:

Be careful what you sign: Avoid signing any waivers or other documents before talking to a lawyer. Signing may keep you from filing a lawsuit against the manufacturer later.

Compensation is usually limited under recalls: Compensation offered under a recall may not cover your future medical expenses and other losses. You may be eligible for more compensation through a lawsuit. For instance, Depuy's recall notice did not mention potential losses like lost wages and pain and suffering. Although Depuy offered to cover medical costs like revision surgery, some patients claimed it only covered a fraction of their costs. These patients say they were left to foot the rest of the bill alone.

Be careful when talking to a helpline representative: Device makers collect information from you during these calls. Sometimes they use that information to limit legal claims. Remember that you may not yet know the extent of your injuries. It's best to talk to a lawyer first to avoid saying anything that could hurt your claim.

Physicians sometimes help device makers: Device makers have close relationships with doctors. They may try to get information, like your medical records, from a doctor to stop your claim. They may also try to get your faulty implant so that you don't have evidence in a lawsuit. Doctors may even try to talk you out of a lawsuit. You should only take legal advice from your lawyer. Also talk to your attorney before turning over potential evidence.

If you decide to participate in the recall, there are several things you should keep in mind:

You may choose treatment other than what's offered under the recall: Not everyone chooses to get revision surgery. Make sure the treatment that's being recommended under the recall is appropriate for you. Get a second opinion if necessary.

Above all, remember that a recall is not your only option. If you have been injured by a metal-on-metal hip device, you may have a legal claim for compensation for your injuries. Contact a medical device attorney to learn more about your legal options.