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The Cobalt and Chromium Conundrum: A Survey of Hip Implant Litigation, Part I

The following is a Commentary by Anthony C. Johnson and Christopher D. Jennings of Johnson & Vines, PLLC. For more on the authors, please click here, or visit them at Johns & Vines PLLC the at the American Injury Attorney Group.

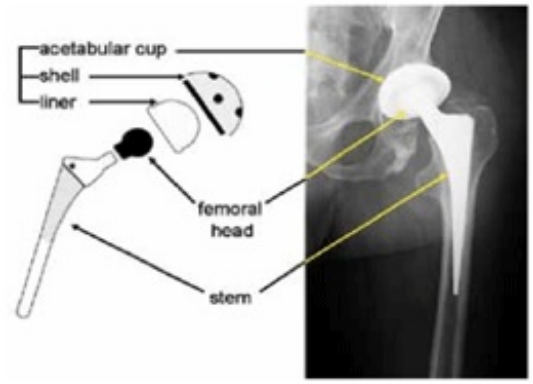
Over the past six years, thousands of lawsuits have been brought against numerous orthopedic prosthetic manufacturers concerning their metal-on-metal (MoM) hip implant devices. Though there is little doubt that many practicing attorneys are well-aware of the existence of this litigation given its extensive media exposure, it may also be likely that many of these same attorneys are not familiar with the historical events leading to the litigation, its status, and what the future may hold. This article provides a brief synopsis on these topics.

An Overview of Hip Arthroplasty Procedures and Metal-on-Metal Technology

Today, two types of hip reconstruction procedures are regularly performed in the United States: Total Hip Arthroplasty (THA) and Hip Resurfacing Arthroplasty (RSA). First performed in 1938, THA involves replacing the entire hip joint with an artificial prosthesis.[1] Developed a few years earlier in the 1920s, RSA involves replacing only the damaged bearing surfaces of the hip joint rather than the entire joint itself.[2]

The Federal Drug Administration (FDA) recently estimated that more than 400,000 hip arthroplasty procedures are performed in the United States on an annual basis.[3] Over the past decade, THA has comparatively become one of the most performed and predictable surgeries available in the United States.[4] And as the American population ages, it is expected to become even more common.[5]

The current litigation concerning metal-on-metal hip implant devices centers primarily on all-metal components used in THA procedures. The artificial hip joint utilized in THA procedures has three main parts: (1) a metal socket (or acetabular cup) component; (2) a metal stem (or femoral) component; and (3) a ball (or head) component that is attached to the stem and articulates with the cup component.



The socket or cup component lines the inside of the hip joint and is made out of metal – usually titanium. Inside the metal socket is the bearing surface, which may also include a liner made out of a polyethylene plastic, a ceramic material, or metal. The stem component is placed inside of the femur (thigh bone) and is made out of titanium alloy, cobalt chrome alloy, or stainless steel. The ball, which replaces the head of the femur, is attached to the upper end of the stem and moves against the bearing surface of the socket. The ball is typically made out of a cobalt chrome metal alloy but a ceramic material is sometimes used.

The term "metal-on-metal" (MoM) refers specifically to the bearing surface that sees the load in the hip joint. When a metal bearing surface is used inside the socket component and is paired with a metal ball, a metal-on-metal bearing is produced. For instance, a metal-on-metal bearing occurs when a metal ball is paired with a metal liner chosen to fit inside the metal cup component.

While the current litigation concerning MoM hip implants is relatively new, the use of metal-on-metal technology in hip implant procedures is not. Metal-on-metal arthroplasty was first introduced into clinical practice in the 1950s and a wave of metal-on-metal hip replacements, made of cobalt-chromium-alloy or stainless steel, took hold internationally in the 1960s.[6] However, the design of these first-generation MoM implants was primitive and a high number of failures largely discredited their use. On the whole, loosening rates (67 percent) and device failure rates (15 percent at 12 years) were high.[7] Moreover, researchers began expressing concern about potentially adverse biological reactions to MoM alloys known as metal sensitivity.[8]

The use of first-generation MoM replacement implants was largely phased out by the mid-1970s as a result of these issues. Also factoring into the abandonment of the MoM design was the rising popularity of the Metal-on-Polyethylene (MoP) approach, which was initially associated with better articulation lower rates of loosening.[9] First developed by Sir John Charnley, it became the implant approach of choice, vastly superseding that of metal-on-metal for the next thirty years.[10]

Yet, the MoP approach was imperfect as well. Over time, researchers noted an unexpected number of loose stems and acetabular cups associated with MoP articulation.[11] This phenomenon, known as asceptic loosening, was found to be a consequence of polyethylene wear. Excessive wear may lead to the impairment of the prosthesis. And researchers found that the debris associated with the actual wear may induce adverse tissue reactions leading to periprosthetic osetolysis.[12]

The discovery of this "polyethylene disease" triggered research to improve the wear resistance of polyethylene

bearing surfaces and likewise led to the development and use of ceramic technology.[13] More importantly for our purposes here, it also led to the development of a second generation of MoM implant designs in the 1980s as MoM configurations were generally thought of as having better wear-rates.[14] The current litigation concerning MoM implants has its genesis in this second generation of MoM configurations.

In 1988, Bernard Weber, a Swiss orthopedic surgeon backed by orthopedics manufacturer Zimmer, developed the Metasul MoM bearing configuration.[15] This MoM design is considered to serve as the precursor for modern MoM designs. It allegedly corrected the issues seen with the first generation of MoM implants through perceived improvements in component design (tolerance and clearance), metallurgy, and manufacturing quality. Improved cobalt-chromium alloys such as wrought or cast, high carbon or lower carbon alloys were developed and used for purposes of improving wear-resistance.

“Viewed in relation to more traditional mass torts involving medical devices, the current MoM litigation is relatively young.”

Weber’s Metasul MoM implant received market clearance by the U.S. Food and Drug Administration in August 1999.[16] It was cleared through the FDA’s pre-market notification (PMN or 510(k)) process as opposed to the more-stringent premarket approval (PMA) process. Under section 510(k) of the Federal Food, Drug, and Cosmetic Act, a manufacturer can market a medical device after proving it is substantially similar to an FDA-approved device that has been previously proven to be safe and effective. Manufacturers can claim substantial equivalence based on “intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.”[17] The 510(k) process is much quicker and cheaper than the FDA’s PMA process. It does not include stringent scientific and regulatory review. Nor does it require that the manufacturer subject the device to clinical trials, testing, or any standards.[18]

Following the introduction of the Metasul MoM system, most hip-implant devices marketed in the United States gained clearance from the FDA through the 510(k) process. Indeed, the majority of the devices currently subject to litigation were cleared through the 510(k) process. Given the recent adverse events concerning the use of MoM hip implants, the FDA recently proposed an order requiring manufacturers of MoM devices to submit PMA applications.[19] This would essentially render these types of implants ineligible for 510(k) clearance.

MoM Hip Implant Litigation in the United States

The short-term clinical successes of the Metasul MoM implant spawned a revival in the popularity of MoM articulation. Numerous manufacturers began developing and marketing new MoM configurations in the 1990s and early 2000s. It was believed that these configurations could allow implant manufacturers to tap a new market of younger, more active patients. Historically, the use of hip implants was limited to patients who were older, less active, and suffered from severe arthritic conditions or hip fractures. But with the new MoM designs, which were made of stronger material and believed to last longer and have better articulation, younger

and more active patients seeking greater mobility became candidates for THA and RSA procedures.

Yet, as alluded to above, serious health concerns associated with the use of MoM implants were being raised at the same time this second-generation of MoM design was introduced.[20] Research reported on metal sensitivity and the detrimental effects of accumulated metal ions released in the body.[21] Aseptic Lymphocytic Vasculitis-associated Lesions (ALVAL), pseudotumors (development of cystic mass on joint), and diagnoses of metallosis were documented in MoM cases, as well as the resulting destruction of bone and muscle tissue.[22] Coupled with the reports of these risks were corresponding reports of early device failure inclusive of instances of loosening and dislocation.[23]

Over the past two decades, the FDA has received thousands of similar adverse event reports regarding various MoM devices from both patients and doctors alike. These reports have led, at least in part, to numerous recalls of MoM devices initiated by the FDA or the manufacturers themselves. They have also led to the current MoM litigation, having generated tens of thousands of lawsuits against numerous MoM-prosthesis manufacturers: Biomet, Inc.; DePuy Orthopaedics, Inc.; Johnson & Johnson; Smith & Nephew, Inc.; Stryker Corp.; and Zimmer, Inc.

These cases are based primarily on products liability, failure to warn, and consumer protection theories. The litigation itself is manufacturer and product specific. And, as is customary in mass tort litigation of this size, individual cases have been filed in both state and federal courts throughout the nation. For those filed in or removed to federal court, the Judicial Panel on Multidistrict Litigation (JPML) has centralized pretrial and bellwether proceedings in most instances on an individualized products/manufacturer basis. In some instances, state court proceedings have also been consolidated in certain jurisdictions – namely in California, Illinois, and New Jersey – and are working in coordination with their corresponding federal litigation.

What follows are synopses of each litigation's background and current status.

In re Biomet M2A Magnum Hip Implant Products Liability Litigation – MDL 2391

This litigation involves Biomet, Inc.'s metal-on-metal M2a Magnum hip implant system as well as a predecessor product of the M2a Magnum system, the M2a 38, which also utilizes a metal-on-metal configuration. Both systems received marketing clearance from the FDA through the 510(k) pre-market notification process.[24] While these devices have not been recalled, Biomet has recommended that patients who received M2a hip implants regularly monitor the status of the device and any related complications with their doctor.

In October 2012, the JPML ordered the transfer of Biomet M2a lawsuits invoking federal jurisdiction to the Northern District of Indiana for consolidated pretrial proceedings.[25] The Biomet MDL is presided over by Judge Robert L. Miller and currently consists of more than 2,300 cases.[26]

The litigation has been marked by several discovery disputes and at least one unsuccessful motion to dismiss filed by Biomet based on preemption grounds.[27] In December 2013, Judge Miller set a scheduling order calling for at least five bellwether trials, the first of which was scheduled to begin in June 2015.[28]

In January 2014, however, Biomet entered into a settlement agreement with MDL plaintiffs' counsel.[29] Under

the agreement, eligible plaintiffs can receive a base award of $200,000 subject to discounts or enhancements should the eligible plaintiff meet certain criteria. The settlement agreement applies to cases pending in the MDL Court and various state courts.

The settlement agreement provides that to be eligible for the base award, a plaintiff must have (1) received a Biomet M2a 38 or M2a Magnum hip replacement system as part of an initial hip replacement that was (2) revised more than 180 days after it was implanted, and (3) filed a case on or before April 15, 2014. For the settlement to become effective, 90 percent of all filed cases qualifying for payments and 67 percent of mediation cases must accept the terms of settlement.

According to the settlement terms, cases that qualify for enhancements and contested cases regarding discounts are subject to mediation. Deadlines regarding the parties' categorization of these cases have passed. In regard to individual non-revision cases (cases where the plaintiff has not had corrective or replacement surgery), Judge Miller recently granted a joint stipulation to dismiss these cases without prejudice, noting a few individual case exceptions.[30] A motion to establish a qualified settlement fund and appoint a fund administrator was filed on September 18, 2014.[31]

Since the settlement's announcement, the Court has conducted numerous status conferences in monitoring its progress. At the most recent status conference held on October 20, 2014, the parties reported that mediation proceedings of Group 1 cases – cases where plaintiffs materially completed discovery requirements before December 31, 2013 – were ongoing and expected to be completed in the next few weeks.[32] The parties also reported that they expected to complete mediation of Group 2 cases – cases where plaintiffs materially completed discovery obligations after January 1, 2014, and before June 13, 2014 – in early 2015. Cases filed by April 15, 2014, but not included in Group 2, will be addressed after the mediation of Group 2 cases is completed. At the status conference, the parties also reported they anticipate the minimum participation thresholds for purposes of effectuating the settlement will be met.

While the settlement plays out, new M2a cases continue to be filed in both state and federal courts throughout the country. It is expected that the parties will also work to resolve these and other cases falling outside the existing settlement's deadlines in a second round of settlement discussions.

In re DePuy Orthopaedics Inc. ASR Hip Implant Products Liability Litigation – MDL 2197

DePuy Orthopaedics, Inc., a division of Johnson & Johnson, is one of the world's largest manufacturers of hip replacement and hip resurfacing products. It began marketing its ASR (Articular Surface Replacement) line in the United States in 2005. As with Biomet's M2a devices, DePuy's ASR systems received marketing clearance from the FDA via the 510(k) pre-market notification process.[33]

In August 2010, DePuy announced it was recalling its ASR XL Acetabular and ASR Hip Resurfacing System devices.[34] The recall came after years of complaints from doctors and patients regarding the devices' early failure. When it announced the recall, DePuy confirmed that after the first five years of the implant, thirteen percent (13 percent) of its ASR implants failed and had to be surgically removed.[35] Plaintiffs in the ASR litigation allege that while the ASR devices were on the market, DePuy was fully aware that the devices were defective but turned a blind eye. It has been reported that, between 2005 and 2010, DePuy sold more than

93,000 ASR systems worldwide, approximately 37,000 of which were implanted in the United States.[36]

"It is possible for complications associated with MoM implants to take several years to develop."

In December 2010, the U.S. Judicial Panel on Multidistrict Litigation transferred federal ASR cases to the Northern District of Ohio for consolidated pretrial proceedings.[37] These cases are before Judge David A. Katz. Numerous ASR cases have also been filed and consolidated in state court jurisdictions – most notably in California, Illinois, and New Jersey – and are being litigated in coordination with the MDL cases.

At least two state court cases that went to trial have produced mixed results. In March 2013, a California jury awarded approximately $8.3 million to the plaintiff in Kransky v. DePuy Orthopaedics, Inc. et al.[38] However, following a five-week trial in Cook County Circuit Court in Illinois, the jury returned a defense verdict in Strum v. DePuy Orthopaedics, Inc., et al.[39] In August 2012, DePuy settled with three plaintiffs in Nevada state court shortly before trial.[40] It was reported by Bloomberg that the women in this case received $200,000 each.

All told, more than 12,000 cases have been filed regarding DePuy's ASR implant devices. The first bellwether ASR MDL trial was scheduled to begin in September 2013. However, that case settled for an undisclosed amount shortly before trial.

In November 2013, DePuy, MDL counsel, and state court coordinating counsel entered into a settlement agreement to resolve their pending cases.[41] Under the agreement, eligible plaintiffs can receive a base award of $250,000 subject to discounts or enhancements should the eligible plaintiff meet certain criteria (similar to arrangement in the Biomet litigation).[42]

To be eligible for the base award, a plaintiff must (1) be United States citizen or legal resident of the U.S.; (2) have undergone surgery to implant an ASR XL Acetabular Hip System, ASR 300 Acetabular Cup System or ASR Hip Resurfacing System at a hospital in the U.S. or at a U.S. Military hospital; (3) have the ASR Implant in place for at least 180 days; and (4) have undergone surgery to remove the ASR Implant for reasons related to the recall on or before August 13, 2013. Reductions to the base award may be scaled and depend on a variety of circumstances including length of implantation and other health considerations such as tobacco use. Notably, participants in the settlement program who are not represented by counsel are eligible for only 71 percent of base and enhanced compensation payments. Enhanced payments may be award in a variety of circumstances (re-revision, extraordinary health events such as pulmonary embolism and/or deep vein thrombosis, dislocation, death, etc.) are to be determined on a case-by-case basis by the claims administrator, claims processor, and special master.

Under the terms of the settlement, DePuy reserved its walk-away rights at 94 percent program participation. In a status report submitted in June 2014, the parties advised the court that DePuy had waived its walk-away rights due to the "overwhelmingly positive support" for the settlement program as evidenced by its high enrollment.[43] In a July 2014 status report, plaintiffs' MDL counsel stated that the participation rates for

qualifying ASR cases in the MDL are in excess of 94 percent and that corresponding results in cooperating state court jurisdictions are similar.[44] In August 2014, Judge Katz extended the enrollment deadline to September 30, 2014.[45]

Regarding non-revised cases, the Court issued an order on October 30, 2014, whereby non-revised plaintiffs may have the choice of (1) dismissing their case without prejudice subject to tolling provisions or (2) continuing with their case.[46] The election deadline is December 31, 2014. Should those that dismiss without prejudice require revision surgery, Judge Katz has ordered that any subsequent claim must be filed in his court. For those plaintiffs that choose to continue with their case, Judge Katz has ordered that their initial discovery obligations must be met within ninety (90) days of the election deadline.

The next ASR status conference is set for January 7, 2015. [47] Continued litigation regarding ASR implants is to be expected even if the settlement terms of the pending agreement are fully and finally effectuated. Indeed, several new cases have been transferred to Judge Katz's court since the beginning of this month.

In re DePuy Orthopaedics Inc. Pinnacle Hip Implant Products Liability Litigation – MDL 2244

This litigation concerns the metal-on-metal configurations of DePuy's Pinnacle Acetabular Cup System hip implants. The Pinnacle system is comprised of a metal liner that was designed for use only with Pinnacle acetabular shells and 28mm metal femoral heads. Like DePuy's ASR device, DePuy's Pinnacle system received marketing clearance from the FDA through the 510(k) pre-market notification process[48] and has been implanted in tens of thousands of patients. However, unlike the ASR, the Pinnacle system has not been recalled.

In May 2013, DePuy announced it was discontinuing sales of the metal liner utilized in Pinnacle systems. [49] In addition to low sales, the company noted the proposed FDA regulation requiring PMA approval of MoM hip implants was also a factor.[50]

The JPML ordered the transfer of all federal actions involving the Pinnacle system to the Northern District of Texas in May 2011.[51] The judge overseeing the Pinnacle MDL is Judge Ed Kinkeade. Numerous state court cases remain pending. All told, more than 6,900 Pinnacle cases have been filed in the MDL.

The first bellwether trial in the MDL proceedings began on September 2, 2014. Notably, the plaintiffs in this case defeated five motions to dismiss and for summary judgment filed by DePuy.[52] The plaintiffs also received favorable rulings regarding expert testimony.[53] However, Judge Kinkeade denied plaintiffs' efforts to bifurcate the issue of the amount of punitive damages.[54] On October 23, 2014, the jury rendered a verdict in favor of DePuy.[55] The plaintiffs' chief trial team was Mark Lanier of the Lanier Law Firm; Wayne Fisher of Fisher Boyd, Johnson & Huguenard LLP; Richard Arsenault of Neblett, Beard & Arsenault; and Jayne Conroy of Simmons Hanly Conroy. DePuy's trial team included Mike Powell and Seth Roberts of Locke, Lord, Bissell & Lidell LLP; Richard Sarver of Barrasso, Usdin, Kupperman, Freeman & Sarver LLC, and Alexander Calfo of Barnes & Thornburg LLP.

The Court has scheduled six other cases as bellwether cases with trials set to occur over the final quarter of

2014 and first quarter of 2015.[56] The second bellwether trial was set to begin on November 3, 2014.[57] However, Judge Kinkeade is currently considering the date and format of the next bellwether trial and whether he will try multiple plaintiffs as opposed to a single-plaintiff approach used in the first bellwether.

Smith & Nephew Metal-on-Metal Hip Implant Products Liability Litigation – No MDL

This lesser known litigation concerns the Reflection 3 (R3) metal liner used in Smith & Nephew Inc.'s R3 Acetabular System and Birmingham Resurfacing (BHR) System. Both systems are modular in that component-selection (stem-length and angle for example) can be customized based on the needs of the patient. The R3 Acetabular System received section 510(k) approval from the FDA in June 2007.[58] The BHR System was approved for sale through the FDA's pre-market approval process in May 2006.[59] And the FDA granted Smith & Nephew supplemental pre-market approval to sell R3 metal liners specifically with the BHR system in November 2008 and again in December 2009.[60] The FDA did not approve (and has not approved) the use of R3 metal liners with its R3 Acetabular System in the United States.

On June 1, 2012, Smith & Nephew initiated a voluntary market withdrawal of its R3 metal liners because data from multiple medical device registries indicated failure rates and the need for revision procedures at higher-than-acceptable standards.[61] It has been reported that approximately 4,000 R3 metal liners were used in the United States between 2009 and the 2012 recall.[62]

As in the aforementioned litigations, those implanted with R3 metal liners allege in lawsuits that they have experienced premature failure and other health complications generally associated with the use of metal-on-metal implants. Cases have been filed in both state and federal courts throughout the nation with a considerable number pending in Tennessee state court in Shelby County (Memphis).

According to Smith & Nephew's most recent annual report, it faces approximately 310 pending legal proceedings (mostly in the United States) concerning its MoM implant products.[63] The cases pending in Tennessee state court have been consolidated for pretrial proceedings with discovery and mediation discussions ongoing.[64] At least two federal court cases have found that state-law defect-based claims regarding the R3 metal liner must fail based on preemption grounds.[65] To date, federal MDL proceedings have not been initiated.

In re Stryker Rejuvenate and ABG II Hip Implant Products Liability Litigation – MDL 2441

Stryker Orthopaedics faces thousands of lawsuits over its Rejuvenate and ABG II Modular Hip Systems. Like Smith & Nephew's R3 system, the Rejuvenate and ABG II are "modular" in that they include several neck and stem components of varying sizes, lengths, and angle settings that are that interchangeable, thus providing surgeons with greater flexibility to offer custom-fitted implants to patients. For example, the ABG II system has eight right stems, eight left stems, and ten modular necks.

Stryker's Rejuvenate system was cleared for marketing through the FDA's 510(k) process in June 2008.[66] The ABG II system received FDA clearance through the 510(k) process in November 2009.[67] After their launch in the United States, the two systems enjoyed considerable success. However, in an April 2012 Urgent Field Safety Notice sent to U.S. Surgeons and Hospitals, Stryker acknowledged reports of heavy metal contamination

associated with revision surgeries.[68] On June 28, 2012, Stryker issued a voluntarily recall of its Rejuvenate and ABG II hip components in the United States and likewise stopped all production and sales of the devices globally.[69] In its announcement, it cited as a cause the "potential risks associated with fretting and corrosion. "[70]

In June 2013, federal cases regarding both the Rejuvenate and ABG II systems were transferred to the United States District Court for the District of Minnesota for pretrial proceedings.[71] The presiding judge is Donovan W. Frank. Several state court cases have been consolidated in New Jersey state court in front of Judge Brian Martinotti – the same judge managing consolidated DePuy ASR lawsuits.[72] The Stryker litigation is somewhat unique in that the New Jersey state court litigation is considerably more advanced than the MDL proceedings. Since late 2013, Judge Martinotti has overseen two phases of mediation, resulting in settlements of 19 of the 21 cases that were mediated.[73]

On November 3, 2014, the parties in both the consolidated state and federal court litigation announced an agreement to settle pending claims concerning Stryker's ABG II and Rejuvenate Modular hip systems.[74] The settlement was brokered by Judge Brian Martinotti in coordination with Judge Frank following the success of Judge Martinotti's early mediation program and efforts by the chief mediator, former U.S. Magistrate Judge Diane M. Welsh.

"The settlement means that Stryker will potentially pay at least $1.43 billion to settle thousands of related claims."

The structuring of the proposed Stryker settlement resembles that of the ASR and M2a settlements. The settlement agreement calls for the establishment of a private settlement program through which claimants who have had their hips revised or who require revision surgeries but are too infirm to undergo the procedure, whether filed or unfiled, can pursue compensation.[75] For qualified claimants, Stryker has agreed to pay a base award of $300,000 for each revised hip, subject to applicable reductions. This includes a base award reduction for those claimants unrepresented by an attorney. An enhanced benefit program will also be made available whereby qualified claimants may seek enhanced awards in addition to a base award. The enhancement criteria and specific amounts will be set out pursuant to an award schedule to be released by the parties. For those claimants that otherwise qualify but have not been revised at the time of enrollment, Stryker has agreed to pay a flat award of $75,000. In sum, the settlement means that Stryker will potentially pay at least $1.43 billion to settle thousands of related claims.

Under the settlement, all claims must be registered by December 14, 2014 regardless of whether the claimant wishes to participate in the settlement or not. Those that wish to enroll and participate must make that election by March 2, 2015. Stryker has up until June 15, 2015 to decide whether to walk away from the settlement based on the number and percentage of people participating. Stryker may terminate the settlement program if the enrollment of eligible claimants who become qualified claimants is less than ninety-five percent (95 percent).

Stryker also faces related litigation concerning its Accolade stem system, which may be used in conjunction with

Rejuvenate and ABG II systems. In 2009, a Class II recall was initiated for Stryker's Accolade TMZF stem after the company became aware of reports of premature failure and related health complications attributed to wearing.[76] Patients who have experienced premature failure and health complications have filed numerous Accolade suits. Those federal cases that concern only Stryker's Accolade stems, with no allegations regarding Rejuvenate or ABG II systems, are not being transferred to the MDL currently. Indeed, Judge Frank recently ordered the remand of an Accolade case back to the district court where it was originally filed because cases concerning the Accolade system are not included in the current cases pending in the MDL.[77]

In re Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation – MDL 2329

Tennessee-based manufacturer Wright Medical Technology, Inc., faces hundreds of lawsuits regarding its metal-on-metal hip products. These claims relate primarily to Wright's CONSERVE hip implant and resurfacing systems. The CONSERVE systems, designed for younger and more active individuals, have demonstrated higher than normal failure and revision rates – similar to those seen with DePuy's ASR system. However, unlike the ASR, the CONSERVE systems have yet to be recalled.

In February 2012, the MDL Panel transferred federal cases concerning Wright MoM implants to the Northern District of Georgia.[78] The MDL is currently presided over by Judge William S. Duffey, Jr. Shortly after this multidistrict litigation was created, the parties agreed the MDL would be limited to cases concerning Wright's CONSERVE Total Hip Implant System, CONSERVE Total A-Class Advance Metal Hip Implant System, and CONSERVE Resurfacing System.[79] Several related state court cases have been consolidated in California.[80] Presided over by Judge Jane L. Johnson of the Los Angeles County Superior Court, this litigation concerns all Wright MoM lines including CONSERVE, Dynasty, and Lineage products.

Lawsuits have also been filed against Wright regarding its Profemur stem system, a modular stem system also alleged to fail or fracture prematurely and cause adverse health conditions. These cases may also be transferred to the Wright MDL should they involve a Profemur system that was connected to a CONSERVE Total Hip or A-Class Advanced Metal System. Otherwise, as seen with the Stryker Accolade stems, Profemur stem cases may be pursued in federal or state court outside the MDL. Multiple Profemur cases outside the MDL have settled, the terms of which have not been disclosed. Recently, a California federal judge ruled that plaintiffs in a Profemur case could pursue fraud and punitive damages claims against Wright.[81]

At present, the parties in the Wright MDL are conducting discovery and engaged in court-supervised mediation. The Court has entered a scheduling order for a bellwether trial program with the first trial set to begin on March 9, 2015.[82] Lawsuits continue to be filed and transferred to the Wright MDL.

Wright's CONSERVE Total and Total A-Class MoM implant systems received FDA marketing approval through the expedited 510(k) process.[83] Likewise the Profemur Stem System also received marketing approval through the FDA's 510(k) process.[84] However, the CONSERVE Resurfacing system received FDA approval through the FDA's premarket approval process.[85]

For the conclusion of this article, plus the footnote citations, please click here.