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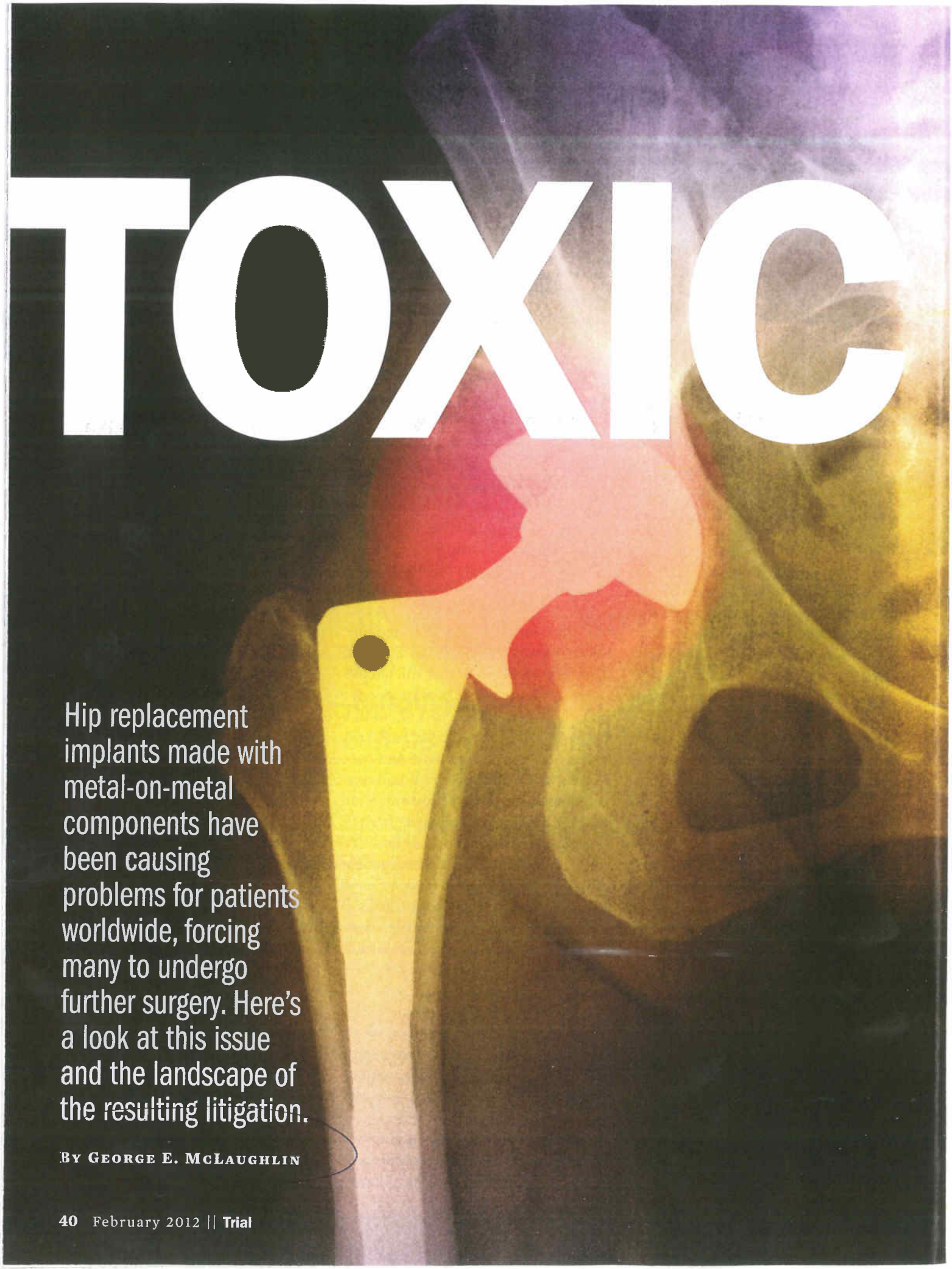

Hip replacement implants made with metal-on-metal components have been causing problems for patients worldwide, forcing many to undergo further surgery. Here's a look at this issue and the landscape of the resulting litigation.

By George E. McLaughlin

HIP REPLACEMENTS

Hundreds of lawsuits have been filed against the makers of so-called metal-on-metal (MoM) artificial hips, alleging that the implants fail prematurely and cause other medical problems. Some models have been recalled, and the medical community and the FDA are looking at the devices closely.

If you are considering representing someone who has been injured by a MoM implant, you need to understand how the implants work, the problems that patients have encountered, potential causes of those problems, and what to look for in your client's case.

There are two types of hip replacement surgery. In hip resurfacing, a metal cap is fitted on the femoral head, and the acetabulum (socket of the ball-and-socket hip joint) typically is reamed and relined with an artificial cup. In total hip arthroplasty, the top of the femur is sawed off below the femoral head, the femur's stem is hollowed, and a metal stem is fitted into it. An artificial femoral head is then placed on the new stem.

In hip replacement surgery, one size does not fit all. The surgeon chooses among myriad styles, shapes, and sizes of femoral stems to match the patient's anatomy and surgical needs. Some femoral stems are one piece, while others consist of two or three pieces. Femoral heads come in various diameters, and they may be metal or ceramic.

Acetabular cups also come in different sizes. Some are all metal, and others have a metal outer shell with a polyethylene (plastic) or ceramic liner.

Some cups are held in place in the pelvis by one or more screws; others need no screws because they are made of recently developed materials that promote the natural regenerative bone process, causing bone to grow into the outer surface of the hip's femoral stem and acetabular cup after implantation. This "bony ingrowth" firmly anchors the components to the surrounding bone, eliminating the need for cement or screws to hold the implant in place.

The articular surface is the area where the cup and femoral head fit together to form the ball-and-socket joint. These surfaces may be made of metal, ceramic, or polyethylene. MoM hips have metal femoral heads and metal acetabular cups. They have been available since the 1960s, but physicians initially were concerned about wear of the metal articular surfaces and the body's reaction to the resulting metal accumulation, so MoM hips were not as widely used as other articular surfaces.

For many years, polyethylene-lined acetabular cups, mated with ceramic or metal femoral heads, were the materials of choice for total hip arthroplasty. However, the polyethylene liner wears out over time, and it wears more quickly in active people. A worn-out liner requires replacement surgery. Occasionally, patients have reactions

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to the accumulation of polyethylene particles caused by articular surface wear. Ceramic hip components have also been an option for many years, but aggressive use can chip or break them.

The MoM hip has become more popular for total hip arthroplasty in recent years. The MoM hip's reemergence is due in part to the development of modern, high-tech, hard metal alloys and processes that can make components with extremely smooth surfaces and incredibly fine tolerances so that the cup and head fit together perfectly as a finely machined bearing. The medical community believed that the wear of these modern metal articular surfaces would be negligible and medically inconsequential.

Manufacturers have aggressively marketed and promoted the MoM hip as the best option for younger, active patients who want to return to an active lifestyle. The MoM hip was also promoted as having a longer service life than other types of hips—20 years or more, according to some patients. They were told this longer service life would reduce the number of times their hip would need to be surgically replaced in their lifetime.

Problems Surface

Metal-on-metal hips appear to be failing and requiring early revision (further surgery to replace one or more components) more often than other types.[1] The most common reasons for revision surgery—which has a lower probability of a successful outcome than the original hip replacement—are pain and recurrent dislocations. Some revision surgeries require well-fixed components to be removed, which can cause bone loss and tissue damage.

Loosening. One of the most common reasons for MoM hip failure is aseptic loosening, in which a component, usually the acetabular cup, becomes loose for reasons other than infection or another organic disease process. Once aseptic loosening has occurred, it will not reverse itself, and revision surgery is necessary.

Osteolysis. While the scientific research is still working to catch up with the clinical evidence, the wear of MoM articular surfaces and the resulting release of metal ions into the body are suspected to cause osteolysis (bone loss) and inhibit or reverse the bony ingrowth process that hold the devices in place. If this is true, it may explain why many MoM hip recipients initially report excellent results from their hip replacement surgery, but later need revision surgery when their acetabular cup becomes loose. Recently published research appears to support this theory.[2]

Metallosis. Another serious complication is metallosis, the body's reaction to the accumulation of metal ions or metal debris in the body. An accumulation of a thick, gray fluid at the hip joint may signal this condition.

Metallosis can cause various reactions and complications, including the development of pseudotumors (an encapsulated collection of metal-stained fluid), tissue death, and bone degradation. Once metallosis occurs, it will not abate until the source of the metal ions and debris is removed. Orthopedic surgeons have expressed concern that even after revision, the accumulated metal ions and metallosis may continue to damage the bone, muscles, and tendons, making a good outcome from revision less likely.

Neurological problems. Some recipients of MoM hips have reported otherwise unexplained symptoms, and there is concern about the effects of long-term exposure to cobalt and chromium ions. Now that the issue has come to the fore, scientific research is being conducted on exposure to cobalt and chromium from orthopedic implants. Some recipients of these hips are reporting headaches, persistent metallic taste in the mouth, memory issues, and cardiac abnormalities, among other problems. Whether any of these symptoms is related to the accumulation of metal ions in the body from wear of MoM hips remains to be seen.

Potential causes of excessive wear. Although the science is still catching up with the clinical findings, some designs of MoM hips appear to be wearing out faster—and producing more metal ions and debris—than manufacturers anticipated. Certain design changes that manufacturers incorporated into their devices to distinguish them, such as a shallower sphere for the acetabular cup, thinner shells, smaller tolerances for the space between the head and the cup diameters, and larger-diameter femoral heads, may be contributing to this excessive wear.

With at least some MoM hips' designs, the acceptable range for the angle of inclination for implanting the cup—the margin of error—is much narrower than it is with other artificial hips. A cup that is implanted outside this narrow range is more susceptible to excessive wear and what is called "edge loading"—a disproportionate amount of weight borne at the rim of the cup—as the ball articulates in the socket. For years, surgeons were not told of this narrower margin for implantation.

Recipients of MoM hips may not experience pain as an early symptom of device failure, so they are being advised to be monitored by their orthopedic surgeons. Periodic testing of cobalt and chromium levels in the blood is now recommended. While both cobalt and chromium are necessary elements for survival and should exist in the body at low levels, some patients are reporting significantly elevated levels—some 150 times the normal level. Without any environmental exposure or other explanation, elevated cobalt or chromium levels in the blood or urine are evidence of a MoM hip that is wearing excessively.

The FDA is continuing to gather information about MoM hip systems, including reports of adverse events that

may be associated with increased levels of cobalt and chromium in the bloodstream. In May 2011, the FDA ordered 21 manufacturers to conduct postmarket surveillance studies, requiring them to submit a research protocol that addresses specific safety issues related to these devices. The agency has stated that data from these studies will enable it to better understand these devices and their safety profiles.[3]

The Litigation

Lawsuits have alleged injury from a few different types of MoM hips, and some cases have been consolidated in multidistrict litigation (MDL).

Zimmer Durom Cup. The Zimmer Durom Acetabular Component (Durom cup) was the first MoM hip to be identified with potential problems after surgeons began to report a higher than normal rate of early revisions due to cup loosening and cup migration. Issues with the coating that is designed to promote bony ingrowth are suspected as a possible cause.

In 2008, Zimmer voluntarily recalled the Durom cup because the instructions for use and surgical technique instructions were inadequate.[4] Zimmer issued a letter to surgeons recommending further training.[5]

Lawsuits alleging injuries from this device that are filed in or removed to federal court are being transferred to MDL 2158, pending in the District of New Jersey. About 12,000 of these devices were implanted in the United States. Many of them remain implanted and continue to fail.[6]

DePuy ASR. Unexpectedly high failure rates for the DePuy ASR MoM hip system, made by DePuy Orthopaedics, a division of Johnson & Johnson, appeared in the Australian joint registry in 2008. What was at the time unpublished data from the U.K. joint registry—indicating that revision rates within 5 years were approximately 13 percent[7]—led to the worldwide voluntary recall of the DePuy ASR hip system in 2010.

About 38,000 DePuy ASR hip devices were implanted in the United States; 93,000 were implanted worldwide. The primary issues in the DePuy ASR failure are cup loosening and metallosis. These cases are being transferred to MDL 2197, pending in the Northern District of Ohio.

Thousands of DePuy ASR hips remain implanted and continue to fail. In some instances, patients ignored the original recall because they were pain free, only to find that their device has since failed and must be replaced.

The reported failure rate is rising. A statement published in 2011 by the president of the British Orthopaedic Society, summarizing presentations on large-diameter metal hips at the organization's annual conference, revealed that early revision rates for the ASR XL were 21 percent at 4 years and 49 percent at 6 years.[8] A 2010 Australian report noted, "Metal/metal bearing surface has the highest risk of revision compared to all other bearing surfaces."[9]

In an interesting approach to handling these claims, and perhaps to discourage some patients from retaining counsel, DePuy has instituted a program to reimburse patients for expenses related to treatment for the DePuy ASR. Using a claims handler called Broadspire, DePuy will reimburse out-of-pocket expenses incurred for medical management, including revision surgery, and also lost income and related incidental expenses. What remains unknown is whether DePuy will ultimately offer adequate compensation to these unrepresented claimants for their past and future pain, suffering, and disability and for future medical care, particularly additional revision surgery.

DePuy Pinnacle. DePuy also manufactures the Pinnacle system, which has a modular acetabular cup with a cup liner made of either polyethylene or metal. Femoral head options are ceramic or metal, and MoM combinations are used frequently.

A significant number of DePuy Pinnacle MoM hips appear to have required early revision. As with the DePuy ASR, the primary issues in failure appear to be cup loosening and metallosis. DePuy Pinnacle cases are being transferred to MDL 2244, pending in the Northern District of Texas.

Wright Conserve. Wright Medical Technologies also manufactures artificial hips with a MoM option. More than a dozen cases have been filed against Wright alleging failure as a result of cup loosening and metallosis. A petition for MDL treatment of the Wright Conserve hip litigation was pending at press time.

Litigation Tips

When you take a hip replacement case, you must first definitively confirm what the device is. Obtain a copy of the device labels from the surgical implant record that describe each implanted component. Do not rely on patient claims, or even physician operative notes, to identify the implanted device. Labels that come in the box with each component should be attached to the medical record.

A client who has a DePuy ASR hip has a case. Even if the person's device has not

MORE ON HIP IMPLANTS

Visit the Web pages below for additional information.

AAJ SECTION
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AAJ LITIGATION GROUP
DePuy Metal on Metal Hip Implant
www.justice.org/litgroups

LITIGATION PACKET
"DePuy Hip Implant"
www.justice.org/exchange

AAJ EDUCATION PROGRAM
"DePuy Metal on Metal Hip Implant Litigation Group"
(Convention track # 411-T27)
www.PlaybackAAJ.com

failed and his or her surgeon has not yet recommended revision, he or she should be medically monitored.

For other MoM hip products, if the device has failed or the client is in significant pain and faces revision, the case is worth considering. But be leery of clients whose devices failed immediately after implant. It usually takes months or years for a hip to fail because of excessive wear, metal ion accumulation, or metallosis. Failure shortly after implantation may be unrelated to the issues prevalent in MoM hip failures.

Most implanted medical devices have a corresponding surgical technique, and often a technical monograph, published by the manufacturer. These are not proprietary confidential publications and often are available on the manufacturer's Web site, labeled "physician information." You can uncover important information in these documents.[10] For example, a Wright Medical Technologies publication available to physicians on its Web site at one time included a "guarantee" of structural reliability in one of its hip components. Later editions did not include the word "guarantee."

Also obtain copies of the device's instructions for use. These are approved by the FDA and are the equivalent of the package insert for prescription medications.

Once in discovery, obtain the manufacturer's published marketing and promotional materials. Many manufacturers use independent contractors to distribute their devices and freely disseminate these marketing and promotional publications, so they do not qualify as proprietary confidential publications.

The implanting surgeon can be your best friend in failed hip implant litigation. Most surgeons are concerned to learn that the devices they implanted in their patients have failed. Most device manufacturers do not want to blame surgeons for improper technique in implantation; surgeons are their repeat customers. But some defendants have argued that the surgeon failed to use proper technique. Consider forcing the manufacturer to commit to its position on this issue before your statute of limitations expires.

With tens of thousands of MoM hips implanted in the United States, we can expect these defective products to continue to fail for years to come. The defendants in these cases have teams of lawyers and virtually unlimited financial resources. But, thanks to the resources available to plaintiff lawyers, you never have to go it alone.[11]

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Notes

1. Unlike other nations, the United States has not had a national registry that tracks the failure rate of artificial hips. The American Joint Replacement Registry is now in the process of being established by the American Academy of Orthopaedic Surgeons (*see* http://orthodoc.aaos.org/ajrr/grp_index.cfm). Australia, Sweden, and the United Kingdom have had such registries for years, and their data shows that MoM hips' early revision rates are significantly higher than those of other replacement materials. The Australian Orthopaedic Association's National Joint Replacement Registry is available at www.dmac.adelaide.edu.au/aoanjrr; the Swedish Hip Arthroplasty Register is available at www.shpr.se; and the United Kingdom's National Joint Registry is available at www.njrcentre.org.uk.
2. Rebecca E. Andrews et al., *Effects of Cobalt and Chromium Ions at Clinically Equivalent Concentrations after Metal-on-Metal Hip Replacement on Human Osteoblasts and Osteoclasts: Implications for Skeletal Health*, 49 Bone 717 (Oct. 2011).
3. U.S. Food & Drug Admin., FDA's Role and Activities, www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241769.htm.
4. *See* U.S. Food & Drug Admin., Recalls Specific to Metal-on-Metal Hip Implant Systems, www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/ucm241770.htm.
5. Ltr. from Cheryl R. Blanchard, Senior Vice President, Research & Development, Zimmer, Inc., to surgeons (July 22, 2008), www.zimmer.com/web/enUS/pdf/DUROM_SURGEON_LETTER_07-22-08_FINAL1.pdf.
6. A packet of information on the Durom cup is available from the FDA at www.fda.gov/downloads/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/UCM161031/pdf.
7. *See* U.S. Food & Drug Admin., *supra* n. 4.
8. The statement can be found at British Hip Socy., Metal on Metal Bearing Total Hip Replacements, www.britishhipsociety.com/pdfs/BHS_MOM_THR.pdf.
9. Austrl. Orthopaedic Assn., *Annual Report 2010, Hip and Knee Arthroplasty* 53 (2010).
10. Older editions of the documents can often be located using the search engine the Wayback Machine at http://wayback.archive.org.
11. AAJ has a DePuy Metal on Metal Hip Implant Litigation Group. For more information, *see* www.justice.org/litgroups.