**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF INDIANA**
**SOUTH BEND DIVISION**

**IN RE: BIOMET M2a-MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION**

**CAUSE NUMBER 3:12MD02391**

**MONDAY, JUNE 17, 2013**

**TRANSCRIPT OF PROCEEDINGS**
**BEFORE THE HONORABLE ROBERT L. MILLER, JR.**

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***United States District Court***
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MS. ELLEN RELKIN

(see docket for addresses)

For Defendant:`

MR. JOHN D. WINTER
MR. JOHN LaDUE
MS. ERIN LINDER HANIG
MR. BLAINE DART

(see docket for addresses)

**THE COURT:** You may be seated.

**(All comply.)**

**THE COURT:** Good morning.

This is 12MD2391, and we are gathered for our status conference for science day and, ultimately, for a hearing on a motion to dismiss in Cause Number 13CV73, Caccia versus Biomet, Inc.

Before coming out, just to be sure we were all on the same page, I spoke with several of counsel.

I guess, before we get to that, we should identify who all is here. I've got the sign-up sheet here. Let me state, for the record, who all is present on the Plaintiffs' side, and, if I leave anybody out, I'll ask you to identify yourselves then.

We have Thomas Anapol.

**MR. ANAPOL:** Good morning, Your Honor.

**THE COURT:** Good morning.

Richard Arsenault.

**MR. ARSENAULT:** Good morning.

**THE COURT:** Good morning.

Daniel Burke.

**MR. BURKE:** Good morning, Your Honor.

**THE COURT:** Good morning.

Margaret Metzinger.

**MS. METZINGER:** Good morning, Your Honor.

**THE COURT:** Good morning.

Robert Dassow.

**MR. DASSOW:** Good morning.

**THE COURT:** Peter Flowers.

**MR. FLOWERS:** Good morning, Your Honor.

**THE COURT:** Good morning.

Fredrick Hovde.

**MR. HOVDE:** Good morning.

Shelly Hutson.

**MS. HUTSON:** (No response.)

**MR. VAUGHAN:** Your Honor, Jeff Vaughan appearing for Shelly.

**THE COURT:** Oh, okay. Let me -- Jeff Hahn (sic)?

**MR. VAUGHAN:** Vaughan.

**THE COURT:** Okay. H-A-H-N?

**MR. VAUGHAN:** V-A-U-G-H-A-N.

**THE COURT:** Thank you.

Lawrence Jones.

**MR. JONES:** Good morning, Your Honor.

**THE COURT:** Good morning.

Mark Lanier.

**MR. LANIER:** Good morning, Judge.

**THE COURT:** Douglass Kreis.

**MR. KREIS:** Good morning, Your Honor.

**THE COURT:** Good morning.

Peter Miller.

Good morning.

**MR. MILLER:** Good morning, Your Honor.

**THE COURT:** Daniel Robinson.

**MR. ROBINSON:** Good morning, Your Honor.

**THE COURT:** Good morning.

Laura Singletary.

**MS. SINGLETARY:** Good morning, Your Honor.

**THE COURT:** Good morning.

Alex Brown.

**MR. BROWN:** Good morning, Your Honor.

**THE COURT:** Good morning.

Justin -- is it "Presnal"?

**MR. PRESNAL:** Yes.

Good morning.

**THE COURT:** Good morning.

John Thornton.

**MR. THORNTON:** Good morning, Your Honor.

**THE COURT:** Good morning.

Alex Davis.

**MR. DAVIS:** Good morning.

**THE COURT:** I'm sorry. I can't make out the first name. Stackhouse.

**MS. STACKHOUSE:** It's A. Layne.

**THE COURT:** Layne, okay.

**MS. STACKHOUSE:** Good morning, Your Honor.

**THE COURT:** Good morning.

Sorry.

And Jasper Ward.

**MR. WARD:** (No audible response.)

**THE COURT:** And Lindzy McQueen.

**MS. McQUEEN:** Good morning.

**THE COURT:** Good morning.

Did I miss anybody for Plaintiffs?

**MS. RELKIN:** Yes. Ellen Relkin. R-E-L-K-I-N.

**THE COURT:** Okay. All right.

And then, for the Defendants, we have John Winter.

**MR. WINTER:** Good morning, Your Honor.

**THE COURT:** Good morning.

John LaDue.

**MR. LaDUE:** Good morning, Judge.

**THE COURT:** Erin Hanig.

**MS. HANIG:** Good morning, Your Honor.

**THE COURT:** Blaine Dart.

**MR. DART:** Good morning.

**THE COURT:** Good morning.

In the conversation in chambers, it appeared that there wasn't much that we had to address urgently. We talked about handling the motions that are starting to come in to strike affirmative defenses, and it seemed to be the

general sense of everybody that it would be best to focus on the substantive issues, at this point, and to defer ruling and, in effect, stay briefing on those until we're a little deeper into the case so they might be able to be addressed along with summary judgment motions when the time comes.

We talked about the possibility of posting either a proposed form complaint or a variety of form complaints on the Website to help attorneys as they are filing these cases understand that John Doe defendants are going to be stricken and that certain Biomet entities are not Biomet entities and shouldn't be sued, identify those that should, in the hopes that we can avoid those problems on down the road.

I think Plaintiffs were going to double check with folks who have filed directly with this court, saying that venue is proper in this court, when it may have been it was meant that venue was meant to be laid elsewhere.

I indicated that the common benefit fund motion, we would await objections -- I assume would come from other Plaintiffs' counsel -- before entering any sort of common benefit fund order, and that if objections came in that looked like they needed to be argued, we would address it at the next status conference, and, otherwise, I would try and get an order out when the motion becomes ripe.

We talked about a couple of duplicate cases and one or two interesting ones where Zimmer might be the only

remaining defendant, which, I think, were filed with a misunderstanding as to the relationship between Biomet and Zimmer.

I think that's everything we talked about in chambers.

Is there anything --

**(No response.)**

**THE COURT:** Okay. And everybody indicated there really wasn't anything else to raise today for status conference. It sounds as though everything's plugging along pretty well, and I guess that takes us to science day.

And as I understand it, the parties have agreed that Mr. Lanier can have rebuttal science or something.

How would we describe that?

**MR. LANIER:** Yes, Your Honor. I think parties have agreed I could save a little time back. My hope is to save a lot of time back for the Court.

**THE COURT:** All right. The Plaintiffs may proceed with their understanding of the science.

**MR. LANIER:** Thank you, Your Honor.

Your Honor, in preparation for science day, what we've done is we've prepared a PowerPoint that will come up with the screens here, we hope. That is the plan. Let's see. Yes, it does, and, your Honor, the PowerPoint doesn't fully track, but it comes close to tracking a presentation

outline.

May I approach the Bench?

**THE COURT:** You may.

**MR. LANIER:** Your Honor, what we've done is we've given one to the court reporter already and providing Defense counsel right now.

I will tell you that this was prepared in a marvelous manner by some really wonderful people at a variety of different law firms, and everybody had a different chore, and so this is a Frankenstein project, in some ways.

And I only say that to say that, as I was looking at it to get ready for this argument, it occurred to me, when I looked at the glossary -- which, to me, is one of the handiest features of this. It may be something you want to hang on to or the parties may want to supplement as time goes on -- it occurred to me that someone was alphabetically challenged when they start with T for "tribology" and then go to C for "corrosion" and P to "polyethylene." And then I found out that the person who was ultimately responsible for putting this together was the tribology people, and they put it in the order of priority and decided that tribology was the most important part of this entire glossary. So we have put in a supplement, which has it in alphabetical order, and we'll tender that in due order to get it together to you

right.

So, Your Honor, this is Plaintiffs' science day presentation. It is not my purpose to be an advocate today. My purpose today is simply to acquaint the Court with the useful terms and the important issues that you, Your Honor, will need to have at your mental disposal as we get into fussing and fighting over discovery and other such things over the next few months and, perhaps, year.

So, with that, Your Honor, here it is, and I bring it to you with a warning. My warning is this. This presentation is built off limited document review and pre-suit investigation. We haven't done a lot of discovery and so that's going to change things and will perceive things a little bit better.

For my science day education, we start with Hip Anatomy 101, the basics we need to know about the hip. I've stolen these pictures. These are not original with me. This is a cut away from the pelvis view. You can see the socket, which is also called an acetabulum, and there are other words that are built off of that, the acetabular cup and things of that nature, but the socket is part of the pelvis that receives the ball or the femoral head, femoral, of course, coming from the fact that it's the head of the femur, the big thigh bone, so the song "The Thigh Bone Connected to the Hip Bone" is generally correct, but there

are a few finer details that didn't make the lyrics. The socket of the acetabulum has a smooth weightbearing lining surface, and there is a smooth cartilage that covers the bony end of the thigh bone on the femoral head. That's basically 101.

Now, that's not adequate, however, so we go to Hip Anatomy 201. Hip Anatomy 201 is not as complicated as this picture would make you believe. No one will get tested over the iliofemoral ligament on the Y ligament of Bigelow. However --

**THE COURT REPORTER:** Mr. Lanier, will you slow down, please?

**MR. LANIER:** I am so, so sorry. I got really excited over this picture.

However, Your Honor, the important things on these pictures are the things that I can illuminate with red circles on the PowerPoint, and this indicates that the cutaway view that we had in the last slide is a bit deceptive. It helps to reveal some of the parts, the anatomical parts, that we need to know the terms of.

But that hip socket is actually encapsulated and so there are ligaments that surround it, and even the ligaments that help hold the joints together and keep that capsule intact are surrounded by more muscle, and that becomes important when we see some of the disease process that can

happen from metal debris.

So, with that, if we look very carefully at the joint capsule itself, you'll see in the picture the synovial membrane. The synovial membrane is that thin layer that's on both sides of the blue space. That synovial membrane actually emits synovial fluid. Synovial fluid looks kind of like an egg white.

In fact, boring trivia, "synovial" probably comes from the Greek word "syn," which means "with," and "ovum," which is a reference to the egg. It was a coined term by Paracelsus when people started getting -- Renaissance. Thank you -- smart.

Anyway, so it's an egg white substance that's kind of filmy and kind of slick. That's your synovial fluid, and that fluid allows the femoral head to rotate and to move in that joint space in a way that is pain free and is friction free, and that's the marvelous way that it works.

You can see also from this the way it's encapsulated. You've got the joint capsule ligaments. You've got a labrum. You've got different features that keep that synovial fluid intact.

As we get older, the synovial fluid's not automatically as flush as it might be when we're younger. That's why I noticed after I turned fifty, when I stand up sometimes, I've got to move a little bit before it starts --

because you've got to get the synovial fluid up into the joints as fully as possible to keep it from being stiff.

Another very useful part of this picture, Your Honor, is, if you look at the femoral head, the way it's drawn, you'll see it to have a lot of redness, and that's because, underneath the cartilage, it's a very blood-rich zone. There's a lot of vascular activity on the femoral head, and that's going to become important as we look at the disease state.

So, with anatomy now to the side, I'm going to shift to the question: Why do patients need artificial hips? What is it that causes this? And there's a number of reasons. The predominate, number one reason is listed statistically, at least, as osteoarthritis, "osteo" referencing the bone, and "arthritis" representing the condition.

So I put on the PowerPoint, first, an actual good ball and socket where everything's great, the cartilage is fine, and you can see it and be happy and run, leap, and do anything you wish to do on that.

I put up next to it an osteoarthritic hip, and you can see how the joint space is narrowed. You can see bone spurs and rough bone. You can see the irregular weightbearing surfaces from the worn cartilage. This is a painful hip. This is a hip that does not work well and

function well, and this is the most typical reason that hip replacements are done.

I think statistically the second most typical reason is a disease called avascular necrosis. "Vascular" referencing the blood flow. "A" in front of it meaning a lack of blood flow. "Necrosis" meaning dead, dead cellar tissue. Avascular necrosis. If we go back and recall the redness in the picture of the femoral head, here, at this top picture that I've put on the PowerPoint, you'll see the blood flow is critical to the integrity of the bone. The blood flow is what heals and repairs bone. The blood flow is extremely important. If there is a lack of blood flow, within twelve to twenty-four hours you have cell death occurring on the osteo level, on the bone level. And when that cell death occurs below the cartilage, the cells start collapsing on themselves, and the cartilage will collapse, as well. And once that happens, you don't have a good, smooth articulating surface, and it is a problem.

I've put up another medical drawing -- these are not mine. These are available in the literature -- showing in a hyper-illustrated fashion that once you start destroying bone integrity, the cartilage, the whole joint can go away.

Now, I say "can" because there are other treatments for avascular necrosis. One is stop it from happening. Doctors aren't totally sure why it happens. There's lots of

different reasons. It can happen from radiation. It can happen from medicine. It can happen from trauma. It can happen from inflammation. There are a number of different ways you can lose that blood supply, but doctors are trying to figure out and have some manner of treating it, and the body will repair itself and produce new cells if it's caught in time. But if it's not, you're going to have the sclerosis and the fragmentation that we see in this X-ray picture, and this is damage that is not going to be repaired by the body and so is open to someone receiving an artificial hip.

Now, of course, there are some other less common reasons for hip implants. There can be trauma to the hip joint. There can be rheumatoid arthritis, which is an inflammation disease inside the joint. In fact, rheumatoid arthritis is considered to be one of the causes of the avascular necrosis, as well, the lack of the blood supply. But it's an inflammation process in the joints, and it can cause significant problems, especially in younger people. And so with younger people, you've got a rheumatoid arthritis issue, and with younger people, you've also got -- avascular necrosis can occur with them, as well.

There are 285,000 annual hip replacements in the United States. It's a fairly common surgery. It's one that has surgeons that specialize in that. These are surgeons

that generally use one product or another, one vendor or another. Sometimes there will be multi-vendor surgeons, but not always. It just depends. The surgeons, when they do this surgery, they get to know the sales staff and the support staff of the manufacturer of the device quite well, so there will be sales people who will deal specifically with a physician and have that physician designated as the go-to person. Oftentimes, these sales people -- in fact, may not be a sales person, per se, but it's the designated representative -- will even be present in the surgery room while the surgery's going on.

So these surgeries themselves are done with some pretty cool tools. One that I don't think --

**THE COURT:** Let me ask real quickly, because I know in some instances a representative from the device vendor is present because of different sizes and they need -- are these -- do these come in different sizes?

**MR. LANIER:** Yes, they do, Your Honor. They come in different sizes. They come in different -- not just dimensional sizes of the ball, but different sizes indifferent ways, and so the representative will bring in, oftentimes, extra pieces, extra parts, extra sizes, because the surgeon may be in the middle of a surgery and decide, "This isn't big enough. I need something smaller." The surgeon's got to manage to replicate that hip joint. Let's

say you're doing the left hip. He's got to make that left hip be size appropriate for the right hip, and that's not something you always know until you get in there.

And the surgery itself -- I initially had a seven-minute clip of a surgery in here for you. I decided to take it out, but it's pretty cool because they go in there and, once they cut through the ligaments and all, they totally dislocate this leg. I mean, it's just like taking the leg -- I mean, it would make a gymnast proud. It wraps it around near the head almost while they go to work on it.

The tools that they're using when they do this are not like we might find in the dentist's office with a little "whooo." I mean, this is Black and Decker stuff. This is real stuff. They have a reciprocating saw that they'll use, and they'll lop off the head of the femur. And all of the bad cartilage, all of it, it all comes off, and they'll just saw it right off.

Then they'll go into the acetabulum, which is that medical word for the hip socket, with a reaming tool.

And, Your Honor, we've not had benefit of getting yet sample parts from the Defendants -- that will come at an appropriate time -- but we were able to bring some show and tell.

And so, for example, if I pull up the ELMO here, you can see this. This is a reaming tool that I've put on here.

It looks like a cheese grater that's made round. And so you've got this round cheese grater, and they'll take that acetabulum, and they just -- and I'm not going to keep doing that to my hand because I just lost an inch of flesh, but they turn that puppy around, and it will rotate. And when they turn it around and rotate it, it reams out, it cleans out and smooths out that acetabulum so that they're going to be able to put a cup or a liner into that acetabulum. But for that liner to go in, they first have got to make the hole or the oval socket clean and ready to receive the liner.

So, with that, Your Honor, we can look at the -- I think I'll bring back up my PowerPoint.

I hit "podium." Did I do right? I may have broken it. Ah, there we go.

So that's the acetabular reamer. It reams out the acetabulum.

Aside from that, you've got to get the femur ready to receive the implant, so what they do is they take a tool like this -- I mean, it looks like a prison shiv or something, you know -- and they take it, and they put it in the top of a femur with a hammer, and they just start pounding it down there. Once they get that done, they take these rasps, and it's a very raspy tool, and they'll take this rasp, and they'll just start working it back and forth

to get the hole the exact dimensions the hole needs to be inside the femur to take the implant itself.

And so that's what's done. And when it's done, they're able to put in the implant, and they're able to place the cup in the acetabulum. And once they've done that, they start trying to attach the head.

Now, the attachment of the head has to be done onto the Taper in such a way that you've got not only the right size for the socket, but the right dimensions for the other hip that is being used so that someone doesn't walk around with one leg shorter than the other, and so this is a process of making sure things fit.

The placement of the cup is a significant issue. We don't know the discovery yet, but we suspect that you will find that it becomes an issue in the case where the parties and the experts fuss. Did the physician put the cup at the right inclination or the right angle? Did the company teach properly? Did the company know the right angle? All of those will be issues, we suspect, in this case.

So when you hear issues about the inclination angle, the question is -- and it makes good sense, if you think of it this way. If the inclination angle is right and the ball works, then the hip is going to have minimal wear. But there's a concern, if the inclination is too extreme, then you're going to have too much weight on the edge of the cup,

and it's going to cause what's called edge wear because it's not going to have the whole diameter of the cup to help distribute the weight and the effect.

So all of these become important issues. They'll become issues also as to the popularity of these implants because some surgeons, we expect, were told that with metal-on-metal and with the larger heads, the exact placement of the cup is not that big of a deal, and so surgeons were quicker to move to this.

It will also -- final point on this -- become relevant because there will be issues about how surgeons actually place that cup. It's not always that easily done. What surgeons will typically do, some, is they will be in the surgery room, and they'll have the patient on his or her side, and they'll figure, "Okay, that corner of the room is forty-five degrees so I'm going to position this cup to go with that corner of the room." There have been tools that have been made by the companies to try and help with cup placement, but those tools are notoriously poor. Everybody's pelvis is a different size. Everybody presents differently. It's just a really difficult issue, but it's one you'll hear a lot about, the cup inclination angle.

So, with that, you've got the implants themselves. Once the surgeon reaches this point, the surgeon's got choices. The surgeon can use polyethylene plastic. We call

it "poly", typically, in these cases, and polyethylene is a reference, generally, to the liner. It's to what is in that cup, the acetabular cup, and it is the surface the ball will impact into.

Now, some hip implants are what are called ceramic-on-metal, and so you'll have a ceramic ball and you'll have a metal cup, and those are one variety that you can find. Another variety is to use a ceramic ball and a ceramic cup. The specific implants that the Plaintiffs believe in this case are problems are what are called metal-on-metal, and those are the implants where you have a metal liner and you have a metal cup.

If I go back to the ELMO, I've got a sample here. It's not the product in question, but it is an example, nonetheless, and you can see it's got the metal ball. Here's the Taper, so this would fit into the femur that way. You've got the metal ball and a metal liner that's going into the hip socket, and that becomes a metal-on-metal joint, and those are the ones that we've got issues with.

If I could go back to the PowerPoint, please.

**MS. KIRKWOOD:** (Complies.)

**MR. LANIER:** Thank you.

Those are the ones that we've got issues with in this case.

So, if we take, for example, Biomet's 2009 pricing

guide, and we look at it, here, they've set out their M2a-Magnum System, and they've got the cup, a little over five grand. They've got the head, which is 1800 plus.

Uh-oh. There we go. Maybe.

**MS. KIRKWOOD:** (Indicating.)

**MR. LANIER:** Thank you.

And then they've got the Taper insert at 535 bucks. So for $7,500, not counting tax, you get your metal-on-metal hip.

It's comparable to the poly system, which would still be the head or the shell, but, inside that, they've got an advanced plastic liner or cup. They still use a metal cobalt chromium head. And your total price, if you're getting that, is a little bit cheaper. You get it for under five grand.

So these are the different types of implants. And if you're a patient and you're going in to get one done, your doctor may tell you his thoughts, he may show you these different possibilities, and you may have some of the literature that's been produced by the company to look at to make your decision.

I'd like to shift gears for a moment now and talk about the history of hip implants for a moment because your issues will not only deal with the medical terminology and the surgery itself, but a lot of the issues deal with the

historical development. Much of what the Court is going to have to be faced with, in some ways, and even the jury, is the classic state-of-the-art argument, and so history becomes very important.

I'll throw up a time line on the PowerPoint and tell you that, in the 1950s, Sir John Charnley came up with the first hip implant, or at least became famous for these hip implants, and he would use a metal head on a Teflon liner, so he would take a metal ball for the femur and have a cup with Teflon.

Which anybody who cooks on a Teflon skillet gets told, "Don't use a metal spatula or a metal flipper on your pancake griddle because you're just going to leave tracks as you cut through the Teflon."

Metal on Teflon did not work real well, and so it was just a matter of time before Sir John Charnley changed his Teflon liner to a plastic liner, a poly liner, and that was done in the 1960s. In fact, history relates that Charnley felt so bad over having done those Teflon liners that he personally saw to the fixing and the repair and the replacement of each of those himself in surgery.

If we go into the end of the '60s, there was a company called McKee-Farrar that introduced metal-on-metal where they actually used a metal liner, as well as a metal ball, but the revision rates were very high, and so that was

not -- didn't make it into the market as they had hoped.

So in the '70s and the '80s and into the '90s, the standard for this was metal-on-poly. And the poly would improve over time, but it would stay a metal-on-poly implant market, by and large, until the '90s.

In the '90s, the middle to end of the '90s, metal-on-metal returned. When metal-on-metal returned, it returned in an alloy of cobalt, chromium, and molybdenum. These metals are, in some ways, very, very hard, and the goal was to get such a hard metal that you don't have a problem with metal wear debris. You've got such hard surfaces that they just won't emit debris.

The problem with that is it doesn't work, at least that will be the Plaintiffs' contention, that when metal-on-metal returned, the companies were trying to address, and their sales literature addressed, certain problems that were out there with the poly. Poly was not perfect. Poly had problems. Among the poly problems, chief, was osteolysis, and this is a situation where, in essence, the bone has an issue and a reaction, and it causes the implant to loosen as the bone retreats from the implant, so osteolysis was a problem.

Another problem with the poly is you do get some measure of debris. Metal-on-plastic will cause the plastic to wear, and so you've got that, and that debris and that

wearing leads to a durability issue.

If you're an eighty-five-year-old man, you may not get a hip replacement. You may use a walker. But if you're seventy-five and like your golf, you may want a hip replacement, and that might be a fine time to get this. But if you're thirty-five years old and you have avascular necrosis from rheumatoid arthritis, then the idea of getting a hip implant that's only going to last for fifteen years or so is not encouraging.

And so the companies were able to say, "Let's get ones that will last twenty-plus years for this younger market," and they did.

We think that you're going to see -- and we're certainly going to be pushing for discovery -- whether or not there were market issues in play, as well. Of course, there's how much money can you charge, that type of market issue. But we think that what we've termed a settled market existed in the '90s. And, by that, there were the companies that had their niche within the market, and there were companies that wanted to get into the market but couldn't break into the metal-on-poly because everybody already had them, and the surgeons were happy with them, they knew how to use that particular model, and they didn't see any need to change. So the idea of making a metal-on-metal market opened up the door for a gain of market share among

manufacturers that were basically limited in their market share by the way the market had already been divided, so these are the issues that we think are there on the poly problems, certainly worthy of discovery and talking about.

Some of these we get from an actual PowerPoint slide that I've pulled up of Biomet, and this is a Biomet slide where Biomet talks about why metal-on-metal is a better option. They talk about the polyethylene debris. That's the plastic wear. They talk about implant failure due to osteolysis. That's the loosening. They talk about the need to hit that younger, more active patient, who might need a better, more durable metal-on-metal hip, and then they put a fourth bullet point about minimal wear debris.

Now, this is important, Your Honor, because you will have a lot of discovery and a lot of scientific issues that come down on this. The wear debris, as cited by the company, is ten to a hundred times less than a metal-on-poly. It looks good. The problem with that is -- we will be addressing and focusing the Court on different measures of weight -- the volume itself may be ten to a hundred times less, but the actual number of particles, the particulate debris, is much greater in metal-on-metal because the particles are smaller.

Here's what I would like to do to show the Court, the metal-on-metal problems. First of all, metal itself has

toxic problems that are not found in the poly debris. The metal toxic problems. Here is wear debris that was taken from a mouse pouch model in a 2012 paper by Akbar. And if you look at the top left-hand corner, that's magnified to one hundred micrometers. That is a massive magnification, a massive amplification of size, so that we can actually see the wear debris. The wear debris are nanoparticles. This is a scientific term for them because their size is so very small, and that's what makes them destructive.

That's like Asbestos. Asbestos wouldn't be bad if it were big clumps. It's the fact that it's so small that it can invade the body on such a precise level to do irreparable damage.

So these are nanoparticles, and what nanoparticles do is they activate immune responses which can lead to chronic inflammation. The body has macrophages, and macrophages are in the different parts of the body. In the lungs, they're pulmonary alveoli macrophages. In the hip, you've got them. In the musculature, you've got them. The macrophages look for foreign invaders. And when they find the foreign invaders, the macrophages will try and throw chemicals and other things at the invaders to eliminate them. If it's a virus, let's go kill the virus. Whatever that foreign invader may be, the body's defenses come, by and large, through macrophages.

The problem is these nanoparticles are so small the macrophages see them as an invader, yet the macrophages are not able to defeat them, and so more macrophages come and more macrophages come, and, ultimately, you've got a chronic inflammation that is -- well, it's bad. It's bad on the body.

The second point on nanoparticles. When nanoparticles are soluble, they can actually release free metal ions that can cause systemic disease, so you're going to get to hear about all of this stuff, discovery, experts and others, as we press on nanoparticles, we press on free metal ions, what studies were done, what studies were not done, were results cherry-picked, are results fairly interpreted, all of those become issues in this case.

Last point on nanoparticles. In the bone, these free ions are possibly also byproducts -- and possibly -- excuse me -- also byproducts of inflammation. In other words, the ions are causing inflammation. They're particularly damaging, and they can actually lead to substantial bone resorption or bone loss, and this will cause loosening of the implants, as well, which can be another problem totally aside from the others.

So you've got the nanoparticles, and they come from the implant itself. The implant can actually emit free metals that can just leach directly from the implant, but

that's not where most of them come from. Where most of them come from is the wear debris.

And what happens, Your Honor, is there are some carbon-based elements in this alloy that are really, really, really hard, and so they have almost a sandpaper effect on a microscopic level.

You and I can look at these little things here, and we can play with them, and I can roll this around, and it feels awfully smooth, but, on a microscopic level, especially if you put a two hundred pound man on the top of this one and you keep this one wedged firm, you've got wear that's happening almost immediately, and the wear is on such a small, microscopic level that it produces these nanoparticles.

Cobalt and chrome are part of the wear debris, and they come in different sizes and in different chemical formulations, but the bottom line is these reek havoc on the body's immune system and on the body's bones and the body's tissues.

It's been known since the 1990s. It's been known through pulmonary toxicology work. That's a lot of the toxicology work that's done by the lung people because a lot of these nanoparticles are inhaled in different work places. There were a lot of welding fume issues and lots of other places where this has become an issue.

Nanomedicine is also an area that cropped up in the '90s. Nanomedicine is: How can we take nanoparticles that are so pervasive and can invade the body -- can we make them in a way that they help the body? Let's put something good on this nanoparticle because the nanoparticles themselves not only will activate the immune system, but if you've got some that have a careful coating on them, they're safe particles so they can stay in the body without the immune system going crazy.

Of course, ultimately, you will also hear dose and duration issues with this because the number of nanoparticles will control the response. Have you got one or two nanoparticles or one or two million nanoparticles? But when you've got millions and millions and hundreds of millions, you've got a whole different issue because it stirs a deeper pot, and so that's what we've got. The nanoparticles cause a massive immune reaction as the body tries to clear the debris. So with metal-on-metal, you've got a toxic problem that you don't have with the plastic.

In addition to that, there is this issue of debris. Is the debris less by volume and weight? Yes. But is the debris less by number? Absolutely not.

While we are told in the Biomet materials that it's ten to a hundred times less than metal-on-poly, in actuality, what the literature indicates to us is a low wear

volume does not necessarily indicate low numbers of biologically reactive particles. Current evidence indicates that the size of wear particles generated by metal-on-metal articulations are very small, and, therefore, the numbers produced may exceed the numbers of ultrahigh -- it's the super deluxe polyethylene particles generated in metal-on-polyethylene prosthesis, despite the differences in wear volumes. So the debris issue is a debris issue with metal-on-metal because you may have a smaller volume, but the number and the size are much bigger.

Now, while I have talked about that article, I should add that poly has changed over time and the generations of it have changed so they've developed a poly that's the ultrahigh type that was just talked about there that doesn't have the osteolysis problem, for example. That's been going for ten-plus years, by and large, not totally, but by and large, so all of this is subject to generational changes.

The third problem with metal-on-metal, the revision rates of metal-on-metal are epically high. Here are the epic revision rates taken from an article by Molli and Lombardi.

I did these specific to Biomet. You'll see the failure rate of the MoIP. That's metal-on-improved-polyethylene. That's the good stuff that

they've got, 2.2 percent.

If you look at the Magnum, you look at the Taper, you look at the M2a-38, you're going to see some changes that, at first blush, may not be that significant. But if you get into it a little bit closer, you realize that a 3.6 percent failure rate is 63 percent greater than the metal-on-improved poly. If you look at the Taper, it's 82 percent greater. If you look at the M2a-38, it's 218 percent higher, and that's a huge difference. So while we look at the numbers, and you think, 2.2 to 3.6 doesn't seem that significant, there's actually quite a significant difference in the revision rates between these.

A final metal-on-metal problem that you don't have in the same way with poly is, of course, inadequate lubrication. It's just -- we suspect that you will find two different sets of conversations about the lubrication. There will be the set that's done by the scientists, the tribologists and the lubrication people. There will be the set done by them about lubrication and how it's working and not working and the problems, and then there will be the set that's done by the marketing people, because the marketing people claimed, we suspect -- the claim was this. Here's marketing -- that there's optimal clearance, that there's precise implants tolerance and 100 percent quality control that provides the optimal clearance and the fluid

lubrication necessary to maintain ultralow wear rates.

Now, this fluid lubrication necessary is basically a full fluid film. It means that there's going to be fluid between the cup and the ball that is sustained throughout the entire rotation area.

The problem with that is, while it's the claim, we believe there's an issue of whether or not lubrication even works. Our position will be that it doesn't, but I'm not here to argue that position. I'm here just to let you know that it is our position.

You'll see things that are going to bring out the engineer in you, Your Honor, and just delight your day and your court reporter's time as she types up our Stribeck curves and talk about normalized fluid film thickness and friction, and those show -- what they do -- there are a number of different ways to check is this metal ball rubbing against this metal socket, and so they've got wonderful tests. One of them is an electrical test where they'll put an electrode on each end and they'll see if an electrical current is passing from the ball to the socket because they're meeting.

So you've got all of these different types of tests that check the lubrication, and we'll do those as we talk in our next installment on Tribology 101.

Now, tribology, a phrase coined, I think, in the

Second Edition of Oxford's English Dictionary. It's where it was first found. It was developed by, the phrase developed by -- or the term developed by a scientist, an engineer over at Oxford. So tribology is the study of interacting surfaces in motion; friction, wear, lubrication, bearings.

Until I got into this work, I had no clue about tribology. I would have thought tribology is the study of native American migration or something. I mean, I didn't know. It turns out it's this massive area. The Department of Defense, huge in tribology. NASA, huge in tribology. They invent all these things and send them up in the space station so, in zero gravity, they can try to figure out how things wear against each other. You know, the Department of Defense is always worrying about this product wearing out or that product wearing out or something locking on the battlefield, all sorts of problems. So this study of friction, this study of how things wear, how you lubricate bearings is a massive area of engineering that gets its own name, tribology. And tribology will talk about true fluid film lubrication, and this is true lubrication. It's where, throughout the whole process, there is a lubrication that's occurring.

There is also a term they use called boundary lubrication, and boundary lubrication is where you've got

some lubrication, but it's basically just around the boundaries. It's not really permeated throughout the entire surface.

And then, of course, they've got mixed lubrication, which gives you some degree of both.

These are terms you'll get to learn. You'll get to see pictures. And I've put these pictures in the booklet. I've got them on the PowerPoint. These are magnified pictures that show scratches in metal implants.

I do not have pictures of Biomet implants yet. I want the record to be clear. I want Defense counsel to know and the Court, of course. I'm not representing this is a picture of one of our Biomet implants or Plaintiffs'. It's just a picture to show some of the scratching that you get under bad wear.

We've got other pictures. In fact, you can see, in this second picture, there are little dots and holes, and those seem to be areas where some of the carbon molecules are peeling off of these implants as they rub against each other, so you've got potting and all the rest.

There have been studies that indicate the number of debris particles that are generated per year and per step, and, as I said, it's not one, it's not one million, but you've got, each step, ten million debris particles, nanoparticles, that are being generated. The number for

each year is a number I can't pronounce.

The danger of these, as I referenced earlier when I talked about the dangerous effects of nanoparticles, is the wear debris is, roughly, the same size as a virus, so you've got a massive number of these invading the body, and the body doesn't recognize them as simply debris from your new helpful hip. They see it as a dangerous invader. And these larger particles of chromium will actually decorate the surfaces of cells, but the problem with the nanoparticles is they can actually enter the cell itself and release hexavalent chromium, and so you'll see people with bad reactions to these implants presenting with blood tests that show high metal concentrations because the metals have made it through the system in such a way that you can find evidence of them in the bloodstream, and it's something that results in cell death.

I've got two types that I would refer the Court to, two terms that you'll become familiar with, if you're not already.

The first are pseudotumors. "Pseudotumors" is a term that was devised, again, by some doctors in England, for some reason. And, for the life of me, I can't figure out where it comes from. I've talked to them about it and tried to get it. It's not a tumor. I hear "tumor", and I think of a cancerous cell growth, malignant or benign. It's

not a tumor at all. They just said, "Yeah, but that seemed to be a good word to use." And that's why they added "pseudo" to it so you would know it wasn't a tumor. It's basically an accumulation of fluid that's showing a body's reaction to a poison that's in the body. It's a noninfectious reaction of the body.

Now, there's another problem that we see over and over in these hip implants as they're removed, and that's metallosis. That's where the metal has actually caused death of the, principally, musculature that's holding together that hip joint, but it can also be in the ligaments themselves, and so the doctors will debride or they'll take out all of the tissue that's dead from this metal debris, and they will put together a new hip for the person when they go back in for their transplant.

So, epilogue. We've got these metal-on-metal hip implants, and they are going, going, and gone. That's not my jury argument to you Your Honor. That's from the article out of *Orthopaedic Cross Fire*. "Metal-on-metal hip Arthroplasty. Going, going, gone." And while this had gained favor in the first decade of the millennium, we are at the point now where it is out of favor. The FDA has issued warnings. They've basically said, "We're not giving that 510(k) approval to these anymore, and, if anybody wants to sell their metal-on-metal hips, they're going to have to

do testing before they sell them and not on the humans that are getting them afterwards."

Your Honor, in closing, we'll be bringing a lot of experts in these cases. You'll get to see experts, of course, in medicine and surgery. You'll also get to see experts in tribology, that friction wear study. You'll get to see experts in fluid mechanics because there's a whole branch of engineering that deals with fluid and what does it take for fluid to truly lubricate.

The idea is once -- think of an axle in a car. An axle in a car is going to have grease, but that axle, as it turns, you've got to have some lubrication, and the turning will cause that lubrication to evenly distribute just because the turning is forcing the lubrication up against the flow of gravity.

With hip joints, you've got -- to some degree, once you start moving, your body will propel some degree of lubrication into that joint. The problem is, until you start moving, it doesn't, and so, when you get up, you've got more wear.

This becomes relevant because we'll have you look at and we'll be discussing -- there'll be **Daubert** issues and all sorts of things -- some of the science used to justify these studies of how much do they wear.

We think that you'll see that a number of these

studies actually have a real human gait where the leg goes up, stops, comes back, stops. You'll also see that a number of the studies were written without a real human gait because any time you stop, you lose fluid lubrication, and you've got to start it up again.

So we think that there was a conscious effort -- and you'll have to go through and sort this, but there'll be an issue, was there a conscious effort to change these studies so that the leg never stops. It's as if someone is doing a figure eight and moving their leg side to side while they're also moving it front to back so that that stopping point on front to back is a point where it's still in movement side to side, so it's kind of this figure eight thing going on. And all of that, fluid mechanics. It's fascinating. You'll enjoy it, maybe.

Metallurgy, Your Honor, is another area where we will have a metallurgist talking about the different types of metal alloys. Are they hard all the way through or do you wind up just placing some hard pieces in the middle of a softer alloy so that those hard pieces start scratching and creating nanoparticles? That will take metallurgists to fuss about those points.

Materials engineers, as well, over the materials and how they've been put together.

Mechanical engineers will be dealing with this stuff

also.

We'll have corrosion engineers because any time you take a metal product and you put it in an aquas environment, which the body is, it's subject to possible corrosion, and so there are some corrosion issues that we'll be looking at, and we'll bring in corrosion experts, accordingly.

How these products are made, are they made properly, and do they have the correct spacing that's needed, that's precision engineering, manufacturing, and metrology. How do you measure these things? How do we measure? It's fascinating, Your Honor. They've got incredible ways. It's not just high school calculus. They've got incredible ways to figure out under a microscope -- they can do a topography of one of those implants that have been removed, and they can create a map that's just phenomenal where you've got like Google Earth, except this is the earth, and it shows where the valleys are, and all of that's got to be done in a way that meets **Daubert** and all the rest of that stuff, but all of those are issues you get to look at.

Of course, the issues of biology, nanoscience, toxicology, is it poisonous, or what have you.

Those are the issues that we think you've got. Those are the terms on a cursory basis.

You've been most patient with me, and I thank you, Your Honor.

**THE COURT:** Thank you, Mr. Lanier.

Why don't we go ahead and take the morning break, about fifteen minutes, and start back at -- why don't we make it an 11:00 start-up and then proceed with the Defense.

**MS. POTTS:** All rise.

**(All comply;**

**Short recess taken.)**

**THE COURT:** You may be seated.

**(All comply.)**

**THE COURT:** It doesn't usually happen, but I think we have fewer jurors than we did.

Mr. Winter, you may proceed.

**MR. WINTER:** Your Honor, may I approach?

**THE COURT:** Thank you.

**MR. WINTER:** Good morning, Your Honor.

**THE COURT:** Good morning.

**MR. WINTER:** Your Honor, we have with us Dr. Mark Klaassen, so, for a couple of scheduling reasons, I'm going to talk very briefly for a few minutes and then turn it over to Dr. Klaassen.

**THE COURT:** Okay. Yeah, we do need to break at noon, so I'll be -- since you folks have two hours, I'll leave it to you folks to work out the timing.

**MR. WINTER:** Well, I'm going to go very quickly and turn it over to Dr. Klaassen, Your Honor.

**THE COURT:** Okay. All right.

**MR. WINTER:** Just to give us some background of where we are today, there are approximately 450 cases in this MDL, and we have a breakdown based on the complaints as to what device is involved, but I think, Your Honor, as we get fact sheets and other information, almost a third of the cases don't even allege a revision, and we have a good percentage of the cases where the implant occurred before 2006, which we believe is a state-of-the-art line in the sand, and we have another group, almost ten percent, where you'll see that, after a great deal of publicity about metal-on-metal, they were implanted, and then we have, roughly, eighty cases, Your Honor -- and I think it's going to be important once Dr. Klaassen finishes -- where the patient was revised in less than eighteen months or was revised after nine years, and there's a lot of explanation that will go into those, but we think those cases are going to have to be put to the side for a couple of important reasons.

The three products that you have, the first is the Taper, which was cleared by the FDA through a 510(k) process in 2000, but the clinical studies on that product, in fact, started in 1995 as part of an investigational drug exemption for a possible PMA application, so there were approximately 150 or so patients in that clinical study with the Taper.

The different aspects of it are laid out there, Your Honor -- we'll get back to that -- but it's cobalt chromium with a Taper metal liner, a couple of different sizes.

The next product was the M2a-38. That is a monoblock design, and it's got, pretty simply, a larger head, and that will be explained to you, why that's important, and it's got a special fixation system, which, when we talk about cup placement, that's important.

And we have the Magnum, which involves maybe two-thirds of the cases that are currently pending before you. It was cleared by the FDA in 2004, and it's got a number of features, which we will get to, Your Honor. Very simply, we do believe that the design of these devices is very important, and when you see the data and how the Magnum is designed, it is a reliable, safe, and dependable product. Here's another view of the Magnum.

In 2006, to assist in fixation, there was this -- the three spikes that were added. Again, that's something that the surgeon, in the exercise of his or her clinical judgment, says, "I want the Tri-Spike." And a lot of the features here, surgeons say, "I would like this for fixation." You have to go out, design it, and test it.

And to follow up on a point from Mr. Lanier, before this product is out the door, its sphericity, its outside curve, is tested through a hundred thousand inspection

points to make sure it is true 180 degrees for the hemisphere, which we think is very important, and it's also something that distinguishes the design of the Biomet metal-on-metal products from others.

There are other metal-on-metal products, which we don't have in this litigation. Some were never sold in the United States.

And, later on today, we'll have argument on the ReCap, which was an IDE device where the PMA was submitted to FDA in 2011, and we'll talk about that.

Very quickly, we think that these design features are what set the Biomet metal-on-metal products apart, and I'm going to turn it over to Dr. Klaassen.

But I want to stop here for a second, Judge. No one will ever accuse anyone of cherry-picking data, but what we have here is the overall revision rates per 100 observed component years, an accepted standard by all the registries and FDA, to look at how well devices perform. This is for all the Biomet metal-on-metal products sold in this country compared to metal-on-poly, so I'm comparing our metal-on-metal to available data that came out, I believe, in March of this year from the New Zealand Registry -- we don't have a U.S. Registry, so we have to compare "X" U.S -- and to the Australian Registry. And if you look at either the revision rate or the revisions per 100 observed

component years, comparing Biomet's metal-on-metal to what we anticipate the Plaintiffs will say should compare to metal-on-poly, they're comparable, if not better, and this is long-term data over many, many years.

So, with that, I want to move -- and I'll come back to this, Judge -- to Dr. Klaassen.

**DR. KLAASSEN:** Thank you.

I'm an orthopedic surgeon.

**THE COURT:** What's your first name?

**DR. KLAASSEN:** Mark.

**THE COURT:** Spell your last name.

**DR. KLAASSEN:** K-L-A-A-S-S-E-N.

**THE COURT:** Thank you.

**DR. KLAASSEN:** So, I'm an orthopedic surgeon. I do primarily joint replacement, and I'm going to be, I guess, a resource for you. And so if you have any questions, feel free to ask, and we can talk about different things.

I'm going to run through some of these slides. And if we need to go different directions, just let me know.

Total hip replacement history. I heard a little bit that was said earlier. I mean, over the years, joint arthritis has been one of the biggest problems with mobility, and we need to move in order to keep our bodies healthy. And if you can't move, then your heart, your lungs, everything starts going bad, so mobility has been

great.

And, of course, I'm a little biased, but, as an orthopedic surgeon, I would tell you that one of the biggest advances in medicine has been joint replacement. And if you look at quality of life benefits of having a joint replacement -- I see it every day in my office, and it's a very rewarding experience to see people do very well with their joints, and you basically change their lives. I think, usually, they rate two things in the highest amount of cost per value -- in other words, the value of the quality and cost to the system -- and, usually, it's the eye surgery like Lasik and joint replacement.

At any rate, total hip replacement history. Back in the early times, they tried ivory, they tried metal-on-metal, stainless steel, Plexiglas. We heard about Teflon. Teflon did not work. It wasn't until Charnley got into the polyethylene that we started seeing some successes. And ceramics also were tried. They've had some problems. When ceramics break, it's a disaster.

So a lot of different things have been tried over the years, and I can tell you that no bearing is perfect. We have not, with manmade materials, been able to replicate what God gave us, and so these things have been a struggle over time, but when what God gave us fails, these things do tend to help significantly.

Okay. So what do we, as surgeons, expect? One of our biggest concerns with any surgery is infection, blood clots early on, and then long-term is longevity and wear.

So infections. The average, across the country -- and I just looked at an article -- in 2009, the average infection rate was .67 to 2.4 percent. I can tell you that at our hospital, the latest infection rate I looked at for just joints was .4, and that's really, really pretty good. But across the county, you'll find, you know, one, two percent rates.

And in a revision rate, you know, what's an acceptable revision rate? Well, if it's my hip, it's zero, but things happen and things don't always work, and so kind of the thought over the years has been a revision rate of one percent per year. So at ten years, you'd expect that ninety percent of the hips would be survivals. So, you know, we all try to do better than that, but that is certainly kind of a standard.

And the early failures, less than eighteen months after implantation, generally infection is our biggest worry. Anymore, with modern implants, it's usually not an implant problem unless there was technical problem putting it in. And there are other reasons, too: The leg was too long, it dislocated, pain, and sometimes we don't know why it hurts or why it didn't work. But, generally, we don't

see, in today's technology, an implant failure in the early period.

So metal-on-metal. Early on -- you know, we heard about the McKee-Farrar and some of the others, Sivash, Ring, Muller -- there were a number of metal-on-metal implants that were tried, and they did not, in general work, but some worked surprisingly well, and we weren't sure why some worked really, really well and others not.

Then poly came around and so we went to poly, and then as we got into using joints in younger and younger people, now we're at a situation where poly is breaking and poly is wearing out.

I like to think of it as, you know, my boat lift. If you have these polyethylenes, plastic that these runners run on, and those things wear out, and they create grooves and wear out. Whereas, the metal-on-metal, like a piston in an engine, theoretically goes through millions and millions of cycles and does not necessarily wear out. So from that standpoint, it was an attractive thought of metal-on-metal. So in the 2000s, we started back into exploring this metal-on-metal.

And some of the problems we had with poly was, in order to do a total hip and get stability because of the anatomy, because of the mechanics, you had a metal ball, a smaller metal ball, and a metal cup with a plastic insert,

so the balls had to be smaller, and so those were more likely to dislocate, and we were more likely to make legs longer in an effort to tighten up the muscles to prevent dislocation, and one of the things patients absolutely hate is having a leg that's too long.

So from a surgeon's standpoint, it was very attractive for me to look at this and go, "Okay. If I can use a bigger head and use a metal-on-metal type of situation, and use this in my younger patients, then maybe I can get a hip that's going to last longer than the fifteen, twenty years."

So second generation came around, large diameter total hip arthroplasties, and, you know, we still developed -- and we started using these, and there's still that nagging concern. We, as surgeons and as doctors, have always worried about metal ions. I don't think that any of us have been nonchalant about that. We always worry about, okay, what's metal going to do in people's bodies long-term.

On the other hand, you know, I look at situations -- I mean, I have metallosis situations fairly often with polyethylene, situations where the poly has failed, and so once they have fractured this plastic and, all of a sudden, they're wearing into a metal-on-metal situation, which is not a congruent situation, you get really accelerated amounts of black tissue. And it's very impressive when you

open a hip -- and I think I saw a picture in one of the other presentations -- where you open a hip and you have this layer of just black just from debris. So those things are certainly concerns and worries in terms of the metal ion sensitivity.

We've tended to not necessarily use them in people that have kidney problems. We've tried to stay away from younger women that are going to have kids because we don't really know -- and we don't think -- there's no evidence that it crosses the placental barrier, but that was something we always worried about, as well.

So from the first generation metal-on-metal -- this is, actually, I think, an article by Schmalzried in California -- they estimated the combined linear wear of acetabular and femoral components in a McKee-Farrar -- and this is, obviously, one that did very well -- at twenty years, was 4.2 micrometers per year, and that's with old metallurgy and old metal.

And then they looked at a Charnley metal-on-poly -- and, again, this is old poly, and all these things have been improved over the years -- and, at twenty years, they reported an average rate of .1 millimeters per year, so, you know, there's significant difference and significant amounts of wear.

So why did surgeons stop in the early '70s? Well,

Charnley's prosthesis was seemingly better. We were worried about the problems. We think that the failures occurred because of deformation of the metal and rubbing against the metal.

Carcinogenesis. That's cancer causing. We were concerned about metal sensitivity.

Infection rates. Infection rates are hard to determine from back then, but there seemed to be a higher infection rate.

And the question of increased strain on the bone. The bone has to hold the prosthesis.

So the metal-on-poly bearing surfaces. You had the Charnley hip in the '60s. You had some disasters in the '80s. Hylamer was one of the first tries at doing some crosslinking, and it failed rather rapidly, and that created some concern about poly. Heat-pressed polys. Some of the second generation polys seemed to do a little bit better. In the '90s, we started getting into oxidized and Highly Crosslinked poly, and now we have this ultrahigh Highly Crosslinked poly. And, again, there's no bearing that works perfectly. I can tell you that with some of the ultrahigh High Crosslinked polys, you still can get some oxidation.

If you look at -- and by "oxidation," plastic rusts, so to speak, much like metal can rust or corrode, and what plastic does, if you think of a plastic part, piece, or

whatever that you have around your house that is old, it starts to kind of get white, and you start getting some of that white, chalky look, and it starts getting brittle, and that is some of the oxidation that we see. And in a human, it's a high-oxygen environment, and some of the Highly Crosslinked polys, there's been some issues, so now we're throwing Vitamin E into the mix to try to stop some of those free radicals that occur in the Highly Crosslinked poly from binding to oxygen and creating some of that oxidation, so it's like oiling the metal. We're putting Vitamin E on the poly.

So technology keeps getting better, and we're getting smarter, but we've had some issues along the way, as we've learned.

And, also, the other thing that's always interesting is what happens in the lab isn't always what happens in the human body, and sometimes we don't figure that out until later.

So metal-on-poly was used for many, many years. There was some issues with oxidation.

I've seen some really interesting things. For example, if I did bilateral knees on somebody -- and we use poly in knees -- and you have them done on the same day, and one polyethylene component at ten, fifteen years is absolutely destroyed and the other one still looks pretty

good. And why is that? Well, was it a technical problem? I think we're finding that some of it could be a technical problem. Some it could be edge-loading type of thing. But also some of it is because of shelf life of the polyethylene. We discovered, over the years, that if poly sits on a shelf for a while, we get into trouble with it oxidizing, and it just wears out quicker.

Osteolysis. We heard a little bit of osteolysis. Osteolysis is where the bone kind of disappears, and it's the body's reaction to debris, whether it be poly or whether it be metal.

I've seen some horrendous osteolysis type of situations with polyethylene.

I've seen metallosis. When you see metallosis, it is a scary thing to see. You know, your bone literally skeletonizes, and you get this gray-looking appearance to the muscle, and, as a surgeon, it really does scare you.

But metal is black. Poly also kind of gives you a white -- is white, and so you don't see quite the particles like you do with the black, but you also see this kind of tan-ish looking membrane that is very much a destructed membrane, as well, and you can get into some osteolysis.

So we heard a little bit about tribology and the study of mechanics, lubrication, friction, and wear.

You know, in cars, we have lubricating oils. In

humans, we have proteins. And our bodies each produce lubricants. Our joints all have lubricants that are natural lubricants and proteins that help lubricate the body. And we see that in joint replacements, as well, and they produce the boundary lubrication, and that's, theoretically, what then protects the device against some of the wear.

So the benefits of metal-on-metal systems, you know, on a metal-on-metal hip, the advantages I see of a metal-on-metal hip -- and, here, I've got an example of a metal-on-metal hip -- is, from a dislocation standpoint, early on, if you've ever known somebody -- I'm sure everybody in this room probably has known somebody -- that's dislocated a prosthetic hip, it is not fun. But with a smaller ball, your jump distance and your distance to dislocate is much less than it is with a larger ball. With a larger ball, it's got to go a lot further before it dislocates. Of course, we don't want it going on edge in either situation because if I'm going on edge on the plastic, I'm wearing the plastic. If I'm going on edge on the metal, I'm creating a stripe wear type of situation, which I don't want either. So that was one of the benefits.

The other benefit is, if I look at what my computer knows my hip looks like -- and here's an example of a femur -- if I can reproduce the size of that femur very similar to what my computer is used to doing, I will recover

quicker. That is why I think resurfacings, actually, do better. I can tell you that if I do a resurfacing hip, even though I have, perhaps, done a little more soft tissue damage in order to dislocate that hip to work the acetabulum and also to do a resurfacing hip, those resurfacing hips will go home the next day, and they, seemingly, do really quite well.

So large diameter heads have helped us, theoretically. And, again, this gets down to the engineering. What we've been taught is that the wear is less with the larger area, and that makes some sense because you're distributing the wear over a larger area.

The metallurgy on these things is important, and I think that was touched on a little bit, but the metallurgy is important in terms of having large carbides. And if you look at it under an electron microscope, it bounces over the top of these kind of boulders of carbides. And if you have large carbides, you don't get down into the alloy and get some of the wear particles, so the metallurgy is important, as well.

Larger diameter heads have certainly showed less wear, and you can actually take -- and this was always interesting -- take a pile of plastic debris and a pile of metal debris, and the pile of plastic debris is certainly much, much larger, and that makes sense. I mean, clinically

and theoretically, it makes sense because you're going to get more wear in terms of volume.

So the other advantages of the large diameter heads was the increased head/neck ratio, and that got away from impingement so that when this comes down, it doesn't hit on the side and cause it to dislocate, so you have a really, really great range of motion with these larger heads.

I think we talked about increased jump distance and a lower risk of dislocation. So when I have a lower risk of dislocation, now I can pay more attention to the leg length because I'm not so concerned about making it so tight by lengthening it, so I have happier patients because my leg lengths are, certainly, a lot easier to make equal.

So cup positioning is important, and we probably didn't appreciate this at first, that cup position was as important as they are with these hard bearings. And by hard bearings, I'm talking about metal-on-metal and ceramic-on-ceramic. But cup positioning is important for getting coverage and to get areas so that the primary bearing area -- the primary bearing area is on the polar part of this and it is contained within the cup so that if you have the cup positioned in a vertical fashion with a high degree of inclination, now we get into trouble.

And, early on, we probably didn't realize how important that was. Kind of the standard over the years has

been forty degrees of inclination with twenty or fifteen degrees of anteversion, and what that means is -- you know, here's a pelvis. And if I have about forty degrees of inclination, you know, and I'm about there -- and anteverted means that I'm forward about fifteen to twenty degrees -- that has always kind of been the standard. With metal-on-metal, towards the later years, we tended to go more and more coverage because we want to have it more hooded to get into less of that situation where we might have an edge loading of that prosthesis.

**THE COURT:** You're reducing the angle of elevation by bringing the top forward?

**DR. KLAASSEN:** Correct, so that it's more covered, so we're taking and we're covering this so we're not getting -- what we don't want is this, where you're just wearing it, and that intuitively makes sense, you know, because regardless of what fluid lubrication or oil lubrication you have, if you're right on that edge, we're going to be in trouble.

But it's not that simple, either. Sometimes the anatomy varies. And if people have dysplastic hips, which means they have some developmental issues, that may be why they developed the arthritic changes.

My fifty-five-year-old with an arthritic hip, unless they had an injury, a lot of them are dysplasia, which means

that, in their development, their cup is too shallow or the cup is too vertical.

And then, as a surgeon, I'm in there, you know, and I have a patient on the side -- or if I'm doing an anterior approach, I have a patient supine -- and I'm trying to figure out what works best, and there's different methods of figuring that out. We have instrumentation that shows us, and we have to look at the body alignment. We put people in a -- if we're doing them on the side, we have pegs and a peg board to try to hold them as straight as we can. But you can get some of this type of motion that sometimes is very difficult to appreciate.

Even with X-rays -- and, many times, I still even use X-rays in an operating room -- it is not always that simple to know exactly where the best thing is, and what's best may be what's best for the person, because if this angle and rotation is different, that can also affect where I want to put the cup because I want to match the cup with the stem.

And so now we're talking about combined version, which means looking at where we're going to put the femoral component, as well as where we're going to put the acetabular component, in terms of meeting those, because you can't just arbitrarily say, "Okay. Your cup should be forty/twenty," because the anatomy may be different. The

femoral side may be rotated differently. And so, as a surgeon on this -- this is the art of being a surgeon -- you've got to kind of match those things and make it work.

So cup placement is very important, and so now we're thinking that with these hard bearings -- and with hard bearings, ceramic-on-ceramic, metal-on-metal -- we need to, perhaps, hood them a little bit more.

And, you know, as a surgeon, you know, I've probably done a couple thousand metal-on-metal hips, and I've had one particular situation of metallosis that was scary.

I've had some cups that have spun, and I think I see that early on, where you put in a cup, especially in women, and, perhaps, the bone isn't strong enough to grow in quickly or hold with these little fins. And if the cup spins, now, all of a sudden -- and by spinning, I mean the cup moves -- and now, all of a sudden, the cup is more vertical, and, now, all of a sudden, you've got a situation where we're in trouble. Hence, I was one of those surgeons who likes those spiked cups because I can drive those in, and I know those things aren't going to move.

So let's talk a little bit about clearance. One of the problems with some of the designs of the cup was that, if the cup is too thin and I'm putting it in a football player who destroyed his hips and he's got real, real, real strong bone, and I'm driving this thing in, the bone,

actually, may deform the cup. If the bone deforms the cup, now we're going to be in trouble, and I'm not going to know that in the operating room probably because it's going to feel okay. But if we create the problem right there, where there's too little clearance and equatorial contact, that's when we start getting into trouble. And that makes sense because now we're scratching the edge rather than bearing on the polar area, and that leads to loosening, increased wear, you know, problems like that.

Too much clearance. You don't want the baseball-bat-in-the-trash-can type of situation either because if I have this kind of a situation -- and this is exaggerating a little bit -- if I have this kind of situation where this is moving around, that's not going to wear well either, so we don't want too much clearance.

And here's where I depend on the engineers. What I want is the optimum clearance, which is adequate loading on the polar area, enough room on the sides to get the lubrication in.

And I was playing with this a little bit ago, where you actually can take this -- and these two are mated together. And if you feel this, it's very, very, very smooth (indicating).

So let me show you something. If I take -- I was just doing this. And if I just lubricate this a little bit,

you can actually feel it. It actually will almost suck in there. You can actually let it almost hang there.

**THE COURT:** Yeah.

**DR. KLAASSEN:** And that lubrication is what lubricates the joint.

**THE COURT:** Does the body produce the lubrication?

**DR. KLAASSEN:** Yeah, your body does.

**THE COURT:** I mean with this configuration?

**DR. KLAASSEN:** Right.

With all the joints, with knees, shoulders, hips, your body produces some proteins and lubricates, and it looks like -- when I open up a well-functioning joint, there is maybe five CCs or less of light-oil feeling fluid.

So lubrication theory tells us that smaller clearances result in increased fluid film thickness and lower wear. If you have too little clearance, you get into trouble. And so if you get any kind of deformation of cup or design issue, then you get into problems, so I think we talked about this, increased clearance and diminished clearance.

So wear debris, you know, we see this in everything, every bearing we have, and nothing that we have made has been perfect. But your body does not like particles in large volumes, and so, with plastic, we see -- with the polyethylene, we see debris, and that creates osteolysis.

We see pseudotumors with polyethylene. I've seen huge areas of bone destruction, and then you'll see other people that have none of this, which is always interesting. They'll have almost as much wear but do not have the osteolysis type of situation.

We now are seeing this with metal-on-metal. You know, we're seeing -- especially one where there's metal debris. You're starting to see some of these.

Now, we haven't been putting these in for a long period of time, so we have about a ten-year history of metal-on-metal, so we don't really know what twenty years and thirty years and forty years down the road are going to do, but I can tell you that I have a lot of very well-functioning metal-on-metal hips. Now, I don't know if twenty years from now I'll be able to tell you that.

So the osteolysis and debris creates bone loss and it can then cause loosening, and that's a problem.

Three reasons for edge wear impingement. The first picture there is actually a picture of a resurfacing. So on a resurfacing, what you do is you shape the ball into a peg so that then you can place a ball that's a cap that kind of goes over that, so we keep the bone. And in space, we keep the same orientation that your computer is used to doing. That's why I think my resurfacing people feel so normal after I've done a resurfacing type of bone.

But you have this large neck, so that can, certainly, impinge on the edge of the cup in a resurfacing situation. It is their natural neck, but you certainly can get impingement.

Usually, we don't see impingement in this type of a situation, unless there's a malposition, because just think how far that would have to go before it would hit that skinnier neck, and so that allows a large range of motion.

Micro separation. And, here again, I'm back to some of this is very difficult to control. We try to anatomically reproduce what is best for this particular patient, and we have all these different sizes, but it's not always perfect, and some people have different gaits and different problems. And if they're walking and they start doing some of this (indicating), that's a problem with almost any bearing.

Now, the poly is more forgiving for a while, but you're going to wear it out, and you're going to destroy it. The metal and the ceramic are not very forgiving for that type of a situation.

But let's say someone has a back problem and has a problem with neurological control of their muscles because they've had a disc, so some of the muscles that control their gait aren't working as well or are weaker, well, they may, actually, get a little bit of piston, a little bit of

that type of a situation, so there's a lot of things that can happen in person that aren't necessarily always thought about ahead of time.

Edge loading. I think we've kind of beat that one quite a bit. Again, that's when we're more like in this situation, and that's a situation we try to avoid with any kind of bearing.

So the top there, left, we have the diagram of a well-functioning hip. Edge loading. Again, we want to stay away from edge loading in anything, whether it be poly, whether it be ceramic.

Ceramic -- and I know we're not talking about ceramic, but ceramic -- if ceramic breaks, it's a total disaster because it's like shards of glass that go through all the tissues, and I can't take enough of the tissue away to get rid of all the shards of glass.

So the problem then is revision. If I put plastic in there, if I put a plastic component in there, and I have shards of glass, it's just going to eat away my plastic. If I put metal in there, I'm going to end up with metallosis, so my only option is to go back to ceramic-and-ceramic, and then I'm still going to be producing a wear machine. So if you get a ceramic disaster, it is an absolute disaster. I have no good recourse for that.

Getting back to this. Steep inclination, you want

to stay away from that.

Reduced coverage, some -- and this is a design thing -- some of the cups cover more of the ball. Some are shallower cups, so to speak, and those can create some more problems, and so you want to get good coverage. Yet, you don't want to get into a situation where you're impinging, so you try to find that happy medium.

So Taper. And here's the other thing is that what we're finding now is that, you know, we see some metallosis in people with any kind of bearing, and it's not related to this bearing, but, rather, to this situation where the metal -- this is a Morse Taper, okay, and the ball is like a cold weld.

So we've gotten very fastidious in surgery. In surgery, I wipe this off. I clean it off. I try and make sure it's totally dry. I have no debris in it. None of my staff touches the inside of this. And I'm very careful about putting this on and then pounding it on. Basically, I have a cold weld because what I want to prevent is anything here that might cause this kind of motion because that will create corrosion, will create metallosis totally different than this. It's the same problem, just a different mechanism of creating that.

And what we're seeing, more and more, with all of this interest on metal-on-metal is the corrosion of this

Taper is a problem in almost any type of situation. There are some modular designs where you actually have the stem and then you have the middle part here to create the appropriate anteversion and then the trunnion, so you actually have a modular situation here, a modular situation here. And some of those have been disasters, as well, and we've only learned that after, you know, putting them in people and going through this. But, again, what we were trying to do, in those modular designs, is try to get something that works best for a particular person and to reproduce anatomically.

So Taper corrosion has been a problem. Every time, I do a revision, you know, generally, the stem is well fixed with modern components, and I pop off this head. And in popping off this head, invariably, I mar the Taper a little bit, and then I'm cleaning it off and everything.

But I have a decision to make at that time in surgery. Okay, do I take this all out and do I split this femur, take a saw and split this femur in order to get the stem out and create all that trauma and injury or do I try to get the best fit and, hopefully, get a good weld? And most of the time, this is what we do because it's such a big deal to take everything out.

So the Morse Taper is becoming more and more -- in our Hip and Knee Society, which I'm a member of, we're

dealing with this more and more, this whole Taper corrosion type of concern in creating a metallosis type of situation.

So metallosis, adverse reaction to metal debris, these are a bunch of terms. I mean, that's kind of self explanatory.

This ALVAL is a scary thing. This is the aseptic, which means no infection, lymphocyte-dominated, which is a cell, vasculitis-associated -- in other words, a lot of inflammation and a lot of vascularity -- and this is what creates these things called pseudotumors.

And pseudotumor is basically -- you know, when we see a mass in people, we worry about cancer. Well, this is not a cancer. It can look like a cancer sometimes because it just destroys things, but it's a pseudotumor. In other words, it's an anti-inflammatory reaction. And we see it with metallosis. We see it with polyethylene. You can see it with any type of particulate debris where the body reacts.

Now, not everybody gets these, and it's always interesting to figure out, and we don't really know why not everybody gets these. But pseudotumors have been seen with different types of situations, and, generally, they're treated with surgery because if you just leave it, more and more your bone disappears, and it becomes harder and harder for me to revise it and change it into something that will

function because I need a base on which to put any kind of prosthesis.

Women, in particular, with metal sensitivity. Women tend to use jewelry all their lives and so they tend to be sensitized a little bit more to metal, and, also, their bone, in general, is more osteoporotic because they've had children, go through menopause, and so their children have cannibalized their skeleton over the years, and so the women's bones tend to be softer, and so it is a little bit more problem in terms of fixation.

Osteolysis, as we said, can be seen with polyethylene. It can be seen -- it's a cell mediated response, and the inflammatory situation can dissolve the bone and loosen the components, and that's a problem. If we loose mechanical fixation, we have pain, we don't have a functioning prosthesis. We have to do something about it.

So hypersensitivity to metal ions. You know, this gets into the immune system. Type IV means that there's a delayed cell mediated response. Type I is like poison ivy. You get exposed, and then the next time you get exposed you have an almost immediate allergic reaction.

The body likes titanium. Cobalt is probably the most toxic of the cobalt chromium, and not everybody is sensitive to it. We try to pick -- our manufacturers have tried to pick metals that are body friendly. The bone likes

to use titanium. That's why all these components are covered with a titanium spray because what happens is your bone grows into this microstructure.

And I like having components that are biologically fixed versus components that are cemented. If you think about cement -- and cement works very well in knees, okay, but in hips we pretty much almost have gone away totally from cement, unless someone really has bad bone or cancer. But, with bone, if we can get the bone to ingrow into this prosthesis, and, let's say, they jump off their truck or off a curb and they break little spiculas of bone, that bone can heel and regrow. If I have cement and I crack the cement, well, my cement is cracked, and I really can't -- that's not going to change over time.

So skin testing, you know, the dermal sensitivity, the costume jewelry. We already talked about that, particularly in women, so we're much less likely to put metal-on-metal in women anymore because of that situation.

Our current recommendations in counseling patients is that -- and I can tell you I would have a hard time getting my asymptomatic patients to come in and have all kinds of testing and that type of thing, but what we're looking for is anybody that has pain or if they're having any symptoms whatsoever, I want them to come in, and we're going to get an X-ray. If I see anything on the X-ray that

concerns me or if they're really complaining, then I'll get what's called a MARS MRI, which is a special MRI that kind of subtracts the metal, because MRIs work by magnets, and, as you can imagine, metal distorts the image, so we get a special MARS MRI, and then I'll do -- if it's a metal-on-metal situation, I will do cobalt chromium levels.

And there's lot of debate in the literature about what is the right number, but kind of the standard that's thought of right now is about seven parts per billion. If it's more than seven parts per billion, then we're probably going to follow it on a regular basis, and, if it becomes symptomatic, worry about it more.

If it's less than seven, we're going to worry about it less. Some guys are getting more conservative and saying four parts per billion is the number, but somewhere in there, between four and seven, is where we start getting worried, if there's a problem.

So routine blood work. We're always worried about infection. I can tell you that when you see a situation, metallosis, it looks like infection, but you won't grow anything. We're always worried about infection. So, SED rate -- these are blood tests -- CRPs are done.

Again, the X-rays, the special MRIs, the Metal Artifact Reduction System.

The joint aspiration. You know, you aspirate the

joint just to make sure there's not infection because infection is probably a more likely situation and, actually, many times, more fearsome because it's sometimes very difficult to get rid of the bacteria once you have an established infection.

So, you know, just to tell you a little bit about the hip replacement, what we do with a hip replacement, if they're lying on their side, is we take the ball off, and then you actually can dislocate this, and you can work the cup, and then you can work the stem. The stem, what we do is we take the stem forward, and in this type of situation, we can get down the shaft.

If I'm doing an anterior approach, you really don't do any different with the anterior approach. One of the advantages of this new approach, actually, is actually where you take the neck, cut it off, put a little traction here, work that, move the leg over, work this, and put it back in, so there's not necessarily a huge amount of trauma, soft-tissue trauma, moving these things around.

You know, this is the type of stems that we use, and these are sized to the patient. We have digital templating that we do before surgery, and so I have an idea of what the size is, but I want to make it fit perfectly, and I want a tight fit because I want the bone to ingrow into this.

I don't have as much control where the stem goes

because that depends on the anatomy of the bone. I mean, it's going to go kind of where the bone directs it. The problem now is that then I have to kind of match my cup because this may not go down in exactly that same orientation that that ball was. I mean, it may be a little bit different, and I think that has something to do with patients' computers kind of reprogramming themselves.

What I tell my joint patients is that, you know, "It will take you about a year" -- and some are faster and some are slower -- "before your computer reprograms itself, and what I want is and what you want is a joint where you forget that you have an artificial hip, forget that you have an artificial knee." To me, that's a well-functioning joint.

Questions? Anything?

**THE COURT:** I think I understand.

Thank you for the presentation.

**MR. WINTER:** What's your pleasure, Your Honor?

**THE COURT:** I don't know. I guess we probably, for the sake of your presentation, ought to break, I would think, so you don't have to interrupt in five minutes.

**MR. WINTER:** Okay.

**THE COURT:** So we'll go ahead and break.

Again, I've got a brief thing at 1:00. Why don't we plan to restart at 1:15.

Is it by telephone, what we have?

Okay. So you can leave your stuff there, if you want.

Thank you, Doctor.

**MRS. POTTS:** All rise.

**(Lunch recess taken.)**

**THE COURT:** You may be seated.

**(All comply.)**

**THE COURT:** I think, Mr. Winter, you've got a little over an hour to go.

**MR. WINTER:** I will try -- I will try to be brief, Your Honor.

If we could go back to -- what do I need to do to get the screen on?

**MS. KIRKWOOD:** (Complies.)

**MR. WINTER:** There we go.

Judge, I just want to go back to the slide before I turned the floor over to Dr. Klaassen. And he referred to that high carbon content, and the Magnum was our first device that incorporated that, and the "as cast" is where you get the high carbon, which creates carbides, which, as he explained, are stronger than the underlying alloy. And, literally, when polished, it creates hills on the top of the ball which protects the underlying alloy.

And I think, when we get further into the science here, you will learn that this high-carbon innovation was

something, around 2003, that an independent researcher in England said, "This is the way to go." So as we walk through this, you're going to see the continuum that both sides have laid out for you, starting in the 1930s to the 1950s to the '60s, '70s, '80s, and a constant process of innovation, testing whether the innovation and its design is satisfactory, and then still learning and then adapting to new science, new understandings. And we think, at the end of the day, when you look at the data on the Magnum and compare it to the science, it is a very good, safe, and well-proven design.

I had stopped just before this slide, and, very quickly, I want to give you a framework because there was some references to FDA clearance, and there is a very robust, you will learn, regulatory oversight to these devices, both here by the FDA and by international standards. And what happens is these international standards and national standards -- the national one is the ASTM. The international one is the ISO. Everything that a company does has to focus on one of these standards, to the amount of metal that you can use to say it's cobalt chromium, to the type of testing you must do to validate your product in terms of mechanical testing. And we'll get into whether someone was doing a figure eight or not, but these are very rigorous standards that everyone tests to.

So when they submit their data to the FDA, they say, "We have complied with ASTMFO4-" -- you know, I'm going to make up a number -- "173," and there is testing and data that would substantiate that. And it will permeate all of the issues that you see, that there is this overview of a system and it's peer reviewed. Hundreds of thousands of engineers get input into this, and these standards get revised over time, as additional information is learned.

And just, very briefly, here are the officers, I believe, as of 2010 or '11, of that ASTM Medical Implant Group. And you can see it's a cross-section of scientists both from industry, FDA, and academia, and they create these standards, and everyone has to test. And even the specifications for how smooth a polish you have to have on your device meets one of those standards, so it's a very rigorous review process, and everyone can get input into it. So if someone in the community thinks something needs to be revised, there's a process, and they go through it. And then there's a revision to the standards, and then everyone tests appropriately. In terms of a parallel, there's FDA.

And, as I said earlier, our Taper device started as an IDE device. We started clinical studies in 1995. In 1999, we submitted that 510 clearance application to FDA. They actually asked us questions regarding the submission. We filed a response, and then they cleared it. And then,

about a year later, we made a submission for the 38s. That got cleared. And along the way, you'll learn that FDA had an advisory committee meet, generally, on this metal-on-metal issue because there was a question as to whether they should be all Class II Devices or all Class III Devices. So FDA is very much involved in this process from the beginning of the second Generation of metal-on-metal.

Even though we had gotten the 510(k) clearance, we finalize our studies on the Taper device, submit all the data to FDA in 2002, and we actually change our labeling, our instructions for use, which we'll get into in a little bit. And then two years later, roughly, we submit our 510(k) on the Magnum, which FDA clears.

And when we start marketing the Magnum, we further revise our labeling, which, we'll show to you, Judge, because, at the end of the day, I hope, as you've learned, there's a lot of risks and benefits that have to be balanced when a surgeon decides what type of implant to use in a patient, and, obviously, our obligation is to provide information through our instructions for use so that the surgeon can make a reasonable, informed judgment and have a discussion with his patient as to what to choose, and I think you will learn that there are many, many options that the surgeon has and that surgeons knew and understood the positives and negatives of all of these devices and then

would make appropriate judgments, which, in a product liability case, from our perspective, would mean we satisfied our duty, even if someone ends up with a revision for hypersensitivity.

For state of the art -- and you've seen parts of this -- the first metal-on-metal hip replacement was done in the '30s. We've talked about Teflon. We've talked about poly, the first ceramic, the issues with polyethylene, the start of the second generation.

And if I could just go down to the bottom, it was in December of 2007 -- I showed you some of that registry data from Australia. In December of 2007, out of the Australian Registry came the first notice, for want of a better term, of a problem with metal-on-metal devices, which was related to a competitor's product, for the most part.

In March of 2010, not that the New York Times defines "notice", but there was a significant amount of publicity generated by articles in the New York Times about metal-on-metal and one of our competitor's products. And then, a month later, in the United Kingdom, was a safety alert, again, metal-on-metal, relating to a competitor's product. And we think those are important, both for your statute of limitations purposes for some of these Plaintiffs. And if someone gets a metal-on-metal hip in December of 2010, with all of this publicity -- and they'll

be submissions to you about all these meetings of orthopedic surgeons in this country almost twice a year -- all this information is well-known and understood, and, again, surgeons will then make judgments with sufficient information.

So I'm going to try and abbreviate a discussion about corrosion and wear because I think you've heard about it. From our perspective, there are two issues, corrosion and wear, and what we think the science will show is that the Biomet metal-on-metal products are designed and manufactured for minimal corrosion and minimal wear.

The reality is there always will be the chance for corrosion and there always will be wear. You can't make a device that doesn't have either one of those. If you design them and make them right, they're going to perform appropriately, which is what we think our devices do, and we'll give you some of the design features which we think support that.

So any metallic device in fluid is going to be subject to corrosion. When you think about rust, you think about tarnish, that's a form of corrosion. And there's an ion transfer proportioned to the surface area that's in the fluid environment, and general corrosion, which is what we're talking about, first, for these types of metal, is less than parts per billion per centimeter squared of

surface area, so it's a really small amount, and titanium and cobalt are on the better side of that corrosion than stainless steel.

Now, what you do, though, is -- there are ways to even minimize that. So if you oxidize the surface area, if you polish it extremely well, very, very rigorous, you're going to minimize corrosion, so that is built in to the manufacturing of these devices.

Now, what happens if you don't do it right, if it's not well polished and you lose your oxide level, in part because of wear -- wear could erode the oxide -- you're going to get more escalated corrosion on top of the wear, which could create a problem, so that's why it is really important to make sure you've got extremely well polished, extremely well manufactured devices.

Now, there's the other part where we talked about those neck adaptors, and you saw a slide from Dr. Klaassen going back. It's an issue for every type of device. They all have some connectors. And if you have those complicated cases where because of the person's anatomy you're going to have to put in more Tapers, you're increasing this risk for the metal corrosion, but that's just a reality of what you need to do to put the device in place, and there are ways that you can design your device in terms of the thickness and size of the Taper to minimize this corrosion.

And what Biomet has, which no other metal-on-metal device uses, is its Taper is titanium, not cobalt chromium, so -- there will be a lot of science on this -- because of that titanium, by definition, you have less cobalt chromium ions to float around, and that may be, in a very simplistic level, one of the reasons why the Biomet metal-on-metal products perform that way.

And there were studies done because the ions in titanium, when they interact with cobalt chromium, there's an electrochemical reaction. But because the ion transfer is positive, titanium to cobalt chromium, the risk of that electromagnetic corrosion, which is different than the general corrosion, is minimized, and that was well thought out in the 510(k) application. All the appropriate formulas are looked at, and that's just a difference in the design, which, clearly, we believe, has an impact here in a positive way.

And those titanium sleeves, those adapters that we just mentioned, they've been around for twenty years in different orthopedic applications, so this was not something new. This was a well-tested use of that metal in that environment, and it turns out, we think, to be very positive.

You've heard a lot about wear and tribology. I'm not going to go through what Mr. Lanier and Dr. Klaassen

told you, but metal components are more capable of hydrogen binding than polyethylene, so that protein that's out there does work to create that film that we'll talk about that does lubricate. And then the question becomes: Can you keep all of that lubrication going? Can you keep it in place? And that's the clearance issue we'll talk a little bit about in a few minutes.

And there are differences. A polyethylene cup, you put a lot of stress on it, it changes shape, so you don't have -- you know, it's just softer. Whereas, metal-on-metal, it doesn't change shape, and you get that wear, issue, and that's something, again, that this is not new and novel, but something understood by surgeons going back many years.

This is -- again, you've already heard about wear, the size, the shape, the amount. It is true that metal particulates are smaller than the polyethylene particulates, but one of the things that goes on when the metal wears, sometimes it actually improves the oxide layer, so it helps to prevent or minimize -- "prevent" is the wrong word -- minimize corrosion, and that's a natural process. And as long as a person's kidneys and other parts of their body are working fine, all those ions can be excreted normally so that --

You know, Dr. Klaassen, I think, said, if you have a

patient with bad kidney disease, metal-on-metal may not be a good idea because you don't know if they're going to be able to clear these ions through normal excretion the way everyone else will. Because the question is not -- the wear exists. It's a question of: Do you have a buildup? Do the blood levels get to a certain point that you need to do something?

And, here, I will go very quickly. The clearance, you know, those three slides that Dr. Klaassen showed you, there is a clear relationship between a certain amount of clearance and the amount of wear that exists, and what we think the science will show is that the clearance for the Biomet metal-on-metal devices is such that wear -- the volume of wear is minimized and that people are perfectly okay with it as long as their body is in the right frame of mind to excrete, or they don't have that hypersensitivity, because it's a type of allergic reaction, Judge.

And surgeons will tell you it's really hard to tell ahead of time if the patient is going to be hypersensitive. There's no good skin test you can do. But if there's a hypersensitivity reaction, it's an allergic reaction. It's, again, something well-known to orthopedic surgeons for years. It started with nickel, mostly, but that can happen and, even with good clearance and wear, you could have that type of reaction.

So, again, you've heard some of this already. Edge loading and what can happen when you have the device pushing against the edge creating debris and excessive wear and whether large diameter heads do or do not play a role in this, what the balance is between a large diameter head and reducing the risk of dislocation, because if you dislocate, you're going to get lots of problems, including excessive wear.

Fretting is that corrosion issue we talked about.

And Number 4, how the femoral component, the head, is designed. There are heads from competitors that are not completely closed, and there's a reason for that design, usually relating to trying to minimize impingement, which Dr. Klaassen told you about. But then if you have an open space, there's places for particles, debris to get in, and that could create problems. That's not for today. But all of the Biomet heads are closed so you don't have that issue.

Small diameter clearance. You already saw some visuals one that.

And then the cup inclination, which Dr. Klaassen explained to you.

So let me move to a science issue, Judge, that, I think, is going to be important here, and I'm going to go through. I moved to Slide 44, Judge.

We had a few early cases, Judge, where we were

collecting medical records before this MDL was formed. Science day, sort of, precedes by a week when we're going to get the first big wave of Plaintiff fact sheets and then start the process to collect medical records. But in preparation for today, we went back and looked at medical records where we got a sufficient number prior to consolidation.

And I can get you the index number for Doe versus **Biomet**, but this is one of them, and what we think is going to be a very important issue here, Judge, is --

**MR. LANIER:** Your Honor, for the record, it's been pointed out to me, unclear who the Plaintiff's attorney may be, but the potential HIPAA violation of using an actual name, unless this is a fictitious name and fictitious records. But if this is an actual name and actual records in open court, there may be some HIPAA issues that need to be asserted by an attorney.

**MS. RELKIN:** Your Honor, this is Ellen Relkin. This is my client, and I have that same reaction.

First of all, I could have brought the records for Mr. Doe, if we were going to have a case-specific issue with Mr. Doe, but I really do think it's inappropriate for snippets of his medical records to be in an open court proceeding which will be available to the world.

**MR. WINTER:** Wait a second, Judge.

These were all provided, pursuant to HIPAA authorizations, which would allow their use in a court proceeding. We didn't go surreptitiously and go get these medical records. We got them pursuant to a valid authorization.

**MR. LANIER:** Your Honor, it's one thing to get them pursuant to a valid authorization for them to use in the litigation proceeding. It's another thing altogether for them to be used in an open court proceeding like this at this point in time.

**THE COURT:** Well, let me ask this. Would it be sufficient -- since there's no record being made with exhibits, would it be sufficient to simply make it -- redact the transcript -- I don't know how many you have here -- to a "Doe" or "Roe" or something of that sort -- would that --

**MR. WINTER:** Sure.

**THE COURT:** Would that satisfy the concern?

**MR. LANIER:** That takes care of HIPAA. Thank you, Judge.

**MS. RELKIN:** Yes, Your Honor.

**THE COURT:** Understanding that this is all visual that we've got. I have a copy of the slides and will change mine to -- should we make this one "Doe"?

**MR. WINTER:** Very good, Your Honor.

**THE COURT:** Okay. So we'll redact the transcript to

make it "Doe" whenever we're talking about this particular patient.

**MR. WINTER:** And what this Doe case involves is someone whose left hip was replaced in June of 2010 and, ultimately, was revised in November of 2011. And when you look at those first set of notes, the surgeon was not at all convinced that the pain had anything to do with the hip, per se, but, actually, was related to prior back problems, something that Dr. Klaassen alluded to. And when you look at the operative note, it is very clear that the surgeon was aware of the risk of metallosis and affirmatively says he didn't see any and that everything else was well fixed, and he looks twice and doesn't see any metallosis.

So one of the things, Judge, is we collect the medical records. We think there's going to be a substantial number of cases where, objectively, you look at them, and there's no evidence of metallosis, metal damage at all.

And we think we're going to have a big group of cases where we have people who have problems having nothing to do with the design of their device, and we're going to meet and confer with our colleagues as to whether, you know, that's a summary judgment issue en mass, individually for a group of cases, because the reality is there is a revision rate for every hip replacement. There's no hip system that is even close to perfect over all time.

**THE COURT:** So as I understand -- and correct me if I'm wrong because, obviously, I don't want to put words in your mouth -- you're not disputing that there can be metallosis at the time of the revision; your position is that not every revision shows metallosis?

**MR. WINTER:** That's correct, Judge.

And when we have metallosis, we're going to have to try and figure out why it exists. But if we have a case where it is clear in the record that there's no metallosis, we think that those cases either should be dismissed or don't belong in this proceeding.

And if we were to go to -- I'll call the next one "Roe." We told you this morning that not quite a third of the cases are nonrevision cases, and we have assumed when a complaint is filed, because we don't have many medical records, we have assumed when a complaint is filed that if the Plaintiff, in fact, had a hip revision, that allegation would be in the complaint. Now, if that assumption turns out to be wrong, the numbers are going to change. But, right now, about a third of the cases, there's no allegation of revision. And if we look at these medical records on Roe, this was a hip replaced in 2008, and there is complaints of pain, which can happen. But this patient is worked up by her surgeon, along the lines of looking at the ion levels, doing all sorts of testing, and there is nothing

wrong with her as you could say relates to metal ions, let alone some objective finding that there's a cyst, there's a mass, there's something going on, even like a lot of fluid.

So, again, we think, Judge, after we collect a lot of medical information, we're going to need to have a meet and confer on how we deal with cases like Roe, and we think there are going to be a substantial number of them. And for lots of reasons, we think they should be dismissed, but that's, you know, for another day, and the science of -- there's no -- there's no objective injury here, so, therefore, how could you have a lawsuit.

I want to go back and pick up the time line and FDA's review and oversight here. I stopped at 2004. I'm picking up in 2009. And FDA requested of all metal-on-metal manufacturers data on the performance of their devices. It's called a 515(i) order. And that 515 section relates to how devices are classified by FDA.

And Biomet has been very proactive in providing information to FDA, convening meetings of external experts to see what they think about our data, what they think about the performance of our device, and we've been updating FDA regularly.

And, in 2010, the end of 2010, Judge, we proposed to FDA a post-marketing variance study -- that's the PMS -- for our metal-on-metal products. We wanted to make sure, as we

collected the data, it was in a form that FDA liked, I mean, very, very simply.

And what happened is about five, six months later, FDA sent out a notice -- that 522 notice you've heard the parties talk about -- saying, "Pursuant to our authority, we want all of you, all metal-on-metal manufacturers, to go out and do this type of study, collect data."

And we did that. We've made submissions to FDA. We also actually revised our labeling, again, and I'll show you some of that.

And FDA gave us some feedback, and, ultimately -- I still think this is true, although, I'm not one hundred percent certain -- I think we're the only metal-on-metal manufacturer that has an approved 522 plan in place and have actually -- we've made submissions to FDA regarding our 522 study. We have six-month requirements for reporting, and you'll see a slide on that. Others may have been -- other manufacturers may have been approved, but, until earlier this year, we were the only ones.

And then, in June of last year, there's another meeting of an FDA Advisory Committee on metal-on-metal devices, generally, and there was a lot of back and forth on many of the issues that the parties have touched on today. And whether or not there's a clearance, you know, we'll await further discovery, experts, and whether or not there

is, in certain areas, a definitive answer, or is this something that twenty or thirty years from now we're going to know better, and that's a science issue for **Daubert** that we'll work on a meet and confer to present to you.

And, finally, in January of this year, FDA issued an order saying -- and Mr. Lanier alluded to it -- "Going forward, we want to look at your data regarding your device for clearance, and we want to make, basically, everything a Class III PMA device." It's not precisely stated that way, but that, clearly, is what FDA's intent is.

And Biomet does have clinical data on its metal-on-metal devices. And once FDA publishes what the four corners of the study requirements are, Biomet's going to sit down with FDA and say, "This is what we have. What do you need, want, or is this amount acceptable?"

So there's a process and a dialogue that's ongoing, and we just need parameters, and we're going to sit down with FDA -- they have most of the data already. In fact, they have it all -- and we'll find out what, if anything, we need to do more to then go submit a PMA.

Very quickly, on our instructions for use. And this device, obviously, is one that only highly-skilled surgeons use. This is not something a general practitioner or a general surgeon does. So there's a lot of training and experience that these surgeons go through, and they have to

do a lot of cases before they have the expertise to do these types of complicated surgeries and deal with the individual patient nuances that, many times, present themselves. So these instructions for use are written for those type of people, and you'll see -- this goes back to, like, 2000 -- our instructions for use, going back to 2000, have had this type of information in them.

We talk about metal sensitivity issues. We talk about fretting and the corrosion and problems on the articulating surface. This is something we were telling surgeons about as a possibility more like thirteen years ago or twelve-and-a-half years ago, Judge.

And we didn't leave it at that, Judge, because as time went on, in 2002, as we were seeing evolving information -- because we did do ion level studies -- we added this information to our labeling so surgeons could make informed judgments. And we keep revising that, and every one -- just so you know, Judge, each one of those boxes that has a part has the instructions for use in the box, but surgeons don't need them in the box. They're well acquainted with them. But, literally, every device that is shipped includes those instructions for use.

And, again, we keep modifying them. In 2006 -- as more information becomes known to us, we communicate that because it is an evolving process. I think both sides have

common ground, that information about these types of products, information about any orthopedic product evolves over time.

This is a change that we made in 2008. And this becomes -- obviously, Judge, depending on when a device is implanted, there's going to be a level of information and understanding. But even someone who had an implant in 2003, this data would have been -- some of this data would have been in instructions for use, so they would know about hypersensitivity and ion levels.

And then as the regulatory agencies like FDA and the UK issued statements and recommendations about how to manage patients once they have a device in place, that goes into our labeling so that surgeons can follow their patients, just like that Roe woman, so you can look at it and you have a template. Okay. They come back. What are their ion levels? Okay. Then you take care of that. Or if their ion levels are elevated, what's the next step? Or if they have evidence of an infection, what's the next step? It is probably well-known to surgeons, but it's re-enforced.

So, very quickly, this is where we stand on our 522 study, and ours compares the different devices cross-sectionally from the time they were marketed, because they were marketed at different times, and the control is a group with metal-on-poly, so that's the basic structure,

each device compared to a group with metal-on-poly.

As of, I think, about a month or two ago, there were more than 160 patients already enrolled in our study and their ions levels have been accumulated on a group of them.

Just to go back to this ten percent at ten year. You have broken out there the data on the three Biomet products that you have in this MDL, seven-year data as of November 30th of 2012. So in terms of survivorship, so that means for the Magnum, a little bit more than 95 percent of the devices that were implanted, seven years later, are still in place. For the 38s, it's 89.9 percent.

And just to stop for a second, when Mr. Lanier showed you that one study, Lombardi, literally, Judge, there are a group of surgeons in Ohio, very skilled surgeons, and it is their data for their patients with the 38s that, literally, statistically moved the number, and what remains to be seen is what were the patient characteristics in that group, which we know was weighted toward women, created their revision rate, whether their activity levels, whether it was their bone -- you know, they had problems with their bones to start with, whether they had that anteversion where the femur goes forward, which creates problems. That needs to be analyzed, whether they were morbidly obese.

But the data is what it is, and the total numbers are what you have there. And while the gold standard is 90

percent, acceptable levels are actually below the 90 percent.

And then the Taper, which has been there the longest, 97 percent of them are still in.

And just as reference there, people have been looking at the ion levels, studying them, and a group did a comparison -- it was published about two years ago -- looking at four different manufacturers' devices and looking at ion levels in different groups of patients. And in that study, the lowest ion levels of the four manufacturers' studies was the Biomet metal-on-metal. And, you know, it's for a different day, but one of the things that those authors point out was the Magnum System was the only one with the titanium Taper.

Now, sort of, in conclusion here, earlier I showed you Biomet versus the two registries, Biomet metal-on-metal versus the metal-on-poly in those two registries, and that's the only registry data that we could access to give you these numbers. So if you compare the Biomet numbers to the other registries, metal-on-metal versus metal-on-metal, you can see that the performance -- I'm not going to say significantly better, but it is, clearly, superior, both in terms of the revision rates.

And even when you skew the numbers to say, "Let's take Biomet's seven-year data," which is that second piece

on the bottom, "and compare it" -- because I don't have seven-year data from those other registries -- "five years" -- so we're looking at seven years for the Biomet, five years for the others -- the performance is, clearly, good.

So, you know, I think when we do get into the nuts and bolts of these different designs, the results that we think you focus on for the Biomet products, it's going to show that these are well-performing products, whether you compare them to other metal-on-metal products or compare them to metal-on-poly, which, I suspect, someone may say, at some point, is the gold standard, they're going to compare fairly and favorably, and we think we've laid out four reasons why the difference in the design of the Biomet metal-on-metal explains the good results for the product.

Thank you, Judge.

**THE COURT:** Thank you, Mr. Winter.

Mr. Lanier, I guess, the right to close the science day presentations.

**MR. LANIER:** Thank you, Judge.

Okay. May it please the Court.

Your Honor, I put together a rebuttal PowerPoint. I didn't have time to print it up because I was fast and furious while we were going through this this afternoon.

Originally, I may have messed up, and I don't think

I necessarily did, but I probably just have the bias that I have as a lawyer because I'm sitting on this side of the V instead of that side so my hackles raise and all, and the reason why is, Your Honor, I really tried hard to only give you the useful terms and the important issues. I tried not to be too much of an advocate at all, but I feel like I need to add in rebuttal the and-why-we-think-they're-wrong stuff because I feel like they've really made an opening statement, in a sense, rather than science education. So what I'm trying to do is -- I'm going to do it, briefly, and I'm going to try and do it in as non-biased a fashion as I can in the spirit of what I think I'm supposed to be doing, but I think there are a few things, if nothing else, on the record, I have to address, or everybody will stone me, and I'll never be allowed to speak to you again.

So, first, an issue that has arisen, because of now whom we know they called, Mark Klaassen, Dr. Klaassen, is the way the company uses the medical community, and we'll be seeking discovery on this. Mr. Klaassen, Dr. Klaassen, of course, is a consultant for Biomet. He's a developer for Biomet. They pay him seven figures, by the best of our math at this point, in excess of seven figures, one of a number of doctors that get paid millions of dollars to be spokespersons on behalf of these things, and we're going to want to get into that. It will be a necessary element for

everybody to understand who it is that's talking and what they have to say.

Second issue on rebuttal, failure rates. A lot has been said about failure rates during the presentation. There are a couple of things we want to underscore. First, while Dr. Klaassen, a Biomet developer, may be happy with a one percent annual failure rate, that is, actually, inordinately high, and that's not an acceptable failure rate for much of the industry.

Toward that end, Biomet sends out a Dear Doctor letter where Biomet is informing, at the insistence of the FDA, certain data. In their Dear Doctor letter that Biomet sent out, they specifically showed that for the M2a-38 the failure rate, at seven years, was in excess of one percent a year. You're down to almost your 90 percent after just seven years, so you've got a failure rate, Your Honor, that far exceeds their one percent that even -- that we take issue with, but, even still, that their own doctor says is acceptable.

If you go to what Mr. Winter showed at the end, I think he's got apples and oranges on his revision rates.

So, for example, if we look at the ELMO in this regard -- if I could go, please, to the ELMO.

**MS. KIRKWOOD:** (Complies.)

**MR. LANIER:** If we look at the ELMO, this is Slide

Number 61 that was presented.

Maybe I'm messing up here.

**MS. KIRKWOOD:** It takes a second to warm up.

**MR. LANIER:** Okay. I'm sorry. I should have given you some warning.

If we look at their Slide 61, what we can readily see here is that they're comparing the Biomet Magnum at 95.47 percent to persuade you that they beat the industry standard because the rest of it is 96.2, at five years, or this, whatever that may be, is another figure that's 91.2 after five years, and they start cherry-picking data.

And the reason I call it cherry-picking is because they take their Magnum at seven years when -- if we go back to the PowerPoint, please -- we know from the PowerPoint itself, if they had looked, instead, at the M2a-38 after seven years, they don't get the 95.47 percent that they gladly show you.

What they need to do is recognize that this is an issue for the Court, but it's not an issue disposed of by the argument of either side. We'll both need to bring experts, hash through all of these statistics. And, ultimately, when we do so, we'll do it not only with Biomet's rates, but we'll compare it to the other companies. Because while the Biomet development surgeon says that one percent per year is fine, that failure rate is higher than

other products that have actually been recalled from the market for being too unsafe.

For the larger head sizes, in excess of thirty-two millimeters, the revision rate for the Biomet M2a, at five years, is over one percent a year. At seven years, it's over one percent a year. If you compare it -- whoops, I'm going the wrong way -- to the Strycker System, which only had 4.2 percent, at five years, Strycker recalled that product because that was deemed too excessive. The Zimmer Durom cup, 6.4 percent, also recalled.

So, next issue, next rebuttal issue -- turn the page -- anecdotal stories versus full data.

We did not bring you anybody as a surgeon or anything like that who could tell you anecdotal stories of "I had a patient where this happened," or, "I had a patient where that happened." And I don't fault the doctor. He's not a lawyer. He doesn't understand **Daubert** and that anecdotal stories aren't allowed in the courtroom like that. But what I want the Court to understand is, the question is -- you know, in this situation, we're being told by their doctor that poly is bad and metal is good, but we read their press releases and the Biomet press releases say they've got poly that exhibits this incredible wear, compared to other poly liners, and they've got Vitamin E poly, and they've got all these different things.

And this doctor may say, "Well, I had a case where I had metallosis in a metal-on-poly implant, so metallosis is not exclusive to metal-on-metal," and I'm sure he did, because what he said was, "I had a metal-on-poly, and the poly had cracked and worn out," and then it became metal-on-metal because the liner's gone, and the metallosis doesn't come from metal-on-poly. It still comes from the metal-on-the-metal. It's just, if the poly is cruddy, and it's a bad poly or something and it breaks, then, yeah, you're going to have metal-on-metal. And if a surgeon doesn't pick it up quick enough, you'll have metallosis, but that doesn't mean that metal-on-metal is just as good as metal-on-poly. That's what these global rates are for, as opposed to an anecdotal story, and that's the reason why the study done by Molli that showed these rates are so important because it shows the Magnum, it shows the Taper, and it shows the 38 compared to the same company's poly, and those are the failure rates. And this is not something we did. This is something that's done with their product. And so is there an anecdotal story here and there? I'm sure there is. I'm sure I could bring some, too.

Now, I've added this bold here that says, "Different revision in monoblock and poly liner," because one thing the surgeon did not tell you, when there's a -- that's all right.

This is the cup. This is the ball. If your cup is a poly liner, the metal outside of the cup goes into that acetabular, the hip, and then you put a plastic liner inside it. Then you've got a metal ball.

Now, in that event, if your plastic liner fails, yes, you have a revision surgery, but what it is is you unzip the leg, you go back in there, you pull out the plastic liner, you put in a new one, and you zip them back up.

Not so, the revision surgery, when you've got a monoblock, which is one of their products, where you don't have the cup holder and an insert. It's all one piece. Then, you've got to go in, and you've got to chisel that sucker out. You've got to take -- and the bone's grown into it from the back, and it is a massive surgery. Then you've got to re-ream it, because you've done that, and take a bigger cup to make anything fit.

And so what's involved in this -- there's not just some thin line between, well, metal-on-poly, metal-on-metal. You say, "Tomato." I say, "Tomato." It's not. There's a huge difference.

Next. I do think it's important for the Court -- and I do think we'll have testimony toward this end, that all of these surgeons, with maybe the possible exception of this doctor -- and he didn't tell us what he's doing

today -- all of these surgeons aren't using this anymore. All of these surgeons aren't using metal-on-metal for a very good reason.

This "Going, going, gone" article, those are Biomet surgeons that wrote that. Those aren't people who were working for the Plaintiffs' Bar trying to seed the literature with wonderful things for me to use in front of a jury. Those are Biomet surgeons. Nobody is using it.

This doctor quoted Dr. Schmalzried. Schmalzried was paid -- I don't know -- ten-plus million dollars by DePuy for being one of their developers on their product. Schmalzried won't even use it anymore. He's testified to that end in their trials. Nobody's using it.

Next issue. Corrosion and wear. And now I'm into what Mr. Winter was saying more directly after lunch. Mr. Winter talked about passivation, and passivation is a word that's a term of art in the corrosion industry worth noting, worth explaining. Passivation. All metal-on-metal hip implant manufacturers claim that they have the secret and best way to passivate or protect their metal from corrosion. So you may have titanium that Mr. Winter was talking about on the sleeve. You may have some other oxidizing covering or porous coating over the ball.

And I appreciate that Mr. Winter says, "We've got the absolute best way to protect our" -- "to coat it so

that our product is not subject to corrosion."

But, in all candor, as lawyers working on every one of these hip implants, every one of the companies says in their sales literature, to every one of the doctors, "Hey, we have the very, very best."

They all think they do, and you'll have to parse through and a jury will have to parse through and see who does, but, regardless of who does, passivation only works when the coating is in place. And any time you have wear, which you've got with metal-on-metal, it wears out the coating, and so you're right back into corrosion land.

Case specific. Doe and Roe. I want to say a couple of things about this. I want to say, first of all, we didn't bring our bellwether cases of horrendous situations to present to the Court. This isn't the time or place.

Second, with all due respect to Mr. Winter, metallosis is only one reason these hips fail. They fail for other reasons. The slide that I had put up before of metallosis also had pseudotumors. Pseudotumors is also known as fluid accumulation, something you will find on the medical records of John Doe. There was fluid accumulation. That is what some doctors use as terminology for pseudotumors. So you can't just immediately dismiss this because the guy had stenosis on his L3, L4 back level, and the surgeon thought that might be a problem, and then he

redoes the hip. Surely, the surgeon didn't redo the hip if he didn't think it needed to be redone. But, regardless, you've got lots of other reasons these hips can fail and need a revision. Metallosis is one. Pseudotumors is one. A dislocation is one. A loosening of the implant is one. So we've got to look at those carefully and not just pell-mell dismiss them.

Now, there are a number that are nonrevision cases, and this is something that the Court needs to address carefully because this will be an issue when you decide the bellwether protocol, if you reach that point.

I would suggest to the Court that nonrevisions are not over yet. There's a reason why we don't look at the revision rate after one year and call it quits. You look at the revision rate after one year, two years, three years, five years, seven years, ten years because the opera is not over until that wonderful lady sings. And just because there wasn't a revision yet in some of these Plaintiffs doesn't mean that there won't be a failure and a revision. It can take time. All the revisions do not come within the first six months of implant. In fact, most of them don't.

And the reason that's important is because Mr. Winter, in one breath, will tell you that all of these nonrevisions just need to be thrown out and that that silly Plaintiff's lawyer shouldn't even be bringing them, and

then, in the next breath, will put up his statute-of-limitations argument that says, "If they didn't file within this many days, within this many years, of this New York Times article, then pour them out for that."

So the Plaintiffs' Bar is left in a position of having to file those cases of those clients who have an issue but may, for some reason or another, not yet have had the revision surgery, and it's just a matter of time. Some of them, thankfully, statistically, won't need that surgery, but many of them will.

Almost done, Your Honor.

Clinical testing for the FDA, next rebuttal point.

With all due respect to Mr. Winter, he spoke in such a way where it almost gives an indication that there was clinical testing being done for these devices for the FDA, and we've pulled up their 510(k) applications.

Here's one for the M2a-Magnum System in 2004, and it specifically says, "Clinical testing was not used to establish substantial equivalence to predicate devices."

Now, was there some clinical testing that may have been done for some reason or another? Perhaps, in one situation, for one device, in 1995. But was there clinical testing that the FDA would use and rely on for these devices to establish substantial equivalence? No.

Last rebuttal point, warnings and usage.

So Mr. Winter puts up -- as he's closing, he says, "We gave these Biomet metal-on-metal instructions for use." This was one of his slides. I have tried to make a copy of it quickly on the spot and put it into my PowerPoint because I was amazed that he would use this slide. This is one of the slides, when we get to the liability case, that I'm going to use. In the liability case, this is my slide, that they weren't warning right. This is my slide that talks about the relatively low amount of particles, when, in fact, it's 20,000 times as many particles. This is my slide that says, "Although mechanical testing demonstrates that metal-on-metal articulating surfaces produce a relatively low amount of particles." That's not at all what the testing proves. You know, the adequacy of this warning is something that will be a huge issue in this case, as well.

You've been very patient with me today, and I thank you, Judge.

**THE COURT:** Thank you, Mr. Lanier.

I'd propose we take a short break before we get to the argument on the dismissal motion.

I realized, today, that I did not set, in the setting, forth a time limit on the arguments. Ordinarily, I go with fifteen minutes per side on a single dismissal motion. I don't know who's arguing.

Will that work for you folks?

**MR. WINTER:** It will for us, Your Honor.

**THE COURT:** I don't know who is --

**MS. RELKIN:** Yes, Your Honor.

**THE COURT:** Okay. I don't know if everybody is staying for the argument. We can set the next conference at this point, if you would like.

**MR. LANIER:** That would be helpful.

**THE COURT:** Would that be best?

Hold on a second. I have to -- I promised I wouldn't bring you folks in on another Notre Dame game so let me get their schedule up here.

Okay. Since I'm not seeing too much of what's going on now, let me ask you folks, first. We've been going six weeks.

Is that what we should hold to, more time, less time? I don't know where you are at this point, as far as the need for these conferences. Obviously, I don't want to make you travel to South Bend just for the heck of it.

**MR. ANAPOL:** Your Honor, right now, we have a bunch of meet and confers on a number of issues. I don't know that we need one, necessarily, in six weeks, maybe either teleconference or let you know if issues arise, but we were thinking, you know, if Your Honor is on board with this, September.

John?

**MR. WINTER:** I think that would work, Judge, and maybe what we'll do is we'll jointly report to you sometime -- we'll pick a date in July and say, "Looks like we're okay, Judge. Let's go to September."

Does that work?

**MR. ANAPOL:** That works, yeah.

**THE COURT:** Let me give you the September date so that those who are planning ahead can get here.

If we do a Monday, you shouldn't be tied up with the home games, but, just in case, they're September 21st and 28th, so, I guess, logically, we might want to get ahead of that. Although, the 23rd and 30th are wide open.

**(Discussion held outside of reporter's hearing.)**

**THE COURT:** People leave on Sunday. I think Monday would --

**MR. LANIER:** The 23rd works good from our end. We're all echoing it.

**THE COURT:** Okay.

**MR. WINTER:** The 23rd will work for us, Judge.

**THE COURT:** Well, let's grab it, set it for 9:30.

**MR. LANIER:** And, your Honor, do we sit in your box, if we come in Saturday for the game?

**THE COURT:** You're talking to the wrong person on that.

**MR. LANIER:** Oh, okay. All right. Just checking.

**THE COURT:** Let's see who's Northwestern's play.

Okay. 12CV2391, and I'll set it for 9:30 as a status conference.

And then you folks want a date in July to let us know how things look? How about July 29th?

**MR. WINTER:** That works for Defense.

(Discussion held outside of reporter's hearing.)

**THE COURT:** And this would just be a --

**MR. DASSOW:** Conference call?

**THE COURT:** Yeah.

**MR. LANIER:** That would be great.

**MR. ANAPOL:** Any time, Judge.

**THE COURT:** Nine o'clock that day then?

**MR. WINTER:** Work for us, Judge.

**THE COURT:** That will be a telephonic conference.

Let me ask the Plaintiffs to place the call because I don't know who all you're going to want to have in on the call.

**MR. DASSOW:** I'll arrange it, Your Honor.

**THE COURT:** Okay. Okay. Why don't we take a fifteen-minute break, and then we'll proceed with the arguments on the dismissal motion.

**MRS. POTTS:** All rise.

**(All comply;**

**Short recess taken.)**

**CERTIFICATE**

I, DEBRA J. BONK, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

DATED THIS 26th DAY OF JUNE, 2013.

S/S DEBRA J. BONK

DEBRA J. BONK
FEDERAL CERTIFIED REALTIME REPORTER