12 jurors present.

One final note before we begin, you must not receive information about this case outside the courtroom. You are not to perform any tests or experiments outside the jury room. You're not to visit the scene of this incident and you're not to do any research in connection with this trial. In examining the evidence in the case, you may, of course, use your common sense and rely on matters of common knowledge and common experience.

Now is the opportunity for the attorneys to make their opening statements. I again remind you what the attorneys say in their opening statements is not evidence. But it's offered to you as a guide to assist you in understanding how the evidence in this case might unfold. All right.

Mr. Kelly, you're making the opening statement for the plaintiff?

MR. KELLY: Yes, Your Honor.

THE COURT: You may do so at this time.

MR. KELLY: Thank you, Your Honor.

Good morning. The maker of any new medical device that's intended to be implanted in human beings must make sure that before they sell it for use in people it is safe and effective. If they fail to do

that, then they're responsible for the harm and loss that results. On December 5, 2007, Mr. Loren Bill Kransky became one of 33,000 Americans to have the ASR XL metal-on-metal hip prosthesis implanted in him.

On February 20, 2012, Mr. Loren Bill Kransky became one of somewhere between 6 and 7,000 Americans so far to have the ASR XL taken out of him in a premature and painful revision surgery because it was defective. Because it had shed metal debris and metal ions both into the tissue of his hip and to his bloodstream. The ASR XL hip was dangerous and it was defective in its design and we will prove that through experts and lay witnesses and the defendants' own employees. But you don't have to rely only on us because the highest management levels of the defendant, DePuy, a Johnson & Johnson company, made that decision themselves on August 24, 2010, when the highest level executives determined this is a defective product that could cause health problems.

Ladies and gentlemen, you will learn in this case that the very defects which caused this product to be recalled in 2010 existed when it was first put on the market in Europe in 2004. It wasn't changed. It wasn't modified. The novel and physical characteristics that existed then, existed throughout its time on the market.

And you will learn that from DePuy's, a Johnson & Johnson company's, own internal analysis in September of 2011, 37 percent of the ASR XL metal-on-metal hips will fail in four and a half years. And you'll hear from a man named Paul Voorhorst, who is a director of biostatistics for DePuy that during the same time frame, one of their own products called the Pinnacle hip, which the president of the company will testify on video before you, was a suitable hip for 99 percent of people.

Andrew Ekdahl, president of the company, will tell you that another hip they made at the same time from 2000 to today, Mr. Voorhorst will tell us had a failure rate of less than 1 percent per year. We will demonstrate for you that this hip, this medical implant incorporated dangers to an extent beyond which any reasonable doctor would have anticipated or expected and that the defendant, DePuy, a Johnson & Johnson company, never told the doctors in America what they knew about the device's propensity -- that's a big word, the device's likelihood, the fact that the device would generate and shed excessive metal ions.

Let me tell you the story of what happened in this case. First, let me talk for a moment about hip surgery if I can.

May I have slide 6, please.

Artificial hip surgery, you will hear in this case, is one of the most common and the most successful surgeries that have been done in the United States in the last 40 years. I think you'll hear that it's somewhere in the top five with cataract surgery. I can't remember which one is one or two. And through the years, different makers of artificial hips have come up with solutions that orthopedic doctors who are the people who do the surgeries learn to do and do successfully. And historically artificial hip replacement is done with four pieces. There are four parts to the surgery. There is a stem which goes into the big bone in your leg, the femur, after the ball is cut off. There is a ball. It could be made of metal or ceramic. Typically one of those two. That -- and you'll hear this word in the case -- articulates or rubs. Think of a hinge in a cup. The cup historically has two pieces. This is why it's called modular, and this case is about the cup.

Every hip that is made must fulfill two principles.

Slide ten, please.

No matter what it is made out of, it must satisfy two conditions. It must stay firmly in place, and it must not shed harmful amounts of debris into the

body. No matter what it's made of, every manufacturer must satisfy those conditions for the reasons I'll talk about in a second. When the doctor does the hip surgery, it's typically for arthritis. Sometimes it is for an accident. But generally in folks 50 to 65, the issue is arthritis. Pain develops when the hip wears out. And the doctor's job is to make sure to the best she or he can that the new hip fits correctly in the person it's going into. And so the first part of the surgery is to go in to what's called disarticulate, actually dislocate the hip, to use a reaming tool that's like a big drill, and to ream out an area to place this cup. I'm going to use this visual presenter for a moment if I can.

I want to show you the traditional components. This cup is made of metal, and it is called the liner. Again, we're talking here about traditional surgery. The liner is metal, and it has holes in the back. The holes serve two purposes. Number one, when the doctor reams, the doctor can actually look through the holes and make sure that as the cup is seated in the hip, it's against good bone. And if the doctor is at all concerned, the doctor may use a screw or more to fix it in the bone.

The liner may be plastic, may be ceramic, may

be metal. Typically liners were plastic. The liner is completely smooth so that after someone puts in a screw or something that's not smooth, the liner fits in so that this ball in this liner rotates freely with no wear because everyone in this case is going to tell you the key in developing any hip is to prevent wear. Every orthopedist who you'll hear in this case will tell you that doctors, their most significant concern is have the hip surgery last once. They only want to do it once. They want it for life because there are complications. There are risks. There are downsides you will hear to doing this surgery more than once, and you will hear that they include the first time you're in the bone and tissue, it's the best chance to get it right.

The chance of infection or other complications increase the next time you have to do it. People are obviously older the next time, and as we get older, the risks of having complications increase. This concept of four parts modular worked for many, many years, and, in fact, ladies and gentlemen, you will hear that from 2000 to today, DePuy Orthopaedics' most successful hip is a modular hip with holes in the back and a liner with no wear. Or very, very little wear and revision rate of less than 1 percent a year.

Were there some downsides to this? There was

some percentage of people who might have wear from the plastic, and over time perhaps as many as 1 percent of people per year could have plastic wear, something called osteolysis, that would affect the bone and require revision. But by 2000 and certainly by 2005, hard plastics that you'll hear about were developed that wore almost as well as ceramic or metal. And I won't get into the science. I will just tell you that science was involved.

The key here is that this is smooth. There is no abnormality whatsoever. Nothing. No ridge, no groove, no nothing.

In 1998, an English surgeon developed a hip that was made out of metal, both parts. And he began to get a following in Europe, and he was selling hips, and Johnson & Johnson, you will see, wanted to get some of that market through its DePuy subsidiary. DePuy's an orthopedic company that Johnson & Johnson purchased. DePuy had been in the orthopedic business for a very long time, and they have a facility in Leeds, England which is where they make their hips, and they have a facility in Warsaw, Indiana which is their headquarters.

Let me just stop here and say there will be a lot of videotaped testimony in this case. To the extent that we can provide live testimony, we will do so, but

you will see that we have had to travel to England and we've had to travel to Indiana and we are not capable of bringing people here from outside of California by subpoena; so much of the testimony we will present to you will be preserved on videotape, and we will ask your endurance and your forbearance consistent with, I'm sure what you'll hear from the judge, that that testimony is the same as if the person is live here.

DePuy decided they were going to enter the market for a monoblock cup. Remember, two pieces. Mono, one. With a bigger ball and a bigger cup because they had someone on staff who had done some theoretical calculations that this kind of an arrangement would last for a very long time. It would be placed on a stem. The ball and head would articulate, and based upon their calculations, this would be superior to plastic because the metal was hard, and it wouldn't wear, and it would be perfectly lubricated. They also suggested that it would reduce perhaps the possibility of dislocation. Actually, you'll find in this case that by 2006, they were producing a modular hip that reduced the risk of dislocation.

Let's talk about this and let's talk about the cup because the cup was new and different. It was unlike anything they had made before. They had no

personal track record with this cup.

Could I have slide 7, please.

In making the ASR XL, they went from four pieces to three. The central difference was not in the size, but in the cup. Now, doctors place these cups in people generally it's somewhere between 45 and 50 degrees. You'll hear 45 to 55 degrees and that's degrees up and down to vertical, but all the doctors will tell you that a cup has to be placed in an individual patient in the place that's best for the patient, that everybody is different, that women actually have steeper pelvises being further straight up and down because of the way they're built for child bearing.

Some people, depending upon age or size or weight or prior injuries or arthritis, when they're laying on the table, the doctor is required to find the place that's best for the patient; so the patient at the end, will have the best result of being able to walk. And so in designing this, the first thing that they had to do was make sure you could put this in anybody. You can't market one size only fits one place because this was sold for all people. And so the cup, like the old cups, had to be capable of being used in people tall and short, slim and fat, male and female in the ways that

the doctors thought they best fit in terms of their angles.

Second, the cup doesn't have holes, and so they knew when they built it there was going to be an issue with visualization. Is it getting put all the way in? Third, with no holes are no screws, and the problem with no screws -- to go back to slide 10 -- the cup must stay firmly in place. Why? Well, two reasons. One, if it doesn't, bone won't grow into the back of it, and this surface on the backbone is actually supposed to grow into, and if it moves, bone will never grow and it will be painful and if this is moving and the head is moving, it's not working right. It's not articulating smoothly. It's rubbing in the wrong way. And that is the second problem.

It must not shed harmful amounts of debris into the body. This cup -- can I have slide 9, please -- had unique design features DePuy had never, ever put on the market before. The one-piece cup, not modular, no screw holes, and it had something that wasn't present on the plastic modular cups.

May I have slide 11.

They decided that in order to put it into the patient, they would create a tool that fit on the inside of the cup but to accommodate the tool, they had to

create a ridge in here. And that ridge -- that ridge which is right here actually did two things. It reduced the amount of area for the ball to smoothly rub on because the cup itself started out at less than 180 degrees. It started at 160. And when they put in the groove, you'll hear during the case they took away what is called bearing surface. The bearing surface refers to this is supposed to bear on that. It becomes a bearing because the last thing anyone wanted to happen was for this to generate wear.

What we know and they knew and the engineers knew was that in normal walking, the ball and the cup are not always going to be in perfect alignment, that people kneel and sit and lay and sleep. They walk and climb stairs. With all of those motions, your hip behaves differently. So there are times when your hip is going to be at or near the edge, and when you put hard on hard on the edge, you risk generating metal debris which is much different than plastic. You will see throughout the pendency of this case that even before this device went on the market, people were concerned about metal debris because when DePuy put it on the market, they had not made a determination of what was safe.

They had not determined if it was safe or not

safe. They had established no acceptable level for metal wear or metal ions in the human being patients. And as I'll discuss with you in a minute, this metal wear came to be called edge wear, and you will probably hear that more times than you want over the next three weeks. Edge wear or rim wear from the inserter tool.

Slide 11.

And you will learn that the inserter tool could have technologically been put on the outside. In fact, ultimately they sold a cup where it was on the outside, that it was never a problem with the modular cups because remember they had an insert that was completely smooth that fit inside the metal. There was no edge. So when it came time to design this cup with the fancy inserter, someone needed to be thinking about what was going to happen in the real patients.

When you make anything new, widgets, alarm clocks, refrigerators, medical devices, you go through a process that's been around for 50 years. It's called failure mode and effect analysis. It sounds fancy, but really it's a fancy term for this concept. A bunch of really smart people get together who know something about what we're going to build and they sit around and say, "Okay, what are all the ways this might go wrong because part of our job is to figure that out before we

ever make this or sell it? How many ways can this go wrong?"

In order to do that, you need to know something about the process. So let me talk to you about the DePuy process.

For a minute. This process started in 2001. And actually, in 2001, DePuy went out and hired doctors on a royalty basis. May I have slide 5. They hired five doctors from around the world, perhaps it was six, but two were from California, which is why we're here. One, Dr. Schmalzried from Los Angeles; two, Dr. Vail from San Francisco.

And these were doctors who were idea people who participated and whose testimony you'll see, and were, as we note up here, royalty based; which means for each one that is sold, there is a percentage paid to the royalty-based surgeons.

These doctors -- it happens that this device, two different kinds of heads were made. One was called resurfacing, that was mostly done in Europe; one was called the total hip, which was done both in Europe and the United States.

You will hear during the pendency of the case that these doctors were primarily interested in resurfacing, but the same cup for both, the same size

head. We're here to talk about total hips. So these doctors, along with some DePuy people, got together, and DePuy did the failure mode and effect analysis in England -- and before we get there, to put this in context, the failure mode and effect team produced a hip in people that had the following failure rates. We're going to compare this to all other hips.

May I see slide 12.

So these are -- you'll hear from experts. We don't have a national joint registry in the United States. In some countries they do. These are 2012, which means data through 2011. So for 2006 through 2011, all hip implants, every maker, every design, every color, every shape, 2.61 failure rate.

When we compare to that, we see that for the England registry -- this up through 2011, five years, 2006 to 2011 -- the ASR failed at almost 22 percent, more than one in five people. DePuy's own internal data, which I've shown you, in less than five years, 37 percent. Australia at seven years, 44 out of 100 people.

Now, this is the person who was in charge of the failure mode and effect analysis. This gentleman's name -- and you'll see him on videotape -- is Magnus Flett. Mr. Flett was charged with the obligation of

getting this group of people together, these smart people, and saying, "Okay, what are all of the ways that we think that if we make this and sell it, it might fail and hurt somebody? Might it be loose? Maybe they won't place it correctly. Maybe there will be metal debris."

The person that was chosen to do this standard form of analysis that's done in the Army and NASA and GM and Toyota and anyone else who makes things, was a man who had spent his entire career designing truck brakes. His specialty was hydraulic truck brakes. He had worked for a company called WABCO for something on the order of 14 or 15 years and finally came to DePuy in 2000, and had no background in the assessment or evaluation of a metal-on-metal hip implant.

I want to play just a smidgeon of the testimony, the evidence that we'll produce in this case.

(Videotaped testimony of Magnus Flett played as follows:)

"QUESTION: I wonder if we can chat for a couple of minutes about your early employment, that was before you got to DePuy, had you ever done any work on the design or evaluation of a hip prosthesis?

"ANSWER: Before DePuy?

"QUESTION: Yes.

"ANSWER: No.

"QUESTION: Had you ever done any work as an expert in the evaluation of safety or efficacy of any medical product?

"ANSWER: Medical device, no.

"QUESTION: Before you got to DePuy had you done any reading or study or research on any features of acetabular implants?

"ANSWER: No.

"QUESTION: Femoral implants?

"ANSWER: Before DePuy?

"QUESTION: Yes.

"ANSWER: No.

"QUESTION: Any work in any way, shape or form about the way that femoral implants or acetabular implants work?

"ANSWER: No.

"QUESTION: Do you have any understanding, background, training or education in the risks of metal ions in the blood of human beings?

"ANSWER: No, I don't.

"QUESTION: Before you got to DePuy

did you know anything about the risks of metal debris in the bodies of human beings?

"ANSWER: Prior to DePuy, no, I don't.

"QUESTION: Did you know what a normal level of cobalt and chromium in a person's blood was?

"ANSWER: I'm not sure anyone in 2000 knew what that would be.

"QUESTION: Well, did you know?

"ANSWER: I did not."

(Videotaped testimony of Magnus Flett concluded.)

MR. KELLY: So the team doing the failure mode and effect analysis determined, under the leadership of Mr. Flett, based upon comparison to modular cups, thinking about how this might go wrong, without considering the ways it differed, that the risk of metal debris being produced, very small; the risk of cup loosening, very small; the risk of excessive wear of any kind, very small. And completed their analysis without identifying the very risks of shedding excessive metal debris, which ultimately required Mr. Bill Kransky's revision.

But it didn't stop there. Because once the failure mode and effect analysis was done, DePuy decided to do additional testing. But they decided to do testing only on machine hip simulators. They tested only at the perfect angle of 45 degrees, and they knew that doctors treating patients, that patients come in all shapes and sizes, that the doctors' obligation is to get this for that patient's normal anatomy, and that based on some studies more than half of all implants placed were outside the 45-degree range because people are different.

And so they tested this cup on a machine at 45 degrees. They did not simulate any other angle. They did not simulate something called microseparation, which you'll hear about, which is the way people walk when your hip changes. They did not simulate a normal person's gait.

They chose not to do what is called a controlled clinical study on people to find out for themselves what would happen if we put the device in people. And we had various groups of people at different centers watched on strict criteria over some period of time, "So we know for ourselves that our product is safe."

And they tested only one size of these cups.

The cups come in, I believe, 12 sizes, and the size cup they tested was not the size cup that was put in Mr. Bill Kransky.

And the person in charge of that was an engineer who, I believe, will be here to testify whose name is Graham Isaac, and he knew and he will tell you that the way to find out how a new product will behave in human beings is to scientifically and clinically test it in human beings and see how they do. That gives you, as a manufacturer, knowledge that you can't get from a machine.

Dr. Isaac -- if I said Mr., I apologize -- may have slide 17, please -- will be here. He has advanced degrees. His title is a distinguished engineer. He is an expert in a field you will hear a fair amount about. It's something called tribology, t-r-i-b-o-l-o-g-y. Tribology, believe it or not, is the study of things that slide against each other. Tribologists study the way to make sure things slide smoothly and don't wear.

He is the person who decided a test at 45 degrees on one size was enough. And he will tell you that he knew clinical tests, a controlled study that he was capable of putting together with his colleagues for the internal knowledge of the folks at DePuy so they could personally assure themselves they have a safe

product, would tell you more than a single machine test.

(Videotaped testimony of Magnus Flett played as follows:)

"QUESTION: So let's come back to clinical trials. You said that that would be actually one way to determine how the new product performs; correct?

"ANSWER: That is the ultimate test.

"QUESTION: It is the ultimate test. It's better than machines, isn't it?

"ANSWER: That is correct, yes.

"QUESTION: Because the machines, you know from your 20 years of history, don't always accurately predict what's going to happen in human beings.

"ANSWER: The machines perform tests, and that's what it does. It doesn't do anything more than that.

"QUESTION: The machines aren't people yet.

"ANSWER: True."

(Videotaped testimony of Magnus Flett concluded.)

MR. KELLY: And so with the Magnus Flett failure mode and effect analysis, with the 45-degree

angle test, the device, the cup, was released to be used by the designing surgeons in 2003, and by 2004 there were some problems that were actually sent outside of DePuy. You'll hear that they were sent to a person in Germany.

And then in 2004 the cup, with both the resurfacing and the ASR XL hip, were released to surgeons in Europe, in Spain, India, because DePuy and Johnson & Johnson are worldwide. You will see through this case that there is a coordinated network of salespeople and internal people who follow how products are doing, both in the United States and elsewhere.

And having released the product in 2004 on the general European market, as early as January of 2005 -- slide 18, please -- they are starting to hear that some doctors have questions and problems.

From the sales department, Dr. DeSmet from Belgium says, "It is a prosthesis with zero follow-up. Will it last two years, three years? Nobody can tell you. They have only theoretical based stuff. It's not even science based."

You'll see that this went to people in the know; Mr. Flett and Andrew Donn, who you'll learn is another engineer.

In June, in 2005, Bridget Clune is marketing,

Johnson & Johnson IE, that stands for Ireland, J&J IE, working in Europe, telling Mr. Flett, hey, I am quite concerned about our failure rate. I have a report from Emad in the Middle East and Jose in Spain.

All of these reports have been technique related, and you will hear as we go forward that every time there is a problem the Johnson & Johnson response is to blame the doctor and claim it's technique, to never look inward, do we have a problem with our product? The failure in the seating of the cup. Have we had a history of failures over the last year or is this phenomenon related to the wider rollout?

And so what she wants to know, the wider roll out, we're giving it to all doctors now. Now we have to have our ears perked up. When we only gave it to our designing surgeons, they are experts with the product, but the product has to be made available and useful for everybody who's been to medical school, not just the people who are on the design team.

This -- and you'll see these -- during the course of the case is an example of so-called surgeon design team minutes, because periodically the DePuy engineers would meet with the doctors they were consulting with.

And here, September of '05, a year and three

months before Mr. Bill Kransky ever had an implant, somebody, because they're hearing it from the doctors, is asking, "Should we have a toxicologist on this team who could talk about metal ions?"

Because one thing you will hear is throughout the period of development and design, no one on the design team was a toxicologist. No one on the design team had a background in toxicology. No person on the design team had specific knowledge about what elevated levels of cobalt and chromium would do to a given patient.

Although, the noise was building, and you will see more e-mails and more comments like this, DePuy decided, let's go ahead and launch in the United States. They did not, before launching in the United States, do any additional testing to determine how much metal would be generated. They did not decide to pause and say, let's do some clinical study. They did not decide to tell anyone that they were having these complaints.

In January they prepared this brochure, and this brochure actually was prepared under the leadership of DePuy's current president. Because in 2006, when the device was launched in the United States, the person in charge of marketing was named Andrew Ekdahl. And Mr. Andrew Ekdahl has, over the years, become the

president of DePuy after he launched this product.

And he will tell us on videotape, and it is a long tape and I implore you to try and stay awake and alert while we play it, because he is out of state, and so we must present him on tape -- that everything -- his testimony will be everything in this brochure was required to be accurate and complete; and that when they sold the device -- and this was for doctors and it was to begin a conversation -- he knew that the most important thing to doctors was to convince them the device would have as little wear as possible.

He knew and DePuy knew that the thing that was most important to the doctors was to prove to them that the device wore as little as possible because that meant, first, that it was safer, and second, that they'd only have to do one surgery on their patients.

You will hear, both from the doctors who took care of Mr. Kransky, Dr. Wendt and Dr. Hansen and Dr. Craig Swenson, who actually was the biggest DePuy user of the ASR in San Diego over a period of time, the most important thing to doctors treating their patients is to do it once and do it right, and code for doing it once and doing it right is "low wear".

So they said to the doctors in their brochures, "ASR XL bearings produce a fluid film interface that

results in a lower wear rate than previously achieved in metal-on-metal articulation." The translation there, no one has a device that wears less.

And in the same brochure they visually demonstrated that bearing surfaces are fully separated and the load is fully supported by the lubricating fluid. Although it's not called out in the middle, there is an additional -- the doctor who told them in middle of the page, "The ASR XL metal-on-metal articulation is designed to allow a thin film of synovial fluid to flow across and lubricate the bearing surfaces to achieve lower wear rates."

What they were telling the doctor was we have perfected something. Synovial fluid is kind of a honey-colored fluid in your joint. If you thought about it like oil, although it is not like oil, it is what keeps everything moving. It's the normal lubrication that your body would make for a regular hip. And they suggest here that if you put this in there will be a tiny, microscopic film always there that will prevent wear because this ball is riding on the thin film. There is no discussion of the risk of getting to the edge.

The American doctors, including the doctors at the Montana Veterans Administration Hospital where

Mr. Bill Kransky was treated, they heard about it. They saw the advertisements. And you'll hear that the way DePuy and Johnson & Johnson operate is that all across the country there are sales representatives, and these sales representatives have close personal relationships with the physicians. They actually go to the surgeries. They assist the doctors. They bring the product. Those sales representatives brought this information to the doctors.

It's 2006. Bill Kransky has not had his surgery yet. Now, Bridget Clune again, and now something here has happened. DePuy has a program where all over the world they have something called KOLs, key opinion leaders. Because DePuy knows that the best way to have other doctors buy their product is to see what famous doctors do.

And in the Netherlands they picked a famous doctor, a key opinion leader; his name, Dr. Bom. And Dr. Bom actually was working on a study for DePuy. They trusted him to work on a study for them. And Dr. Bom, on June 28, 2006, a year and a half before Bill Kransky's surgery, stands up and says, "Dr. Bom made an official statement during our ASR study meeting. He declared that with his experience with the BHR and ASR, his results show a significant failure rate for the ASR.

He will not use the ASR anymore."

So this isn't some doctor who's invisible or untrained or young or inept. They now have information from the local representative to the head of the marketing to the engineer. We have a big problem here. A key opinion leader for an entire country is done with us, with the ASR. It continues to be sold.

Let me just pause for a moment before I start 2007, because in January of 2007 -- and I don't have a slide -- DePuy launched two new products. Those products were what are called ultra-high weight polyethylene. I missed a word. But they now had a plastic that was almost as hard as the metal. And they were marketing it. It was called Marathon and a sister product called Ultrex for those doctors who didn't want to use the metal.

Starting in January, there were two additional products on the market that were suitable instead of the ASR. By May, another surgeon design team -- now it's May and DePuy acknowledges, we have to increase the articulating surface. We have a problem. The problem is high ions, the problem is excessive wear, and we realize that the cause of it is the groove. The ball is rubbing on the groove, particularly in people who you can't get it exactly to 45 degrees on; 50 percent or

more of the patients whose natural anatomy doesn't permit, because the steeper it is, the more it's rubbing.

We know, they know there's a problem. They don't tell any United States doctors. They don't tell anyone anywhere.

It's June. Another -- it's June in England. A salesman reporting again to marketing and to the engineer, "I presented in Cornwall," which is a city in England. "A doctor got up and attacked us on serious design flaws of the subhemispherical cup causing much more edge rim loading, the wear." Now it's not even news anymore. We know. What do we do? We keep selling it.

In June, DePuy tests a new cup because they want to go to a bigger size. And the object of the test is to set the criteria and do the test. So this test required that this new ASR XL, bigger than anything they've had so far, had to perform at least as well as the Pinnacle. So they did the test.

And it says, "The acceptance criteria was set such that the ASR should wear at a similar or lower rate than the Ultamet." And the Ultamet is the modular with a metal insert. And the test results showed when they did that, the ASR, the wear, was 16 times greater. The

metal wear was 16 times greater than the Ultamet implants. 2.52 millimeters cubed to .15 millimeters cubed.

They knew that they had a product now, when they compared their two metal implants on their own test, that it was producing 16 times as much metal. They acknowledged, we do not meet the acceptance criteria for this test. And I want to show you two things.

Would you go back to slide 23 for a minute?

Remember when they made the brochure? Well, you'll see it in evidence, but when they talked about wear, it's right here. And do you see that little blue line? That's supposed to be the ASR. What they told the doctors, the ASR's wear was only 1 cubic millimeter. Now they had a test result that was 2 1/2 times that, in addition to being 16 times the test itself.

Could we please, then, return to the last slide?

What did they do? They did not report this to American doctors. They did not make an announcement. They did not tell anyone. They changed the test, and they tested it against some other things until they found one it could beat.

In September, they know there's a problem.

We're still three months from Mr. Bill Kransky's surgery. There is no information given to the doctors. So they have an engineer evaluate it, another engineer. You'll see him on videotape. He reconfirms, "Rim loading is a phenomenon where the wear area crosses over the edge of the bearing surface leading to massively increased wear. Rim loading can occur when a component is oriented at a steep angle."

No one is told. The information is not shared with the doctors. But it is shared with people in marketing and engineering and the people responsible for the ASR's design. And they make suggestions. "Significantly redesign the ASR cup to reduce lateralization, remove the internal groove. B, redesign to remove the internal groove. D, optimize the groove to reduce the effect on wear." They keep selling.

In November, a doctor in Australia, Rodney Dalziel, who had already contacted them the prior October says, "I was simply appalled by your most recent communication. By now, as I told you earlier, the response to all the failures is, 'These are surgeon errors. The surgeon has used bad technique. They have picked the wrong patient.'" There was never any guidance given to surgeons on what patient was the wrong patient.

He says, "To imply that suboptimal patient selection and surgical technique have contributed to the premature failure is absurd. This is a standard technique of companies to offset the responsibilities."

And on December 5, 2007, Mr. Loren Bill Kransky undergoes the ASR implantation at Fort Harrison in Montana. You'll learn that 1 of 11 citizens in Montana is a veteran, that Mr. Kransky is a veteran, that Mr. Kransky is entitled to VA benefits. That is where he gets his healthcare and that's where he had this surgery.

And that surgery, as I'll talk about in a few minutes, was done by a doctor named Peter Wendt who was a board certified orthopedic surgeon. He had gone to the Medical College of Wisconsin. He had done an orthopedic residency. He had worked for the VA for a number of years. He actually taught at the University of Wisconsin Medical School.

And at the time that that surgery was done this is what people were told by DePuy about metal wear. "Histological reactions have been reported as an apparent response to exposure to a foreign material." That's like saying, some cells will react to something. We don't know the reaction. We don't know the foreign material. It's generic.

"The actual clinical significance of these reactions is unknown," when they know that they have been getting reports of pain and revisions, the histological reactions that are an apparent response to the foreign material have unknown clinical significance.

"Implanted metal alloys release metal ions into the body." That's a true statement. But what is not told is how much they know about the ions and the cup placement and the frequency and the complaints.

In 2008 DePuy publishes this book. This book is an attempt to try and get surgeons to put all cups in at 45 degrees. And it shows in pictures, and this picture was selected by DePuy, of what it looks like when you have excessive metal wear and ion release in a hip joint.

Mr. Kransky underwent his surgery at Fort Harrison. As we'll talk about in a minute, he ultimately had his DePuy ASR XL in place for 50 months; and during that time, he would have any number of other health problems, which it is not claimed are related to the DePuy hip. But he had problems related to the DePuy hip, which he should not have had at the same time he was having everything else going on. You will hear that these are problems he should not have had because of that hip.

It's 2008. Now, they're told by a surgeon who has done more than 200 of those procedures in Europe, "Yesterday" -- and this comes from Graham Isaac, the scientist I talked about -- "we were given some clinical data which compares metal ion levels between BHR and ASR. It shows that under certain conditions ASR is susceptible to extreme metal ion levels, but in the hands of the same surgeon, the BHR doesn't have that problem," And the BHR is another product.

And here is the concern: "The concern, it has the potential to seriously affect our business." There is no mention in this e-mail anywhere, which you'll have in evidence, of a concern about the potential of hurting people.

"We need to discuss at the earliest possible opportunity as I believe we need to start an ASR upgrade sooner than our plans had suggested." And remember, all the way back in the beginning of 2007 we're talking about, the surgeon design team, "We need to get rid of the groove. We need to fix this." We're now in April of 2008.

In May, Paul Berman, who you'll see on video, the head of U.S. marketing, he has responded to that e-mail I just showed you. "We will ultimately need a cup redesign, but in the short-term, manage

perceptions." Mr. Berman's concern is that we tell the doctors, we manage the perceptions. There is no mention here about managing the patient.

And now it is now a day later, two days later, we're talking about the design change. We're going to do it. The surgeon design team, again -- now it's almost a year. We're going to remove the groove. We have to do it. Isaac explained, DePuy is looking at removing the groove from the ASR cup because the groove reduces the bearing surface.

But now marketing, Mr. Berman again, "Out in the field one of our people has confirmed that another company's reps are telling surgeons we're making a change. We must keep the project under total wrap. I propose any future reference to ASR II will be called Project ALPHA."

Not only are the doctors and hospitals and other people not told about what is really happening; now the marketing department is applying a code name to the safety change that has agreed to be made.

In August, again, we need to reduce ions. In August, there is a safety assessment, and the safety assessment takes into consideration something that doesn't have anything to do with safety. It considers what is the average selling price for all of our

products?

You will hear that whether or not each ASR made $800 more in sale price should never have been a consideration. This was their premium brand. You will see here, ASR XL, $4,300 -- excuse me. $4,400. Plastic and other metals here, substantially less.

The device remained on the market, but sales started to tip down. And when sales started to tip down between July and August of 2008, the DePuy managers and executives got together and re-reviewed the fix to the cup, the removal, the secret redesign, Project ALPHA, and decided the business case for the project could no longer be justified. There was no mention, no analysis of the number of patients who might go on to still get the device and suffer the elevated ions and the excessive metal.

And on top of all of it, knowing what they knew about their own testing, knowing about the elevated ions, knowing that they had actually decided to change the device, and then canceled it, in December of 2008 they bought a full-page ad in the single most important journal in the United States for orthopedists, *The Journal of Bone & Joint Surgery* -- and actually, it was stuck to the front -- advertising that the ASR XL had a 99.2 survivorship. They said nothing about the ions,

nothing about the metal wear.

In 2009, or at the end of 2008 after that came out, a surgeon wrote and said, "We have abandoned the ASR cup due to 15 to 20 percent failure rates. I've never had so many patients, and it's affected my reputation."

And even more troubling, ladies and gentlemen, a day later, the current president of DePuy gets an e-mail from Dr. William Griffin. Dr. William Griffin is a royalty surgeon for DePuy. He works on other projects. He never worked on the ASR. You will hear everyone describe him as a thoughtful, competent, and excellent doctor. He writes because he is personally concerned about the device. He's at a place called OrthoCarolina, which is in North Carolina.

And Dr. Griffin has actually figured out all three problems of the ASR. Most importantly, the articular surface is too small. "The 160 degree low profile shape, the increased dome thickness, the recessed rim of the articular surface, all combine to dramatically decrease the effective articular surface. This leads to edge loading. This design makes a cup put in at 50 behave like a cup put in at 75."

And what he's talking about, of course, is the higher the angle, the greater the likelihood for the

wear. And he recommends, in the balance of this, to Mr. Ekdahl, take it off the market.

It's now March. Now DePuy's own people in Australia, Mr. Raph Pascaud, "Look, the issues seen with the ASR are most likely linked to the inherent design of the product. This is something we should recognize." This is a DePuy person.

The number one qualified surgeon in Northern Ireland, a personal friend of Mr. Graham Isaac, writes in March, "This is the tip of the iceberg. My concern is there are many more patients out there having problems."

Now we do an analysis. Should we take it off the market, and how should we? In September of 2009, you will hear that DePuy decides, we're going to stop selling it. We're not going to recall it, but we're going to stop selling it. But let's analyze first, if we stop selling it, how much business will we lose? And that's the purpose of this analysis in September of 2009 in Europe.

Can you tell me what would happen for ASR and ASR XL rationalization if we do one of these things; take them off the market first, wait six months, wait six months, leave it on, leave it on only for doctors he refers to as "big cutters." They decide that if we

leave it on for six months and wait, to move our customers to Pinnacle. We're going to move them to the modular device. Remember, it's been on the market since 2000. If we wait that long and we move them over to our other product, we'll lose 15 million.

Dr. Beverland began in May of 2010. Now he's talking to other doctors. He's finally figuring out, "This has been the worst problem I've faced in my surgical career. It has been a real nightmare."

And then finally, the recall. And they claim that we're doing this because we've just got some new information that shows a higher-than-expected revision rate at five years. We are issuing a voluntary recall.

At that point, as I said, there are some 33,000 patients that had the DePuy ASR XL implanted. One of those was Mr. Loren Bill Kransky. Mr. Kransky is a native of Mile City, Montana; went to high school there, grew up there, went to the Air Force after high school, did four years in the Air Force, did two tours over seas, one in Vietnam.

While in Vietnam, Mr. Kransky was exposed to Agent Orange. As you'll hear in this case, he developed health problems related to that that are not related to his hip and that we don't claim are related to his hip.

Mr. Kransky is the grandfather of five and

great-grandfather of two. He's here with his wife and two daughters, both of whom happen to be nurses, as you'll hear.

Mr. Kransky had a hip surgery in 2002 with a modular hip. It was also done at the VA. It was done by another doctor who rotated. The Veterans Administration hospitals have doctors who stay four or five years and rotate somewhere else. In 2002, in the right hip, he had had arthritis, and so he had a modular hip replacement. That hip is still in place today. Metal liner, plastic insert, ball like this, never had a problem.

In 2006 he retired. Mr. Kransky's work history: Went to high school, went in the service, returned home, and there was a little corner market, if you will, a convenience market in his town that he worked in in high school, which he bought and called Bill's Minute Mart.

Mr. Kransky and Mrs. Kransky operated that store for ten years, at which time they sold it. Mr. Kransky then actually went to college, thinking that he might become a minister. And, too, while he was in junior college at that time, he actually became involved with a program called Kairos. The Kairos program involved Christian ministering to people in jail.

He volunteered in Montana, and the more he learned about it, he learned that there was no such program in the neighboring state of North Dakota. He ultimately became a state employee in the state of North Dakota, worked there bringing that program there, worked as a correctional officer for some 25 years for the state of North Dakota before returning home to Montana.

In 2006 Mr. Kransky retired. He had -- as a person who was 60 years old at that point -- no shortage of problems that he had over time, some related to Agent Orange, some related to other things. He retired with a disability in 2006 from the VA and the social security. He wasn't disabled in the sense that he couldn't walk around.

You'll hear from him that one of the big problems, though, was that there was a big stairway at the jail that he worked in in North Dakota that was tough to navigate.

I will tell you also that Mr. Kransky, born in 1947, was a smoker who smoked his entire life, began smoking when TV ads said it was good for you. I'll also tell you that there's nothing in this case to connect smoking to his hip, to metallosis, to metal debris; that Mr. Kransky during his life had other problems. He has diabetes from the Agent Orange. He's had cataracts.

He's had other issues as well.

But you will see actually -- because we asked and we wanted to make sure this wasn't going to be a problem in this case. We actually directly asked the other side, do you claim that something about Mr. Kransky's past health history made him an unsuitable person for the ASR XL. And so we asked, "Do you contend Loren Kransky was not a suitable candidate for receiving the DePuy ASR XL, knowing that he had a lot of health problems," and the answer was "Defendants state they do not contend that Loren Kransky was not a suitable candidate for receiving the ASR."

And fearing that someone would criticize him for smoking or some other thing that was not appropriate, we asked them, "Do you claim or contend that Mr. Kransky" -- 56, please -- "was himself in any way comparatively negligent," which means that he did anything wrong, that he was at fault.

And they responded under oath, which is an admission in a case like this, "Defendants state that they do not contend that Plaintiff Loren Kransky was comparatively negligent."

Now, let me talk for a second here about Mr. Kransky's hip surgery. It was done in 2007. It was done by Dr. Peter Wendt. Dr. Peter Wendt, as I

mentioned, is a board-certified orthopedic surgeon. Dr. Peter Wendt was trained at the University of Wisconsin. You will see him on videotape. He currently practices in Anaconda, Montana, about 900 miles from where he was before.

I'm told than in Montana 900 miles is not very far, but he moved from Fort Harrison to Anaconda. He practiced in Milwaukee; he taught at the medical school; he worked at the Veterans Administration, and from 2007 to 2011 he was at Fort Harrison, which is the VA hospital which is where Mr. Kransky went.

He learned about the ASR XL from his product rep, because he uses the DePuy products. He was told by the product rep that it was a good product. He believed that it would last longer. He will testify that if he had known there were not clinical trials done on people, he would not have used it, that if he had known what DePuy knew about the amount of ion and metal release, he would not have used it, that in Mr. Kransky's case, he believed he put it in correctly, he did the surgery correctly; that postoperatively, an X-ray was taken, that the hip itself is identified as being in good position, that it's positioned somewhere between 56 and 60 degrees, which for Mr. Kransky, was the appropriate place to put it.

And, of course, we had to make sure that there's not a claim that Dr. Wendt did anything wrong, and so we asked that question. May I have slide 54. "Do you contend that Dr. Wendt failed to follow any warnings or instructions that you provided in connection with the DePuy ASR hip implant?"

Response: "Defendants state they do not contend that Dr. Wendt failed to follow any instructions provided by the Defendants in connection with the implant."

And then we went a step farther because we wanted to know if they were claiming that any of Mr. Kransky's healthcare providers or physicians had failed or -- in any way to follow any warning or instruction, and they told us they do not contend that any of Mr. Kransky's healthcare professionals, Dr. Wendt or his primary care physician Dr. Trotsky, or his orthopedist, Dr. Hansen, had failed to follow warnings or instructions provided by the defendants in connection with his hip implant.

Now -- 55, please -- Mr. Kransky, recognizing that he was done with working for the state of North Dakota, was looking forward to retirement with his wife. He had some hobbies. You'll hear about them. He loved driving. He loved classic cars. He loved working in

his yard. But he also had other health problems.

During the time that he was -- had the ASR XL, you'll see that he underwent other health problems, which included having one of his kidneys removed in 2009 because he developed something called transitional cell cancer. He had chemotherapy for that, which focused his attention on beating the disease.

He had some recurrence and underwent radiation treatments. Ultimately, the Mayo Clinic people told him, "Mr. Kransky, we're stopping. It's not working. You're not going to survive this." Mr. Kransky did not accept that. He returned home to Montana and received additional chemotherapy treatment. You will see that he is here today.

In 2011 he had an aortic aneurysm, which the aorta is the primary blood vessel that supplies blood to and from the heart. The aneurysm is a leak. The repair is actually done, these days, you can do it by what's called laparoscopic.

He had a left renal artery stenting, which means that you take a stent, you put it in the artery. It sends blood to the kidney to make sure that the blood flow is normal.

He had a stroke. Let me say, ladies and gentlemen, that in this case there is no claim that

these things were caused by the ASR XL, but there is also no claim that these things caused metallosis, high chromium, high cobalt, or the need for William Kransky to go through what he went through with his hip.

You will hear that Mr. Kransky, throughout his life, had diabetes secondary to his Agent Orange exposure, but which he continued to work until he retired. That he had had a heart attack, that he had high blood pressure, that he had high cholesterol.

And one of the things we have the benefit of this case is we have the benefit of the videotaped testimony of his primary care doctor, a Dr. Thomas Trotsky. Dr. Trotsky has been with the VA for 14 years in Mile City. He is Mr. Kransky's doctor from 2007 to the present. There is no one in this case, ladies and gentlemen, who knows Mr. Kransky better, who has seen him more frequently, who knows more about his medical condition, than Dr. Trotsky.

You will see -- 58, please -- after the hip went in, that Mr. Kransky made visits periodically to Dr. Trotsky and told Dr. Trotsky, "This left leg is giving me problems." And you'll also see that during many parts of this chronology Mr. Kransky is being treated for other things, for cancer or for renal stenting or for other problems. So there is not the

referral to the orthopedist to go get this checked out. The aim here is to get this better. By 2010, in the winter, Mr. Kransky learns of the recall and he brings it up, but it's not on his mind because he's treating with the cancer. By 2011, you'll see that the frequency of the visits increased. He's falling, has pain in the left hip.

Finally, you'll see that Dr. Trotsky refers him to an orthopedist, Dr. Brooke. Dr. Brooke believes that Mr. Kransky should get the hip revised, but now Dr. Wendt has moved to Anaconda; so Mr. Bill Kransky is looking for a local doctor to do this. He checks with the doctors in Billings. The doctors in Billings do not want to revise a patient who they did not put the ASR XL in. He has a difficult time finding a physician. He ultimately talks to a lawyer, and that lawyer said to him, "I actually know a physician that you may want to talk to, an orthopedic surgeon." The orthopedic surgeon is Dr. Hansen, is the person who ultimately did the revision. Dr. Hansen is also a board-certified orthopedic surgeon. Dr. Hansen is practicing in Powell, Wyoming, 90 miles from Billings. Dr. Hansen agreed to see Mr. Kransky as a favor to Mr. Johnson. Mr. Johnson and Dr. Hansen, as I said, have been friends for 20 years. And Mr. Kransky went to see Dr. Hansen.

Dr. Hansen evaluated him in October of 2011. And at that time, he thought, "You know, I think you are a candidate because we've done cobalt and chromium blood levels, and you are complaining of pain and you are complaining of grinding and popping and what we find when we do your bloodwork" -- let's just put those slides up for a minute -- is that in September and October of 2011 bloodwork is done. As you'll see here, Mr. Kransky's chromium and cobalt are elevated.

The recall notice suggested anything over seven parts per billion is concerning and should be monitored closely. You'll hear from doctors who will testify here -- in fact, I believe one of the doctors will testify for the defense that the current recommendation is patients with anything over two parts per billion.

We believe that the likely probable range here of the cobalt is between 47 and 53. The 109 is probably an artifact because it spikes out of range. In either event, the 47 and 53 are somewhere between six and seven times normal. Dr. Graham Isaac and everyone who testifies here will tell you that cobalt is cytotoxic. That means cobalt kills human cells. Cobalt is toxic. Dr. Hansen saw that. He did Mr. Bill Kransky's examination. He knew that he was having a complaint of popping and grinding in the hip, and he wanted to do

surgery, but Mr. Kransky was not well enough because his health had been declining; so Mr. Kransky went back and had to spend three months getting strong enough to have this surgery. His doctor, Dr. Trotsky, will tell you on videotape that he believed that Mr. Kransky, at that point, in that time, was being poisoned by the ASR hip, that Mr. Kransky's condition was such that he was cachectic which means he was thin, his color was wrong and, ordinarily, you would not do surgery on such a person, but in this case, he believed that if the surgery wasn't done, that Mr. Kransky would die. This is part of his testimony on that point.

(Videotaped testimony of Dr. Trotsky played as follows:)

"QUESTION: Do you recall how he progressed during that admission?

"ANSWER: I recall thinking many times he was never going to be able to have surgery but what eventually was the slow gradual improvement to the point that in conjunction with Dr. Shannon, a nephrologist, and myself, Dr. Hansen thought Bill was a suitable candidate for the surgery. However, what was really driving the equation was everyone's

conviction that unless the hip was replaced, Bill would die, and I know he discussed with Dr. Shannon and both Dr. Hansen also that despite what Dr. Moore had said, we thought we're dealing with a man who was slowly dying from being poisoned."

(Videotaped testimony of Dr. Trotsky concluded.)

MR. KELLY: And the surgery ultimately was done on February 20, 2012, and Mr. Kransky got better after the surgery. He actually recovered after the surgery. Now, before we came here, we needed to do our job and make sure that the surgery was caused by the metallosis and Dr. Hansen actually had a picture taken during the surgery.

Exhibit 61, please.

This is what was shown at the surgery. The black area in the middle will be described by Dr. Hansen as metallosis and he will say that he also found something else in there that's called a pseudo tumor, not cancer, but pseudo tumor means like a tumor meaning a collection of extra tissue that wasn't supposed to be there that was produced by inflammation. You will recall earlier I showed you a picture from the DePuy

brochure in 2008 showing metallosis.

If we could go to the next slide, please.

You can see that the metallosis in both pictures is present, and Dr. Craig Swenson, one of our experts who will be here, will tell you someone who's done more than 200 of these, someone who was an opinion leader for DePuy, someone who was personally visited by the president of DePuy at one point to make sure he was a satisfied customer, will come here and tell you that what Mr. Kransky showed at the time of his operation is classic metallosis from the DePuy ASR XL.

After Mr. Kransky's surgery, he developed something called a hematoma, and a hematoma is when blood actually collects somewhere. It wasn't in the hip. It was in his thigh, and the postoperative bleeding collected there and the hematoma, sometimes we think of it as a bruise. It's a collection of blood. At some point, someone cultured that and they found that in the hematoma there was something called staph epidermis which is the staph on your skin. We needed to make sure that the reason this happened was not infection.

So Dr. Hansen was asked and you'll hear him testify that before the operation, Mr. Kransky was worked up for infection. He did not have an infection.

That during the operation, a culture was taken. That culture was sent to the lab. After two days, there was no infection. That after the happening of the surgery, he did not believe there was an infection, that when he was in the wound, he did not see anything that's called granulation tissue. Granulation tissue typically occurs when we see an infection in place. And finally -- slide 63 -- the only positive culture that anyone ever saw was after the surgery, in the hematoma, days later, from an organism that typically comes from the skin.

Dr. Hansen, you will hear -- I mentioned Mr. Johnson earlier. Dr. Hansen, you will hear spoke with Mr. Johnson about Mr. Kransky's case, and Mr. Johnson suggested to Dr. Hansen that it would be helpful if he inserted in his description of the surgery that he thought that this was more likely than not some legal terms to try and help Bill Kransky get the procedure covered for payment because he was outside the VA, and Dr. Hansen did that. Dr. Hansen also will tell us in this clip right now that if someone was to suggest that this was an infection, he would disagree with them.

(Videotaped testimony of Dr. Hansen played as follows:)

"QUESTION: And so if an expert was hired and an expert offered the opinion

that it was an infection in Mr. Kransky's hip that caused the need for this revision, would you be critical of that?

"ANSWER: I would disagree with it. Again, other people have a lot of information and expertise in this kind of an area. You show them a picture of all that black stuff inside the wound, they can't say that was caused by a low-grade staph epidermis infection, subclinical infection because that doesn't happen. There's only one way you can get that black stuff in the wound, and that's by metal ions staining the tissues."

(Videotaped testimony of Dr. Hansen concluded.)

MR. KELLY: Again, like so many of these witnesses, you'll see the entirety of Dr. Hansen's testimony on videotape. Let me just have your attention for a few more minutes, and I give you my word I will close. We are bringing to you an expert whose name is Dennis Bobyn. Dennis Bobyn is one of the foremost tribologists in the entire world. In fact, in some of DePuy's own literature, they cite Dr. Bobyn's papers.

Can I have Exhibit 66.

He's been the director of an orthopedic

research laboratory. He's collected explants. He's examined explanted hips for more than 30 years. He's co-authored papers. There's actually an award given. It's called the Otto Aufranc award. I had never heard of it. It's given in Europe. He's the only person in history who's won it six times for publishing papers on the science of tribology. Dr. Bobyn is going to be here, and Dr. Bobyn is going to testify that the ASR has design defects that cause it to fail at a much greater rate than other hip implants, that whatever the claim the benefits were, were outweighed by the risks and that Mr. Kransky's ASR XL hip implant was defective. And Dr. Bobyn has seen the implant, and he, on his own, has taken pictures.

He will come and explain the wear on the rim that he was able to photograph and identify without the use of highly sophisticated equipment. He will talk about the kind of testing that was available, the things that could have been done, the things that could have been learned, the actions that could have prevented the need to have this product on the market as late as December of 2007 or even in 2006.

Can we go to black, please.

Mr. Kransky, as you will hear and see, had complaints in 2008, he had complaints in 2009, he had

complaints in 2010, he had complaints in 2011. He fell. It hurt. Yes, he had other problems going on, but his retirement did not need and should never have been complicated by this. We will present evidence that his medical expenses to get him well and fit enough for surgery and then to get through the surgery and then to basically spend two months until April of 2012 overcoming the hematoma, going back to Miles City, spending two months in the hospital was something that no person should have had to endure to get well enough and strong enough.

Mr. Kransky has other health conditions. You will not hear us ever claim that some other health condition is relevant here. The only thing that is relevant is the four years, the 50 months that his life was affected and should not have been, and at the end of this case, we will come back to you and ask you to make a substantial award for what he has endured, and we will ask you in fairness to make an award of punitive damages to send a message and make an example of the defendant for the behavior in this case which persistently ignored what they knew or they persistently failed to tell anyone, the doctors, to share with the doctors making the patient decisions what they knew; so the doctors could make a fair choice for their patients because

everyone here will tell you the doctors relied 100 percent on DePuy, and the patients relied 100 percent on the doctors, and the doctors had the right to know for their patients. And the information was kept from them so that they could make intelligent decisions, and in doing that, DePuy acted in a way that showed they were indifferent, that they were not concerned with the additional people who might be hurt, especially in light of the fact that they had a perfectly suitable alternative device that sold for $800 less.

We will ask you to make an award in a substantial amount that is sufficient to get the attention of Johnson & Johnson and DePuy based upon the evidence you'll hear of their financial condition and their earnings so that they don't do this again. And we are confident that the evidence presented will demonstrate that the device was defective, that there was a failure to warn, and that the conduct here was both oppressive and malicious.

Thank you, Your Honor.

THE COURT: All right. We will take our morning recess.

Let me see counsel at sidebar without the court reporter for just one second.