IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION.	MDL No. 2272 Master Docket No. 11 C 5468 Chicago, Illinois December 19th, 2016 10:03 a.m.

TRANSCRIPT OF PROCEEDINGS - Status
BEFORE THE HONORABLE REBECCA R. PALLMEYER

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(Proceedings heard in open court.)

THE CLERK: 11 C 5468, In Re: Zimmer NexGen Knee Implant Litigation for status.

THE COURT: Good morning, ladies and gentlemen.

Why don't we get your appearances for the record.

MS. GABROY (telephonically): Good morning.

My name is Rebecca Gabroy for Plaintiff Phillip Castro.

THE COURT: Good morning.

MS. GABROY: Good morning.

MR. MORRIS: James Morris on behalf of Plaintiff Goldin.

THE COURT: Good morning, Mr. Morris.

MR. MORRIS: Thank you.

MR. RONCA: Good morning, your Honor.

Jim Ronca for the plaintiffs' steering committee.

THE COURT: Good morning, Mr. Ronca.

MR. MILROOD: Good morning, your Honor.

Tobi Milrood for the plaintiffs.

THE COURT: Good morning.

MR. HOUSSIERE: Good morning, your Honor.

Charles Houssiere for Ms. Wilson.

THE COURT: Thank you. Good morning.

MS. PIERSON: Good morning, your Honor.

Andrea Pierson for Zimmer.

Also with me is Peter Meyer. We'll be addressing the general NexGen matters. (Unintelligible) is also here as well, your Honor.

MS. BUTLER: Abigail Butler for Zimmer.

MR. MANDLER: Good morning, your Honor.

John Mandler for defendants.

THE COURT: Good morning.

Okay. We have on the agenda for today -- the parties have proposed a discussion first of the *Wilson* matter, *Eckman*, mediation issues, Craig Watson's case, an update on Track 2, and then scheduling status conferences for 2017.

In addition to our general status in this lead case, I have individual statuses set in several cases, including -- in addition to Mr. Watson's case, *Turner v. Zimmer*, *Feehrer v. Zimmer*, *Reed v. Zimmer*. And I expect that we will turn to *Goldin* and the pretrial issues relating to that case as well.

So let's begin with the joint proposed agenda for the conference that relates to the lead case. I think the first matter on that agenda is the *Wilson* update and deadlines in that case.

MR. HOUSSIERE: Yes, your Honor.

We have an agreed -- oh, I'm sorry, Judge.

We have an agreed amended scheduling order, and it

tracks the initial notification of docket entry and minute order of July the 11th. The only -- there's some additional things we added to it for designation of lines and page of depositions and so forth.

The only thing that's really changed from the minute order is we changed the date for the replies to the motion *in limine*, the *Daubert* motions, and summary judgment to the 21st of February, and then the hearing will be the following day. Otherwise it's essentially the same with some additional information that both Zimmer and we have agreed to.

MR. BENNETT: Your Honor, may I approach?

THE COURT: Sure.

MR. BENNETT: I have the scheduling order.

(Document tendered.)

THE COURT: Okay. So the plan is that you will get reply memos to me on the 28th, and then we will hear -- we will have a hearing the following day?

MR. HOUSSIERE: The replies will be on the 21st --

THE COURT: I am sorry. The 21st.

MR. HOUSSIERE: -- and the hearings will be the following day, on the 22nd.

MR. BENNETT: And the question we have, your Honor, is, do you have that date available, obviously?

THE COURT: Let's take a look. I think you will

recognize that I may not have every word read if I am not getting it until the 21st. Let's take a look at the schedule for that. February is looking kind of crazy right now.

MR. BENNETT: And, your Honor, if you want to, obviously, move the hearing date back to give yourself more time to read it, that's fine. The only concern we had was giving you time to issue an opinion before the trial date.

THE COURT: Which is -- what is the trial date in this -- in *Wilson*?

MR. BENNETT: March 13th.

THE COURT: March 13th.

MR. BENNETT: Jury selection is March 10th.

THE COURT: Right. So we would really, really need rulings pretty promptly.

You know what? Let's go ahead and leave it as is. Let's leave it on the 22nd as you have proposed. I think that should work.

I do -- the complication I have is a criminal trial that is set to start on February the 6th. Exactly how long it is going to go, we do not know. I think the parties have somewhat exaggerated the length. At least I am hoping that is the case.

So let's assume that we can have the arguments on the 22nd.

MR. BENNETT: Thank you, your Honor.

THE COURT: All right.

MR. HOUSSIERE: Thank you, Judge.

THE COURT: What other *Wilson* issues do we have?

MR. BENNETT: None.

Just an update. Dr. Corey's deposition is going forward on Wednesday. That's the plaintiff's causation expert --

THE COURT: Okay.

MR. BENNETT: -- expert.

And our engineering expert, Dr. D'Lima, who you will recall from the *Batty* trial, he'll be deposed January 17th, I believe -- or January 18th.

MR. HOUSSIERE: Yeah.

MR. BENNETT: So we're moving forward with discovery, the fact and expert discovery. And so there's no other issues to resolve at this point.

THE COURT: All right. Great. Thank you.

MR. BENNETT: Thank you.

MR. HOUSSIERE: Thank you, Judge.

THE COURT: All right. I think the second matter on the agenda is an update on *Eckman*.

MS. PIERSON: Good morning, your Honor.

Mr. Morris and I are here on *Eckman* this morning.

Just one development in the *Eckman* case that, unfortunately, we both believe really impacts the schedule.

In that case, there is a single orthopaedic surgeon who both implanted the product and revised the product. His deposition was scheduled to take place about ten days ago, and the afternoon before the deposition, his mother passed away, so we had to reschedule the deposition.

THE COURT: Right.

MS. PIERSON: Given the holidays, though, he is unavailable to be deposed until January the 6th. We've taken that date, but as a consequence, that really impacts all of the deadlines that follow.

So I have been communicating with Mr. Morris and his co-counsel about a new schedule. I think we collectively believe that the best solution would be to move the trial setting, if possible, to May. If we do that, then we can provide to you a proposed schedule that essentially backs everything up about three weeks.

Apologies that we need to make that request, your Honor, but, unfortunately, when there's only one surgeon who is responsible for the two index procedures, it's a pretty important witness.

THE COURT: Right. Right now we have it set for April 10th.

MS. PIERSON: That's right.

THE COURT: I think it is fine to move it. February and March are starting to get really, really dense,

so I think maybe that -- it will work to move this to May in any event.

Now, on dates, I think the -- I think any week would work except for the 22nd of May.

MS. PIERSON: Got it.

So we'll work together to come up with a proposed schedule, and then we'll submit it to your staff this week for your consideration.

THE COURT: That would be great.

MS. PIERSON: Okay. No other things to report on *Eckman*. Everything is going well.

THE COURT: Okay. Great.

MS. PIERSON: Thank you.

MR. MORRIS: Your Honor, may I be heard?

THE COURT: Sure, Mr. Morris.

MR. MORRIS: My daughter graduates from high school sometime in May or June. Regrettably I don't know exactly the date.

THE COURT: Well, I am sure you will get those dates from her, and we will make sure that you are there.

MR. MORRIS: All right. Thank you, your Honor.

THE COURT: Good. Sure.

All right. I think the next matter on the general agenda is a report on mediation.

Have you continued your efforts there, Mr. Ronca?

MR. BENNETT: Yes, we have. And we have some dates we're looking at, and we've narrowed it down to one of two mediators -- you may recognize them -- Mort Denlow and Dennis Burke. And so we're working to get those scheduled, and we need to talk to them about dates they're available. We've looked at dates that we're available, but we needed to, obviously, make sure that they're available.

The one thing we would like to have ordered by the Court is a deadline for whoever is going to be participating in the mediation, to get us certain records. And there's a list of records. I'm not sure how you want to handle that, whether I should e-mail those to you or I can read them on the record right now.

We both talked about it, and we've come to an agreement on what we need, but we do need something by January 21st to give us time to analyze them and make sure that they're appropriately in the mediation.

THE COURT: Mr. Ronca, anything you want to add?

MR. RONCA: Thank you, your Honor.

We understand that we're going to make a serious attempt at mediation, but right now it's been very amorphous as to where we're going with that.

What Mr. Bennett and I talked about was setting some deadlines for getting certain steps done that are necessary if you're ever going to have a successful

mediation.

So we need to pick a mediator. We need to pick dates when everybody is available. We need to --

THE COURT: Right.

MR. RONCA: -- meet with the mediator before the mediation to find out the structure.

The defendant needs records on all cases. In some cases they have them all; but in other cases, they may not. We need that to see who could participate in the mediation. And we need some -- we're going to need some court deadlines of these things because otherwise -- you know, we've been five years in the litigation. The 5950 cases have been sort of sitting in the back of the bus all this time, and we need to move ahead towards a resolution, and in order to do that, we need to set some dates.

Now, we're willing to work with Mr. Bennett and agree to some dates and offer them to you, because it's really only going to be stuff for us to do and report back to you, or we can talk about them now.

THE COURT: Why don't we talk briefly about them right now.

MR. RONCA: So one thing we have to do is agree on a mediator and find out when they're available.

So when do you want to do that by?

MR. BENNETT: Let's do that by next week.

MR. RONCA: By December 30th?

MR. BENNETT: Yeah. I mean, obviously, if we can't reach them or if they're busy because of the holiday, it may go over, but that --

MR. RONCA: Let's just make --

THE COURT: That makes sense.

MR. RONCA: -- like a soft deadline.

THE COURT: Right. Agree to mediator by December 30th.

MR. RONCA: Agreeing to what participants in the mediation need to supply to Zimmer.

THE COURT: So agree to a records requirement of some kind, a disclosure --

MR. RONCA: Sure.

THE COURT: -- requirement.

MR. RONCA: Yes.

THE COURT: That sounds -- that sounds good.

Can we say that that would happen by -- well, I would think that by, say, January 5th or 6th.

MR. RONCA: Have the list or have the records supplied from all the cases?

THE COURT: The list of what --

MR. RONCA: The list --

THE COURT: -- is necessary.

MR. RONCA: We could probably have that by

December 30th also.

THE COURT: Oh, okay. Good. Good.

All right. And then maybe 14 days to actually do the production of those materials.

MR. RONCA: Let's say January 15th.

THE COURT: Right.

MR. RONCA: What do you think?

MR. BENNETT: (Nodding.)

THE COURT: January 15th is a Sunday. So we're going to say --

MR. RONCA: January 16th.

THE COURT: -- January 17th.

MR. RONCA: 17th.

THE COURT: The 16th is the holiday. The 17th. January 17th for all plaintiffs who are participating in the mediation to produce these disclosure -- to make this disclosure to the defendants --

MR. RONCA: Okay.

THE COURT: -- as proposed on the 30th.

MR. RONCA: And then, finally, we know that certain representatives of Zimmer are available February 20th to 24th. The PSC will make themselves available on those dates for a start of these -- this mediation. I think we ought to get that in the books.

MR. BENNETT: Well, one second there.

We gave them multiple dates. We -- in an effort to work out something that works for everyone, we gave them multiple dates, including dates in March. And now that *Eckman* is being pushed off to May --

MR. RONCA: No. No. No. *Eckman* is in April.

MR. BENNETT: Well, it may be -- it's in --

MR. RONCA: In May now.

MR. BENNETT: Yeah. We can also get dates in April.

One thing, if you recall, your Honor, that we had a position early on was that mediation would occur before *Eckman*. The -- what was contemplated in the order was that we would have two High-Flex trials. And at the time, that was going to be *Lewis* and *Wilson* --

THE COURT: Right.

MR. BENNETT: -- followed by mediation followed by *Eckman* and *Joas* if we were unsuccessful in mediation.

THE COURT: Right.

MR. BENNETT: Because of the *Lewis* dismissal, things got all messed up as far as the order. So *Joas* went from the back of the line to the front of the line. I'm setting *Goldin* aside. It's not really a High-Flex case.

And so our position has always been that the mediation would occur after *Wilson*. It would go *Joas*, *Wilson*, mediation --

THE COURT: And then *Eckman*.

MR. BENNETT: -- and then *Eckman*.

And so that's why I -- and just in case your Honor were to rule otherwise, I gave them dates we were available because I wanted to make sure that this process was going forward. But certainly what we've always contemplated from the beginning on this whole process is that the mediation would occur between *Wilson* and *Eckman*.

MR. RONCA: But circumstances changed, and because they changed, what we're talking about here is slowing down the process again several months. I mean, really -- on our side of the case, particularly for the 5950 cases, you know, our position is, we should move to remand because, you know, they're just -- they've been waiting all this time, and they haven't gotten a trial yet. And, frankly, that's the recalled product.

We've taken an 1800-case MDL, and now it's down to -- what? -- 318. And it's time to get this mediation moving and not push it out even two more months because that's just going to delay the ultimate resolution of these cases. People have been waiting for years.

If we're going to go ahead with a mediation, it can run on the same track as *Wilson*. *Wilson* is not going to make that much difference in anybody's estimation of the settlement values in these cases, and I doubt we're going to

resolve the cases in the first time we meet.

But if we don't get the thing moving forward, we're going to be out the five and a half, six years and have one 5950 trial and plaintiffs asking for a remand of all the cases back to their districts. I think we need to move at a parallel track. Let *Wilson* proceed. Let *Eckman* proceed. But let's get started. What are we waiting for?

MR. BENNETT: Your Honor, may I just address that?

First off, we've done a lot of work in the last five years. And this idea that there's been delay, it certainly hasn't --

MR. RONCA: I didn't say that.

MR. BENNETT: -- it hasn't been on our side. The dismissals that we've seen have not been because of something we've done.

This -- the date of the mediation and the date of the *Eckman* trial after mediation was by agreement. I'm not sure what has changed in Mr. Ronca's mind, but certainly by agreement we had something out here.

And to talk about a remand now based on a one-month difference, I don't understand it, but certainly we are prepared to go forward seriously with mediation for *Eckman*. And, you know, what's very important is we do not delay and use mediation as a way to somehow sidetrack *Wilson*. We want to move forward with *Wilson*. We want to make sure that it's

not off schedule. We don't want there to be any arguments that, hey, now that we're doing the mediation, that somehow we shouldn't be working *Wilson* up for a *Daubert* hearing.

So that's our -- our biggest position right here is that *Wilson* should be moving forward; and certainly, in our view, mediation should occur behind *Wilson*, which is a CR-Flex case, which we have not tried one of those yet, and it involves similar loosenings we have not tried yet, and that mediation occur after that yet before *Eckman*.

MR. RONCA: What I recall is having a conversation with the Court -- and I can't remember if it was in chambers or on the telephone -- and it came down to when Mr. Houssiere was available to try *Wilson*. And when it was determined to be March, we talked about doing the mediation -- or at least starting the process in February when everybody had time.

In fact, you said yourself, your Honor, in that conversation, well, we'll have *Goldin* in January, and we are going to have *Wilson* in March, and we have a whole month sitting in there between there. Why don't we do something? At least that's my recollection of what your comment was.

And the circumstances changed, is that the order of the cases changed. But I think Mr. Bennett will tell you how many CR cases there are in the whole litigation is very few.

MR. BENNETT: It's ironic because that's what started all this.

MR. RONCA: Right. But we're going to try the *Wilson* case with an eye toward the remaining inventory, and the remaining inventory has very few CR cases --

THE COURT: Right.

MR. RONCA: -- while there's over a hundred 5950 cases --

THE COURT: That have not been tried.

MR. RONCA: -- sitting around.

THE COURT: Right. And I do not want to wait on them any longer either.

I think this discussion that we are having may be one that involves -- for which we need another person in the room, and that would be the mediator because I don't know what his or her schedule might be.

But I do -- I am with Mr. Ronca that we want to do this sooner rather than later. My only concern about not waiting until after *Eckman* is I don't want the Zimmer people to say, "We are really not in a position to negotiate effectively until after we get a verdict in *Eckman*." I don't know that you would say that anyway. That would be my -- because I don't want to waste your time and the mediator's time on a discussion that is going nowhere.

Other than that, I would like to do it sooner rather than later. I am really concerned about the -- I don't call it a delay -- the long time that these cases have

been here and the many, many plaintiffs that are wondering whether anything is ever going to happen with their case. So I really do -- I do want to move forward.

It may very well be that you will meet with the mediator soon and the mediator will give you dates in February and/or late March. It might be that it works perfectly to wait until after *Eckman*. I don't want it to wait -- I don't want it to be the middle of the year before you finally get before a mediator. I want it to happen early next year. Whether that is before or after *Eckman* is not as important to me as it may be to Zimmer. I think it should happen as soon as it is convenient for you and the mediator.

All right. Are there other issues on mediation we need to address?

MR. RONCA: No, your Honor.

THE COURT: All right. So let me --

MR. RONCA: But maybe we should set a date to report back to you on how we're doing.

THE COURT: Well, I will be setting status conferences for the rest of 2017 --

MR. RONCA: Okay.

THE COURT: -- at the end of the session here today. So we will certainly -- I will certainly be seeing you again.

MR. BENNETT: Thank you, your Honor.

MR. RONCA: Thank you, your Honor.

THE COURT: All right. The next matter we have is Mr. Watson's case. And I know that Mr. Watson is here.

THE CLERK: 12 C 1759, Watson versus Zimmer.

THE COURT: Good morning.

MR. MEYER: Good morning, your Honor.

Mr. Watson and I have been meeting by phone, and we met this morning as well. I'll give you a quick background on where we stand and hopefully make some recommendations to the Court on how to proceed with his individual case.

THE COURT: Good.

MR. MEYER: As you know, Mr. Watson is a *pro se* plaintiff. We believed his case was a Track 2 case; and, as a result, he was included on the omnibus motion for summary judgment that we filed. And he filed a response on November 22nd in which he made a number of points.

First, he noted that he wasn't pursuing a high-flexion theory, but he also noted that his records indicated that he had achieved high flexion. He also noted a desire for discovery.

On December 8, he e-mailed us a request for production. Now, one major hurdle to Mr. Watson receiving discovery is that I believe right now he's not subject to a protective order as a *pro se* plaintiff, and much of --

THE COURT: Right.

MR. MEYER: -- what he's seeking is confidential documents.

So what we would propose first is to work out a protective order whereby Mr. Watson could gain access to the documents that Zimmer has already produced.

THE COURT: Right.

MR. MEYER: Now, I've looked at the request for production, and it looks like the vast majority of what he has requested are documents that Zimmer has already produced in common discovery, things like the design history file, the 510(k). The 510(k) is the documents that were submitted to FDA to get clearance for the -- to market the product.

He's also sought manufacturing records. And manufacturing records are required to be produced as part of the defendant's fact sheet.

THE COURT: Right.

MR. MEYER: And so we'll make sure that those were proposed as well.

But most of what he's seeking has already been produced to the PSC.

So our position at this point is, we should not be answering individual discovery in this case, instead we should be turning him over to plaintiff's co-leadership who has access to all of these documents. And under CMO-1, they would coordinate with Mr. Watson to get him the materials

that he needs from the documents that we've already produced after the protective order has been entered with respect to him.

That process, getting a protective order in place and producing the documents, might take 30 days. At which point I think he'll probably want to review his -- those materials.

And I believe he has some uncertainty as to whether he wants to pursue a Track 1 case or a Track 2 case. I think he's still making that determination. I think we should give him an opportunity after he sees the documents to make that determination and then set a hard date by which he should come forward with expert evidence, whether it's an expert report under Track 2 where he is pursuing a theory other than high flexion or whether it is a Track 1 CMO-11 declaration. And I would propose March 15th as that date if the Court believes that gives him enough time and Mr. Watson believes the same.

THE COURT: Mr. Watson, does that date work for you?

MR. WATSON: I hope so. Yes.

THE COURT: Good.

All right. I think that's a very reasonable proposal.

The first step, of course, will be for you to sign

a protective order. And I do not think there should be any problem because I know you are not a knee manufacturer; and you have no interest, so far as I am aware, in spreading Zimmer's confidences to its competitors, but I want to make sure that is in writing and that you sign that before you get access to the discovery.

Now, the discovery -- the plaintiffs' steering committee does have kind of a bank of documents. And I assume that many -- maybe many of them, maybe most of them are in electronic form. But one way or another you should have access and have an opportunity to look at them and make some notes and then let us know whether you think you properly belong in Track 1, which is the high-flexion track, or whether you properly belong in Track 2, which is a group of people who have claims against Zimmer that are unrelated to high flexion but, nevertheless, assume a defect on the part of the knee that would have to be litigated.

So that's -- in order to proceed down that Track 2, you also need an expert report, and I think it sounds like Mr. Meyer is going to be able to explain that to you as well. So March 15th would be the date for that disclosure.

Mr. Milrood, anything you wanted to say?

MR. MILROOD: Yes, your Honor.

Tobi Milrood on behalf of the PSC.

We're happy to cooperate with Zimmer and Mr. Watson

to provide the materials that are in the possession of PSC.

It would be helpful to understand -- of course we haven't seen what the requests are, and we're not sure what Zimmer's position is on those that should be produced.

Again, while we're happy to cooperate, we don't want to overburden Mr. Watson by giving him the entire repository of all of the documents, many of which may not be --

THE COURT: He may not even need.

MR. MILROOD: -- responsive to his request.

THE COURT: Right.

MR. MILROOD: So I think Zimmer is going to have to work with us to help us sort out which ones are particularized to answer the request for Mr. Watson. And we'll cooperate -- we'll figure out who may be easier to produce specific responses to these requests, but we're happy to cooperate.

THE COURT: Great. Good.

All right. So March 15th.

And then what I need right -- is a status right after that because my hope would be that right after that, we will be able to set a trial date. So I am going to set a status right after March 15th.

How about -- how about March 20th, a Monday -- or Tuesday? Is Tuesday better, the 21st?

MS. PIERSON: Your Honor, I apologize for interrupting, but later you said we are going to talk about dates for the status conferences.

THE COURT: Yes.

MS. PIERSON: And it would be great if this could be --

THE COURT: Coordinated at the same time.

MS. PIERSON: Yeah.

I intended to suggest March the 23rd, which is the last Thursday of the month. I don't know if that works for all of you.

THE COURT: Actually, that is fine for me. That would work well with this March 15th date for -- why don't we say March 23rd for at least one of the overall statuses, and we can set those -- the rest of those in just a moment.

MR. WATSON: March 23rd, then --

THE COURT: Right.

MR. WATSON: -- after --

THE COURT: March 23rd for a status --

MR. WATSON: -- coordinating all of this anyway.

THE COURT: -- in your case.

All right. Good.

MR. WATSON: Thank you very much.

THE COURT: Good. Thank you very much.

MR. MEYER: Thank you.

THE COURT: All right. The next item on the overall agenda is the Track 2 update. So let's turn to that issue now.

I know there was -- there is an omnibus motion that's pending.

MS. PIERSON: Yes. Thank you, your Honor.

Just one thing to report there. When we were before you last time, we had asked for permission to take the deposition of the plaintiffs' expert in those cases, Dr. Jonathan Courtney. We had asked for permission to do that in December. Unfortunately, Dr. Courtney's schedule wouldn't allow that. So we've scheduled those depositions for January the 12th and 13th by agreement of the parties and in coordination with Dr. Courtney.

So we just wanted you to know we weren't ignoring your minute entry that permitted us to do it in December. We appreciate that courtesy. The holiday schedules just made it impossible, unfortunately.

THE COURT: Okay. So you will be deposing Dr. Courtney in early January?

MS. PIERSON: That's correct.

THE COURT: All right.

MS. PIERSON: Thank you.

THE COURT: All right. Thank you.

Are there other issues on Track 2?

MS. PIERSON: Sorry. Just one more, your Honor.

MR. BENNETT: One of the Track 2 cases, the *Turner* case -- there's only four of the Track 2 that were going forward. And Track 2 may be a misnomer now because I believe you converted them to Track 1, but --

THE COURT: Well -- right.

MR. BENNETT: -- one of them -- one of them is being dismissed with prejudice. And we have an agreed order that we're going to be submitting for that.

THE COURT: That's great.

MR. BENNETT: So it goes from four to three now.

THE COURT: Okay.

MR. BENNETT: Okay.

THE COURT: Good. Thanks.

MS. PIERSON: The last thing on the agenda, your Honor, for us is the schedule for status conferences for 2017.

THE COURT: Right.

MS. PIERSON: In 2016, we held them, generally speaking, on the third Thursday of the month. If it were possible to move that to the fourth Thursday of the month, I think that may work a little better given the trial schedules and what I see in the deadlines there.

So that would mean for the first five months of the year, we'd be looking at January the 26th, February the 23rd,

March the 23rd, April the 27th, and May the 25th.

THE COURT: Yes.

MS. PIERSON: I don't know if those days are available for the Court.

THE COURT: I think those dates are fine. We are going to have to look.

THE CLERK: February 23rd is not good.

THE COURT: February 23rd is the jury seminar.

Yes. You know what? Those dates are fine except February 23rd, which probably is not fine. So if we could find a different date in February. Other than that, I think we can use the dates that you have proposed.

I could do it on the 22nd. I could probably do it -- push it into, like, early March, March 2nd. February is a short month.

MR. BENNETT: Your Honor, February 22nd is the date of our *Daubert* hearing in *Wilson*. So we could do it that date.

THE COURT: Yes, let's do it that day, February 22nd. Good. All right.

MS. PIERSON: We'll put together a complete list for the year and get that to the Court so that you have all the dates through the year. Just knowing January and February helps a lot.

THE COURT: Okay. Good. Thanks.

MS. PIERSON: That's all we have on the agenda for the general status conference, your Honor.

THE COURT: All right. Well, we have some other cases on our list to call. We are going to call *Goldin* last, but we have got a couple of other matters to call.

So I guess the next one would be Turner.

THE CLERK: 11 C 6441, Turner versus Zimmer for status.

MR. MEYER: I think that was the Track 2 case that we discussed the dismissal of.

THE COURT: All right. We can move on to -- well, we talked about Watson. We can move on to Feehrer, then.

THE CLERK: 13 C 1941, Feehrer versus Zimmer for status.

THE COURT: I think I wanted Ms. Feehrer to be here in person, and I see that she's not.

Have you had --

MR. MEYER: I recall your order, your Honor. I think the order instructed her attorney to be here, maybe.

THE COURT: Well, she is still represented. That is the -- the issue here is that she has regularly corresponded with the Court and described her dissatisfaction with her lawyer, but her lawyer hasn't withdrawn. So I do need to get this straightened out, and it looks as though neither she nor the lawyer is present.

All right. I am not exactly sure what to do about that apart from maybe give it one more try. So, in other words, set it over for another week and set status for next week and -- wait. That is not next week. Next week is -- that will be the day after Christmas. Am I -- wait. Hold on.

MR. MEYER: That's right. Next week would be the week between Christmas and New Year's.

THE COURT: Yes. That is not going to happen because the 26th is actually the holiday, the federal holiday.

All right. I am going to put it off to early January, and I will indicate in the next order that failure of counsel or Ms. Feehrer to appear in person will result in a default -- I mean, a dismissal for want of prosecution. That would be January the 5th at 9:00 o'clock.

All right. And then the last -- hold on. Yes, the last case unrelated to *Goldin* is *Reed v. Zimmer*.

Anybody here on that case?

MS. PIERSON: Reed is one of the Track 2 cases --

THE COURT: Right.

MS. PIERSON: -- that we talked about earlier.

THE COURT: Oh, that is the one where Dr. Courtney was being deposed and now -- is that right?

MS. PIERSON: That's correct.

THE COURT: Okay. I don't think we need to do anything on that right now.

Great. Let's turn to *Goldin* in just one moment.

Is everyone ready to proceed with the arguments on those motions?

MR. MORRIS: Yes, your Honor.

MR. MANDLER: Yes, your Honor.

THE COURT: Okay. You know what? I want to get some water. I will be right back.

(A brief recess was taken.)

THE CLERK: Court resumes in session. Please be seated.

12 C 2048, Goldin versus Zimmer.

THE COURT: Okay. We have already got your appearances.

We are here for arguments on two issues. One is *Daubert* and, in relation -- connection to that motion regarding Dr. Bal, the motion to strike his supplemental or additional report that was filed in December. And the other matter that I have is the motion for summary judgment.

How would you like to -- in what order would you like to argue these?

MR. MANDLER: If your Honor has a preference, we can certainly do that. To us, it made a little more sense logically to have the *Daubert* argument first followed by the

summary judgment motion.

THE COURT: I think that is fine.

MR. MANDLER: And, your Honor, let me take a chance to introduce a couple of the other folks at counsel table.

Josh Busch and Haroon Anwar as well will be joining us for the *Goldin* trial.

THE COURT: All right. Good morning. Welcome.

Ms. Butler.

MS. BUTLER: Good morning.

I have two separate presentations prepared. I've got a presentation on Zimmer's motion to strike this new affidavit from Dr. Bal, and also a *Daubert* presentation. They're interrelated, so I thought I'd just sort of go through them back to back.

THE COURT: That is fine.

MS. BUTLER: But one thing I do want to say at the threshold is, I know from appearing in front of you for the last five years that you've read all of this. So I'm sensitive to the Court's time. And I really do want to focus in on the things that you have a question about or information that would be helpful to you in analyzing the situation that we're in --

THE COURT: Okay.

MS. BUTLER: -- right now.

So I'm just going to launch in; but, you know, if

there's something --

THE COURT: I'm sure I will interrupt.

MS. BUTLER: -- that you want to focus on -- okay.

THE COURT: Yes. That is fine.

MS. BUTLER: All right. I'm going to -- before I get started, I'm going to try to move this over a little bit so I can . . .

All right. So as you know, we've filed these two motions that relate to Dr. Bal's testimony. And since the beginning of this case, we have all been operating under very tight deadlines. Mr. Morris set them out in his briefing on the motion to strike.

THE COURT: Right.

MS. BUTLER: I remember probably in June -- I mean, June is really when this case started, which was only about six months ago. Mr. Morris was here for the first time. We were talking about the tagline that he has on his Web site about trying any case. He was full in. We were full in. You were full in, your Honor. We all made a commitment to get this case ready for trial by mid-January. And as we stand here today, counting the intervening holidays, we have only 16 business days between today and jury selection in this case.

And so up until now, we really have functioned with no disputes. We've worked together to accomplish the

deadlines in this case. I've got a slide here that shows the chronology of the discovery -- the expert discovery that we've taken in this case. And you can see how close together all the dates are. And this really was taken from Mr. Morris' opposition. I have added a couple of dates in here just for reference because they do pertain to the motion to strike. I added in the date that the Bal supplemental report was received by us and filed with the Court, which was just on December 5th.

And also at issue is this date that we provided Ms. Goldin's own X-rays to Mr. Morris prior to Dr. Baier's deposition. And that date was November 4th.

Now, there is some dispute as to what rule applies to this Bal affidavit, but a rule must apply to it.

Our position is that these are expert opinions that are governed by Rule 26 of the Federal Rules of Civil Procedure. I know that Mr. Morris has taken the position and plaintiff has taken the position that this Bal affidavit is being submitted pursuant to Rule 56. We don't agree. We don't think it is proper to apply Rule 56 to expert opinions.

It is true that these opinions are being submitted in response to our motion for summary judgment and in response to our *Daubert* opinions. But if the rules operated such to allow this, there would be no purpose for the rules. Experts would hold their cards close to their chest while the

period of expert discovery was going forward, during the time they submit their expert report, while they're being deposed. They'd just hold that tight. And once that deadline has passed, they'd lay their cards on the table. And our rules were designed to prevent that. And that's exactly what's happened here.

If you just read the affidavit -- and I know that you have. We've all read it. It's 28 pages long. It's twice as long as his expert report was in this case. And the opinions go well beyond facts that are within his personal knowledge. And you cannot use Rule 56 that way.

We prepared for and took Dr. Bal's deposition. We had a report that came in in the middle of June. I took his deposition. I had his report. I spent the day with Dr. Bal. I asked him questions about his report. And when I left that day, I think it's reasonable for us to rely on the opinions that came out of both the report and the deposition.

Now, granted, I had some confusion about them because there were some contradictions that I uncovered between his report and his deposition, but I did have an opportunity to question him about that.

But now we have the Bal affidavit, a 9,000-page document that is chock-full of new opinions, new cites to literature. The Bradford Hill criteria are coming up for the first time. I didn't have the benefit of any of that when I

took his deposition.

So if we took a -- take a look at the rules that could potentially apply to this, the first rule that we talked about in our briefing is 26(a)(2)(D) in conjunction with CMO-10. Your Honor set a deadline for expert reports, and we met those deadlines. Their report came in on June 15th. I took Dr. Bal's deposition on September 7th. Zimmer's expert reports were served on September 30th. And our experts were deposed on November 10th and 11th. In fact, we were before your Honor on the 10th where we talked about the scope of this case and what the issues were going to be.

No one -- at no time during any of that discussion did Mr. Morris say, "I'm planning to submit a new affidavit from Dr. Bal."

We sat here on the 10th in front of your Honor and had a discussion -- Mr. Morris was on the telephone -- about what the scope of the issues were in this case, and we talked specifically about whether it was a high-flexion case. And we all agreed then, as we've all agreed many times before, that it's not.

And then I spent the whole day with Mr. Morris on November 11th when he deposed our expert, Dr. Bal -- or Dr. Baier. And, again, no mention of this report.

And your Honor will recall that something similar came up in the *Joas* matter just a couple months ago with

Dr. Steffey. And the shoe is on the other foot this time. At no point did we ever get any heads-up from Mr. Morris that this was coming.

THE COURT: Wasn't Steffey, though, a new witness?

MS. BUTLER: Yes. Yes. True.

As I said before, this has never been a High-Flex case, and we've all said it. We've all said it time and time again. Mr. Ronca stood up in June and acknowledged that this case wasn't a High-Flex case. He says, "Ms. Goldin believed, because she had to get in and out of the bathtub and get up off the floor, that her flexion was greater than 128 degrees." And that's why it ended up as a Track 1 case. But as it turns out, that may have been physically impossible. She might have gotten close to it, but not there. So this remains a failure-to-warn claim.

This Court recognized the same thing in August, that this is a failure-to-warn case.

Now, one of the justifications that Mr. Morris and the plaintiff brings forward to you for this affidavit is that the *Joas* opinion somehow changed the scope of this case. But, your Honor, this isn't a High-Flex case. And even if it was, that opinion came out in October. And he still hasn't explained why December 5th we see this affidavit for the first time.

And we can parse through the affidavit. I know

some cases have done that. We can do that. In our briefing, we have pages comparing the opinions that were articulated to us in his report, in his deposition, and in the affidavit. And we can do that if your Honor would like to.

Just very quickly, they've admitted that this isn't a rebuttal report, so I'm not sure that I really need to address that; but if it was, it's not timely. Dr. Baier was deposed November 11th, and our expert disclosures were due before that. The 30 days runs from our expert disclosure deadline.

And is this a supplement report? The Court set a deadline for submitting information that would need to be exchanged under this rule, and the deadlines that the Court set were October 31st and November 18th. So nothing explains why this is happening now.

And I know I keep -- I keep coming back to that, but part of what we have to analyze is the potential harm and the prejudice to Zimmer if we go forward with this affidavit. There is no time to cure it. We don't have time to take another deposition. We start trial in 16 business days.

That's really -- that's the crux of the argument right there. And I am happy to answer any questions that you have about it.

THE COURT: I want to hear a response first.

Mr. Morris.

MS. BUTLER: Are you going to need this?

MR. MORRIS: Excuse me?

MS. BUTLER: Do you want me to unhook this?

MR. MORRIS: No, you can leave that as it is. I'll just argue.

As your Honor, I'm sure, is aware, Rule 56 provides, under Section (c)(4), Affidavits or Declarations, "An affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated."

That's exactly what Dr. Bal has done in the affidavit that was attached to plaintiff's response to the motion for summary judgment.

With regard to the fact that this affidavit was produced December 5th, as counsel just noted, we have been on a very, very ambitious schedule getting this case ready for trial in January. In fact, all of the significant depositions were taken this fall: September, October, November. The depositions of the treating physician, the explanting physician; the deposition of the plaintiff was taken late summer; the deposition of Dr. Bal; the deposition of Dr. Rullkoeter, Dr. Baier. And so the accumulation of evidence has really occurred over the last three or four months, and that is not a large time span in ordinary

litigation. There is some time that is required to digest it.

In addition, I would also raise for your Honor the fact that we're dealing with a theory, the failure-to-warn theory that was not completely developed in the multidistrict litigation that your Honor has overseen. In fact, there are only a couple of depositions that even touch on this issue of whether or not there was any type of warning regarding obesity, morbid obesity, super obesity. It just wasn't developed.

And so the only development that has been able to occur in this case is through our review of the depositions that were taken during the MDL, which, as your Honor knows, are voluminous, and getting that information into the hands of our experts and being ready to cross-examine their persons. But really, you know, it comes down to what the Court really assesses regarding the implications of the affidavit.

So let's take Zimmer's position that, you know, they're caught by surprise. I would argue that the affidavit is nothing more than an amplification of what was stated in his deposition. They disclosed a copy of his *curriculum vitae*. In his *curriculum vitae*, he disclosed that he was on the board for Amedica Corporation. He disclosed his other qualifications as a person in industry. They had an ample

opportunity to cross-examine him on those issues and say, "Well, did any of that concern labeling or warnings?" They never asked those questions.

He did expand on that in his affidavit to explain it in response to a point that they made in their motion for summary judgment arguing that the judge should not even get to the merits, but should dismiss the case because he's not qualified. And, in fact, he is. He is an expert that is a medical doctor. He's an orthopaedic surgeon. He was a consultant for Zimmer. He is an engineer. He is a lawyer. He is licensed to practice law in Missouri. And he is eminently qualified to review the issues involving the labeling.

Now, where the track -- or the train leaves its track is on this discussion regarding High-Flex. At some point, the Court determined that High-Flex was a necessary element to the design defect theory. And your Honor set a bright-line at 120 degrees, I think, of flexion that a plaintiff had to achieve -- or shown -- be shown to achieve prior to the time that they had replacement surgery in order for them to meet Dr. Brown's theory that at that point there would be edge loading and so forth that would cause the device to fail.

And it was an important distinction because it distinguished the High-Flex device from predicate devices,

the standard and other devices. And when the Court made that decision, the Court was also good enough to allow certain plaintiffs who believed they achieved high flexion to submit an affidavit saying as much, and that also allowed them to maintain a Track 1 status.

And that's what happened in Goldin. In Goldin, there was no record of her flexion before the time. And so she submitted an affidavit saying that "I believe that I achieved high flexion." And the devil is always in the details.

Part of the Brown report discusses loads, but there was never any direct fixation on the implications of the load in device failure.

And in a situation like Ms. Goldin's where she's 5'1", weighs 250 pounds, 260 pounds, certainly load was an unknown as to its impact because Zimmer never studied it, never tested it; and in all of their studies that they did, the heaviest person they looked at was a 225-pound male who was six-foot tall.

And so we -- when we initially evaluated the case, the question in my mind was, well, who is to say this is not a High-Flex case? I mean, we know that after her revision surgery, she achieved 125 degrees. It's in the records. And every doctor that you depose on this issue says, look, the best estimate of what a person's flexion is, is what they

achieved before implantation occurred.

Well, what are the implications of what they achieve after revision occurs? Would it be more than what they had before implantation? Not likely. So what does that tell us about Ms. Goldin? She likely truly was a high-flexion candidate. All right?

But -- and we felt -- we felt that it was important to analyze that issue for your Honor and for the jury so that the jury would be able to see that there is a distinction in the High-Flex design from the standard and from other designs.

But when the Court rendered its decision in *Joas* and reviewed Dr. Brown's subsequent affidavit and his subsequent testimony, Dr. Brown apparently arrived at the decision that there was really no difference between the High-Flex and the standard, and that the High-Flex may provide a greater safety at High-Flex than the standard.

And so my review of *Joas* is that it doesn't dispose of the issue completely because I think every case stands on its own merits, and I think every case can be reviewed differently, even by Dr. Brown concerning the weight and repetition issues, because the one thing that we never analyzed carefully is, what is the implication of added load and added repetition to the ability of the device to handle high flexion? And we don't really know what that -- that

opinion is, but Dr. Brown or some other doctor could certainly step forward and say, "Hold on. I've looked at this, and you guys have not carefully analyzed these specific elements. And had you, you would have seen that the device fails." And that's why it's reported repeatedly in the literature.

And this is often the case. In pharmaceutical and medical device cases, oftentimes neither the science nor the industry's own evaluation of its own product touches on all of the relevant points and eliminates any possibilities of other explanations. And sometimes that only happens at trial.

So we were going down that path of trying to figure out if there's a distinction. Because when we presented this case, I wanted to be able to convince that jury that this isn't just a failure to warn, but there's a reason there's a failure to warn. Because the jury, in my opinion, is going to have to look at this -- and they're going to have to consider some of the engineering aspects around the knee.

Now, while there may not be a design defect, they're going to need to understand the knee. They're going to need to understand what made it fail.

And in our particular case, Goldin, both the explanting surgeon, both the defendant's experts, Dr. Bal -- every medical expert that's looked at the case says the

device failure was due to her weight. No debate about that.

And so what we've done with Dr. Bal is we've created a general liability expert as well as a specific liability expert. He opines on both things in his report, and his affidavit is nothing more than an amplification of that.

Now, should the Court consider this to be a Rule 26 supplementation, which it was never intended to be, then there is certainly an option for the Court, and that is to allow the defendants to take another deposition of Dr. Bal on the opinions stated in the affidavit. Another option would be for the Court to continue the case. If they feel like they need to go find a new expert or a new rebuttal person, fine. There are options that the Court can take that don't deprive the plaintiff of a jury trial.

And we would urge the Court to consider Dr. Bal's affidavit for just what it is, an affidavit in response to their motion for summary judgment based on his review of all of the available information at the time of that briefing. Certainly he is allowed to consider the opinions of their experts who had just recently been deposed. Certainly he is entitled to take those thoughts into consideration and to look at the motion for summary judgment, quite frankly, your Honor.

I want to make one last point, if it's okay with

you. We didn't know until the motion for summary judgment was filed that Zimmer would take the position that it had warned the plaintiff. If you review the product labeling in this case, your Honor, neither in the Contraindications section, the Warnings section, the Precaution section, or the Adverse Effect section do they say one word about obesity, about heavy, about any kind of warning in that population.

They suggest to the Court now that in the patient counseling section where they include the word "heavy" along with "physically active patients," they claim now that to be a warning. But it clearly doesn't fall within the sections that Dr. Bal, as an expert, would rely upon in determining whether or not they've warned.

The surgical technique they point to, the last section, the last piece says that the patient should not be obese. Should not. It doesn't say shall not. It doesn't say here's what will happen. It doesn't say the device will fail earlier. It doesn't mention the morbidly obese. It doesn't mention the super obese. That's not a warning.

And at the end of the day, your Honor, we didn't know until they filed that motion for summary judgment that they would take the position that those were warnings. They easily could have said, "We didn't have to warn. That's a matter of common knowledge." They could have taken that position, but they chose not to. They joined the issue and

decided to say they had warned. And now that they've said that they've warned, the sufficiency of the warning, the adequacy of the warning, what the warning says is all fair game for the jury.

THE COURT: It's your position, as I understand it, that the warnings in this case -- or the communications from Zimmer to potential customers were inadequate because they did not appear in the right document, among other -- perhaps among other inadequacies.

MR. MORRIS: They certainly didn't appear where the Food and Drug Administration says they ought to appear.

THE COURT: All right. And that -- the notion that Zimmer would rely on these other places for this -- for the disclosure, these other locations for the disclosure, was something that you were not in good faith aware of until the summary judgment brief.

MR. MORRIS: Well, I'm sure that it had been discussed. And, you know, we looked at it from both -- from both positions as we went through our discovery because I didn't know exactly what position they would take, but yes. I mean, I didn't have valid documentary proof until they filed the motion for summary judgment where they -- I mean, throughout it -- I tried to count them -- and it was almost too many to count -- where they say "Zimmer's warnings," "Zimmer's warnings," "Zimmer's warnings," "Zimmer's

warnings."

And it's one -- and I pointed this out in my briefing. If you say something loud enough and long enough, sooner or later people believe it. And that's what's happening here. I mean, their entire research and marketing team that we deposed -- that the MDL deposed, if you ask any of those people: Jarv Campbell, if you -- I could go down the list of witnesses. They all knew that this device was routinely implanted in obese people. They -- in fact, their percentages -- I can pull up Mr. Campbell's deposition where he notes that there's like -- 83 percent of the people were obese that were getting the device.

So for them to suggest now that there's a warning, I mean, it wasn't conveyed to the medical establishment or they wouldn't have been putting it in all these people.

And so I, quite honestly, did not know. I mean, I'm not going to tell them how to defend their case or how to try their case or how to handle litigation. That's not my role. My role is not to instruct them. I just say to the Court that they had an option.

THE COURT: All right. Reply, Ms. Butler?

MS. BUTLER: Yes, please.

I am at a loss as to how we are here 16 days before trial and he is saying they did not know that we were going to claim that we had warned. And this was unplanned, and I'm

sorry. I mean, this is the first I've heard this, and I don't have extra copies of this. These are two pages from Dr. Baier's expert report that we served back in September. Paragraph 24 sets out the language in the package insert that he's talking about.

Paragraph 26 says, "Zimmer's warnings are appropriately addressed to orthopaedic surgeons; should be considered from their viewpoint."

And it goes on from there. It talks about how physicians or surgeons in the position of Dr. Baier and Dr. Bal know what the word "heavy" and "obese" mean.

There is no mystery here. And I am very concerned as I sit here and I listen to Mr. Morris talk about what this case is and it isn't. We are days from trial, and I'm still hearing him talk about high flexion and its role in the failure here.

THE COURT: Let me ask you one final question on this issue, and that is, if the Court were to deny your motion to strike, what -- what prejudice would you feel should be addressed and how?

MS. BUTLER: Well, I heard him mention while he was up here that the Court could, as an option, allow this affidavit into evidence and continue the trial date.

The first thing I would say in response to that is, we think we're entitled to summary judgment whether this

affidavit comes in or not. You can look at the report, the deposition, the affidavit, some of it, all of it, but we think we are still entitled to a ruling as the evidence stands today. We are ready on that.

But if you allow this affidavit in, I don't know how we can address it and still be ready to show up here for trial on January 16th. I'm entitled to take discovery on all the new information that's in his report. He's got a whole new methodology laid out there now of these Bradford Hill factors.

THE COURT: I have got to return to my original question.

So you are saying the only way to cure the prejudice is to grant summary judgment?

MS. BUTLER: No, that's not what I'm saying, your Honor.

THE COURT: All right. If I were to deny the motion to strike and say no, I am not continuing this case, we are going ahead, and also deny summary judgment, suppose all those things happen, what will you insist would be necessary to cure the prejudice?

MS. BUTLER: I would -- we would have to have an opportunity to cross-examine him outside the presence of the jury on his methodology and on his opinions as he stated them.

THE COURT: If I had -- if I had scheduled a *Daubert* hearing and said I want to hear the witness testify before we put him on before the jury, and his additional material had never been submitted, but he came up with all that stuff from the witness stand, what would happen then?

MS. BUTLER: Well, at that point, I think a couple of different things could happen. We could just examine him here in front of you at the hearing, or we could ask that it be continued and take his deposition, or we could ask that it shouldn't come into evidence and shouldn't be heard at the hearing because it wasn't timely submitted.

THE COURT: All right. Why don't we move on to the summary judgment argument.

MR. MANDLER: Your Honor, would you like to hear a separate argument on the *Daubert* motion first or -- I think we had --

THE COURT: I think they could be -- either way. They could be combined. But if you would prefer to just focus on *Daubert*, we could do that.

MR. MANDLER: I think that probably makes a little more sense.

THE COURT: All right.

MS. BUTLER: All right. This was actually -- this clip is the first clip that I wanted to show in my *Daubert* hearing anyway -- or in my *Daubert* arguments anyway. And

I -- Mr. Morris came up here and he talked to you about how we had an opportunity to question Dr. Bal about his qualifications at his deposition, which I did. And I asked him very directly if he had ever drafted a medical -- or a warning for a medical device, and he told me no, he hadn't.

Then the affidavit comes in. And I know there's an argument over semantics about whether or not he drafted warnings and package inserts as CEO of this Amedica Corporation that he owns, but he never disclosed that to me in his deposition.

And this is a good clip of just him talking about the warnings claims. And, again, to say the other side had no idea that we were going to use these warnings, that's going to become very clear to you that, in fact, they did as we listen to these clips.

(Audiotape played in open court.)

MS. BUTLER: Now, if you look at the time stamp on this deposition, this exchange occurred at 9:58 in the morning. Okay? I think the deposition probably started at 9:00. I just asked him about the package insert and I just asked him about the surgical technique. It was clear at 9:58 that morning that Zimmer was relying on the warning that is in those two documents.

As your Honor knows, in applying Rule 702 and *Daubert*, this Court must be a gatekeeper and ensure that any

expert testimony is both relevant and reliable. We know that the first step is looking at his qualifications. And you heard him tell his qualifications, so I'm not going to belabor this point.

But if you just look at the language that's in the Bal affidavit, I think it's disingenuous, at best, to answer a question, "Have you ever drafted a warning for a medical device?" "No," and leave it at that when actually this is actually your experience. And he never told me this in his deposition. This is what he said in his deposition: No, I've never drafted a warning for a medical device.

I'm not going to belabor this point. I've said it. Our briefing says it. And so I think we should probably move on to the substance.

So this is the package insert that Mr. Morris alluded to. It is in a section that has the title "Patient Counseling Information." "Complications and/or failure of total knee prostheses are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients that fail to follow through with the required rehabilitation program."

Dr. Bal in the clip that I just showed you agreed with me that warnings are contained in package inserts.

The surgical technique. This is the other document that's come up and will come up time and time again. Again,

under the Patient Selection section, it says the patient should not be obese.

Now, I heard Mr. Morris stand up and say that this occurs too late in the surgical technique to constitute a warning. Well, I would agree that "6, The patient should not be obese" is at the end of a list of things that a surgeon needs to bear in mind when selecting the appropriate candidate. It is by no means at the end of the document. I would know what page it was on if I knew that they were taking issue with the location of these things in the documents. That's something new.

I also haven't heard, up until today, that they didn't occur in the document where the FDA mandates that they occur. That's new, too. But this is not at the end of the document.

You can see from the briefing and everything that we've submitted that Dr. Bal takes issue with words that are used in our warning: "heavy" and "obese," both of them. So early on in the deposition, I asked him if he knows what the word "heavy" means. And he told me "no." And so then I put in front of him his own patient surgical guide that I found online. He gives it to his patients. Those documents use those words. And I'll play the clip for you.

(Audiotape played in open court.)

MS. BUTLER: So I've shown him his patient guide,

and now he tells me there is a definition that he understands for the word "heavy."

And here's the experts from his patient guide:

"Does my body weight affect knee replacement?"

"Obesity will increase the risk of complications from surgery, such as blood clots and slower wound healing. Ideally, your weight should be within reasonable limits before knee replacement surgery. In some cases, for excessively heavy patients, knee replacement is not an option without drastic weight reduction, such as with gastric bypass surgery."

He goes on. He uses the word "heavy" two more times in that section.

I also asked him what the term "obese" means.

(Audiotape played in open court.)

MS. BUTLER: So Dr. Bal agreed with me in the deposition that the patient, Ms. Goldin, was both heavy and obese. Those are the exact words that have been used in Zimmer's warnings, but he still takes the position that those are vague and ambiguous and leaves a trained orthopaedic surgeon to guess what they mean.

I also asked him what the warnings should say instead.

(Audiotape played in open court.)

MS. BUTLER: So he can't or won't tell us what the

warning should say. He's quick to nitpick it and talk about the fact that some of the terminology is vague, but he hasn't told us what it should say, and he doesn't know what it should say because he has no idea what data Zimmer had or didn't have at the time of the implant surgery. And those are design defect claims, which I understood before today he wasn't making.

I also asked him whether obesity should be a contraindication.

(Audiotape played in open court.)

MS. BUTLER: Based on what I just showed you, these opinions should be excluded. They're not helpful, they're not supported by anything, and they're contradicted by his own words at his deposition. There is no question that Ms. Goldin was both heavy and obese. Everyone in this case agrees.

Moving on to the causation opinions. At the end of the day, I think that what I'm about to say is their theory, though I have doubt about that after hearing what I heard this morning. But I believe the claim is that Ms. Goldin's implant loosened because she was encouraged to and did perform high-flexion activities, and while doing so, the obesity put an undue strain on her implant. That is what I believe their theory to be.

But the problem here, your Honor, is that the facts

of the case do not fit that theory. Their theory requires that Zimmer and Dr. Windsor, one or both of them, encouraged Ms. Goldin to engage in high-flexion. Ms. Goldin had no idea until the time of her revision surgery in 2011 that she even had a High-Flex knee, and she did not testify that she was ever encouraged to do high flexion.

Dr. Windsor did not testify that he encouraged Ms. Goldin to perform high-flexion activities either. In fact, when Dr. Windsor was asked about flexion, he said that he encourages all patients to get to at least 107 degrees because that's what's required to reciprocate stairs and that's what he believes is a full range of motion.

Not only was she not encouraged to engage in high-flexion activities, all of the facts suggest that she never got high flexion, ever.

Here's the flexion -- here's a flexion chart that we put together. And the plaintiff has made the claim that preimplant flexion is indicative of post-revision flexion and that all the doctors in this case agree, but that is not true. What is true is that, if you look at an unoperated knee, a knee that's never had a knee replacement, whatever flexion you get at that point can be indicative of what you get after the first knee surgery. It has nothing to do with subsequent knee surgeries.

Dr. -- he -- Mr. Morris asked Dr. Buchalter in his

deposition about that, and Dr. Buchalter said, you know what, I can't say that flexion after the implant, post -- like prerevision -- prerevision flexion is indicative of post-revision flexion. He said, "I can't say that because it's a different knee." Dr. Baier agrees. Different products, more bone has been removed, more soft tissues have been released. That doesn't work.

Not to mention the fact the one entry on this chart that shows that she ever got high flexion was in 2012. Once she got to 125. That is not weight-bearing flexion. That is being in the doctor's office and laying down on a table.

We've talked before in this courtroom about body habitus. This is an X-ray of Ms. Goldin just prior to her surgery. And you can see the impingement at the back of her leg. The tissue on her thigh and her calf prevent her from ever getting high flexion. She was asked in her deposition if she -- if her -- if she could bend her knee far enough for her thigh to reach her calf, and she said no.

Another thing that they point to, Dr. Bal talks about her activity level and says, "Well, if she was gardening and getting in and out of the bathtub, then she must have gotten high flexion," but he doesn't have any information about how she was doing those tasks. He doesn't know how she was getting in and out of the bathtub. And as for gardening, she said she never kneeled to do gardening.

She "stooped" is the language that she used.

So we can't just assume or use common sense, as Dr. Bal would like to do, that she reached high flexion. There isn't any evidence in this case to suggest that.

THE COURT: I realize this is kind of a fine line, but, to me, these arguments, many of them, are not really aimed at Dr. Bal's qualifications or methodology. They are really summary judgment or trial arguments. They may be winners, but I am not really sure they are directed at, I should exclude Dr. Bal.

I think what you are telling me is that the jury should not believe Dr. Bal for a variety of reasons -- circumstances relating to Ms. Goldin's own situation, what the records might show about her situation, what he has done in his own practice, *et cetera*. Those could all be winning arguments, but I am not sure they are arguments about why I should exclude his testimony.

Maybe we should turn to summary judgment, the summary judgment argument.

MS. BUTLER: We can certainly do that if you want to, your Honor, but what I would say in response is this whole -- take this principle that post-implant flexion is indicative of what you would get after a revision procedure. He doesn't have any literature to support that. There's no literature to support that. What methodology did he use in

coming to that? There isn't any.

THE COURT: That is one piece of his testimony. It's not his entire report. And what you are asking me to do is to strike his entire supplemental report in its entirety, and I just -- some of these arguments relate to that, but many do not.

Yes, Mr. Morris.

MR. MORRIS: Would it make any sense, your Honor, for me to respond to the *Daubert* argument that she's just made before we move on to the summary judgment?

THE COURT: All right. Why don't we do that, and then we'll turn to summary judgment.

MR. MORRIS: Thank you, your Honor.

I'll try to go through these quickly.

With regard to the first point that she made regarding Dr. Bal's qualifications, whether or not he is qualified to render an opinion regarding the warnings issue, as he says in his affidavit that's attached to the motion for summary judgment, which was also attached, by the way, to the *Daubert* response, is that he worked with a team of people at Amedica who developed warnings, cautionary statements, and so forth. And he did not say -- he was consistent with his testimony in the deposition. He did not say in his affidavit that "I personally drafted them," that "I personally reviewed the FDA's recommendations or qualifications regarding what a

proper warning should state." He didn't go to that bridge.

He did state in his affidavit that he has certainly had meetings with the FDA and he's talked to the FDA. So he definitely has a level of sophistication and knowledge that exceeds that of the layperson.

And when we go back to Rule 702, despite the fact that we have *Daubert*, *Kumho Tire*, the whole progeny of cases regarding gatekeeping responsibilities of the federal judge, where it all begins is with Rule 702. 702 still allows testimony to be offered of a scientific or a medical expertise on behalf of someone that has experience, knowledge, education, and training beyond that of the layperson. And certainly Dr. Bal has that. Not to mention the fact that he was retained and worked as a consultant for Zimmer, was paid for by Zimmer to consult on their medical devices. So with regard to his testimony at his deposition and his affidavit that was offered, they are not inconsistent.

Is there -- well, I'll tell you, rather than taking the time to set up the ELMO -- your Honor, I apologize for not having a PowerPoint, but I do have the label, and this is the label for the NexGen Knee. And I know you can't see it from this distance, your Honor, but I'm just going to tell you that this is the further part of the label. They have the indications for use. Then they have Contraindications.

Contraindications, there's no mention of obesity, heavy, nothing. Not a word.

Then they have Warnings. And they set forth some things in their warnings. You can see a couple points there. And then all of this material right here is part of the Warning section. Not a single mention of obesity. Not a single mention of heavy. Nothing.

And then we can go down here to Precautions. Precautions, not a single mention of obesity. Not a single mention of heavy. Nothing.

Then we can go to Adverse Effects. Adverse Effects actually starts out by talking about loosening. And we can turn to the next page. That's part of adverse effects right up there. Nothing. Nothing about obesity. Nothing about heavy.

And then finally we get over here to the last page, and there is the Patient Counseling Information. And what it says is, "Complications and/or failure of total knee prosthesis are more likely to occur in patients with unrealistic functional expectations, heavy patients, physically active patients, and/or patients who fail to follow up with their required rehabilitation program."

Now, is that telling doctors that they should warn virtually everybody that the device can fail? Because it sure sounds like it because they lump in physically active.

How many people are physically active that get these knees? Probably a lot. That's probably why they're getting it, because they want to be physically active. And they lumped them in with heavy patients.

Well, here's the point: The fact that Dr. Bal uses the term "heavy" in his own personal instructions regarding the use of these devices on his Web site, if you heard what she just testified to and what she just said in her PowerPoint, Dr. Bal's statements are far more expansive than Zimmer's, far more detailed, far more explanation, and yet they're coming in and trying to say one little word about heavy patients is somehow a fulfillment of their duty.

And at some time your Honor will get to the case law, and the case law here is clear of what their duty is. And their duty does include conspicuousness, prominence, placement, all of those issues that are important in warning. And Dr. Bal is aware of those things. As a medical doctor, he reviews warning labels on all kinds of products all the time. He knows about that, he has more sophisticated knowledge than the layperson would, and he is capable to testify on that.

One last point I'd like to make on the term "heavy": A person can be 6'2", weigh 220 pounds and be heavy, but not obese. When we get to talking about the details of the obese population, the morbidly obese

population, the super obese population, there are distinctions that are going to matter to the jury. Obesity is seen as a BMI over 30. Morbid obesity is seen as a BMI over 35. Super obesity is seen as a BMI over 40. Ms. Goldin at the time of her implant had a BMI of 45.

So even if they had mentioned obesity as a warning, which we contend that they did not -- understand that when we get to trial in front of that jury, I'm going to walk in here and I'm going to say two things.

I'm going to say, number one, they didn't warn because in all these sections within the label where the FDA expected them to, they did not.

And then I'm going to say, number two, if you disagree with me about that, then we're certainly going to show you that whatever they said was inadequate because it's not enough to just say obese. Obese covers people that are 30 to 35. It doesn't say anything about the morbidly obese or the super obese. And those distinctions matter.

What your Honor will find is, in the epidemiology of this whole issue, they rarely, in most of the studies, looked at people that had a BMI of over 35. Zimmer had its own internal registry. They could have done it. They chose not to.

THE COURT: Here, too, I think these are important arguments, but, to me, they -- and, again, maybe there is a

finer line than I am focusing on --

MR. MORRIS: Right.

THE COURT: -- but, to me, these sound like summary judgment --

MR. MORRIS: Okay.

THE COURT: -- or trial arguments as opposed to Dr. Bal's methodology or --

MR. MORRIS: Right.

THE COURT: -- his qualifications.

MR. MORRIS: I'm with you, your Honor. I'll go back and focus.

If we look at the report -- and I'm talking about the report. I'm not talking about the affidavit, your Honor. I'm talking about the report that he furnished way back when.

THE COURT: His original report.

MR. MORRIS: Yes, your Honor.

In paragraph -- you know, she states in her argument to the Court just five minutes ago that this issue about location is something new.

Well, if we go back to his report, Paragraph 25, he states, "Moreover, in my experience, physicians look to the contraindications, warnings, and precautions portions of product labeling for information upon which to cancel the patient as to risks and benefits."

That's the location. He says it right there in

black and white. Regardless if your Honor, for some reason, decided to strike the affidavit, in his original report, he said it. And they're going to have to deal with it at trial.

There is one other section. They say, "Well, he doesn't say what the warning should have said." Well, if you heard his testimony as she played it back for your Honor, he certainly delineated some things that he thought needed to be in the warning.

But once again, if we go to his report, not the affidavit, in Paragraph 33, he states, "An appropriate warning would have included an instruction that the high-flexion design should only be used in patients that require high flexion and information about the lack of study in persons with a BMI in excess of 40 indicating no basis that the benefits will outweigh the risks in that population."

So as to the suggestion that he didn't set those things forth, he set those forth actually in his report a long time before the affidavit. He did expand on those in his affidavit, and I believe the expansion that he has provided is beneficial to the jury in understanding the facts and issues in this case and would be beneficial for them not, you know, being confused about the issues.

But all in all, if you look at his CV, which was attached in response to *Daubert*, if you look at his original

report, you will see that he's not only qualified under 702, under *Daubert*, its progeny, and his opinions have a reliable basis in that he both went through his methodology from the standpoint of a differential diagnosis in his report. The fact that he mentions Bradford Hill in his affidavit is something that we can discuss if the Court wants, but I can tell you that I tried a bunch of cases where I didn't mention the Bradford Hill criteria in the expert report, but I sure put it on at trial.

THE COURT: All right. Let's turn to the issues -- the summary judgment issues.

MR. MANDLER: Yes, your Honor. If I could have a minute just to swap out the laptops and get my slides up.

THE COURT: Sure.

MS. BUTLER: I don't want to have to call my tech guy up.

THE COURT: All right.

MR. MANDLER: Good morning, your Honor.

John Mandler for defendant, Zimmer, on the motion for summary judgment.

Obviously for all of the reasons that Ms. Butler mentioned, we believe that the Court should both grant our motion to exclude Dr. Bal's affidavit as well as exclude his expert opinion.

But my argument this morning and our motion for

summary judgment does not rely on either of those things. We take the motion for summary judgment, including the Bal testimony and the Bal affidavit, in account in this motion.

And second -- to the extent any of this is a bit repetitive, some of the issues that Ms. Butler covered and some of the testimony from Dr. Bal, I apologize. I'll try to move through that quickly, but I think, as your Honor indicated, some of these are directly related to summary judgment issues. And so I'll be covering them in that context.

Okay. I thought it would be useful to start our discussion on the motion for summary judgment in reviewing the causes of action that are yet at play from the short form complaint.

First of all, these five causes of action -- design defect, manufacturing defect, breach of an expressed and implied warranty, redhibition, and unjust enrichment -- were all subject to a meet and confer that I had with Mr. Morris on November 14th of 2016. We spoke primarily because Zimmer was trying to figure out if it needed to address all of these causes of action as part of its motion for summary judgment. At that point, Mr. Morris told me that the plaintiffs would not be going forward on any of these five causes of action.

There were an additional two causes of action -- negligent misrepresentation and violation of the New York

Consumer Protection statute -- that he told me that the plaintiffs still intended to go forward on. So we covered those in our initial brief. Plaintiffs did not address them in their response and offered no opposition to our argument or reasoning as to why those should be dismissed. So I don't plan on spending any time on those this morning. And I would urge the Court that, because the plaintiffs have offered no opposition to those, that that summary judgment should be granted on those two as well as on the five that counsel had previously indicated they were not going to pursue any further.

That leaves us with just two causes of action, which I intend to address this morning: the failure to warn and the punitive damages claim.

As to the failure to warn, it comes in two flavors, both negligence and strict liability. However, as we pointed out in our brief, under California law, the standard is the same. There's no differentiation among the Cal- -- I mean -- I'm sorry -- the New York courts as to the elements for failure to warn under either negligence or strict liability.

That can be found in the *Estrada v. Bercow* case, an appellate court case, 1480 3d 529 (2005), as well as the Second Circuit case in the *Fane v. Zimmer* case, 927 F.2d 124.

Turning to the failure-to-warn claim, there are two key elements that if the plaintiffs cannot prevail on, they

cannot go forward with the failure-to-warn claim. Their failure-to-warn claim will fail if Zimmer is able to show that it warned of the risk that actually caused the injury in this case.

And, second, Zimmer will prevail if any of the alleged defects upon which they claim there was a defective warning did not actually cause the plaintiff's injuries.

And if Zimmer prevails on either of the two, plaintiffs cannot go forward with their claim and Zimmer is entitled to summary judgment.

As to the first element, the adequacy of the warning, New York law has adopted the learned intermediary rule as it relates to the adequacy of warnings for pharmaceuticals and for medical devices. That means that the courts can address the adequacy of the warning as an issue of law.

Mr. Morris has said over and over so far this morning, when I get to the jury this, when I get to the jury that, the jury is going to decide this. And I imagine he'll do it again in response to this. But I think it's important to be clear that issues of the adequacy of the warning under New York law as applied by New York courts are routinely dealt with as an issue of law.

The application of the learned intermediary doctrine in this case is particularly important because it's

undisputed -- the facts in this case are undisputed that the plaintiff had no idea what device she was getting implanted with -- did not know until after her revision surgery -- had no discussion at all with her doctor about that device; saw no brochure, no literature, no packaging. So the only communication and the only warning went from Zimmer to Dr. Windsor, the implanting surgeon.

In fact, New York courts have confirmed that there is no duty to warn the patient in this setting, in the setting of pharmaceutical and medical devices, when there is a learned intermediary who is prescribing those medicines or devices.

Going to the point that I just made, both New York -- New York courts have routinely held as a matter of law that a drug manufacturer will not be liable if there's evidence showing that the warning specifically warned of the side effects that occurred. That's the *Alston* case from the Southern District of New York, 2009.

And then, secondly, where a warning is provided by a manufacturer to a physician through package inserts, which give specific detailed information of the risk of the product, the manufacturer is absolved from liability as a matter of law.

So the question really is, what is the side effect or the harm that this plaintiff, that Ms. Goldin is

complaining of in this case and wasn't warned against?

And that part, of all of the motions this morning, is easy. Mr. Morris already said it this morning. They put it in their brief. And their claim is all the doctors that have reviewed Ms. Goldin's case post-revision agree that the cause of her device failure was her weight.

So the question is, was there an adequate warning of the potential for a failure -- an adverse -- a failure of the device due to weight? And that -- if that warning exists, then as a matter of law, the Court can find that it was an adequate warning.

We started to look a little bit at the materials this morning. There will be three different inserts because there were three different components: a tibial component, a femoral component, and then the actual kneecap component as well. Each of them had their own inserts. Each of them had identical language: "Complications or failure of total knee prosthesis are more likely to occur in heavy patients."

The warnings included specific instructions to the surgeons to consider the entire insert. The idea that somehow a warning in one section of the insert versus a warning in another section of the insert is insufficient is not supported by any of the materials in the case or supported by the case law in New York. And I'll get to that in a minute.

But the implanting surgeon is instructed that the possibility that the implant or its component may wear out or need to be replaced should be discussed with the patient, and that includes the warning we just looked at, which is, "complications or failure of total knee prosthesis are more likely to occur in heavy patients."

So that's both -- the same warning applies both in the femoral component and in the articular surface component.

And here is the instructions to the surgeon, that "operating surgeons should study carefully the following recommendations, warnings, instructions, as well as the available product-specific information, product literature, and the written surgical technique." In other words, Zimmer is telling the surgeon, look at all of this as a package, consider it as a package.

And then, finally, we looked at the surgical technique that tells a surgeon under the Patient Selection section that the patient should not be obese.

So the issue is, what caused the injury to Ms. Goldin? All the doctors agree it was her weight, and Zimmer specifically warned of an increased risk due to her failure from the patient's weight.

Plaintiff's response -- and we heard a little bit of it already this morning, and in their briefing they set forth a number of things that -- in response to this

argument.

Obviously, going back to the *Daubert* motion, if Dr. Bal's opinion is excluded, then they don't have a basis for any of these and we don't have to get into the details, but their responses are threefold.

First, the terms "heavy" and "obese" in the Zimmer warnings are too vague, and we'll get into that.

Second, there's not a warning related to the things that Zimmer didn't test about. In other words, there's pages and pages in their response brief that says, Well, they didn't test about this. And they didn't test about that. Therefore, they didn't warn about it.

And then, finally, there is still at this late date -- and, again, we talked about this a little bit earlier -- there is still illusions that there wasn't a warning about a risk from the design defect related to high flexion.

And I'm going to go through one at a time why these arguments don't make sense. I'm going to start with the heavy and obese argument, that they're too vague, and we're going to look at these six reasons why that argument doesn't make any sense.

First, Dr. Bal admitted -- and we saw that testimony earlier this morning -- that he actually understand -- -stood the terms "heavy" and "obese." He uses

them in his own patient guide and in his own literature. He agrees that Ms. Goldin was both heavy and obese.

Dr. Bal didn't offer any other alternative warning to the language that warned about an increased risk with a heavy and obese patient.

Dr. Windsor, the surgeon himself, understood the terms, and he agreed that Ms. Goldin was both heavy and obese.

And before I get into the details of each of these six, I want to respond to something that Mr. Morris said this morning, which is, Well, they use "heavy" and they use "obese," but in some sections, they only use "heavy" and they don't really define the different subparts of "obese."

While that may be true for a hypothetical plaintiff and it may be of concern for a hypothetical plaintiff, it is not of a concern for Ms. Goldin.

The testimony is unanimous that each of the surgeons that looked at her, both the implanting surgeon, the revision surgeon, both sides' expert surgeons, everybody agrees she was heavy and she was obese.

And while I understand this is a bellwether trial, it's not a class action. In other words, Ms. Goldin isn't representing all other potential plaintiffs. She has to make her claim based on her own situation.

If the warning was sufficient to warn Ms. Goldin in

Ms. Goldin's situation, that's the end of the inquiry for the Court. And since everybody agrees she clearly was both heavy and obese and there's a warning against that, then under the New York case law, that is sufficient for the Court to rule as a matter of law.

I'll try to move through these relatively quickly because some of this we covered already this morning.

Dr. Bal, from his testimony that was played this morning, understands what "heavy" means. He understands what "obese" means. He agrees that those are commonly accepted terms in the medical community. He uses them in his own patient guide, in his own warnings. He uses them without trying to define them by BMI or, without any further explanations, he uses the terms "obese" and "heavy," as we heard from his testimony this morning and we can see in his own patient guide.

He agreed that Ms. Goldin was both heavy and obese under any definition. He didn't offer any proposed alternative warning. And while we heard this morning about, Well, it should have been in a contraindication section or it should have been in this or that section, his actual opinion doesn't say that. When asked whether he thought it should be contraindicated, his response is, "I can't say it is; I can't say it isn't."

Now, again, we're not in the *Daubert* section of it,

but this is not helpful expert testimony for a jury to say maybe it should be contraindicated and maybe it shouldn't. But, in any event, he can't then say because it wasn't contraindicated, there was a failure of warning, when he doesn't hold that opinion himself.

Like Dr. Bal, the implanting surgeon, the person who actually has to be warned here, understood the terms, understood that in the medical community overweight is between 25 and 30 and obese is a BMI of 30 or above.

Dr. Windsor also agreed that Ms. Goldin was both heavy and obese. And clearly, clearly --

"So the BMI would put her, in your estimation, in the morbid obese category?

"Super obese." That's the term that Dr. Windsor used, "super obese."

"And certainly would put her in the heavy category?

"Well, of course," Dr. Windsor says.

Okay. So the next argument in opposition to the warnings that are included in the product insert and in the surgical technique is that there's no warning about the issues in which Zimmer did not test. There's a couple of problems with this argument. I'll put them up when I go through them one at a time.

First of all, New York does not recognize a failure-to-test cause of action. That is separate from a

design defect claim. If there's a failure to test, it's related to whether or not a product is effectively designed.

We have heard over and over that both Dr. Bal is not going forward with the design defect theory and the plaintiffs themselves are not making a design defect theory. That was one of the causes of action that Mr. Morris told me they weren't pursuing when we had our meet and confer.

So if you're not claiming a product is defective, there is no relevance of a failure-to-test theory. It's separated from a failure-to-warn theory. And all Dr. Bal can speculate about is what additional testing might have shown.

First of all, he hasn't done any additional testing or reviewed any additional literature that shows additional testing to say what the outcome would have been, so he's only speculating about that.

Second, if Zimmer had done this testing he's trying to define, there's nothing to say that it would have been -- shown any sort of negative effect. If it didn't show a negative effect, there would be nothing to warn about.

Third, if the testing did show a negative impact on obese people for the use of this device, it has to be something different from what they already warned about. In other words, if they did testing and they showed there was an increased risk to obese people or heavy people, that's what they've already warned about. They said there was an

increase of failure for those folks. So all of this is three levels of speculation that doesn't allow or support a failure-to-warn theory.

And, finally, because, under New York law, the failure to test is a sub-element of a design defect and plaintiffs have abandoned that, that cannot support their opposition to failure to warn.

THE COURT: Well, on that score -- let me just point out, I am certainly with you that failure to test is not an independent claim. After all, if Zimmer never tested the product, but it worked perfectly in everybody, nobody would ever care that they never tested it.

MR. MANDLER: Right.

THE COURT: So there's got to be -- when you make a failure-to-test argument, you have got to say, if you tested it, then we would have found out, *et cetera*, in a design defect context.

I am not sure that is precisely the same analysis in a failure-to-warn case. Suppose a medication has been tested in men but never in women, and I have got the condition, whatever it is, and the doctor says, "Look, it has never been tested in women, so we don't know what the outcome might be." It seems to me that is something that ought to be disclosed, that we just don't know. And that would not -- and to say that there is an obligation to disclose that we

don't know certain things is not the same thing as saying you are trying to make a design defect claim.

MR. MANDLER: Yeah. Toward that end, as to how it fits in with the failure to test, I'd recommend to the Court the case law -- it's not New York law -- from the Western District of Virginia. And we cite it in our brief. And it goes through how a failure-to-test claim interacts with a failure-to-warn theory.

THE COURT: Right. Right. Okay. I think I recall seeing that.

MR. MANDLER: Yeah. That's the *Cisson v. C.R. Bard* case --

THE COURT: Right.

MR. MANDLER: I think it was a shoulder case.

THE COURT: C.R. Bard, right.

MR. MANDLER: Yes.

-- at 2013 WL 3821280.

What the court looks at there is the multiple levels of speculation that is required to take a failure-to-test theory and get to the conclusion: therefore, there wasn't an adequate warning.

So regardless of what -- the plaintiff's theory on lack of testing, it's undisputed, according to the plaintiffs, all the doctors agreed that the product failed because of Ms. Goldin's weight. And there's a specific

warning that there's a potential for failure due to weight in the warnings themselves.

Okay. And then the final response is that the warning is deficient because -- it suffers because it didn't discuss extra load that an obese patient can achieve when they are in a high -- in high flexion.

The problem with this is, plaintiffs have already abandoned this theory -- this high-flexion design defect theory of the case. While -- Dr. Bal has professed that he is not giving any opinion on it other than to incorporate the opinions of "the engineers." And by that, he meant Dr. Brown.

And we sort of went over this last time we were in front of the Court. Obviously he can rely on other experts' reports, but he can't simply parrot those other experts' reports and give them as if -- you know, and read them as if he's giving them the same, and they're not going to come into evidence.

The Seventh Circuit has adopted this rule in the *Dura Auto Systems of Indiana v. CTS* case where it says if it's an area that's outside the expertise of the testifying expert, while they may have the ability to rely on it for some reasons, they certainly can't give it as if it's their own opinion. And in this case, Dr. Bal said he is not intending to give any sort of engineering opinions.

And, finally, even if you could do that, Dr. Bal's design defect theory doesn't establish or discuss that the NexGen Flex was defectively designed for high flexion either in the obese population or the nonobese population.

And, finally, as we went through, there's no evidence that Ms. Goldin engaged in high flexion.

Now, I understand that Mr. Morris will want to say, well, that's an issue for the jury. There's going to be evidence on both sides. But there has to be some evidence to get us to that point other than just mere speculation.

So in sum, Zimmer warned of an increase of risk of a failure due to the patient's weight, and Dr. Bal hasn't addressed or offered any other alternative proposal.

But there's a second element if -- that if Zimmer prevails on it, it's entitled to summary judgment on it as well and that's the causation.

The alleged defects in the warning did not cause the plaintiff's injury. And plaintiffs seem -- Mr. Morris seemed to think we had to make an either/or argument, that by saying that we did warn, somehow we've abandoned the argument that Dr. Windsor was well aware of the increased risk of the implant in heavy/obese patients. It's not an either/or argument. We're making both arguments, and both certainly are true.

So plaintiffs are not going to be able to show

causation between their alleged failure to warn and Ms. Goldin's injury because Dr. Windsor testified that he was well aware of the risk of implant failure in heavy/obese patients. He testified that he did not rely on Zimmer's materials, but instead relied on his own expertise in selecting the product.

And, finally, the plaintiff here had no choice but to have the surgery. She wasn't selecting the product itself, so she was relying on Dr. Windsor, who made the decision to use the product independent of the warnings that Zimmer put in the labeling materials.

Let's look at those things in a little more detail.

First of all, Dr. Windsor already knew of the increased risk of implant failure in heavy or obese patients. The question -- I think this was Mr. Morris' question.

"Assume with me that they were aware of issues involving obese patients. Would you have liked to have been furnished with that information?"

And the response: "To a degree, but most surgeons know that there is an increased risk of, for example, aseptic loosening in obese patients in any implant design."

And that's the very issue we're dealing with here.

Finally, Dr. -- or, second, Dr. Windsor did not rely on any of Zimmer's materials in selecting the NexGen implant. He based it on his own experience with the implant

longevity, his own clinical performance, consulting with the patients, his own medical judgement and training as a surgeon. And we've provided the citations for that in our statement of undisputed material facts.

He said that based on his years of experience, that the NexGen Flex would best treat the plaintiff's medical condition, and he chose it on that basis.

And, finally, even yet -- even today, after all of his review of the subsequent materials, he does not believe the NexGen Flex was defective and it put plaintiff at any other higher risk than other products that were available at that time. While she did have a risk that was disclosed to her of premature failure due to her weight, it's no different than from any other device, in Dr. Windsor's view.

This is how he phrased it: "The fact that -- the implants that I use, generally speaking, I only use because they seem to be, at least in my hands and from what I've seen over the years, the best as far as longevity and clinical performance."

And that's the key phrase and the key reason that the plaintiffs aren't going to be able to show causation as a matter of law. "I only use them because . . ." his own experience.

We went on to ask him, "Is there anything about either the surgical technique or the product inserts,

Dr. Windsor, that you think failed to warn you about some risk of using this product with obese patients?"

"Correct. Quite frankly, most people that are obese -- most people are obese that I operate on. So I would have to abandon the entire system, which is just, I mean, not done."

"And then, finally, do you have an opinion whether the NexGen High-Flex product that was implanted in Ms. Goldin put her at a higher risk versus other available products in 2009?"

Answer -- "And what's that opinion?

"There is no difference."

So whatever the warning was -- and we have gone through and shown that there was a specific warning for the specific failure that happened with Ms. Goldin -- Dr. Windsor has said he selected that opinion based on his -- I mean that device based on his own history of using it successfully, his own knowledge. He had his own knowledge of the risks of early failure. He warned the clients -- his clients of that risk of early failure. And most importantly, there was no difference between the devices that he had to choose from between -- and nothing would have changed his mind as it relates to which device he selected for Ms. Goldin.

And, finally, as we said, Ms. Goldin in Dr. Windsor's testimony -- and we quoted her testimony as

well in our moving papers -- she had no other option other than to suffer the pain going forward than to have her knee replaced.

So in sum, on our failure-to-warn claim and our motion for summary judgment, under New York law, Zimmer warned -- adequately warned of the exact risk that caused the injury, and any alleged defect in that warning could not be shown to have a causative link to the plaintiff's injury.

I'm just going to go through very quickly, your Honor, the other remaining cause of action, which is the plaintiff's punitive claims, understanding that the Court will likely want to reserve that.

But an obvious point, if the failure-to-warn claims fail, if Zimmer is to get summary judgment on failure-to-warn claims, the punitive damages claims is derivative, and we would be entitled to summary judgment on that as well.

Second, the plaintiffs had not established a *prima facie* case for punitive damages under the elements of New York law. It's said to be an extraordinary remedy under New York law, that Zimmer must have acted maliciously, wantonly with a reckless suggestion of an improper motive or vindictiveness.

And, finally, they must show a recklessness close to criminality. And I would propose that the record in this case doesn't come anywhere close to showing that. There is

no evidence that Zimmer engaged in any of this type of conduct. Zimmer, in fact, warned of the increased risk of failure due to weight, the exact thing that happened to Ms. Goldin. Dr. Windsor and the medical community were already aware of the risk, Dr. Windsor testified. Dr. Windsor doesn't believe that the NexGen Flex Gender Specific was defective or that Zimmer failed to warn in any manner.

Based on those undisputed facts, your Honor, we would ask for summary judgment on the punitive damages claim as well.

THE COURT: All right. Thank you.

Let's take just a five-minute recess, and then I will hear from plaintiff on summary judgment.

(A recess was taken.)

THE COURT: Okay. I think we are ready to hear a response on summary judgment.

MR. MORRIS: Thank you, your Honor.

In terms of the backdrop for the learned intermediary discussion, the Court is well aware of the learned intermediary doctrine and the fact that warnings are intended to go to the physician, the physician then to pass those along to the patient.

As long as we're citing cases from other jurisdiction, there's a case in Pennsylvania state court that

went all the way to the Supremes called Simon versus Wyatt, a case that I tried where, in fact, the learned intermediary decision was used to set the case cite on JNOV after I obtained a verdict. And we took it all the way to the Supreme Court of Pennsylvania, and they decided that the patient's discussion with the physician and what she would have done in that case is relevant. And in that particular case, the Supreme Court -- actually, it was the superior court. The intermediate court there reversed it and the Supreme Court later affirmed the case on behalf of the plaintiff.

I want to talk to you briefly about Dr. Windsor. And I'm going to cite some pages and lines in his deposition that I think are important for your Honor from the standpoint of foundation.

At Page 24, beginning at Line 13, I asked Dr. Windsor, "In terms of your preparation for your deposition today, have you had an opportunity to review the chart on Ms. Goldin?"

He said, "Yes."

If we go down to Line -- to Page 25, Line 17, "And did that help refresh your memory as to your care and treatment of Ms. Goldin?"

His answer was "yes."

The next question I ask is, "Had you not reviewed

her records and the CD, would you have even recalled this case?"

And he answered "no."

On Page 37, I asked him at Line 7, "Once again, for the record, sitting here today, do you recall Ms. Goldin?"

"Answer: Vaguely. Maybe not."

This deposition took place on August 18th, 2016, some seven years after he had implanted this device in Ms. Goldin.

The reason those two sections are very relevant is nowhere in his chart, nowhere in his records does he state that he ever warned her of an increased risk of obesity or that there would be any limitation on the years that the device would work due to her obesity, that she was at a heightened risk of device failure. Nowhere in his records does it state that.

And so the fact that he doesn't remember the conversation with her, doesn't even remember her is important because, according to Ms. Goldin, "He never warned me. He never mentioned that obesity had any impact. He never discussed it with me. But if he had, I would have wanted to know, are there other devices that I could have used?" She would have wanted to know that. She would have wanted to know, is there another option, some other kind of surgery? "Rather than a replacement surgery, could I have, you know,

arthroscopic surgery? Is there something else that we could have done, or could I have just been encouraged to wait?"

Goldin is a unique case, your Honor. Ms. Goldin at the time was 5'1", 250 pounds, roughly. She has since lost over a hundred pounds. She weighs less than 150 pounds today. And she did that without the need of -- she had bariatric surgery, but the bariatric surgery didn't work. So she did it the old-fashioned way after her revision and lost a whole lot of weight. This is a very motivated person. And that's going to be important at some point, but I just wanted the Court to be aware of it.

So why is it important that I'm pointing this out? Because in his deposition, Dr. Windsor testified as follows, on Page 53, beginning at Line 13, I asked him, "As the manufacturer of the product, do you rely on them to provide you information regarding the performance of their product?"

His answer was, "Yeah, sometimes. Yes. And also the clinical literature that we see and obviously reports of performance at national and international meetings."

So this suggestion that was just made by Zimmer that Windsor does not rely on what they tell him is false. He, in fact, testified that he does.

Further, I asked him specifically at Page 67, "Based on the literature that you received from Zimmer, was there any contraindication of this device in obese patients?"

He said, "No."

"Did they ever suggest to you, as a physician, that it would be inappropriate to use this particular device in obese patients?"

He says, "They didn't specifically contraindicate it. I never recall hearing or seeing a recommendation to totally avoid this implant.

"Did they ever provide you with any specific body mass index above which you should not use the product?

"No."

And here's the truth of this case -- you know, these courts are supposed to be about truth at some point. And the truth of the matter in this case is they didn't say anything in the warning section. That's where a doctor looks. They didn't say anything in contraindication. That's where a doctor looks. They didn't say anything in precautions. That's where a doctor looks. They didn't say anything in Adverse Effects. That's where a doctor looks.

In all of those sections, even if he had been the most conscientious physician in the world and gone and looked, he wouldn't have found it. He wouldn't have found it.

What they may say about the counseling information I think is an ambiguous statement that any jury would look at and say, well, come on, that's the best you can do? A

billion dollar corporation. That's the best you can do?

So if we go on and we look further at Dr. Windsor's deposition testimony, I asked him whether or not they had ever furnished him any information regarding the load and what implication that had on obese people. On Page 89, he says, "I, myself, don't particularly recollect to their point."

And why are all these questions that I'm asking about what they told him important? You know why? Because he was a consultant for Zimmer and he had used 99 percent of the time Zimmer products in his practice at the Hospital for Special Surgery in New York City. It may be one of the largest and most esteemed institutions in the country.

If anybody would have known that there was going to be a warning or a contraindication or a precaution regarding this device, it would have been Dr. Windsor. I mean, he is not, you know, your routine orthopaedic surgeon in Orange, Texas performing surgeries occasionally in between treating the high school football team. This guy is at the top of the list of orthopaedic surgeons. And because he is, Zimmer paid him $7 million in consulting fees.

And that's important because at one point in his deposition, I say, "Well, you know, it's true that you didn't warn her about obesity."

He goes, "No, I did."

So he somehow miraculously remembers that even though he doesn't remember the patient, even though it's nowhere in his records, even though he had to review the chart to even remember the case, he somehow now remembers that he warned her about obesity.

But I had already proved in his case -- in this case that his practice had changed. On Page 136 of his deposition, I asked him, "Has your practice changed with regard to utilization of the High-Flex knees in obese patients?"

And he says, "Currently to a degree, yes."

Then on Page 137, "And has your counseling with regard to obese patients changed since 2009?

"Answer: I have based on the general data available in total knee replacements in those types of patients.

"And how has it changed? If you can just describe that to the jury."

And here's his answer on Page 137: "Certainly we advise patients that are morbidly obese or super obese, meaning a BMI 35 or BMI 40 and above, that they're at an increased risk of mechanical failure, whether it be loosening, implant breakage, instability, infection. And generally we don't contraindicate the operation, we say it's a good idea to lose weight, but, practically speaking, they

don't. And currently if they do lose weight, they usually gain it back." So he's got an attitude about that.

But he definitely testified that his prescribing practice has changed; and that's important because, just like a pharmaceutical case where, lo and behold, a medical article comes out that says that aspirin causes blindness, for instance, it would change the consultation that patients have with their doctor.

And in this instance, I asked him when this change occurred. And he said, "Generally over the last probably three or four years.

"All right. And so since 12 -- 2012 or so?"

And he says, "Roughly around there, yeah."

And then I asked him at Page 140, "And the counseling that you've just mentioned that you currently go through was not available to her in 2009. Fair?"

And he says, "At that time, no. We didn't see a specific difference. There are some clinical studies that looked at obesity clinically, and there's a variety of studies out there for obesity and how they would do functionally. So as time wears on, you get these clinical evaluations over time.

"Question: Nonetheless, Zimmer had not specifically advised you as a physician in 2009 that you were to counsel her in that fashion?

"Answer: As a company, no, I don't think the company did."

Critically important. This whole issue about failure to test, in my meager legal opinion, is premised on the law in New York and in many other states that a manufacturer has a duty to remain abreast of scientific advances, literature, other information available in public domain regarding the use of these products.

There, in fact, has been information in the public domain going back to the '80s about the risk of obesity in populations with medical devices -- knee devices. And the failure-to-test issue comes about as part of the "should have known." Because they're an expert, because they manufacture the device, because they take on that duty, they should know the potential harms. If you test about it, then you can release some type of information. Whether it be a warning or not, it just depends on what your study shows. But that's their duty. That's the manufacturer's duty.

And so what Dr. Windsor is telling us, telling the Court, is that we didn't really have this information in 2009. Keep in mind these products have been on the market since the '60s, these implants. This particular implant, the standard, had been on the market since the '90s. And the High-Flex had been on the market, I guess, since maybe '98, '99, something along there. But there was definitely plenty

of time to look at it. And they had an internal registry that they could have used to study it, but they didn't do it. And had they done it, they would have had information, better information.

I'm almost shocked that they take the position that their counseling the patients mention of the word "heavy" constitutes a specific and detailed warning. Almost laughable. Or that their comment in the surgical technique, the last comment they make in that section, Section 6, says that the patient should not be obese.

Once again, there's an important distinction in obesity between obesity and morbid obesity and super obesity. And the effect is different in the populations.

So in terms of the law -- counsel spoke to you a little bit about New York law. And as I've said to you, the manufacturer must keep abreast of knowledge of their products as gained through research, adverse reaction reports, scientific literature, and other available methods.

Second and equally important, they must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession. That's *Baker v. St. Agnes*, 70 A.D. 400.

There are several important considerations that directly affect the adequacy of the warning, including location and conspicuousness of the warning and the method in

which the warning is communicated to the ultimate user. That's New York law as well, *Anderson v. Hedstrom Corp.*

The warning must be commensurate with the risk involved in the ordinary use of the product, *Martin v. Hacker*.

And, finally, the great quote from *Baker:* "An uncommunicated warning is no warning at all."

New York law has long recognized that a manufacturer has a duty to know and should have known. What should they have known? That's a fair question to present -- be presented to a jury.

And in this particular instance, when the case is completely tried, there's going to be an adequate amount of information, both from the liability depositions that were taken in the MDL long before I even knew about *Goldin* or long before I ever knew about NexGen. And many of those depositions are going to bear on the issue of what they knew and what they could have done.

I think we cited to you in our summary judgment briefing some comments from Jarv Campbell, an employee of Zimmer, where he goes through and he details the number of obese patients that were in the patient population that Zimmer knew about. Susan Zogbi also was deposed on some issues regarding obesity. So there will be adequate testimony for the jury to rely upon with regard to liability.

As to the issue regarding causation, clearly, had Ms. Goldin received the type of information that Dr. Windsor now provides to his patients post-2012, she would have had the ability to make a different decision. One of those decisions could have been to use a predicate device that had a longer and more proven track record. That certainly was available to her.

The other thing, if somebody had told Ms. Goldin, "Ms. Goldin, rather than lasting 15 years or more, like they routinely do, because you're super obese at a BMI of 45, your device is likely to file -- fail inside of five years or, heaven forbid, at two years," like it did, she likely would have said, "I want to pass right now on that, and I want to lose some weight and get myself a device that has a proven track record."

She could have made those decisions. But the only way she could have made them is if Zimmer had told Dr. Windsor to be forewarned about that and to pass that along. And we take the position that they did not warn him as such.

THE COURT: All right. So if she had been given this warning that you believe Zimmer should have issued, she would have had options.

One, she could have chosen a standard knee, but there's no evidence that the standard knee would have

failed -- would have been less likely to fail, right?

MR. MORRIS: At this point there's not, your Honor. I mean, I thought we would have that testimony until we got the *Joas* decision. And I understand where your Honor went with that because that was Dr. Brown's position on that, but he's not the only expert in the world that may review this.

What we do know is that the predicate device, the standard, went through PMA process. This product did not. It went through the 510(k).

So the study and testing is different in the devices. And that's why -- you know, Zimmer wants to throw out any discussion of design defect and any discussion about the design of the High-Flex device; but respectfully, your Honor, the fact that it didn't go through the clinical testing necessary in a PMA-approved product, at some point it should be highly relevant.

THE COURT: I have got a lot of things to say about that, but I -- well, let me just return to my original question.

The other possibility was, had she received what you believe would have been appropriate warnings -- had she been told, for example, that because of her excess weight, her device was not likely to last 15 years, it was more likely to last only five years, she might have made another decision.

Is there evidence that -- do we now know that people that are super obese, that their knees fail at -- we know that their knees are more likely to fail, but do we know that -- for example, that a knee that would otherwise likely last 15 years in an ordinary -- a person of ordinary weight is likely to last only five years in a person who --

MR. MORRIS: I don't know --

THE COURT: -- has body mass above 40?

MR. MORRIS: I apologize, your Honor.

I don't know that we have that bright of a line in any epidemiological study where they say, you know, definitely it won't last more than five or three or whatever it may be.

There are studies that do show that in the obese population, they fail at an earlier rate than they would in the nonobese population. There's no --

THE COURT: Okay.

MR. MORRIS: -- no dispute about that.

THE COURT: And the other thing that you said was, it's possible, had she received what you believe would have been more appropriate warnings, better warnings, that she would have said, "Better I should just make every effort to lose weight now. Lose weight now, and then I will get the implant when I am in less risk for failure."

And I don't know what the circumstances are in her

particular case, but I know that in some situations, the pain that an individual is experiencing in his or her knee or knees makes it impossible to exercise, and that is often identified as a cause for the excess weight. Now, I mean, I think we can all talk about whether or not diet has more to do with it and so forth.

But at least it would be your position that, in spite of whatever pain she was experiencing with her knee at that moment, she had -- if she received proper warnings, she could have or would have lost the 100 pounds she has lost since the knee was replaced?

MR. MORRIS: Yes, your Honor.

THE COURT: All right. A brief rebuttal, and then I think we should be finished.

MR. MANDLER: I'll try to be brief, your Honor. I wrote down a couple of points I'd like to address.

Mr. Morris started out his presentation about -- discussing the fact that he believes the facts show that Ms. Goldin was not advised of the risk due to her obesity, to her weight, that the -- her implant may fail early.

First of all, that's not the testimony that Dr. Windsor gave. I would urge the Court to look at the Zimmer statement of undisputed material facts where we've cited in great detail what the facts actually are. And, you know, while the parties may be entitled to their opinions,

they're not entitled to their own separate facts. And I think it's clear from his own testimony that Dr. Windsor believed he gave that warning.

He testified at Page 78, Lines 4 to 23, "So in all, was it your anticipation that she would have a successful knee replacement, that it would last for a predicted period of time that you routinely counsel patients?

"Ordinarily, except that I did present in anybody that has a body mass over 35 -- and hers was in the 40s -- I always say that the longevity is possibly and probably compromised based on the fact that she was well above a normal weight."

Further on at Page 142, Lines 10 to 143, one, Mr. Morris asked, "Just so we're clear, in 2009, you did not advise Ms. Goldin that there was a risk posed by her weight?

"Answer: No, I did.

"With regard to the particular NexGen Knee and its longevity. We've been through that.

"Correct.

"It's just basically in general knee replacement?

"Right.

"Regardless of design?

"Right. That weight plays a factor, of course."

So the suggestion that she wasn't advised and there's no basis in the record that she was is incorrect.

Beyond that, there's a basis in the medical records. There's medical records of a Dr. Lisa Vasanth, who is an associate of Dr. Windsor's, who did the preoperative consultant with Ms. Goldin, that she was advised during the preoperative medical consultation about the risks, the known risk, and that she also signed a consent form that she received of these notices.

The fact that Ms. Goldin -- at the end of the day, though, the fact that Ms. Goldin now says she never received this information is immaterial to Zimmer's ability to prevail on a failure-to-warn claim because the question is, was her surgeon warned?

Whether or not he passed those warnings on -- and we believe there's sufficient evidence to show that he did -- is immaterial. It's Dr. Windsor's existing knowledge that negates the causal link between Zimmer's warnings and Ms. Goldin herself.

Second, the question of whether it was listed as a contraindication -- the risk of premature failure, whether it was listed in a particular section of the warning materials and the product insert I think does not undercut in any way the warning that Zimmer gave.

First of all, as we heard earlier today and I pointed out earlier, Dr. Bal himself has not given the opinion it should be a contraindication.

Second, in the Adverse Effects section -- and I didn't quote this and I didn't show it, but it's going to be found in Exhibit C to our motion, your Honor, Docket 50-3. It's the actual full text of the product insert. Under Adverse Effects, the very first one listed says, "Loosening or fracture/damage of the prosthetic knee, components, or surrounding tissues." That's the potential adverse effect. So it's right there that says it's an adverse effect.

And then over and above that, Zimmer tells the doctor, "Counsel your patient that that adverse effect may occur in heavy patients."

Now, the idea somehow that that doesn't apply to Ms. Goldin because she's super obese is nonsensical. She's two levels above heavy.

So Zimmer warned loosening is a risk, premature failing can happen in heavy patients, and somehow that's not a warning to Ms. Goldin because she has a BMI of 45 and she's super obese. That doesn't make any sense.

The question about whether or not Zimmer did warn about load or about High-Flex or things that could have been tested for all go to the design defect theory that plaintiffs have said over and over again they're not pursuing. So while they can be pointed to as potential things that Zimmer may have discovered or warned about, they go to a theory that the plaintiffs are not pursuing.

Finally, on that element, all of the things that Mr. Morris says that Zimmer may or may not have found if they did additional testing are all two or three levels of speculation for which he has no expert and no one to testify about.

Mr. Morris stated that it's clear from the evidence that Zimmer knew that its products -- its knee products were going into obese patients. That's not a surprising issue. They did know that there's certainly going to be a certain percentage -- from their own materials -- a certain percentage of these knees that go into obese patients. That's why they put the information in.

If we were to say that Zimmer isn't required to counterindicate these knee products for all obese patients, that means we're taking away the ability of folks who have an obese -- have a problem with obesity to actually get their knee replaced and improve their lives. Not everyone is going to be able to lose the weight first before they get a knee replacement. They may not be able to sufficiently move without pain to lose the weight they need to lose to have a better life.

Instead what Zimmer does is, it puts this information in the hands of the people who know best: the consulting surgeons, the doctors of the patients. And they can say, "I know it's a greater risk; but, on the other hand,

it may be a greater risk that you may be willing to take because it's going to improve your life." That's exactly what happened here.

The idea that somehow the Flex was approved through the 510(k) process and the standard was somehow at a full approval, first of all, is incorrect. The standard also went through the 510(k) process, I understand.

Second, there's no expert to testify about any of this. Dr. Bal said he is not an expert in FDA material. And moreover, the whole issue of FDA approval is subject to a motion *in limine*, which Zimmer forward and plaintiffs have not opposed in any way. So we anticipate that the whole question of FDA regulatory issues will be treated the same way it was treated in the *Batty* trial and it looked like it was going to be treated in the *Joas* trial.

Finally, the whole back-and-forth that the Court had about knowledge about how long a product will last, how much it may be compromised by obesity, you know, the percentage at which it may last, last a number of years, it may last less than if the patient wasn't obese, that -- none of that is resolved in the literature. And, moreover, plaintiffs don't have an expert, including Dr. Bal, that puts that theory forward and explains any of that or offers of any of those opinions. So it's all just argument on behalf of counsel that isn't backed up by any facts or any expert

opinions.

In conclusion, your Honor, I'd like to turn back to, you know, where are we at, where are we at at the end of the day.

We've argued three motions this morning: the motion to strike the late-filed Bal affidavit, the *Daubert* motion, and this motion for summary judgment.

THE COURT: Right.

MR. MANDLER: Obviously, your Honor, if you were to grant this summary judgment motion, there's no need for the Court to reach the motion to strike Bal and the *Daubert* motion.

THE COURT: Right.

MR. MANDLER: However, if the Court were not to grant the motion summary judgment, to answer a question that you put to Ms. Butler earlier, that -- what would we need to address the prejudice of the late-filed Bal affidavit? We would certainly need to redepose Dr. Bal. And we believe that should be at the plaintiff's expense since they completely failed to comply with the disclosure requirements of Rule 26.

We think we'd have the right to rebrief the *Daubert* issue after we explore his new methodology, his new reliance on literature, and his new application of the Bradford Hill criteria, none of which was disclosed previously.

Finally, if all of that means that the trial has to be continued, Zimmer is going to lose a substantial deposit of having a block of rooms for trial.

This is not an easy matter where we can just read his affidavit and be ready to go forward. In the same way that we have a right to depose him on his original opinion, we have -- now that he's come forward with new opinions and, importantly, new bases and reasons for opinions, all of which Rule 26 requires to be disclosed, they can't just say, well, we gave the opinions earlier, now we're giving the reasons. We have the right under Rule 26 to know that ahead of time and to be able to examine him on that through the course of a deposition.

So the prejudice is significant. It may or may not be important depending on how the Court rules on the motion for summary judgment.

Thank you, your Honor.

THE COURT: All right. Thank you.

Well, I think that concludes arguments on these motions, and I will be preparing a written ruling and getting it to you as quickly as reasonably possible. I recognize that we have a January trial date, and I recognize as well that the holidays are going to keep everybody busy, but we are going to do our best to get something out quickly.

One other thing that I wanted to mention just

quickly. I see that you provided a draft revised questionnaire that begins with the questions in the *Batty* case and then makes some revisions that are consistent with the facts here, and then a proposed letter to the jurors as well. And I have had a chance to look at those items. They look pretty good.

Are there other issues we should take up right now?

MR. MANDLER: I don't think so, your Honor.

MR. MORRIS: Nothing from the plaintiff, your Honor.

THE COURT: All right.

MR. MANDLER: Maybe to confirm that our final pretrial will be on the 12th, which is the day before jury instructions.

THE COURT: I think that is the --

MR. MANDLER: I mean jury selection.

THE COURT: That's fine. Yes.

I've said with respect to -- I think I said this with respect to Ms. Batty and *Joas*, but let me just remind you, this is an important case and any other bellwethers is very useful to us. Regardless of how they are resolved, they provide information that is useful as we go forward.

With that said, this is not a class action. Ms. Goldin is an independent person with her own independent interests in this case, and I think it makes sense for you to

spend at least a few minutes talking about whether this individual case could be settled.

All right. Thank you.

MR. MANDLER: Thank you, your Honor.

(Which were all the proceedings heard.)

* * * * *

CERTIFICATE

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

/s/ Amy M. Spee *1/5/2017*

Amy M. Spee
Contract Court Reporter

Date