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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE:	*	
ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LITIGATION	*	Case No.: 1:17-cv-742-LM
THIS RELATES TO:	*	March 11, 2021 12:32 p.m.
CARRIE LEE BARRON and NICHOLAS BARRON	*	

TRANSCRIPT OF STATUS CONFERENCE
HELD VIA VIDEOCONFERENCE
BEFORE THE HONORABLE LANDYA B. McCAFFERTY

Appearances:

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Meghan Johnson Carter, Esq.
Dennis A. Costigan, Esq.
Motley Rice LLC

Russell F. Hilliard, Esq.
Susan Aileen Lowry, Esq.
Upton & Hatfield LLP

For the Defendants:
Katherine A. Armstrong, Esq.
Mark Cheffo, Esq.
Paul A. LaFata, Esq.
Emily Van Tuyl, Esq.
Katherine Unger Davis, Esq.
Dechert LLP

Appearances:
(Continued)

For the Defendants: Pierre A. Chabot, Esq.
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P R O C E E D I N G S

THE CLERK: Good afternoon, your Honor. Can you hear me?

THE COURT: Yes, I can.

THE CLERK: Okay. I will announce the case and I let the attorneys know, your Honor, that after that you may ask who's going to be arguing and that they should mute themselves and/or close their video, depending, because I know we have a lot of people.

For the record, this is a motion hearing and status conference in Barron vs. Atrium, et al, which is 17-cv-742-LM in the master Atrium MDL C-QUR litigation, which is 16-md-2753-LM.

THE COURT: Okay. Can everybody hear me? Okay. Good. Excellent. Good to see everybody.

Let's do this. Let's start by having counsel just identify themselves for the record and then let me know who will be arguing.

MR. HILLIARD: Your Honor, good afternoon. Russ Hilliard for the plaintiffs, and I believe Attorney Orent will be doing most of the arguing.

THE COURT: Okay. Thank you.

MR. ORENT: Good afternoon, your Honor, Jonathan Orent for the plaintiffs. And, actually, also I want to introduce -- I don't know if Dennis Costigan has formerly

appeared before the Court previously for a hearing. He will be arguing one of the motions today and Meghan Johnson Carter, who I believe your Honor is familiar with, will be arguing as well.

THE COURT: Okay. All right. Good to see you.

All right. And if you aren't arguing, if you can turn off your video. You'll still be able to see the screen, we just can't see you, and it uses up less -- I guess it uses up less bandwidth and we're less likely to have problems with our video. And if you're not arguing, if you can mute. And sometimes I mute so that you don't hear the noise here. And if I forget to unmute, just -- just signal me.

Okay. Go ahead with the defendants. Go ahead, Attorney Cheffo, Attorney Armstrong.

MR. CHEFFO: Yes, good afternoon. I'm Mark Cheffo. I will be arguing one of them. I just want to just preview for your Honor -- I'm sure this is probably not the first time you've had a situation like this, you see a lot of faces. And the reason why is we are -- there actually are going to be a number of people arguing today these motions.

As your Honor I'm sure can appreciate, there's a lot of folks who have worked on this case for a long time and these are -- not to say that these are not all very important motions, but I think they're appropriate for different people to have an opportunity to present argument, often on the motions that they've worked on. So that's why you may see a

broader collection of faces and lawyers than you might have otherwise.

So I will let them introduce, but I just wanted to give your Honor that little background. That's why you're seeing a lot of folks today.

THE COURT: Thank you very much. And I appreciate seeing -- associates in the firm, is that generally -- that's great. Very happy to see that. Although if I call you Attorney Armstrong, forgive me.

Go ahead, Attorney Armstrong.

MS. ARMSTRONG: So, your Honor, I will be arguing several motions today. And just to amend what Mark has said, we did assign certain motions to some associates to argue. They -- and they are, as you can see, Emily Van Tuyl on the screen and Kate Unger Davis, as well as Paul, who had planned to argue some motions for today.

But Jon and Paul worked into the wee hours of the morning, I think, to try to resolve as many motions in limine as possible and I think we've reached agreement on all except for about three or four. Paul will correct me if I'm wrong. And three of them were assigned to me. Mark may have the other one. But as a result, Kate and Emily will not have a chance to argue today, but we did want them to be able to observe the proceedings.

THE COURT: Oh, that's too bad, because I would have

liked to have heard them argue.

So my understanding -- let me just go over what I think is on for today and you can tell me what's been crossed off. Okay?

Before I even start with that, let me just confirm, we don't need to do anything on the -- per the agenda right now; we can just address the motions in limine that are -- that are on for today. There's nothing really pressing in the agenda we need to talk about.

MS. ARMSTRONG: We have one question for you, but we can address it at the end of the motions in limine.

THE COURT: Okay. All right. Now, I noticed that there is no Plaintiff's Motion in Limine No. 5, at least that I can find. Did you just skip that number or did somehow Motion in Limine No. 5 -- did I lose it?

MS. ARMSTRONG: That was skipped.

THE COURT: That was --

MS. ARMSTRONG: I think it was just a skipped number.

MR. ORENT: I think that would be the reason why lawyers are not doctors. I think that patient would have been dead by now.

MS. ARMSTRONG: They may have -- they may have had a Motion in Limine No. 5 and decided not to file it.

THE COURT: Okay. All right. Good. So that takes

care of my first question.

Then I got an email this morning. I will say -- just so that Kate and Emily have a little sympathy, too, a shared sympathy -- I was ready to go, had done all the reading and the research, my law clerk and I working to prepare all those motions. So I got up this morning and thought, oh, gosh, okay, so I'll start discarding what I -- what my -- my notes and my cases and the case law.

So I just want Emily and Kate to know I did a lot of work in preparing for naught. But, of course, I'm not going to -- I'm not going belittle and berate lawyers who can reach agreement on something and take it off my plate, even though I was very prepared.

All right. So there is -- in the email that I got, you indicate that you've resolved a certain number of motions. You did not address Plaintiff's Motion in Limine No. 7. You included Plaintiff's Motion in Limine No. 6. Number 6 is the marijuana use motion that you all stipulated to that I never had to rule on.

Number 7 was included for today, so I just want to clarify Plaintiff's Motion Number 7, dealing with anxiety and depression. You have reached agreement on that or I need to rule on that?

MR. LAFATA: We have, your Honor. And I apologize. It was an early morning. But you're correct that the numbers

were mixed between 6 and 7.

To be clear, the motion on marijuana use was resolved a while ago. I think we reflect that on the agenda.

THE COURT: Yes.

MR. LAFATA: And motion 7 is the one about prescription medications during pregnancy. We have resolved that motion.

THE COURT: Okay.

MR. LAFATA: I apologize for that typo.

THE COURT: That's all right. That's all right.

So, now, there is still pending in the master case a motion to strike, plaintiff's motion to strike. It deals with affirmative defenses, boilerplate defenses. And I bet you haven't given that a lot of thought in preparation for today, but it's document number 1206 and I will need some sort of indication from you that you've reached some sort of agreement with respect to it or I will issue a ruling to resolve that before the Barron trial because that motion to strike definitely would affect Barron.

So you probably haven't given that much thought, but I want to put it on your list of things to perhaps resolve or attempt to resolve and then just let me know you can't and I'll -- I'll resolve that.

All right. The -- there's one little thing -- I think I know the answer to this, but it was just a little

ambiguous.

Count VIII was the loss of consortium for Mr. Barron and Count VIII is gone. Am I correct on that?

MR. ORENT: You are, indeed, your Honor.

MS. ARMSTRONG: Yes, your Honor.

THE COURT: Out of the case. Okay. All right. There was just a little confusion in one of the documents. I just wanted to make sure that that is the case. I thought it was.

Okay. All right. Let me clear this off my list. Hold on. Okay. So --

MS. ARMSTRONG: So -- your Honor, I received an email from Paul, and he can correct me if I'm wrong, that certain motions were reassigned to Kate and Emily, so you may be hearing from them.

Is that right, Paul?

THE COURT: Oh, good.

MR. LAFATA: That's correct. We had a lot of email traffic, your Honor, as you can imagine, with the motions getting resolved. But you will hear from Attorney Van Tuyl and Attorney Unger Davis today, yes.

MR. CHEFFO: I think one of mine went over to one of them.

THE COURT: Okay.

MS. UNGER DAVIS: Passed.

THE COURT: All right. And the only plaintiff's motion in limine for today is Number 3. Am I right?

MR. ORENT: Well, your Honor, as it so happens, we resolved that one just a few moments ago. And so --

THE COURT: Okay.

MR. ORENT: -- there's an agreement on that one.

So all of plaintiff's have now been resolved. I believe there's four motions that remain outstanding. Those are plaintiff's -- excuse me -- defense number 8, defendant's number 4, as well as the two on ADRs and on complaints. There may be another one. Am I missing --

THE COURT: Okay.

MR. LAFATA: I think number 7. I'm sorry, your Honor.

THE COURT: It's is going to be argued today? 7 is live?

MR. LAFATA: Yeah.

THE COURT: Okay.

MR. LAFATA: That's my understanding, yes.

Number 9 --

THE COURT: 2 --

MS. CARTER: Yes, your Honor.

MR. LAFATA: 2, 4, 7, and 8 -- 2, 4, 7, and 8 are all on the table and 9 was narrowed, but I believe is still on the table.

THE COURT: Oh, okay. 9 is a partial agreement is what you told me in the email this morning. That's the same. Okay.

MR. LAFATA: Yes, your Honor.

THE COURT: So there are basically four and a half motions to argue.

MR. LAFATA: Yes.

THE COURT: All right. Now, number 9, we'll get to that last. So let's do this in order of 2, 4, 7, 8 and then we'll get to 9.

But what is the partial agreement on 9? Just somebody articulate it for me so I can know what the scope of that is before we even get there.

MR. LAFATA: There --

MR. ORENT: It's --

MR. LAFATA: Oh, go ahead, Attorney Orent.

MR. ORENT: No, no, you --

MR. LAFATA: There were a couple issues that were keyed up by the motion, your Honor. The one that -- we have an agreement the plaintiff may introduce evidence that a witness received compensation in connection with their employment with Atrium or Getinge, but may not identify that it came from Getinge unless it is to refresh the witness's recollection.

What that leaves is whether the amount of payment may be admissible and there's a question about whether net

worth of Atrium is admissible. So those are the two parts that we -- we -- we talked about and worked on, but didn't resolve. But we did resolve at least that one part.

THE COURT: Okay. So you do concede that -- that plaintiff may introduce evidence that a particular witness received some sort of bonus money; is that -- are we talking about like extra money, more than their salary, they received some sort of extra payment?

MR. LAFATA: It's compensation. It could be salary or bonus, just compensation --

THE COURT: Okay.

MR. LAFATA: -- in connection with their employment. And that could take different forms.

THE COURT: Okay. Okay. All right.

And you didn't reach agreement on whether or not the amount was admissible and you didn't reach agreement on the issue of Getinge's net worth.

MS. ARMSTRONG: Atrium's net worth.

THE COURT: Atrium's net worth. All right.

MS. ARMSTRONG: Is that right, Paul?

MR. LAFATA: That's right.

THE COURT: Okay. I -- I don't -- I'll have to look at this, but I remember it being Getinge, not Atrium. Am I wrong about that?

MR. CHEFFO: Your Honor, you're --

MR. LAFATA: Well --

MR. CHEFFO: You probably do remember from the jurisdictional discovery, if that's what you're asking, Getinge is ultimately a parent company --

THE COURT: Yes.

MR. CHEFFO: -- and then Atrium is the operating entity, Atrium. So is that what you're thinking of?

MS. ARMSTRONG: But Getinge is not a party. But Paul --

THE COURT: Right.

MR. CHEFFO: The main thrust --

MS. ARMSTRONG: The agreement is --

MR. CHEFFO: Oh, sorry.

THE COURT: I think the motion was about Getinge's net worth.

MR. COSTIGAN: Yeah --

THE COURT: Is that right?

MR. COSTIGAN: -- the motion said Getinge's --

THE COURT: Okay. Okay.

MR. COSTIGAN: -- payments to Atrium. And we've narrowed that, essentially, to the value of what those payments are as the main thrust of the argument today.

THE COURT: Okay. And what's the dispute -- we'll get there, obviously, but what's the dispute regarding Atrium's net worth? That was not, I don't think, in the motion, so

that's why I'm asking here.

MR. LAFATA: What was left over from the discussion -- I'm speaking of the meet-and-confer discussion -- what's left over from that is whether net worth evidence is admissible, and it's probably going to be in connection with enhanced compensatory damages is my understanding. That was left over from our discussions and we could not resolve that part yet.

MS. ARMSTRONG: But is it Atrium's net worth or Getinge's net worth?

MR. LAFATA: Well, I thought it was Atrium, but now I'm trying to open the motion to check. Maybe Attorney Unger Davis can --

MS. UNGER DAVIS: I mean, I think that we moved to exclude sort of evidence of financial condition of the companies, you know, and Getinge and Atrium are, you know, what we were moving on there.

THE COURT: Okay. I know --

MS. UNGER DAVIS: So my understanding is that there's agreement as to Getinge, but not as to Atrium, on net worth.

THE COURT: Okay. And is the enhanced compensatory something that was just part of your discussions, but it's not actually in the motion in limine? Okay. All right. So --

MS. UNGER DAVIS: So I think we make the point, your

Honor, in the motion in limine that there are no punitive damages here and there are no punitive damages allowed under New Hampshire law; that, rather, what we have are enhanced compensatory damages. And under New Hampshire law, that is not to punish or deter. Therefore, our position is that financial condition and net worth of the company is not relevant as to damages.

And I don't believe that plaintiffs, you know, took on that point in response.

MS. ARMSTRONG: So, but just to clarify, are we arguing about Atrium's net worth? Have we reached agreement that Getinge's net worth is out?

Paul and Jon?

MR. LAFATA: We did not -- I don't believe we reached agreement on whether any evidence of net worth is in or out. I -- the agreement that we reached was whether evidence that a witness was compensated in connection with their employment, in that case either Atrium or Getinge, could be used in cross-examination, leaving aside the amount. So we did not reach agreement on net worth.

MR. ORENT: Just to be clear, I think given the stipulation that we all entered into as a result of the -- the hearing on piercing the veil, if you -- we would be -- we're talking about Atrium. And to the extent -- and I don't want to step on Mr. Costigan's toes by stealing the argument from him,

but I think that more to the point, to the extent that the purchase price, vis-a-vis payments, is an issue because it implicates certain witnesses directly in terms of the amount of money that they received and were held on to by the new company following the merger. It lends to their credibility, like any other witness.

So that's --

THE COURT: All right. We're not arguing the motion right now, though. I'm just trying to get a handle on --

MR. ORENT: Right.

THE COURT: And it may be that we -- when we get there, I may just need to perhaps have a little further briefing on the enhanced compensatory issue and this issue of whether or not Atrium's net worth is somehow relevant.

Getinge's net worth is off the table. All right? I'm not seeing any way in which that would be coming in.

Is that right? Everybody's in agreement on that?

MS. ARMSTRONG: Defendants certainly are.

THE COURT: Do you agree with that, Mr. Orent?

MR. ORENT: I do, your Honor.

THE COURT: Okay. So it's really just a question of Atrium's net worth and this whole enhanced compensatory. And I may hear argument on it and I may not be able to give you a sense yet, but we'll get there. We'll get there.

Let's start, because I have -- and I'm going to have

my -- I have an alarm ready to go to remind me. I've got to be a panelist at a presentation at three o'clock. I don't envision this going till 3:00, at all, but I just want you to know if it does go and Emily and Kate are surprisingly long-winded, then I may have to cut folks off and just reschedule. And we'll do it sometime next week, sometime very quickly. But I doubt that will happen. So I do want to try to get through these motions in limine as -- as, you know, efficiently as I can.

It sounds like number 9 -- and I'm not going to hammer counsel for trying to work out things and make stipulations and enter into agreements thereby maybe complicating the scope of a motion in limine in terms of what I know about it, how prepared I am. It may be that we just need to have just a little further briefing with respect to that issue to -- for me to be comfortable giving you a ruling on it because it doesn't -- it's not really something that I prepared for carefully with respect to Motion in Limine No. 9. But we'll get there. It may be something that counsel can just persuade me.

Okay. So let's start then. We are going to resolve today Defendants' Motions in Limine 2, 4, 7, 8, and -- and we'll get to 9 and see if I can help you resolve what's remaining there.

So let's start with -- unless anybody needs to talk

about anything before we start, we'll start with Motion in Limine No. 2.

MS. ARMSTRONG: Your Honor, that's --

THE COURT: So --

MS. ARMSTRONG: I think that's been assigned to me to argue. And this is our motion in limine --

THE COURT: Lucky you. Okay. Hold on.

MS. ARMSTRONG: Yes.

THE COURT: Hold on one sec.

All right, Attorney Armstrong then. We'll start with your Motion in Limine No. 2. This is the evidence -- you want to exclude or limit evidence of third-party complaints and medical device reports that were received by FDA regarding Atrium's surgical mesh products.

So go ahead.

MS. ARMSTRONG: So let me take the exclusion part first and the -- the argument there is keep it -- keep in mind that there's two categories of complaint filed. Complaints come into the company and the company monitors them and those are the complaint files maintained by the company.

Some of those, based upon the requirements, the criteria established by the FDA, may get converted to MDRs and reported by the company as medical device reports. In the pharmaceutical world, these are referred to as adverse event reports. In the medical device world, they're referred to as

medical device reports. But they're reports of adverse events.

So if they come into the company and the company determines that they meet the criteria for reporting to the FDA, they'll get submitted by the FDA as an MDR. But anybody can submit an MDR to the FDA. It's not just the company. So that a doctor -- it's usually a doctor or a hospital that would submit an MDR to the -- the FDA and there are certain -- there are certain categories of hospitals or what are called device user facilities that are actually mandatory reporters. But most of it is voluntary reporting by hospitals and doctors.

A patient could submit -- I mean, if a patient knew how to figure -- fill out an MDR or they could contact the FDA and maybe the FDA would complete an MDR based upon the information provided. I'm not sure about that, but patients are certainly able to report -- file MDRs with the FDA. And the lawyers can report if they have -- you know, based upon the -- their clients and the claims that are being made either to a company or in litigation -- to the FDA as well.

To the extent this -- you know, this information is also conveyed to the company, it would be included in the complaint files and, again, the company would evaluate whether or not they meet the criteria for reporting to the FDA.

The reason why we've asked for it to be excluded is that this is all pursuant to the fact that this is a clear product under the 510(k) process. I mean, that's what

establishes the reporting requirements. And given your Honor's ruling on -- on the FDA -- on the 510(k) process, we think it's difficult for the company to explain, this is -- these are the -- these are the complaints, the adverse event reports that we've provided to the FDA -- without being able to explain all of the other information that was provided to the FDA in the course of the 510(k) process.

So just -- now, again, that's -- that deals with the FDA. That wouldn't exclude the plaintiffs from talking about complaint files -- and we'll discuss those as, you know, part of the second half of our argument in terms of the extent to which those should be limited -- but it would only -- but the argument is only that the actual reporting to the -- the reporting process to the FDA should be excluded based upon the fact that we can't, you know, also talk about all of the other information, all of the testing that we've done that was also given to the FDA. If that's going to be excluded, we shouldn't have to -- there shouldn't be evidence of just the -- you know, the adverse event reports that were given to the FDA.

So that's the first part of our argument. I will stop there if you have any questions or I will continue to the rest of our argument.

THE COURT: Go ahead, Attorney Armstrong.

MS. ARMSTRONG: Okay. So the rest of our argument is assume that the MDRs come in, and this also applies to

complaint files that are maintained by the company, that they should be treated as hearsay and inadmissible for the truth of the matter asserted, which is -- which is causation, basically; the idea that it was the -- the mesh that actually caused the adverse event, the cause of the adverse event that was supplied or that was -- that was complained of, that -- if they're offering it for that causation, that's being offered for the truth of the matter asserted. It's clearly an out-of-court statement and it doesn't fall within any of the hearsay exceptions.

They're not -- for example, they're not -- they're not -- but -- they're not business records. They're -- they may or may not be made at the time of the -- of an incident with a person of knowledge. They are subject to biases. I mean, I -- just as an example of bias, a doctor whose patient experiences an adverse event postsurgery may be more inclined to try to blame the device that was used rather than his own surgical technique. So they are subject to biases and so there's -- there's indicia of -- of lack of trustworthiness with them.

But more than that, as a matter of science, it's well recognized within the scientific community -- you know, the sign -- scientists have a hierarchy, you know. And they -- the most -- you know, the thing that they would give the greatest weight to in terms of causation is what's called a

double-blind controlled study. But even that -- then the next level is epidemiology.

When it comes to individual case reports, those are considered -- even in the world of science, even in -- even excluding the fact that, you know, some of these may be litigation-driven or something that like that, but in the world of science, such anecdotal case reports are not considered evidence of causation because they don't -- they lack the controls. They're just coincidence at this point. You have -- the only connection is, you know, the timing of the event and the adverse event and the fact that an implant was involved. But they haven't been subject to the rigor and controls that other scientific evidence has been. So they -- they're not considered evidence of -- of causation by scientists.

So just to -- so some of the -- and also the FDA in its -- in its regulations recognizes that these are not evidence of causation and should not be construed when the company submits an MDR, or when anyone submits an MDR, they should not be construed as admission by the party submitting them that they are -- that they are an admission of causation.

Just to -- to identify a couple of the cases that we've cited. They were -- you know, in the *Bartlett* case, the court held that they were inadmissible -- inadmissible hearsay; they could be offered for notice, which we're going to -- which I will get to, but if they were offered for notice,

a limiting instruction should be given. The court imposed additional limitations such as that the contents should not be recited, nor should the actual reports be shared with the jury.

Also, in *DeLuca*, the court held that even if the adverse event -- and it was talking about -- it was talking about drug adverse event reports. But even if the information were accurately reported that they have inherent biases such as I've already discussed and that they're secondhand reports should not be admitted for the truth of the matter asserted. So that's the -- that's the -- the idea that they -- they can't be admitted on the issue of causation.

As to notice, courts have held that adverse event reports and MDRs are admissible on the issue of notice, but there is the potential for prejudice there. I mean, you're basically, you know, asking the jury, if you give a limiting -- number one, almost all courts that have admitted them have recognized that limiting instructions should be given. But even with a limiting instruction, you're basically asking the jury to make a distinction between the doctor or a plaintiff or a lawyer or a claimant, you know, asserted that the mesh caused this adverse event, making a distinction between that kind of statement as a notice statement and the fact that the device did cause the adverse event, which would be inadmissible hearsay.

So that's a pretty settled distinction that juries

are being asked to make. So -- so steps should be taken to make sure that there's not undue prejudice to the defendant and that the confusion is avoided.

And so we've identified certain limitations that we've asked. First, we would ask for a limiting instruction to be given, that these are not evidence of causation, they're just being offered for notice. If it's being offered for notice, then it has to predate the plaintiff's date of implant. So -- because if it comes in after the date of implant, it's not relevant to the issue of notice.

And then it should be limited to -- to substantial -- it should be limited to the V-Patch product. The plaintiffs argue that -- for a broader -- that it should be all C-QUR products. But if your Honor will recall when we were talking about which cases were most representative for the bellwether, Mr. Orent argued strenuously, I think, that, you know, it should be a V-Patch case and that -- because V-Patches were -- or are the most used C-QUR devices in the MDL pool and that other devices were not sufficiently similar to the V-Patch case, so those cases could be appropriate bellwethers.

So having already said that there's differences between the devices, the plaintiffs shouldn't now be able to argue that they're all essentially the same and all the complaints come in. So we argue that it should be the same -- the same product.

And the other thing is that because of the risk of -- again, you need to be careful about how these are used. We also argue that it should be the same injury. Basically, I think the plaintiff in this case claims an infection. But it should be the same injury as the plaintiff.

So those are the limits that we would argue and that -- one of the cases that we cited, which is the First Circuit case, deals with substantial similarity. It's not a -- it's a drug or medical device case, but it's *Downey*. But the court -- in the *Downey* case, the First Circuit said we need not probe the ramifications of that forfeiture because the argument puts the cart before the horse. Without a showing of substantial similarity, the evidence was not significantly probative and evidence that is not significantly probative may be excluded entirely.

And the Court also noted that the risk of prejudice if devices -- if products that were not substantially similar were entered as complaints about the -- about products that were not substantially similar were introduced, that that risk of prejudice could not be cured by a limiting instruction.

So those are the limitations that we would ask if MDR -- if either MDRs or complaints do come in, those are the limitations that we ask.

I wanted to say a couple of things about the cases that were cited by the plaintiffs. Most of them are not drug

or medical device cases. And the -- you know, and a complaint that, you know, a mechanic -- a home appliance that I bought doesn't work is not the same as a complaint about whether there's medical causation in a drug or medical device case. I don't think those cases are sufficiently comparable.

But just to address the cases that they cited that did involve drug or medical devices, the first one was *Taylor*, which was where they were admitted on punitive damages. And I'm going to talk about that in a minute.

But the Court was addressing substantial similarity there and the Court held that there was not a sufficient difference between erosion of vaginal or urethral tissue, was not enough to undermine substantial similarity. That's not really the issue here. The issue here is whether the other types of injuries -- those are -- those are very comparable injuries and we're talking about injuries that are very different from infection. A lot of the complaints deal with injuries that are very different from infection and those shouldn't be allowed here.

Contratto was a discovery case, which is not at issue here. We've produced all the MDRs, so we're not arguing about whether they're discoverable or not.

The same is true of *Ingram*, which is a discovery case.

In *Worsham*, the time frame was limited, which is

a -- which is the limitation that we're asking for, and the testimony concerned -- that was at issue in *Ingram* concerned the exact same injury that was alleged by the plaintiff, which in that case, it was a drug case -- oh, no, I'm sorry, it was an IUD case. In that case, the injury was tuboovarian abscess. So it was the exact same injury. So that was -- that's consistent with what we're asking for here.

And then the last case that they cited that involved a medical device case was *Gale*, which dealt with the -- a motion to dismiss. It really didn't address the admissibility of this evidence at trial. So I read it. I couldn't really see how it was apposite to this issue at all.

The last argument they make is that it is -- it is -- the -- a couple more arguments.

They argue that it's relevant to the issue of punitive damages. Again, punitive damages are not at issue in this case. They're seeking enhanced compensatory damages under New Hampshire law. And since it is a -- since it is still a form of compensation, it may -- may look a little like punitive damages, but the -- the New Hampshire courts have been very clear that this is a form of compensation. It's not intended to punish the defendants. And so since it is a form of compensation, we think there ought to be a tight nexus with the actual injuries that the plaintiff is alleging.

And then, finally, the plaintiffs make an argument

that it's not -- that it shouldn't be treated -- excluded as hearsay. The first is that, you know, they argue that we haven't disproven each exception, but it's really their burden to prove that an exception applies when it's -- when it is -- when it is hearsay. They also cite several district court cases that have held that it wasn't hearsay and admitted it for the truth of the matter asserted.

They do not address the Fourth Circuit court opinion which reversed that decision by a trial court that it had admitted it for the truth of the matter asserted. The Court held, no, it was -- it was hearsay, it should have been -- it should have been limited to the issue of notice. The Court ultimately didn't reverse on that grounds, I think it found harmless error, but obviously we want to avoid error in the first place here. But the court made -- the Fourth Circuit made very clear that these were inadmissible hearsay and not subject to any exception.

I think we'll start there unless the Court -- the Court -- the plaintiff's argument also really doesn't address the scientific standards for causation which make clear that anecdotal reports and case reports are not considered evidence of causation.

I think I will stop there unless the Court has any questions for me.

THE COURT: I may have questions after I hear from

opposing counsel. So let me just go ahead and let opposing counsel jump in here.

MS. CARTER: Yes, your Honor. Meghan Carter, and I will be arguing this for the plaintiffs.

Now, some of the things that Attorney Armstrong mentioned we did not necessarily see in their briefing, so I am not sure if Attorney Orent will be able to keep himself from jumping in at the end.

And one thing that I'll note before we start arguing is a -- while we have counterpoints to all of Ms. Armstrong's arguments, much of this is hypothetical. There are no specific medical device reports or complaints that they have mentioned. And so when you're looking at these, it's really the particular evidence and the context of how we plan to introduce it and argue at trial that's relevant. And I don't see how any broad ruling now would help in that individual situation.

THE COURT: So you're telling me, Attorney Carter, that you don't have any adverse events, MDRs, at this point that you intend to introduce --

MS. CARTER: No.

THE COURT: -- or did I mishear you?

MS. CARTER: Not -- that is not true, your Honor. Defendants have not pointed to any specific --

THE COURT: Okay.

MS. CARTER: -- reports that they want to exclude.

They're only speculating as to that we might introduce them and how we might introduce them.

THE COURT: Okay. How many are we talking about here? How many reports, and are there different buckets of reports?

MS. CARTER: Yes, your Honor, there are --

THE COURT: Can you describe them?

MS. CARTER: -- a number of different reports. There's a bit -- over 27, 28 different inspections of these facilities and there have been a number of different complaints and most importantly, the failure to investigate the complaints, follow up with the complaints, and some of these, the failure to report the medical device reports to the FDA. While some of these complaints are directly related to infection and V-Patch, that particular injury, the infection, it's too limited because it's the end result of several design failures that come together. And some of those different design failures include the coating or the sterility and there's different instances that are different complaints at the facility.

So it's hard to exactly give you any one specific incident, but, yes, there are buckets of complaints that are going to be relevant.

THE COURT: Okay. Can you just summarize the buckets for me? And I'll let Attorney Armstrong tweak that if

she would like, but I just want to get a sense of what kind of evidence we're talking about, how much is there.

And I understand one bucket, I think you said, was you know, basically infection; and another bucket might be defects in the product, coating, sterility; and then another bucket that would deal with failure to inspect or investigate?

MS. CARTER: Failure to investigate the complaints, the failure to find a root cause when a complaint is given.

And some of this is getting a little bit into the discuss -- into other areas that Jon may end up jumping in, but they're issues that the product seemed to share between the product lines. They're issues of their quality systems and their lack of the design history files in their quality systems, their failure to open corrective and preventative actions, which are CAPAs, whenever there is a defect in a product or if there is a product that is -- doesn't match what it's supposed to.

There's a lot of different areas. It's --

THE COURT: Okay. Let me ask Attorney Armstrong, would you like to just -- I'm going to let you interrupt for the moment and just describe, sort of as you understand it, these buckets of reports, if you will. I'm just speaking in shorthand, but the buckets of reports, what am I looking at?

MS. ARMSTRONG: So, again, in terms of the complaints, we're not trying to prevent them from discussing

the fact that complaints come in to Atrium. Atrium has -- has to evaluate them and Atrium, you know, has to decide -- you know, has to deal with them somehow.

That sort of general evidence, not complaints -- and again, to the extent it's offered on the issue of notice and it's on the -- offered on the issue of how the plaintiffs -- that Atrium dealt with the complaints, we're not specifically seeking to exclude that.

Your Honor has excluded evidence of the 510(k) process and so we have been discussing with Attorney Orent how evidence of FDA inspections comes in consistent with the 510(k) -- your Honor's ruling on the 510(k). And as your Honor noted in your -- one of the last two orders that you entered, we -- we indicated that our regulatory stipulation is conditioned upon reaching a factual summary. And I think you gave us a deadline for the -- for dealing -- for proposing the factual summary. Factual summary specifically deals with inspections.

So we are still trying -- so we're not saying that plaintiffs can't talk about inspections at all, but we're trying to reach a factual summary with them about the inspections that would -- would -- would take the place of, you know, like the actual FDR reports. And that process is still going on.

So these types of process arguments that

Ms. Carter's describing, we're not specifically by this motion seeking to exclude those. We're seeking -- the -- the motion that we're seeking is much more limited and much more precise. First of all, we think -- we would exclude MDRs as opposed to complaints, but we would exclude MDRs submitted by the -- to the FDA on the grounds that we can't say we also gave the FDA this information. But that doesn't exclude all the complaints and every MDR at the company starts off as a complaint, so it would still be captured within the complaint files. So that was the first argument.

But our second argument in terms of how these -- these documents should be used is, number one, not proof of causation, because that's hearsay; and then, number two, on notice certain limitations should be given.

So just to give you an example: If somebody reports -- somebody made a complaint that a patient had an infection after being implanted with the mesh. And we would -- there would be a bucket of infection cases. Another plaintiff or another claimant may contend that the mesh became separated. That's a very different issue. And the process that would lead to separation is -- is very different than the process that would lead to an infection. And so that would be a different bucket. And we would say that that bucket, because it's such a different injury than what is being asserted in this case, that that should not come in even as notice because it's not notice

that the mesh could cause infection, which is the injury claimed by Ms. Barron.

So -- so the first -- so -- again, so my overarching point is that most of what Ms. Carter just said about the complaint process and how the complaint process took place, we're not seeking to exclude evidence of the process. We're seeking to exclude specific reports that are not -- and in terms of whether we've identified a specific report, we're -- we're dealing with these as a category. You know, as a category, medical device reports are -- are considered case reports and not evidence of causation. That's true by the FDA; that's true of the scientific community. So that's a categorical objection.

And as to the buckets, again, we think it's their burden to prove substantial similarity and we don't think they can show substantial similarity when it's a different -- when it's a different injury for the reasons that I've explained.

THE COURT: What about the design defect claim --

MS. ARMSTRONG: Well --

THE COURT: -- aspect of the --

MS. ARMSTRONG: Well, the fact -- the fact that it causes, like, say, separation, that may -- I mean, if there's something about the coating that causes separation, that may be a different design defect then something about the coating that causes infection, if that's their allegation. We don't agree

that there's causation in either of those cases, but there's no reason to assume that the attribute of the product that causes separation would be the same as the attribute of the product that causes infection, if that's their claim.

So that's where the substantial similarity becomes important. And so we would -- again, one of the limitations that we're asking for is that it be the same injury.

THE COURT: Okay. All right.

Attorney Carter, go ahead.

Thank you, Attorney Armstrong.

MS. CARTER: The thing with the substantial similarity is you have to look at this evidence -- and Attorney Armstrong was discussing that separation -- a complaint of separation would be different than a complaint of an infection. Well, that's not necessarily true. Separation may have to deal with the failure for ingrowth in the product and -- which also can be related to foreign body reaction. And all of that together can also be related to infection.

So just because the end injury seems different, it doesn't mean that it's not the result of the same design defect. And our experts actually discuss the different failure modes and how they work together and the different things that they can cause.

And one thing that I'd note about these reports is we're not necessarily using them for the truth that -- the

statement in there. They can be used for nonhearsay purposes and, also, experts can rely on them even if they are hearsay because experts can rely on otherwise inadmissible evidence to reach their opinions.

And I'm a little bit confused about her -- about Attorney Armstrong's arguments today versus what was in the briefing because she was saying she wants to exclude the MDRs but not the underlying information.

MS. ARMSTRONG: That -- I -- I don't mean -- I apologize for interrupting. Tell me to shut up if I shouldn't interrupt.

But just to clarify, the argument that I made about excluding the MDRs is consistent with what was in our briefing. Again, there's a difference between a complaint and something that rises to the level of the MDR and gets actually reported to the FDA. Our argument on exclusion of the MDRs, which doesn't -- which is only the information -- only the form that actually went to the FDA, the underlying complaint filed that this argument does not apply to. All of our arguments apply to complaints, but this specific argument doesn't apply.

And that -- just based upon your Honor's 510(k) ruling and it was in our briefing papers was that if you're going to exclude evidence of testing that's given to the FDA, you shouldn't also permit them to say, and the company reported this many adverse events to the FDA.

Again, there's a -- each MDR has an underlying complaint filed that's internal to the company that doesn't involve talking about the FDA and we're not -- this part of our argument doesn't go to that. But as to the actual information that's communicated to the FDA, then we're saying you can't say we can't -- we told the FDA XYZ, but we're excluded from saying we also told them ABC.

MS. CARTER: I think there's a -- our motion on 510(k) is related to the 510(k) process. And -- but the process itself is not about safety and efficacy.

Now, plaintiffs have not moved to exclude any testing results or any studies. All of that would still be relevant. We're not trying to prevent defendants from saying we did study this, we did test this, and whatever they're trying to say relative to that, but they have been cited for the failure to submit device reports in their complaint system. And one thing the plaintiff is going to have to deal with is their complaint statistics. And so we're going to have to deconstruct their statistics about their complaint rates and failure rates. And part of doing that is showing that their reporting system to the FDA and their complaint handling system is not robust. There's not investigations; there's citations of oral reports not making it into medical device reports. And what's in the medical device reports may be relevant for reasons other than the truth of it.

And in New Hampshire, the duty to warn of dangerous defects, it includes more common law duties. It's the duty to acquire knowledge and investigate and test this product for defects and when they're getting a number of reports, those reports and the trending of those reports is important.

MS. ARMSTRONG: So, again, our argument on notice is that -- not to exclude them. Except for MDRs, we're not seeking to exclude based upon the FDA argument that I made before.

As to process, again, we are working with the plaintiffs on a factual summary that will address these process issues so that that information can be admitted into evidence in a manner consistent with your 510(k) ruling. That's still under works.

We're not -- if the Court doesn't exclude the MDRs entirely based on our primary argument, I'll ask them to come in on the issue of notice, which we concede a lot of -- most courts have let a lot of them come in on the issue of notice but that there just should be limitations to avoid the risk of prejudice. There is a -- a significant risk of prejudice.

But all of these process arguments that Ms. Carter is making, those are the subject of a separate discussion between us and plaintiffs regarding this factual summary that we're going to submit to the Court. They're not -- they're not --

MS. CARTER: Well --

MS. ARMSTRONG: -- germane to our motion in limine.

MS. CARTER: -- your Honor, the complaints themselves, the MDRs, actually come from the company. And part of the MDRs include what the -- what Atrium did to follow up. Atrium is allowed to, when they're able to, contact the doctor or the reporter who made the report and they can say all of these things and that they did follow up or if they didn't follow up and what information is in there.

And as far as the hearsay and whether or not the reporter is reliable, Ms. Armstrong said herself it can come from a number of different sources and she hasn't given a specific one as to what that source is and whether it's relevant and if Atrium did, in fact, follow up in that individual case.

MS. ARMSTRONG: So -- your Honor, can I also address the argument regarding experts? Because I forgot to.

Experts --

THE COURT: Okay.

MS. ARMSTRONG: -- can rely upon information that is -- that is reliable, but, as I said, the scientific community is does not consider case reports to be evidence of causation. That's very well established, that case reports -- and the Fourth Circuit, again, said that -- rejected that argument as well and said, you know, the --

THE COURT: It seems --

MS. ARMSTRONG: And -- and even when the expert says I relied upon those, they don't independently come into evidence. That's true for all realized materials by experts.

MS. CARTER: Generally with case --

THE COURT: Okay.

MS. CARTER: -- reports it's also a single case report. And I -- when you're looking at the hierarchy of evidence, generally it goes to weight, not admissibility.

MS. ARMSTRONG: I --

THE COURT: I'm going to stop you both. I'm going to stop you both because I think that -- I'm just -- there's no way that I'm going to be able to rule on these. I think I agree with a lot of what Attorney Armstrong is saying in theory with respect -- other than the 510(k) process, that process versus these complaints. The 510(k) didn't really deal with design defect issues.

But my -- my thinking on this is I'm going to give you a ruling and explain where I do agree with Attorney Armstrong and where I think, Attorney Carter, you're going to have to make the case at trial. And I don't think you disagree with the fact that ultimately you're going to have to show that if they are hearsay, you've got exceptions to -- to the hearsay rule or they're otherwise admissible.

So let me just tell you that I'm going to go ahead

and give you a ruling on this. I would say this is one that would benefit from further briefing because to the extent we can narrow these disputes before we get in front of a jury, we are going to be better off. That's why I'm asking about the different buckets and I'm trying to get a sense of, well, what are we talking about here, because ultimately it would be helpful, I think, to litigate some of these questions before we get in front of the jury.

So let me just tell you that as to motion number 164, defendant's motion in limine to exclude or limit evidence of third-party complaints and medical device reports, I'm going to -- I'm not going to find that admission of these materials would necessarily be prejudicial in light of the Court's -- my prior ruling excluding from trial evidence and argument regarding the 510(k) clearance process.

Now, I do find that these materials, to the extent they arise out of facts and circumstances substantially similar in material respects to the facts and circumstances underlying plaintiff's injury, they are potentially relevant to issues raised by the parties' claims and defenses, including, in particular, the existence and nature of defects in Atrium's product, Atrium's knowledge of such defects, and the question of general causation, which obviously raises hearsay issues. I'll address that in a moment.

For this purpose, such materials are relevant if the

complaints or reports concern surgical implantation of the same surgical mesh product used in plaintiff's surgery as well as patients who suffered injuries comparable in nature and etiology to plaintiff's.

As to the hearsay argument, now, I am not going to make any determination on that until I have the opportunity to observe exactly how plaintiff intends to use these materials at trial.

Now, plaintiff may offer the materials for a nonhearsay person -- purpose as, for example, to establish Atrium's knowledge of reports regarding potential defects in the mesh product or if offered to establish the truth of such materials, plaintiff may be able to establish the applicability of one or more hearsay exceptions. Again, I can't rule on that until I hear the arguments.

Now, as to defendants' argument that the probative value of these materials would be substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading -- the 403 arguments and that, therefore, they should be excluded, again, I'm not going to be making that ruling until I have the opportunity to observe the materials and how plaintiff intends to use the materials in the context of a trial. It's just too difficult. Unless you want to do further briefing, give me more specifics, then I can give you a sense of how I am likely to rule.

I think defendant has offered persuasive argument that the materials have the potential to be prejudicial, confusing, misleading, excludable under 403. But, again, I -- I need to make that determination with more information.

Now, so I think what I'd say at this point and my ruling at this point is I am granting this motion in part. I am excluding evidence of third-party complaints and medical device reports to the extent they do not arise out of facts and circumstances substantially similar in material respects to the facts and circumstances underlying plaintiff's injury. And to the extent such materials are offered to establish that defendant had notice of them at material times, they are excluded unless defendant received them or had the opportunity to review them prior to the date of plaintiff's surgery.

I'm going to otherwise deny this motion without prejudice and with leave for the defendant to raise it again at trial when or if appropriate. And I would encourage counsel to do further briefing on this and I would allow further briefing on this so that we can narrow this a little bit better before we hit trial.

All right. So that's Defendants' Motion in Limine No. 2. Let's go to number 4. This is the motion to exclude certain opinion testimony of Dr. Price.

MR. CHEFFO: Yes, your Honor. Mark Cheffo.

Let me say at the outset certainly I don't want to

put, you know, opposing counsel on the spot here, but this argument can either be a little longer or a little bit shorter. And I say that for two reasons.

One is, you know, we initially had the understanding based on their multiple designations that they were trying to designate Dr. Price as an expert. And, frankly, we have, you know, a number of arguments as to why that's not appropriate. But I also see in their most recent brief, you know, it basically says that Atrium is attempting to heighten the standard of Dr. Price's testimony by claiming he's being offered as an expert and there's also some other references to him being a fact witness.

So I'm, again, not being pejorative. If there's no disagreement here that he is -- he's not an expert, then that would obviously save some of my voice and the Court's time.

And then the second point, again, in fairness, notwithstanding the fact that, as you can see, there's been substantial discussion about a lot of the different motions here, the timing of this one was such that we actually made this ruling before the 510(k) ruling and there's actually been discussions, I know, that Attorney Orent and Attorney LaFata have had about the scope of them.

So when I read kind of the context and I see questions that at least in my mind, respectfully, are, you know, clearly going to the 510(k) process, if Attorney Orent's

view is, you know, no, that's not what we're going to be asking for, then that, I think, covers a lot of these questions.

I mean, just as an example, you know, if this device was not approved -- this is a question: Okay. If this device was not approved, if it went through a different regulatory process where safety and efficacy were not shown -- and it goes on. That seems to be directly related.

Now, my assumption -- and, again, I'll let Mr. -- Attorney Orent respond -- is that in light of that, you know, he would agree that that's kind of what -- would kind of open the door, if we can't talk about the process, asking a doctor to talk about the process.

So that -- that's just, you know as a preliminary. So I can kind of get into the argument --

THE COURT: Okay. Let me let -- I'm going to let Attorney Orent respond.

Go ahead, Attorney Orent.

MR. ORENT: Thank you, your Honor. Good afternoon.

You know, I guess that we've always treated treating physicians like Dr. Price, whose deposition was taken way back in 2019, as fact witnesses with the caveat that they are experts in the field that they practice and that their decision-making, one could consider their opinions part of their decision-making process. And so it's a little bit blurred.

But to the extent that the defendants are asking whether he's going to be giving 702-type opinions, I don't think he is and I don't -- I don't read anything that we've ever done as saying that he would.

With regard to the FDA piece, we are not going to be offering that piece of testimony. That was elicited at a time where, again, two years ago, we didn't know what the rules were going to be. And so the disclosure there, when we designated deposition cuts, was made without knowledge of what your Honor's ruling would be.

So to the extent that those questions are being raised, we're not seeking to admit those and, you know, we --

THE COURT: Okay.

MR. ORENT: -- we sort of take whatever rulings your Honor has and look at them in the context of -- of what clips we intend on playing.

THE COURT: Okay. Good. Well, that certainly limits the scope then somewhat.

So let me hear from defendants on number 4.

MR. CHEFFO: Okay. And, like I said, your Honor, so I'll try and do that, but I -- what I may do is kind of shorten this conversation. And I hate to do it, but it may well be that -- because it's not clear to me and, I mean, I'm not going to quibble that they did designate an expert, but it's good to hear there's not -- you know, I had designated testimony, so I

don't really know exactly what is being withdrawn or not. This may be something that we need to talk about, you know, a little bit more and see if there's really disagreement on. So maybe I'll just give a short preview and then you can give the -- give us some guidance.

But, look. The bottom line is if, you know, it is true -- let's talk about the expert issue. It is true that, you know, just like lawyers are -- you know, kind of have some expertise, and many courts have held this, we're not kind of experts in all practice areas. Just because you're a doctor, you know, generally doesn't mean that you have expertise on coating design issues of mesh, right, you know, all the other things that would kind of go into this case. And I think some of the issues here would -- would not be kind of admissible or appropriate questions because they -- they do get into some expert -- notwithstanding the fact that there was no -- so they wouldn't meet any of the 702 standard if we went through them and there also was no report here.

And I think, you know, particularly --

THE COURT: But wait a minute. Stop, stop, stop. Your whole point in starting this was to say, Judge, I'm going to limit the discussion because I don't think he's an expert, I don't think he's proposing him as an expert, and this 510(k) issue, that'll take a lot of time, but I think we can cut it out. And now you're going back to arguing the expert issue.

And so let's just cut through the smoke here. The only thing that I really need to consider with respect to this motion in limine is whether or not, you know, Dr. Price gets to testify, whether it's relevant, whether he lacks personal knowledge, et cetera. The other arguments that you make, Orent -- Attorney Orent just said I am not asking him any 702 materials, so I don't think you need to get into all your 702 arguments. So that's off the table.

He's going to be a fact witness, but I think Attorney Orent's saying, well, he's kind of an expert. He's not going to concede he's not an expert. He's not a retained expert. He's a fact witness. He's not going to give 702 opinions.

So it seems to me that accomplishes the shortcutting that you were proposing, so I think --

MR. CHEFFO: Yes.

THE COURT: -- the only thing you need to argue is your other -- it's inadmissible on grounds of irrelevance, lack of personal knowledge, potential for unfair prejudice. Right?

MR. CHEFFO: Yes, your Honor. Thank you.

And the only reason -- you're right, I wasn't -- I was giving you a preview. The only reason, and you'll see, I'll give you some examples, why I was kind of melding it -- and I got the point, I'm moving on -- is just that some of the questions kind of like aren't clear to me, right, whether

they're just --

THE COURT: Let me ask you this. Let me ask you this.

What question could Attorney Orent ask of Dr. Price during a hearing that you would suggest is crossing the line? What kind of questions would he be asking him that would -- that concern you?

MR. CHEFFO: So -- so a number of them in kind of the redirect. I mean, so, you know, basically questions that were saying, you know that there's another process; you know that there was no human trials of people; the first -- these are kind of -- I'm paraphrasing Mr. Orent's questions.

THE COURT: Yup.

MR. CHEFFO: Do you know the first time that somebody ever -- the first person who received this implant -- this device was the first patient, right, things that go to like you didn't do testing, you didn't do reports. That's one.

Then there's things where he's asked about, you know, if you were to assume that -- if you were to assume that the coating stayed in someone's body for X period of time, would you assume X. And then he says, well, it's -- it seems like a logical assumption, but I'd have to see some studies.

There's a number of these questions, right, and they're in the brief. They're essentially -- our kind of main point here is, one, FDA and we'll probably have an agreement on

that; but then, two, it's basically -- you know, Mr. Orent is a very good lawyer, right, but like if I were to show you that Atrium called up the polypropylene manufacturer before and they had these kind of conversations, would that, you know, kind of impact your view.

And there's -- and there's a reason why that is -- just a little bit of the context here I think that'll help your Honor. The issue here is the way this worked, at least in this case, right, it'll probably be different in other cases, but this doctor testified that -- well, let me take a step back.

No one's going to question what -- he's a fact witness. We're not trying to exclude, you know, the guy who actually did it; like what you did, what you know, what you observed. Of course that's all kind of fair play for both sides.

He basically said the way his hospital system works was that they actually had a separate committee, right, that picked the medical devices. Right? So it wasn't like maybe a pharmaceutical case where the doctor can say, you know, you should get X drug or Y drug or Z drug. He basically said, we had a committee and they did the safety and efficacy and probably pricing and other reasons.

So when he used the particular mesh, he did not preuse that. In fact, this may have been one of the first that he had used. He's used some other products. Right?

So all of these questions about, you know, had you known, you would have done something different, right, they're really not applicable here to this case because, essentially, this was off the shelf for him based on this -- this other committee that wanted to -- that made these determinations.

So that's the first, and then it really just goes to the kind of questions, like I said, where it's the speculation. And, you know, he says -- and we cited some of these in our brief -- you know, I assume that's true; or does that seem like a logical thing, yes, it seems logical, but I would have to look at assumptions; or, you know, Mr. Orent would say, if you -- if you assume this fact, and he says, well, I wouldn't know that fact, but if you assume it, does this seem right. So those are the basis, you know, of the arguments kind of beyond.

But to be clear, and then I'll see if your Honor has questions of Mr. Orent, we are -- you know, if you ask me the kind of questions that we have no issue with and those would be tell me anything about -- you know, you're a fact witness -- the medical records, what -- what you did, what your discussions -- what your notes say, what your treatment course was, things like that, you know, that are appropriate. But basically -- and these are mostly like in pages 1, you know, 35 to 145 or so. Right? There's a line of questions that are -- you know, not only call for speculation, they're leading, but they also essentially are -- are incorporating facts or

incorporating as facts information that this witness clearly does not have. And to the extent that then we're getting into kind of an expert area, that was why there was the discussion of experts.

MS. ARMSTRONG: Your Honor, may I clarify just one point on the issue of the expert issue and allowing him to testify as an expert?

The rules, Rule 26 specifically and the case law surrounding it, makes a distinction between, you know, hybrid -- when we're dealing with a hybrid witness, somebody who's a fact witness but also has expertise, it makes a distinction between those opinions that they formed in the course -- doctors are the prime example -- that makes a distinction between those opinions that were formed in the course of the doctor's treatment of the patient and opinions that are being formed specifically for litigation after the treatment is over. They're new opinions that are being formed for the -- for the -- for the litigation.

So part of our motion goes to the fact that to the extent the questions were intending to elicit new opinions that were not reflected in his medical records and were not opinions that were formed at the time of his treatment, then that sort of takes him out of the hybrid and then puts him into the -- you know, the regular expert where he really -- you should have a report and that type of thing.

So that's an important distinction to make when we're considering the questions that are being asked of the plaintiff is do they go to opinions he formed at the treatment time or is he being asked to make assumptions and speculations and, you know, agree with new opinions.

THE COURT: Okay. All right. But I thought the scope of his testimony and the dispute centered around the failure to warn and the fact that, hey, had I known this, I would not have used this product. I thought that was the Dr. Price testimony.

So -- and I remember pretty clearly from the briefing that Dr. Price -- even though they have this committee, Dr. Price specifically testified that he does review -- he reviews the -- all the insert materials for any product before he inserts it. And so that would go, I think, against this theory that this is this bifurcated approval process. Dr. Price testified that he would never use a medical device without first looking at the insert material.

So I think -- Attorney Orent is patiently quiet there. I think that the scope of this is somewhat more narrow than what defense counsel is worried about, but I could be wrong about that.

Go ahead, Attorney Orent.

MR. ORENT: I think your Honor made the very point I was going to make, and that is this is not the type of 702

testimony that an expert would offer. What the defendants are going to do at this trial is they're going to say that the duty to warn runs through the learned intermediary, Dr. Price.

And so what on one hand they're doing is they're saying we have to warn the doctor, not your client; and then on the other hand, when I asked the doctor how things would have affected his decision-making process, they're trying to tell me that I can't offer that -- I can't elicit that testimony from him.

And the reality is that these were very -- they were hypotheticals that were asked to the doctor based in fact and they are the -- they -- your Honor can admit them either as they are or certainly under 104(b) as conditional upon me proving the fact. But the bottom line is that these are questions that go to the heart of Dr. Price's decision-making process. Had he known X, would he have done Y. And that's --- those are factual-type questions.

You know, the notion that this is expert testimony and, therefore, would have been an expert without a report under Rule 26 is really form over substance. This deposition was taken more than two years ago and both parties have had ample time to look at it. So, really, this -- this notion that there's something new or surprising about his opinions is really misplaced.

At the heart of this is really the notion of can a

doctor discuss the facts that would influence their decision-making process in prescribing a medical device for the permanent implant into a patient. And so I did go through a number of different aspects. I asked him if he was aware of whether or not the device had been tested, which certainly goes to the doctor's views on the safety and efficacy of the device. You know, a lot of doctors won't use a device unless there's a certain proven track record, regardless of whether the FDA says it or not. This doctor was told certain things from the sales representative and believed it to have Omega-3 fatty acid. The box shows O-3FA in it. And so to ask him, well, Doctor, if you, in fact, learned that there was no Omega-3 fatty acid in it or I'm able to prove that to the jury, would you have ever used it and the answer is no, that goes to the heart of the failure to warn, where the defendant's package claims one thing and the documents and testimony from the corporate witnesses show the other.

So I think your Honor understands this. I'll defer to our papers for the rest of the argument unless your Honor has further questions.

MR. CHEFFO: Your Honor, can I just --

THE COURT: Do -- do the defendants intend to press the argument that his testimony's irrelevant because he didn't make the decision, the committee made it? Do you also intend to press the argument he lacks personal knowledge of the truth

of the premises of the questions? Are you still arguing that or --

MR. CHEFFO: I think it depends on the question.

So I -- I think the way you characterized the first part is that he did say that -- you're right. I mean, he basically did say he reviewed some other information.

I think, look, like a lot of these, right, this is one that is not categorical. It's question by question, right, you know. So, you know, that's why I was suggesting earlier maybe we go through some of these. But what we are saying is, you know, to the extent that, you know, the form, the presentation, the way these were created, I just think that there's fundamentally something wrong, calls for speculation on many of these. He's asking to assume.

I mean, when you look at some of his answers, he says: And when I say that, I mean I don't have the studies to prove that, but that sounds like a reasonable assumption.

Right? That --

THE COURT: Right. But as Orent -- as Attorney Orent said, this is two years ago. The landscape has changed. You guys have stipulated in and out all kinds of things. He may ask completely different questions than that. So just the fact that those questions had been asked -- you know, I commend counsel for agreeing and stipulating on so much of this case.

This motion, I look at this motion as a fairly

straightforward motion. I don't understand how Dr. Price doesn't get to testify as to what -- frankly, what you're trying to keep out. So persuade me why this motion in limine has merit. I've taken out the expert piece. We've cut that out. There's not going to be any 510(k) questions.

But you're still arguing that Dr. Price cannot testify because he didn't make the decision with respect -- now, I agree it's going to depend on what the question is at trial. But with respect to your brief and with respect to the scope of Dr. Price's testimony, I -- I am inclined to deny this motion because, to me, this one seems fairly straightforward. It's relevant, nonprejudicial, and it's likely to be helpful to the jury.

So tell me why that is wrong before I give you that ruling, because I will change my ruling if you persuade me.

MR. CHEFFO: Yeah, sure, and I'm trying, your Honor.

First of all, I mean, if this was general scope -- the point is that we're -- you know, assuming this is going to be deposition testimony, right? So he's not going to testify. So, you know, your comment that he may have a different question or he may reframe it, this is the record that we're talking about. Right? So this was the designated --

THE COURT: Okay. All right.

MR. CHEFFO: So we have to look at -- I mean, if he says we'll work out a stipulation, we won't use these, but they

want to play this video, presumably, exactly the way this is. Right? So I think that's why we have to look at the exact question --

THE COURT: Okay. Good point. Go ahead. Next point.

MR. CHEFFO: Okay. So to that point, when you look at the question, putting aside the issues we've talked about, when you ask questions of a fact witness, right, that are leading, that call for speculation, that put facts that the witness said he doesn't know, right, in his brain essentially after the fact, that is a core portion of what we're talking about. It would be no different than if any of us did it, right?

If you assume with me and I can show that -- to the ladies and gentlemen that, you know, anything, any question you ask a witness, and then they say, well, you know, I suppose. The point is he doesn't say -- you know, for the most part, he doesn't say, you know, yes, this is something I considered, this is something I would have relied on. He basically says, I don't know, you know; I -- I'd have to look at other records; that seems logical, but I'm assuming.

So, you're right, there probably could be other ways if we were wordsmithing this where we could have directions and -- but all I have, really, for this motion to argue is what's on the page, your Honor.

THE COURT: Okay. Attorney Orent, do you have anything further?

MR. ORENT: Just to -- to get rid of one false premise, which is that just because a committee accepted this -- this mesh, this product, to put it on the shelf, defense counsel is inserting the premise that it was the only mesh and that Dr. Price didn't have the choice. And I think that the record shows -- the whole reading of the deposition shows that he, in fact, did have a choice among the various products that the hospital bought. This was not it. And I think that's something to pay close attention to.

Again, I think under Rule 104, my hypotheticals can come in as --

THE COURT: Yes.

MR. ORENT: -- as -- thank you, your Honor.

THE COURT: Yes. This motion is denied.

As to defendant's argument that Dr. Price's challenged testimony is necessarily irrelevant because it was not Dr. Price who made the decision to select defendant's product but, rather, the hospital Dr. Price worked for, the Court, I, reject that argument as premised on a clear mischaracterization of Dr. Price's testimony.

Although Dr. Price's hospital did play a significant role in selecting defendant's product, Dr. Price testified that he would never use a medical device without first reviewing all

the insert materials.

I have a good law clerk who sent me the actual citation. It's document number 201-1, his deposition at page 35 lines 13 through 20. The clear implication is that Dr. Price retained discretion in his choice of medical devices and a degree of control over the product selection decision.

As to defendant's argument that testimony is inadmissible because Dr. Price lacked personal knowledge of the truth or accuracy of the premises of the questions posed by plaintiff's counsel, that argument -- I reject that argument. The personal knowledge that Dr. Price needed to rely upon to answer the questions posed was his knowledge of whether the information would have impacted his willingness to use defendant's product had he been made aware of it. To establish the relevance and, therefore, the admissibility of the testimony at trial, plaintiff will bear the burden of establishing the accuracy of the information recited in counsel's line of questioning which plaintiff will attempt to do through evidence and witnesses other than Dr. Price. Plaintiff need not establish Dr. Price's knowledge of the information's accuracy.

Likewise, I reject the argument that it's prejudicial because the questions were posed to Dr. Price by plaintiff's counsel. Defendant will have the opportunity to challenge the accuracy of the information posed to Dr. Price at

trial.

So the challenge testimony is relevant, nonprejudicial, and likely to be helpful to the jury. So Document 166, which is motion number 4, is denied.

So now let's go to 7 and 8 and then we'll get to 9.

Let me just make sure for our court reporter -- I think our court reporter is going to need a break here. It has been -- 12:30, 1:30 -- I think so. I've got to give our court reporter a break.

So let's take a ten-minute break, ten-minute recess, and we'll come back and do 7 and 8 and then we'll look at 9. Okay?

So come back at just five after 2:00. All right.

MR. ORENT: Thank you, your Honor.

THE COURT: Anybody need to say anything before the recess?

Just turn your video off and mute your mic and we'll all turn everything back on in ten minutes.

(Recess taken from 1:54 p.m. until 2:07 p.m.)

THE COURT: Okay. Are we ready, Attorney Van Tuyl? Am I saying at that correctly?

MS. VAN TUYL: It's Van Tuyl, your Honor, Emily Van Tuyl.

THE COURT: Van Tuyl.

MS. VAN TUYL: Thank you.

THE COURT: All right. And you'll be arguing motion 7. Will you also be arguing 8?

MS. VAN TUYL: No. Only motion 7 for me, your Honor.

THE COURT: Okay. Okay. All right. Let's start with 7.

And just so folks know, I've got something at 3:00, so I'll probably need to cut us off before 3:00, maybe ten minutes, just so that I can get ready. But I think we'll be fine in terms of the time we have left.

So, go ahead, Attorney Van Tuyl.

MS. VAN TUYL: Thank you, your Honor.

In motion number 7, Atrium is asking your Honor to preclude the plaintiff from presenting evidence or from arguing about medical conditions that some other plaintiffs or some experts may attribute to C-QUR, but that Ms. Barron is not alleging she experienced here. And our brief on Motion in Limine No. 7 includes a list of examples of conditions that we would be seeking to exclude. We pulled those from the plaintiff's long form complaint in the MDL.

I think, your Honor, I may be the beneficiary in part of your ruling on Motion in Limine No. 2, which Attorneys Armstrong and Carter argued earlier.

If I understood your ruling correctly -- and I don't mean to misrepresent anything as I did try write down as close

as I could. But if I understood your ruling on Motion in Limine No. 2, your Honor has excluded MDRs and complaints that are not substantially similar to the complaints -- the issues in this particular case.

And so what that means for Ms. Barron is that -- and on this motion -- is that if there are complications or alleged injuries attributable to C-QUR in some other cases, but not by Ms. Barron, then those other conditions ought to be excluded as not relevant and they should be excluded not only because they aren't relevant to Ms. Barron's case, but also because there is a risk of undue prejudice, confusion to the jury, and unnecessary cumulative evidence.

So first on the relevance piece, your Honor, those other conditions -- so, again, conditions that aren't substantially similar to the ones that Ms. Barron is alleging, ones that she isn't alleging she experienced at all, those other conditions aren't relevant because Ms. Barron has to prove at trial that there was a causal nexus between the alleged product defect or negligence and the injury that she's alleging she experienced. And that's true for all of her claims, whether it's her negligence claim or strict liability claims or failure to warn or for a design defect.

We cited many different federal cases that support our position on this point, your Honor. I do want to call your attention to one in particular because I think it succinctly

summarizes what we're trying to say. It's the *Tyree* case from the Southern District of West Virginia. The court there said that for claims that require evidence of injury -- and then went on to list these particular claims. I'm quoting: Strict liability for failure to warn, strict liability for design defect and negligence, only if the injuries experienced by the complainant are relevant, end quote.

So, again, that's consistent, I think, with what your Honor said earlier on Motion in Limine No. 2 and consistent with what we're asking for in this motion, that unless they -- unless we're talking about complications for injuries alleged by Ms. Barron in this case, then they ought to be excluded as not relevant.

The other point, your Honor, is as to prejudice. We, by the way, do not think that other conditions not alleged by Ms. Barron are not relevant, but we also think that introduction of evidence or argument about those other conditions would be unduly prejudicial and it would risk juror confusion and needless presentation of cumulative evidence.

As your Honor might expect, the parties will be presenting a substantial amount of complex scientific and medical evidence already from experts and -- in this case regarding the injuries that Ms. Barron does allege and allowing the plaintiff to then introduce evidence regarding complications not at issue in the case would further complicate

the presentation of evidence and, again, involve needlessly cumulative evidence and increase the risk of juror confusion. Basically, there would be a lot of time spent on irrelevant conditions.

We've cited again in our briefs many different decisions where federal courts have excluded evidence of complications allegedly associated with the company's product but that the particular plaintiff didn't experience. And they did that either because they found there was no or minimal probative value and/or because they found that any probative value was substantially outweighed by the risk of prejudiced confusion.

So, for example, where the product was a pelvic mesh in the *Tyree* case that I mentioned, the court there excluded that evidence. It excluded evidence of complications purportedly caused by Boston Scientific's mesh not experienced by the particular plaintiffs in that case.

In the *Coursen* case, a Ninth Circuit decision, the court found no error in the trial court's decision that where the product was an IUD contraceptive device and the alleged injury was pelvic inflammatory disease, the court found no error in the trial court's decision to exclude evidence of pregnancy, which is arguably a failure of a contraceptive device. So no error in excluding evidence of pregnancy when none of the plaintiffs alleged that injury or that -- that

complication.

We've also cited some pharmaceutical cases that ultimately reached that same conclusion, that complications that might be attributable to the device or to the product by other plaintiffs but are not attributable to a device by the particular plaintiff, that those other conditions ought to be excluded.

A few other points on this, your Honor. Plaintiff's opposition cites just one case, the *Herrera-Nevarez* case from the Northern District of Illinois that is specifically on this point, so only one case on this specific issue of the admissibility of evidence about complications a plaintiff did not experience. We really view that as an outlier in some ways, including because it reached a different result from all of those cases that we've cited in our briefing, but it's also important to note that the court in that district -- that case didn't even engage in the 403 analysis, so didn't reach that point and didn't go through the entire analysis that we're asking this -- this court, your Honor, to do.

Going back to the cases that Atrium cites, I also want to highlight that in -- in those cases that we cite where the courts did find undue prejudice, there were only one or maybe two conditions, other conditions, not alleged by the plaintiff -- only one or two other conditions not alleged by the plaintiff at issue there and still those courts found that

that was enough for undue prejudice and risk of juror confusion and needless presentation of cumulative evidence to all come into play and to be a reason to exclude that evidence.

Here, as you can tell from our briefing and from the plaintiff's long form complaint, there are a whole host, a long list of other conditions that we'd be asking the Court to exclude in part because if they were admitted, that is even more confusion, cumulative evidence, just given the volume of other conditions that the other plaintiffs in the litigation are alleging.

I'm happy to answer any questions that your Honor has on particular cases or specific issues, but for those reasons, we'd ask your Honor to grant our motion.

THE COURT: Question. I'm thinking about your first opening argument with respect to plaintiff's motion or defendant's motion number 2.

My memory is that that is not an argument that was raised by the defendant with respect to these complaints and these -- you know, these adverse reports, DMRs -- I forget the acronym.

But it does -- I'm starting to rethink my ruling on number 2 because it does seem to me that it goes to design defect, although ultimately there may be a reliability issue with respect to complaints and adverse reports in terms of adverse conditions so that number 2 is probably on pretty solid

ground, my ruling that is.

And, again, I'm thinking out loud here and asking for your reaction. It could be, in fact, that basically -- and Attorney Orent can address this, but perhaps there are experts or other ways you were intending to establish these other adverse conditions and so that would be why you didn't make that argument with respect to motion number 2, that you wouldn't be relying on complaints in these reports to make that argument.

But she makes a good point. I've already said they've got to be substantially similar and I think ultimately for design defect that's a weighing of risks and benefit. And I think the *Herrera* court gets that right because ultimately it's risk benefit and whether it's unreasonably dangerous and if the benefits come in, it seems to me the risks come in.

And so with respect to just the design defect, Count II, it does seem to me that while it's not relevant at all, obviously, to causation of her injuries or failure to warn, but it could be relevant to design defect.

So let me ask you to respond, Attorney Van Tuyl, and then I'll let Attorney Orent square these two legal issues for me.

And hold on one second I just need to shut a door so that it doesn't keep opening.

Go ahead.

MS. VAN TUYL: Thank you, your Honor.

On Motion in Limine No. 2, I certainly do not want to disturb that ruling and think that that was -- that was the right way to go. And so it may be that I am analogizing things that ought not to be analogized.

But I think the arguments are consistent. What we're arguing here in Motion in Limine No. 7 on the relevance piece specifically is that regardless of which of the plaintiffs claims we're talking about, there does have to be that causal nexus between the alleged defect or the negligence and the particular plaintiff's alleged injuries. So Ms. Barron here.

And we've cited cases in our briefing on that point. I think you've already said that that -- that seems clear to you on the warnings piece and so you'd like to focus on the design defect claim.

For that, the -- the element of a design defect claim includes the following: The plaintiff must prove, among other things, that the design of the product created a defective condition unreasonably dangerous to the user -- to the user at issue, so Ms. Barron -- and the condition caused injury to the user. And in that second element -- which I think it may be actually the fourth element of a claim -- but in that second part that I quoted, the condition caused injury to the user, the condition refers back to the defective

condition unreasonably dangerous to a user.

And so in a defective design claim, the alleged defective condition, the attribute of the product, has to be shown to be unreasonably dangerous to that particular user and that same condition, that same alleged defect, must be what caused the harm.

And so that's why when you talk about relevance, that's why allegations of other injuries are not relevant to a design defect claim. They're not relevant to the unreasonably dangerous nature because that has to be specific to the -- the defective condition that affected the user and it's not relevant to the causation piece either.

THE COURT: Okay. Attorney Orent.

MS. CARTER: Your Honor, I'm actually going to be addressing this one as well.

THE COURT: Oh, I'm sorry. Go ahead, Attorney Carter.

MS. CARTER: We'd object to the characterization of the injuries.

Defendants artificially narrow and define her injury as simply an infection. What was going on inside of her was an inflammatory mess. It's not simply an infection. It's an amalgamation of all -- it's -- the same mechanism is causing all these different injuries. And I know Attorney Orent would go very deep down this hole for you, but basically it all goes

to the characteristics of the mesh and the pore size and the antiinflammatory response and all of these are related.

And even when you're looking at these conditions, you can basically put them into two categories, benefits and risks. And they're trying to exclude artificially all the risks when we know they're going to obviously give all the benefits, which is -- which is unfair, because the risks are relevant to the totality of the risk profile of the product and the surgeon has to balance all of the risks and benefits. And even Dr. Price discussed in his deposition; when you have a new device and there's any kind of new risk, it has to be more beneficial.

Now, I know you spoke of the failure to warn and a design defect is slightly different, but in New Hampshire, in determining unreasonable danger, the court considers other factors than just the plaintiff's injury. They consider such things as social utility and desirability and the magnitude and probability or the foreseeable risk of harm has to deal with all of this. And the social utility of a device cannot be artificially limited to one of the risks for it.

And it also -- these different complications and conditions go to the overall safety of the device, their notice and knowledge and the overall risk of the device.

THE COURT: If that is correct, Attorney Carter, why didn't you guys make the argument in Motion in Limine

No. 2 -- make the same kind of argument with respect to just complaints and reports?

MS. CARTER: So perhaps we misunderstood that motion a little bit then when we were arguing it. When we think -- when I was thinking of conditions, I'm thinking of things that are happening with the plaintiff, not necessarily the evidence of what it's in. Whether it's in a medical device or whether it's in the label, whether it's in a study, those are all evidence of the conditions.

Now, Motion in Limine No. 2, I thought, was more based on the specific evidence or the -- the piece that it was in. Now, Motion in Limine No. 2 would contain some of the conditions and all of the relevance of those conditions would still be the same. It's -- that's just a mechanism for introducing those conditions.

And to be frank, those -- these arguments would still apply there when we're talking about substantial similarity. It is much broader than defendants are trying to artificially narrow it to you. And, your Honor, when citing New Hampshire law about substantial similarity, you did not necessarily define exactly what you meant by that because it can be different. When you're using it for notice, it's a lower threshold than if you're using it for other purposes. And I think that will largely depend on what we introduce and how we introduce it.

MS. VAN TUYL: Your Honor, may I respond to some of those points?

THE COURT: Of course.

MS. VAN TUYL: Thank you. So first --

THE COURT: Of course.

MS. VAN TUYL: Thank you.

First, I did not intend to mischaracterize or artificially narrow the injuries that the plaintiff is alleging, either in briefing or in argument here.

So I heard Attorney Carter mention infection and inflammation, but certainly if there are other injuries that the plaintiff is alleging she experienced, then those would all go in the bucket of injuries she's alleging she experienced. What I'm talking about in this motion is the other stuff, right, the other conditions that she is not alleging. So apologies if I misrepresented anything. Certainly not my intention.

As to those other injuries that she does not allege she experienced, again, I would go back to the language that I quoted earlier about the elements of a defective design claim. And I pulled that, your Honor, from New Hampshire's civil jury instructions. It's not something that I invented. But, again, the elements of a device defect require the proof to be specific to the condition, the attribute of the product or the defective condition that was unreasonably dangerous to the user

and also specific to the condition that caused the injury to the user.

So, again, I think that that makes clear that other conditions aren't relevant on whether there was a design defect -- defective design attribute in this particular case that caused the alleged injuries to Ms. Barron.

I also heard Ms. Carter mention notice and that perhaps there was a lower threshold for notice. I -- it is not my understanding that notice is at issue in this motion, that this evidence is evidence that they would intend to go to notice. If it is, then I'd like to be able to respond to that, but I did want to clarify that point.

And then my final -- my final point, your Honor, in response to what Ms. Carter said is that it -- I think there is a risk here, not only of juror confusion from expert testimony on conditions not at issue, not only a risk of cumulative evidence on conditions not at issue, but I think there is a risk here with the introduction of evidence on these other conditions that there will be a misimpression in the jury's mind that they can think of C-QUR as a generally unsafe product inconsistent with what those elements of design defect require. That they can think of the product as a generally unsafe product based on those other conditions and that would be, I think, an impermissible prejudicial purpose for this evidence to be introduced because, again, there has to be that causal

nexus between the alleged defect, the unreasonably dangerous condition for this user, and the condition that caused injuries to this particular user.

MS. ARMSTRONG: Your Honor, may I amplify something that Ms. Van Tuyl has said?

THE COURT: Briefly.

MS. ARMSTRONG: Okay. So if -- plaintiffs can either prove their case, prove the elements that Ms. Van Tuyl has articulated -- they can either prove those elements with respect to the injuries, whatever they are, claimed by Ms. -- Ms. Barron or they can't. And if they can prove them with respect to the injuries claimed by Ms. Barron, they don't need all this other evidence. If they can't, they shouldn't be allowed to prejudice the jury, as Ms. Van Tuyl has explained, with this other evidence that's not related to injuries -- that are not the injuries suffered by Ms. -- Ms. Barron and -- and let the jury, you know, render a verdict based on whether or not the product is capable of causing things -- other things. That would be an improper basis and that would burden -- they can either make their case with respect to her injuries or they can't.

And all of this other evidence, in addition to being extraneous and prejudicial to the jury, just amplifies -- I mean, the case with respect to Ms. Barron's injuries is complicated enough. If you add in all this other stuff, you're

just making the presentation of evidence that more complex.

THE COURT: Okay.

MR. ORENT: Your Honor, if I could interject.

THE COURT: That makes sense.

Go ahead, Attorney Orent. Obviously, we're at 2:30. This one -- I'm telling you, this one, I'm -- I might need to take under advisement because I need to be really clear on design defect and whether or not what Attorney Armstrong's just described in amplifying what Attorney Van Tuyl has argued, the -- if, in fact, they are correct, then it looks like my ruling on Motion in Limine No. 2 stands and is fine. But if, in fact, design defect is much broader than what they're describing, then I'm just not understanding why on Motion in Limine No. 2 defense counsel would not make that argument.

So that's going to leave me a little perplexed and I want some time to think about it and I would call counsel perhaps back for further argument. I would not do that to you without giving you the opportunity, obviously, to file something to help clarify this for me, but what Attorney Armstrong just said makes common sense to me in terms of design defect, that you can't allege all kinds of other defects and risks if you can't establish that, in fact, she did suffer the inflammatory mess that Attorney Carter describes; that those were risks she did, in fact, suffer and -- and were caused by the mesh.

And so there's some common sense to what Attorney Armstrong is arguing and I -- I -- you know, I want to read the law more carefully on design defect before I give you a ruling on this.

I'm happy to hear from you, Attorney Orent, on it if you can help clarify this for me.

MR. ORENT: Your Honor, and I think you're making -- you made an excellent point and I would like to say we've gone far afield from the briefing on this at this point and that does concern me. And there's been, I think, a lot of focus on the design defect claim without respect to the negligence claim that we have that is still alive and well. And that is what did the defendant know, what was their duty of care and did they breach that duty of care.

Now, when we talk about defective design and we talk about the unreasonably dangerous condition, okay, we're talking about the condition of the device. And what the defendants have not yet done is ever explain how any of the injuries are different because we believe that there is a systematic response that occurs in everybody because of the device -- the design of this device. That manifests differently in different complications, but it is the same underlying mechanism that governs all of the complications.

That's our case.

THE COURT: Okay. Let me stop you. Let me stop you

then.

So when we were arguing the Motion in Limine No. 2 and were talking about substantially similar and I'm saying it's got to be similar injury, you're thinking the defense argument is going to be, Judge, they're all the same, so, really, there's no -- you can require that I get over this hurdle of substantially similar, but ultimately they're all substantially similar.

MR. ORENT: That's right, your Honor.

THE COURT: They're all from this product.

MR. ORENT: That's absolutely right.

MS. ARMSTRONG: The defendant would agree with that.

MR. ORENT: And, you know, this is -- you know, it's funny because Meghan and I were talking after -- during the break and, you know, I thought, you know, that that is a -- you know, we can meet that burden.

And the reason is, your Honor, whether we were looking at a C-QUR device where there is -- you know, the pore size is causing the contracture of the device and this whole panoply of problems or even the defendants' earlier predicate, the ProLite device, they share the common design element, the common defective attribute. And so the complications at the cellular level, at the -- the way it works, that is, the information that the defendants knew or should have known, has been available for 30 years even though the C-QUR itself has

only been available for a little bit more than a decade.

And so our case -- and this is what Dr. Klinge does so well. As your Honor knows, he talks about the general state and attributes of each of the design aspects of this device and how separately they are problematic and they're a disaster when it all comes together.

And so when we talk about all of the different attributes of this particular device that Ms. Barron had, the inflammatory response in her can trigger scarification and it does; and our pathologist will talk about how safely it should be very limited around the filament, but in this case it's bigger than that, the creation of a fistula and the infectious process -- these are all part and parcel of the same mechanisms.

This is not an airplane where we're coming in on a claim that the -- that the engine was malfunctioning and trying to introduce evidence that the software guiding the plane was off. Okay? That's the kind of case where you want to really pay close attention and this similar characteristic and similar injury really matters.

But on a medical device where we're claiming that it is the totality of the device part and parcel and we're explaining to the jury exactly how complications occur and that testimony is going to be almost universally true, but what's different is how that manifests in the individual, all of the

information that the company had at its disposal is relevant.

Now, there's also a bunch of other reasons along the relevance tree for adverse impacts, adverse events. The defendants are going to get up and they're going to claim that there's a .25 percent complication rate. Now, of course, we're allowed to undermine that by showing that their complaint handling was wrong. These complaint processes are two-way streets.

So going back to MIL Number 2, the MDRs, not only does the company report MDRs, but they also get complaints from MDRs. And so their failure to follow up is evidence in and of itself.

So these issues are all so intertwined and we're so -- I feel so far afield from the briefing that we've got to be really precise. And on the first page of the defendants' motion here they argue what a whole swath of the plaintiff's injuries are not, which we actually disagree with fundamentally. And so I think this has really just gotten so far afield from the way I see the case and I see that all of these things are so intertwined, so interconnected, that -- that really --

THE COURT: Okay.

MR. ORENT: So --

THE COURT: I appreciate the way you see the case, Attorney Orent, and I have to say what you're saying is very

helpful to me. I don't want to suggest otherwise. But ultimately I need to understand the case.

MS. VAN TUYL: Your Honor --

THE COURT: You have an understanding, Attorney Van Tuyl has an understanding, I have got to have an understanding. Because, ultimately, on Motion in Limine No. 2, I am ruling -- frankly, I think I'm saying I can't yet rule, really; I need to see specifics and context. But basically I do agree with defendants on the premise that it's got to be substantially similar, these complaints, these MDRs, reports. And all the while, frankly, your argument is there's really no difference between any of these. So substantial similarity is a nothing burger. It's a nothing test, basically. And that's not helpful to me. I need to understand this.

Now, obviously, we had Science Day. And I took notes. I took good notes during Science Day. But ultimately this is a critical piece of this case for me to understand. It's good that you have an understanding, it's great that Attorney Armstrong and Van Tuyl have a different understanding. I need some clarity on this. And this is -- this is clear as mud right now to me because Motion in Limine No. 2, this argument was not asserted by counsel and I do not understand it. I just don't understand it. Or at least a concession that, well, yes, but they're all substantially similar, Judge. And when we were talking about different buckets, it sounded

like there was the concession that there are different sort of types of complaints and types of injuries, but you're saying essentially everything's in one -- it's the same bucket, I think.

MR. ORENT: Well, more or less. I mean, I wouldn't go quite that far. I mean, there are going to be certain complaints where, for example, MDRs on -- when you open the package, the device is broken in the package and there may be some issues that are -- are far astray.

And so we don't disagree with your Honor's analysis there. I just feel confident that we can meet that burden at trial of showing for the ones that -- that we think, the ones where there is a -- an injury at play related to one of the design characteristics of the device, we feel that -- that that is part and parcel of what we're claiming here.

So I'm not sure our legal analysis is any different. I just -- I think that my concern comes in where people try and predefine what the plaintiff's injuries are without -- without us having the opportunity to actually respond and say, well, look, we think, and here's why these issues are so substantial and so similar and why this is relevant.

And I think on an evidentiary by evidentiary piece basis that they'll actually become clear and I think part of your Honor's confusion is that we are talking about it in this amorphous, hypothetical situation. But I can assure you that

any document that we would try and put in, we are prepared to demonstrate why that is relevant.

MS. ARMSTRONG: And --

THE COURT: Okay.

MS. ARMSTRONG: -- your Honor --

THE COURT: Let me just -- I think I'm going to cut off debate on number 7, just because I need to look at the law.

As I understand it, there are just a smattering of cases that hold there's a risk utility balancing test and what Attorney Van Tuyl is saying is, Judge, that really is tied, frankly, to injuries of the plaintiff and the inflammatory injuries, the infection. And anything that sort of falls outside of that, Attorney Van Tuyl is telling me, that's not really something that can come in under design defect; it's got to be a defective design as to what harmed her.

And I think that -- you know, I've read -- I need to read these cases more carefully, but the way it's worded in many of the cases, it sounds as though it is a broader examination than just a plaintiff's injuries. However, it does seem to me that if you can't establish plaintiff's inflammatory mess, as you describe it, it doesn't seem fair then that you would be able to bring in other types of injuries to other potential plaintiffs. That does make common sense to me. But I don't think the case law in this area is particularly clear and so I want to look at it more carefully.

What is your response, Attorney Orent, just very quickly, with respect to this issue of design defect and injuries specific to the plaintiff? I know that there are cases that do seem to imply what you were just arguing or Attorney Carter's arguing that's broader than it's just risks and utility -- risks and benefits, so it's all risks.

MR. ORENT: I think -- I think that's right. And Ms. Carter can certainly get deeper into the case law than I can on this, but, you know, I think as a -- when a -- when the doctor makes a decision or when the jury decides whether or not a device is, "unreasonably dangerous," that's the totality of the potential complications arising. And the -- the particular harm is a -- is specific causation. But we have to prove that the device in total was unreasonably dangerous and I think that the jury gets to consider all relevant evidence relating to the propensity of that device to cause harm or that aspect of the device to cause harm.

THE COURT: So if this -- if this were a grill and the grill blew up on somebody's porch, caused a huge fire, you would suggest that there could be evidence that in that trial that the grill is unreasonably dangerous and caused this big fire and the person suffered serious burns, that the jury could hear evidence that the wheels were really poorly manufactured and in other cases, the wheels had fallen off the grill and the grill had harmed somebody.

MR. ORENT: No, I -- I think my -- and I'll let Meghan jump in if I'm wrong, but my understanding is if I get a burn from the grill top, but I get some other condition from the grill top that's, you know -- you know, a -- I -- I get some sort of weird cut and an infection -- I don't know. It's hard for me to come up with -- and that's sort of why, when I used the airplane analogy, I mean, we're -- in this particular case with a medical device where we're -- where we're talking about what a doctor looks at, which is the entire risk profile of a device, I think that the doctor looks at all of those aspects because they want to judge it comparatively against what else is available on the market.

And so a doctor wants to use the safest device with the fewest complications and so the doctor is going to look at each of those aspects and not care which -- which one it is. They're going to want to -- so a car maybe would be a better example, where you don't care about whether -- whether it's the brakes or the crumple zone that has better attributes for safety, but want the safest car. And in a similar vein, a doctor looks at it as I want to do the job, which is fixing the hernia, with the fewest amount of complications possible. And that's what Dr. Price essentially testified to.

It's -- the interesting thing is that in this particular case, if we boil down and actually look at our exhibit list on the MDRs that actually do appear and the

complaints that do appear, they're all related, though. And so in some sense, again, the filing of this as a motion in limine out of the zone of the particulars as to what we're really arguing about makes this dangerous because we're talking about emails with infections, we're talking emails with fistula, we're talking about emails and reports of the whole panoply of issues that are the central issues in this case. We're not going on this -- this wild goose chase, so to speak.

THE COURT: Okay. And so ultimately you would suggest then that whatever other health risks or conditions, those would be in the same ballpark as what Ms. Barron suffered anyway. We're not talking about wheels on a grill. We're actually talking about basically different sorts of inflammatory internal responses that a person has.

MR. ORENT: That's right. These are all going to be things that advised the defendants about various aspects of the product that we claim are defective.

And, you know, we have looked at and we did a very good job, I think, of creating a relatively -- for a case of this complexity -- small exhibit list and we worked very hard. We want to advance the ball. We're not looking to go on these sort of side trips.

And so what concerns me about the handling of this as a motion in limine is it's all definitional. It's all how do you define what is Ms. Barron's actual injury. And I think

when the Court sees the evidence that we're actually trying to put forward, the relevance will be pretty straightforward for any of the actual --

THE COURT: Okay. Let me ask the other side a question. I know, Attorney Armstrong, you want to say something, but my time is so limited. I'm going to -- we're going to reconvene.

Can you actually give me a renewed Motion in Limine No. 7 that is tied to specific exhibits? And you could use exemplar exhibits: Here is an example of one, Judge, they want to use this as an example of a risk to show that it's unreasonably dangerous and we're arguing that that should stay out. And I'm wondering if you couldn't do the same thing with respect to motion number 2, which obviously I gave you a sense of my ruling, but I said I'd need to hear it in context and I said I agree with you it's got to be substantially similar.

Ultimately, Orent -- Attorney Orent is saying, Judge, we're going to meet that burden on all of these complaints and reports that we are going to try to admit. There may be this universe of other reports and complaints, but we're not going to admit those. The ones we're going to admit, they are going to be -- it's going to be obvious to you this is the same sort of injury.

So I'm thinking if you could reframe number 2 and number 7 with specific exhibits, that's going to help me a

great deal in understanding the issues that I'm going to see at trial and I can meanwhile research this design defect argument, the argument Attorney Van Tuyl is making, and make sure I really am understanding that design defect and what it means in this kind of case before I rule on it and I'd be ruling on it in the context of specific exhibits.

So that would be something I would welcome the opportunity to do before the trial. It gives me a sense of what the issues are really going to be at trial. So --

MS. ARMSTRONG: Your Honor --

THE COURT: -- is that something you could do, Attorney Armstrong?

MS. ARMSTRONG: Yes, that's something that we could do.

Let me just, to clarify, is your Honor seeking examples or do you want us to go -- I mean, the exhibit -- Mr. Orent referenced a short exhibit list which both sides have exchanged, but there's also a more fuller, very long exhibit list.

So we can definitely do with it respect to examples and maybe that's a place to start to clarify the issue. And then if you feel like you need to go exhibit by exhibit, then maybe we can schedule a time to do that or submit additional briefing on that.

Does that make sense?

THE COURT: It does. And I trust counsel to determine what I'm going to need to really understand this trial.

Ultimately, I don't want to spend two days researching this and trying to figure this out while the jury's twiddling its thumbs. I want to get -- I want to get a handle on this before trial so that when I make a ruling, I know what I'm talking about, I'm giving you a ruling that I think is correct on the law and in the context of the evidence.

And I don't want to waste the jury's time. That's one of my pet peeves as a judge and I explain it to you now so that you know ahead of time. You bring me these disputes before we get to trial because I want to resolve them so that I am not having a jury waste its time. I do not want to have to tell them, oh, I'm going to have you come back tomorrow so I can have my law clerk and myself stay up all night and research this issue. I don't want that. What I want to do is solve as many of these evidentiary questions as I can before trial.

So I would welcome that. I would welcome -- you know, I'll let you decide the scope of the exhibits and the evidence. I do think exemplar exhibits, if you can at least agree, this is a pretty good exemplar of this bucket of material, it'll -- and we'll see what the judge says. And if you look at the exemplar and I'm like, I agree with Attorney Orent, this seems like the same sort of inflammatory mess, so I

think I would probably let this bucket in, then we move to the next exemplar and I'll give you a sense. And then that way I know what I'm really looking at in the case as opposed to, you know, trying to figure out these, you know, hypothetical right now at least, questions with respect to what is the injury and what -- you know, what are the -- what's the defect here in the design. And I know the basics of it, obviously, but I don't know what the specific exhibits are that you're talking about. You both do.

So it would be very helpful, I think, if we could decide these issues in the context where I'm looking at actual exhibits. I think that's the bottom line. And that would be number 2 and number 7.

MS. ARMSTRONG: Your Honor, we will do that.

THE COURT: Now, number --

MS. ARMSTRONG: I mentioned that we had a question for the Court that we wanted to reserve till the end, and I know that the Court has to leave. Do you have time to hear our question?

THE COURT: I do have to leave. Is it an easy one or is it something -- because I'm going to have you back on 8 and 9, so --

MS. ARMSTRONG: It pertains to one of the deadlines that you gave us, so I'll try to be quick.

On Luna document --

THE COURT: I'll tell you what. A deadline, I'm not going to care. If the two of you agree on a new deadline, you give it to me and I'll grant it.

MS. ARMSTRONG: Well, we haven't agreed on a new deadline because what we've agreed was that -- these were the Luna motions to exclude the regulatory experts. Your Honor asked why we had not submitted a stipulation on that.

THE COURT: Yes.

MS. ARMSTRONG: What we -- what, at least from the defendant's perspective, I -- we wanted to wait until after the Barron trial to try to reach a stipulation as to those so that we could -- so that any stipulation we reached would be informed by our experience with the Barron trial.

So we still, you know, hope to reach agreement and submit it prior to the Luna trial, but we'd like to be able to postpone it until after the Barron trial so that we can incorporate lessons learned from the Barron trial into whatever we agree to.

THE COURT: Okay. All right. I just don't like to keep my motions -- as you may tell, I don't like keeping them around on my docket for months and months.

MS. ARMSTRONG: Could we --

THE COURT: So I need to look. I don't know how old that Luna motion is.

MS. ARMSTRONG: They're pretty old, but could we --

I don't know how old they are. Could we agree to maybe possibly take down the motions and refile them within a certain --

THE COURT: That -- you know --

MS. ARMSTRONG: -- if agreed?

THE COURT: In the interest of moving cases, yeah, that makes sense. I'd be completely open to that.

MS. ARMSTRONG: So we'll work on an agreement on --

THE COURT: So that -- okay. That -- that would be great. And that works for me.

So we will reschedule this. We'll reconvene and we'll deal with 8 and 9, unless you're able to resolve them. But 8 and 9 -- half of nine, I guess. And you're going to talk about number 2 and 7 and perhaps giving me some context, factual context, with real exhibits.

And I'm happy to merge all of those into one date and one hearing or just next week we could reconvene and do 8 and 9 in a quicker Zoom hearing and then you can continue to work on these exhibits and whatever it is you might want to file separately with respect to number 2 and number 7.

Now, I've given you a preliminary ruling on number 2, but, again, it was essentially I need to see this stuff in context, but I think it needs to be substantially similar.

If ultimately Attorney Orent is correct and every single exhibit that he intends to admit is substantially --

it's a substantially similar type of injury, then -- then that makes it very easy and I think ultimately I can square my ruling on number 2. I will then look at number 7. And he's saying the same thing with number 7, that ultimately, Judge, it's not going to be a question because the other conditions are conditions that she really did have, that these risks are not so broad as to be completely untethered to her injuries.

So, in any event, what I'm hoping is to bring those down to earth a little bit and let me have a sense of what the real evidence is and give you a much more informed ruling.

So I think you guys know where I'm coming from, so I don't think I need to say anything more. You can work with Attorney Esposito to get either a quicker Zoom hearing where I can resolve these two other matters for you quickly and then we'll schedule a more substantial hearing where I can actually study exhibits and study your briefing before a hearing and then hear argument and I'll be able to -- you know, I'll be able to ask much more, I think, helpful questions and get more helpful answers once I'm -- once I'm actually in the weeds.

So, ultimately, I am going to be late for my little meeting, but I appreciate everybody's work and I'm sorry we didn't get to hear from -- Attorney Davis I think is the only one we missed. And I will -- I'll do whatever counsel wants by way of quick hearing, longer hearing, or just one bigger hearing where we put them all together and resolve the

remaining issues.

And I appreciate you doing -- taking care of the Luna motions, too.

Yes?

MS. UNGER DAVIS: Your Honor, one quick question. You had mentioned on Motion in Limine No. 9 that you might want some additional briefing on the issue of enhanced compensatory damages. Would that still be helpful to you?

THE COURT: You know, let me -- let me -- I'll issue an endorsed order being more specific about that, giving you more clarity, if I really do think I need that.

Enhanced compensatory damages is a tricky issue in New Hampshire. And I think there are some recent cases -- if I'm not mistaken, Judge McAuliffe has written recently on enhanced compensatory damages in New Hampshire and I would -- I'll look at that and if I need further help from you, I'll definitely ask for it.

MS. UNGER DAVIS: Thank you.

MR. ORENT: Your Honor --

THE COURT: All right, everybody.

MR. ORENT: Thank you. I was going to just say one --

THE COURT: Go ahead.

MR. ORENT: -- one final housekeeping item is the identity of the third -- we've agreed on the third trial as

being the Shumaker case.

THE COURT: Good. Let Attorney Esposito know that and we can put that into the agenda for our next meeting.

MR. ORENT: Okay.

THE COURT: Excellent.

MR. ORENT: Thank you, your Honor.

MS. ARMSTRONG: Thank you, your Honor.

MR. CHEFFO: Thank you.

(Proceedings concluded at 2:56 p.m.)

C E R T I F I C A T E

I, Liza W. Dubois, do hereby certify that the foregoing transcript is a true and accurate transcription of the within proceedings, to the best of my knowledge, skill, ability and belief.

Submitted: 3/22/21

/s/ Liza W. Dubois
LIZA W. DUBOIS, RMR, CRR