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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

CARRIE L. BARRON AND NICHOLAS BARRON	*	17-cv-742-LM
	*	May 13, 2021
	*	10:10 a.m.
V.	*	
ATRIUM MEDICAL CORPORATION, ET AL.	*	

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE LANDYA B. MCCAFFERTY

APPEARANCES:

For the Plaintiffs:
Jonathan D. Orent, Esq.
Dennis A. Costigan, Esq.
Motley Rice LLC

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

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

Pierre A. Chabot, Esq.
Devine Millimet

Court Reporter:
Susan M. Bateman, RPR, CRR
Official Court Reporter
United States District Court
55 Pleasant Street
Concord, NH 03301
(603) 225-1453

P R O C E E D I N G S

THE CLERK: For the record, this is a motion hearing in Barron versus Atrium Medical Corporation and that is 17-cv-742-LM, and it is part of the master case, which we will have a status conference if necessary, and that is Atrium 16-md-2753-LM.

THE COURT: Okay. Thank you very much.

Let me just -- any members of the public watching this hearing, just understand that our local rule prohibits any sort of broadcasting or recording, or even taking a screenshot of the Zoom screen would violate our local court rule, so I just want to warn folks of that.

Let me just tell you how I'm thinking I'll organize the argument today.

What I'm thinking of doing is starting with the Daubert motions and having Ulatowski, which is a plaintiffs' motion to exclude him. We'll start with that one and then we'll move to Pence, which is the defendant's motion to exclude.

Ulatowski's motion is document 224, Pence's is 225, just for the record.

I'm thinking ten minutes per side on each of those motions. I've obviously read the briefing and had the benefit of your arguments in writing, but I'm thinking ten minutes apiece. That would get us a total of 20 per motion. Then

I've got to give you my ruling assuming I'm prepared to do that after I hear argument.

That might get us to about 11 o'clock perhaps, especially if you're judicious in your use of time, and then we can move into the motions in limine. We'll take a break obviously for our court reporter, but I think we could pound through the motions in limine and have a break and be done by 1:00 if not sooner.

How does that sound to folks in terms of the order of events?

Yes, Attorney Armstrong.

MS. ARMSTRONG: Yeah, I have one question.

Our motion in limine number 5.

THE COURT: Yes.

MS. ARMSTRONG: Our arguments in Pence -- certainly in Pence and to a certain extent in Ulatowski -- in Ulatowski we tried to -- it's mostly related to Pence. Let me just back up.

So the first argument that we make in Pence incorporates the arguments we make in motion in limine 5 and so we can incorporate those into our Pence arguments, but if we did so, it may not be necessary to have a separate argument on motion in limine number 5 which has to do with excluding regulatory evidence.

Mark Cheffo is arguing those motions, so I'll let

him if he has anything to add.

MR. CHEFFO: Yeah, I was just going to say I think to some extent, your Honor, it's a little bit of six of one, half a dozen of the other, but they are intertwined exactly as Ms. Armstrong is saying. And I don't have a strong preference if you want to deal with it but, you know, frankly, without getting too much in the weeds, the parties had discussed apparently a stipulation where much of this would be -- we basically have no regulatory experts, right, and, you know, we kind of I think broke down on how we would characterize that, but there was an agreement if the 510(k) is out, everything else is out.

So a lot of the arguments about, you know, Pence and perhaps even Ulatowski, you know, if a lot of the evidence is ultimately not permitted, or rather excluded, then there kind of may not be as much need for regulatory experts.

So we could take it in whatever order your Honor has thought about it because you could do it either way, but I just wanted to highlight that there is a significant tie-in. And if you were to, like I said, exclude some of the evidence that we have already each excluded, it might actually substantially narrow the issues for the Daubert hearings.

THE COURT: Okay. So are you suggesting that we should start with motion in limine number 5?

MR. CHEFFO: I'm throwing that out there. I

actually think that that might actually frame the issues, because if your Honor agrees, like, for example, on X and we argue that the person shouldn't be able to talk about it, then that becomes a moot issue.

So, yes, your Honor, I think that probably might make sense.

I don't know if Jon has a different view of that.

MR. ORENT: Your Honor, we're prepared to go however the Court wishes. I do see these issues as separate issues, but I'm happy to go however the Court wishes.

THE COURT: You know what, I'm going to stick with the order I proposed just because that's the way I've structured my thinking and the order of, frankly, my notes and my order of events, and so it would just be easier I think for me to keep the schedule I have because I've thought about Ulatowski and Pence. Obviously I understand the motion in limine number 5 as well.

What I think it might be easy for us to do is sort of -- the ground will shift obviously for motion in limine number 5 depending upon my rulings on Ulatowski. So I'll let counsel handle those nuances and just make sure you make me aware of them as we move into motion in limine number 5.

To the extent my rulings on Ulatowski might help clarify 5, then just make that clear to me when we get to 5 and maybe the scope of the argument there is somehow more

narrow.

All right. So hold on a second. Let me put my motions in limine materials off to the side for the moment.

All right. Let's go ahead then with document number 224, which is plaintiffs' motion to exclude Ulatowski.

Go ahead, Attorney Orent.

And I will have my law clerk or my case manager, someone give me a warning at like when you have one minute left of your ten so I can just cut you off. I'm not very good at cutting people off, I don't like to do that, but I'll try so we can keep things on track.

And then we'll let defense counsel argue for ten minutes, and then I'll try to gather my thinking and give you a sense of whether or not I need to take it under advisement or whether or not I've heard anything that has -- you know, whether or not I have been persuaded to sort of change my take on things based on what I've read on paper, okay?

So go ahead, Attorney Orent.

MR. ORENT: Your Honor, I'm going to be very brief this morning because I do think we were fairly thorough in our papers and I don't want to be repetitive of that.

So to start with, I would like to just quickly talk about the context in which we're entering this motion which is following up on the Court's exclusion of the 510(k) process itself.

And as your Honor recalls, you excluded 510(k) under Rule 403, as opposed to Rule 401 and 402, recognizing in part the danger of prejudice and juror confusion over the specifics of the 510(k) process itself.

At that point your Honor invited the parties to go back and analyze how their respective regulatory experts' testimony would be affected by that decision and to come back, and so here we are now following up on that.

And what the defendants did is they submitted a series of opinions that we believe following the exclusion of the 510(k) information, the 510(k) evidence, Mr. Ulatowski is not qualified to offer, he has no discernable methodology for, and he dangerously gets into the state of mind of various entities, including the FDA, and because of that we think that his testimony should be excluded in total.

Now, we're going to later discuss this morning Dr. Pence, and we think that there's a substantial distinction between the two. And the primary distinction that I'm going to start with is that in Mr. Ulatowski's report he actually doesn't really have any opinions that are truly not intertwined with his regulatory opinions, and so -- specifically his 510(k) clearance opinions.

According to the defendants, they seek to, and this is from page 6 of their brief, bring forward his testimony on his credentials on industry standards and practices for

medical devices, prescription device labeling, public health communications, discussing how the C-QUR device is comparable to other devices, the C-QUR device is not misbranded due to health endangerment, C-QUR design records support a legitimate basis for the C-QUR coated mesh, and so on and so forth.

And so if we look at, first of all, look at what these opinions are -- and I think that the proof is really in the pudding with regard to each of these opinions. If we go into the actual opinions of Mr. Ulatowski, the Court will see that his opinions on prescription drug, excuse me, prescription device labeling and public health communications do nothing more than read documents and provide a narrative without any true opinions other than an expression of the FDA maybe thinks this or the FDA maybe thinks that, but there's no true opinion there. There's no analysis that goes into it.

So, for example, relating to the public health opinions. On the public health opinions Mr. Ulatowski literally just reads and rehashes in his report what the FDA says on its website and what other various public communications have been made. There's no opinion there. There's no reason that an expert needs to offer this evidence. In fact, it would be better from a fact witness in this case or from a medical expert, quite frankly.

With regard to his opinions relating to the safety of this device -- let's start with the comparability to other

devices on the market. That's not the standard for whether or not a device is safe. That's the 510(k) standard that the Court excluded.

Mr. Ulatowski is not a medical expert. He's not a bioengineer. He's not -- he doesn't have a relevant set of experience or expertise to opine on the safety of the device and how the performance compares to other devices. He doesn't have and doesn't go through in his report any analysis of the peer-reviewed literature of the basis for that opinion or for any of his opinions in that matter. He doesn't go through all of the literature and explain from the mechanics, from the human clinical trials. He doesn't have that background.

And then likewise, "The C-QUR devices are not misbranded due to health endangerment." Again, he's relying upon the 510(k) clearance of the label and what FDA does or doesn't do with the label, not whether or not it adequately communicates warnings that are necessary to doctors and health care providers. He doesn't have that medical expertise, the medical device design expertise to provide that sort of testimony.

Likewise, going through the design records, he doesn't have that background. He's never designed a device. What he does is he has his -- he's got impressive experience with the FDA going at and reviewing what the FDA receives. That's not the same thing as meeting the industry standard of

producing a safe medical device.

And so these problems are pervasive throughout the defendant's -- excuse me -- throughout his report, and really the report is devoid of methodology. It's devoid of any of the things that would make an expert report reliable to pass the 702 standard.

Now, with regard to the most dangerous aspect of Mr. Ulatowski, the defendants actually make this very point in their brief.

So in their brief on page 13 they state, and this is on the issue of when we raised state of mind, that he's going to be speaking in a state of mind for the FDA, they say, this is literally page 13, "Mr. Ulatowski has decades of experience at the FDA and is aware of what FDA actually did or customarily would have done in a given situation."

What the FDA would have done in a given situation is state of mind evidence. It's guesswork. Particularly when he then goes on to say, "It is my opinion that if Atrium were an independent entity and not a holding of Maquet, there may have been no complaint for permanent injunction entered against Atrium."

There's two problems with that sentence. First of all, it's pure conjecture. And second of all, it says may, not was, okay? There's no basis for this opinion. It is pure conjecture and it is pure state of mind.

He then goes on to say, "If Atrium stood alone, at worst FDA could have issued another Warning Letter to Atrium."

So this is -- the defendants then claim that this is based on specialized knowledge based on his years of work at the FDA that will help the trier of fact to understand the evidence.

Well, the point of introducing evidence, and this is the argument that your Honor is going to hear later, is not whether or not Atrium ever received a warning letter but whether or not they adequately were tracking complaints, the underlying fact of whether or not they were provided notice that their complaint handling was wrong, whether or not the underlying issue of tracking and trending complaints, the underlying issue of their manufacturing process not having standards that they followed, and have an uneven thickness of coating. He doesn't get into any of those things, any of the details that one would expect to see in an expert report.

And so really what he's doing, and the case law really describes this, is he's relying upon his excellent credentials and the voice of the FDA, or the apparent voice of the FDA, to gloss over the lack of methodology, the state of mind testimony, and his lack of medical training and design experience that would be necessary to actually put forward the opinions that do withstand the Court's prior 510(k) ruling.

And just finally, I know I'm running up on time

here, your Honor, so I'm going to just say that if your Honor looks to the other cases where Mr. Ulatowski has been offered on industry standards, he has been excluded. For the same sort of testimony that he's offering here he's been excluded on numerous times.

Again, the finding is he is a regulatory expert and his limitation is purely that he is a regulatory expert and he doesn't have the rest of the background necessary to offer the opinions that he's offering here.

So unless your Honor has further questions, and again in an effort to be brief, I will reserve the balance of my time I guess to respond to any questions or any arguments the defendants raise.

THE COURT: Okay.

Obviously Mr. Ulatowski wrote his report before he knew the ruling on the 510(k) matters. So how was he to know that he needed to separate out opinions? So just the fact that, you know, he references 510(k) in his report is not persuasive to me that I should exclude his other opinions.

What is difficult for me with Ulatowski is figuring out what is he offering in the case, what are his opinions that are based on industry standards and, you know, that look like they might be admissible.

Obviously the 510(k) stuff is out and we're not going to reargue that here, but what is it that he is offering

above and beyond the 510 regulatory process? And I think you're saying nothing, Judge, it's all -- basically he's an expert on that and to the extent he says anything else, he's not an expert on it and he's opining as to the FDA's belief about something.

Let me just go through what I thought your challenges were.

Number one, you were saying exclude him because they're too closely related to the 510(k) clearance process, that was one argument, and that to me is not going to persuade me. I can certainly figure out and keep out, and the defendants know to keep out any portion of his opinion that deals with the 510(k) clearance process.

But as to industry standards, he's clearly an FDA expert. I mean, I just know he's massively got -- his qualifications seem impressive in terms of that.

It seems as though, too, he served for seven years on this World Health Organization that I think Pence acknowledges as a source for industry standards, and he was a member of its premarket study group and steering committee.

So it seems as though he would qualify as an expert in industry standards, but my question really is what is he offering the jury with regard to industry standards.

So with regard to your first argument, Judge, it's just interrelated to the 510(k), I'm not going to exclude it

for that reason.

But nature of the law was I think your second argument, he's opining on the nature of the law. I think basically I've already essentially ruled on that and have held that opining regarding the nature of the law and the relative safety assurances provided by the FDA's premarket approval process and 510(k) clearance process are excluded, okay?

The next argument you make is that he gives a narrative regarding the regulatory history of the product I think, and again I've kept that out. That 510(k) clearance process material, that's out.

FDA's motives and beliefs. We've had this come up in other context I believe with other experts in that FDA believes. I think he says that, you know, a few times in his report, but when he testifies, I think it's just shorthand of saying this signifies that the FDA would do this.

I'm just not troubled by him using shorthand. I don't like any witness talking about what another witness believes or what an agency believes, but I think it's shorthand and I think I've held that in prior motions.

You also wanted me to keep out any statements about third parties' states of mind. He talks about patients. That's out. I mean, you know, obviously you can tell me why I would be wrong, but I don't see that as admissible.

You talk about him having an unreliable,

unascertainable methodology, that's an argument, but I think he certainly lays out what his thinking is with respect to industry standards. So in essence that's another one of your arguments.

And then finally you deal with a portion of his opinions, his opinions as to clinical significance of polymer science. That seems like, okay, there's an area where I might have to rule, I might have to make a ruling because he's giving opinions on something.

What else does he opine on that I really need to rule on? And ultimately I just went through your arguments. Let me let attorney -- is it Attorney Cheffo, you're going to address Ulatowski?

MR. CHEFFO: Attorney LaFata, your Honor, is going to address this one.

THE COURT: Okay.

Attorney LaFata, what is it that this man is going to opine on regarding industry standards that's going to help the jury in this case?

I'm left with all of these arguments I just went over with you, plaintiffs' arguments, but I'm still at a loss as to understand. Tell me what he offers the jury.

MR. LAFATA: Yes, your Honor. And thank you for the directed questions. That helps us to answer what's on the Court's mind.

I think part of the difficulty may be that, as Peggy Pence testified herself, the regulatory and industry standards are interrelated in this industry. This is a highly regulated industry. Almost anything they do is going to be regulated by a very invasive regulator.

So in the real world there is not a lot of daylight between what the regulators say ought to be done and what the industry says ought to be done. That's why oftentimes there's a coherence in those things.

The Court mentioned that Timothy Ulatowski was the FDA's chair and the U.S. delegation to a global committee to write some industry standards, and then later on you probably saw in his report that he was then the head of the FDA to bring in those standards into the FDA's regulatory system.

So there's a back and forth, and that's probably why it's difficult to disentangle them. And this is not a disputed point, your Honor. Dr. Pence testified the very same thing in her testimony because that's just the way it is.

Now, to be more particular about answering the opinion, throughout this report -- and the Court is right that the report was written when 510(k) was in play, and that is the animating basis behind the cases the plaintiff is citing. If a Court excludes 510(k), a Court will also exclude experts talking about 510(k). The cases will rule if no FDA evidence comes in, then none of this evidence comes in. That's what

the cases are saying.

But throughout this report Ulatowski will cite ISO standards, biocompatibility test reports on the final ISO standards on page 44, for example, what those standards require that go into labeling, what does the industry require that goes into labeling, what is -- page 53, the Good Laboratory Practices regulation about what is a proper study, how to do a proper study. Page 54, it's industry practice for a manufacturer to provide the information the FDA wants to see in its premarket submissions. And so you see that these things are kind of interrelated.

Now, where the rubber also hits the road, Judge, is in responding to Peggy Pence. If the Court is going to permit Peggy Pence to go into the particulars of is something misbranded, we say that's a legal conclusion, but if the Court allows that, then it should allow Ulatowski to say it's not misbranded. Really that's kind of a regulatory conclusion that plaintiffs' expert would be making.

This is on page 85 through the balance of the report, Judge, and he's going through and addressing and citing specific references. For example, Peggy Pence references the Global Harmonization Task Force, which is an industry group, a lot. I don't know if she -- I don't recall if she recognized that that was disbanded and was superseded by yet another standard, IMDRF. Timothy Ulatowski explains

that in his opinion.

If Peggy Pence is testifying about the wrong industry standard or a superseded one, the jury should hear that most of the analysis the plaintiffs' regulatory expert is offering is obsolete and superseded.

There are some terms of art, your Honor, that are used in regulatory submissions and studies and labeling that someone like Timothy Ulatowski can't explain to the jury. There's a term fair balance, for example, that's used on page 92. That's a term that's not only used in the industry but at the FDA to explain when there is data about a complication or data about an adverse event, how do you report that to consumers -- how do you report that to doctors rather. That's part of the analysis, and that blends -- it can blend, just as Peggy Pence said, those two standards.

Your Honor, if that addresses your question, I'm happy to go on to some other point, but I want to pause to see if you had anything more on that point.

THE COURT: No. Very helpful. Very helpful. Keep going.

MR. LAFATA: Thank you, your Honor.

To address a couple points that I heard, one of them had to do with whether the methodology is appropriate. I thought it was useful to see what plaintiffs said was an appropriate methodology for Peggy Pence.

This is on page 5 of the Pence brief, "Dr. Pence clearly outlines her methodology in her report stating, I arrived at my opinions after review, critical evaluation, synthesis, integration, and analysis of the body of relevant evidence and utilized the same regulatory and industry standards as those utilized at medical device companies in performing premarketing and postmarketing responsibilities." That's page 5.

That's exactly the same standard that -- I mean, if you look at -- Timothy Ulatowski has an entire section on methodology, section 7. So to hear that there is no methodology, I don't know if it was missed in the report, but it closely lines up with what the plaintiffs are proposing to this Court is an appropriate methodology for this kind of expert.

Kumho Tire is the Supreme Court case that recognizes that experience, and no one is debating that 40 plus years of experience is qualifying, but connecting what you're experienced in your professional career, it can tie into the analysis, and that's what's happening. Plaintiffs say that worked for Dr. Pence. We say that worked for Timothy Ulatowski.

Plaintiffs also say, for example on page 6 of their brief for Peggy Pence, that her opinion on the subject is helpful to the jury. That's a variable the Court out to

weigh. "Dr. Pence may state based on the evidence whether defendants met or exceeded the standards of good practice in the medical device industry both in regard to its interactions with the FDA and the relevant devices." That's page 6 of their brief.

So, your Honor, if the Court is going to permit in a host of regulatory evidence outside of 510(k) and the Court is going to allow the plaintiffs to present a regulatory expert to talk about that and other FDA evidence about its postapproval actions, then the Court needs to also allow Timothy Ulatowski to respond to those opinions, which is a major component of his report here.

The cases that the plaintiff cited in reply -- and by the way, the industry experience is not even challenged anymore in the reply, but the cases that are cited in the reply are all following this pattern.

For example, the Ethicon Physiomesh attachments that was put onto the brief, that Court had already ruled on excluding FDA evidence. Ethicon was only proposing Ulatowski to read two labels side-by-side and line them up. This is on page 5 of that opinion. That's not happening here, so it's really not appropriate to be citing. Those are really narrow opinions.

Now, otherwise there are opinions where Timothy Ulatowski has been admitted under a Daubert standard and

testified in federal court. These are in his report at the back where he refers to several federal cases in the District of Texas where he testified as well as state courts.

So, yes, Dr. Pence and Timothy Ulatowski have had courts that narrow their opinions or admit their opinions in full. The Bair Hugger forced air warming device products case in Minnesota completely allowed Mr. Ulatowski to testify over a Daubert challenge and said that his opinions addressed the negligence claim "head on." That's exactly what's happening here, your Honor.

There was some commentary about the state of mind of the FDA. I agree with the Court's kind of statement that there's some shorthand going on here, but I also want to highlight on page 13 of Atrium's brief the Mirena IUD case that four FDA employees "may opine on what the FDA would have done in a typical situation when presented with a set of facts."

That's helpful for the jury to understand the climate that Atrium was operating in. Plaintiffs' theory is that Atrium was an unreasonable manufacturer in the climate.

Mr. Ulatowski is going to say let's look at the climate they're operating in and compare it to what others were doing and what the FDA said they should do. Is that reasonable? He gives particular opinions in 90 pages about how and why it's reasonable under those standards. This is

just an example of one authority that says that's appropriate.

Just a brief comment, your Honor, about some of the opening parts of Mr. Ulatowski's opinion in case there's some questions about it.

We require experts to show their work. And so when an expert doesn't lay out the things they look at, how they arrived at their opinion, they may be criticized for not showing their work and saying this is the type of documents I looked at, this is what they say. That's not the same thing as going into court and reciting all of that.

So I don't think the Court ought to be distracted by a regulatory summary. It's really a way for an expert to show how they arrived at their conclusion in case say they're cross-examined did you look at this, did you look at that. I think that's part of the normal disclosure requirements.

Again, plaintiffs didn't depose Timothy Ulatowski. There apparently were not questions about the adequacy of what was disclosed in this. So it's really in the interest of being thorough.

Your Honor, I can reserve the balance of my time, as Mr. Orent has done as well, or if there are other questions from the Court.

THE COURT: Okay. I didn't get a message that it was ten minutes so you must have a few minutes perhaps.

Attorney Orent, do you have anything else to add?

I have to say that was helpful to me because he's plucking out things from Ulatowski's opinion and explaining to me how he's opining on industry standards. And ultimately your motion obviously goes after his opinion with, you know, broad arguments. I will address those arguments and tell you where I agree and disagree with them, but your opening salvo here was basically, Judge, this guy says nothing, this guy says nothing outside of his 510(k) regulatory opinions that's really going to be helpful to the jury, and I'm thinking I know there were things in there that seemed like they were industry standard opinions but ultimately it's not coming to the front of my mind.

I've pulled up, however, quotes from his report that are consistent with what Attorney LaFata is saying, and so I'm not inclined to buy that he's just excluded.

I want to address each one of your particular arguments, however, and then move on to Pence.

Do you have anything though you want to say in rebuttal?

MR. ORENT: I do, your honor.

Part of the problem I think with Mr. Ulatowski's report is he doesn't actually offer opinions, you know, as -- he was on the global task force, there's no question about that, but he doesn't go through and offer opinions on the industry standards that are separate.

So let's go to the example that Mr. LaFata gave on page 54. Page 54, this is what the defendants are trying to put in. "FDA assessed the nature of the coating on the devices, its manufacturing application to the mesh and biological effects. In the end it is evident from the clearance orders that FDA concluded that the mesh with the coating did not render the devices comparatively unsafe or ineffective. Rather, in clearing the devices FDA found that these devices met the premarket general control to establish there was reasonable assurance of safety and efficacy."

This is what he says on safety and efficacy. That's 510(k). That was excluded by the Court. There's no new opinion in there.

If we go to -- likewise, if we go to analysis of health and endangerment, he does mention in this one ISO 14971, but then he really says virtually all the adverse effects listed in C-QUR labeling are common to surgical meshes, risk of pain, and he goes on to try and assess the relative risk without a scientific medical background to do so.

Likewise, he talks about in his report that he has reviewed the peer-reviewed medical literature and the CER done by Atrium, and he concludes that the device is safe.

He doesn't have the medical and scientific background necessary to make that conclusion. That is medical

testimony that should be offered by a medical doctor.

So the problem, to bring this back to our motion, is that Dr. Pence on one hand offered the very specific basis for her opinion. So she would say FDA regulation this, Global Harmonization Task Force this, ISO this, and it is clear on the face of the report we met that disclosure requirement.

As you yourself said, your Honor, you could not discern on the surface of the report what he was talking about and how that was separate from 510(k), and that's what Rule 26 requires. He had an opportunity at the beginning of this case. These published cases on the exclusion of 510(k) have been out there for years. We have been involved in the majority of those cases, and the defendants had knowledge on the front end. In fact, not only did they have knowledge, they had Dr. Pence's report and Mr. Ulatowski addresses her report.

But instead of dealing with the standards that she does apply in the multitude of ways that she does, they made the decision -- they made the gamble that FDA was coming in. They lived by that and now they're trying to make this opinion something that it is not, something that it was never intended to be.

And so that's the problem I have with this is that on the surface, on the very face of this report it purports to do one thing. It's almost impossible to find those opinions

that Mr. LaFata talked about. And then when you boil it down into the actual surface, into the actual details of those opinions, the actual letters of those opinions, we find that they are medical opinions. They are biomechanical testing opinions. They are things that should be held by somebody other than a regulatory expert and there is no reference generally throughout this report to the specific standard and how the specific standard was or was not met, and that's the difference between Pence and Ulatowski, your Honor.

Again, just finally, there's a difference between saying what the belief that the FDA would do under a set of circumstances, and the case law on that circumstance says -- you know, that's like if I go to a store and I have a ten dollar bill and the price on something is two dollars, I know that if I wanted to buy that item, I could buy it. And that's what the case law basically says with FDA regulatory. That if it's that cut and dry, an expert may opine on what it would have done under those ordinary circumstances.

But this isn't an ordinary circumstance. There was injunctive relief. And what Mr. Ulatowski is saying -- he doesn't even say they would have. He says they might have done something different. That's right from page 13.

So really what we're talking about in this instance is opinions that weren't disclosed -- that he is qualified to offer but they weren't disclosed, and now there's no

methodology to back it up. And where the opinions are given, they go too far beyond his expertise.

And so we're not able, just like the Court wasn't, to separate out the good from the bad, and so we think in the interest of fairness he needs to be excluded in total.

And I would just say we made our decision not to depose Mr. Ulatowski based on the four corners of his report. If he is going to opine on things that are outside the four corners of his report, then I would respectfully ask this Court to allow us if he does survive the Daubert process to depose him on these new purported issues that weren't clearly disclosed.

So thank you, your Honor.

THE COURT: Okay. I feel as though the ground has shifted with regard to this expert because as I went through your arguments, Attorney Orent, I summarized them when I started and I can give you a ruling based on those arguments, but you did not lay out sections of his industry standard opinion testimony for me and say, Judge, this is not really an opinion that is untethered from his 510(k) regulatory. It's essentially one and the same. Here's another opinion that they will potentially try to extract from Ulatowski but they can't because it really is an opinion on the 510(k) process.

I know, because I've looked at his report, that there are things that he says that seem to be industry

standard statements.

You're saying to me that they really aren't. They are tethered to his 510(k) opinions and ultimately he's saying things about industry standards that he doesn't have qualifications to say.

So ultimately this is a different -- I think this is a fundamentally different kind of argument that you're making now with respect to Ulatowski.

MR. ORENT: I would recognize that to some degree, your Honor, and let me, you know, give you the difficulty that I'm having because a lot of what I just said is in response to Mr. LaFata.

And quite frankly, just as your Honor had difficulty piercing through the opinions and knowing exactly what he was going to say, I didn't truly have an appreciation as to what the defendants believed that Mr. Ulatowski at a specific level was going to offer for opinions until we got these examples.

And so it's a chicken and egg situation where unless I have full disclosure in a proper Rule 26 report, I can't make the precise argument that I just made on my rebuttal because I don't know exactly what's being offered.

And so I do recognize that these arguments go beyond the papers, but the information that we were provided on the front end as to exactly what he was going to testify to

are -- it's a different animal, and so, you know, I certainly recognize, your Honor, that the ground has shifted and, you know, again I'm just speaking in rebuttal but, you know, to the extent that these -- and I guess that's why we're arguing that these opinions are so intertwined with 510(k) as our first argument, you know, that your Honor wasn't persuaded by. You know, I guess had we known --

THE COURT: My assumption is that there are pieces of his testimony that could be extricated from the 510(k) clearance process. That there are things that he opines on with regard to the industry standards that are not related to the 510(k) regulatory clearance process.

Again, I'm not as familiar with every word in his report as you and Attorney LaFata. However, I asked Attorney LaFata a specific question based on your opening salvo because I'm thinking, okay, off the top of my head I can't really come up with the extraction process. Do it for me, Attorney LaFata. So he goes through and he talks about numerous examples.

Now, what your rebuttal is is, Judge, that's the first time I'm really hearing that as a separate opinion. And so -- what I need to do I think is to give you my ruling on the motion as its written.

I can tell you that -- obviously trial is July, is that right, we've got that scheduled? I have a bunch of

trials this summer. I think July is reserved for Barron. Okay.

And ultimately because we're still in this pandemic situation and I'm not going to want to have a jury sitting there sharing and breathing air together while I ruminate on issues that I could have decided before trial, and I don't have to have my jury sitting there breathing shared air while I'm hearing lawyers argue about something that I could have figured out before trial.

So it is a unique situation in terms of how willing I will be to let you rebrief something, but I can tell you that I can rule on the arguments that you've made, Attorney Orent, in your motion. I haven't heard anything that persuades me my original assessment of your arguments is wrong. So I'm going to give you a ruling on the arguments as I understood them before I came to the bench this morning, but I can tell you that if you're correct, Attorney Orent, with Mr. Ulatowski, I don't want to get hung up on having to look at and comb through his report every time they're asking him a question and you're saying, Judge, I've never heard this before. It's not in his report. Look at his report. Exclude this.

I don't want to be in that situation during a pandemic. I don't like being in that situation normally. I would rather decide these issues so I don't have to have a

jury waiting.

So what I will say is that I'm going to rule on these issues, the challenges you've made, so that everybody knows based on the motion you filed what my ruling is.

And I will say to you that I would like to figure out what in Mr. Ulatowski's report is coming in and what isn't coming in based on my rulings on the arguments you've made in your motion.

That may require new briefing so that you can point me to specific opinions. And obviously it looks like, Attorney LaFata, you could write this with a dictaphone this afternoon because you know what the arguments are.

MR. LAFATA: I'm just reading from his report.

THE COURT: It would be helpful to me to be able to assess this looking specifically at the arguments, and that hasn't been presented to me yet. I've got a motion to exclude and I've got various arguments.

What I would like to do is just go through those arguments. I don't think my rulings on them are going to surprise you, but I would like to rule on the motion as it is, and then I will give you an opportunity to do further briefing along the lines of the argument that you are making today and give obviously Attorney LaFata an opportunity to respond to that.

Now, if I need further oral argument on a motion

like that, I'll get you on the screen, but if I can do it without oral argument, I will try to do that. I've obviously heard oral argument in a sense on the motion, but it's new and the ground is shifting, and I just don't feel comfortable without looking at the report and looking at the arguments and making an assessment. And I would rather do it before the trial than do it in the middle of the trial because, as you can see, what's going to happen is I rule on your motion, Attorney Orent, and the arguments you made, and ultimately I think my ruling is going to leave open the fact that Ulatowski can testify on certain things, industry standards.

That doesn't answer the question though as to whether his testimony is truly separate from the 510(k) regulatory process. I would need to read the whole thing and assess that carefully. I just can't do that on the fly. I just can't do it.

So let me deal with 224, your motion, and the arguments. And first -- your first argument was that I should exclude Ulatowski's opinions because they're too closely related to the excluded FDA section 510(k) clearance process evidence. I think you know my answer to this, but let me just put it on the record for you.

The Court has previously granted plaintiffs' motion to exclude evidence related to the FDA section 510(k) market clearance process. I did that in an endorsed order, just so

the record is clear, dated December 11, 2020, in document 205, and it's a transcript of the December 10, 2020, hearing.

Plaintiff argues that all of Ulatowski's opinions should be excluded as well either because it is clearly within the scope of the Court's prior ruling because it is so intermingled with his opinion regarding excluded matters that it must also be excluded or because Ulatowski's primary expertise is in FDA regulatory matters rather than in industry standards.

The parties agree that to the extent Ulatowski's opinion is clearly within the scope of the Court's prior ruling the opinion testimony is properly excluded.

Expert opinion testimony to be excluded on this ground includes all opinion regarding the section 510(k) clearance process, including the FDA's determination that defendant's product was substantially equivalent in certain respects to other products, the capacity of the section 510(k) clearance process to support a finding of safety or effectiveness, and defendant's compliance with FDA regulations and directions in connection with the section 510(k) clearance process. Outside the scope of the Court's prior ruling is such proffered expert testimony as defendant's compliance with industry standards in developing, manufacturing, labeling, and marketing its product, the extent to which clinical studies establish the safety or effectiveness of the product, whether

the product was mislabeled or misbranded under either FDA regulations or industry standards, whether the product complies with generally applicable FDA safety standards and the reasons for the large number of negative clinical reports about the product.

Plaintiff argues first that such opinion should be excluded because in Ulatowski's written expert report his opinions regarding industry standards are often intermingled with his opinions regarding the section 510(k) clearance process. However, at the time he authored his report Ulatowski had no compelling reason to segregate his opinions regarding industry or FDA safety standards from his opinions regarding the section 510(k) clearance process.

Nothing in the record suggests that Ulatowski will be unable to express opinions regarding industry or FDA safety standards without reference to the excluded opinion testimony.

The Court therefore denies plaintiffs' motion to the extent premised on the intermingling of non-excluded with excluded expert opinion.

Plaintiff argues second that such opinion should be excluded because Ulatowski is primarily an expert in FDA regulatory methods such that his opinion is no longer a good fit with the parties' theory of the case.

The Court disagrees that there is a ground for excluding any portion of Ulatowski's opinion testimony because

he is primarily an expert in FDA regulatory matters.

Plaintiff falls short of leveling a Daubert challenge to the adequacy of Ulatowski's qualifications arguing only that his qualifications to opine regarding industry standards are massively outweighed by his qualifications as an FDA expert.

The Court notes that Ulatowski served for seven years as the World Health Organization's Global Harmonization Task Force, he served on that, including he was a member of its premarket study group and its steering committee. This experience is sufficient to qualify him as an expert in medical device industry standards.

Moreover, the Court is not aware of any authority for the proposition that an expert may only offer expert opinion in the expert's primary area of expertise.

The Court therefore denies plaintiffs' motion to the extent premised on the fact that Ulatowski is primarily an FDA expert.

Now, your second argument was he should not opine on the nature of the law. I think I've already ruled on that, but I will put on the record.

Plaintiff argues that Ulatowski should not be permitted to offer opinion or testimony regarding what they refer to, plaintiffs refer to as the nature of the law. Plaintiff argues that where Ulatowski offers opinion comparing

the relative safety assurances provided by the FDA's premarket approval process and its section 510(k) clearance process his opinion is at odds with established law and his opinion usurps the province of the Court by offering what amounts to jury instruction and his opinion risks misleading the jury by suggesting that compliance with FDA guidelines has direct bearing on whether Atrium was negligent in developing and marketing its surgical products.

To the extent premised on these arguments the Court denies plaintiffs' motion as moot because I've previously ruled on this. Ulatowski's opinions regarding the nature of the law and the relative safety assurances provided by the FDA's premarket approval process and its 510(k) clearance process are excluded as opinion regarding or in connection with that 510(k) clearance process.

You also argued that Ulatowski's narrative regarding the regulatory history of the product should be excluded as factual rather than expert testimony.

To the extent premised on these arguments, the Court again denies plaintiffs' motion as moot.

Ulatowski's recital of the regulatory history of defendant's product is excluded as opinion regarding or in connection with that 510(k) clearance process ruling.

Also, you argue that Ulatowski's opinions as to the FDA's motives and beliefs should be excluded. You argue it

should be excluded as speculative and improper. I think I grant this in part, deny it in part.

To the extent Ulatowski makes reference in his report to what the FDA believes, the motion to exclude is denied. Examples of such references include Ulatowski's opinion at page 82 of his report, it's in the record at docket number 141-2, that, "The FDA believes that a fact of risk communication on matters of public health interest like surgical mesh is important to inform doctors and assist them with patient care," or its also at pages 93 to 94 of his report that, "Since the consent for permanent injunction did not prohibit continued manufacturing of C-QUR, I must conclude that the FDA believes the C-QUR devices meet the statutory reasonable assurance standard."

The Court finds that such references do not constitute improper opinion as the FDA's intense motives or state of mind. Instead, Ulatowski's references to what the FDA believes operated as shorthand for describing FDA policy or conclusions reached by the FDA in connection with a specified inquiry. Moreover, Ulatowski adequately explains the factual basis he relies upon for ascribing such belief to the agency.

Under Federal Rule of Evidence 702 an expert may offer opinion testimony so long as the testimony is based on sufficient facts or data. And First Circuit jurisprudence

establishes that an expert may offer opinion testimony so long as the expert has achieved a meaningful threshold of expertise in the given area.

Because the testimony is well within Ulatowski's area of regulatory expertise and because its factual underpinnings are clear, no grounds exist for excluding Ulatowski's opinions as to what the FDA believes.

By contrast, where Ulatowski opines that the FDA would not have sought injunctive relief against Atrium but for the fact that Atrium's corporate parent was Maquet as he does at page 75 of his report, his opinion appears to be both speculative in that his report does not make clear what factual basis he might have had for offering such an opinion and improper as an opinion regarding the motives of an agency. Courts to have considered that kind of question have routinely excluded such testimony. This Court agrees that such testimony is properly excluded at trial.

Accordingly, motion number 224 is granted as to Ulatowski's proffered opinion regarding the FDA's motives or intentions for seeking injunctive relief against Atrium.

Ulatowski shall not offer opinions or testimony at trial as to the FDA's motives or intentions and shall not offer speculative testimony as to the FDA's state of mind.

You also make an argument that Ulatowski's opinions as to third parties' states of mind, and this I think has

merit.

Plaintiff argues that Ulatowski's opinions should be excluded as speculative, improper, and outside the scope of his expertise. To the extent he opines regarding the states of mind of non-party patients who were implanted with Atrium's surgical mesh product, the Court agrees.

Examples of such opinion may be found at page 81 of Ulatowski's report where he opines that, "When a manufacturer encounters enforcement action for its devices, patients implanted with the device may become concerned about the effect, if any, the action has on their welfare," or at page 82 where he opines that, "The doctor's ability to influence patients' decisions may be hampered when the patients become aware of information on a device before their doctor can inform them of the information and discuss it with them." These are just two examples.

Nothing in the Court's record suggests that Ulatowski is an expert in the psychology of patient litigants or that Ulatowski is qualified to opine as to the factors influencing a medical patient's decision-making. Similarly, the record does not suggest any adequate basis in fact for the proffered opinion.

Accordingly, because an expert's testimony is only admissible if the expert has achieved a meaningful threshold of expertise in the given area and because expert testimony is

only admissible if sufficiently grounded in facts or data, Ulatowski's opinion regarding the decision-making of non-party medical patients shall be excluded from trial.

You next argue that Ulatowski's opinions should be excluded because they are not grounded in a reliable methodology but rather solely in Ulatowski's own experience.

The Court agrees with the plaintiff that as stated by the advisory committee in the notes to Federal Rule of Evidence 702, "If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply taking the expert's word for it."

However, it is also well established that, as the Supreme Court observed in its Kumho Tire case, the purpose of the Daubert gatekeeping requirement is in part "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."

As in Kumho Tire, the Court further stated -- I'm sorry. As the Court further stated in Kumho Tire, "No one

denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."

Here knowledge and experience of the regulatory process are in effect the methodology that characterizes the practice of a regulatory expert.

Ulatowski describes his methodology at pages 29 through 31 of his report expressly stating that his methodology in forming his proffered opinions was the same one he used while employed at the FDA and still uses in his current consulting capacity.

Accordingly, plaintiffs' motion is denied to the extent premised on Ulatowski's purportedly unreliable or unascertainable methodology.

And finally, you seek to exclude his opinions as to clinical significance or polymer science or the severity of medical risks.

Examples of such opinion may be found at page 82 of Ulatowski's report where he opines, "To his knowledge it's not established to a degree of scientific certainty that polypropylene used in surgical mesh devices degrades to a clinically significant degree," or at page 67 where he opines that based on his literature reviews "the severity of the adverse events with C-QUR devices did not differ demonstrably from other surgical mesh devices."

The Court agrees with plaintiff that Ulatowski is

not a clinician or a scientist and that he would be unqualified to offer scientific or clinical medical expert opinion.

In his report, however, Ulatowski does not purport to do so but rather offers opinion as to the regulatory significance or impact of reported scientific or clinical findings. This he is clearly qualified to do.

Plaintiff may raise this challenge at trial should Ulatowski attempt to opine outside his area of expertise, for example, by offering opinion as to the clinical or medical importance of a scientific finding. However, it doesn't appear to the Court that Ulatowski is offering that kind of opinion in his report but rather is offering an opinion only as to the regulatory significance of those findings.

So the motion is denied to the extent premised on the argument that Ulatowski offers clinical or scientific opinion.

Now, obviously this ruling is based on the motion that was filed, and I think other arguments have been asserted here. And to the extent you want to pursue those other arguments, Attorney Orent, I would need you to brief them very clearly to me ahead of time and will give, obviously, Attorney LaFata time to respond appropriately to do that and get the argument in front of me so that I can rule on this before I get to trial.

That's my ruling based on what you argued in your motion. And ultimately with respect to whether the FDA believes or doesn't believe something, clearly if it's speculating about something the FDA would do and it's not based on facts and data, then I'm saying that that is not something I'm inclined to admit or allow.

But if in fact he's basing his assumption on how the FDA would respond to something that is based on facts and data, then I felt like his opinion when he says the FDA believes or the FDA would, it seemed as though in those cases it was based on facts and data within his regulatory industry standards expertise.

That's an area where ultimately at trial I think that is a fine line, and so ultimately I would like counsel when we get to those portions of the testimony to the extent you're not clear on it, to the extent you need to get clarity, I can rule on specific instances in the context of the actual statement and testimony. But ultimately here I'm trying to give you a sense of the way I'm going to rule and how I'm ruling on this based on what I'm seeing in the report by way of quotations that I'm culling from the report.

So to the extent you need clarity with respect to that, you know, I would appreciate you seeking that clarity with respect to areas of Ulatowski's testimony.

So that's my ruling with respect to 224. That took

longer, much longer than I thought.

I think we're probably going to need to give our court reporter a break.

Let me just hear from our court reporter if you can go for another 30 without a break.

THE COURT REPORTER: Yes, your Honor, I can.

THE COURT: All right. Thank you.

Let's try Pence now and at least perhaps hear the arguments, document 225, and this is defendant's motion to exclude Pence.

I will let Attorney Cheffo handle that. Go ahead, Attorney Cheffo.

MR. CHEFFO: Thank you, your Honor.

It is a little hard to kind of disaggregate from the limit, but I'm going to try and I'm going to try and keep to my -- I'm going to write down how much time I have, and I'm going to frankly -- you know, I know your Honor reads the papers carefully so I'm just going to hit the high points. And obviously if your Honor has questions, it is helpful as well to direct them.

Here's kind of the overall issue. You know, what the Court has done in the 510(k) -- sorry. This is not to reargue either now or later that issue, right, but the concept -- I think it's important to say that these are somehow different than it's a before and after.

What you've heard is that there's a 510(k) process, right, and that goes into all things, including labeling and testing, right, and then there's all of the things that happen after that, whether they are investigations, whether they are inspections, whether they are reports, but those are largely based on what happened before, right? So in other words, did you -- when it was cleared, there are certain qualifications, certain requirements. Have you violated those, right? So they're not like before one thing happened and after.

And the reason why I say that is because the same is true for these industry standards, right? And this goes for both sides, right, which is frankly why we made the proposal that -- and why I think, you know, this recent New Jersey case that you may have seen, it's in our papers, where kind of after two trials the appellate court reversed both of those jury verdicts, right?

Because the issue is if we start to try and slice the salami, you know, too thin, we get into all kinds of problems. And that's why you'll recall, and we'll talk about it later but, you know, we heard earlier that in December Mr. Orent said, I don't intend to talk at all about, you know, the FDA, right? He also said, and I agree with this, we believe to the greatest extent possible that the jurors' independent judgment should be exercised without relying on the finding of somebody else.

And that's really what -- you know, and I don't want to snatch defeat from the jaws of victory with respect to Ulatowski, but honestly a lot of what Ulatowski is going to do is frankly responding to Pence, right, because we don't have the burden of proof.

So Pence is talking about all these things so let's just talk specifically, you know, about industry standards. The industry standard is largely to follow the FDA, right? So they're not -- there may be some things, but they're not different like in a lot of other industries. It's not like making bubble gum.

So we think much of what she is doing is essentially saying these are industry standards, but it's really code for essentially picking up kind of FDA -- or talking outside -- you know, when you talk about methodology, there's literally no methodology that Pence uses. She says, well, I relied on this. I relied on that. You can't really discern, you know, which parts of it she did or didn't rely on.

So I think, you know, fundamentally this is kind of the other side of the coin, right, because if you're going to talk about -- if you're going to exclude anything that happened up until clearance and then essentially let someone talk about all of the things that the FDA did afterwards, one of the jurors is going to kind of question, well, how did this

product even get in the market, why has the FDA approved, what are they doing.

Your Honor was concerned about not having -- my words not yours -- kind of trials in trials. I think you said there would be hours of complex testimony, but I mean talk about -- the 510(k) process is pretty simple, right, in terms of you could probably do that in a few hours. Here's what happened. You submitted some records. They came back. Here's the study. You put it up.

Much of what Pence is going to talk about, right, if allowed, could potentially take days, certainly much longer than the 510(k). So it's not kind of here's one part and here's the other.

So I think we need to consider the fact that it's just inherently frankly unfair. I think you'll hear some law today, but this is kind of an equity goose/gander argument, right, in the sense that if we allow someone to basically just talk about industry standards which are tethered to the FDA regulations, everyone admits that, at one point in time, you know, it's just not equitable and I think it will be absolutely confusing to the jury. So that's kind of point number one.

You know, we've spelled out in our briefs the methodology. I think again this is essentially just someone's kind of gut reactions.

You know, we heard about Mr. Ulatowski's, you know, qualifications, or alleged lack thereof, but, you know, she's never worked for the FDA. She's never been a doctor or a surgeon. She's not a biostatistician. She's not a hernia repair person. Yet she wants to offer opinions on all of these things.

In plaintiffs' response to the motion they say, "Dr. Pence may state based on the evidence whether defendants met or exceeded the standards of good practice in the medical device industry both in regard to its interactions with the FDA and the relative devices." Right? That's at page 6 of their just recent response.

And again, this goes to this point that it's kind of -- it's just really -- and this is what I think all of the cases we'll talk about in the next motion, but they talk about the fact that you cannot disaggregate the issue of 510(k) and then talk about FDA and industry standards and have kind of a fair jury. You know, we'll be up at I think, you know, kind of before the Court on every issue, did we open the door, you know.

And recall again Mr. Orent said in the December 10th hearing -- he also basically said that -- I don't want to misquote him. "It's plaintiffs' intention, quite frankly, to not utter the words FDA during the course of this trial." That's what he said when he was arguing that the 510(k)

shouldn't be let in.

Now we're kind of in a whole different world here where we shouldn't talk about FDA until we get to the point of, you know, kind of 483s or some other issues or violations of industry standards.

The premarket testing -- and again, I don't want to spend a lot of time on this, you know, if this kind of goes hand in hand with your Honor's 510(k) ruling but, you know, I'm also mindful of what the Court said. These reports and things were written prior to your Honor's rulings but, you know, to the extent that there's any controversy about that, she talks about all types of things. That you should have done prior testing. They should have been tested in human beings. If you had done the testing, it would have revealed all these other, you know, kind of potential adverse events or issues, right?

So if the point is that someone is going to say you should have done this, here's all the things you should have done before, but we can't talk about clearance, obviously we think it's from an equity and goose/gander perspective, she shouldn't be able to talk about anything that should have been done prior to clearance.

The same would be true of labeling, right, because the labeling process -- you can't talk about what the labeling should say and say, well, there's an inadequate label or it's

misbranded if you've now excluded the fact that the labeling is part of the 510(k) process, right? It's submitted to the FDA. They look at the labeling, they give some comments, they determine, and all of that interaction back and forth, you know, would -- again, how can you basically say that I think this is inappropriate and it violates industry standards when at least their response -- or the jury may determine that, well, did they submit this? Did the FDA look at it? Did they have a chance to make comment? Was there any issues with respect to that?

THE COURT: Doesn't that assume, though, Attorney Cheffo, this 510(k) clearance process really does actually clear a process, determine that it is safe? And I thought the whole point of, you know, the whole point of plaintiffs' expert testimony on that was it's a grandfathering process, and in this particular instance the product that they are trying to essentially attach themselves to and say we're substantially similar to was actually never determined to be safe.

Again, I know we argued those months ago.

MR. CHEFFO: Right, right.

THE COURT: There is relevance to the 510(k) clearance process, but ultimately I determined that it was prejudicial and potentially confusing to the jury because there would be fights over what really is the 510(k) clearance

process, what does it really effectively do, and that would be confusing to the jury.

So just saying, Judge, you kept out the 510(k) clearance so you should keep out this is not necessarily that persuasive to me because the 510(k) clearance is a unique animal for all the reasons you guys have argued that, but in any event, go ahead. I didn't mean to cut you off.

MR. CHEFFO: We'll talk about it. I mean, I think there is this recent New Jersey case. There is the Lewis case. It's not different. I mean, that's why -- I don't want to reargue this. I know your Honor well enough. I've done this long enough.

We just fundamentally disagree. It's not this kind of amorphousing -- I can't just go and put the product on the market without going through this.

People can quibble about that it's not a PMA, right, but there's a two or three year process, right, where they went back and forth. We could show you a truckload of information where there was cytotoxicity testing, there was labeling issues, there was back and forth. I mean, there's a mountain of information over the course of three years.

So it's not just a matter of, hey, here's a form, I'm just like somebody else, right? You have to go through this process in order to get approved to use in human beings, right? So, see, people could argue about it, but the point

is -- and then there is labeling discussions, right?

So what I'm suggesting is you've basically said we can't even talk about that, right? We can't even say, hey, look, you know, people can disagree about whether this is the end all and be all, whether there could have been other things, what it actually means, but it's not so confusing if we spend with a jury two or three hours and say, by the way, we didn't just wake up one day, right, and put this product on the market. There is a whole other process.

What the plaintiffs want to say is, well, that's totally different, that means nothing, and that's just not the case, right, because no one could get something. So my arguments are flowing from that.

I think there is a misperception, your Honor, in all candor, about how fulsome that process is and how important it is, but having ruled -- again, this is why the courts basically -- the Bard case that we cited, the Lewis case, this New Jersey case whose name is not in front of me, they all basically say you can't cut and slice, and that's why, you know, that's why -- again, this isn't coming from me, but in the December argument Mr. Orent said, wait a minute, I'm not even going to talk about the FDA. At another point he said it would be kind of having my cake and eat it too if I talked about consent decrees. His whole point was you can't divorce this, right? You shouldn't be able to talk about the

FDA. We should listen to people. What he said and I think what your Honor adopted was the question, is this product unreasonably dangerous, and we should look at the facts around it, not about people, you know, kind of people talking about at one point FDA compliance and at that point you can't talk about it.

As I said, this would be different if we had industry standards or regulations or procedures that was not so highly regulated. There's probably few industries, you know, maybe nuclear, you know, industries, but there's almost nothing that you can do, right, with these products. If you want to change the label, the font size, if you want to do different things, it's all kind of through this regulation. The same as the 510(k) process.

Now, the plaintiffs basically say -- also they cite to the Kellogg case and they say that the lack of objective industry standards, because that's what we've highlighted, that are there are no standards. You know, we heard that argument about Mr. Ulatowski, but, you know, there's nothing that Dr. Pence has referred to.

It's true that the Court said that it goes to weight, but the Court also went on to say that, "Defendant may offer evidence that it in fact complied with FDA regulations. It will be the jury's function, if the evidence permits, to determine if an applicable standard of care was breached."

Again, so this goes back to, you know, if you're going to give them this much, then you have to basically talk about what the standards were from the FDA on the 510(k).

I'm sorry. It's the Hrymoc versus Ethicon case that I was struggling with the name. That's the New Jersey case. And there one of the key reasons that the appellate court vacated the two judgments following a jury trial was because the plaintiffs brought up the exact type of evidence here. The plaintiffs talked in their opening and closing about how clinical studies were needed and clearly required and said the same while cross-examining the defendant's experts. The Court said, "This is inherently unfair allowing plaintiffs to fault defendant for not conducting testing while stopping defendant from explaining that the 510(k) didn't require that."

The complaint handling process. We've highlighted that. I'm just going to talk about that briefly. You know, Dr. Pence should not be permitted to offer opinions about postmarketing surveillance of the complaints. She opines that Atrium's complaint statistics are unreliable because in her experience the patients underreported complaints, but she admits that Atrium complied with industry standards for complaint handling.

In her report she says, "Atrium, like many if not all medical device and drug manufacturers, relies on

hospitals, surgery centers, healthcare providers, and patients to report patient complications and product complaints to Atrium personnel." So it met the standards.

She doesn't know if the calculations are incorrect. She didn't look at the complaint. She doesn't know if they're underreported. She hasn't reviewed the full complaint files. She didn't look at the FDA's website tracking. She didn't look at any data to assess whether the rate of complication with C-QUR is higher or lower than any other medical mesh device.

THE COURT: I got a message a moment ago, I would say two or three minutes ago, that you were up, time was up, but I had interrupted you so I was going to wait and cut you off after a few minutes. So I think I'm going to go ahead and cut you off and let Orent jump in.

Go ahead, Attorney Orent.

MR. ORENT: Your Honor, I want to start off by saying I think what I just heard was a reargument of the 510(k) motion and a premature motion argument on the FDA inspections, and what I didn't hear was focus to the three things that we actually really intend on putting Dr. Pence forward for and that we specifically respond to in our argument. And that is, we believe that Dr. Pence can talk about the industry standards relative to labeling and the defendant's failure to warn of what they knew were

complications and hazards of this device but did not disclose. That is based on the common law duty, but it's also based upon industry standards as well as ISO standards, the Global Harmonization Task Force, and other standards enumerated in her report that is not relying on what the FDA did in the 510(k) process because the FDA 510(k) process, that's a floor, not a ceiling.

And so the defendant had a common law duty, which is what they're liable to, to adequately warn. The defendant didn't. They violated both industry standards and again these written standards. That's what Dr. Pence is going to talk about.

Next, complaint handling.

The defendants, you just heard, I think misunderstand what it is that Dr. Pence contends was inaccurate with their complaint handling.

Now, the defendants both had a common law duty to follow and track complaints to make sure -- in that six years between the time of launch of the device and the time that my client, Carrie Barron, was implanted, they had a duty to make sure that that device was safe and effective for the treatments that my client was receiving it for.

In this particular case they didn't fulfill that obligation because they didn't track complaints and because they didn't do a proper trending analysis, and there were more

than 38 inspections conducted that found problems with their complaint handling.

They didn't know what the complaint rate was, and that's the point. The point of this isn't that the FDA said this or the FDA said that or that there was a consent decree. The underlying facts are what are important. The factual findings. That there were tons and tons and tons of unreported complaints, and that the company when they were given complaints they didn't properly file them as complaints. Instead, they made a mockery of the situation. They made jokes, crass jokes when complaints came in, and they didn't get reported into the complaint database. That's the point.

When you get a report of an infection, which my client had, and the chief of sales says it's because you're an expletive, referring back to, you know, various -- well, I'm going to just leave it at that, expletive, instead of making sure that the complaint was handled, that is an issue in play in this case, and that's what we're arguing.

Third. Manufacturing process doesn't conform with the industry standards.

One of the key factors in this case is the coating that was applied to the mesh and other decision-making.

There were numerous inspections and discussions in depositions where the defendants didn't have an actual specification for the thickness of the coating on the device.

That is a major issue. And what Dr. Pence said is, look, you can't do that. You need to specify it and then you need to manufacture in accordance with your specifications. You can't alter the specifications on the manufacturing floor just because you want to.

And so what Dr. Pence does is she goes through the various industry standards that actually do relate to how to do these things, not what a finding means but how do you do this, and she concludes that there is a problem with the way that Atrium is comporting themselves in performing a very particularized task.

And so that's what we believe Dr. Pence can testify to, that's what we believe she should testify to, and she's got real world experience. Dr. Pence has worked for Eli Lilly, Serono Labs, Triton Biosciences, Amgen, and she's done this work in her professional life for 47 years. She has looked at whether or not someone needs to do X because they're seeing Y in a test result. That's what she does. She gives the sort of guidance in-house, and that's what she's saying here is, look, there are all these red flags and you didn't do anything. You didn't do a human clinical trial because there were so many red flags in the intervening six years between launch and Ms. Barron's implant. You had an obligation to do that. Here are the standards that say that plus my experience in the field.

So what I didn't hear was an argument from Mr. Cheffo on those issues. And I think that her methodology and the fit are clear in her report and in her deposition.

And so, your Honor, for the balance I'm going to rest on my papers. I know that we have gone long this morning. So unless your Honor has any further questions, I'm just going to leave it where that is.

THE COURT: Okay. We're going to take a ten minute break and then we will come back.

Is ten minutes sufficient? Let me ask my court reporter.

THE COURT REPORTER: Yes, Judge.

THE COURT: Okay. If we come back at ten of 12:00, so 11:50. So everybody just turn your mic off. Turn your video off. We will come back and I'll just give you my ruling on the --

MR. CHEFFO: Your Honor, could I have a minute to respond when we come back?

THE COURT: Yes, you can have one minute.

I will confess, Attorney Orent, that your background is very different than it has been in every other one of these hearings, and it's a little disorienting not to see your child's artwork on the wall behind you. I don't know if that's throwing anyone else off, but ultimately all those diplomas are not quite as nice a background as your child's

drawings.

But anyway, let's take a ten minute break and we will be back. I'll give you a minute, Attorney Cheffo, and then I'll give you my ruling on document 225.

Then we'll go into the motions in limine.

MR. CHEFFO: Thank you.

MR. ORENT: Thank you, your Honor.

(RECESS)

THE COURT: All right. We're back from our break. Our court reporter is back with us.

And let me give Attorney Cheffo another minute or two to respond.

MR. CHEFFO: Thank you, your Honor.

I've had a few minutes to collect my thoughts, so thank you. I'm going to try to keep it to a minute or two.

So we obviously disagree that I haven't addressed the issues. I think they're in the briefs.

Again, what I think the plaintiffs want to do is differentiate these two issues, and they can't be.

We didn't hear any response to the flaws that we did talk about. The fact that she wants to offer a causation opinion, right, that's in her deposition. She testified that C-QUR mesh causes serious harm in alluding to Atrium as a manufacturer of a medical device that has the potential to cause serious harm and that in this case it did, we know that

in this case it did. So she's not qualified. She's not a causation expert.

Also with respect to -- and this is in her deposition at page 130. She speculates that had Atrium performed premarketing clinical trials, infections and drainage and the heavy seromas and rashes would have been seen in those trials. This implies that the mesh would have caused those problems. Again, so she's going well beyond her expertise, her methodology, and what's appropriate. That also goes to all the premarket testing that I did talk about.

With respect to the labeling, one quick point on that. In our motion at page 12 we note that the FDA had follow-up questions with respect to specifically the V-Patch labeling during the 510(k) process, right? So again to the extent that -- that's the product, right, in this case. To the extent that we're not able to talk about the back and forth specifically on this product on this label because of the 510(k), Dr. Pence shouldn't be able to talk about, you know, the labeling issues with respect -- post that without incorporating our ability to have kind of a rebuttal or the context to those issues.

Finally, there's two other quick points that are made, but I just want to highlight them for the record here.

In her report she talks about at page 27, you know, a resin and the use of a certain resin, whether it should or

should not have been disclosed. Again, she's not a causation expert. That's well outside her lane.

She also has an opinion with respect to fixation. That's at page 10. There's no evidence in this case that kind of a lack of permanent fixation, at least in the Barron case, has any relevance because that's not -- there's no allegation that I'm aware of that that was an issue in this case.

So hopefully I kept to my time, your Honor.

THE COURT: Okay. That was pretty good.

Let me just ask you, though. I know it is true that 510(k) clearance includes an element of approving labeling and that's excluded, but Pence proposes to say the product is mislabeled because it does not provide adequate safety warnings which is independent of the 510(k) label approval process. As I think Attorney Orent described it, it's the difference between a floor and a ceiling, and that's a different conclusion and she's talking about industry standards there.

MR. CHEFFO: Right.

THE COURT: Can you address that for me?

MR. CHEFFO: Of course, your Honor.

This goes to really any failure to warn case, right, you know, and outside kind of preemption context.

I mean the idea, right, that -- and to me it's just kind of -- my answer would be just basic evidence, right? So

if Mr. Orent's position is, well, just because the FDA went through a clearance process and there was a label it approved, does that give a pass to a company forever to say it's preempted and the labeling is appropriate? No. No one is arguing that, right?

They're saying, well, you should have done more. It's a floor, not a ceiling, as he argues. We kind of disagree fundamentally with some of the characterizations, but let's just take that analogy. What we have here is -- we can't even talk about the floor, right? We only talk about the ceiling.

So if a jury is going to say -- you know, it's one thing to say it went through this whole process for three years, here's what happened, there was a back and forth, the FDA looked at it and here's what they came to. It shows a level of reasonableness, right, that you didn't just put a product on the market. There was FDA involvement.

And then if someone later wants to come and argue, well, we don't think that that was appropriate or things changed, but to keep out completely the back and forth, the floor, if you will, and only talk about the ceiling without any context, I mean that's -- again, I don't want to repeat this point, but this is the problem, your Honor, with what I think the vast majority of cases, many of which the Motley Rice firm has been involved with, the courts have basically

said, and as Mr. Orent said because he knew that, if you're going to not talk about -- if you're going to keep this stuff out, we're not going to talk about FDA at all, right, because you can't start the story midway, and that's really what would be happening with the label, not giving people an understanding of that whole labeling process, right, what happened, how did we get from -- because all I think Dr. Pence wants to come in and say, well, this is unreasonable and you should have done X, Y and Z, but there's a lot that happened before we got to that part of the story.

MR. ORENT: Your Honor, if I might just have 30 seconds to respond to a couple very brief things.

THE COURT: Go ahead.

MR. ORENT: First of all, we're not saying that the defendant cannot offer the evidence of what they used to make the decision that the label was in their opinion sufficient or the testing that they used to make their decisions.

What we're saying is it doesn't matter what the FDA says about their evidence. What matters is the truth of the evidence. Did the evidence that Atrium had on hand, was it sufficient to justify their belief that they didn't have to do more testing or were there safety signals in the material itself that required them under their other duties to do that additional testing or the industry standards.

And for this really Dr. Pence is not relying upon

FDA, and these three areas that we're talking about are really industry standard areas, okay? And when you heard my argument, you didn't hear me reference FDA with one exception. That is where these complaints -- the failure to properly handle complaints and there was an inspection done and a finding.

And as I said before, the issue isn't that the FDA found this and saw this. The issue is the underlying fact of the condition that they didn't track complaints. And when they're going to get up -- their medical experts and their corporate experts are going to get up and talk about we only had a .0025 complaint rate, well, we're going to say, well, you didn't track your complaints and here's 38 inspections that showed that they were sitting around not in the right place.

So there's a very fundamental difference between interpreting what the regulations require in that having your cake and eat it too way, which I still stand behind my statement, and using a fact of something, a condition to demonstrate ignorance -- or failure in a duty sense, and that's the point here.

MR. CHEFFO: Your Honor, this is why it's so important, because Mr. Orent -- I'm sorry to take a few more minutes on this, but this is critically important.

THE COURT: 30 seconds. Go ahead. 30 seconds.

MR. CHEFFO: It doesn't matter what the FDA says. You need to look at the facts. But again, the FDA tells a company what to do, how to report, when to report, how it should treat things, right?

So the jury is supposed to say did a company act reasonably based on X, and someone is going to say, well, I looked at these reports. But if you don't have the context of -- there's very, very specific rules and guidelines about how they're supposed to do it, what they're supposed to do. You can't just let a jury kind of figure out whether the industry standards, which are essentially the FDA rules, determine whether they think it's appropriate or not if a company is fully complying with the FDA guidance. They at least need to know that if we're going to let this evidence in.

THE COURT: Okay. Thank you. Thank you.

All right. Document number 225, which is defendant's motion to exclude Pence.

The first argument I think is somewhat similar to an argument made by plaintiffs with respect to Ulatowski and that exclusion of her opinions because they're too closely related to the excluded 510(k) clearance process evidence, and I make basically the same ruling I did with respect to Ulatowski. That's not a basis to exclude her testimony and I'm not going to reiterate what I said about that with respect

to Ulatowski.

Now, defendant challenges the admissibility of Pence's opinion testimony that it does not fall within the scope of the Court's prior ruling, but I didn't find a cogent rationale for excluding that which fell outside the Court's ruling. Her opinion is clearly relevant to issues raised by the parties' claims and defenses and would be helpful to the jury.

Accordingly, the Court denies the motion to the extent premised on the entanglement of Pence's testimony with the excluded regulatory evidence.

The next argument or challenge is that Atrium's premarket clinical testing was inadequate and that she shouldn't be allowed to opine on that.

Pence offers her opinion that Atrium's premarket clinical testing of its surgical mesh products was inadequate by the metric of applicable industry standards.

Defendant argues that her opinion is necessarily based on an unreliable methodology because applicable statutes and regulations do not require more testing than Atrium performed.

The Court disagrees with defendant's argument. As discussed in connection with plaintiffs' challenge to Ulatowski's methodological reliability, I would cite the same Kumho Tire language with respect to the purpose of the Daubert

gatekeeping requirement.

Pence describes her methodology at pages 8 through 9 of her report. Pence asserts that in forming her opinions she utilized the same regulatory and industry standards as those utilized by medical device companies in performing premarketing and postmarketing responsibilities.

She further asserts that the methods she used in forming her opinions were no different than those she has used in her practice over the course of her career and as an expert in regulatory affairs, industry standards, and medical product research and development.

The Court finds that Pence's methods are in fact the methodology that characterizes the practice of an expert in the application of industry standards.

Moreover, defendant's argument that her opinion must be unreliable because statutes and regulations do not require more testing than Atrium performed is beside the point because Pence's proffered opinion addresses the requirements of industry standards only.

Accordingly, the motion is denied to the extent premised on the purported unreliability of Pence's methods.

All right.

She opines on Atrium's complaint statistics as unreliable.

Defendant next argues that Pence's opinion is

unhelpful and unreliable where she opines that Atrium's methods of tracking complaint reports provides an unreliable indicator of the number of or nature of the complications suffered by patients implanted with Atrium's devices.

Defendant asserts that Pence has not explained the methods by which she formed this opinion and characterized it as in effect merely a personal opinion.

However, at pages 50 to 53 of her report Pence provides a cogent and detailed explanation of how she formed her opinion regarding Atrium's methods for tracking complaint reports together with citations to facts.

Moreover, one of the consequential issues in this litigation is the question of whether Atrium had adequately disclosed risks associated with its product. If its methods for tracking complaint reports do not reliably reflect the complications actually experienced by patients using Atrium's product, that fact will be helpful to the jury.

Accordingly, defendant's motion is denied to the extent it addresses Pence's opinion as to the reliability of Atrium's methods for tracking complaint reports.

Now, with respect to her purported causation opinion.

Defendant argues that Pence offers opinion outside the area of her expertise where she discusses research papers finding risks associated with use of Atrium's surgical mesh

products.

For example, at page 27 of her report Pence opines that Atrium should have warned of the device-specific risks associated with C-QUR products, including increased numbers of infections, persistent seromas requiring treatment, and intense and chronic inflammatory responses and foreign body reactions in some patients, including persistent symptomatic rashes.

The Court agrees with defendant that Pence is not a clinician or a scientist and that she would be unqualified to offer scientific or clinical expert opinions. In her report, however, Pence does not purport to do so but rather offers opinion as to whether clinical findings warranted disclosure under applicable industry standards. This she is clearly qualified to do.

Now, defendant may raise this challenge at trial should Pence attempt to opine outside her area of expertise, for example, by offering opinion as to the clinical or medical importance of a scientific finding. However, because Pence does not offer such an opinion in her report but rather offers opinion only as to whether such findings warranted disclosure, the motion is denied to the extent premised on the argument that Pence offers clinical opinion as to causation.

Next, with respect to the inadequacy of Atrium's labeling.

Defendant next argues that Pence's opinion is irrelevant and unreliable where she opines that Atrium's labeling disclosures are inadequate. Defendant asserts that such opinion will be unhelpful to the jury because it is unclear whether Atrium's labeling disclosures played any role in the specific causation of plaintiff Carrie Lee Barron's injuries.

However, nothing in the Court's record suggests that plaintiff offers Pence's opinion regarding Atrium's labeling disclosures in order to prove specific causation. To the contrary, plaintiff appears to offer the opinion in order to establish Atrium's failure to comply with regulatory and industry standards in marketing its product. Moreover, Pence explains in details in her report her grounds for concluding that the identified failures to warn involved material risks.

Defendant does not challenge Pence's actual methodology but rather offers only the straw argument that her methodology cannot be ascertained from her report.

Under Daubert and Rule of Evidence 702 expert testimony is admissible so long as it is relevant based on sufficient facts or data and is the product of appropriate application of reliable methods. Pence's opinion on Atrium's labeling disclosures meets these requirements.

Accordingly, defendant's motion is denied to the extent it addresses Pence's opinion regarding Atrium's

labeling disclosures.

The final argument is in regard to her having a personal opinion or federal requirements that are dressed up as industry standards.

Defendant finally argues that Pence should not be permitted to offer her own personal opinions or statements of federal regulatory standards in the guise of offering opinion as to industry standards. The Court agrees it would be improper to permit Pence to do so.

However, the Court's review of Pence's expert report does not suggest that where Pence purports to discuss industry standards she is instead offering either her personal opinion or federal regulatory requirements in lieu of industry standards. To the contrary, Pence generally provides a basis for her opinion that industry standards are as she describes.

The Court accordingly denies the motion to the extent premised on this argument.

Now, defendant will be at liberty at trial to cross-examine Pence regarding the sources of her opinions regarding industry standards in order to ensure that she's not offering her own personal opinions or statements or federal regulatory standards in lieu of industry standards.

All right. That's my ruling on all of the arguments in document number 225. That document is completed -- that order is completed.

So let's move to the motions in limine.

Let's do 5, 8 and 9, and then let's do 2 and 7 at the end because 2 and 7 relate to the exemplars and I want to separate them out.

So let's start with 5, 8 and 9, and how about five minutes per side on that.

So let's start. These are defendant's motions in limine. Who's going to argue these motions, a variety of you or --

MR. CHEFFO: Yes, your Honor. I'm going to argue 5.

I frankly think -- I'm going to try to do it in five minutes. There's a lot of meat in this one, but obviously if you limit us to five minutes, that's fine.

THE COURT: I'll give you ten minutes if you think that makes more sense.

MR. CHEFFO: I will try to do it quicker, but this is an important motion for us, your Honor.

THE COURT: Okay. Let's give you at least ten minutes then on 5.

Go ahead, Attorney Cheffo.

MR. CHEFFO: Thank you, your Honor.

Your Honor knows what you said with respect to the 510 clearance. I'm going to try not to repeat too much of what we talked about, but we do think that much of what we

heard and what your Honor said today I think bleeds into this.

We did hear that it's plaintiffs' intention, quite frankly, not to utter the words FDA. We heard from Mr. Orent if we're correct in what the FDA rule is, we're not going to produce evidence that there's a consent decree out there because that would be having our cake and eat it too. No equivocation. No controversy. That was December 10, 2020.

The plaintiffs have it seems kind of completely changed their view on this one. They write that they're not mentioning the FDA because it's not feasible but they're relying on incidental purposes for this type of evidence, and these purposes run the risk of kind of derailing I think much of what the Court has tried to avoid which are kind of trials within trials and rabbit holes.

It's important to note that much of this evidence -- and we're talking about things like the consent decree. We're talking about the warnings. We're talking about the inspections.

So, first of all, this regulatory correspondence concerns -- it does not concern the design or warnings of C-QUR. It routinely largely focused on the manufacturing process, and the plaintiffs' manufacturing claims have been dismissed with prejudice.

The consent decree.

In addition to what Mr. Orent suggested, the

consent decree involves multiple facilities, product lines, several different entities, and there certainly is the risk here that any adverse inference from the FDA will be unfairly applied to Atrium.

So we go through in our brief, so I'm just going to highlight some of the points, really what these things say and what they don't say and what the FDA has told us about them.

And again, if you were going to look at kind of the FDA regs and the import -- so, for example, on its website the FDA states that the manufacturer should be prepared for an FDA quality system inspection at any time after the 510(k) clearance.

So again, right, there's this process, there's qualifications, and then the FDA relies on those in order to determine whether they've met those standards. So they are intertwined.

Secondly, these are just judgments of -- like the EIR, for example, and this is Exhibit 8 in our papers, is characterized as just a judgment of the FDA inspector, and in our brief we've highlighted a number of issues, including kind of the inequity but also kind of the hearsay issues.

The face of the 483 form says that they do not represent a final agency determination, and the FDA says that warning letters are informal and advisory.

And I know that what the plaintiffs have said and

likely will say is that, oh, this just goes to notice, but, you know, as your Honor did -- so we have a number of arguments, but I would also kind of highlight and request the Court to also go through the same process that you did with respect to the 510(k). Not only -- you know, you didn't determine that it was irrelevant, but it was kind of an issue. Though I think -- when you look at all of these types of issues, that's also I think a very powerful reason to kind of keep much of this out.

You know, we also -- you know, particularly with some of these documents they actually come after the facts surrounding Mrs. Barron's surgeries and the issues. So in other words, to the extent that they're talking about notice, those arguments wouldn't necessarily apply.

So what we're basically doing here is trying to substitute kind of an FDA inspector's judgment and determination for the jury without an opportunity to kind of fully -- there's certainly no depositions of these. I don't expect these folks would be called at trial.

You know, jurors will be left with the impression and the confusing notion that the FDA has already determined that Atrium acted negligent and that it would be hesitant to substitute their judgment for the regulatory agency. I think these are particularly powerful. Particularly when you look at the fact that -- and again, we cited these in our briefs.

Each of these instances the FDA said these are not a final determination. These are not a fact finding. These are just judgments, right?

And I think it's really important about, you know, how the perception of the jury -- particularly since I think we all agree that the facts of kind of what happened, what the company knows as opposed to, you know, kind of the judgment of an FDA inspector at a point in time.

And again, I think a lot of these -- it's also important to note that they don't go to the issues in this case. They're not -- they're manufacturing related largely. And particularly with things like the consent decree, they involve different people, different products, different sites over a period of time. And to kind of pars all of those out would I think be unwieldy and would leave, again, the jury with the misimpression that somehow the FDA found that there was liability or negligence with respect to Atrium's processes and these particular issues.

Now, I think briefly in the cases that we've cited, you know, in the Lewis versus Johnson & Johnson case the Court said admission of evidence regarding FDA enforcement actions against Ethicon runs the same risk of misleading the jury as the 510(k) clearance process. Jurors are likely to believe the FDA enforcement relates to the validity of the plaintiffs' state law claims, which it does not.

I also talked briefly previously, I won't read it again, with respect to the Hrymoc versus Ethicon case.

And I think, you know, your Honor, when you look even at the cases that the plaintiffs have recently cited in their papers, they -- the two cases that the plaintiffs cite. The McGinnis case where the Court excluded evidence regarding the 510(k) clearance process but also held that there will be no reference to the FDA, this is the case the plaintiffs cited.

In another case that they cited they quote the title of the motion but not the ruling, and the FDA there ruled that -- I'm sorry, that was actually in the McGinnis case -- the FDA may not be referenced in this trial.

In the Tyree case the Court excluded the 510 process but it also excluded all other evidence, and that's true for the cases that are cited throughout. It's generally an all or nothing proposition.

Plaintiffs have said that, well, we can just redact the word FDA. And, you know, respectfully that's just clearly not workable. Any sophisticated jury will kind of figure out what this is. It will lead to confusion about why it was redacted. Is it another agency? Is it law enforcement? You know, that would probably be no more satisfying than saying, you know, all of the materials that are submitted back and forth during the 510(k) we should just take the FDA process.

So that's certainly not a workable solution.

Briefly on the consent decree. I think there's a number -- in addition to the prejudice Rule 408, as we've talked about, I think would kind of bar this evidence of settlement, so preclude it for two reasons according to the First Circuit. The first is, and this is from the McGinnis case, "It promotes a public policy favoring the compromise and settlement of claims by insulating potential litigants from later being penalized in court for their attempts to first resolve their dispute."

And also from the McGinnis case, "Such evidence is of questionable relevance on the issue of liability or the value of a claim, since settlement may well reflect a desire for peaceful dispute resolution," and it goes on.

So the point is in addition to the prejudice there's the Rule 408 considerations. There's a lot of reasons, as the Court knows, why a company would enter into, you know, a consent decree.

And in fact the McGinnis case the Court determined that allowing at least in that case a settlement agreement it was reversible error.

The plaintiff hasn't provided a legitimate basis to circumvent Rule 408. I think this is really important. The plaintiffs' opposition cites to cases that indicate that the consent decree may be admissible to show notice, but that

makes no sense in the context of this case because the consent decree was entered into after plaintiff's V-Patch mesh was implanted so that's not a plausible basis here.

So I'm going to stop there. I think I've hit my ten minutes, your Honor, without you having to cut me off.

Thank you.

THE COURT: Okay. Thank you.

The consent decree was entered when? I know the FDA filed the complaint in 2015. Was it also the same year? Did the consent decree enter the same year?

MR. CHEFFO: Let's see. I have a timeline here. So the consent decree -- I may need to buy a vowel. Is it 2015? I think it's 2015, but one of my colleagues will correct me if I'm reading this wrong.

MR. ORENT: Your Honor, it's actually Exhibit 7 to defendant's papers, and it's dated 2-13-15.

MR. CHEFFO: Yeah. Thank you, Jon. That's what I have, too.

THE COURT: Okay. And when did Ms. Barron have her surgery?

MR. ORENT: I believe it was back in 2012. In the fall of 2012.

THE COURT: Okay. Let me ask you this, Attorney Cheffo. The FDA comes in basically in 2012 and issues its EIR and then comes in again in 2013 and issues the EIR as well as

this Form 483 and then files a complaint.

Now, the EIR talks about numerous complaints of infection associated with C-QUR products, including the V-Patch, and saying that Atrium hadn't followed up on these, and product design or addressing observed problems with product sterilization, and memorialized all this in Form 483.

So when you're defending -- you're representing the FDA defending against this EIR and ultimately the complaint that's filed, are you holding up the 510(k) clearance process as a get out of jail free card at that point? Is that something that you're relying on to say all those findings are irrelevant because you cleared -- you gave us 510(k) clearance?

MR. CHEFFO: No, no. I don't -- so no. The quick answer, your Honor, is no, but they're not irrelevant to the ultimate findings, right, because the --

THE COURT: Okay. I'm going to stop you there. Tell me how you will argue -- if you're representing Atrium now in 2012 as against the FDA, tell me what your arguments are that the 510(k) clearance process essentially clears Atrium and you shouldn't file a complaint, you shouldn't enter this EIR because the 510(k) clearance process has exonerated us of certain things. What are those things that the 510(k) process has exonerated Atrium of?

MR. CHEFFO: Well, your Honor, that's not the

question I think, respectfully, right? I mean, that's not the point. No one is saying that because you get a clearance or a label or approval for any product or medical device or pharmaceutical that somehow you get a pass.

The issue here is when the FDA comes in, right, and they make these findings -- first of all, they're largely -- they're judgment issues, right, so they're not factual findings, and then they could be things that are dealing with the -- largely they deal with things like the manufacturing process or maybe a page was missing. They could be serious. They could be totally different.

But what they do look at is they say your product is approved for X, here's the specifications, right? So in order to find out if -- they absolutely look at the 510(k) clearance because you have to sell and manufacture your product in accordance with what was cleared, right, so that's how --

THE COURT: Okay. Is that in the EIR? Are there references to the 510(k) clearance anywhere in the EIR or the Form 483 or frankly in the consent decree?

MR. CHEFFO: Well, yes, because there's specifications. I mean, do they say 510(k)? I don't know that, but they basically -- you're able to sell a product that's been cleared, right? You have to sell the product in conformity and manufacture in conformity what's been cleared.

That's what they judge. So what they looked for for one person's product maybe and not in other companies. So it is tethered, right, and then there are just general issues.

So there are two arguments here. Yes, it is related, and two --

THE COURT: How? How? Give me three examples, three specific examples from the EIR that it is tethered to the 510(k) just so I can understand your argument.

MR. CHEFFO: Okay. Well, there's three reasons why. My argument is that the specifications, right, you have to go through this three-year process during the 510(k) and then you get cleared, right? And you have to talk about all the things you're going to do, how you're going to manufacture it, what you're packaging, what you're labeling.

Your Honor, if you want us to go through all of the EIRs and try to specifically off the top of my head -- but I would say -- so what they do is they look at the product in the way that it's supposed to be specified and manufactured pursuant to the clearance, and they come in with their chalkboards and notes and everything else and they find out if there are violations or things that need to be corrected, right.

But it's going to be different if you manufacture hip implants versus this implant or that. So it's absolutely related to the entire process. They then find out if there

were any deficiencies, and they give you an opportunity to go back and fix and work with them or tell them why you think that they're wrong.

So there are two points. It's absolutely related specifically to the product, and then it is also not, you know, kind of a factual finding.

And remember it could be things related, these 483s generally that have nothing to do with this product with this plaintiff with these issues, right?

So this goes almost like your Honor's kind of questions and rulings on the MDR, right? There could be a lot of different things and findings that go on but, you know, this is not about kind of everything in a plant because they come in, they could spend two or three days, and they can look at all the paperwork.

So it is related. I'm not going to tell your Honor that every single entry is directly, there could be general things in terms of bookkeeping that a company needs to do, but it is based on the specifications for the specific product. That's what they're looking for.

THE COURT: Attorney Orent, go ahead.

MR. ORENT: Well, your Honor, I want to start off by saying I think your Honor made an excellent point, and that is the specs are in the design history file, okay? Every company maintains a file that contains the specs and what the

device is. There are ISO standards. There are whole industry standards as to -- as well as regulations, but the point is that there's a design history file, and the underlying facts I think are important for this.

These are not issues -- let me back up for a moment.

I want to just state again our purpose is not to say the FDA said this and therefore it was a bad product. So the issue of the consent decree, we -- it's not our intention to introduce this unless the defendant takes positions that are directly contrary to the assertions made in that and such it would be used for impeachment of corporate officers and it would be very relevant to those key points because the company admitted to these items.

And under the cases that we cite, and we cite cases where consent decrees are established, we cited two particular cases, the issue there -- the issue in our case would be we would use it to impeach a witness, but it is not our intention to introduce it for the purpose of the underlying findings in and of itself. So I want to just make that perfectly clear that my position is today the same as it was when we met in November and December and it has not changed.

And as your Honor knows, my position with regard to these individual inspections is similar. We tried to go down a route where I would have someone stipulate to the notion

that an inspection was conducted on such and such a date and here was the finding, and we went through a process where I enumerated the 38 individual inspections that were conducted and the relevant findings and the defendants did not want to agree to a clean stipulation of those facts. And so the only way they get this evidence is -- and the evidence that we're seeking to introduce is the condition at the facility at the time.

And so the document -- and taking Mr. Cheffo's example, which was Exhibit 5, it says on its very face, "This document lists observations made by the FDA representative during the inspection of your facility," their inspectional observations, and then it goes on to talk about they don't make a final agency determination.

Well, we're not using it for a final agency determination. Again, it is -- and the case law that we cite supports that they are admissible to show the condition and to show notice and knowledge.

And so let's look through specifically what these findings are that I think are important and that are going to be right at issue in this case.

So speaking with that particular document, Exhibit 5, there's the Bates numbers in the lower right-hand corner. And so if your Honor turns to the one that ends in 0188406, so it's actually -- on the ECF it's page 7 of 9, we see that the

defendants -- the observation -- so this is a factual observation. "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests a marketed device may have caused or contributed to death or serious injury. Specifically, MDR reports for the following complaints were not submitted within 30 days of your firm becoming aware of the complaint."

And then it goes on and it says, "C-QUR V-Patch infection, 8-28-12. C-QUR mesh adhesions, 2-13-13. C-QUR mesh infection, 10-18-12. C-QUR mesh infection, 7-2-12."

Then it goes on to observation number 8 on the next page. "Complaint files are not adequately maintained."

So when the defendant gets up and tells the jury we've got a complaint, right, that this device is safe, and they are taking that position that this device is safe in the abstract, I am absolutely entitled to put in evidence in this case, both in my case in chief and to cross-examination, that shows that this company did not make adequate attempts to maintain a proper complaint handling system, that they were given lots of notice of many instances that are very similar to those, including like our plaintiff, and that the data that they are representing from their own internal systems are so unreliable that the jury should discard them. And what we're going to do is we're going to offer these reports as proof and notice and knowledge to the defendant as of the conditions as

of the date of the inspection.

So both the inspections before Ms. Barron was implanted are obviously relevant to notice and knowledge in terms of what the company knew or should have done prior to her implant, but the ones that occur after her implant are also admissible and they're admissible because the defendants have taken the position that the device today is safe and efficacious and meets that reasonable test where the benefits outweigh the risks. And I'm entitled to put on evidence that shows the benefits do not outweigh those risks, and that includes these documents.

And so my intention is not trying a case that is reliance on the FDA per se because there are other standards that require complaint handling, but these documents, one, they're both FDA documents but they're also private companies retained both by Atrium and by FDA as a contractor, but they enforce these -- they're there to perform inspections on the conditions of the facility. Those are issues of fact, not of legal determination or legal consequence.

And so that's the evidence in this case, and the reality is that we cannot get away from the fact that this company had hundreds upon hundreds of complaints that were not properly logged in their files and that they have no basis for articulating that this is a safe device and for withholding certain information from their labels.

So without repeating myself I will just rely on our papers for the balance, your Honor. Thank you.

MR. CHEFFO: Can I just respond quickly?

MS. ARMSTRONG: Your Honor -- your Honor, I'm sorry to interrupt, but I just wanted to make a couple of points as regards to what Mr. Orent said, if that's okay. Then I'll turn it back over to Mr. Cheffo, but I'll be brief.

THE COURT: Go ahead.

MS. ARMSTRONG: First of all, he said the company admitted the FDA's allegations. That's absolutely incorrect.

If you look at the consent decree, it makes clear that the company is not admitting the truth of any of the allegations made by the FDA. It was entered into for purposes of settlement only.

The second thing is he talks about -- he cites these findings in the FDA's reports to say that the MDRs were not submitted to the FDA. It's important to distinguish between what a complaint is and what an MDR is.

Complaints come into the company. Complaints are evaluated by the company regardless of whether or not they meet the standards for sufficient to the FDA and they're used -- when the company says we have only so many complaints, they're looking at the complaint files, not the MDRs. Whether they were properly submitted to the MDR -- and then the company's response to the FDA in hiring an outside expert is

demonstrated that their evaluation of the complaint would not have changed one bit based on whether or not these were submitted to the MDRs because they were already included in the complaint files and they evaluate complaint files.

Whether or not something gets submitted to the MDR is a regulatory requirement, and we're not, you know, dismissing that, but it doesn't change how they evaluate the complaint.

So it's important to keep in mind the complaint and MDRs are different things. Every MDR that a company files starts with a complaint to the company, and that complaint is included in their complaint files and evaluated.

I'm going to let Mark --

MR. CHEFFO: Your Honor, just to be brief, I mean, I think we kind of heard really the point I think, and this is consistent with all of your prior rulings.

You know, basically Mr. Orent is saying we want to show kind of a condition at a period of time. You know, why? They want to basically say, well, the jury should assume that because there were some violations and there were some issues that you should assume that this is kind of a bad, sloppy company.

They've dropped with prejudice their manufacturing defect, right? So that -- you know, arguably they could say at this time this lot there was an issue with infection.

That's not what this is about. This is basically just pure and simple trying to kind of tar the company. It has nothing to do with notice. No one is going to ever get up and say that there was never, you know, a violation or everything was done perfectly. No company would ever do that.

This idea, the before and after is -- you know, if it's for notice that -- you know, I disagree with the before arguments for the reason I said, but after the fact that somebody came in and found something at a point in time after this plaintiff was implanted, I think that's very far afield.

And the last issue is that, you know, what they're really trying to use this for is basically a surrogate for causation, and there's been no evidence, right? Their experts have had plenty of time. They've had all this information to basically put together. They've taken depositions, they've looked at it, they've done expert reports to say that anything with respect to these issues led to from a causal connection either general or specific causation to the specific injury or allegations in this case. There are none. That's why they dropped the manufacturing defect claim, your Honor.

So this is purely and solely to basically create a bad impression of a company based on the fact that these were -- and for all the reasons we said, they're not factual findings. They're observations. They're hearsay.

So for the reasons that we said here and in our

brief, we would strongly urge, your Honor, that -- the plaintiffs don't need this information, right? They can get through the facts. They could ask questions, you know, and if the whole point is that they don't need the FDA, they'll add certain facts. And obviously if we were to kind of open the door to these issues, that's a different story.

THE COURT: All right. I've heard enough. Thank you very much.

The defendant's motion in limine number 5 is denied.

Through its fifth motion in limine as amended at document number 226, defendant seeks to exclude from trial certain FDA EIR, establishment inspection reports, Form 483 observations, and warning letters, as well as the consent decree of February 3, 2015, through which the parties resolved claims stated in a complaint FDA filed against the defendant and three related corporate entities and some of their officers.

The reports, Form 483s, and letters contain the FDA's observations arising out of a series of inspections of defendant's facilities and those of the other related entities that took place from 2007 to 2013.

Defendant argues first that the materials should be excluded from trial because the Court has excluded evidence regarding the FDA section 510(k) market clearance process and

therefore should also exclude evidence regarding FDA's inspections of the defendant's facilities and the issues it observed there.

In the alternative, defendant argues that the materials are inadmissible as comprise offers or negotiations pursuant to Federal Rule of Evidence 408 and that the materials are inadmissible hearsay not subject to any exception pursuant to Rule of Evidence 802.

The Court disagrees that the admissibility of the materials is governed by the Court's prior decision to exclude evidence of the section 510(k) clearance process. The Court excluded those materials because of their limited probative value and the risks they posed of confusing or misleading the jury.

The reports, Form 483s, warning letters, and consent decrees by contrast are plainly material to the parties' claims and defenses. Including, in particular, defendant's knowledge and notice of the issues the FDA's inspectors observed and do not pose a significant risk of confusing or misleading the jury.

To the extent the materials pose a risk of confusion due to the fact that they reference problems at facilities operated by corporate entities other than defendant, they can readily be redacted to remove such references prior to presentation to the jury.

Moreover, to the extent offered to establish defendant's knowledge and notice of the issues the FDA inspectors observed, they are not barred by Rule of Evidence 408 and are not hearsay.

In addition, even if the materials were offered for the truth of the statements they contain, they are subject to the hearsay exception as public records and that they constitute reliable observations of FDA inspectors and report factual findings and matters observed under the FDA's investigatory authority, 803(a).

And with regard to the 408 argument, I would cite Wegerer versus First Commodity Corporation of Boston, a Tenth Circuit case, 1984.

That is my ruling on motion in limine number 5.

I have to end this at 1 o'clock today. So we have 20 minutes left.

What I can tell you is that I can rule, I don't need to hear argument, on the defendant's motion in limine number 8.

The motion to exclude the polypropylene manufacturer's warning, that is document number 174, that is denied.

Through its motion in limine number 8, also document number 174, defendant seeks to exclude from trial the warning issued by Lyondell Basell, the manufacturer of the

polypropylene used in Atrium's surgical mesh product that its polypropylene was not to be used in implantable medical devices like defendant's.

Defendant specifically seeks to exclude the manufacturer's material safety data sheet and its letter to purchasers of its polypropylene resin. Both of which contain that warning.

Defendant argues that the data sheet and letter are both inadmissible hearsay subject to no exception. The Court disagrees.

Neither the data sheet nor the letter are hearsay if offered to show defendant's knowledge and notice of the manufacturer's warning rather than for the truth of any statement contained in the warning.

Moreover, the probative value of defendant's knowledge of the warning outweighs its potential for prejudice.

So motion in limine number 8 is denied.

Now, let's quickly go to motion in limine number 9. I think the parties reached some level of agreement with motion in limine number 9, and I think I have some questions about where the remaining disputes are.

This is a motion to exclude evidence and argument regarding financial information of former defendant Getinge.

The parties have stipulated -- let me just see if

I'm right about this. The plaintiff is not going to seek to put on evidence of Getinge's net worth, and the parties have further stipulated -- and this I don't understand. You've stipulated that plaintiff would be permitted to introduce evidence that a witness employed by defendant received compensation in connection with the witness's employment. Is that the stipulation? That seems so unremarkable that a witness who works for Atrium would be paid by Atrium, you are stipulating to that, or am I missing something?

MS. UNGER DAVIS: Your Honor, my understanding was the point of that was that we would stipulate that the employee was paid by Atrium but not -- plaintiffs would not be identifying that it was Getinge unless it was to refresh the witness's recollection.

THE COURT: Okay. I'm just not understanding. What's the reason that plaintiff would want the jury to know about Getinge? I can't -- just remind me of why that would be something you would want the jury to know. Why is this even a dispute?

MR. COSTIGAN: We -- your Honor, this is Dennis Costigan for the plaintiffs.

We don't, to be honest with you. We have that agreement with the defendants.

There are some issues with stock sales and sale prices, and some of the witnesses in this litigation may be

testifying who have been paid in excess of $100 million associated with the sale of Atrium to Getinge.

We think we can get that information to these folks without mentioning Getinge. We have no intention of bringing Getinge into this. For purposes of impeachment and --

THE COURT: Can I just stop you, Attorney Costigan?

The reason that you want to ask these witnesses about their income or their salary, whatever, is to show bias in favor of Atrium or whoever is paying this.

Ultimately the defendant is Atrium. There are obviously connections to Getinge. The jury is going to be confused by which corporate entity is paying.

You just want the jury to hear that they've made a bunch of money and so they're biased in favor of Atrium or Getinge or whoever is paying them.

MR. COSTIGAN: That's correct, your Honor. Yes.

THE COURT: Okay. So where is the dispute? Tell me what the dispute is that I'm supposed to help you resolve. Is it that you disagree on the amounts?

Like you are saying, Attorney Davis, nope, we're not going to let you do amounts. You can ask them are you being paid by the person that you're working for.

That doesn't seem like any sort of agreement to me. You're agreeing that you're going to let them say you work for Atrium, you get paychecks from Atrium, you get paid by Atrium?

MS. UNGER DAVIS: Correct.

THE COURT: That's what you've been willing to stipulate to. Why can't they ask the amount? Why doesn't that show some sort of bias? Especially if it's a really exceedingly high impressive amount of money. Why wouldn't that just, you know, imply bias? You can obviously rehabilitate a witness, but why wouldn't that be something plaintiff could ask?

MS. UNGER DAVIS: Sure, your Honor, and thank you for pointing us to that particular issue.

I think that is where we disagree as to whether or not plaintiffs can introduce the amount of the employee compensation, and the issue here is really one both of relevance and of prejudice.

So as to relevance, plaintiffs have admitted in their papers that this is not probative as to any of their claims, but as they've stated here, they want to introduce it as to bias.

So, first, I would point out that plaintiffs don't introduce any case law to support either the relevance or the lack of prejudice here.

And instead, your Honor, what I would point you to is the Laplante decision by the First Circuit, and there -- that was a products liability case as well. The First Circuit said that allowing Honda's profits in as to the credibility of

Honda's proffered explanation was highly attenuated, the relevance, and that the prejudice was overwhelming. So here, your Honor, we have very much a similar posture.

In addition, the relevance here is further diminished because the evidence is stale. So these stock files were more than a decade ago. They were also payments by Getinge who is not a defendant here. And as your Honor stated, that's likely to confuse the jury.

But the prejudice here really flows from the amount and not the fact that the employees were paid by their employer. As you've said and alluded to, that's fairly self-evident. I don't think that that is something that is beyond, you know, the grasp of the jury. But the amount to the tune of tens of millions of dollars or $100 million is where you get the prejudice, and that amount is -- you know, there's a real risk that will bias the average juror against Atrium.

The other problem here is that it essentially allows in backdoor evidence as to Getinge's wealth. The parties have agreed, we did at the last hearing in front of your Honor, that Getinge's wealth is not going to come in.

But allowing in evidence that Getinge paid $100 million to a single individual obviously gives rise to the inference that Getinge itself is a wealthy corporation, and we're well aware of, you know, the risk that there is to

defendants of bias against wealthy corporations.

So those are, you know, some of the reasons that we think that the amount here is prejudicial and should be excluded.

THE COURT: Attorney Costigan.

MR. COSTIGAN: Well, your Honor, again, there is a distinction between this and the Laplante case.

In the Laplante case the judge offered that the amount of money for the sales, it was an ATV line that Honda was putting out there, seemed to be probative of the credibility of the explanation that Honda gave as to why -- it was essentially going to a core issue, which was Honda wanted to make more money. So the judge said it seems like maybe Honda is lying, and the reason they lied is because they made a boatload of money off this.

Here it would be a specific witness, and the amount definitely matters. I mean, if you have someone who is going to testify on behalf of Atrium and they're an unpaid intern or they make $50,000 a year, generally anyone is going to be fairly loyal to their company that employees them, but that's completely distinct from someone who has made hundreds of billions of dollars off them.

I think the Getinge aspect of it -- as we've said, we don't necessarily need to say Getinge, you know. Those words don't have to come out of anyone's mouth.

And secondarily as to any potential prejudice, I mean, it would show the witness's bias, and your Honor is more than capable of giving a limiting instruction as to what the jury is able to use that information for.

So I think just saying, you know, employee X was paid -- you sort of hit the nail on the head when you asked us the question at the beginning. That's not really an agreement. That's kind of -- everyone knows that and what does that get us.

So I do think that the amount is central, you know, just as Ms. Davis does. I just happen to come down on the other side of it. That if we're trying to prove bias, the more money you get the more likely you're going to be able to forgive some of the conduct or explain away some of the conduct.

MS. UNGER DAVIS: And your Honor --

THE COURT: I have some questions. Are we talking about one witness?

MR. COSTIGAN: Ted Karwoski would be the witness who was paid the significant portion of money. Well, there are a few that have been paid between stock buybacks and everything, but when we're talking about the $100 million, that would be Ted Karwoski.

MS. UNGER DAVIS:

So Ted Karwoski --

THE COURT: Excuse me. Excuse me. Please --

MS. UNGER DAVIS: I'm sorry.

THE COURT: Please do not interrupt me when I'm in the middle of asking a question. I'll let you speak, but please don't interrupt.

So you're saying that you want the jury to hear that they received in compensation from their employer, you're not going to say Getinge or anyone, you received $100 million in the form of payment, that's what you want to get -- you want the jury to hear?

MR. COSTIGAN: Yes.

THE COURT: Okay. And it's one witness. Did this happen ten years ago? So it got paid ten years ago $100 million?

MR. COSTIGAN: Yes.

THE COURT: Okay. And how -- I'm having trouble with ten years ago as opposed to the bias. Obviously $100 million, that's a lot of money, I agree, but they're testifying in July of 2021, and I think Attorney Davis was arguing that that's ten years, that's too attenuated.

If they were certainly scheduled to receive more stock options or they were scheduled to receive some sort of gargantuan payment, that would certainly help your argument, but the fact that they had this windfall profit from the company they're working for and it happened ten years before

the trial, that's more attenuated for me. So I'm having a little more problem with it.

MR. COSTIGAN: Yeah, they have continuing consulting relationships with Atrium as well, and I am sure there may be some sort of questions as to the amount of money and amount of years that could make something attenuated, but when they still have a relationship with them and are still working under the auspices of some sort of golden parachute that he received, I do think that goes directly to their credibility.

THE COURT: Okay. I think I need to hear more specifics on this.

Attorney Davis, go ahead. What were you going to say?

MS. UNGER DAVIS: Thank you, your Honor. I'm sorry I interrupted you. It's a little difficult on Zoom sometimes.

THE COURT: It's okay. Go ahead.

MS. UNGER DAVIS: So I was going to say a couple of points in response to what Mr. Costigan has said.

The first was that Ted Karwoski received $30 million and I believe it was Steve Herweck who received $100 million.

But further to the point, you know, as Mr. Costigan said, the evidence in Laplante was offered to show, I believe he said, essentially that Honda was "lying" and wanted to make

"a boatload of money."

Your Honor, as I understand it, they would be offering essentially similar evidence that, you know, our witnesses made a boatload of money and therefore were biased or were lying in their testimony that they were giving.

Additionally, Mr. Costigan mentions the possibility of giving a limiting instruction, and the District Court in Laplante gave a limiting instruction and the First Circuit said that that was insufficient to cure the prejudice and ordered that argument and evidence of the wealth of Honda should be excluded on remand.

THE COURT: Okay. I think I need to hear some more facts with respect to this. I would be more inclined I think on the bias question if there were some evidence regarding the future, but the fact that they got this windfall ten years before, I'm troubled by -- the amount of the windfall is -- both its prejudice and its relevance is just gargantuan. I mean, it will take people's breath away.

So it's got high potential for, you know, prejudice, and I have to hear a little bit more I think on bias to be persuaded that it's not unfair prejudice. Like at this point that is such a large amount of money the jury will stop breathing in the courtroom. That is just stunning.

You know, ultimately that is the kind of thing that when judges hear this kind of thing -- you know, I've got to

weigh unfair prejudice. It can be prejudicial, absolutely, but if it's unfairly prejudicial, I have to keep it out.

It's clearly probative on the issue of loyalty to the company, but ultimately I'm leaning towards that being too prejudicial. You know, I could see the jury -- you know, I could see the jury really hating the defendant and the wealth associated with that. I just -- I worry about the unfair prejudice.

That's where my mindset is right now, but if you can give me some more facts that would tend to tie the testimony in July of 2021 and a bias because that individual has the possibility of receiving some compensation in the future, that I would find perhaps more compelling and the prejudice less unfair. But ten years before and this gargantuan amount of money, I feel that could be pretty dangerous in terms of the prejudice.

Again, I'm talking -- frankly, I'm just telling you off the top of my head that's where I am on this.

So I think I need more with regard to this future compensation, Attorney Costigan.

So that takes care I think of motion in limine number 9 unless you can come back to me with more facts about what he may be compensated in the future, but meanwhile I think we should all start looking for jobs in this industry.

MR. COSTIGAN: Thank you, your Honor.

THE COURT: We still have number 2 and number 7, and those frankly are going to take some time anyway because I've looked at the exemplars that you've provided. Thank you for that.

And the whole point of, you know, you sending the exemplars in to me was so that you can get a sense of how I'm going to rule with respect to, you know, third party complaints and the substantial similarity requirement.

And so what I would like to do is have Donna just schedule us for another hearing and we will go through number 2 and number 7, and I'll give you clear rulings on those and give you a sense of where those exemplars fall for me, and I think we can do that in probably an hour, hour and a half.

And then to the extent you have any other issues that are still outstanding, you can at least bring them to my attention, seek permission to brief, but I will be overly I think lenient with respect to briefing on issues before trial just because I'm going to want issues to be resolved that can be resolved before trial.

So I'll let Donna take it from here in terms of scheduling that because ultimately I need to get ready for two other hearings that I have today so I need to get off at 1:00.

I believe I have ruled on document 224, document 225, document 226, and 174.

I still have to rule partially on 174 because motions in limine 7, 8 and 9 were all in that one document.

So I still have partially 174 and I have 164 left to rule on.

Although I've given you preliminary rulings on those at the last hearing, you provided the exemplars and asked for more clarity on substantial similarity.

So I think all we have left are motions in limine 2 and 7, but I'll let you let me know if there are other things that are still pending that I have not ruled on.

And we are looking good I think, you know, for a trial in person at the court in July. In New Hampshire things are very good here.

However, I will be very open to requests from counsel to be remote. We will try to set you up and make it work for counsel who cannot be there in person for whatever reason.

If there are witnesses that you would rather have testify via video, we have big screens in our court. We have good technology. I'll be very, very I think liberal in terms of allowing counsel to do what you want to do regarding an in-person hearing with witnesses and with lawyers, but the jury will be there in person. I'll be there in person.

I think it's looking very good for July. The numbers vaccinated in New Hampshire continue to rise. All the

protocols that the court has been using thus far in the height of the pandemic, we didn't have one episode of transmission. Now we have an added layer of safety because so many have been vaccinated. We don't need to know every person that has been. We just know there are a large number of people who have been, and that's just going to be another protocol built in to the masks, the social distancing, the ventilation that we have, the careful attention we're going to pay to your safety, the jury's safety.

So I think it looks good for an in-person trial in July, and, you know, that's where I'm headed right now. If something obviously changes, we can talk about that, and I'm sure you want to talk more specifically about protocols. We could do that at another time.

It's good to see counsel per usual, and I will be seeing you again probably hopefully in the next -- I'm gone next week, but perhaps the week after that we could do a hearing on these two other motions in limine, but maybe -- Attorney Esposito is going to have a challenge because I have a bunch of trials starting in June and it's nonstop, and then I go into July with Barron.

So it might be a little tricky, Donna, but Zoom does make it a little easier. So I'm going to leave that in your capable hands.

I am ready to go on motions 2 and 7 and the

exemplars today. So if it were scheduled the week I get back from vacation, I certainly would be ready to go.

All right. Thank you everyone.

Court is adjourned.

(Conclusion of hearing at 1:03 p.m.)

C E R T I F I C A T E

I, Susan M. Bateman, 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: 5-24-21 /s/ Susan M. Bateman
SUSAN M. BATEMAN, RPR, CRR