UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LITIGATION	16-md-02753-LM
CARRIE LEE BARRON AND NICHOLAS BARRON v. ATRIUM MEDICAL CORPORATION, ET AL.	17-cv-742-LM December 10, 2020 3:05 p.m.

TRANSCRIPT OF MOTION/STATUS CONFERENCE
HELD VIA VIDEOCONFERENCE
BEFORE THE HONORABLE LANDYA B. MCCAFFERTY

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P R O C E E D I N G S

THE CLERK: Good afternoon, your Honor.

THE COURT: Good afternoon.

Hello everybody.

Go ahead and announce the case.

THE CLERK: I will. Thank you.

For the record, this is a motion hearing and a status conference in the Barron bellwether case, which is 17-cv-742-LM, part of the Atrium C-Qur Mesh MDL, which is 16-md-2753-LM.

THE COURT: Okay. And let me just -- I can see everybody. I'm very familiar with everyone on the screen.

Let me just ask, who will be arguing the motion in limine for defense today?

MR. CHEFFO: Your Honor, it's Mark Cheffo. I'm going to be arguing one of them, the Dr. Pence motion, and Katherine Armstrong will be addressing the Ulatowski.

THE COURT: Okay. And how about the motion in limine, who's going to argue against that?

MS. ARMSTRONG: That will be me, your Honor.

THE COURT: Okay. All right.

Attorney Orent, you're taking plaintiffs' arguments, all of them?

MR. ORENT: (Nods affirmatively).

THE COURT: Okay. All right. Good. All right. Just wanted to clarify that.

Let me just start -- before we get into motion in limine document No. 147, which is what we're going to start with, let me just update you on some decisions the court has made with respect to jury trials.

And as you may know, because I think I've told you our process with respect to criminal trials, the court really meets once a week and we talk about the data and we update ourselves. We talk about criminal jury trials and civil cases as well.

And we are consulting with an infectious disease expert on a regular basis and he also gives us advice with respect to trials, and he has advised us -- we cancelled jury trials for December, and he's advised us to have no jury trials in January.

And obviously this is a civil trial. My feeling is that I'm comfortable doing this trial as a hybrid, which was an idea that frankly I came up with when we were debating a video trial in this case, and I have decided that I think a hybrid approach, which would involve me overseeing a jury of whatever we decide, probably as many as maybe twelve just because of the situation, me presiding with and over the jury in person

with perhaps one lawyer from each side being in the courtroom at a time and then everything else occurring via video.

That seems to me to be the safest and most effective way to handle a three-week-long, three-to-four-week-long jury trial with some complicated issues as this one brings.

So I think -- and this will be probably happily received certainly by defense counsel. I think I am not inclined to do a full solely video trial. I think -- I'm fairly confident I think the hybrid method is the one I'm most comfortable with if the data continues to just be pretty bleak.

I also do think that there is some possibility that a vaccine could start helping us as we turn the corner into the new year. I don't know how soon.

Dr. Bromage does not want us doing jury trials in January, and so I can't really justify doing this trial in January as we've planned it for January, I think January 20th, but I would like to bump it into February. I don't want to bump it too much. And I'm thinking we'll stick with our hybrid method.

By February the numbers still could be bad, and maybe counsel would talk me into March just to be on the safer side. You could probably talk me into that,

but I don't want to move it too far. It's not fair to continue our criminal trials with the Speedy Trial Act and all the other constitutional issues and then have a civil trial, even though we have less, far less people in a courtroom in a civil case. And doing it the way that I have planned to do it, it still is hard to justify I think not having criminal trials and me going ahead and having sort of a hybrid jury trial in this case.

So I feel better about a February/March date, and so I do want to hear from counsel. And I know I'm springing this on you and it's news, so you don't have to respond immediately. In fact, we can talk about it at the end of this hearing if you would like to have some time to think about it, process it, but I'm thinking February or March and you could help me pinpoint that today.

Voir dire. You guys did a Herculean effort to come up with voir dire. Tracy Uhrin, our deputy clerk, looked at it carefully and she thought that -- even though it was extensive, she thought it made a lot of sense in terms of the number of questions and the checkboxes. So I still just need to go through that and comb through it and make sure I have my standard questions in there.

There are some things that are duplicative of the Court's initial questionnaire so we'll take those questions out, but basically I just need to take the work that you've done and get it into a format that I can have Donna e-mail to counsel, have you look at it, make sure you're good with it, and then Tracy Uhrin is going to want to send it out to our pool early. In fact, if we were still going in January, she was planning to be on this video hearing and try to get that voir dire out by next week. So that puts that off for a bit. I'll finalize that and get it to you via e-mail and let you comment on that. If need be, we can have another quick video conference to finalize those details in the voir dire.

Summary judgment is pending. That is document No. 94, and I think I would like to have a video hearing -- has that been scheduled yet? I would like to schedule it within the next week or two and resolve that for you.

It may be that Donna is shaking her head thinking, no way, there's no way we can fit that in because we've been trying to fit in a number of hearings in my calendar in the next two weeks and I think it might be a challenge, but I would like to do that if not in the next few weeks, certainly in very early January

so you have an answer to that.

So what I envision doing now is hearing arguments from Attorney Orent on the motion in limine, document No. 147, and then Attorney Armstrong arguing against, and then we'll move into the regulatory experts.

I might take a little recess, let you process and take a break maybe ten minutes before we get into the regulatory experts. We'll see how it goes.

So any comments, concerns, questions just about the procedural matters that I just dumped on you at the beginning of this hearing?

MR. ORENT: I have one question, your Honor, and that is the lawyer who is present in the courtroom, is that more to observe the jury or is that individual going to be allowed to question from that courtroom? What's your --

THE COURT: I envision you deciding that. I envision you deciding who you want in the courtroom. I would hope it would be somebody who would be lead counsel asking a number of questions.

Now, I know you'll divide up witnesses, different lawyers will have different witnesses, and it may be that -- and I haven't thought this through, I would certainly welcome your input, but it seems to me

that our courthouse is big enough that we could give you staging areas so that, you know, counsel are separated in a separate courtroom or area of the courthouse where we have really good ventilation and I feel safe with people being in there, and you could watch the trial streaming and know when it's time for you to come in now and question a witness. The witness obviously would be via video.

In some ways because of the way the video software works if the witness and the questioner, lawyer questioning are both remote, both on Zoom, the witness can see the questioner better. If you're questioning from inside the courtroom, the witness is looking at you at a distance. They can see you because they're seeing the view from a camera looking into the courtroom.

But I'll leave all those decisions up to you and we'll finalize those kinds of issues in terms of, you know, how many lawyers should be part of your team and on location, and hopefully you can make those decisions regarding quarantining and isolating before you are exposing yourselves to each other.

I can't imagine in a three-to-four-week trial you would want to be in a hotel in New Hampshire by yourself. So I imagine you would want some sort of team.

So we can talk about those details, but I would envision one lawyer, lead counsel, connecting with the jury so that there's the benefit to the jury of seeing a lawyer connected to the case and talking to witnesses.

So for me I think that would work best, but ultimately it's your case. So I would leave that really -- those decisions in your hands.

MR. ORENT: Okay. Thank you, your Honor.

MR. CHEFFO: Thank you, your Honor.

I don't have any questions right now. I think it would be a great idea, as you suggested, to maybe give us a few minutes, Jon and I and others, maybe we could just, you know, talk or agree as we do on many of these issues on some of it, and if not, then we may have some other questions.

So that would be great maybe to have a few minutes after this substantive session.

THE COURT: That's great.

I would be happy, too, to just have you go meet and confer and propose a date, February or March. I don't need to have one today, but I just wanted to give you a sense that I think I'm looking at February or March for a hybrid, you know, three-to-four-week trial.

MR. CHEFFO: Yeah. So not to interrupt you,

so I mean to the extent that your Honor would indulge us actually -- you know, there's teams, there's experts, there's other schedules. So maybe if you can give us a few days, he can check his calendar and strategic view, and I will do the same with our team, and maybe we can get back to you if that would be all right, if Jon doesn't mind that?

THE COURT: That's the least I can do. I'm definitely pulling, you know, the rug out from under you by moving the trial, so absolutely. And I would prefer to have obviously a date that everybody agrees on that works for everybody. We'll work within that.

I know I have a criminal trial in April that I promised that has been bumped from November, December, January, and they picked April because they thought it was more likely to happen.

But I think with a civil trial like this even if it's still dangerous, our protocols are excellent and I still think we can do a jury live.

And we've talked about ways we can keep them even safer in terms of coming to the courthouse and doing it in person, and the online voir dire questions help that a great deal because it will whittle it down and make it a lot easier to pick the jury.

So I do think we could do it safely. I

just -- I didn't want to have a jury trial going in January where we've cut off criminal trials. It's just not fair.

So we're going to go February or March, and I'll let you get back to Donna maybe within the next three or four days.

MR. CHEFFO: Yes, your Honor.

THE COURT: Does that sound good?

MR. CHEFFO: It sounds great. Thank you.

MR. ORENT: Yes, your Honor.

THE COURT: Okay. So now let's do the motion in limine. I would like to hear argument on document No. 147.

And this is your motion, Attorney Orent, regarding the exclusion of evidence regarding the FDA 510(k) process, and I know you have a witness I guess as a backup in case I deny this motion. Your witness would be Pence, but I know you're attempting to exclude evidence, at least even evidence that Pence would presumably testify to regarding the FDA 510(k) process.

So let's hear your argument on that, and then I'll hear from Attorney Armstrong.

MR. ORENT: Thank you, your Honor.

I'm going to try not to get into too much detail that we've already discussed in our brief, and I

think that we've gone into significant detail in the papers for this particular issue.

There are seldom issues of law like this that have been so universally ruled upon in one direction, and that is that the FDA's 510(k) process is not a safety regulation. It is instead -- it is an exemption from proving safety to the FDA. Not only has the U.S. Supreme Court held that, but multiple circuits have held that, and I am unaware of a circuit court of appeals that has held the other way.

Simply put, your Honor, the FDA 510(k) standard -- because it is not a safety regulation, it has no relevance to the standard of care or to the ultimate question that the jury is going to answer in this case.

The ultimate questions are going to be: Was the defendant's device unreasonably dangerous such that it was defective, did it lack adequate warnings, and was the conduct of the defendant's negligence in the design, manufacture, distribution of the device?

Those questions aren't answered by the 510(k) process at all. Instead, what the Court will get is a series of confusing statements and confusing testimony from both sides related to what the FDA 510(k) process means.

Your Honor needs to look no further than Mr. Ulatowski's expert report in this case to see the level of confusion that would be raised should this issue be allowed to be argued by the parties.

510(k) is a pure issue of law, the law gets instructed by the Court, and there is no need for evidence to indicate that there was an exception to safety and efficacy.

I would say that the cases cited by the defendant, while some of them refer to the 510(k) process and do allow it into testimony and allow evidence of it, they too universally hold that 510(k) is not a safety or effectiveness regulation.

And I think if your Honor looks to the supplemental authority that we filed with the Court which is the order from Judge Story in Georgia, the federal MDL there in the Physiomesh MDL, the Court notes that the probative value is outweighed substantially.

And the Court focuses in on, first of all, that there's minimal probative value on that side of the ledger because it is about something less than safety and it has no evidentiary value, and they recognize -- Judge Story recognized even the courts that have admitted FDA evidence, they acknowledge that there is limited probative value.

And moreover, because this case involved a special 510(k), which is an even lesser rigorous -- or less rigorous standard than the simple 510(k), the amount of probative value that should be placed on this is even less.

And when the Court looks at the confusion of issues -- the likelihood of misleading the jury, confusing the jury by suggesting that 510(k) clearance constitutes some sort of certification of safety by implying that the V-Patch device underwent a more rigorous process when in fact the 510(k) clearance has only established equivalence to devices that themselves were never tested through the FDA's PMA process.

Second of all, introduction of the evidence has a potential to lead to a mini-trial. It would include at least two additional witnesses on a whole breadth of testimony that is unrelated to the ultimate issue that the jury is going to have to answer. That ultimate issue being, again, was this device defective, was it safe.

Now, the Court in New Hampshire in the Bartlett v. Mutual Pharmaceutical case, that's the case on point that defendants cite to relating to the admissibility of statutes and regulations for a negligence per se to set that standard of care. Once we

establish that the FDA, as all of the courts have held, federal, Supreme Court, as well as the circuit courts that have ruled on it, because it's not a safety statute. It is an exemption from safety. It does not set a standard for negligence per se or negligence.

And in fact, if your Honor looks to the language of the Bartlett case, your Honor will note that New Hampshire Supreme Court has suggested that safety codes are generally not to be accepted as absolute standards of care unless they have been incorporated into statutes or ordinances, and that recognizes that safety codes under limited circumstances can be used to set that standard of care.

There's nothing in that supreme court decision, the New Hampshire Supreme Court decision, or any other New Hampshire law that says that something less than safety, that an exemption from safety can set a standard of care.

So there's absolutely no case on point in New Hampshire law. And so quite frankly, your Honor, I think that looking at the standard for probative value versus prejudice and confusion, that there is little to no probative value of the 510(k) -- special 510(k) process versus the likelihood of confusion and likelihood of creating additional confusion.

As I've said, not only would there be additional expert testimony from Mr. Ulatowski for the defendants, but there would also be additional fact witnesses that would need to be called.

The defendants would then raise issues of Buckman, which is whether or not fraud on the FDA occurred, whether or not plaintiffs can put evidence in of fraud of the FDA to prove -- not fraud on the FDA as an independent cause of action, but that would lead to additional litigation on those sorts of issues.

And so I think the cleanest, simplest way forward is for this Court to adopt what all of the other mesh courts -- excuse me, what the vast majority of mesh courts have held, which is that this should stay out of admissibility and should not be admitted.

In the interest of disclosure, I will note that there was also recently -- and I was not able to get my hands on a printed copy of it. There was also a recent Bard MDL decision on this 510(k) issue. I will say there that the Court did likewise conclude that 510(k) was not a safety statute.

There the Court made a little bit different determination and did find that it was quote-unquote part of the story, but that the judge himself would issue a jury instruction explaining the process and how

the device was cleared.

It remains a question mark as to how that's actually going to be applied, but it is in the interest of disclosure not entirely a one-sided field in terms of the admissibility issue for other purposes; that is, the jury getting an instruction as to what that process is and what it means.

So with that, your Honor, I will rely on our papers unless you have any further questions on this.

THE COURT: I do not. Thank you.

Attorney Armstrong.

MR. CHEFFO: Katherine, you're on mute.

MS. ARMSTRONG: Good afternoon, your Honor.

THE COURT: Good afternoon.

MS. ARMSTRONG: We would respectfully submit that the issue of 510(k) clearance for this device and the entire regulatory process and context in which the events that are relevant in this litigation, that are going to be discussed in this litigation, transpired are relevant to at least three issues.

They're relevant to the sufficiency of Atrium's testing and research. They're relevant to whether Atrium was noticed of certain alleged properties that plaintiffs have attributed to polypropylene and the C-Qur coating. They're also relevant to the issue of

enhanced compensatory damages. Whether Atrium's conduct rose to the standard that would make enhanced compensatory damages appropriate.

Regarding the issue of safety and efficacy, I mean, the fundamental law I would suggest in plaintiffs' argument and in any of the cases that they rely upon, which are not universal and -- you know, this idea of the weight of the evidence, it's somewhat illusory because a lot of the cases they cite are preemption decisions which are arguments we don't make. A lot of the cases are within the Fourth and the Eleventh Circuit which has decided the issue and courts are bound by it. So the fact you have five more cases within those circuits following Eleventh Circuit law doesn't really add to the body of evidence.

And so it really comes down to a few cases which we would suggest are really flawed in their reasoning because of this bright-line that they're drawing in terms of it's either a safety statute or it's not a safety statute. Because what you have in fact with medical devices is you have a two-tiered system. You have PMA approval, premarket approval, which is what you have for certain medical devices that are like brand-new. They don't compare to any other medical device that's ever been marketed or ever sought FDA

approval. They're brand-new. So they have to independently establish their safety and effectiveness, and that's the same type of standard that we usually see with prescription drugs. It's usually premarket approval.

And it's important to recognize that that is an extraordinary level of regulation. It is a level of regulation that virtually no other industry is subject to. I just can't think of an industry that is subject to that high a level of regulation except perhaps atomic energy. I don't know a lot about atomic energy regulations, but it's an extremely high level.

For medical devices, it's second tier, and those are for devices that could show -- number one, they had to be Class II devices. So they've already been classified into a level where the FDA deems that it doesn't require the same level of premarket review. And they have to show that they're substantially equivalent to another device, and that predicate device acts as a proxy for safety and equivalency because, for example, you've heard a lot about polypropylene in this case. Well, it is a reality that polypropylene has been used in many medical devices for decades, and that type of use and market use acts as a proxy for safety and effectiveness.

So the FDA establishes these two tiers, and it's only because we have those two tiers and the 510(k) process gets compared to this rigorous PMA approval, more rigorous PMA approval process that plaintiffs are even able to make this argument.

In other industries where you don't have PMA approval and industry regulations are routinely admitted -- or compliance with industry regulations are routinely admitted in litigation, the jury is told, you know, it's some evidence for you to consider. It's not conclusive on the issue of whether the defendant was negligent, but you can consider it and give it the weight you think it deserves.

That's all we're asking for here is for the jury to be permitted to consider this evidence, not to be told that the FDA approved and gave formal certification that the device was safe and effective. We just want to tell the jury what actually happened in this case.

And what happened -- and also if you look at the history of the regulations -- and it's not something that's coming from our expert. They want to attribute it to our expert. If you go through his opinion, he cites FDA's own statements. He's not speculating on the FDA's state of mind as the plaintiffs try to portray it.

He's not saying anything that doesn't find support in the statute itself or in the FDA's guidance.

For example, if you look at the statutory definition of what substantial equivalence means, and this is in the statute, if there's technical differences with the predicate device, then the device manufacturer has to show that the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Now, that's a comparative statute -- a comparative standard, you know, in contrast with the PMA standard, which is independence, but it's still looking at safety and effectiveness.

If you look at -- in 2010 the FDA said that the 510(k) process has become a multifaceted premarket review process that is expected to assure that clear devices provide --

(Court Reporter asks Attorney Armstrong to slow down)

MS. ARMSTRONG: In 2010 the FDA said that the 510(k) process has become a multifaceted premarket review process that is expected to assure that cleared devices provide reasonable assurance of safety and effectiveness.

We provide other statements from the FDA in our briefing and our expert provides cites to other statements in his report but, for example, most recently -- for example, in the 2017 guidance documents the FDA said whether submission of a new 510(k) is required depends on whether the change could significantly alter the safety and effectiveness of the device.

The other thing is that if you look at what actually happened in this case, all we want to do is, again, present the regulatory history and tell the jury what happened.

Prior to getting clearance to the mesh that's involved in this case the FDA raised the question about cytotoxicity prior to clearance and requested another cytotoxicity study. That's the FDA raising a safety concern.

And then Atrium provided the protocol for the second study that the FDA had requested. The FDA reviewed that protocol and provided input on the protocol. Atrium incorporated the FDA's feedback and provided the study and provided the results of the study, and then the FDA cleared the device.

And if you look at a document that the plaintiffs attached as Exhibit 2 to their reply, the FDA

specifically inquired about adverse reactions and allergic reactions to the fish oil component of C-Qur. That's a safety question, and the FDA required additional disclosures and explanations.

Another thing that you have to keep in mind is the statutes and the regulations that govern what is valid data to submit to the FDA. Those are questions of regulations and statutes as well, and a lot of what plaintiffs' experts on materials are going to say is that somehow the Atrium studies were not sufficient. They're weren't valid. They challenge the validity of Atrium's own studies.

Now, the fact that the FDA found those studies to be validly conducted and, you know, actually reviewed the protocols and signed off on the protocols and said that that study would satisfy -- would answer the question that the FDA had asked is relevant to telling the story in this case.

And what happens with the cases the plaintiffs rely upon is they started with the presumption -- they started with the Supreme Court's decisions in Lohr and Riegel which were preemption decisions and involved a very, very different question. In those decisions the Court was trying to decide whether the express preemption clause in the medical device amendments to

the FDCA would, you know, ban all contradict medical device manufacturers. It was looking for, you know, whether it would be a sweeping ban against these cases with possibly very narrow exceptions.

And in reaching its holding in those cases it looked at a typical FDA review process at a specific moment in time, which was decades ago, but the Supreme Court is not a finder of fact. The Supreme Court engaged in the factual analysis in order to compare and contrast PMA and 510(k) approval to determine whether or not there was going to be this sweeping grant of, you know, this really broad defense to liability granted to device manufacturers of 510(k) devices. The legal holding is the preemption holding, that's what's binding on courts, and we in no way ask this Court to revisit the preemption holding.

But the courts have been -- but the Eleventh Circuit, the Fourth Circuit, the Seventh Circuit, the cases that the plaintiffs rely upon then elevate the factual discussion which is, you know, like I said, it's an average, it's fixed in time to a legal holding, which it's not, and treat it as a legal holding and then preclude it.

They also -- this idea of prejudice and the fear of mini-trial -- like I said, you know, evidence of

compliance with regulations is introduced in trials all the time. It may take two witnesses. It may take a few hours. It doesn't turn into a mini-trial.

In cases involving PMA devices it's introduced regularly. It's introduced in prescription drug devices. Juries don't get confused. They don't give it overweight. They find drug manufacturers and medical devices liable often, you know, when they deserve to be found liable and they don't give it too much weight. They don't treat it as a preemption defense. They're told -- they're instructed by the judge that it's some evidence and they can give it the weight they want, and they give it appropriate weight, and both sides tell -- and here, you know, the plaintiffs would present, okay, we would present our evidence of what actually took place, you know, this is what -- this is the submissions that --

THE COURT: Okay. But why are you introducing it? Obviously it's part of the story. We can't deny that. It happened.

But what is it coming in for? It's coming in to show that Atrium essentially complied with this 510(k) process, and the evidentiary value of that is you want the jury to think that the product is therefore somehow safe in a regulatory sense. Isn't that right?

MS. ARMSTRONG: We want them to consider some evidence that the company was not negligent.

But just to give you an example, the example that I just gave with the -- they challenge the validity of our studies and they challenge the validity of our studies on cytotoxicity, but the FDA specifically asked for cytotoxicity data and it indicated that our study was valid.

They want to have an argument between experts on the validity of that study. They want to put that study in evidence and have an argument on the validity of it, but they don't want to tell the jury that that was, you know, a study that was done to respond to an FDA request and the FDA determined that the protocol for the study was valid, scientifically valid, and that the study answered the question that the FDA had asked. They just want the jury to hear about the study in a vacuum without all of this.

So it provides needed context to the jury so that the jury can understand what the complete story is. If you don't have that, you give the jury the impression that all of this took place in a vacuum without any kind of regulatory involvement whatsoever, and that's even more misleading and it can't be corrected by a limiting instruction. The judge can instruct the jury, you know,

regarding the limits of this evidence, you know, there's only some evidence for them to consider.

The plaintiffs can introduce evidence saying, you know, this is a less rigorous process than the PMA process and there wasn't a PMA approval in this case. We're not saying they shouldn't be allowed to introduce that evidence or, you know, cross-examine our expert witness on that, but they want to keep it out entirely which creates this -- which takes the entire context that all of these events transpired out of the picture and the jury is left with this completely -- there's this picture that doesn't reflect the reality of what actually happened.

We just want the jury to know what happened, and then it's up to the jury to decide how much weight to give that and they'll be told -- and you can give the jury an instruction of what's involved with the PMA process and what's involved in the 510(k) process. We think that type of instruction as part of the instructions at the end of the case would be appropriate and make sure that they don't, you know, misunderstand that it's a type of preemption. It's not, and we don't suggest that it is, but without that evidence they're going to have a very, very incomplete -- they're going to have a very, very incomplete picture. And that was

the conclusion that --

THE COURT: Could I just ask you -- let me ask you a couple of questions.

MS. ARMSTRONG: Sure.

THE COURT: First, the predicate device in this case. A finding that the Atrium product is substantially similar to a predicate device where the predicate device has not been deemed safe, how is that anything really helpful to the jury other than saying to the jury, yeah, this device is similar to another device? We haven't given that predicate device a green light on safety, but we're going to let this device into the market. We're going to let this device in.

Go ahead.

MS. ARMSTRONG: The FDA is saying we're not giving it a green light on safety. The FDA is saying we have a lower -- we're not -- we don't -- we haven't undergone the formal PMA approval process.

THE COURT: Right.

MS. ARMSTRONG: We're not going to give the manufacturer a letter that says we've determined that this device is safe and effective. But again, in other industries manufacturers do not get letters from regulatories saying that we've determined that your process or that your product is safe and effective.

That's a unique thing for PMA approval processes, and yet in other industries compliance with regulatory standards is admitted. So again you're comparing it to something that's unique to, you know, drugs and medical devices that doesn't happen.

What the FDA has said is that we've found that it's substantially equivalent to prior medical devices, and that substantial equivalence -- they can't do that unless they've determined that the changes made to the new device have not impacted safety and equivalence. And it's the fact that these devices have been -- again, the prior devices are a -- this was recognized by the Court. I think it is the Biomet decision. Actually, let me see. If I could just have a minute to refer to my notes.

(Pause)

So the plaintiffs cited the District of Arizona's decision in Bard, in the Bard MDL that was pending in Arizona, and in its preemption decision which the plaintiffs cite it excluded the -- it rejected the preemption argument.

Again, we haven't made that argument. We're not asking the Court to revisit the Supreme Court's preemption holdings. And so it did not agree with the defendant that 510(k) approval could result in

preemption, but when it came to admissibility, it said -- when it came to admissibility, it said the evidence was nonetheless admissible. "The FDA grants a 510(k) clearance only where the device is as safe and effective as a predicate device and does not raise different questions of safety and efficacy than the predicate device." "The 510(k) process may not speak directly to the applicable standard of care under Georgia law, but it does have probative value in the determination of this action."

Other courts have recognized this decision as well. We cite the Biomet decision and we cite the Otero decision.

Again, you're comparing it to a standard that's not, the PMA standard that's not applicable to any other industry for the most part. I mean, there are probably exceptions to that, but it's generally a high level that's not usually applied.

But we don't require other industries to have a letter from the regulatory authority saying we approved this device, we approved this process as safe and effective in order to introduce evidence of regulatory compliance.

I think I've almost used up 15 minutes.

If the Court has any other questions?

THE COURT: Well, I certainly have read the circuit decisions that plaintiff is relying on, the Fourth, the Eleventh, the Seventh, the new Georgia case, and certainly the issue you raise with respect to the Lohr case, the Supreme Court decision. It seems as though every litigant makes that same argument and every Court is rejecting it, and I'll just read from -- I think this is Bard in the -- is Bard Seventh Circuit? I'm getting my circuits confused, but I think this is the Bard case where the Court says that -- the Supreme Court held that state law product liability claims were not preempted because the 510(k) does not amount to a safety regulation requiring device producers to meet any established design standards. The entire analysis turned on the Court's finding that the "510(k) exemption process was intended to do maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents," not impose new regulatory requirements on devices.

And so court after court has essentially rejected the argument that Lohr is really a preemption case and, Judge, you just shouldn't rely on it when you make your 510(k) ruling because it's really a preemption case.

And it seems as though the circuits, at least

these major cases that plaintiff is relying on, Boston Scientific, Kaiser and Bard, reject that argument, and it seems persuasive to me.

MS. ARMSTRONG: With all due respect, your Honor, that's where I think the courts are conflating the factual discussion from the Supreme Court. And again, the Supreme Court, with all due respect to the Court, is not a finder of fact. And the factual discussion -- again, it's trying to discuss the average -- compare the average PMA process with the average 510(k) process at a specific moment in time, and they're confusing that with the legal holding of Lohr and Riegel.

But if you look at Lohr, in the very same decision the Supreme Court recognized that while a device cleared under the 510(k) process has never been formally reviewed for safety and effectiveness, the FDA may well examine 510(k) applications with a concern for safety and effectiveness.

And then if you look several years later at the Supreme Court's decision in Buckman, the Supreme Court explained that 510(k) clearance was intended to ensure that medical devices are reasonably safe and effective.

And then the First Circuit -- and this was a

securities action alleging off-label marketing for uncleared indications. The First Circuit said under section 510(k) of the Food, Drug and Cosmetics Act, the agency can clear a device that is substantially equivalent in safety and effectiveness to an existing approved device and thereby allow the device to be used for the same intended process.

This bright-line division between safety and effectiveness -- there's two tiers, nobody disputes that, but this bright-line that PMA is safety and effectiveness and therefore safety and effectiveness is completely irrelevant to 510(k), that's not what the Supreme Court said.

With all due respect to the Eleventh Circuit, the Fourth Circuit, and the Seventh Circuit, that is not in fact what the Supreme Court said in those decisions.

And if you look at other places in its decisions -- if you look at Buckman, that becomes clear. And we're not proposing to overstate what the FDA did. We just want to accurately present what the FDA did.

THE COURT: Okay.

Attorney Orent.

MR. ORENT: Just briefly, your Honor.

I want to pick up where defense counsel left off, and that is the issue here and the concern here is

that the jury is going to infer that a finding under 510(k) means that the device is safe and effective and that it has more import than the FDA believes itself to have nor that the courts have ever found it to have for the 510(k) process.

In fact, when defendants talk about cytotoxicity studies -- when evidence comes in about cytotoxicity, the question is, is the device cytotoxic and what evidence is there, not did the FDA say that the defendant can market this device. That question is immaterial to whether or not the device is safe and effective and/or cytotoxic. The FDA didn't put a rubber stamp and say, yes, we looked at your evidence and, yes, it is not cytotoxic and you are full safe and effective. But the arguments that the defendants put forward today lends towards that very same type of confusion.

So what the FDA -- excuse me -- what defendant did in terms of the original MEM elution study, and then when the FDA asked it to provide more data, they provided more data. The question of whether that data supports safety or effectiveness in the absolute sense, which is what we have to contend with in this case, that's for the defendant to question. If the defendant thinks that their data proves that this device is not safe or effective, then what the FDA may or may not say

isn't material to that.

And what the defendants are trying to do is to substitute the judgment of the FDA in lieu of their experts and in lieu of defending the data and what they did. And the point of this trial is to find out whether or not the defendant acted reasonably under the circumstances when they knew that their ultimate responsibility was to make an absolutely safe and effective device. It was not to pass some minimum threshold as the defendants would have you believe based on 510(k).

Now, importantly -- importantly, the 510(k) process does not set that bar as to what a manufacturer should reasonably do to ensure that its device is safe and effective. Passing the 510(k) hurdle doesn't show that a manufacturer has done what it needs to do.

And defendants say, well, in very few other industries, maybe the nuclear industry, do you get a certificate that says under PMA your device is safe and effective. Well, maybe aside from the nuclear industry.

There's no other industry as important as the human body. We're putting things into the human body, and there is an indefinite difference between the 510(k) process and the PMA process. This is such a complicated issue that the lines are even being blurred in this

argument.

And so it is essential -- I think that this argument underscores the reason that this is essential and needs to stay out of trial.

And this cuts both ways, your Honor. There is evidence that we are giving up as part of this. This is not like we are trying to have our cake and eat it too.

There is numerous evidence related to a consent decree that we have offered the defendants in part of motions in limine that your Honor will be seeing. We've told the defendants we don't intend -- 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 eating it too. Just like with Dr. Pence.

So we understand that there are a myriad of issues, but all of these issues start coming in once we substitute the FDA's judgment for the judgment of the jury, because then we have to introduce the process of the consent decree and we have to show that their facility was forced to be shut down by the FDA and we have to show that there to this day is still someone who has to report to the FDA on a regular basis under a consent decree.

That's all evidence that shouldn't come in

because it doesn't -- it doesn't -- it usurps the role of the jury. Just like what the defendants are trying to put in.

So for that reason, your Honor, we think that this evidence has low to no probative value, that the jury can be given an instruction that the device was legally marketed in the United States, but that that process does not involve safety and efficacy. That has been done. It's been done in Massachusetts in the transvaginal mesh litigation in the state court there. It's been done throughout the country.

So the jury is not operating in a complete vacuum, but the Court should be the one that identifies what the law is.

Thank you, your Honor.

THE COURT: All right.

Attorney Armstrong. Anything further?

MS. ARMSTRONG: I would just conclude by saying that, you know, like I said, the evidence -- I don't think there's a risk of undue juror confusion. I think it could be dealt with with a limiting instruction from the Court.

And like I said, if it were a PMA case, nobody would doubt, nobody would question that the evidence was admissible of regulatory compliance, and the jury would

still be told that it's a minimum standard, you know, it's not the ultimate, you know, it's just some evidence for you to consider. And they routinely decide that in pharmaceutical cases and in PMA medical device cases, and they get there without giving undue deference to == and they realize what their role is and they follow the Court's instruction, and they get there without, you know, treating the FDA's process as preemption, which we're not arguing that it is.

And in terms of the prejudice, I would just end by saying, you know, there's one side in this case that wants to present the transactions, the research, the studies, the development of the device, the how it got to market, they want to present the complete story to the jury and tell them everything that happened, and one side that wants to strip from that story a very important context that, for example, with respect to cytotoxicity, not only did the FDA ask for more data, they signed off on the protocol that was used to provide that data, and they fully had the power to say that data was insufficient and we're not going to clear this device, and they didn't do that.

One side wants to strip that part of the story out, and it's an important part of the story. And to go through and say this happened, this happened, and this

happened, and leave out, you know, this entire regulatory framework in which all of these events were transpiring, we suggest that that would be highly misleading to the jury.

THE COURT: Are you saying, Attorney Orent, that studies should be excluded?

MR. ORENT: No, your Honor.

As I believe I indicated before, the standard in terms of meeting whatever -- the data that the defendants collected, the animal studies that the defendants performed, the benchtop testing, that stands on its own merit for what it stands for and that's what we think the jury should look at, not what the FDA said about it, and that's where we disagree with the defendants.

THE COURT: Okay. All right.

Does anybody want to say anything else?

(No response)

Okay. All right.

I've given this one obviously a lot of thought, read your submissions, read case law. It's obviously an important issue to both sides.

Ultimately, I come down on the side of excluding this evidence not because it's utterly irrelevant. I agree there is some relevance. It's low.

But ultimately, I am persuaded by everything I've read and by the circuit opinions that have so held. Ultimately, that the risk of misleading and confusing the jury, that substantially outweighs the minimal probative value.

I don't think plaintiffs are correct that there's zero probative value, though. I do think there is some probative value here. It's just that it I think is substantially outweighed.

Let me go through my thinking on this and make a record of it. Let me start just with relevance and that prong and Rule 402.

The Court agrees with the many other courts to have discussed the caution that the FDA does not make any independent determination of a device's safety in connection with the section 510(k) clearance process and that the FDA section 510(k) review for substantial equivalence to a predicate legally marketed device is not the same as an independent finding of safety or effectiveness.

Courts that have discussed this specifically are the U.S. Supreme Court case in Medtronic v. Lohr, the Riegel case, as well, more recent, and the Fourth Circuit in the Bard decision, among numerous others.

The Court agrees with the defendants that the

principles of safety and effectiveness in some sense underlie the FDA section 510(k) clearance process.

However, in this case the device cleared for marketing under section 510(k) has no predicate device anywhere in its regulatory lineage that ever received an independent finding of safety from the FDA.

Thus, the fact that this device received clearance under section 510(k) has very little bearing on whether the device is safe for its intended or foreseeable uses.

Accordingly, the Court agrees with plaintiffs that the probative value of Atrium's successful reliance on section 510(k) clearance for the devices at issue in this litigation is low as to the specific question of those devices' safety.

However, the Court does not find that evidence of the FDA section 510(k) clearance process is entirely irrelevant to the question of device safety, let alone to other facts of potential consequence in the litigation.

In Bartlett, which is the case decided by my colleague, Judge Laplante, he persuasively predicted that the New Hampshire Supreme Court would not treat violation of a statutory requirement as establishing a per se breach of the defendant's duty of care but rather

would allow the jury to consider that violation as evidence of a breach. That is, the Bartlett Court, Judge Laplante, predicted that the New Hampshire courts would find a party's compliance or noncompliance with applicable regulations to be at least potentially relevant to the question of that party's negligence.

This Court agrees with that prediction and on that basis finds that evidence regarding section 510(k) clearance is at least marginally relevant to questions at issue in this action.

Federal Rule of Evidence 402 authorizes the exclusion only of irrelevant evidence. It doesn't permit courts to exclude relevant evidence on the basis of low probative value.

The Court, therefore, declines to exclude the parties' 510(k) evidence as irrelevant under 402.

But with respect to 403 as to the potential of the evidence to mislead the jury, the Court has reviewed the reports of the parties' regulatory experts regarding the section 510(k) clearance process. The proposed opinion testimony and related evidence is complex and voluminous.

The Court finds that to present the jury with hours of complex testimony regarding regulatory compliance would risk confusing the jury by creating an

exaggerated impression of the importance and significance of regulatory compliance and distract the jury from the central and primary cautions before it; namely, whether Atrium's surgical mesh devices are or are not unreasonably dangerous.

Now, to the extent there is a risk that to exclude evidence of the section 510(k) clearance process might be confusing or misleading to the jury by creating an incomplete or confusing picture of the device's regulatory status or by leaving an evidentiary gap or gaps that jurors might fill with incomplete knowledge or inaccurate beliefs about whether a legally marketed medical device has necessarily been tested for safety, on balance I find that risk is minute in comparison.

The Court joins other courts, the majority of courts, that have considered the question in a comparable context. Including, for example, the Eleventh Circuit in the Boston Scientific case, 873 F.3d, the Fourth Circuit in the Bard case, 810 F.3d, and the Seventh Circuit in Kaiser, 947 F.3d, to name just a few, in finding that the limited probative value of this evidence is substantial ly outweighed by its potential to mislead.

The complexity and amount of evidence that would be required to convey a working understanding of

the section 510 clearance process and its significance is far out of proportion with the importance of the evidence for this case.

The Court, therefore, grants plaintiffs' motion in limine number 147 based on the potential of the section 510(k) clearance process evidence to mislead the jury.

Accordingly, all evidence regarding the FDA section 510(k) clearance process whether proffered by defendants or plaintiffs shall be excluded from trial pursuant to Federal Rule of Evidence 403.

So plaintiffs' motion 147 is granted.

Now, obviously that affects frankly a great deal of what is left in the regulatory expert's testimony.

And I was a little surprised to hear actually, Attorney Orent, you would just exclude anything dealing with the consent decree because it involves the FDA, but that certainly simplifies matters.

What I'm wanting to do now, and then take a brief recess, let you regroup -- what I'm thinking I would like to do very quickly with you is go through the sections of Ulatowski and the sections of Pence that ultimately I think I still need to decide. And so let me just give a shot at it here, and we'll recess. I'll

let you regroup. I would like to get your thoughts.

Attorney Armstrong, you're doing Ulatowski?

Attorney Cheffo, you're doing Pence?

MR. CHEFFO: Yes, your Honor.

THE COURT: Is that right? Okay.

MR. CHEFFO: And when you're done -- I just had a quick question, but I'm going to save it until you're done, if that's okay.

THE COURT: Okay.

Ulatowski -- one of the arguments, and it came in different flavors, but it basically was dealing with Ulatowski opining regarding the nature of the law, and that was about the PMA process, 510(k).

I assume that whole section with respect to Ulatowski is now mooted by my ruling on the motion in limine.

Do you agree with that?

MS. ARMSTRONG: Your Honor, if he is not going to be allowed to talk about the 510(k) process, then he's not going to be allowed to compare it against the PMA process.

THE COURT: That's what I thought. All right.

And then his discussion of the regulatory history of Atrium surgical mesh products, that was another objection, and I presume that that is also now

moot.

MS. ARMSTRONG: I would cite to the extent it is in the context of the regulatory history that it seems like your Honor's ruling applies to that.

What I would say is that if you go through Mr. Ulatowski's report, he talks about things that happened and he will say this met regulatory standards, and then he'll also say this also met industry standards and he will explain why.

As I understand from plaintiffs' position, they still intend to have Dr. Pence testify about industry standards, and to that extent Mr. Ulatowski should be able to meet that testimony, or even if she didn't testify, be allowed to testify to it if they're conceding the industry standards are relevant.

It's not like there's ever -- in his report there's a section regulatory standards and industry standards. They're intermingled together throughout his report.

THE COURT: Okay. I thought there was more of that kind of thing in Pence's report than in Ulatowski's.

MS. ARMSTRONG: It's -- I don't know in terms of volume. I didn't do a volume comparison, but I know that Mr. Ulatowski does talk about industry standards,

but it's interwoven throughout his report as opposed to being in a separate section.

THE COURT: Okay. All right.

And then obviously his opinion regarding the FDA's 510 clearance would be mooted by my -- that whole section would be out.

I'm just looking through the arguments, the Ulatowski arguments that are made by plaintiffs.

What would be left -- I would have to decide on the argument that he can't give opinions as to the FDA's motives or beliefs, and he makes certain statements -- do you know what I mean when I say that, that whole section of the argument? If not, I can give you examples.

MS. ARMSTRONG: No, I understand what you're referring to, but again I think that that is -- number one, I think it was to meet some of Dr. Pence's arguments. She would say I think this was a violation of standards, and he would say, I don't think it was, I don't think the FDA would have found it was a violation of standards.

If they're not going to put in her opinion that it was a violation of FDA regulations, then he's not going to have to respond to it. I mean, we obviously wouldn't agree with the characterization of it

as state of mind evidence. But if neither side is going to be talking about the FDA, then it only comes in if evidence of -- you know, if they bring in evidence of -- if Dr. Pence testifies I think this would have violated or it would have been this, then Dr. Ulatowski should be allowed to meet that evidence. But if they don't do that, then, no, that evidence wouldn't come in under your ruling.

THE COURT: Well, I'm just trying to think of the sort of boxes that we could put certain evidence in that's still relevant and admissible potentially that these two experts would talk about.

One might be labeling and warnings and industry standards with regard to that.

MS. ARMSTRONG: And Dr. Ulatowski does talk about industry standards with respect to labels and warnings.

THE COURT: Okay.

Okay. The consent decree and enforcement letters, that's out according to Attorney Orent. So that would not be a bucket of information the jury is going to hear about?

MR. ORENT: Your Honor, what we're hoping is that the -- and what we've offered to defendants is that the FDA conducting this inspection and finding X, Y, Z

would be a fact that -- it's not the fact that the FDA performed an inspection and found A, B, C, D problems with the complaint handling system. The important thing for the jury is to understand that an inspection was done and that Atrium didn't fix the system.

So it's classic notice and knowledge, but we have offered redactions of certain documents as -- or, quite frankly, this would be the opportunity for a stipulation as to fact that an inspection was performed. There were some private inspections also performed that were paid for by Atrium.

So we're not seeking to put in the FDA quote-unquote process, but there are certain facts under that umbrella that I want to just be clear. For example, the 2009 through 2013 complaint handling issues were pervasive throughout the company, and we think that they are relevant to material issues of fact and would want them in. We just don't care that it's the FDA, and we don't think that the jury needs to know that it's the FDA that found those.

THE COURT: And that would be Pence talking about the complaint handling process being, look, not meeting industry standards?

MR. ORENT: Correct.

Now Pence -- and the distinction between her

report and Ulatowski's is she actually goes through what the other standards are, the other industry standards. So she references the Global Harmonization Task Force, she references other very specific standards, and then also has actual experience additionally to that.

So to the extent that she's offering information that's grounded in some other standard rather than an FDA regulation, we would believe that she is allowed to submit those, and she does distinguish this, unlike Mr. Ulatowski.

THE COURT: Okay. Her testimony or opinion regarding the FDA and the section 510(k) clearance process is obviously out.

The whole section of her opinion dealing with Atrium having violated not the FDA but the FDCA process by making a false statement to the FDA, that would be out as well, I presume.

MR. ORENT: Your Honor, we -- it is our intention, quite frankly, to not utter the words FDA during the course of this trial.

We believe to the greatest extent possible that the jurors' independent judgment should be exercised without relying on the finding of somebody else.

And so -- like I said, as there may be very

particular instances of information that Atrium was sent that provides notice and knowledge that is relevant, that can be redacted or entered through a stipulation.

Information like what you're talking about here -- it's not the question of what the FDA did or knew or found but whether or not the company actually said this and it mattered to a doctor.

So our testimony would come in that there was no omega-3 fatty acids that will come in through a variety of fact and experts.

And then we're going to ask Dr. Price, the implanting doctor, Dr. Price, did it matter to your decision-making, and the jury will hear from the actual doctor on that.

Whether or not that's a violation of the Food, Drug, Cosmetic Act I don't think is necessary for a determination of the jury.

THE COURT: Okay. All right. And that was -- that alleged false statement would have been made during the 510(k) process anyway.

Am I right about that?

MR. ORENT: It was made there, but quite frankly it's on the packaging, your Honor.

THE COURT: Okay.

MR. ORENT: The way we're looking at this case

is we're looking at the evidence that was made public to doctors and health care providers and the information that they would rely on under the circumstances of this case.

THE COURT: Okay. Well, since we're still on Pence -- and I know you had a question, Attorney Cheffo --

MS. ARMSTRONG: Your Honor, I'm going to --

THE COURT: I was just going to say I'm going to take a recess and I'm going to let you regroup if you can talk to each other and maybe simplify this somewhat, but I was just going to go over quickly what I think I still have to decide and then take a recess, come back, and hear from you on each of these.

Does that make sense or would you rather propose something else?

MS. ARMSTRONG: Well, it does, except that I think that what Mr. Orent just said about, like, the inspections, it sort of reveals some of the problem with this entire motion.

I realize your Honor has decided it and I'm not asking you to revisit, but I don't understand -- and maybe, you know, maybe your Honor has to see how the evidence comes in at trial, but I don't understand how you tell the jury that an inspection was done -- let's

talk about the sterility issue, for example.

What the FDA found in this in an inspection was that the -- when you validate your sterility, you're supposed to use the device that's the hardest to sterilize. It may not be C-Qur mesh, it may be some other device, and you're supposed to use the device that's the hardest to sterilize. And the FDA in its inspection determined that they didn't properly demonstrate that the device used was in fact the hardest to sterilize.

Now, Atrium has an answer to that and they responded to the FDA, but that was the FDA making a determination based upon FDA standards, not based upon industry standards. That was based upon FDA standards.

And they want to be able to tell the jury that somebody made this determination but not say that it was the FDA and not respond that it was based upon the FDA standards, and then we have to be able to tell how Atrium responded to the FDA and demonstrated that its sterilization process was in fact properly validated and how they did that with reference to FDA standards because it's all happening in that context.

And then it's also relevant if the FDA -- the FDA completely has recall authority over PMA devices and over 510(k) devices. If the FDA thought there were a

bunch of medical devices out there on the market that were not sterile, the FDA would recall those devices, and it didn't do that.

They want to say that some entity somewhere based upon some amorphus industry standards, and not say what the actual standards were, found some issue with sterility but not let Atrium tell the entire story and make the point that the FDA has never determined -- made a finding that the products could not be marketed and had to be recalled.

MR. CHEFFO: Your Honor, this is where I was going to go.

If you want to take a break, obviously I don't want to keep you.

You made the point, you know, that there's a minute, you know, kind of chance of it coming in I think in your order, I'm just paraphrasing I think what you said, but I think that would be true, right? That's why this is really going to require I think a lot more kind of analysis, because as Katherine said -- I mean, if the -- you know, I frankly -- you know, Mr. Orent said, which I think tells a lot, right, I don't want the FDA, I don't want the words, the initials, to come in. Right? This is a medical device case. I don't want to talk about the FDA.

So the idea that it's the FDA, as Ms. Armstrong said, is going to come in but we're not going to say it's the FDA because we want to try and parse it, what we're going to have is -- I mean, this is going to be an impossible evidentiary -- let me give you another example, you know, which is the question that I wanted to ask --

THE COURT: But I've just got to stop you. I mean, he's essentially giving you a gift by saying we're not going to talk about -- what about the FDA and the consent decree process and the enforcement letters, what about that process is good for the jury to hear from your perspective?

MR. CHEFFO: Yes. There are things that are pro and con, there's no question, about strategic issues, but what we're talking about really is trying to figure out what -- you know, the jury is going to hear this --

THE COURT: Right, right. There are going to be -- I hear you. There are going to be some sort of adjacent evidence that would be FDA related. But what I've said is I am not going to allow this hunk of FDA evidence that deals with the 510(k) process because it is hugely misleading, prejudicial, and it has real potential for confusion. That to me is a bucket of

evidence that I am not allowing in the case.

I did not say that I would not let anyone utter the phrase -- the word FDA. That was something that Attorney Orent sort of offered up almost as I think somewhat of an olive branch in a sense. He's saying I'm not going to hammer them with any of the FDA. I'm not going to bring up the consent decree.

Now, that's not in front of me really. Frankly, I am not going to get into a debate about the outer edges of what's coming in.

I am tasked today to deal with the bucket of evidence that we just talked about, the 510(k) process. I find that -- that to me is not really even a close call. Although I do find Attorney Armstrong persuasive and she had me at moments, but I ultimately do not find that argument a close call. So that bucket of evidence doesn't come in. That's my ruling.

The fact that Attorney Orent is throwing up other possibilities, that's not in front of me right now and I don't want to get into debates about the edges because ultimately those are issues I have to decide in the context of the trial. I cannot tell you whether or not I'm going to let someone utter the acronym FDA in a particular context. And so ultimately what I need to do today is give you a sense of what about Ulatowski is

still coming in and what about Pence is still coming in, and, you know, I'm trying to figure out, okay, what is still left here that I need to rule on. And so that's what I was going to take a recess for, to give you time to regroup to perhaps maybe narrow the scope of what I'm going to rule on.

But ultimately I think in Pence -- I think I'm still left with you want to keep out any of her statements about Atrium's premarket clinical testing being inadequate. I think I still have to decide the complaint statistics are unreliable. She opines on that using industry standards. You describe her as having given a causation opinion and you want that excluded, and then the labeling, the inadequacy of Atrium's labeling.

Those issues seem still on the table for Pence, but I could be wrong, and so I was just going to throw that out there to you and have you say, no, Judge, you really don't need to decide all four of those anymore. That's what I want you to tell me right now in terms of where we go before we recess.

MR. CHEFFO: Your Honor, I got the last three. What was the first one you said?

THE COURT: The first one was the premarket clinical testing is inadequate and she opines using

industry standards about that, and I think your argument is that that should be out.

MR. CHEFFO: Well, I mean, it is. If we could take -- yes, I think it also relates directly to your other ruling because the idea of saying --

THE COURT: Okay.

MR. CHEFFO: You know, I think it -- it's part and parcel with your 510(k) ruling, right, that you didn't do this and this.

THE COURT: So that's out then? You could tell me that that's out, and you would know the case better than I, and this is your motion. So is that now mooted?

MR. CHEFFO: If Mr. Orent agrees with that, you know, I think it's moot. I mean, I think to have someone say you can't talk about the fact that you can get it cleared under 510(k) using this test but I'm going to backdoor it and say, well, there's these other things you didn't comply with, and we can't say that we did comply with the 510(k) because there's industry standards? I mean, that would seem to be inherently unfair.

So if you're going to keep out the 510(k), then I think any questions about, you know, that the testing was inadequate would be part and parcel. It's

the flip side of this.

THE COURT: Do you agree with that, Attorney Orent?

MR. ORENT: I don't, your Honor.

THE COURT: You don't. Okay.

MR. ORENT: I mean, I disagree with what the fundamental standard is, and I also disagree with Mr. Cheffo's analysis. I'm very cognizant of the fact the Court wants to take a break so I don't want to go on and on.

THE COURT: Well, this is your motion. This is your motion, this Pence -- I'm sorry. This is Attorney Cheffo's motion so I think he can tell me essentially what he still wants to argue.

Now, again it might make sense at this point to adjourn and allow you both to meet and confer and figure out frankly what's left by agreement between counsel rather than have me try to read your minds about what is still left of Ulatowski and what's still left of Pence.

And I'm wondering if maybe I'm better off leaving that to you after having ruled on the motion in limine and then have you both regroup and perhaps let me know what issues are still alive. Perhaps you can just put in front of me jointly what the remaining

disagreements are that I need to rule on for you. I'm wondering if that would be more efficient.

MR. CHEFFO: That might be. I mean, I think if, Mr. Orent, you agree, I think it will give us a chance. It's hard to do it on the fly without the reports and the papers. Maybe we could do that and make it more efficient for your Honor.

THE COURT: Right. I mean, I do think you talking on the phone with Attorney Orent about what's left of Pence's testimony regarding premarket clinical testing seems to me something that the two of you can figure out.

And you'll have an understanding of what he intends to put Pence on, if he does at all, with respect to clinical testing, premarket clinical testing.

You make your argument to him based on the ruling it doesn't come in.

So I feel like these two motions really do become qualitatively difficult for me to rule on at this point without real clarity in terms of what you think you're still going to propose your experts will testify about, and I think that's ultimately your call, and then you put it in front of me for a ruling.

MS. ARMSTRONG: Your Honor, I think that it makes sense to allow us to -- to adjourn and allow us to

confer and narrow our arguments and narrow our issues because otherwise -- otherwise we may not -- we need to reach agreement first on this -- yeah, how your Honor's ruling today impacts our other arguments, and we need to do that without thinking on the fly and appearing like we're trying to just keep rearguing 147, which I don't think is -- we would like to. I would still like to change your Honor's mind.

THE COURT: I hear you.

MS. ARMSTRONG: But I understand that people probably don't have time for us to reargue that over and over again, and I'm concerned if we try to do the other motions today, that's going to evolve into us rearguing 147 over and over.

So I do think it makes sense for us to adjourn and try to narrow the issues for your Honor.

THE COURT: Okay. Could we do that? Could we revisit this, Ulatowski and Pence and what remains and the motion for summary judgment, at the same hearing or should we separate those?

Now that we've got some distance before the trial, do you think it makes more sense to separate them, or we can certainly let you decide that as well. If you're able to really narrow Ulatowski and Pence by agreement, then perhaps I can hammer out your remaining

disagreements quickly, and then we can go to the motion for summary judgment.

MS. ARMSTRONG: I think we should discuss that as part of our discussions.

THE COURT: All right.

MS. ARMSTRONG: If we narrow it a lot, then it shouldn't take too long to argue them.

THE COURT: Okay. And you've been successful doing that so I'm going to leave that in your hands.

And you know ultimately what I need to hear back from you on, which is you need to pick a date for the motion for summary judgment to be argued. I would like it to be fairly soon, within, you know, maybe early January at the latest, and then decide what's left of Ulatowski and Pence and whether you can argue those on the same day as the summary judgment motion.

And then I do need you to decide on a trial date, when we start this trial. It won't be January 20th. So pick a date in February or March.

I do think you might be safer if you pick March. If you could go with a trial date in March, I'm just guessing, our infectious disease expert thought we might see some leveling out by March. So that's my hope.

And we are doing a hybrid trial so it's not a

full, you know, a full courtroom, so I think March might be safe. You could pick February. If you prefer February, I'll give you a February trial date, though. I just want to make sure we have something more solid for you, but I'll let you pick.

So if you can just let Donna know then in the meantime, and she'll put this on for -- the motion for summary judgment is document No. 94, and we can hopefully have that resolved at the same time that we resolve these regulatory -- the scope and the regulatory testimony.

And I think that's it for now. We don't even need a recess because we can just adjourn.

Did I cover everything? Is there anything else that anybody needs before I get off?

MR. CHEFFO: Not from me, your Honor.

MR. ORENT: I would ask about one logistical item which is, right now the final pretrial report I think is due January 5th, and your standard pretrial report sort of itemizes everything that is to be done.

We've been sort of serially submitting piecemeal various elements of that. Including we are going to send Donna either today or tomorrow, Attorney Esposito rather, a copy of the agreed upon statement of the case.

And so I guess my question for your Honor is, is your expectation to get a complete package of everything or is that altered based on sort of how we've been proceeding? I just want to make sure we're not over papering you but at the same time comporting with what you're looking for.

THE COURT: I think -- as long as you both are in agreement and you're submitting jointly agreed to documents, I think I'm certainly not going to hold you to some separate submission that you have to submit separately.

In the typical case there's just not as much meeting and conferring. I know that counsel for both sides will make sure whatever is not, that you don't agree to, you've got to get it in by the date the pretrial statements are due.

But ultimately, that date I'm sure was set with the January 20th trial in mind. So ultimately, meet and confer, set a new deadline, propose it to Attorney Esposito, and I will approve it.

MR. ORENT: Okay. Thank you, your Honor. I appreciate it.

MR. CHEFFO: Thank you, your Honor.

THE CLERK: Can I just mention one thing, Judge, just about scheduling --

THE COURT: Sure.

THE CLERK: -- that Chief Deputy Uhrin brought to my attention with the jury trial.

February includes generally school vacation, and I don't know if getting jurors may be tougher that month or even counsels' schedule, but I just figured she mentioned it to me so I would mention it to everybody.

THE COURT: Okay. Keep that in mind as you decide on a jury trial date then. All right.

Well, it's good to see everybody. Have a good rest of the month.

Hang in there. Everybody continue to stay safe.

Court is adjourned.

(Conclusion of hearing at 4:33 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: 12-21-20

/s/ Susan M. Bateman
SUSAN M. BATEMAN, RPR, CRR