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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

IN RE: ATRIUM MEDICAL CORP. C-QUR MESH PRODUCTS LIABILITY LITIGATION	No. 1:16-md-02753-LM
CARRIE LEE BARRON AND NICHOLAS BARRON, Plaintiffs. v. ATRIUM MEDICAL CORPORATION, ET AL., Defendants.	No. 1:17-cv-00742-LM November 12, 2020 1:05 p.m.

TRANSCRIPT OF MOTION HEARING
VIA VIDEOCONFERENCE
BEFORE THE HONORABLE LANDYA B. MCCAFFERTY

APPEARANCES:

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P R O C E E D I N G S

THE CLERK: For the record, this is a motion hearing in the bellwether Barron case, which is 17-cv-742-LM, which is part of the Atrium C-Qur Mesh MDL, 16-md-7523-LM.

THE COURT: All right. Good to see everybody. Let me just have counsel who are on the screen go ahead and identify themselves for the record, seeing as our transcript won't really have a rendition of exactly what was on the screen. So, how about if everybody just identifies themselves for the record.

MR. HILLIARD: Your Honor, Russ Hilliard, plaintiffs' liaison counsel. Good afternoon.

THE COURT: Good afternoon.

MR. ORENT: Good afternoon, your Honor. Jonathan Orent.

THE COURT: Good afternoon, sir.

MS. LOWRY: Good afternoon, your Honor. Susan Lowry for the plaintiff.

THE COURT: Good. How are you?

MS. SCHIAVONE: Good afternoon, your Honor, Anne Schiavone for the plaintiffs.

THE COURT: Good afternoon.

MR. CHEFFO: Good afternoon, your Honor. I don't know if that's all the plaintiffs' lawyers. That's all I could see. It's Mark Cheffo for the defendants.

THE COURT: Good afternoon.

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

MS. ARMSTRONG: Good afternoon, your Honor. Katherine Armstrong for the defense.

THE COURT: Good to see you.

MR. LAFATA: Good afternoon. This is Paul LaFata from Dechert also for the defendants.

THE COURT: Okay. Excellent. All right. So, what I'm going to do, before I put on my little iPhone timer here so I can keep track of time -- and I'm doing that just so we can get through these motions and also so that I can time this for our court reporter, who's going to need a break at a certain time. Otherwise, I can just keep going, and, unfortunately, that's not always good for our court reporters.

So, let me just note who is going to argue number 92, Langstein?

MS. ARMSTRONG: Your Honor, I'll be arguing Langstein.

THE COURT: Okay.

MS. ARMSTRONG: Katherine Armstrong.

THE COURT: All right. And for plaintiffs, Attorney Orent, are you doing all the arguing?

MR. ORENT: I am, your Honor.

THE COURT: That's fine. Good, especially seeing as I see your artwork has even increased. It's becoming a veritable museum behind you, so that's good.

All right. And who from defense will be arguing 96, Guelcher?

MR. CHEFFO: Your Honor, Mark Cheffo. I will be, and, just to save you, I will be also arguing Klinge.

THE COURT: Okay. All right. And then who will argue 100, which is Dunn?

MR. LAFATA: This is Paul LaFata. I will be addressing the Dunn motion.

THE COURT: Okay. Excellent. All right. So, let's start, then, with Howard Langstein, plaintiffs' expert, defendant's motion 92 to exclude opinions and testimony of Mr. Langstein. Hold on one moment before I set any timers, because I don't want to deprive you of your time. Hold on a sec.

MR. CHEFFO: Your Honor, it's Mark Cheffo. While you're doing that, can I just ask a quick procedural question, and I suspect this will be --

THE COURT: Of course.

MR. CHEFFO: -- a goose-gander one. I think we all read your 15-minute rule, and we're, I think -- I don't want to speak for Mr. Orent, but I'm sure he's diligent as well. The question I had was would you consider or are you anticipating maybe if we reserve two minutes for rebuttal? I know you're going to hear arguments on our motions next week, so that's why I said goose-gander, if you can entertain it. I suspect

Mr. Orent would want the same, but, again, it's kind of for you, so whatever is most helpful.

THE COURT: It would be excellent if you're able to time it. I think some of these might be less time consuming than others, and so just alert me. I think Langstein there are numerous arguments. So, it seems to me that Attorney Armstrong is going to use her 15 minutes, and I don't mind giving a very, very brief rebuttal after Attorney Orent goes, giving Attorney Armstrong a little bit of time there, and I will try to remember to do the same for everybody. I'll be especially eager to do that for you if you're able to finish before the 15 minutes.

MR. CHEFFO: Okay. Thank you.

THE COURT: All right. So, let me just get my computer here. Okay. Just so you can see it, my iPhone has a timer on it, so I'll just be looking at that, and I'll try to politely give you a nudge as it gets near the end. And, obviously, I'm not going to cut you off arbitrarily, and I'll want -- I'm sure I'm going to ask questions and want to give you time to answer them. So, I think you know me pretty well at this point in terms of my style. But I am trying to keep it to 15 minutes, if I can.

All right. So, Attorney Armstrong, defendants' motion number 92, and I have studied these, as you can imagine, and I've studied them in the order of the challenge. So, the first

challenge is what Atrium knew should be excluded; your second argument he shouldn't opine as to the design or functioning of the particular product for various reasons; failure modes comes next. So, I've ordered my notes by argument, and I think my notes reflect the order of the argument presented in your brief. If not, I'll just ask you to wait a moment so I can find exactly where you are in my notes, but, hopefully, I can follow right along with your arguments.

So, Attorney Armstrong, go ahead.

MS. ARMSTRONG: Thank you, your Honor. I'm going to try to stick to the order in our brief as well. If I get off track, I apologize. It's not intentional.

So, yes, you're right. Our first argument is that Dr. Langstein purports to render various opinions about what Atrium knew or what Atrium should have known based upon his review of the company documents and other documents. Numerous Courts have addressed this. We've cited to the Court in Keystone, Sanchez, Rezulin and Zofran, and they've all said that it's not proper expert testimony for an expert just to narrate what is in company documents and then opine as to the state of mind of the defendant. So, we believe that should be excluded.

The plaintiffs have argued that, while he's not purporting to opine about state of mind, but he's providing context, but that's really semantics. If he's on the witness

stand and he's saying Atrium knew this, Atrium knew this, Here's this Atrium document, and he's offering his interpretation and inferences drawn from that, that's exactly what he's doing, and that's exactly what courts have said that experts should not do, that it's beyond the realm of appropriate expert testimony. Of course, the plaintiffs are free to introduce, to the extent they are otherwise admissible, Atrium documents, and the jury will draw its inferences from them, but it's just not appropriate expert testimony.

Our second ground for exclusion is that he lacks the expertise to render an opinion on the V-Patch design, which he purports to do. The plaintiffs have -- they talk about he's not just a plastic surgeon, he's also a general surgeon, he's done a lot of hernia surgeries. Our criticism of him is not -- I mean, we recite what his background is, and that background includes being these days primarily a plastic surgeon. We don't deny that he's had general surgery experience and that he's done hernia implants and explants. He's never done them with the C-Qur mesh, though. He has no experience with the C-Qur mesh.

But that type of clinical experience, even if he had sufficient general surgery, hernia surgery background, that type of clinical experience does not make somebody a materials expert, and he admits that he's not a materials expert, and he says he has no training in material science. He's not -- he's

not -- he's never performed any biocompatibility testing on medical devices.

This case is very like the Napolitano case that we cite, and in that case the purported expert, he was a surgeon also, and he actually had experience with the product at issue, and the Court still said but, you know, that doesn't make him a materials expert, and he can't really opine about those things. So, the first grounds on design is just his lack of expertise in that area.

And then the second basis for excluding those is there's not really a reliable basis. He doesn't perform reliable methodology to render his opinions, and that shouldn't really be surprising. If you don't have expertise in an area, then your ability to use a reliable methodology is going to be compromised, because you don't have experience doing that. He admits that he doesn't have any clinical studies to support his opinion regarding the lack of ingrowth. The other thing about lack of ingrowth is that he doesn't really establish that it's relevant to this case; he doesn't testify that there was a failure of ingrowth in connection with Ms. Barron's mesh, and so there's also a lack of fit there.

When he talks about inflammation, he's admitted that he's not an expert on inflammatory response. Again, that's from his own testimony. He doesn't have any clinical studies to support his opinion. He cites one animal study, but it's

actually contrary to what he says. And, you know, we cite cases in our brief where the Courts have said you can't rely upon a study and then say, Oh, but I disagree with that study's conclusions.

And then on infection, the only thing he really relies upon is one case series. It is not a sufficient basis for his opinion, because there's no comparison, and he admits that he can't draw causation conclusions from it; it wasn't designed to do that. It's a case series by a single surgeon, so it doesn't control for different patient populations. It doesn't control for operative techniques. He does not have a reliable opinion to support his opinions.

So, that is our arguments on why he should not be allowed.

And then plaintiffs in response say, well, he's not going to offer opinions on general causation, and he's a specific causation expert, and if that's the case, then he should not be allowed to testify about these things. They can't have it both ways. They can't say, Well, we're not going to hold him to the same standard as a general causation expert but then allow him to testify to all of these things, again, under the guise of background, or context, or whatever it is supposed to be. If he's not a general causation expert, he shouldn't be testifying about design and general causation.

The last issue with him is his specific causation

testimony, and one thing to note here on specific causation is -- and Mr. Cheffo will address their general causation and materials experts, but one thing that is significant here is that there is just a complete lack of a connection between his opinions and their general design experts. They're going to say, Well, he's entitled -- if he, himself, is not qualified to render an opinion on materials, he's entitled to rely upon the opinions rendered by Dr. Klinge or Dr. Guelcher, except that he doesn't say that he does. He nowhere cites their reports, nor does he discuss what their reports are about. Their reports are about the propensity of polypropylene to degrade, and they admit, and Mr. Cheffo will talk about this, they admit that they don't know what the clinical significance of that is, that what it means for --

THE REPORTER: I'm sorry, Ms. Armstrong. You froze for me.

THE COURT: It was maybe two sentences' worth, so maybe just back up a little bit.

MS. ARMSTRONG: Okay. Do I need to back up?

(Record read by the court reporter)

MS. ARMSTRONG: I think I know where you are. So, Dr. Guelcher's and Dr. Klinge's reports address the propensity of polypropylene to degrade, but they don't address the clinical significance of that. Neither does Dr. Langstein. He doesn't make the connection between that observation and what

it means in terms of clinical outcomes for a patient. He doesn't say, I relied upon Dr. Guelcher's report or Dr. Klinge's report. He doesn't say Ms. Barron's mesh degraded, and that's why she had an adverse outcome. He doesn't render any opinions about degradation whatsoever. He does not connect the dots between those experts and his specific causation opinion, and that's a critical missing element. They are allowed to have multiple experts, but they've got to link them up, and they don't do that, and Mr. Cheffo will speak to that as well.

In terms of his specific causation opinion, he purports to perform a differential diagnosis. We don't disagree that a differential diagnosis is a reliable methodology. It has to be a real differential diagnosis, though, and it has to be performed reliably -- excuse me -- reliably. I'm not going to manage that word, so I'm just going to leave it mangled. Hopefully, the court reporter will fix it for me.

You know, they cite cases where the Courts say, Now, we've looked at the expert's opinion, and he or she went through each alternative causation and explained in detail why he or she excluded that alternative causation. You can look at Dr. Langstein's report. He doesn't do that. He basically says, well, smoking could be an alternative causation, but I don't think it was. I don't think GERD was an alternative

causation. He doesn't really explain why, and he doesn't discuss a lot of potential alternative causations, let alone tell you why he excluded. You can't look at this report and say, Oh, well that's a differential diagnosis. He just doesn't do what is required by a differential diagnosis.

And in terms of specifics, for example, he admits that smoking is a cause that can contribute to poor wound healing. He just says, Well, Ms. Barron didn't have poor wound healing, and, therefore, smoking's not a factor. That's in direct contradiction to her own testimony, where she says from day one the wound never healed properly. That's her testimony.

THE COURT: But isn't that a really -- isn't that a walloping line of cross-examination for you, as opposed to a reason to exclude it?

MS. ARMSTRONG: Well, all of this is a walloping line of cross-examination, but the reason why we have Daubert hearings is because Courts have recognized that the ability to cross-examine a witness is not sufficient protection from juries hearing unreliable evidence. If it's unreliable, then you shouldn't have to get to the issue of whether cross-examination will do the job for you, to begin with. If it's not a reliable methodology, it needs to be excluded in the first place, and that's in recognition of what the Supreme Court in Daubert and, you know, Joiner, and all of the progeny to Daubert recognized; that expert testimony is so powerful

that there has to be a gatekeeping function, and if you just rely upon cross-examination, then there's no gatekeeping function, and you don't really sort of balance out the powerful impact of expert testimony. So, that's the smoking factor that he identifies.

He also doesn't really give a good explanation for excluding her gastrointestinal chronic issues. There are other factors that he doesn't address at all. He doesn't address the fact that she's had four pregnancies after each of which the hernia increased in size. He doesn't address that. He doesn't address the short time frame between when the hernia surgery was performed and her last pregnancy, even though her treating physician had advised her to wait. He doesn't address the prior complaints of pain even prior to being implanted with C-Qur mesh that she had around her umbilicus or her naval, and he doesn't address her prior abdominal surgery. So, he doesn't perform -- if he performed a truth differential diagnosis, that would be one thing. He doesn't. It's *ipse dixit*. He says, I just don't believe these caused it, but he doesn't explain how, and he doesn't even address some alternative causes, and he has to do that.

Our last area was that he should not be able to render opinions about the instructions for use, which are the warnings to the company of the product. This is based upon his own testimony.

The plaintiffs in their response say they don't agree with how he characterized it, so I'm just going to read it verbatim as to what he says. "Dr. Langstein, are you planning to offer any opinions on the instructions for use for the V-Patch mesh or any other C-Qur mesh product?" "I will address -- I will only address the fact that I've reviewed them and I believe the use of the product in this case was consistent with the instruction for use."

That's all he plans to say. That's not a critique of the warning, that's not an opinion about the adequacy of the warning, and he shouldn't be permitted to render one at trial.

THE COURT: So, if he were to testify consistent with the limited quote you just gave, then you wouldn't have any objection?

MS. ARMSTRONG: He's basically saying that the surgery was performed consistent with the instruction for use. Yeah, I mean, he can say that. We might disagree with it, but we're not seeking to exclude him from saying that.

THE COURT: Okay. You're saying he just can't go on opining about them beyond what he said in his report, which was nothing?

MS. ARMSTRONG: What he said in his deposition.

THE COURT: In his deposition. Okay.

MS. ARMSTRONG: What he said in his deposition.

THE COURT: Okay. All right. Attorney Orent. Can I

start you off, Attorney Orent, with the general and specific causation issue? Because it looks like somewhere along the way in a plaintiff brief plaintiffs I think in some ways mischaracterize Langstein's disavowing of any general causation opinions. I lifted what I can see to be several what I would call general causation opinions. They come from his specific causation conclusions, I believe, but I'm just wondering about clarification from you on that. I think it was document number 108 where you or someone on your team said Dr. Langstein is not offering general causation opinions.

MR. ORENT: So, your Honor, thank you very much, and I think one of the things that would be helpful for me to explain to the Court is, where each of these experts -- and I'm going to just digress to briefly discuss all of the experts quickly to explain how Dr. Langstein's testimony fits in. But essentially we have, starting with Dr. Dunn, who talks about the raw polypropylene and the raw materials, how they're manufactured, how they're processed. Dr. Guelcher then talks about the interactions at the cellular lever. Dr. Klinge will talk about what we've termed "general causation," but really what we're talking about is, is this mesh defective? And then Dr. Langstein is going to talk about the specific causation based upon what is known about this device.

So, he is not our, quote, unquote, general causation expert, but in order to do a proper differential diagnosis, he

needed to be informed of what are the types of things that he can include in his differential and what factors play into it. So, his testimony is not true general causation; he's going to be focusing on the specific plaintiff aspects of it. But it needs to be -- he needs to be able to say, I ruled something in, and he needs to be able to explain how he ruled it in, but at trial that is going to be within the boundaries of Dr. Klinge's testimony.

THE COURT: Okay. I'm going to give you -- can I just -- help me out a little bit. So, in Langstein's report -- all right. I'm going to just lift from it. This is docket 93-1 at page 6. "The procedure of coating the mesh with the fish oil can result in a myriad of failure modes, chief among those being: 1) infection, 2) lack of ingrowth of the mesh, and 3) increased inflammation." That sounds like general causation to me. He goes on in the same report, also same page, "Protracted inflammation substantially increases the risk of infection. When placing the inflammation source (i.e. the mesh) intraperitoneally, in close vicinity to the bowel, the risk of infection raises dramatically." Same document, pages 6 through 7: "It is also well established that polypropylene elicits inflammation in soft tissue."

I could go on, there were other examples, but these do seem like general causation statements.

MR. ORENT: I'm not going to disagree that they seem

like general causation statements, but the intention of them is to explain later on how he's able to perform his differential etiology, that is, when the doctor who performed the explant of this device saw various things and noted them in the medical record. How is it that Dr. Langstein is able to say that he rules them in and then, therefore, cannot rule them out? So, this is explaining the basis for his methodology, but this is -- you're right, this is not going to be the topic area of his testimony. But, of course, he needs to be informed with that information. When it gets to specifics as to the mechanisms and the pore size of this device and its propensity to increase the inflammatory response, that's all within Dr. Klinge's testimony. In fact, there's no better person on this planet than Dr. Klinge to talk about those sort of things.

But Dr. Langstein, certainly as a physician, is capable of interpreting the peer-reviewed medicine and understanding what the relative risks of various devices are so that they can inform and advise his specific opinions.

THE COURT: Okay. Go ahead.

MR. ORENT: So, I would like to start, I guess, with the state of mind, what's been classified as "state of mind testimony," and there's a difference between saying that this is what the company thought they were, you know, and paraphrasing the thoughts as the case law has described in doing what Dr. Langstein has done. What Dr. Langstein does,

again, is he looks at these corporate documents to understand whether or not these devices can be ruled into his differential etiology or ruled out. So, when he talks again to this inflammation, when he goes and he looks at an animal study -- now, mind you, the difference between the animal studies we're talking about here and in the cases cited by defendant is these are not peer-reviewed animal studies. These are where an organization is hired by Atrium or Atrium does them directly, and that there's a proprietary interest in drawing certain conclusions, okay? So, they're not peer-reviewed.

And what Dr. Langstein does is, he looks at it, and he has largely agreed with the conclusions of them, and really what he does is he looks at, for example, the fact that the coating has lasted for two years. And so, when he looks at his differential etiology, he says, okay, well, is there a significance to the coating being there for two years in this particular patient? Is that something that I need to consider in ruling it into my differential etiology? And, of course, the answer yes for a multitude of reasons. Number one, it affects the porosity of the device; number two, their internal tests tell us that this is not Omega-3 fatty acid, but it is, in fact, saturated fatty acid, so it alters the pH, it increases the propensity for infection.

Dr. Langstein is then able to correlate these findings with the very limited study that was done on this, found a

19-percent increase, and it all -- all of the information points in the same direction. So, he's looked at all of the available information out there and drawn and been able to draw into his differential etiology these notions that are out there in the science. So, that's the importance of the corporate documents.

The other aspect of the corporate documents is he's able to say, well, should this have gone on a warning? Now, when defendants ask him about the instructions for use, he is not going to offer testimony as to how to write a set of instructions for use. That's outside of his expertise. What he is going to testify to is, number one, whether this doctor, the implanting doctor, followed the instructions for use and met the standard of care. Number two, he's able to testify as to whether or not there was information within the corporate files of this defendant that would have played a role in the decision-making process or should have been involved in the decision-making process of a doctor; that is, should a treating doctor have been told this information? That's within a physician's wheelhouse.

Now, likewise, when we talk about these other notions about can he testify about -- he's not a biomaterials expert. That's the other big critique of Dr. Langstein. And Dr. Langstein, he is not a biomaterials expert. He is a surgeon. He is a plastic surgeon, and what he does by way of background

is he treats, and he does only about one of these a month, but he treats the most severe hernia repairs where a patient has had numerous disasters go on in their abdomen, and he conducts a reparative surgery and focuses on restorative anatomy, something that is outside the expertise of general surgeons, and it requires a much higher degree of skill, a much higher degree of preparation. And so, it's not an apples-to-oranges comparison when you look at a general surgeon that can do a hernia mesh procedure in 45 minutes versus one of these multiple-hour procedures that Dr. Langstein does.

But, importantly, he is not a biomaterials expert. What he is, is a surgeon who's familiar with materials used in the body, and he can testify to the body's reaction and the appropriate body reaction to the materials. So, again, he's perfectly capable of saying, based on his review of the literature, and based on his review of the medical records in this case, whether lack of tissue ingrowth or the creation of a scar plate, which is over-scarification due to the pore size of the mesh, whether or not that had a negative impact on the patient such that he includes it in his differential etiology.

Likewise, he can talk about the lack of porosity, based on 50 years of studies that have been done, and talk about the propensity for infections. One of the big themes in this case, again, is Ms. Barron had an infection, and the lack of porosity of this device is directly correlated with that.

You get lack of porosity through two mechanisms, and Dr. Langstein will talk about this: number one, the coating didn't resorb completely in Ms. Barron; number two, contraction of the mesh, because the pore size was not large enough originally.

So, he's going to take those aspects and talk about those things, and that's a perfect example of the application of general causation to the patient and specific causation and what we meant by he's not testifying to general causation. He's not going to say, for example, the minimum pore size necessary should have been X, they could have done this, designed it that way.

Now, when we talk about -- the notion that he cannot connect the dots I think is a red herring. First of all, to include something in a proper differential etiology, you have to look at whether or not that substance, general cause, is capable of causing the harm, okay? There's really no issue of general causation in any medical device case where the label, the warning label itself, says it can cause infection, says it can cause all of these panoply of harms that our client actually did suffer. The issue is comparatively to this device; compared to other devices in existence or compared to the state of the art was it defective, unreasonably dangerous? The notion that he has sufficient information to include these types of things into his differential etiology, of course he

can. They are on the instructions for use, they're in the warnings, and any surgeon would have to include mesh infection being caused by the mesh in a differential etiology.

Now, when you look at his differential etiology, the defendants threw out a number of issues that he, quote, unquote, didn't include in his differential, and it's really important that we address these. Number one, the case law doesn't say that in an expert report that that individual has to explain away every single possible factor that they ruled in or ruled out. They have to be open to questioning and be able to explain their basis for it. Now, in this particular instance, smoking, Dr. Langstein does rule out smoking. The reason he rules out smoking is because the doctors in this case, the medical records, not the patient, who claims one thing, but the experts, the doctors find no healing issue, and so, when they explant this mesh there's no history in the medical records of a healing problem. And, in fact, based on the tissue, based on the experience that this patient had, he's able to rule out lack of healing as a potential cause, and so with lack of healing goes smoking.

Likewise, multiple pregnancies is not a contributing factor to mesh infection. It may increase your risks of having an additional hernia, but that's not in the differential for a mesh infection and a balled-up mesh that causes other problems, a fistula. And, so that doesn't belong properly in the

differential etiology. Likewise, GERD, esophageal reflux, does not properly belong. It could not have caused the harm that we're alleging in this case that he found.

So, if your Honor looks to the deposition and looks at the individual alternative causation that they try and ask, the real focus is what is in the differential, and what has been excluded, and why has it been excluded, and has Dr. Langstein satisfactorily answered that?

Just a couple of other notes. Dr. Langstein has been retained over the years by numerous companies because of his surgical expertise with biomaterials in complex hernias. So, TELA Bio is one company. It's a biologic hybrid. LifeCell, another biologic manufacturer for hernia repairs. They've used him as a key opinion leader. He's actually testified for defendants in hernia litigation related to biologic products, and he certainly, like he did here, he used the general state of knowledge to inform his case-specific opinions.

So, I think when your Honor looks at the depth of the quotes and the detail to the explanation and his detailed analysis, your Honor will find that, number one, he did an appropriate job looking at all of the relevant studies. Whether you call it general causation or information background for specific causation, the labels I don't think really should hang us up. The important thing is that he included the mesh in his differential for very particular reasons, and he

excluded these other items for, likewise, very particular reasons that are justified, that are based in the medicine and based on information that could only be gleaned from internal documents.

The last critique I want to just quickly address is the single-study issue, the notion that Dr. Langstein only relied on a single study that's 19 percent case series. Well, first of all, your Honor, I want to point out that the defendant -- the reason that there aren't many studies on this product is because the defendant didn't finance them. We believe in our case in chief we will show that the defendant actively played a role in what got published and what didn't get published. Number two, like any other doctor, and you'll hear this, the weight of the evidence, with all of our experts, they use multiple lines of evidence to inform their opinions.

And so, in this particular case, we do rely on the actual human clinical studies related to this product. We, likewise, also rely on animal studies related to this product. But that information on itself isn't enough, and so we have to look at the general body of scientific literature. Again, this is a well-studied material, that is, hernia mesh is, and there's about 60 years' worth of medical peer-reviewed literature that talks about all aspects of design; and just like the defendant relies on those when they go to the FDA, our experts rely upon that other data in informing their opinions

about very specific attributes of these devices.

So, really, it's looking at the full body of information and then drawing inferences from the pros and the cons of everything. And that's what each of these experts is going to talk about when they talk about the weight of the evidence, and certainly the defendants may criticize how they weigh one particular attribute versus another, but that is truly fodder for cross-examination, and it is not certainly within the Daubert sphere, appropriate to Daubert, someone who can testify with specifics as to why something is included or excluded from a differential etiology.

Thank you, your Honor.

THE COURT: Okay. Thank you. That was about a minute over, but close. I'm going to give Attorney Armstrong a few minutes. Go ahead.

MS. ARMSTRONG: Your Honor, Mr. Orent actually said something that I agree with, and that is that labels shouldn't hang us up. I think that this falls into the if it walks like a duck category. If it looks like a generic causation opinion, it's a generic causation opinion, whether they want to call it "background," "context" or "ruling in." He's reaching an opinion regarding whether or not the design of the device is defective and whether that gives rise to these failure mechanisms that he describes and that your Honor quoted at the beginning of Mr. Orent's presentation. That's a generic

causation opinion. He does not have the qualifications to render a generic causation opinion, and it doesn't matter how he describes it or what -- if he's ruling it in because generic causation is established, it's still a generic causation opinion, and he doesn't have the expertise, and he didn't do the type of work that is required to do a generic causation opinion. He didn't follow that type of methodology, because that methodology is just not in his wheelhouse.

In terms of him being able to rely upon their other experts, he doesn't purport to do so, and he doesn't link up any of the things that they say to his own particular opinions and the failure mechanisms that he talks about. For example, Mr. Orent made a lot of points about porosity. Dr. Langstein doesn't say anything about porosity in his report. He doesn't say, These are the clinical effects of porosity, these are the problems with porosity, these are how porosities contributed to Ms. Barron's injuries. He doesn't do the linking up; he doesn't connect the dots for them.

And Mr. Orent didn't even discuss degradation, which is the primary focus of Dr. Klinge, Dr. Guelcher and Dr. Dunn's reports. Mr. Orent didn't mention it, because Dr. Langstein doesn't mention it. He doesn't say that the mesh degraded and that it caused these things. There's just no linking up between their general causation experts and Dr. Langstein, their specific causation expert, and they're trying to backdoor

it in by saying, Well, he has all this background and context, and that's ruling in, but none of it's connected, and none of it is within his expertise.

In terms of the instructions for use, again, Mr. Orent in his argument just now expanded upon what Dr. Langstein said he was going to testify to at his deposition, and we would just rely upon his actual words at his deposition.

And in terms of the alternative causation, well, you heard just now with Mr. Orent explaining why he thought those alternative causations could be excluded, but that's not in Dr. Langstein's report. He doesn't say he purported to do that. The only thing he really addresses is smoking, and Mr. Orent says, well that's based upon the medical records, but Mrs. Barron would know whether or not her wound ever stopped draining between when the hernia surgery took place and when the explant surgery took place, and he doesn't and Dr. Langstein -- even if Mr. Orent is correct, Dr. Langstein still has to explain why he didn't account for Ms. Barron's testimony, and he can't.

THE COURT: All right. Do you want to have another minute, Mr. Orent, or are you good?

MR. ORENT: If I could just address one thing, and that is, again, this notion of his lack of qualification and then this inflammation piece -- excuse me -- degradation piece.

Number one, Dr. Langstein is perfectly qualified as a

medical doctor to assess the medicine and draw the connection between the literature and these notions of general cause and what happened in this particular individual.

With regard to this notion of degradation, we're going to hear a lot about degradation throughout the rest of today. It's important to understand "degradation" is actually a terrible term to explain what actually degradation is. Degradation or oxidative degradation is really taking a very long chain of molecules that make up polypropylene and pulling out small molecules so that you have a shorter molecule. There are practical impacts of it, but it is not disintegration like it would sound like it is. Importantly, the way I think about degradation is --

THE COURT: That's one minute, Mr. Orent.

MR. ORENT: Sorry.

THE COURT: So, if you can really hurry up here. I wanted to give you a quick opportunity to respond, but I definitely don't want to lengthen this hearing longer into the evening, for sure. Go ahead.

MR. ORENT: It's like rust on a bridge, and the important thing for the Court to understand right now is it produces inflammation. Dr. Langstein talks about inflammation. That's what a treating physician sees, that's what a medical doctor sees. All of the other experts talk about what brings us from polypropylene to degradation to the inflammation.

Thank you, your Honor.

THE COURT: All right. Thank you.

Okay. I'm prepared to give you a ruling on Mr. Langstein and document number 92. Having carefully reviewed the briefing, having listened carefully to oral argument, I am going to deny document number 92.

With respect to what Atrium knew, to the extent defendants seek to prevent Langstein from opining that Atrium had knowledge of the results of certain studies performed on Atrium's C-Qur mesh product, the motion is denied for the following reasons:

Defendants correctly note that Langstein, who's never worked for Atrium, lacks any basis for offering opinion as to Atrium's intent, motives or state of mind. However, the Court finds that Langstein's report does not contain opinion as to Atrium's intent, motives or state of mind. In relevant part, Langstein opines that Atrium had knowledge of the conclusions reached by the authors of studies conducted either internally by Atrium or by consultants working on Atrium's behalf. Moreover, Langstein has a clear basis for offering his opinion that Atrium possessed knowledge of these studies and their results. In each instance where he offers such opinion, unremarkable opinion, frankly, Langstein cites in support documents produced in discovery by Atrium establishing that Atrium had records of the studies. In effect, Langstein's

proffered opinion as to Atrium's knowledge of the studies is a shorthand way of expressing his expert opinion as to the clinical implications of the studies' results while also acknowledging that the studies came from Atrium. This is not the equivalent of offering improper and speculative testimony as to Atrium's intent, motives or state of mind.

Under Rule of Evidence 702, an expert may offer opinion testimony so long as the testimony is based on sufficient facts or data. Because Langstein had a clear basis in fact for stating that Atrium knew about these studies and their results, the motion is denied.

With respect to the extent to which defendants seek to prevent Langstein from offering opinion as to the design or function of Atrium's product, the motion is likewise denied, because, first, defendants correctly note, one, that Langstein has not used Atrium's product in his clinical practice; two, Langstein is not a biomedical engineer or material scientist; three, that Langstein has not performed his own material science research or his own medical device biocompatibility testing; and, four, that Langstein has not reviewed manufacturing sterility testing for Atrium's product.

However, First Circuit jurisprudence establishes that an expert's lack of specialization in the field in which the expert offers an opinion affects not the admissibility of his opinion but the weight the jury may place on it, and that's the

Mitchell case, 141 F.3d at 15 in the First Circuit.

Langstein is qualified to offer his proffered opinion as to the design and function of Atrium's surgical mesh. He is a highly experienced reconstructive surgeon, who has both personally cared for hundreds of abdominal wall hernia patients and who is the Medical Director and co-founder of the Abdominal Wall Reconstruction Program at the University of Rochester School of Medicine. He has worked extensively with surgical meshes other than Atrium's and has studied relevant scientific literature and manufacturing specifications regarding Atrium's product. He does not offer any opinion falling outside the reasonable confines of his areas of expertise.

To the extent defendants seek to prevent Langstein from offering opinion that the design of Atrium's product can result in lack of ingrowth, that is, failure of the patch to incorporate into human tissue as intended, increased risk of inflammation and/or increased risk of infection, the motion is also denied and for the following reasons:

Defendants correctly note that Langstein has not reviewed or identified human clinical studies establishing any of the three putative failure modes of Atrium's product and has not reviewed manufacturer's sterility testing studies of Atrium's product. Defendants further correctly note that Langstein is not an expert in inflammatory responses or in infectious disease.

However, First Circuit jurisprudence establishes that an expert's failure to rely on human clinical studies or, indeed, on any particular form of scientific evidence or data does not render the expert's opinion so unreliable as to be inadmissible. And I'll cite, and I'll repeatedly cite, this case from the First Circuit: Milward versus Acuity Specialty Products, 639 F.3d, and specifically here at Page 24. The same First Circuit case, Milward, also establishes that, even if the factual underpinning of an expert's opinion is weak, that weakness is a matter affecting the weight and credibility of the testimony rather than its admissibility. Defendants' arguments do not raise any of the traditional indicia of methodological unreliability. That would be absence of peer review, absence of acceptance in the scientific community, unacceptable error rate, failure to explain methodology and so forth. Instead, defendants' arguments, once again, go to the weight and credibility of Langstein's opinion.

To the extent defendants seek to prevent Langstein from offering any opinion regarding the component materials of Atrium's product, the motion is denied for the following reasons:

Defendants argue that Langstein should be excluded from offering opinion as to the component materials of Atrium's product because, although he expressed an intention to offer such opinion, he purportedly did not specify the nature of the

opinion he intended to express. In fact, however, Langstein's report contains Langstein's opinion that the component materials of Atrium's product, its propylene mesh, polypropylene mesh, and its fish oil coating have a tendency to result in inflammation and infection. Indeed, it is precisely the component materials of the product that Langstein identifies as being the factor that results in increased risk of an adverse clinical outcome.

To the extent defendants seek to prevent Langstein from offering opinion that Atrium's products specifically caused plaintiff Carrie Lee Barron's injuries, the motion is denied for the following reasons:

Defendants argue that Langstein's differential diagnosis methodology is unreliable. Specifically, defendants argue that Langstein used an unreliable methodology to rule in Atrium's product as a potential cause of Barron's injuries and used an unreliable methodology to rule out Barron's comorbidities, namely her history of multiple pregnancies and her history of cigarette smoking as potential causes.

It is well established that differential diagnosis is a proper scientific technique for medical doctor expert testimony; however, differential diagnosis requires that the steps taken as part of that analysis, the ruling in and the ruling out of causes, were accomplished utilizing scientifically valid methods. I get that also from the First

Circuit, Granfield versus CSX Transportation; and, again, Milward I would cite as well.

Now, again, once again, I think defendants' arguments go to the weight and credibility rather than admissibility. The defendants' arguments that Langstein used an unreliable methodology to rule out Barron's comorbidities as potential causes of her injuries are also without merit; and I'm saying also that their arguments that Langstein used an unreliable methodology to rule in is without merit, goes more toward weight and credibility than admissibility. I'm also saying that the argument about unreliable methodology to rule out is without merit. Langstein discusses Barron's comorbidities and provides opinion within the scope of his expertise that they were unlikely to have caused her injuries.

Defendants correctly note that Langstein made an arguable factual error in connection with ruling out Barron's history of cigarette smoking as a potential cause of her injuries, although Attorney Orent just explained his perspective and argument on that. Defendants' arguments regarding Langstein's arguable factual error do not go to methodological unreliability but, rather, to the weight and credibility the jury will assign to Dr. Langstein's opinion. Defendants may cross-examine Langstein regarding his grounds for ruling out Barron's history of smoking as a potential cause, but Langstein's arguable factual error does not

constitute grounds for exclusion of his specific causation opinion.

With respect to the instructions for use, now, this one, it seems to me, that through -- to the extent defendants are seeking to prevent Dr. Langstein from offering any opinion regarding instructions for use of Atrium's product, that motion is denied for the following reasons:

Through his report Langstein offers opinions as to the instructions for use only to the very limited extent that he opines that the plaintiff, Carrie Lee Barron's, hernia repair surgery using Atrium's surgical mesh was performed in accordance with accepted guidelines and instructions for use. Langstein's deposition is not inconsistent with this. Under Federal Rule of Civil Procedure 26(a)(2)(A), a party must disclose its experts opinion by the court-ordered deadline for doing so, and it's well settled that undisclosed expert opinion is subject to exclusion. So, to the extent he goes far beyond that limited, very limited, statement then I do think at that point defendants can stand up, approach sidebar and ask for me to exclude it. But with respect to the limited nature of what he's saying about the instructions for use, it seems to me that that is a timely disclosed and very limited opinion. So, that's denied.

With respect to general causation, to the extent defendants seek to prevent Langstein from offering any opinion

as to general causation, based on plaintiffs' counsel's assertion made in briefing that Langstein did not offer general causation opinion, the motion is denied for the following reasons:

In the course of this hearing plaintiffs' counsel has clarified plaintiffs' position as to Langstein's opinion. Specifically, plaintiffs' counsel's clarified that, to the extent Langstein offers general causation opinion, he does so only in support of his methodology, differential diagnosis and as it ties into his specific causation analysis. So, with that clarification, no grounds exist for excluding Langstein from opining in this limited manner as to general causation.

Thus, for all these reasons docket 92 is denied in full.

We will now move to the next document, which is, Mr. Cheffo, document number 96, and the doctor at issue is Scott Guelcher. Attorney Cheffo, go ahead.

MR. CHEFFO: Yes, your Honor. Thank you very much, and I'm going to set my little clock here, too, so I can try and stay on track.

So, we're not going to cover a lot of the law. Your Honor is very familiar with it, and we've talked about it in the brief. But having said that, just one point I think is really important that covers Dr. Guelcher and covers I think the rest of the three experts, right. The relevance fit aspect

of Daubert is really a core aspect of Daubert, as the Court knows. The Supreme Court has basically told us in various cases that evidence must be relevant and reliable. What I think you've heard and will hear largely throughout this is kind of the reliability aspect. That's what the plaintiffs have largely focused on. But the relevance requirement is echoed in 702(a), evidence is admissible if, A, the expert's, dot, dot, dot, specialized knowledge will help the trier of fact, right, understand the evidence to determine the fact at issue.

So, in our view, and there is a reason for this, the plaintiffs, you know, being good lawyers, have focused on the reliability aspect, but they want to discount and essentially dismiss the relevance aspect, and here's why: You'll hear about or hear in the next argument degradation, migration. They are part of the causal chain that would need to be established, right? Mr. Orent talked a little bit about how he might do that, but there's no fit here, because -- and I strongly encourage your Honor, I know you have done this, but we can read essentially the experts,' right, particularly Dr. Langstein's deposition and his expert report, and he does not talk about these issues in any way that would provide notice, as your Honor articulated those rules. So, we'll talk about in a minute the specific experts here.

And, again, Mr. Orent will correct me, but we tried

to, and I tried to look a little bit in the cases these experts have been used before by Mr. Orent and his firm, and typically what they do is they have -- one of the experts says, Well, this can degrade from a materials perspective, a bench science, and then they usually have had, as I understood it, a pathologist who said, I specifically looked at this material, and it actually did degrade, right? And then, when you have that, then the specific causation expert says, Well, it can, here it did, and now I can relate that to -- but what you're going to hear in these arguments, and you've seen the papers and you can look until kind of the cows come home, is that -- I've actually never seen it before where people say, I don't know anything about this particular product, I've never touched it, I never tested it, I don't know the materials about it. It's made of polypropylene, so on the one hand they say it's like 60 years of polypropylene, but, of course, the whole point of their case here is that this is somehow different with Omega-3 fatty acid coverings. So, the point here is you have to connect the dots, right? And the plaintiffs just clearly have not done that.

So, let me summarize the three points, as your Honor asked us to do. I think that, in addition to the fit issue, Dr. Guelcher talks about degradation, and he talks about *in vivo* kind of conclusions, what but we know from his report is all he's ever done is do kind of *in vitro* testing, right? Even

there it's kind of well outside -- and we cite some of the standards -- it's all about the 20 percent versus 3 percent peroxide. So, you have kind of opinions based on *in vivo* based on *in vitro*. Then you have the fact that there's, which we'll talk about, no data, facts or testing on C-Qur. Imagine a materials expert who wants to offer an opinion on something but literally has never seen, touched, tested or looked at any data regarding the product that he wants to come into court and talk about.

And then he's, obviously, not qualified to opine on the clinical effects of mesh degradation. And this is kind of the problem, right, is that, on the one hand, we're hearing, No, no, no, no, he's not going to talk about it, and we say, But here's what he's going to talk about, and essentially, one, it comes very close to what we're saying he's going to talk about; but, two, we're not looking at the actual expert report and the depositions, right? It's one thing for Mr. Orent to say, Well, here's kind of how it's going to work out, but we have to be able to rely, as we have in this case, on what the expert reports actually say and what the deposition transcripts say.

So, let's get a little bit more specific, with your Honor's indulgence, into this expert, Dr. Guelcher, Scott Guelcher. He talks about C-Qur might degrade after it's implanted, right? That's his opinion, it might degrade. He

hasn't looked at the data on C-Qur; he can't identify a single C-Qur device that's been degraded; he didn't look for any scientific study about C-Qur; he admits that his opinions are general to polypropylene. So, again, there is an element here of polypropylene. We all agree with that, but unless the plaintiffs are willing to stipulate today that they're going to say this is just about polypropylene, it's the same, but, as I understood their entire case or their other expert report, is there's an issue of this particular polypropylene and also the coating issue and how it interacts. So, he hasn't looked at the C-Qur, he's never held it, he's never examined it, he didn't request an exemplar. Imagine that, not asking for a particular example of it before you're going to come into court and talk about it.

I know your Honor asked -- these are questions that, frankly, every good judge asks in every Daubert hearing, right, well, isn't this just kind of weight? But at some point, right, it has to be more than just cross-examination, because jurors believe people in white coats, and that's why in these types of situations where people are -- this isn't just a cross-examine issue. These are methodologies. From a methodology, in order to opine on specific properties of a medical device, it's kind of -- it would seem, and I think it is, if we looked at the methodology, 101. You actually have to know something about the actual medical device and the

substance, you have to touch it, you have to feel it, you have to do research, you have to understand it, right, you have to look at it, you have to test it. It can't be based on extrapolation of some data that you can't even say relates directly to it and what he's basically talking about what's going to happen in the body, which he hasn't even done as to polypropylene. So, he's never tested the hernia mesh, he didn't look for any studies, he didn't review C-Qur studies, he didn't look at the C-Qur data, and he doesn't know the complication rate for C-Qur, yet he wants to kind of offer an opinion about how this product will perform.

Let me just say in a minute, your Honor, why this is so potentially, I won't say dangerous, but perhaps misleading for the jury or at least unhelpful. If we were to basically have somebody come in and talk about, like if you leave your car, right, in your garage, at some point maybe over years just natural air will -- the tires, right, the rubber in your tires will kind of degrade at some point, right? And you throw that out there to the jury. And here's the thing: I looked at it. In the heat and the oxygen it will degrade. Then someone goes out and has a car accident. But, in fact, the experts who actually are going to talk about it will say it's because there's like a slipperiness of the tire, right? The point being that what the expert, the first expert, talked about is not what the causation, the nexus, right, because they don't

have this pathologist to say that this was actually a defective product?

So, all these issues are not tied into what, in fact, Dr. Langstein has talked about. It's, frankly, not good enough, respectfully, to just say, Well, I'm saying this is about inflammation, and I have somebody doing these random studies on polypropylene not related to this and then say that's all tied into an inflammation analysis, because it's just too far removed.

There's a few other points to make. There's also -- there's no ability and he cannot say that the degradation is linked to a specific complication, right? So, you heard Mr. Orent say, well, it's kind of, it's somewhat -- I don't know that I disagree -- but "degradation" doesn't really mean "degradation," it means anything else. But, nonetheless, it's not tied to any complication or any human or clinical aspect, as you'll hear also in kind of my next presentation. But here it's just like, I've done some bench science on polypropylene, don't really know anything about C-Qur, don't know how it's going to interact. And, again, remember this was a product that was only implanted in Mrs. Barron for two years, right? So, by their own expert report he says, I've done this kind of assuming a lifetime implantation. So, we don't know -- he hasn't said, Well, over 25 years the degradation would be "X", or, Here's what I would assume. But what's relevant here is

what's happened in two years, like, what would you expect? What's happened under kind of certain body systems? We don't know any of that, nor does Dr. Langstein elucidate any of those or say, Here's how I've taken this into account, here's how I've used this. But, again, the key issue here is we're missing a pathologist, right to say, Ah-hah, the tire failed or the mesh failed. We don't have that. No one can tell us about the actual mesh in the case.

And also no one comments about if degradation impacts the actual clinical outcome. We don't know, right, and this is where it goes into the world of double speculation, we don't even have anyone who will testify, Dr. Langstein, any of these other folks, that there was degradation, right? No one will say that this product actually degraded in the body. We have these issues of kind of reactive oxygen species. I'm certainly not going to get into the weeds on the details of that, your Honor, how the oxidation affects, but if that is a factor, right, wouldn't you want to know the materials? Wouldn't you want to know about the oxidation levels of these particular products? You would if you're going to be talking about C-Qur mesh, but if you don't know anything about the product you can't make any of those determinations, and Dr. Guelcher didn't make any of those determinations.

Now, he relies on a paper that he coauthored examining polypropylene outside the body. Again, as I've said a few

times, it's not performed on C-Qur, it doesn't reflect the ROS in the body. First of all, it's not in the body, but notwithstanding that the ISO standards suggest a 3 percent hydrogen peroxide solution, and he used 20. This is not a cross-examination issue, this is a methodology issue, right? If basically the ISO says, if you want to replicate body systems, you should look at test data using a 3 percent hydrogen peroxide, and you use 20, that is not a cross-examination issue; that is a methodology issue. Not notwithstanding the independent studies, both of them were written by mesh experts.

Now, finally, I'm just going to -- and I want to reserve a minute or two -- but my last point in following the outline that we have in the brief is the clinical effect of oxidation or degradation in the body. This is a person who's not an MD, not a pathologist, not an epidemiologist, didn't review case-specific medical records, admits he can't offer patient-specific opinions, he has no expertise in clinical trial research on this subject, not involved in clinical research regarding polypropylene, and he hasn't studied clinical outcomes involving polypropylene. So, as to him, any kind of comment of how this might impact in any body systems based on his lack of knowledge or information about the actual product, lack of *in vivo* studies and his lack of expertise in this area -- if this was just about doing a polypropylene study

under bench science, yes, that would be something that I don't think any of us question that this person can talk about, but basically taking these incredible leaps and trying to say, because of this amorphous degradation data on polypropylene that somehow we're going to let the jury believe -- because that's the point, right, your Honor? The point here is he's going to testify. He'll say, Degradation, what is that, right? I don't understand that. Migration, what is that? And they want to actually create the impression that that somehow causes inflammation in the body, right? And if they had the studies to do that, wouldn't you have seen them in these briefs, if they had the testimony that said it, in fact, does? But it can't be the *ipse dixit* of kind of Dr. Langstein down the road just saying, Yeah, inflammation, all this stuff going on and, you know, Jurors, you should rely on it.

So, I'm going to stop there, your Honor. I think I stopped at 13 minutes, so maybe I have a minute or two after that.

THE COURT: You sure do. You sure do.

All right. Attorney Orent.

MR. ORENT: Your Honor, I promise to be shorter this time. I want to start off by describing, again, what oxidation is, and it is not disintegration of the device, but it is, in fact, the molecular degradation from a large molecule to a small molecule. What that does is it changes the strength of

the mesh, it hardens it, it causes surface cracking, which, in turn, causes an increase in inflammation. This is well studied. There are studies that go back to the 1980s with Liebert and Williams, Costello, de Tayrac, that followed the arc of the importance of degradation to clinical outcomes, most recently articles by Moalli, Badylak.

The important thing for Dr. Guelcher is what Dr. Guelcher does is he talks about it in the body. So, the testimony that Dr. Dunn is going to talk about is that Dr. Dunn actually did test this device, and what he found was that there were certain what are called carboxyl peaks in the FTIR spectrum which show that degradation has occurred, which means that the antioxidants that are present in the polypropylene have been used up, which means that this degradation process, as a matter of basic chemistry, has started to happen, has continued to happen, and it continues to happen as more mesh gets exposed. So, the surface -- we know from Dr. Dunn's work that the surface has degraded before it even goes into this device. What Dr. Guelcher then talks about is how this process continues in the body because of macrophages. Macrophages, which you will not see really the defendants mention and the importance of them, are part of the inflammatory process. Whenever the body gets implanted with some foreign body, the body's inflammatory process comes in, and it releases a number of different cell types, and that's what Dr. Guelcher talks

about. He talks about the presence of these macrophages which release peroxides to try and clear out the foreign substance, and they attack the surface of the polymer, causing it to crack and break and split, which in turn, again, causes more of this.

Now, all of this is modeled out, and it is well accepted. This is not, and Mr. Cheffo draws distinctions between some of the vaginal mesh cases, where there was a pathologist that actually came in and looked at the explanted mesh. Unfortunately, number one, we didn't have the explanted mesh from this particular client; but, more importantly, we know because of the manufacturing process here that this particular mesh already was degraded before it went into the body. This mesh went through heating at extrusion and then during the crosslink and curing process, where the Omega-3 actually was converted into these saturated fats. It releases peroxides into the material. Those peroxides then, in turn, break off these carboxyl groups from within the mesh. And so, Dr. Dunn took this mesh and put it under the FTIR spectrum and saw that these carboxyl groups exist, that this mesh has, in fact, degraded. Dr. Dunn then talks about it at the macro level -- excuse me -- at the micro level, at the cellular level. Why is that important? And so, the baton is handed off to Dr. Guelcher within the body, and Dr. Guelcher talks about these ROS molecules and the practice on the inflammatory process.

Counsel is absolutely right. He's not going to talk about the end points in humans. That's what Dr. Klinge is going to talk about. Counsel, likewise, is right that he doesn't know about the failure rate of the C-Qur device, because he's talking about polypropylene. And after antioxidants are expended polypropylenes are all the same. The difference between different types of polypropylene is before the antioxidant package is expended. But, again, Dr. Dunn's work before talks about the reasons why that are both theoretical through the mathematical equations that can be done to prove that this heating process uses up the antioxidant package, but then it's also verified by actual testing.

So, that's really the limited nature of Dr. Guelcher's testimony. As far as this notion that he violated the ISO standard, a couple of things. One, he's doing something very different than the ISO test was intended to do. ISO 1099 part 13, which is the test that Mr. Cheffo is referring to, is actually the *in vitro* degradation test for the -- not to prove degradation but actually to look at the leachate materials and the byproducts and look at it and its potential effect in each organism. That's different than the test that Dr. Dunn, Dr. Guelcher and Dr. Iakovlev published on. This test, this series of studies, was actually peer reviewed and published in two very distinguished journals. So, I think that we need to understand this apples-to-oranges comparison in terms of what

the end points of each of these materials are starting to prove.

Now, Exponent, which was hired by the defendants in vaginal mesh litigation, actually went to go and disprove the work that Dr. Dunn and Dr. Guelcher had done on the benchtop testing, and they actually proved their very point, and they classified their paper as intentionally oxidized. So, really, again, this is one of those items where the devil's in the details. I urge the Court to pay very particular attention to what these experts are saying and not what they're not saying, because it's really these transition points, and the clinical impact as far as a treating physician or someone in Dr. Langstein's position is this notion of inflammation, and that's where Dr. Guelcher really talks about why is it that there's this level of inflammation seen at the cellular level, what is it that these reactive oxygenated species do, where do they come from, and how are they important in this case?

Unless your Honor has any more questions, I will leave it at that.

THE COURT: All right. Very good.

Attorney Cheffo.

MR. CHEFFO: Thank you. I'm going to try and keep it at two minutes, your Honor. I don't know if I misheard or Mr. Orent misspoke, but, just to be clear, as I understand it, this mesh was never examined by anyone. So, when we talk about it

being examined by the doctor, Mrs. Barron's mesh, to my knowledge -- this is just like the pelvic mesh issues, right? I mean, the idea here is to say that it's different there because there you'd actually want to find out if the mesh was degraded. The fact that there was some testing done of some other mesh, not this mesh, and then you determine that this particular mesh was degraded, when no one has ever looked at it before, during or after is not the way science is done.

He also said, you know, and I agree, right, he talks about in the body. Just think about it. Again, this is where we -- kind of where it started, right? This is a person who is a professor of chemical and biomolecular engineering, right? He's not a doctor, pathologist, epidemiologist, toxicologist, he didn't review the records, but yet he's the guy who's going to be talking about it in the body. And he also has never done any *in vivo* studies. Even if we kind of disagree on the ISO, at best, right, even if that was credited, that's an outside-the-body study. So, having somebody -- and he also agreed, Mr. Orent also agreed, excuse me, that the antioxidant work is important. I think he said he recognized it, but they don't know what it is, right? They have no idea what it is. So, it's important to know what's going on in the body. This is a person who's not a doctor, no medical training. He's a chemist, right? And he didn't do any body testing. It's important to know antioxidants. They don't know. It's

important to actually find out this product, whether, in fact, it degraded or had any issues, however you want to define degrading, degradation or migration.

The fact is we have zero, zero evidence from any of the these guys, right, as to what happened with this particular mesh? And we know that this is not kind of a monolithic or like a spark plug you put in your car and you expect it. By their own testimony and everybody's testimony, the different body systems, how it's used, what happens in the body, the length of time, the antioxidant packages, this is kind of like a, you know, there's no one size fits all, and yet what we're hearing here is that none of the experts really know anything about this product.

And let me just say one thing from a sort of practical perspective, your Honor. The fact of the matter is you've already let in, understandably -- you've ruled, so we're not going to kind of quibble about that, obviously, but this is -- Dr. Langstein's going to be able to testify in this case, right? These folks are really kind of, they are outside what the core testimony is of Dr. Langstein, right? What this will do is just create another entire confusion amongst the jury as to why we're talking about these issues when they're not tied in any of the expert reports, and these are people who really are not qualified to talk about, particularly Dr. Guelcher, what's going on in the human body with respect to these issues.

So, thank you, your Honor, for the opportunity to talk about this today.

THE COURT: Anything further, Attorney Orent?

MR. ORENT: No, your Honor.

THE COURT: A really minor, minor question; I'm not sure it's material. But at some point the parties dispute whether Guelcher offers a clinical opinion, and it appears as though he does offer at least one clinical opinion. I just want to clarify that with Attorney Orent. And it may be a matter of semantics, but he talks about the clinical effects of polypropylene mesh oxidation and degradation in the human body in that he says it leads to adverse effects in the implantee, including pain, scarring and inflammation.

Are you suggesting somehow that that is not a clinical opinion?

MR. ORENT: So, pain, scarring, those are generic end points that really don't discuss the clinical aspects of anybody. So, when we talk about scarring, that's a process, and you can talk about it in the abstract.

THE COURT: Okay.

MR. ORENT: And, likewise, these are processes. He's, like I said, talking about it at the cellular level. He's not going to be talking about the entire organism.

MR. CHEFFO: Can I just -- I mean, I don't think there's anything more clinical than pain.

MR. ORENT: Well, your Honor, if it makes your job easier, I can state that he will not mention the word "pain," he will not testify to any pain. That's not our intention, just to make that crystal clear.

THE COURT: Okay. I think I want to start really with Guelcher's expertise and just make sure it's in the record, because he seems a highly qualified expert in this area. He is a professor of chemical and biomedical engineering at Vanderbilt University; he's the Director of the Vanderbilt Center for Bone Biology; he performs original research in biomaterials design and development; gene and drug delivery, tissue engineering and related fields. He's published 96 peer-reviewed articles in those fields, including four on the design of scaffolds that degrade in the presence of oxygen, two on oxidation and degradation of polypropylene pelvic mesh and 24 on biologic tissue grafts. In addition, he's coauthored two abstracts presented at scientific meetings relating to oxidation of polypropylene in biomedical devices. And I've just culled from his resume some of his expertise.

I'm going to sound like a broken record, I think, because, again, your arguments go to weight and not admissibility. I'm not in agreement that we're talking about typical Daubert gatekeeping on methodology and typical arguments that I need to keep from the jury. Ultimately, these are going to be arguments you're going to make in your

cross-examination, your opening and your closing statements.

So, first, document number 96, the motion to exclude Guelcher is denied, with one exception which we'll get to near the end. But with respect to the argument that Atrium's product -- he should not opine that Atrium's product can degrade *in vivo*, to the extent defendants seek to prevent Guelcher from opining that Atrium's product is subject to oxidative degradation after implantation in the human body, the motion is denied for the following reasons:

Defendants correctly note that Guelcher relied on studies that did not involve Atrium's product but, rather, other polypropylene samples. However, as previously noted, First Circuit jurisprudence establishes that, even if the factual underpinning of an expert's opinion is weak, that weakness is a matter affecting the weight and credibility of the testimony rather than its admissibility. And, again, I cite Milward. There are two Milward cases. I think it is the same Milward, but there are two different Milward cases. This is 639 F.3d.

To the extent the defendants believe Guelcher's opinion is weakly supported due to his reliance on studies of polypropylene degradation in products other than Atrium's, their argument goes to credibility or weight rather than to admissibility.

Defendants also appear to argue that Guelcher's

opinion is irrelevant because plaintiffs purportedly do not argue that polypropylene degradation caused plaintiff Carrie Lee Barron's injuries. However, this argument is disingenuous, because plaintiffs' experts collectively offer opinion testimony that degradation of a polypropylene mesh in the human body increases the risk of complications, including inflammation and infection, and plaintiffs' theory is that Barron's injuries were caused by such complications.

To the extent defendants seek to prevent Guelcher from opining that the addition of antioxidants to a polypropylene mesh may slow but will not prevent oxidative degradation following implantation in the human body, the motion is denied for the following reasons:

Defendants correctly note that Guelcher relied on studies that did not involve Atrium's product but, rather, other polypropylene samples. Defendants further note that Guelcher has no specific familiarity with the antioxidant properties of the coating Atrium uses in manufacturing its surgical mesh product. However, as previously stated and discussed, First Circuit jurisprudence establishes that, even if the factual underpinning of an expert's opinion is weak, that weakness is a matter affecting weight and credibility rather than admissibility.

To the extent defendants believe Guelcher's opinion is weakly supported due to his reliance on studies of

polypropylene degradation in products other than Atrium's, their argument goes to credibility or weight rather than to admissibility. Moreover, defendants' arguments do not address the traditional indicia of methodological unreliability, that is, absence of peer review, absence of acceptance in the scientific community, unacceptable error rates, failure to explain methodology and so forth. Guelcher's opinion that antioxidants are only effective until they are depleted through reaction with oxidants is of general applicability to all antioxidants, not merely to the antioxidants Atrium uses in manufacturing its surgical mesh product.

To the extent defendants seek to prevent Guelcher from offering opinion regarding oxidative degradation of polypropylene following implantation in the human body on the ground that such opinion will not be helpful to the jury, the motion is denied for the following reasons:

Defendants correctly note, again, that Guelcher does not opine that Atrium's surgical mesh product degraded following implantation in Barron's body and does not opine that Barron's injuries were specifically caused by such degradation. However, to prevail in their lawsuit plaintiffs must establish both general causation that Atrium's product can cause injuries like those Barron suffered and specific causation that Atrium's product was, in fact, a substantial factor in causing Barron's injuries.

First Circuit jurisprudence establishes that general and specific causation are discrete, if related, issues and that a plaintiff like Barron must establish both. Again, that's the Milward case, 820 F.3d at 471. While Guelcher offers no opinion as to the specific causation of Barron's injury, his opinion is clearly relevant and potentially helpful to the jury in connection with the question of general causation.

To the extent that defendants challenge the helpfulness of Guelcher's opinion on the ground that Guelcher relies in part on *in vitro* studies, their arguments go to the weight and credibility rather than admissibility. Again, that's the Milward case, this time the older Milward case, 639 F.3d.

With respect to Mr. Guelcher's qualifications to opine as to clinical effects, to the extent defendants seek to prevent Guelcher from offering opinion as to the clinical effects of oxidative degradation of polypropylene mesh following implantation in the body, the motion is granted as to pain and opining as to pain but is otherwise denied for the following reasons:

Defendants correctly note that Guelcher is not a medical doctor, and that he does not perform original clinical research, and that he did not consult plaintiff Carrie Lee Barron's medical records. Defendants further note that

Guelcher has not worked with or studied Atrium's product specifically. On these grounds defendants argue that Guelcher lacks the qualifications to offer expert opinion as to the clinical effects of oxidative degradation of polypropylene mesh following the implantation in the body.

However, First Circuit jurisprudence establishes that an expert need not be a specialist to offer admissible testimony so long as the expert has achieved a meaningful threshold of expertise in the given area. Guelcher is well qualified to offer the limited clinical opinion he proffers through his report. Guelcher is a qualified biomedical engineer with significant experience in biomaterials design and development, drug and gene delivery and tissue engineering. He's performed original research on oxidative degradation of polypropylene in medical devices. He opines, in summary, that degradation of a polypropylene mesh following implantation in the human body can cause pain, scarring and inflammation in the implantee. His expertise in biomaterials design and biomedical engineering qualifies him to offer that opinion with respect to scarring and inflammation, not with respect to pain, and Mr. Orent has agreed to remove any mention of pain to the extent he offers any clinical opinion.

So, with that one exception, document 96 is denied.

And now we're going to take a break for the benefit of everybody, but mostly our court reporter, and we will be back

here at 10 of 3:00, so 2:50. All right.

(Recess taken from 2:35 p.m. to 2:52 p.m.)

THE COURT: All right. Attorney Cheffo, defendants' motion -- this is document number 98, and I'm not sure I'm pronouncing it right. Maybe Klinge?

MR. CHEFFO: I think it's Klinge, too, but Mr. Orent knows better than both of us, so he can tell me if I'm getting it wrong.

THE COURT: Okay, go ahead. You both have done very well, so keep going.

MR. CHEFFO: Thank you, your Honor. And thanks, again, for the opportunity. I'll have to say I wasn't quite expecting the immediate feedback, but it's helpful for us, so I know that took some work on your part to do that. So, thank you for that.

So, your Honor, the one thing, on the break also I had a chance to go back in another case that you've been relying on. It's actually, again, instructive to know where the Court's frame of mind here is, and I just say this because I think we're in two different categories, right? So, the one quote I think from the case we have been talking about is when the factual under pinning of when an expert's opinion is weak it's a matter affecting the weight and credibility of the testimony, dash, the question should be resolved by the jury, right? And that's at least what we've been talking about.

But the next sentence says, of course, following Joiner, and I know your Honor is aware of this, but a District Court properly may exclude expert testimony if the Court concludes too great an analytical gap exists between the existing data and the expert's conclusions. So, I don't think what I'm going to be saying is inconsistent, you know, which is, sure, if there's facts and people quibble about them, and we may argue and disagree whether it's methodology or facts, but I would, again, submit in a case when you have no data about the product, right -- this isn't beyond good lawyers and good experts, right, to say, hey, can I take this, can I test it, can I look at some data? They have mounds of discovery and information. When there's no testing of the actual product, when there's no clinical studies of the product, when there's no actual knowledge of the product or how it works or any effort to kind of replicate in the real world, we would just submit that that brings us into the Joiner category as opposed to perhaps let kind of the lawyers fight it out in cross-examination. There is a point, right, where it's kind of a bridge too far, and we think as to some of these that's kind of the basis of our argument, your Honor.

So, Dr. Klinge is a former hernia surgeon who used mesh. He offers opinions that C-Qur is defective but no case-specific opinions, as I understand it. He doesn't allege that there's any purported defects in the mesh that he's

identified with respect to Mrs. Barron's injuries, and he does talk about, we believe, some state of mind, knowledge, corporate conduct and speculative issues for which we both moved here, but he's also been excluded in other courts for those same types of issues. I think that some of the other things, he's talked about it being over-engineered, the pores too small, which is the porosity issue we've talked about, and he's also talked about there being safer alternatives to the C-Qur mesh.

So, to start on what, again, I think are some methodology issues -- and we know that at least Courts in the Lipitor, Judge Gergel in the Lipitor MDL and Judge Rufe in Zoloft, we did highlight one example of where he looked at a particular study, and you have the deposition testimony in front of you in the brief, where he basically says, Yeah, I read that, I agree with that, you know, I relied on it, but I don't agree with the authors, with no explanation. So, that is a methodological flaw, and that kind of cherry picking is exactly what both of those judges in those MDLs have looked at in determining in large regard striking the experts in those cases.

In addition to that, in order to form conclusions from a methodology perspective, there are certain, again, rules of the road. These aren't just factual disputes, but there is no data experience or testing in humans to kind of support these

theories, and it is a well-accepted methodology that animal studies and bench science can be instructive, but they cannot replace findings and clinical study data, and they don't even necessarily always have to be double-blind placebo-controlled trials, but you have to have I think under the methodologies and what many of the Courts have looked at kind of common practice, you have to look at certain clinical data. And here we can search the record high and low. There's no clinical study that patients report more migration with C-Qur other than mesh, right? So, if your opinion is that this product is kind of less safe or has more issues than other products, one would think you have to have a baseline. What is the rate, what is the testing in humans, what does the data show, and then what do others show before you can draw those conclusions? But we don't have any of that. Dr. Klinge cannot point to a single clinical trial that implicates there are more complications of any kind with C-Qur compared to any mesh. So, a bridge too far under Joiner to be able to say, I'm going to form that conclusion when, at best, I have a few animal studies and a few things we've already talked about. I won't repeat them again.

But these are folks who haven't looked at C-Qur mesh, right? It's somewhat extraordinary in an MDL bellwether that we're now going to have doctors talking about the products without ever having looked at specific data on these products.

So, they talk about, you know, polypropylene

degradation. Again, the data that they've relied on doesn't support that. There's no evidence that C-Qur degrades, right? He has not talked about -- he admits that he has no data that C-Qur degrades. He's never seen degraded C-Qur mesh. He's not aware of any physician or researcher reporting fragmented polypropylene fiber. His opinion that the degradation is an option or a risk that may occur is speculation.

Again, if we had specific data, your Honor, that said here's the run rate, here's the failure rate, here's the issues, or conversely, I think I would have a much harder argument and, honestly, probably would not have been here today making this motion if -- I may disagree with it, but if their testimony or their expert opinions were, you know, 99.99 percent of this happens and it happens within two years or 100 percent, then we can disagree with that, but you're basically saying it's everything. But that's not what any of these experts are saying, right? They're saying it's possible, it may, there's various factors.

So, no one is even saying in connection with Mrs. Barron in the two years that it was implanted within her here's data that's showing that there's a high likelihood of failure within those situations, right? We don't have any analogous data or clinical trial information that would actually relate the usage, the fit, the bridge too far to what Mrs. Barron actually has experienced. What we have is mesh generally,

polypropylene can degrade over some period of time under some conditions, not in everybody. That's exactly the speculative type of testimony that I think is what Daubert is for.

Now, again, because they can't figure out whether, in fact, this mesh -- imagine, again, and I don't mean to continue with the hypotheticals, but we're in a situation that we're having folks who will talk about potential possibilities, but no one's saying there was degradation, and then someone's going to basically say, even though there's no one saying that in this case there was degradation, I'm going to be able to say that I think the inflammation or infection was caused by degradation, which the experts who talk about it can't even say occurred in this particular case. No one can say that, because there's no data for that. He testified that no physician has an explanted mesh, has indicated degradation for this specific patient.

On the oxidation issue from a qualification he opined that C-Qur oxidizes in the body and oxidation causes the mesh to degrade, and he relies on the OIT testing to support that, but he admits that he's not an expert in OIT testing and actually doesn't know anything about the test. This is the back and forth in the deposition:

"Are you an expert in OIT testing?"

"OIT testing?"

"Yes, sir."

"I don't know what it is. What is the abbreviation for?"

"Are you an expert in oxidized induction time testing?"

"No."

Again, his opinions with respect to the coating. Now, I know the advocates, the lawyers, the good lawyers will talk about cytotoxicity and how this can have infection, but the actual experts, the basis for that, the evidence, is that he opines that the coating effectively closes the pores, inhibiting tissue growth, and cytotoxicity causes cell death, chronic inflammation, increased risk of infection; yet he can't opine that the coating is unsafe, he only has a concern about it. That's speculative. That's a methodology issue. He's not prepared or was not prepared to opine that C-Qur coating is cytotoxic. It may be, but he hasn't made that conclusion. He can't say whether C-Qur coating is cytotoxic, nor has he formed a conclusive opinion that C-Qur coating is cytotoxic in any particular patient. So, he relies on Petri dish testing to form coating concerns. So, he has concerns it may affect some people, it's possible, it's theoretical. This is not typically a methodology that experts would be allowed to testify with respect to general or specific causation. And he admits that his testing, quote, has serious limitations and, quote, do not reflect real life.

Just briefly, I think there's anecdotal communications from two doctors. You're right. If you were to ask or say, Could you cross-examination on those, the answer would be, Yes, but I think the question, again, is that it's not forming the types of views here. You have to look at what the methodologies, what's generally accepted, right, for people to form these types of conclusions, and it's not basically looking at the types of information and data that this particular expert has looked at in order to form his conclusions.

Now, he's admitted that he's not offering any plaintiff-specific causation opinions.

With respect to inflammation markers, he claims that certain inflammatory markers reflect intensity of inflammatory reaction. He also offers opinions on other aspects of the inflammatory markers. But these are irrelevant, because he's not actually tested C-Qur inflammatory markers.

Again, this goes to the idea that, in order to say this is better than that, or there's more rate than that, what's the inflammation rate, he doesn't know what the inflammation rate -- he hasn't tested the inflammation rate for these products, so how can you make conclusions about this product versus other products?

Same thing is true for weight, your Honor.

And, finally, I want to, again, be mindful of the Court's schedule and time and the court reporter, but I don't

know what Mr. Orent will tell us about the opinions concerning knowledge and state of mind and corporate conduct. We think reading the clear language of the report and what he said, that if it was so easy, all of us to just say, well, this kind of goes to the state of mind or knowledge, I think you have to really look at what the core is of what he's trying to talk about and what positions he's offering in testimony, and he's actually been excluded from offering these opinions in the pelvic mesh litigation. That's the Ethicon Pelvic Repair, the West Virginia litigation in 2014.

So, unless your Honor has specific questions, I know you've been through this, or maybe you'd like him to address them and I'll reserve a minute or two, if I could.

THE COURT: Yeah. So, basically you're saying in the West Virginia case the judge prohibited Klinge from citing as Atrium's knowledge Atrium's own research and documentation, or were you saying something else there at the end?

MR. CHEFFO: It's under the caption of kind of state of mind, corporate conduct should be included. Just to be clear, your Honor, I don't think anyone -- we've all kind of been in these rodeos before. I mean, having somebody's own kind of corporate documents, right, saying is this a factual document, usually you don't need five experts to say it or a kind of biomaterials person, but leaving the implication like what the jury is supposed to do, what's the implication of

that, did they know that, does that mean that they are negligent, was it wrong, that's usually what the Courts, right, don't allow these folks to do? But getting in a document that says on "X" date, and usually it's a regulatory person, Did you inform the FDA, when did this study come out? But drawing the conclusions how that may have violated a standard of care or what companies knew or what they should have done, those are the types of things that, in my experience, more often than not and much more often than not the Courts limit that, because they basically say we don't really need an expert to tell the jury what they should be thinking about whether the company violated the standard of care, whether this is something they knew or should have known. That's exactly what the negligence and other standards are.

But to be clear, no one's suggesting that we're trying to keep out otherwise admissible documents; it's just the impressions and the testimonies that these folks are trying to --

THE COURT: But what's remarkable about him saying that Atrium knew because these are Atrium documents? And if there's a case, if there's a case that says that, while that may be an obvious proposition, an expert should not be allowed to say that Atrium knew because these are Atrium documents, that that would be improper. What is the case that says that, because I'd like to look at it? Obviously, I already held with

respect to one expert that I didn't see it as really opining on intent or motives; it was sort of stating the obvious, that these are propositions in Atrium documents, so, therefore, Atrium must know about this. So, if there's a case, that's what I want to know, because I want to look at it before I get off this video conference, study it carefully, and make sure that I've got this right. Obviously, I can correct myself later.

But I'm not seeing this as falling into that sort of danger zone. I agree that Klinge testified in other cases, and he made some statements about mesh manufacturers and their concerns and their intent and their motive and how they should have been more concerned about their mesh design rather than telling a nice story, I think he testified, rather than telling a nice story to physicians to justify selling their inferior mesh products, blah, blah, blah. I mean, I can see where a judge keeps that out. But simply saying, well, these are in Atrium documents, therefore, Atrium knew -- and, again, I'm willing to keep that out. It's just not going to make or break plaintiffs' case. They are Atrium documents.

And so I'm willing, certainly, to reconsider that, to the extent it is improper for the expert to say that in front of the jury, but I'm just not seeing it as falling into some sort of danger zone. He's only saying it to the extent they are Atrium documents. He doesn't know whether the specific

Atrium employees or CEOs and others at Atrium who testify know. But what are they going to say, No, I never knew that?

MS. ARMSTRONG: Your Honor --

THE COURT: I can see that Attorney Armstrong might want to say something. Go ahead.

MS. ARMSTRONG: Your Honor, if you look at the cases that are cited in our brief, one of them is Rezulin, the other one is Zofran. I am having trouble finding my notes, the names of the other ones. I think we cited about four cases.

THE COURT: Give me the cite again of the one that you think is the most persuasive, because I'm going to go get it, and I'm going to reread it just to make sure.

MS. ARMSTRONG: I would say Rezulin. Let me find that cite for you.

THE COURT: Okay. And if you find it, just give it to me at any point, because I can come back to it.

MS. ARMSTRONG: Rezulin is 309 F.Supp. 2d 531, and what they do is they talk about two aspects of this use of expert testimony this way. One is the state of mind aspect, that it's speculative to speculate about the state of mind. The other is it's just pure narration, and that's what Mr. Cheffo was getting at, they're just reading documents into the record. Notice, again, is a question for the jury. It doesn't require expertise for the jurors to determine whether or not there's notice to the defendant or not. They can read these

documents and draw their own conclusions. They're just using the expert as a narrator, and Courts have rejected that as well. Again, they describe it as narration.

MR. CHEFFO: And just really quickly on this point, your Honor, I think, again, maybe it's just that I'm a little jaded or -- again, I don't think, and I don't want to be presumptuous with Mr. Orent, but this is not just like an authentication-type issue, right, like, Okay, is this a document, can you look at this, is this the FDA, read it, it's one page, did they do this? Yes. That's not what this motion is about. That's not typically -- what usually happens is a lot more, and that's what we're trying to avoid, if you give us some guidance, I think, about what your view of this is. This is not trying to keep out otherwise admissible documents or having an expert refer to a specific document.

But there's two issues, right? One is just this whole kind of story, and then there's a 50-page document, they tell one issue and they highlight. But there's usually a lot more subtle commentary, and if you kind of allow that or don't have very strict rules on it, then the trial becomes much more cumbersome, much more -- particularly if we're not going to be able to do it live, about what it is. So, I suppose we'll hear from Mr. Orent what he actually thinks this expert wants to say.

THE COURT: All right. Let me just say this, and help

me out, Attorney Orent, just on this one issue, because I do want to make sure that I get this ruling correct. I mean, I'm giving you my sense of it obviously as a trial judge, but there is a part of me that is open to this notion that having the expert say, "Atrium knew this," that's a problematic statement, I can see that, and I know they're relying on a case, Ethicon I think is the name of the case, Attorney Armstrong, where it looks like the judge did exclude Klinge's testimony that was similar to what it looks like I'm allowing.

Now, again, I don't find it highly objectionable, but I'm also wanting to know is this a hill you're going to die on, or can you live without Klinge and was it Langstein saying Atrium knew; here are the Atrium documents, therefore, Atrium knew? You don't have to have them say that Atrium knew. I mean, I think the jury's going to hear "Atrium documents" and they're going to presume Atrium knew or certainly should have known. That is so obvious. Can you live without your expert actually saying, Atrium knew that blah, blah, blah because blah, blah, blah was in their own documents? Can you live without that in terms of Langstein and Klinge?

Because I'm giving you a lot of the rest that you're asking for, but I do see what they're saying with respect to this, and I think Attorney Armstrong is correct, having looked just at the language quickly of Ethicon, and, again, it's an F. Supp. 2d. I'm not sure I necessarily would have kept it

out, but it is, it's kept out, because the Court found that it was impermissible state of mind testimony, which is exactly what Attorney Cheffo and Armstrong are arguing here. So, I'm inclined to reverse myself on that portion of Langstein and allow this portion with respect to Klinge. Can you live with that? Because if for some reason your whole case is counting on that, I want to hear the argument, but I can't imagine it.

MR. ORENT: So, your Honor, can we live with it? Yes, but I think that the Court needs to understand that there's two very important distinctions here that you're not being given right now.

THE COURT: Okay.

MR. ORENT: The first is -- there are two bases that Mr. Cheffo is arguing that documents should not be used with these witnesses. The first basis --

THE COURT: He's not saying that they're not to be used, I don't think. He's saying he doesn't want your expert saying Atrium knew --

MR. ORENT: Correct.

THE COURT: -- because of these documents Atrium knew.

MR. ORENT: Right. And number one, as your Honor pointed out, that's actually not state of mind. That's not the kind of testimony that Judge Goodwin in West Virginia was talking about. He was talking about the sort of comments that you were talking about a moment ago. And, in fact, we were

very well aware of that Daubert decision, obviously. Not only was my firm and myself personally involved in that litigation very heavily, but we read the opinion again prior to issuing this report and made absolutely sure that we didn't run afoul of any of those margins that were there.

Here's the issue, though. This is the real important issue. Mr. Cheffo and Ms. Armstrong are arguing about those documents that are evident on their face. When we're talking about complex issues of medicine a lot of the issues are not evident on their face as to what was actually known. Interpreting an animal study requires an expert to explain it: What's the significance of this, Doctor? What does this mean, and put this in context of what the company knew, okay? Was this a red flag? Why? It's not putting it into the state of mind, but it's providing expert interpretation of a document that requires it. It is, by definition, outside a layperson's understanding.

And so, I think we need to have context. Whenever we talk about excluding documents in an amorphous sense, we have to look at what are the documents? Because internal documents are these animal studies.

THE COURT: Again, he's not arguing to keep the documents out. He's just arguing, Judge, don't let the expert sit there and say, because of these documents, Atrium knew what was in the documents.

MR. ORENT: Again, I think it's important that these experts utilize them. One of the things that's really important about these cases is, and your Honor is undoubtedly aware because of the 510(k) regulatory process that the defendant chose to go through, there's very limited data that the company collected, okay? There was benchtop testing, there were some animal tests, and then they relied upon studies in the peer-reviewed literature to say that their product was comparable to these others, and that's what substantial equivalence means, and you'll hear that argument later, but at its underpinning the company made determinations that this product was safe based upon this limited data of information. I need to be able to ask Dr. Klinge, Could a company have believed that their device was safe based on this information? I need to be able to ask him, What does this mean, what does this inflammatory finding mean? Did the company interpret it correctly? All of those questions require expert interpretation, and that's --

THE COURT: Okay. That seems legit, but asking, Did Atrium know --

MR. ORENT: Well, again, it's what are we asking they knew? Did they know that there was a tissue response and increased inflammation response that would lead to X, Y and Z, where he's putting together the puzzle pieces based on different scientific works that are happening within the

company, and were the red flags there, and then he concludes that a particular piece of information is a case? He's not going to be opining that these people are bad people.

But my issue is we're dealing with this in such a vacuum right now that I get the sense that Mr. Cheffo is arguing somewhere where I have no intention of going. If you look at the report, within the four corners of the report that Dr. Klinge offered, he's very particular on what he relied upon and what he's going to testify. We're not using him to talk about whether or not Atrium was negligent in terms of their statements within the company about some of these emails that go back and forth. He didn't rely on those emails, he didn't rely on that sort of information, so he's not going to talk on those sort of things. So, we just need to be very particular. Dr. Klinge is going to say the things that he was disclosed to say, and I still haven't heard with any degree of particularity what that is that he can't say based upon the documents that he's using. Again, those are primarily animal studies or other documents that provide some basis for more detailed scientific information. It's not his purpose to talk about corporate motives, corporate intent or even the proprietary of corporate conduct.

MR. CHEFFO: Your Honor, should I stand down, or should I just take 30 seconds while you're on this issue only?

THE COURT: I'm looking at all of my notes with

respect to what you argued in the brief, and obviously you've alerted me to certain opinions about what Atrium knew, and you're saying they should be excluded.

MR. CHEFFO: Right.

THE COURT: So, I'm looking at those right now, and you quoted, Atrium knew the C-Qur line was denser, and Atrium knew of the propensity for increased inflammatory response caused by increased density. Additionally -- this is all from Dr. Klinge.

MR. CHEFFO: Right.

THE COURT: Additionally, Atrium knew it was using a monofilament resin manufactured by Secant Medical that was not intended for use in medical devices. Those are just some examples. Atrium should have been aware of the likelihood of degradation and subsequent oxidation.

MR. CHEFFO: Right.

THE COURT: That seems an area that you're not necessarily arguing he can't say. It seems to me you're saying how can he say, an expert, say Atrium knew anything.

MR. CHEFFO: Well, I think there's two issues. One is the narrative issue, right? But just to be clear, this is why. I wrote it down, and forgive me if I didn't get it exactly right, but he said, you know, I need to be able to say could a company have believed it was okay to submit an application to the FDA based on a report. What goes more to state of mind

than speculation, right? How could someone have done this? Now we get into, like, you're trying to basically say here's a document -- I think Mr. Orent was talking about it in the context to explain it -- here's a study, look at this, question from lawyer: Based on that, could a company have responsibly submitted an application to the FDA? Isn't that exactly state of mind? Isn't that exactly corporate conduct? Isn't that exactly -- because we know they did, and we know that it was approved or cleared by the FDA. So, the idea of basically questioning the state of mind of how someone could have done it -- you know, this is not a psychology exam. This is, right, a materials expert? The idea is, if the facts come in and the record is there, the lawyers can argue that later at some point, if your Honor allows it, but allowing people to question and experts to opine on what a company knew and should have done and could have done, that's exactly what all these cases talk about.

THE COURT: I know, but here you have documents that themselves are internal Atrium documents. I don't know what they had in Ethicon in terms of what Klinge was talking about, but here whatever they say has to be tethered to the actual evidence, the documents and the data, and what Attorney Orent is suggesting is that his experts will opine and will be tethered to the actual documents that were Atrium documents.

I think this ultimately is something that I could

revisit ultimately during trial. This is not one of those issues, classic Daubert issues, really; this is one of those basic evidentiary questions as to whether somebody can testify in the manner in which we're talking. It's hard for me to rule on it without being in the trial and hearing what the evidence is, what documents is Attorney Orent sure that I'm going to agree with him that these experts can answer the question he's going to -- I need to see the documents, I need to hear the testimony in order to really make a ruling.

So, I think with respect to this portion of both the Langstein and this Klinge argument about what Atrium knew, I will tell you that I don't see it as a stretch. Now, I don't know what was in Ethicon, I don't know what the documents were in that case, but I don't think I would have prohibited somebody from saying, based on those documents, the company documents, the company knew that "X" was true. That's just my sense of it. So, I might not agree with the ruling in Ethicon, it may not control -- it may not have facts that are similar to this case.

So, what I would say to you is that my reaction to this issue is as I originally held with Langstein. This just doesn't seem like state of mind to me. It seems like it is hardly a stretch for somebody to say based on Atrium documents Atrium knew "X," assuming they're based on the documents.

So, I'm going to say to you that my ruling is going to

be the same with Klinge as it was with Langstein. I will revisit this at trial if ultimately this does not pan out as I am hearing it and as I anticipate that the evidence will come in based on what I'm hearing.

So, this does not seem to me to be a hill that you're going to die on, Mr. Orent, but ultimately if, in fact, it comes close to something like state of mind or intent evidence and it comes out in a way that would be more like what Klinge did in Ethicon, then I think at that point I would reverse myself on this particular question.

So, I'm going to say to you that I'm going to make a provisional ruling on that small aspect of Klinge and Langstein and alert you to that fact. But with respect to the other, obviously, scientific arguments that you're making with respect to qualifications and reliability, obviously, I want to give you a ruling on those that's solid that gives you a ruling so you can move forward in the case and understand how I'm going to handle these expert witnesses.

So, I don't want to cut anybody off. I think, Mr. Orent, I just immediately started asking you questions. I may have cut off Attorney Cheffo as well.

Were you done, Attorney Cheffo?

MR. CHEFFO: I was, your Honor. You gave me plenty of time. Thank you.

THE COURT: All right. Attorney Orent, keep going.

I'm sorry I interrupted. I think you don't need to address the issue of what Atrium knew. I understand your argument, I understand Attorneys Cheffo's and Armstrong's arguments as well. At this point I think that I'm giving more weight to your argument, Mr. Orent. I'm not seeing it as crossing that line, but I need to be in the thick of it, and I need to hear the evidence, and ultimately that's a sidebar; counsel comes to sidebar and alerts me that, Judge, remember that issue we discussed? You ruled on it provisionally, you wanted to hear the context. Here we are. And I'm going to listen to Mr. Cheffo and Armstrong tell me why I need to exclude it. Okay?

MR. ORENT: We'll be very mindful of that, your Honor, as we put on our case. Thank you.

THE COURT: Okay. So, go ahead with Klinge.

MR. ORENT: Your Honor, I just want to start off by talking about who Dr. Klinge is and just to give a brief background. This is a guy who's written between 250 and 300 peer-reviewed publications on this topic. In fact, Dr. Klinge has written more articles on this topic than some of the entire reliance lists of all of defendants' -- of particular experts that defendants use. Now, another important thing is that he's written peer-reviewed literature on every single area of his opinion. So, these articles in collection have been cited, according to ResearchGate, more than 10,000 times in peer-reviewed publications Dr. Klinge has been cited. In fact,

Atrium on these very opinions that they attack Dr. Klinge on, pore size and inflammation and weight, all of these different things we included in our Daubert opposition, we included statements from the company where they actually take the opposite position in day-to-day business. So, on the one hand, they cite him to the FDA when they're pushing their regulatory process, when they're putting on a PowerPoint presentation trying to sell the benefits of this device. As the Court can see, they talk about Dr. Klinge. Dr. Klinge is the pioneer. He is the most known name when this comes to hernia meshes, which is why we've used him in this particular case.

Now, I think defendants take issue with some of his statements because Dr. Klinge is very particular with his language and he is very precise. So, I want to go through a couple of things just very quickly that I think are worth addressing. Number one, with regard to his, quote, unquote, disagreements, those by and large are -- and we cite in our opposition the full discussion as to why he disagreed with one of the internal studies, animal studies, that was done, and you can see just by reading, and this is on pages 10, 11 and 12, the level of precision that Dr. Klinge answers a question and depth that he gives as to why he disagrees.

So, for example, when he disagrees with the statement about tissue being well incorporated, he then asks them, What do you mean by "well"? And then he goes on to talk about,

Well, they used this particular stain, and it's possible to draw this inference from this, but authors in the field tend to overstate it because of X, Y and Z. Here's the most that they can tell you without doing more research. That's the level of detail that Dr. Klinge gives in his report. So, when they ask him, Is this device cytotoxic, Dr. Klinge actually says something along the lines of, I have concerns that it is, and he further explains what he means by that, and what Dr. Klinge means is that there's a very precise definition of cytotoxic. When you're talking about cytotoxicity, you're talking about cell death on contact. That does not mean that the cells can freely proliferate as they otherwise would, and in his deposition he talks about the fact that there is this combination of saturated fats, and he's done his own research, and he's looked at the peer-reviewed literature, and there's no question that there is an inhibition of cell growth and proliferation, but whether that reaches the technical definition of "cytotoxicity," he does not know, because there's only one MEM elution test that shows it's cytotoxic.

But then there's this whole literature, and that's the kind of balance when we talk about the weight of the evidence approach -- Dr. Klinge says this is important clinically because X, Y and Z, but he plays it so true that he's not going to overstate something, and so he's not relying on the one MEM elution test that defendants use as part of their ISO data. He

goes to the peer-reviewed literature, and says, You know what? It's clearly not healthy, but I don't know that it fits that technical definition. That's the level of precision he uses. When the defendants talk about OIT, oxidative induction time testing, they confuse whether someone is an expert in order to undertake and conduct a test versus qualified to opine on the importance of the resulting values from it. There's a very big difference here between the two.

And one of the big things, as your Honor has now heard on multiple occasions, this notion of oxidative degradation, or, as I like to call it, "mesh rust," and one of the things that is important, that is really important about this is this notion that the defendants didn't use a medical grade polypropylene. And what does that mean, and when we talk about degradation, what does it mean? Well, it means this whole antioxidant package that we've talked about that's used up prior to implant, what kind of testing do you do? Well, the difference between a medical grade is something like Ethicon's proprietary PROLENE mesh in a commercially industrial grade polymer like the Pro-Fax 6523 that Atrium uses.

And so, what Dr. Klinge does is he actually uses this OIT test, and he talks about -- and if your Honor looks at all the research and all these opinions, there's a series of dog tests from like the '70s and '80s where they look at with PROLENE suture oxidative degradation, and the point of this is

that oxidative degradation occurred in that medical-grade polymer, and it occurs a lot quicker in the LyondellBasell 6523 test. He interprets that, contextualizes it in the light of the work that Dunn has done and everything else. So, that's the other important point.

But as far as his porosity testing, his porosity opinions over engineering opinions, those are based on the underlying polymer. Let us not forget that at its core this is a device that is intended to have the coating resorb into the body, and what's left is a polymer of what is PROLITE mesh. Now, Dr. Klinge himself has actually published numerous peer-reviewed studies talking about the weight of PROLITE mesh, talking about the porosity, and he talks about the comparative value of weight versus pore size and the importance in terms of the biologic suitability of the mesh.

So, when you then go to his opinions on inflammatory markers, again, the importance here is this notion of increased inflammation. There are multiple causes of increased inflammation. They are everything in this particular product from the coating and whether it is borderline cytotoxic, but it's really made up of these saturated fats, but it's also the pore size and the amount of mesh, the amount of material, and it's the type of material. So, this study talks about -- again, this is a peer-reviewed study. It talks about the inflammatory system's response and why you get this jump start.

And actually Dr. Klinge explains the importance of it and why is it that complications occur two and three and five and ten years later and not just three and six months after implant. All of these things are tied together. Dr. Klinge actually explains in detail both in his report and his deposition how all of these things work together, but they set the table so that when Dr. Langstein talks about the actual amount of inflammation, the infectious process, the jury is going to understand at a cellular level, at a granular level and from a design standpoint why it is that this was a situation that is resulting from this device.

And so, unless your Honor has any more questions, I think it's very obvious why we chose Dr. Klinge and his tremendous amount of research and thousands -- Dr. Klinge and Dr. Klosterhalfen together have reviewed more human explants of polypropylene meshes than any other people on the planet. So, I think their credentials, their peer-reviewed work and their opinions are irrefutable at this point.

Thank you, your Honor.

THE COURT: Attorney Cheffo.

MR. CHEFFO: Yes, briefly, your Honor. Most of the times that you read of, whether, again, it's looking at Zoloft or the Lipitor MDLs, these are folks who published as many or hundreds of times, right? So, usually what happens before court, right, and your Honor knows this for Daubert, is that,

just because someone has a lot of initials after their name or has published a lot, the idea is what they're doing in the courtroom is similar to what they did under the peer-reviewed literature, and we're here with these people because the answer is absolutely no. I mean, if this was a peer-reviewed study, it would be different than putting in a report here, and I think, again, you know the idea just to -- Mr. Orent talked about weight, he looked at the weight. But here's what he testified: Quote, No reasonable definition of lightweight or heavyweight and that, quote, differentiation in lightweight and heavyweight is meaningless. So, we heard a lot about he's published on it, he's looked at it, he's looked at weight, but from a clinical or actual impact it's meaningless. So, why are we going to let someone talk about something if it's meaningless.

There are two last things, your Honor. I would just come back to and leave your Honor with this. In my experience, at least, in looking through the case law, it's somewhat unprecedented to have kind of a panoply of experts particularly on materials who have not looked at the data, they don't know anything about the specifics of C-Qur, they haven't actually tested it, they don't have any studies, clinical studies of how it's used in human beings, they don't know how it has impacted in the body with respect to pH, some of the other issues he talks about. The best they can say is maybe it is cytotoxic,

maybe it will cause a problem. It's possible.

And, again, the idea of, putting aside even just the general parameters of Daubert, this is at its core speculative testimony, right? The jury, if they're allowed to hear that, We can't tell you in "X" number of cases or the percentage that this actually happens, we've looked at it, we've seen it, as opposed to when we've done bench science testing and we've looked at the polymers and everything else we think it could perhaps degrade, when no one tells us that we've studied what a degradation looks like or what a migration looks like or the issues, to the extent there are any, with respect to the coating, how it affects any human beings, none of that has happened. They are smart folks. They've spent a lot of time and effort. You have to ask yourself why is it that you wouldn't give these folks the actual materials, the data, before you're going to let them testify before a jury?

MR. ORENT: Your Honor, if I might just respond to that very briefly, what Mr. Cheffo is doing is he's arguing against First Circuit law. The Milward case explicitly says you don't need epidemiology, and in this case there is no epidemiology. Dr. Klinge explains this, that there is no registry, there's no large-scale human studies on this product, and there couldn't be, because it would be unethical to test a product on humans for certain end points and cut them open. He talks about that.

And to say that these opinions aren't based on these products is just misleading. If your Honor looks at page 21 of 50 of our attachments, this is Atrium's own words, internal: Conclusion: Atrium bare polypropylene mesh outperformed similar bare polypropylene mesh in a study where one-twenty-one were explanted due to relapse. That's a study that they quote Klinge on, okay? He's using the base polymer that's in this product. There are lots of other things.

Now, with regard to the statement that Mr. Cheffo just read about weight, what he's talking about is the relative importance between porosity and weight of mesh, and if your Honor reads that entire soliloquy or back and forth, rather, your Honor will see that what Dr. Klinge ultimately says is, Look, the single most determinative factor in whether a hernia mesh is going to work is not material and it's not weight. It is pore size. He then talks about these publicly available descriptions of light, medium-weight meshes. There's no true definition. What you really need to do is get into the nitty-gritty and see what is the definition of a lightweight, what's the definition of a medium weight. Again, you have to look at the devil's in the details, and these out-of-context quotes are not fair representations as to what his balanced testimony is.

Again, going back to the cytotoxicity issue, there's no question in Dr. Klinge's mind that this is a bad product in

regard to the tissue response to it at that level because of alterations in the pH. No question about it. The question is, is it technically cytotoxic to that definition, to the definition where it kills cells on contact? There's certainly reason to believe it. There are the studies on cell inhibition and cell growth inhibition, and this particular product failed the MEM elution test. Dr. Klinge relies on that, but he is not willing to go to that one step further and say beyond it's a concern because he doesn't have the amount of data that he's willing to say that.

That's very different when you talk about the biomechanics of the mesh. Dr. Klinge actually is the first human being on this planet to determine what the needs of the abdominal wall are and determine, based on that, how much material strength in terms of newtons is actually needed. And when he says it's over-engineered, what he talks about is that it only needs to be, I think it's 32 newtons, though I could be mistaken at this point, he states what that strength level is, and that because they use more material than is necessary it creates an excess inflammatory response. That's what he means by "over-engineered."

He also talks about this excess inflammatory response can do X, Y and Z, including creating an additional scar plate, which inhibits motion, which causes pain, which causes contracture, which causes all the hallmark injuries that our

client suffered. So, when I say that he is peer reviewed on each of these elements, each of these elements is not only directly relevant to polypropylene mesh that is well known and well accepted, but actually, again, he is very well aware of the base mesh and the coatings and has done as much work as anybody and relied upon multiple lines, human studies, animal studies, cellular responses, he's looked at all of the different types of data available and formed his opinions in very much the same way that the Bradford Hill criteria would be utilized, and it is totally consistent with the Milward opinion.

And if Mr. Cheffo, his statement as to what level of proof is necessary, Atrium certainly never maintained that data. We're not able to get that data. It just doesn't exist, and the First Circuit does not require it. Thank you, your Honor.

THE COURT: Okay.

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

THE COURT: I will tell you that I haven't really reined in on this particular motion. I don't want to rein you in, Attorney Cheffo, because I don't think you've gone over your time, and I certainly asked a lot of questions and interrupted folks. So, I want to give you maybe a couple of minutes here. Go ahead.

MR. CHEFFO: Yeah, thank you, your Honor. I think on

this one, Mr. Orent has I think on this one really mischaracterized what we're saying here. We understand the First Circuit law. No one's saying it has to be epidemiology. What you're hearing a lot, I think you'll either hear it at trial, if you allow all these motions, but what you're hearing is kind of lawyer argument about filling in all the blanks. We've all read these reports. This is exactly what we're not supposed to be doing, saying, well, here's what he really meant and when he talked about heavyweight. You haven't heard at all today a reason as to why someone didn't actually test this, why they didn't actually use this particular product, right, why they didn't actually run those tests. We've heard every explanation and excuse possible where there's no epidemiology. But there are -- there's not that many -- there are clinical trial data, there are studies, and the point is, if there's no data to form conclusions, then you shouldn't have those opinions and conclusions.

And our point of what we're saying, it's not for Mr. Orent, as a good litigator, to explain away what may happen. It's to look at what they actually said. And the reality is -- we've heard a lot now about pore size, right? Again, Dr. Langstein doesn't talk about this, right? So, the idea is that it has to -- all of these kind of potential, hypothetical, theoretical issues in the abstract -- he keeps talking about polypropylene, right? And the plaintiffs can't

have it come out of both sides of their mouth -- because I guarantee you, your Honor, what you're going to first hear in this case is that, because everybody knows polypropylene is used in all kinds of products, right? It's in the body. It's been studied for 60 years, right? The FDA has approved it, allowed it over and over again. So, what they're going to then do is say, Oh, but this product is different, right, it has this mesh coating? So, on the one hand, they want you to say we don't even have to look at the product, because it's just like polypropylene, but then their whole case or at least some of their case will be talking about, based on what their experts have said, on the specifics of C-Qur. And it's, again, incredibly I think unprecedented that you would have these folks come in and not ever having tested. Forget about doing clinical trials or epi-data or other stuff. We're talking about even just basic testing and looking at the actual testing and showing it, and what they've looked at they have not formed any definitive conclusions. Mr. Orent has in his closing argument that we're hearing, but that's not what the experts have done, your Honor.

THE COURT: All right. What are maybe two or three differences between Atrium's polypropylene and other polypropylene? Give me maybe three differences.

MR. CHEFFO: Me, your Honor?

THE COURT: Yes.

MR. CHEFFO: Let me say this: It's the plaintiffs' argument that -- so objectively there's mesh, right, that is polypropylene? People call it "bare mesh," right? And then there is coated mesh, and it has a coating, and one thing that is different is that -- the plaintiffs like to call it "fish oil" -- it's Omega-3 fatty acid. Whatever you do there is a coating on, there because one of the issues, right, is that, when you place the mesh between usually your abdominal wall and an intestine, you want it to integrate into your abdominal wall, right, so it forms a barrier, but you don't want it to adhere to other organs, right? So, that's a coating between the mesh. That's kind of generally what happens. A hernia is when your intestine comes through your abdominal wall. So, that's one issue. But, again, the plaintiffs, on the one hand, are saying that there's different antioxidant packages, and they don't have the difference. So, it's not a monolithic. It's not exactly the same process or how it's manufactured as to everything.

THE COURT: Okay. I think with respect to Klinge, I have carefully considered everything you filed, and let me just start with the last argument, what Atrium knew. We spent a lot of time on this. I think you know where I stand on that. I'm going to make my ruling the same as I did with respect to Langstein. The argument is the same. But, depending upon how the evidence comes in, I'm willing to revisit that, as it could

certainly cross a line into impermissible state of mind testimony. I just need to hear it in context, and I just can't get that context from the papers at this stage.

So, with respect to what Atrium knew, I think you know my ruling is I'm denying it, but I'm open to revisiting it, depending upon what happens.

With respect to the other arguments concerning Klinge, I'm just going to sound like a total broken record here, but I'm, once again, very -- I'm persuaded that ultimately these arguments go to weight, not admissibility, and I can just hear the line of cross with Mr. Cheffo cross-examining Klinge: You've never dealt with C-Qur mesh? That's correct, sir. You've never seen data on C-Qur mesh? You've never tested the C-Qur mesh that was used in Ms. Barron's surgery? You have no evidence that the C-Qur mesh degraded? I can just hear the line of cross, and it would go and go, and it would be potentially effective. But, again, Attorney Orent is correct that ultimately the First Circuit does not require that there have been testing on the actual C-Qur mesh at issue here in the case.

So, let me go through my denial with respect to Dr. Klinge and explain why I'm denying defendants' motion to exclude his testimony. First, to the extent defendants seek to prevent Klinge from opining as to the design defects in Atrium's product because he purportedly ignores contrary and

relevant information without adequate explanation, the motion is denied for the following reasons:

Defendants correctly note that in deposition Klinge expressed disagreement with some of the conclusions expressed by authors of a study he relied upon in partial support of his own opinion. The study in question was a histomorphologic study of C-Qur devices implanted in rats and was conducted by Atrium. However, Klinge relied on the study only for certain of his findings, namely, that after Atrium's C-Qur mesh was implanted in rats all subjects displayed fibrotic reactions in the first three weeks after implantation, and subjects displayed high rates of encapsulation and vascularization, as well as adhesions, granulomas and evidence of pore ingrowth. Klinge's reliance on that data is not inconsistent with his disagreement with some of the authors' conclusions, including the conclusions that after 24 months subjects showed favorable tissue responses and the meshes were well implanted, or that by seven months subjects displayed biologically stable tissue responses. Klinge's reliance on that data, in particular, on data collected in the first few weeks after implantation is not in conflict with the authors' conclusions. Indeed, Klinge does not address the authors' overall conclusions regarding the effectiveness of the mesh in his opinion.

Moreover, in deposition Klinge provided a detailed explanation for his disagreement with the authors' overall

conclusions. For example, Klinge disagreed with the metric the authors used to determine whether the mesh was well implanted, opining that, although the meshes were implanted, there was an undesirably small space between the individual fibers of the mesh.

To the extent defendants seek to prevent Klinge from opining as to the inflammatory and fibrotic activity of the foreign-body reaction and the biomechanical impact of Atrium's product on human tissue, the motion is denied for the following reasons:

Defendants correctly note that, in support of his opinion on these matters, Klinge did not rely on human clinical studies and did not rely on studies specifically comparing Atrium's product with other surgical meshes. However, First Circuit jurisprudence establishes that an expert's failure to rely on human clinical studies or, indeed, on any particular form of scientific evidence or data does not render the expert's opinion so unreliable as to be inadmissible.

Again, that comes right out of Milward Number One, 639 F.3d 11. Milward also establishes that, even if the factual underpinning of an expert's opinion is weak or perceived as weak, that weakness is a matter affecting the weight and credibility of the testimony rather than its admissibility. Moreover, again, defendants' arguments do not address the traditional indicia of methodological unreliability, that is,

absence of peer review, absence of acceptance in the scientific community, unacceptable error rate, failure to explain methodology and so forth, as I've already held earlier today. Defendants do not challenge the methodological reliability of the animal studies on which Klinge relies but, rather, challenge only the absence of data from human subjects and the absence of data from Atrium's specific product. These challenges go to weight rather than admissibility.

To the extent defendants seek to prevent Klinge from opining that polypropylene can degrade in the human body following implantation, the motion is denied for the following reasons:

Defendants correctly note that in support of his opinion on these matters Klinge did not rely on studies or experience specifically involving Atrium's product. In addition, Klinge does not opine that the product will necessarily degrade following implantation. Further, Klinge concedes that not all clinical implications of polypropylene degradation following implantation are known. As to Klinge's reliance on studies that involved products other than Atrium's, once again, that argument goes to weight rather than to admissibility.

As to the uncertainty Klinge expressed regarding whether degradation will always occur following implantation and as to the clinical effects such degradation would cause, it

is well established that lack of certainty is not for a qualified expert the same thing as guesswork or speculation. Klinge offers extensive expert opinion as to the mechanisms by which the properties of degraded polypropylene could be expected to lead to adverse clinical outcomes. The fact that Klinge declined to opine that those mechanisms would always be at issue or would always lead to adverse outcomes does not render his opinion unreliable, speculative or unhelpful. Defendants do not challenge the reliability of Klinge's methods but, rather, challenge only the strength of the data he relies on and the probabilistic nature of his opinion. Again, these challenges go to weight rather than admissibility.

To the extent defendants seek to prevent Klinge from offering opinion as to the applications of oxidation induction time testing of polypropylene degradation rates, the motion is denied for the following reasons. I'm going to try to explain here my understanding from the reading and the materials, what oxidative induction time testing does. It determines the thermal stabilization of a polymer by measuring the time between melting and decomposition of the polymer typically at a heat between 190 and 220 degrees Celsius. Klinge relies, in part, on an oxidative induction time testing performed by Atrium to compare one of its polypropylene surgical mesh products with a similar product produced by one of its competitors. Based on the reported results of that testing,

Klinge opines that the results have alarming implications for Atrium, in particular, given that Atrium's manufacturing process involves curing its C-Qur mesh at temperatures above 200 degrees Celsius.

Defendants correctly note that Klinge is not an expert in oxidative induction time testing. However, again, it's well established that an expert need not be a specialist to offer admissible testimony so long as the expert has achieved a meaningful threshold of expertise in a given area. Moreover, an expert need not have expertise in every experimental method employed in the studies upon which the expert relies in order to offer reliable opinion as to the implications of the results generated by the experiments. Klinge is a qualified expert on the use of surgical meshes and hernia repair, having performed over 300 hernia repairs using textile meshes and having extensively studied oxidative degradation in polypropylene meshes. Klinge is qualified to opine as to the implications of the results of Atrium's oxidative induction time testing.

To the extent defendants seek to prevent Klinge from offering opinion as to design defects in the fish oil coating of Atrium's product, the motion is denied for the following reasons:

Defendants argue that Klinge's opinion regarding the fish oil coating of the C-Qur mesh are unreliable and speculative, because Klinge is purportedly unwilling to offer

firm opinion that the coating is cytotoxic and because Klinge relies, in part, on *in vitro* studies. As to Klinge's purported unwillingness to offer firm opinion that the fish oil is cytotoxic, the Court notes preliminarily that Klinge does, in fact, offer opinion as to the cytotoxicity of the coating. Specifically, Klinge opines, with supporting citations, that the cytotoxicity of the fatty acids remaining after the curing process was acknowledged by Atrium and WuXi App Tec, the testing company engaged by Atrium. "The testing demonstrating cytotoxicity of its coated mesh was secondary to the fatty acids remaining after curing of the fish oil, which caused disruption of the cell membrane." I'm lifting that language about cytotoxicity from document number 99-1 at page 22. This supports his conclusion that "the cytotoxicity of the coating leads to cell death, chronic inflammation and increased risk of infection," same document at page 3.

Moreover, even if Klinge opined only to potential as opposed to certain cytotoxicity, as noted, lack of certainty is not for a qualified expert the same thing as guesswork or speculation. The purported lack of certainty in Klinge's cytotoxicity opinion is not grounds for exclusion.

As to Klinge's partial reliance on *in vitro* studies, laboratory studies of reactions taking place outside the body, *in vitro*, as noted, an expert's failure to rely on human clinical studies or, indeed, on any particular form of

scientific evidence or data does not render the expert's opinion so unreliable as to be inadmissible.

Again, I would cite the two Milward -- the older Milward opinion for those propositions.

To the extent defendants seek to prevent Klinge from offering opinion as to whether the fish oil coating of Atrium's product causes harmful changes to pH levels, acidity in the body following implantation, the motion is denied for the following reasons:

Defendants argue that Klinge's opinions regarding pH changes caused by the fish oil coating of the C-Qur mesh are unreliable and speculative, because Klinge purportedly lacks data showing that increased acidity is associated with adverse clinical outcomes. As a preliminary matter, the Court notes that Klinge cites extensive data that in his opinion establish adverse clinical affects caused by increases in acidity, document 99-1 at page 22. Moreover, to the extent defendants challenge the soundness of the data upon which Klinge relies, as noted, it is well settled that the soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact. When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony. Again, that comes right out of Milward, 639 F.3d, at page 22.

Defendants' argument, to the extent accurately premised, therefore, goes to the weight rather than to the admissibility.

To the extent defendants seek to prevent Klinge from offering opinion based on anecdotal evidence, the motion is denied for the following reasons:

Defendants note correctly that Klinge cites anecdotal reports in partial support of portions of his opinion. Specifically, Klinge opines that Atrium also received complaints from physicians implanting C-Qur devices who were experiencing high rates of infection and inflammatory responses in patients, and that, "In 2011, a Dr. Mazen alerted Atrium to the fact that he was seeing about 90 to 95 percent infection rates after the implant of a C-Qur device." That comes from document 99-1 at 11.

The Court agrees with defendants that Klinge's causation opinion would be methodologically unreliable if Klinge based his opinion solely on such anecdotal evidence. However, Klinge recites the anecdotal evidence together with extensive experimental and other sources of evidence. Klinge's limited partial reliance on anecdotal reports does not render his causation opinion so unreliable as to warrant exclusion, again relying on Milward.

To the extent defendants seek to prevent Klinge from offering opinion regarding inflammatory markers, the motion is denied for the following reasons:

Defendants note correctly that Klinge discusses the results of studies associating implanted polypropylene meshes with increased inflammatory markers relative to implanted textile meshes. Defendants further correctly note that these studies did not involve Atrium's product but, rather, other polypropylene surgical meshes. Defendants argue that, because these studies did not test Atrium's products specifically, they are irrelevant to any issue the jury will be called upon to decide. The Court disagrees. To the extent that Klinge's opinion regarding inflammatory markers is based on studies that did not involve Atrium's product, defendants' arguments go to weight rather than credibility. As noted, it is well settled that -- and I'm saying this now for I think the tenth time -- the soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact. When the factual underpinnings of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony, again quoting from Milward.

And, finally, with respect to mesh weight, to the extent defendants seek to prevent Klinge from offering opinion regarding the effect of mesh weight on clinical outcomes, the motion is denied for the following reasons:

Defendants note correctly that Klinge concedes that there is no consensus definition of lightweight versus

heavyweight in the context of surgical meshes. Based on this absence of consensus, defendants assert that Klinge's opinion regarding the effects of mesh weight on clinical outcomes is necessarily speculative and unreliable. The Court disagrees. In fact, Klinge notes that in the absence of a consensus definition of lightweight versus heavyweight in the context of surgical meshes, it is impossible to rely on a mesh manufacturer's characterization of a mesh as light or heavy when comparing meshes. For this reason, Klinge explains it is necessary for him and other researchers to look past manufacturers' characterizations of their mesh products to the products' actual characteristics to determine their relative heaviness. Klinge then discusses studies finding that lighter meshes with larger pore sizes tended to be more biocompatible than heavier meshes or meshes with smaller pores. Defendants' straw argument regarding the absence of a consensus definition of lightweight versus heavyweight in the context of surgical meshes does not go to methodological reliability, therefore, that portion of the motion is denied, and the Court denies the motion *in toto*.

With respect to what Atrium knew, I think you know that can be revisited.

All right. We have one motion left, and I can see that Mr. LaFata is ready to go. We saved the best for last, Mr. LaFata. So, I'm not sure how you can beat Cheffo,

Armstrong and Orent, but I'll give you an opportunity. Eager to hear from you, so go ahead on our final motion to exclude Dunn, Russell Dunn.

MR. LAFATA: Yes, your Honor. Thank you. Can you hear and see me clearly? This is the first time I'm speaking. I want to make sure. Okay, great.

Well, as you've recited, Russell Dunn is the next motion up, and we filed a Daubert motion on him. He's a chemical engineer. I know you've read the papers, and his opinion is that C-Qur is defective because the polypropylene in it can oxidize, and he determined that in a laboratory setting. This may be unlike some of the other Daubert motions that the Court has been ruling on today. It is not against a blank backdrop, and we have recited this in our papers. Dr. Dunn has been excluded repeatedly under Daubert for rendering many of the same opinions that are presented before the Court right now in this motion.

The first point in our brief, though, you instructed us to go by the order of the brief, is that Dr. Dunn does not have the necessary expertise under Rule 702 to opine that C-Qur is defective. The defectiveness of C-Qur, which is a medical device, has to involve assessing how it performs as a medical device, that is, how it is implanted. It's not about whether it performs this way or that way in a laboratory, and that's really what Dr. Dunn is doing.

Dr. Dunn admits he does not have expertise in by biocompatibility, which is how medical devices would perform inside the body, or biomaterials or medical devices. Simply, he is not a medical device expert. So, he's a chemical engineer. He can do experiments in a laboratory, but he doesn't design medical devices, he doesn't for companies who develop medical devices. This is not his area of expertise. He's been pulled out of his areas of expertise and put into court to render an opinion that a medical device is defective, in this case C-Qur.

This is partly why Dr. Dunn has been excluded repeatedly under Daubert in mesh cases. These are the Boston Scientific cases that we cited for the Court. This is the Mathison case, 215 WL 2124991, is the one that I'm referring to here. On page 22 -- 21, rather, the Court had acknowledged that all of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body. So, that's exactly the same opinion he's rendering here, that his belief is premised, his opinion is premised on this view that polypropylene mesh will undergo oxidative degradation, back to Mathison. Yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility, same thing we have here, and in that case that he's not qualified to opine on the way that polypropylene may affect the body physiologically. That's exactly the same as we have here.

And Dr. Dunn, to his credit, acknowledges this often in deposition. He cannot say what effect the polypropylene will have on the body physiologically. He's not a doctor. He doesn't implant hernia mesh. He's a chemist. He's a chemical engineer. The problem, though, is to proffer him as an expert to say that a medical device is defective is inherently drawing in the performance of that device in the body.

Now, the Court has referred to the Milward versus Acuity case in the First Circuit often today. I think it's important to note that that case would not apply to this motion. In that case, on page 15, the Court said that it was uncontested that the expert in that case had the expertise necessary to render the opinion that he rendered in that case. So the District Judge did not have to pass on that, and the First Circuit didn't rule on that. In that case, this is also from page 15, that expert was, quote, acknowledged as a leading expert on the study of the toxic effects of chemicals and drugs on the human body. So, in this case we do not have an expert who has expertise on the effects of a polypropylene medical device on the human body.

THE COURT: Can I stop you? I just want to make sure I understand Dunn is an expert in this case primarily for *in vitro*. No? I'm understanding Dunn to sort of 99 percent of his report and his testimony would be *in vitro*, he says something rather almost in passing about *in vivo*, and that

that's the issue you're having a problem with. In other words, 99 percent of his testimony you don't have a problem with, because he's qualified. It's just when he opines about *in vivo* effects?

MR. LAFATA: Well, with respect, your Honor, I think it's more than that. Page 49 of his report, the entire heading is Atrium's C-Qur Devices are Defective Devices (sic). You cannot render an opinion on whether a medical device is defective from a test tube. The performance of a medical device depends on what it does in the human body. So, it's an attempt, I think, to salvage Dr. Dunn by saying that he is only talking about laboratory test tube testing, but that's inconsistent with presenting his opinion that the product is defective, and that's why this Court over and over again, the Boston Scientific Court, has held that Daubert does not permit Dr. Dunn to bring that kind of an opinion in Federal Court. Those are the authorities I think that are persuasive here and not Milward, because Milward is a situation where this was not a subject of dispute.

Another point I think --

THE COURT: Can I ask you a quick question?

MR. LAFATA: Please. Yes.

THE COURT: So, Dunn was not allowed to testify in Boston Scientific because he was not an *in vivo* expert, but he was permitted to testify in many other cases. I think he was

permitted in Ethicon, he was permitted in Bolt, he was permitted in both Ethicon cases, the South Dakota and the West Virginia, I think. So, maybe you could help me understand why he was permitted in all those other cases but Boston Scientific excluded him. Did he go too far in terms of his *in vivo* statements, opinions in those -- go ahead.

MR. LAFATA: That question is briefly addressed in our papers. In Ethicon -- and, actually, I think the Court in Mathison addressed this, too. In Ethicon Dr. Dunn's expertise were not challenged, so that is one of the important differences between Mathison and Ethicon, according to that Court, and that's another way in which Milward is being distinguished here. There's a direct challenge to the applicability of his expertise in this case. How? He's a chemical engineer who has plenty of expertise in the laboratory but is being proffered to say on page 49 in his report that this is a defective device, a medical device is defective. He does not have the expertise, and he admits this, to say what the performance of a medical device would be in the human body; ergo he cannot say that a medical device is defective.

THE COURT: Isn't he making that statement based largely on the chemical at issue, the polypropylene?

MR. LAFATA: I agree with that. He is making that statement based largely on the chemical, and that's part of the problem, because a chemist can have a viewpoint about a

chemical in a laboratory, but that's different than how a chemical performs in the human body. That's why we have experts who analyze the performance of a medical device in the human body. And Dr. Dunn, again to his credit, is not claiming that that's him, but the attorneys who are proffering him are putting him in the position of saying that this is a defective device. That is intertwined with the performance of this compound in the human body. You can't say that's a defective device if you don't know how a medical device will actually perform. And when we kind of confronted him with the studies about the actual performance of C-Qur in the human body, plenty of studies and lots of patients who have had success with it, it's simply being pushed aside as, Not my area of expertise. But, again, that's the problem, your Honor, and that's why under Rule 702 this is not an expert who can come in. That's why under Boston Scientific the Court held that Daubert and Rule 702 don't permit this type of opinion.

THE COURT: Let me ask you, though, could I limit him to talking about the inherent properties of polypropylene as a polymer? I mean, he's clearly qualified to talk about that.

MR. LAFATA: And that kind of goes to the second point in our brief, your Honor, which is that laboratory opinions about generic properties of polypropylene do not have the Daubert requirement of fit, and what that means is there has to be a sufficient connection to the facts of this case. This

case is about a medical device, not just an abstract analysis of a chemical.

So, we explained some of this in the references to his deposition. Dr. Dunn doesn't know whether any laboratory degradation would happened inside the body, and even if it did happen he doesn't know whether that would compromise the safety of the product. So, on page 136 of the deposition he was asked, Does the fact that a polypropylene medical device can potentially degrade make it defective? His answer is, Not in of itself.

So, the problem is a theoretical opinion of a chemist may be interesting in a faculty room or in a journal, but in a courtroom Daubert requires a connection between a theoretical opinion and the question the jury has to answer.

So it continues. On page 133, Dr. Dunn admitted the polypropylene mesh actually might be safe for use in the human body. He says that degradation, quote, doesn't mean that it wouldn't be safe. So, under Daubert it would be extremely I think misleading and confusing to the jury to have a chemical engineer come in and say there's a defect in polypropylene, and, therefore, there's a defect in C-Qur, and I don't know how it works in the human body, because they're intertwined. You can't analytically separate the performance of a compound when it's supposed to perform in a human body.

THE COURT: Let me just ask you, because I'm

definitely hearing what you're saying, what about the fact that he has written in peer-reviewed journals? I think he has also written chapters in books, and he has opined on oxidation and degradation of polypropylene in the transvaginal mesh cases.

MR. LAFATA: Yes, your Honor.

THE COURT: Why wouldn't that be enough in terms of qualifications for him to say what ends up being a small portion of his report, that, in essence, This chemical of which I am an expert, about which I'm an expert, this chemical inside the human body would be a hazard or would cause me concern?

MR. LAFATA: So, a couple of responses to that. Number one, I don't think it would be accurate, respectfully, to say this is a small part of his report, because this is an expert being proffered to say the product at issue in the case is defective. So, in my view, I would submit that is the core of his opinion in the case, and that that was what was excluded in Boston Scientific.

But to your question about the literature, and we discussed this briefly, I believe, in our brief on page 9, I think it is, that this is an expert who has not published on medical devices except when he was retained as an expert in medical device litigation in which he and Dr. Guelcher published together in an article, and I think the Court is probably familiar with case law that litigation-driven opinions deserve skepticism. It is often the case that experts may have

some incentive to kind of shore up their credentials, especially if they have been excluded repeatedly under Daubert, but that is not the same thing as the scientific behavior in the scientific field.

And the Court should I think be wary about making sure you're getting genuine science in the courtroom as opposed to a genuine scientist who's coming in to speculate, and that's what I think is the danger the Court is facing with allowing someone like Dr. Dunn to come in, and I believe, again, that's why he's been repeatedly excluded.

Dr. Dunn admitted on page 182 along the same lines, that whether there's a mechanical failure in polypropylene and whether that has any physiological effect on the patient is beyond his expertise. So, it would be a bit -- it's kind of an appendage opinion, your Honor, to the panoply of experts that the plaintiffs will be allowed to present in the trial based on your rulings today. This is not an expert who is really adding to the -- it's an appendage, and I think it would be highly confusing under 403 to bring something like this in.

But the third point that we said in the brief -- I'm just mindful of the time; I know you gave some guidance on that -- if Dr. Dunn says that he has concerns and questions about polypropylene as a medical device, Dr. Dunn is certainly entitled to his concerns and his questions, but Daubert says on page 90 that to come to court and testify and give an expert

opinion you need, quote, more than subjective belief and unsupported speculation. Your concerns may be valid in another forum, but the courtroom's not the place for that. The plaintiffs have the burden here, your Honor. They have to come forward and say that elements of Rule 702 are met for Dr. Dunn.

And continuing with this, for example, he says on page 93 of his deposition, Studies on this material outside the body and my testing and my work raise a concern over what may be happening *in vivo*. So, what this is, is someone who's done laboratory testing and has worries about what will happen outside the lab. That's not an admissible expert opinion.

The last part of the brief that we talked about has to do with some chemical tests. These tests were excluded in the Boston Scientific opinions that we cite for the Court. In this case Dr. Dunn bought some polypropylene mesh on the market commercially, he put it in some bleach in the laboratory, and he found that it oxidized. This was commercially available polypropylene, according to his report at page 30. He says it's similar to what's used in hernia and transvaginal mesh, but it is not the same.

I'm just mindful of the time. I'll briefly wrap up, your Honor.

On page 30 he's pretty clear that he's not testing C-Qur, so Dr. Dunn did not take C-Qur and put it in bleach and see if it oxidized. He was testing generic polypropylene.

This was excluded in the Boston Scientific court on page 22 as lacking sufficient indicia of reliability. There is no written protocol he filed, as the Court explained. There was not a sufficient sample size, as the Court explained. In this case he's testing a sample. Plaintiffs' lawyer sent him a sample of two different kinds of C-Qur mesh, and he did not test those in a chemical sense to see if there is oxidation. He put them in the machine to see if there is oxidative behavior, once it's been opened and once it's been kind of whatever's going on in the laboratory. We really don't know. So, that's the test that is there. But the rest of it was excluded here, your Honor.

And I'm just mindful I'm over the time, so I'll just wrap it up there. Thank you very much.

THE COURT: No, I appreciate that. You're just one minute over, and I interrupted you multiple times, so I'm fine with that.

Okay. So, Attorney Orent, help me out with this one in terms of Russell Dunn and whether or not he can testify to the *in vivo* statements that he makes. They're not challenging his expertise with respect to *in vitro* science, but they are saying to me that he does not have the qualifications. This is somewhat different than he's relying on "X" and he shouldn't be relying on "X," or he's not using this. They're saying he's not qualified to opine on the *in vivo* effects of polypropylene

and the C-Qur product.

MR. ORENT: So, let me just back up and say Dr. Dunn does clarify, and there have been all of these statements made about him where he says, quote, unquote, I'm not a biomaterials expert. He clarifies that he is a materials expert, biomaterials expert, with regard to polymers. That's one thing.

However, I think that the real issue is this: Can Dr. Dunn say that this device is defective based on the performance of the polymer? I think the answer is yes, and here's why: Dr. Dunn understands that there is a set of performance specifications. There are requirements that this product must fulfill. It must last a lifetime. If the product is not able to withstand, the polymer is not able to withstand the chemicals that it will encounter over the lifetime, then it cannot meet its requirement, and I think that he is capable of saying that.

Beyond that, though, I don't think he intends to really say much more about it being, quote, unquote, defective. He really is talking about the manufacture process, the oxidation of it, and the polymer leading up to the point where it's placed in the body, where Dr. Guelcher will continue from there.

THE COURT: Are you willing to concede that he'll stop then, when he gets to the internal, when he gets to the *in vivo*

degradation, if you will, and won't opine as to a hazard or concern with respect to that? You're saying that he is an expert in biomaterials with respect to polymers, and with respect to that he can testify, but he won't go beyond that?

MR. ORENT: That's absolutely correct, your Honor.

THE COURT: Okay. Can I stop you just for a minute? And I know I'm cutting into your time, but just to try to shortcut this.

Mr. LaFata, if, in fact, he is limited just to the biomedical polymer expertise that he has and is not opining that *in vivo* degradation occurs and it is a hazard or concern, do you maintain your objection?

MR. LAFATA: Well, so, I'm not sure, because the way you frame it sounded a little differently from what I heard from -- so, if what I'm hearing correctly is that there is no hazard, as in this is not a defective device, then that I think would change --

THE COURT: He can testify as to polymers, and he does have an expertise with respect to polymers, and I think that's correct, based on my memory of reading all of Dr. Dunn's materials, but I will tell you that this expert gives me the most pause in terms of his ability to go that one step further and talk about a hazard, a concern. And he doesn't opine on the nature of the hazard, he doesn't give details. He's simply essentially making a glancing or a passing reference, and that

concerned me. So, I will tell you that I was inclined to grant this to the extent that I would exclude him from making those statements.

But let me have Attorney Orent jump back in, because I, obviously, cut him off. What I want to do is see if I can essentially reach some sort of stipulation on Mr. Dunn that would keep him within his wheelhouse, and then, essentially, we would have a much easier ruling on document number 100. I'm just trying to make my job a little easier. That's all.

MR. ORENT: Of course, your Honor, and we are willing to do that. You know, I think the word "concern" is perhaps what's caused the issue, or perhaps it's the use of the phrase "defective" in reference to the total product. I think it would be appropriate for me to ask him questions in the generic of, Would it be safe to use polypropylene in an application where it was intended to be exposed to oxidation for a lifetime and sort of the polymer aspect? That is, to put it another way, on page 4 we summarize his opinions, and those opinions I don't think run afoul of what we're all talking about. And maybe that's the cleanest way for me to say that, is that, as far as this aspect of his opinions, we're going to stay outside the body.

THE COURT: Okay. Let me say with this one I think I'm going to withhold any ruling on this, because I think that the two of you can come up with a way to limit Dr. Dunn's

testimony that will be acceptable to Mr. LaFata and acceptable to the Court. I'm sympathetic to his arguments, so I will go so far as to say that, but I have a sense, Mr. Orent, that you're willing to cut him off at a reasonable point, because I think I'm willing to agree with you that he's an expert in that limited respect in terms of the biomedical polymers, but beyond that I think Mr. LaFata makes some very good points.

So, I think, rather than rule on this, what I'd like to do is to send it back to you and have you reach an agreement to limit Dunn's testimony consistent with what we just talked about. If you're not able to do that and you still need me to rule on this, then put it in front of me, and I'll try to give you an opportunity to be heard briefly, and I'll try to give you a ruling on Dunn finally so that you know what ultimately I would do with him.

But I think I'm inclined favorably toward Mr. LaFata's arguments, except I do agree that, Mr. Orent, you're correct, I think that in that limited respect he's a biomedical expert, but that very limited respect, and if he's not going to testify about the hazard and the concerns of the *in vivo* implantation, then it seems to me that's going to remove I think a great deal of Mr. LaFata's objections. But I'm going send that one, punt that one back to you and see if you can't limit the scope of Dr. Dunn's testimony accordingly and then make my job just a little bit easier on him.

So, thank you, Mr. LaFata.

And thank you, Attorney Orent.

Thank you, Attorney Armstrong and Attorney Cheffo. Thank everybody who worked behind the scenes. As you have associates, I have law clerks, and they do good work, and you all do good work, and I benefit from it. And what I want to do is to give you rulings quickly so that you know what I'm going to do before trial starts, and so my effort is to try to give you these hearings. I'm going to hear from you. I will have read everything, but I'm going to hear you out and then try to give you a ruling that day so that you can leave with an understanding of what I'm going to do with your key experts.

So, those are the key medical experts of plaintiffs' case. Next time, and I don't think it's been scheduled yet, but we'll find a good schedule for the defendants' medical experts, so we'll be dealing with plaintiffs' motions. We'll do the same thing we did today with respect to timing. You did a great job, and I appreciate that.

So, unless anybody has anything else we need to talk about with respect to documents number 92, 96, 98 or 100, let me know. And it looks like Donna might have something to say.

Go ahead, Donna.

THE CLERK: I just was going to say, Judge, it is scheduled for a week from today, the 19th, at 1:00.

THE COURT: Okay. Well, that will give me one week.

So, I will get everything read and carefully prepared, and I'll look forward to hearing from counsel in one week. Is there anything else before we get off?

MR. ORENT: Two things, your Honor. First of all, plaintiffs are very mindful of your opinions today and your bases for those opinions, and we would request the ability before your Honor undertakes another round of Daubert review, I would like to make the offer that we go back and, certainly without prejudice to our clients, take another look, and if there are issues we think can come off the table in light of the context in which your Honor rules, perhaps that would be of benefit to everybody. So, I make that offer in the first instance, if that is attractive to your Honor.

THE COURT: That is very attractive to this judge, so I'd be willing to have Donna even reschedule the hearing, give yourselves another week, if that's going to help you. I'm not worried right now about the pandemic, because we're all on video, and you're all safely ensconced in your apartments or your homes. So, we can reschedule this in the next month or two when it's looking very, very dark even up here in New Hampshire in terms of our numbers. So, if you're willing to work on that, I'm completely open to that. That is music to my ears. So, to the extent you can narrow the scope of the upcoming hearing, please do so and feel free to consult with Donna about rescheduling it, although that's hard for her. She

does a lot of work putting these together and scheduling them in a time that works for you. So, if there's any way you can look at them quickly and resolve some of them, perhaps, or narrow the scope of some of them and get me that information before the currently scheduled hearing, I know Donna would be happy with that, and I like to make Donna happy.

In any event, I'm very open to that. I appreciate that, and I appreciate all the work of excellent counsel on the screen before me. So, thank you all very much, and I'll look forward to seeing you either in a week or two, and in the meantime, please, please, stay safe, be very careful, and have a Happy Thanksgiving.

MR. ORENT: Thank you. You as well, your Honor.

THE COURT: Take care.

MS. ARMSTRONG: Thanks, your Honor.

MR. CHEFFO: Thank you, your Honor.

(WHEREUPON, the proceedings adjourned at 4:34 p.m.)

C E R T I F I C A T E

I, Brenda K. Hancock, RMR, CRR and Official Court Reporter of the United States District Court, do hereby certify that the foregoing transcript constitutes, to the best of my skill and ability, a true and accurate transcription of my stenotype notes taken in the matter of In Re: Atrium Medical Corp. C-Qur Mesh Products Liability Litigation, No. 16-md-02753-LM.

Date: 11/24/20

/s/ *Brenda K. Hancock*
Brenda K. Hancock, RMR, CRR
Official Court Reporter