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 June 1, 2021 10:15 a.m.

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

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P R O C E E D I N G S

THE CLERK: For the record, this is a motion hearing in Barron versus Atrium, et al. It is 17-cv-742-LM. This is in the master MDL Atrium case, which is 16-md-2753-LM.

THE COURT: All right, everybody. So, I have my list of all the topics that we need to go over today. The major topics are, obviously, the motions *in limine*, defendant's motions *in limine* no. 2 and no. 7. No. 2 involves the exemplars I think more than no. 7. So, what I'm thinking is we start with no. 7, argue that, let me hear arguments, and then we'll do no. 2, and we'll talk about the exemplars, and I'll anticipate that you will include arguments with respect to the exemplars.

And when I say "exemplars," I'm talking about the exhibits that are attached, and I can, just for the record, let the record reflect that the exemplars are Defendant's Exhibits C through L that are at document numbers 220-3 through 220-12, and then for plaintiffs the exemplars are Exhibits 6 through 16, and they are at document number 222-6 through 16. So, defendant's exhibits use letter nomenclature, and plaintiff's exhibits are numbers that actually do correspond with the document number.

I'm thinking it might be best for you guys to refer to them as exhibits as opposed to the document numbers. I'm thinking that you will think of them and you will have written

notes reflecting these exhibits as using the exhibit numbers. Am I right about that? I think we should be consistent so that, if you're referring to Plaintiffs' Exhibit 12 you would use "Exhibit 12" as opposed to "Document Number 222-12." Same for defendants' exhibits; if you just refer to them by the letter name as opposed to "Document No. 220-" and then the corresponding number. I'm guessing that you have it by exhibit name. Is that correct? Does that make it easy for you to be consistent?

MR. ORENT: It does, your Honor, for the plaintiffs.

THE COURT: And it does -- I can see Attorney Van Tuyl shaking your head.

MS. VAN TUYL: That's correct.

THE COURT: All right. So, then, that way we will all refer to these exemplars by their exhibit nomenclature. All right.

And so, I'm thinking start with 7, then go to no. 2, and we'll, obviously, talk about the exemplars when we talk about no. 2. Anybody have an issue with that?

MS. ARMSTRONG: Your Honor, this is Katherine Armstrong. The way we had organized our argument was that we had sort of glommed (ph) Motions *in limine* 2 and 7 together in the supplemental brief that we filed, and what we had planned to do was we're dividing the argument between me and Ms. Van Tuyl. I was going to present an overview of our argument,

which would be applicable to both motions 2 and 7, and then I was going to turn it over to Ms. Van Tuyl, who will discuss the exemplars. We can stop after the overviews, since that will include motion *in limine* 7, if you want, before we get into the exemplars. But that was how we were planning on proceeding, if that works for the Court.

THE COURT: That is fine, and I want to, obviously, accommodate what works best for you as well.

MS. ARMSTRONG: We're just trying to avoid repetition on 2 and 7, because the arguments overlap significantly.

THE COURT: Yes. 7 deals really with the evidence of conditions that plaintiff has not experienced; and then no. 2 really deals with these MDRs and third-party complaints, and they regard other patients, other complaints, and you are moving to exclude them based on the fact that you argue they're not substantially similar. So, I think I can be persuaded to just join 2 and 7.

Do you have any problem with that, Attorney Orent --

MR. ORENT: I do not, your Honor.

THE COURT: -- if we do them together? Okay. All right. Let's do an overview of 2 and 7, if we could, along the lines that Attorney Armstrong talked about and then separate out no. 2 and the exemplars or just the exemplars. We'll leave those to the end. I can actually separate 7, I think, doctrinally a bit from 2. So, let's go ahead and make the

arguments with respect to 2 and 7, and if you want to throw in some exemplars that is fine, but we'll get to the exemplars and, I'll give you full argument time on those, whatever ultimately you feel like you need. So, let's hear arguments, then, from Attorney Armstrong on 2 and 7. And I know you're not going to address exemplars, Attorney Van Tuyl is.

But, Attorney Van Tuyl, if there's something you want to interject and say, I'm perfectly open to that, but we will give you full and fair time to talk about the exemplars.

So, go ahead, Attorney Armstrong, since they're your motions. We'll do an overview of your arguments on 2 and 7, and then I'll let Attorney Orent do an overview argument, and then we'll go from there.

MS. ARMSTRONG: Thank you, your Honor. Just to begin by way of review, because we've argued these motions once before, and with respect to at least motion 2 the Court excluded evidence of third-party complaints, medical devices, Medical Device Reports to the extent that such complaints or reports did not arise out of facts and circumstances substantially similar in material respects to the facts and circumstances underlying plaintiff's injury, i.e. the same surgical mesh product that was used in plaintiff's hernia surgery and injuries comparable in nature and etiology to plaintiff's. To the extent that such materials may be offered to establish defendant's knowledge of them, the Court further

excluded them except to the extent defendant received them or had the opportunity to review them prior to the date of plaintiff's hernia surgery, and the Court asked for the parties to submit supplemental briefing being more specific about exactly what "substantial similarity" meant and to provide some exemplars for the Court's review. So, that briefing has been submitted and the exemplars have been submitted.

So, just by way of overview, I think it's important to note that this is the first bellwether to be tried, so we think it's all the more important that tangential evidence having little probative value be excluded. It's also worth noting the parties have exchanged what are called short exhibit lists, which are a subset of the exhibit lists, and it's also worth noting that approximately one-third of the exhibits or about 100 documents would be covered by these motions. So, there's a substantial body of evidence at issue.

In terms of our argument, as we discussed last time with the Court, all of the plaintiff's claims, failure to warn, design defect and negligence, they require a causal nexus between plaintiff's specific injuries and the tortious conduct by Atrium, and, as a practical matter, plaintiff can either establish that causal nexus to her injuries or she cannot. If she can't establish a causal nexus between V-Patch and her injuries, then there's no reason to -- the jury should render a verdict for us, but there's no reason to introduce all this

other evidence. If she can, you know, then she doesn't need all the evidence dealing with other products and other injuries, if she can establish a specific causal nexus between the V-Patch and her injuries.

I also wanted to note that this is not a situation where if the Court were to grant our motion the plaintiffs would be precluded from introducing any evidence of complaints and MDRs. We're going to propose -- I will get to it in a minute -- we're going to propose certain criteria, we propose it in our paper, to satisfy the substantial similarity requirement, and there are documents that would meet those criteria. So, we're only talking about excluding some of plaintiff's evidence, not all of plaintiff's evidence, on complaints and MDRs.

The other thing I wanted to talk about, because I also wanted to reiterate, and we cited this in our opening papers and we discussed it last time, the First Circuit -- it's not a medical device or pharmaceutical decision, which is what we would tend to try to concentrate on, but this is a First Circuit decision where the court had held, "We need not probe the ramifications of this forfeiture because the argument puts the cart before the horse. Without a showing of substantial similarity, the evidence was not significantly probative, and evidence that is not significantly probative may be excluded entirely." And the court further held that the risk of

prejudice could not be cured by a limiting instruction. So, this substantial similarity requirement is quite important.

The other thing I wanted to address was the purpose of the MDL is not to preclude the Court -- if the Court grants an MDL the Court is not thereby precluded from revisiting any of her motion *in limine* rulings at trial where the Court is dealing with a specific document and has the circumstances in which it's entirely able to use. The plaintiffs can always approach the Court and say, We've established an appropriate foundation for the documents, whether it's a hearsay exception or something else. That's the plaintiff's burden, and if they think they've met that burden at trial as to a specific document, they're always free to approach the Court and say, We've met the burden as to this document. But we're talking about an entire category of documents.

Plaintiffs cite Sprint/United Management Company versus Mendelsohn, which is a Supreme Court decision, for the proposition that motions *in limine* may not be used to exclude entire categories of evidence, but the plaintiffs don't correctly state the Supreme Court's holding, which the Court did not hold that the District Court erred in granting a motion *in limine*. The Court of Appeals had treated the Court's ruling on the motion *in limine* as a per se rule that evidence with other supervisors was irrelevant to proving a discrimination in an ADA case. The Supreme Court held that the Court of Appeals

erred in treating it as a per se rule. And the court noted that the *in limine* motion did not suggest that the evidence is never admissible. Thus, even though the District Court granted the motion *in limine*, the Supreme Court held there was no basis in the record for concluding that the District Court applied a blanket rule. So, the error in Sprint was not a per se exclusion of evidence or was not the granting of the motion *in limine*. It was the Tenth Circuit's treatment of the motion *in limine* as a per se rule. The Supreme Court did not reverse the granting of the motion *in limine* and recognized that the District Court writ remained free to revisit any of its rulings.

The basic purpose of the motion *in limine* is to keep the parties from arguing in opening or prematurely publishing to a jury evidence that may be excluded by the Court. It gives the Court -- the Court makes a preliminary finding that, you know, the evidence is not relevant or not sufficiently probative. But, again, as to specific pieces of evidence the Court can always revisit those at trial. So, this is not the kind of categorical per se ruling that plaintiff -- we're not seeking that kind of per se ruling or categorical ruling that plaintiff suggests, because that's not the purpose of a motion *in limine*. It's never the purpose of the motion *in limine*.

So, we have tried, as the Court directed, to be more specific as to claims that are substantially similar, and we've

identified three criteria for the Court's consideration. The first is that it be the same product, and in this case that product is the C-Qur V-Patch mesh. Now, we want to clarify what we mean by this. We don't disagree that polypropylene was used in all of Atrium's surgical mesh products, and to the extent the evidence is offered on the suitability of polypropylene to be used in medical devices, we're not objecting on different product grounds as to that. They still have to meet the other two criteria that I'll get to, but we're not saying that -- we're not denying that polypropylene was used in all of these products and that evidence of the suitability of polypropylene for use in surgical mesh might be relevant if other criteria are met.

But to the extent they are focusing on other design aspects of the V-Patch which are not shared in common with other devices, then we would object to the evidence of other devices. And we've identified in our papers, I won't go over them here, but we've described in other papers what we think the salient aspects of the V-Patch design is.

Our second criteria is the same injury, and this is where it overlaps with motion 7, because motion 7 is to exclude evidence of other injuries, and the grounds for that exclusion is, again, that other injuries are not substantially similar, and, therefore, their probative value is insufficient. We've examined plaintiff's allegations, and we've examined her expert

reports. So, we've looked at those claimed injuries that are supported by expert testimony or proposed expert testimony from the plaintiffs, and it appears that plaintiff is alleging to experience inflammation resulting in infection, fistula and scarification. Scarification. I'm sorry if I said that wrong. Not trying to scare anybody; it's just scars.

So, infection, fistula and scarification due to the V-Patch. So, those are the injuries. Those are the injuries that we think there should be substantial similarity, or those would define what the substantial similarity requirement is, and that would exclude really sort of very different injuries such as -- you know, there's no allegation here that the mesh failed to adhere to the muscle or organ. There's no bowel resection here. There are a number of injuries that are alleged in the complaint that were not things that were experienced by Ms. Barron.

The plaintiffs try to say it's all the same thing because it all results from inflammation, and we believe that proves too much, and it provides an insufficient basis for the Court to establish a substantial similarity requirement, and the reason for that is that inflammation occurs with any surgery. It's part of the healing process. And so, you're going to expect inflammation following any surgery. So, all they have to show is that a particular complaint also included an allegation of inflammation and that's enough to show

substantial similarity. That's going to open the flood gates, and it's not going to provide a basis for excluding anything. So, again, we think their arguments regarding inflammation proves too much.

We've cited a number of courts that have excluded evidence of other injuries. They're cited in our briefs, so I'm not going to cite or discuss all of them, but they include Soldo and Sweitzer and In re: Davol, which is a mesh litigation, In re: Cook. And, again, I'm not going to cite all of them. Footnote 4 of our brief has numerous cases.

In addition to the design allegation, the argument about other injuries is also relevant to the failure to warn, because in a particular case you have to tie the inadequacy of the warning -- again, you have to show a causal connection with what was experienced by plaintiff. So, the duty to warn has to do with the duty to warn of the effects that were actually experienced by plaintiff. If it's another injury, then there's no causal connection between the failure to warn of another injury and the plaintiff's alleged injuries.

I'm not going to review all of our cases, but I do want to discuss plaintiff's cases for a minute, because they're either inapposite or they're actually consistent with our position. The first -- we're going to focus on cases involving pharmaceutical or medical devices, because we just think that those cases present unique issues of causation, making the

other cases inapposite, and most of the case cited by plaintiffs are not pharmaceutical or medical devices. But the way in which a human body reacts to a drug or medical device is highly idiosyncratic. It's not the same as a household appliance or an automotive device, automotive product.

Just discussing some of plaintiffs' cases, they cite Jones versus Textron. Again, this is consistent with our position, because it was the same product, it was the same circumstances as the plaintiff's. Plaintiffs also cite cases addressing the discoverability of the evidence rather than admissibility, which is not at issue here, but those cases include Contratto and Ingram. Plaintiffs also argue the relaxed standard when such evidence is offered on notice; however, the only case they cite in support is Pukt versus Nexgrill, which they incorrectly cite in their brief as "Joseph," which was Mr. Pukt's first name, not his last name. But there the plaintiffs allege that a same grill had a defect that started a fire, and the court excluded evidence of fires involving other grills that were different models, sizes and designs. So, the actual holding of the case is consistent with the position that we've taken here.

Other cases consistent with our position include Taylor, which is cited by plaintiff, where the evidence was limited to vaginal erosion, the plaintiff's injury, involving the same sling device, and Worsham versus A.H. Robins, where

the Court affirmed the admissibility of evidence regarding prior incidents involving the exact same injury alleged by plaintiff. So, the cases by plaintiffs really do not contradict the position that we are taking in this litigation.

The third criteria we have suggested that should be met to show substantial similarity are similar surgical circumstances. Ms. Barron's surgery was an initial repair of a ventral or umbilical hernia in an open procedure. So, courts have recognized that the circumstances of the incidents must be similar. Again, we cite cases in our brief supporting that, including Pukt, which is a case relied upon by plaintiff, Sweitzer and In re: Davol, and there are additional cases cited at pages 10 to 11 of our brief.

We're not making a distinction between ventral and umbilical. We think those are close enough that we're not making a distinction in that, but the mesh may have been used in different parts of the abdomen or in some cases the pelvis, which is actually an off-label use that was not promoted by Atrium. The surgeries may also be laparoscopic or open, and I think Ms. Barron's was an open surgery, which present very different risks, and so we think there ought to be circumstances, similar circumstances.

That is our overview of substantial similarity. There were previous aspects to our argument that were previously argued before the Court, so I won't get into those, unless the

Court wants us to. But other than that, I'm going to pause here and see if the Court has any questions or if the Court wants to let Mr. Orent do an overview before Ms. Van Tuyl begins her discussion of the exemplars, but when the Court says it's okay, I will pass the speaking baton to Ms. Van Tuyl.

THE COURT: All right. You said there were three prongs to your definition of substantial similarity. I just want to make sure I got all three. Basically same product. You do note, however, if the introductory purpose of the evidence is to show suitability of polypropylene, that you could see that meeting substantial similarity. Same injury, number two. And the third one was basically the same surgery?

MS. ARMSTRONG: Substantially similar surgery.

THE COURT: Gotcha.

MS. ARMSTRONG: Again, we're not distinguishing between ventral and hernia surgeries, but we are distinguishing between open and laparoscopic and ventral and hernia versus other parts of the body.

And if I could just clarify our position on the first prong, if it's introduced to show the suitability of polypropylene we're not objecting on the basis of that prong. We may still object on the basis that the other two prongs are not met.

THE COURT: All right. Now, let me, just before Attorney Orent gives his opening, let me just respond to the

issue of Sprint and -- I think you're describing it correctly. I think Attorney Orent's briefing also described it correctly and didn't mischaracterize it. Let me just say that because of this trial and the way I intend to run things, I know that I've given counsel a sense of the need in this case to keep the case moving. In other words, I don't want to have moments in the trial where the jury is twiddling its thumbs. So, while it's difficult to rule on specific evidence outside the context of the trial, particularly with regard to hearsay and Rule 403, I really need a context to make those types of rulings. I have given you or promised you, frankly, that I would give you a sense of how I'm likely to rule on specific exemplars, and my hope is that this kind of provisional ruling -- which is, I agree, subject to change if things happen that are different at the trial, the context ends up being very different than what the briefs described. So, I agree with what you're saying, Attorney Armstrong, but my hope is that I give you a provisional ruling so you have a sense of how the case is likely to come in should the context at trial be similar to the context that is presented to me in these arguments and briefs. I'm also hopeful that this exercise will assist everybody in resolving many evidentiary objections outside the presence of the jury.

Now, I want to reiterate my approach, which will be to conduct the trial such that I will trust the lawyers to get

their evidentiary objections ruled on in advance of the trial itself. In other words -- let me tell you what I mean by that. I'm not going to be happy to encounter objections to evidence that could have been ruled on outside the presence of the jury, okay? I'm going to give you advance, as I said, provisional rulings here, because that way you'll be better able to plan your objections and make a record outside the presence of the jury, for example, in the early hours before we start the trial or after the close of trial every day. Trial's going to start at 9:00 and end every day at 4:00 p.m. I intend to meet with counsel every single day of trial at 8:00 a.m. in the morning so we have one hour where you can put issues in front of me and at 4:00 p.m. after the jury leaves for the day, and I'm going to hopefully limit that to an hour so you can go back for the end of the day, have some supper and relax.

But that is where I am hoping to resolve evidentiary objections. Some of them could be done in bulk, I think, just as you have supplied exemplars to me here. I know that they are exemplars, because they are examples of, if you will, buckets of other evidence that you intend or you think the plaintiff will attempt to admit. I think that we can move through the trial this way. You could make your objection in the middle of trial, preserve it for the record as it's being introduced, and unless the issue is brand new, and, of could, that happens in a trial, but unless it's brand new we shouldn't

need a sidebar. I will make records throughout the arguments with respect to evidentiary issues in the morning, at lunch, and after the jury leaves. There will be a record of you having objected, plaintiffs and defendants, to any of my rulings, but then in the middle of the trial you need to preserve your objection. You can object, I can indicate "Overruled" or "Sustained" for the reasons stated in an earlier hearing. We won't need a sidebar.

I've summonsed a jury to come to the courthouse to breathe shared air during a pandemic, and I'm not going to expose them to one second of breathing shared air, and when lawyers and judges are talking perhaps hot air, that involves them twiddling their thumbs waiting for an evidentiary hearing.

I hope counsel's clear on this. I will check in with you every morning and every afternoon to see what issues I can resolve for you before the trial starts that day or ends at the end of the day. I'll use the lunch hour to do the same. We will be efficient and keep the trial moving that way. So, my hope is that I give you a sense of how I will rule, likely rule. You know how the evidence is likely to come in. I don't necessarily. I am giving you provisional rulings to help you gauge how I'm likely to rule with respect to this evidence at trial. So, I'm going to do my best with respect to these exemplars, and I'm going to do my best to give you a sense of the scope of the substantial similarity test as I intend to

apply it during the trial.

I agree, though, you will be free to make your arguments, renewed arguments, new arguments to persuade me to do something else with a particular exhibit, but I'm hoping that we can resolve these things that require research and require argument, we can do it in those hours at the beginning of trial, maybe in the lunch hour, and after the trial ends. That's my hope, to keep the trial moving so the jury is not ever sitting there just twiddling their thumbs.

So, having said all of that, I just wanted to address that for you, Attorney Armstrong. I agree with what you said about the provisional nature of these rulings, but I do hope that it gives everybody a sense of how I'm likely to rule. So, then you can come in, put evidence in a bucket.

For instance, Attorney Orent, you've got a witness coming on the stand, you have 20 exhibits you know you're going to admit, you know the defendants object to 10 of them. Let's get that on the record, and I'll be familiar with them, hopefully, because you've brought them to my attention before trial, and we've had a million hearings on motions *in limine* and other Daubert hearings here, and I've tried to give you on-the-spot rulings so you have a sense of where I'm going to go. My hope with all of that is that we will keep the trial moving and we won't have the jury sitting there while I'm trying to figure out evidentiary rulings that are new to me.

Now, I'm a trial lawyer, I was a trial lawyer for my entire career. I'm used to surprises. I know that happens. I'm understanding of that. I'm talking about things that you know you could have brought to my attention, and I just want to make sure I'm familiar with the issues, I've researched the law, and I can give you a good answer to those questions outside the presence of the jury and we can just keep the trial moving somewhat smoothly. We'll be slow and we'll be tedious at times behind the scenes, but the jury will not see that. That's my hope, that we will move quickly and smoothly.

So, having said that and only addressed the procedural question, let me let Attorney Orent go ahead and summarize your arguments with respect to no. 2 and no. 7.

MR. ORENT: Thank you, your Honor, and I want to start off by stating that in this case under the risk-utility approach plaintiffs need to show that a product is defective as designed, and the test, is if the magnitude of the danger outweighs the utility of the product. That's what ultimately the plaintiffs will have to prove in this case, and in so doing the jury must be able to evaluate many factors, including the usefulness of the device, the desirability of the product as a whole against the risks as a whole of that device. Moreover, when a device like this -- well, let me stop there.

That's a standard that the plaintiffs have to prove in this case, and if you listen to the defendant's argument you

would have us or the defendants would have us ignore both elements that question or evidence that questions the usability of the device, that is, does the device work as intended, and, separately, what are the risks associated with the device. The jury needs to look at all of that evidence in order to reach its ultimate decision in the case. So, when we look at their standard that they enunciated today, the same product, same injury, similar surgical circumstances, there's almost no event that will ever be able to meet that criteria, because it is so narrow. Nor does the case law require it. Instead, what the case law requires when being offered for proof of causation, the idea of substantial similarity, it's a function of the theory of the case. It does not require that the circumstances surrounding the other incidents be identical. And the courts have held that a proponent of the other evidence need not establish what caused her accident in the sense that she must prove but simply must articulate a supportable theory of why the evidence is relevant under plaintiff's theory.

So, in this particular instance, when we look at what the defendants claim are substantially equivalent -- excuse me -- substantial similar events, the defendants very narrowly define the plaintiff's injuries in this case. I think they said inflammation, infection, fistula and scarification, saying that the body is, quote, unquote, highly idiosyncratic. However, that's not what the testimony that the jury is going

to hear will be both from plaintiff's experts and defense experts. The jury is going to hear that, in fact, polypropylene mesh as well as the coating on this product, the C-Qur V-Patch, induces a particular cellular reaction in all people. It may manifest differently in different individuals, but the same pattern of inflammation and scarification is present in everybody.

Dr. Balydak, who is an expert witness for the defendants, we anticipate that he will say that the inflammatory process is expected, anticipated and necessary. We disagree that it is necessary, but it's definitely expected and anticipated.

Now, when we talk about the risks and benefits of a device, one of the key aspects of the device is that, when you introduce a new device into the marketplace, like Atrium did with the C-Qur V-Patch and its entire line of C-Qur products, by introducing a new device with new risks the benefits of that device must exceed those new risks. That's the law. And so, in order for the benefits to exceed the risks, number one, it has to work. The C-Qur V-Patch coating is a fish oil coating that was intended to reduce the tenacity of adhesions. It does not work, period. The evidence before this jury will be that the device never worked as intended. The jury is entitled to hear that, even though we're not alleging specifically that adhesions were the cause of all of the panoply of problems that

Ms. Barron suffered, but her implanting doctor, Dr. Price, certainly was entitled to know that the device did not work as it was intended, therefore, any of the additional risks presented by that device did not exceed the benefits.

Moreover, this device through its risk process, through the induced and increased inflammation, does produce excessive and harder adhesions. That same process is also similar to the reactions, the cellular-level reactions that cause excess scarification, the same sort of things that can lead to fistulization, which is a tunnel that actually goes through the body and leads to drainage. So, these notions are not -- they're not separate from one another. The problem with the defendants trying to adhere to this notion of same product, same injury, same or similar circumstances is that they are arbitrarily drawing a line as to where the product needs to be the same. We would argue that it needs to be the same attribute of the product at issue.

So, for example, when we're arguing about the coating, whether or not the coating is safe, our experts will tell you that the coating, the saturated fat that was advertised to contain Omega-3 fatty acids but didn't, was unsafe. It caused cellular death and also separately magnified inflammation where it didn't cause death. The jury is entitled to look at all instances of evidence and information where the defendants evaluated that coating. Likewise, where the polypropylene base

is utilized and the defendants have information related to that polypropylene base the jury is entitled to infer and gather information from the circumstantial evidence offered relative to the defects and the effectiveness or lack of effectiveness relative to that base mesh. The jury is also able to evaluate the combination of those two, even though the combination of those two isn't always in the V-Patch mesh. It is always in a C-Qur mesh. So, we have to be very careful about the elements of the product and the utility of it.

Second, the same injury. We're not talking about a case where there's a faulty tire in a car and the engine has a propensity to blow up and there's two totally unrelated circumstances. In this particular case our experts are testifying that it is both the separate defects within the product but as well as their collective and even greater defects when married together as a total product that caused the harm. And so, when you look at the injuries it goes towards the risks of the device, but it also goes towards some element of chance. That is, when a series of events are caused by the same mechanism the jury is able to evaluate and should be able to evaluate all of those without the arbitrary distinction in that end point.

And, likewise, the similar surgical circumstances. The defendants have offered no reason as to why, for example, an open procedure is different than a laparoscopic procedure.

They don't offer separate warnings on their device. It is purely arbitrary. And there is no expert in this case that will say that the C-Qur V-Patch device had a different panoply of risks and benefits depending upon whether it was used as an open or laparoscopic. There's no evidence in the case whatsoever on that, because there's no difference. So, we have to be very careful so that we're not applying the standard incorrectly.

And we also have to look at what the purpose of the evidence being admitted is. So, for example, and I want to just quickly jump, and I know that we're going to get to these documents in a moment, but I just want to quickly jump to one of the defendant's exhibits, because I think it is instructive, which is Exhibit C, which is the actual MDR, Device Report, the MEDWATCH report, and I'm going to skip for the moment the series of emails at the beginning of Exhibit C, but I want to focus on the Med Device Report, the MEDWATCH report. There's a sentence that says, He reported that all of the coating had come off in some places and he was concerned since it had been less than 30 days. He would have thought that the coating would stay on long longer.

Your Honor, that's the piece of information that I think is most relevant to the jury hearing this particular case, and this example is why it's so important that we look at the actual documents. And so, when you look at that particular

quote in context, we see that it is the same coating on the same base polymer, and the issue is the amount of time that the coating remains on the polymer and what Atrium was told in 2008, four years before our plaintiff was implanted.

We will be introducing evidence throughout the trial that, number one, the coating was not applied in a uniform manner, such that it was thicker on some lots of product and thinner on others; and, second of all, that it did not resorb in a consistent manner throughout the human body. Even on a single product it would not be resorbed consistently. And so, you have incidents like this, as demonstrated in 2008, where the coating is gone within less than 30 days, but we also have other incidents where it goes on for two years and permeates for more than two years in the human body. And so, part of idea that this coating was never suitable for its purpose, it didn't work, is that it was unpredictable in and of itself. And so, that's what this document shows us.

And so, when you look at the same product, the same injuries, similar circumstances, application matters. In this case it's the Atrium C-Qur Edge Mesh, again, the same base mesh, same base polypropylene, and it's the same type of coating. The issue with it is the same issue. And so, I would posit that this is classic notice and knowledge testimony.

So, your Honor, I think that the notion of this narrowly defining our case is relatively arbitrary and that the

evidence needs to be examined on a document-by-document approach, and that what the defendants are trying to do is trying to get the Court to issue a broad ruling over very narrow documents that have very particular applications to the case at issue, and that the Court should reserve ruling categorically and instead focus on the actual documents so that we can discuss the actual relevance related to these individual documents. Thank you, your Honor.

THE COURT: Attorney Armstrong.

MS. ARMSTRONG: So, I will be brief, and then I'll either turn it over to Ms. Van Tuyl, unless the Court has questions, or unless the Court wants to hear further from Mr. Orent.

Mr. Orent basically says that the evidence of complaints and MDRs broadly, with a very broad scope that he suggests, are all relevant to the risk-utility test, but if you look at the case law the case law says that the claims that require evidence of injury, including strict liability, only the injuries experienced by the plaintiff are relevant, and the test for -- if you look at the civil jury instructions in New Hampshire, the test for a design defect claim is that the design of the product created a defective condition unreasonably dangerous to the user and the condition caused injury to the user. So, there has to be a causal connection between the risk at issue and the injury that's experienced by

the user.

Now, what Mr. Orent is proposing that the test of substantial similarity be would be the same attribute of the product. Now, we've already conceded that if it's the polypropylene and its suitability that's at use, the fact that it's a different product is not enough to exclude it, but you have to still meet the other two criteria, which are other injuries and similar circumstances. What Mr. Orent is proposing is that you essentially eliminate those other criteria, other injury and other circumstances.

But those are not things we made up. Those are things that courts came up with, and we've cited numerous cases supporting that those are criteria for determining substantial similarity. Plaintiffs haven't cited anything to the contrary. In fact, as I discussed, plaintiffs' cases support the criteria that we're proposing. So, he's proposing a substantial similarity test that basically doesn't find any support in the law.

And he also -- I also wanted to address his point about open versus laparoscopic surgery, where he says that the risk of -- that the use of the product is no different. But the risks of the surgery are different, and his own experts, I'm sure, would concede that open surgery is much riskier than laparoscopic surgery, it's much more invasive, and any time you have a more invasive procedure there's more risks involved.

So, there is a difference between open and laparoscopic surgery.

If your Honor doesn't mind, before she gets into the individual exemplars, I would like for Ms. Van Tuyl to chime in, if she thinks there's anything I've missed or that we want to bring to the Court's attention, if that's okay.

THE COURT: That is fine. And I think I'm going to separate out and go ahead and rule on the question of injury, which is what's specifically addressed in no. 7, and give you a ruling on that, and then I want to hear more argument with respect to no. 2, substantial similarity, and we'll talk specifically about exemplars.

But, Attorney Van Tuyl, do you have anything to add at this point, particularly with respect to motion *in limine* no. 7, conditions not suffered by plaintiff?

MS. VAN TUYL: Your Honor, Ms. Armstrong has, as you would expect, covered it very well. The one thing that I will reiterate and amplify is that I think what we heard from Attorney Orent is that all of the risks of the device should be considered. Ms. Armstrong has just explained now why that's not the case under the case law. But I will add to that that it's black-letter law that for a warning defect claim the warning alleged by the plaintiff as something the defendant should have given about the product, that warning must be specific to the risk claimed by the plaintiff. So, that's just

consistent with what Ms. Armstrong has said, but I did want to add that warning aspect piece.

THE COURT: Thank you.

Attorney Orent, you'll get the last word here.

MR. ORENT: So, I want to go back to Ms. Armstrong's statement, and she's absolutely wrong, because there isn't always a difference between an open procedure and a laparoscopic procedure. It depends on so many circumstances. For example, in umbilical hernia surgery the cut might only be two or three centimeters, and so you cannot categorically say that one is more risky than another, but that's even immaterial. The point here is that the device risks are no different, and that's the key.

As far as plaintiff's burden, the defendants gloss over the unreasonably dangerous aspect of the device. We have to prove that the device was unreasonably dangerous to the end user or to in this case the learned intermediary. So, in proving that a device is unreasonably dangerous we have to show both the risks and the benefits. And so, evidence that goes to demonstrate both a lack of benefit, that is, the device doesn't work, means that the doctor can't justify any risks. And so, evidence from MDRs or from any source that show that the device doesn't work are extremely important, because it undercuts any other arguments that the defendants make, because no risk is acceptable if the device doesn't work. So, that's the first

thing.

The second thing is this notion of risks and that the plaintiff needs to have suffered the same risk in order for it to be admissible. We don't think that that's what the case law says. Again, we have to prove that the device was unreasonably dangerous and that it is the same attributes of the device that present that risk. And so, in this case, this is a novel device, a doctor has the right to evaluate whether or not all of the aspects, when combined, are balanced by the benefits of the device or the benefits exceed that level of risk, and that's what we think the case law says.

When you get to the particulars, and that's really what we're talking about, are the particulars of individual MDRs, we look at what is the evidentiary value within the individual MDR towards going to prove one of the things that I enumerated, and I think, where I did here, I was able to walk the Court through a very particularized reason for an MDR that that demonstrates we meet our burden.

So, for those reasons, your Honor, I think that you should deny the defendant's motion. Thank you.

THE COURT: All right. I am going to rule on no. 7, and then we'll move to no. 2 and I'll hear further arguments.

Through its motion *in limine* no. 7, which is document number 174, defendant seeks to exclude from trial evidence of health risks potentially posed by defendant's product that

plaintiff did not personally experience. Defendant argues that such evidence would be irrelevant to any issue raised by plaintiff's claims and potentially prejudicial. The Court agrees with defendant that evidence of potential health risks that plaintiff did not, in fact, experience would be inadmissible to establish, for example, specific causation of her injuries. However, plaintiff alleges a design defect in defendant's product, which requires her to show that the product was unreasonably dangerous.

As a matter of New Hampshire product liability law, whether a product is unreasonably dangerous is determined "...by the jury using a risk-utility balancing test," and I'm citing Vautour, 147 New Hampshire at 154. "Under a risk-utility approach a product is defective as designed if the magnitude of the danger outweighs the utility of the product." And Vautour cites Keeton, *Prosser and Keeton on the Law of Torts* for that proposition. This approach requires a multifaceted balancing process involving evaluation of many conflicting factors. That's Vautour quoting another New Hampshire Supreme Court case called Thibault.

At the hearing of March 11 the Court invited the parties to supplement their briefing as to whether a product liability plaintiff can offer evidence of injuries that differ from the plaintiff's own injury in order to prove the existence of a design defect. The Court does not find that the parties'

supplemental briefing squarely answers this question perhaps because the New Hampshire and First Circuit cases do not provide significant useful guidance on this narrow issue.

However, at least one court from a foreign jurisdiction has cogently discussed this very question in a case involving a similar legal framework. In Herrera-Nevarez versus Ethicon, Inc., this is a Northern District of Illinois case, August 6th of 2017 -- I'll give you the Westlaw cite: 2017 Westlaw 3381718. In that case a medical device product liability action arising under Illinois law, the Court considered a motion *in limine* to exclude evidence of other incidents in which the complications suffered by the third-party patients differed from those suffered by the plaintiff. The Court noted that under Illinois product liability law whether a product is unreasonably dangerous is evaluated under a test that involves weighing a broad range of factors, including, among others, the magnitude and probability of the foreseeable risks of harm. That standard is comparable to the standard the Court just discussed with reference to the New Hampshire Vautour case.

The Court in Ethicon continued: "Contrary to defendants' contention, it defies logic to say that this means that all the benefits of the product may be admitted - as defendants plainly intend to do - but only some of the risks may be admitted. Plaintiff must, of course, establish that the

design of the product caused her particular injury. But the Court declines to prevent her from offering evidence about the overall risks and benefits of the product in attempting to prove that a design defect exists - an element distinct from causation. The Court therefore denies defendants' motion *in limine*..." That entire quote is at star page 6 of the Ethicon decision.

I adopt the Ethicon court's reasoning. Specifically, I agree that, in light of the fact that the dangerousness is measured by reference to a risk-utility balancing test, it defies logic to suggest that the jury should be instructed to weigh the overall utility of defendant's product against its attendant risks but to consider only the limited subset of those risks that arguably contributed to plaintiff's specific injuries. To do so would invite courts to find that a given product was unreasonably dangerous from the perspective of certain potential plaintiffs but not others, an illogical and anomalous result. The Court, therefore, declines to preclude plaintiff from offering evidence that defendant's product may have caused some patients to suffer injuries that plaintiff did not personally experience. Defendant's motion *in limine* no. 7 is, therefore, denied.

Defendant may, of course, raise its objection again at trial in the event that plaintiff offers such evidence for any improper purpose or offers evidence of injuries so far removed

from plaintiff's design defect theory that the risk of confusing the jury would outweigh the probative power of the evidence.

All right. Now let's move on to talk more about substantial similarity with respect to the third-party complaints and the Medical Device Reports, the exemplars that plaintiff and defendant have submitted at documents 22 and -- I'm sorry -- 220 and documents 222. So, let me, since this is defendant's motion, let me just let Attorney Van Tuyl go ahead and begin to talk about substantial similarity and the test in the context of these specific exemplars that you've provided to the Court to essentially help me help you understand how I'm likely to rule with respect to specific buckets of evidence in the case.

Go ahead, Attorney Van Tuyl.

MS. VAN TUYL: Thank you, your Honor. My approach here was going to be walking through each exemplar one by one, but before I do that I want to hear from you whether that's okay and that's your expected approach as well.

THE COURT: That's fine. Are you going to start with your exemplars?

MS. VAN TUYL: Yes.

THE COURT: Okay.

MS. VAN TUYL: And I will just walk through one by one, unless your Honor has a different approach, and start with

Exhibit C, which is the same document that Attorney Orent was just referencing, and so I'll explain our position on that, and then, if you'd like to hear from him again on the same exemplar, or you want me to walk through the rest I'll defer to you on that.

But as far as Exhibit C goes, this is the first in our list, and this document, as Attorney Orent said, attaches two MDRs, they are regarding the same incident, and that incident involved, according to the information received by Atrium, it involved what we would call a different product, not the V-Patch product, and what we would call a different injury, mesh adhering to the bowel, which is not something Ms. Barron claims here, and a, quote, white, pasty, glue-like film over the bowel, again, not something that she's claiming here.

Other pertinent information about this particular set of MDRs is that there are differences between the plaintiff's surgical circumstances as described in the MDRs compared to Ms. Barron's surgical circumstances. So, for example, the patient reflected in the MDR had dislodged surgical staples and also had comorbidities of obesity and diabetes, and that information is important in particular on the risk of prejudice of this evidence. It's also important to relevance, because it's the third prong that we've set out in our relevance test, but it's also pertinent to the prejudice.

If this type of document is introduced, then we will

need to introduce our own evidence to explain why comorbidities of diabetes and obesity can impact wound healing, even though Ms. Barron didn't have those comorbidities in this case. We would also need to introduce evidence explaining why there are additional risks if surgical staples become dislodged, even though that's not something Ms. Barron experienced here. And that would for this particular document and similar ones quickly devolve into I think mini trials where experts and other witnesses are debating whether those comorbidities, the staples dislodging and other surgical circumstances, do actually change the risk profile of the patient reflected in the MDR.

One other note that I wanted to add, a few other notes that I wanted to add on this document, plaintiffs' response brief indicates they'd like to use it to show just regarding Atrium's complaint-handling procedures. I'm not entirely sure what the intended context is on that point, and so, if Mr. Orent addresses it, then I will respond, but as far as I read this document it's not showing any deficiency in Atrium's complaint-handling process, but, again, we would need to know how plaintiff intends to use it, how plaintiff intends to argue to be able to fully respond there.

And then a few other notes. As I mentioned, the patient-specific factors here, the risk of a mini trial, and I'll just add to that as one of the risks of introducing this

document and this type of evidence the risk of juror confusion. I think you've heard it from Mr. Orent that he does intend to introduce this type of evidence really to show causation, right, to show that the product caused the particular complaints reflected in this MDR and also caused Ms. Barron's particular injuries. That introduces a big risk of juror confusion, even if the Court were to provide some sort of limiting instruction about how this evidence could be used and interpreted, introduces a very big risk of juror confusion because that is not a proper use for this evidence based on the case law.

So, I'll pause there and ask whether your Honor has any questions, whether you'd like Mr. Orent to respond, or whether I should move to the next document.

THE COURT: Maybe, Attorney Orent, you comment in your chart about Exhibit C that the document, Exhibit C, shows delayed or improper MDR reporting involving C-Qur mesh, which does involve the same polypropylene mesh and coating as in the V-Patch that was implanted in Ms. Barron. So, tell me how this document does that.

MR. ORENT: Well, first, your Honor, if we walk through the document it begins with a series of emails dated August 14, 2012, and if you see in that series of emails there is a question and follow up about why the FDA is not getting complaints. As you see, the second email starts, "Thanks, Ms.

Wolf, I received your reply."

THE COURT: Hold on one second. I've just got to get to that email. And I want to make sure -- I start at the bottom to get to your first email. Okay. Let me go scroll to the bottom.

(Pause)

THE COURT: Okay, I think I'm with you. I've read the first two emails.

MR. ORENT: Okay. So, as you see, your Honor, going from the back forward on, if you look at what's page 3, essentially, of this exhibit, it starts with, Mr. DePaolo gave your name as Atrium Medical's quality assurance manager who is responsible for MDR submission for C-Qur mesh. We have a number of questions and concerns that we will address in an Additional Information request letter. Our immediate questions at this time are: 1. Have you submitted any MDRs since 2009 besides these 3 MDRs?"

So, let's pause there and go back and understand that Atrium has a duty, a legal obligation, to report certain types of complaints to the FDA so that they can be tracked by the regulatory authority. We're now in 2012, three years since the last complaint had been registered, and there's a discrepancy between what FDA thinks that they should have -- excuse me -- between what Atrium thinks it should have and what the FDA actually has. And as we go down, we see that there are

actually specific incidences of where there are no records or reports related to various complaints that were filed or should have been filed. We also see that Atrium doesn't track. On number 3, Atrium has not received certain reports.

So, one of the things that we anticipate seeing as a defense in this case is that Atrium's experts and Atrium's fact witnesses from in house are going to get up and they're going to tell the jury, We have a .000 whatever percentage complaint rate, and this document goes part of the way to showing that Atrium is not meeting its burden. This is yet another incident of Atrium failing to properly document and file its complaints with the FDA but also internally, and that's points 1 and 3, or actually 1, 2 and 3. And the communication that goes on through the rest of the email sort of documents this. So, that's the relevance of those emails.

The second aspect of this is, if we go to the actual MDR Device Report itself, this is the line that I read before, which defense counsel did not respond to, which is, in 2008 Atrium was given affirmative notice and knowledge of -- he reported that all of the coating had come off in some places, and he was concerned since it had been in less than 30 days.

Now, the defendants can argue that diabetics or obese people have different risks, but that's not on the IFU. The IFU doesn't say the coating is less predictable for certain classes of people. It says nothing. And the coating, this is

a major design flaw of the coating, that it is not predictable. And one of the things that is necessary with a mass-produced medical device is that it function predictably in all people that it's implanted into, and if it is not capable of being predicted for a particular group or subgroup of people, then it needs to have a specific warning about it. And the defendants can cross-examine whatever expert is talking about this particular document, but at the end of the day we see two things: number one, the lack of predictability in the coating, and then this document is being filed four years later, four years overdue, because if you look on the MDR, it's a 2008 MDR on a series of attached reports to the FDA in 2012, four years later. So, your Honor, I think that that is the purpose of this particular document or particular set of documents.

MS. VAN TUYL: Your Honor, may I respond?

THE COURT: Yes. Now, I don't want to spend hours and hours and hours and hours and hours on each exemplar separately, because I do think your arguments overlap with other exemplars. So, what I would suggest is perhaps argue -- make your argument with respect to substantial similarity that Attorney Armstrong proffered to me in her argument and which you've proffered in your brief with respect to what you think are the exemplars that absolutely, without question, meet that standard, should be excluded, as opposed to going through each separate exemplar, because we will be here all day. Look,

we're not even past exemplar number one, Exhibit C. So, that's the way I'd like to do this, and I want to give you free rein to basically focus on the exemplars you think best illustrate this. So, go ahead and respond to that, and then move on to what other exemplars you want to draw my attention to.

MS. VAN TUYL: Yes, your Honor. I will respond to some specific points that Mr. Orent made first, and then we can move on. With respect to the specific points he's made, there are really two pieces I think to what he said. One is that he's claiming this particular document shows complaint-handling deficiencies within Atrium; and then, two, that it shows notice or knowledge of some deficiency in the coating. So, on the first piece, on the complaint-handling piece, of course we disagree that this particular document shows deficiencies in Atrium's processes. It's a long back and forth with FDA that would require time in front of the jury explaining what it does and does not show, but what I see in this document is actually Atrium being responsive to FDA's requests and that there being a discrepancy but within FDA's records, not within Atrium's, and there being discrepancies that may be explained by the fact that MDRs do not always come from Atrium, and in this particular document it appears that FDA received some MDRs directly from reporters, like hospitals and facilities. Those were not initially routed through Atrium, and so this document reflects Atrium and FDA trying to square their records in

particular with respect to some of those MDRs that would not initially have come through Atrium or have been reported on to FDA through Atrium.

So, we do disagree this shows complaint-handling deficiencies, but what Mr. Orent says and what I say today is less important than what our witnesses would need to say at trial, and I think that goes to the potential risk of prejudice and mini trials involved with this particular document and ones like it. It would take I think more time than what we've taken even so far today with this particular document for expert witnesses or company witnesses or both to speak to what was actually happening in this particular piece of correspondence.

THE COURT: Okay. Let me ask Attorney Orent just a basic question. Obviously, it's C-Qur, it's the C-Qur Edge product, rather than C-Qur V-Patch here, but ultimately this communication about the C-Qur family of products occurs prior to Ms. Barron's surgery. Why wouldn't a document like this fall into a notice argument as well, notice of problems with respect to the product itself?

MR. ORENT: It absolutely would, your Honor. When I was talking about the notice of problems with the coating, that's very specifically what I was referring to, and I was being very particular on the notice relating to the coating.

Also, again, we have a negligence claim in addition to our product liability claims, and the failure to adequately

track complaints, which is something that we will hear time and time and time and time again throughout the course of this trial means that the defendant didn't know, they systematically didn't have a big picture of all of the red flags as they came in, and so the jury will get the sense that this is a company that didn't know or didn't care as complaints came in and was very tardy when it ultimately did report things the right way.

MS. VAN TUYL: Your Honor, I believe Ms. Armstrong would like to address something.

MS. ARMSTRONG: Your Honor, I just wanted to make sure that it was clear the difference between complaints and MDRs, and Ms. Van Tuyl referenced the differences between internal and FDA documents. Complaints come into the company, and the company evaluates those complaints. Sometimes, based upon what the regulations are, a complaint has to be forwarded to the FDR (ph), and if it is it's called a Medical Device Report or an MDR. However, when the company evaluates the complaints to evaluate the risks and benefits of the product or when it says the complaint rate is X it's referring not to MDRs, it's referring to the entire set of complaints, not just those that were forwarded to the MDR (ph). So, whether or not a particular complaint was forwarded to the MDR (ph) -- and I think Ms. Van Tuyl has explained what's going on here, and that's that some things came into the FDA independently of Atrium, but whether or not something gets forwarded to the FDA

or not or whether it's late in being forwarded to the FDA doesn't change the body of data, complaint data, that Atrium evaluates, and doesn't change how Atrium evaluates those complaints. So, if it says the complaint rate is X, that that's based upon evaluation of all complaints, not just -- and whether or not certain complaints were or were not sent to the MDR (ph) doesn't change that evaluation. So, I think it's very important here that there be a distinction which the plaintiffs keep conflating and trying to collapse in saying that if we didn't forward an MDR to the FDA, that, therefore it wasn't evaluated, and that's not true.

THE COURT: Let me ask you a specific question following up to that exact point, Attorney Armstrong. Plaintiff s' Exhibit 9 is a letter from a patient directly to Atrium, and what's unclear to me looking at 9 and 10 is what Atrium did with that complaint. So, that would clearly fall into the pile of what you're describing as complaints. Did, in fact, Atrium, then, follow up with that complaint and turn it into an MDR?

MS. ARMSTRONG: I'm going to let Ms. Van Tuyl respond as to a specific document. She's more familiar with the specifics than I am.

THE COURT: This is the one where the patient writes and says, I don't want to sue you. I don't want to hire a lawyer. I've had all kinds of problems. If you just pay my

surgery bills I'll forget about all the pain and hassle of it, and it's a different defect, the mesh floats around and wraps around I think his colon. And then there are emails between executives at Atrium that mock this patient.

And so, what I'm left wondering is what did Atrium do with Exhibit 9, with that complaint, Attorney Van Tuyl?

MS. VAN TUYL: Yes, your Honor. I want to make sure that I don't misrepresent, I don't have all of the documents at my fingertips as to what the company did with this particular complaint, but I believe that we'll be able to demonstrate at trial that the company did address this as a complaint, and this goes for really all of the complaint-related documents that are at issue in these exemplars. We would want to be able to take the time during trial in front of the jury to demonstrate that for any particular complaint we did treat it as a complaint, we did an analysis of whether it needed to be reported as an MDR, and we either did or didn't report it as an MDR based on that analysis.

So, this is going to be a recurring question I think with each of the complaints at issue here and a recurring evidentiary issue where we will need to, again, take that time to explain how a complaint was processed and whether it was reported as an MDR or didn't need to be, and that could come in the form of company witness testimony, expert witness testimony and/or other documents that have been produced in the case.

So, I can't speak with perfect confidence about this particular document, and I don't want to misrepresent, but, in general, it's a great question and I think an important one that goes to the type of time that we would be investing in dealing with these documents.

MS. ARMSTRONG: And, your Honor, just to remind the Court something I said at the beginning of our argument, there were a hundred of these types of documents listed just on the plaintiff's short list. That's not even including their entire exhibit list. So, if we were to spend 30 minutes to an hour on each document, that's a hundred hours or potentially a hundred hours.

THE COURT: We're not going to do that. I'm going to give you a sense, I think, of how I would rule with respect to buckets of evidence like this.

I'm still interested, though, in plaintiff's Exhibit No. 9, and, Attorney Orent, you submitted that and you submitted the email. That the executives at Atrium responded to that complaint certainly doesn't indicate that Atrium would have taken that complaint seriously, but maybe there is some evidence somewhere else that you're aware of, Attorney Orent, that Atrium actually did address this complaint as an MDR.

MR. ORENT: Your Honor, I will be completely candid with the Court. I do not know in this particular case whether this was ultimately submitted. What I will tell you is that

this is now the second example of profanity-laced or ridden email about individual harms related to people, and so in this particular instance I don't know whether or not it resulted in MDR.

I will say one other thing which is I think very important. The defendants would have the Court believe that there is no importance to the MDR process and that both their complaint handling and MDR issues were mere clerical mistakes that had no real-life human impact. That is just not true.

One of the things that the MDR process does is, obviously it advises regulators, but it also is a source of public information on what types of things are going on with the products, and so it is not unheard of for doctors to regularly look at the MDR database to see are there trends of problems, what's going on with this. It gives a real-life sense as to what is going on in terms of the types, quality, color and frequency of complaints.

And in this particular instance we've now just heard this defense over how great Atrium was at liaising with the FDA. Well, it turns out they weren't great, because we've got 38 inspection reports that show that they weren't tracking their complaints, they weren't elevating them to MDRs, that they, in fact, ultimately entered into a consent decree, because this wasn't just a regular dialogue, this was a pervasive problem that resulted in real-life problems for

people, and this is part of the problem, is this cavalier attitude.

And so, if Ms. Van Tuyl or Ms. Armstrong want to represent to the jury that it's just an MDR, I will then be free to say, Well, what about this one, what about this one, what about this one, and it shows the pervasive pattern of disregard for human life which is at the very crux of our negligence case, and it's at the very crux of our defects case here, in this particular instance.

We've seen other emails motion *in limine* no. 1 dealt with where they're talking about infections, which are a serious problem with this product, calling the individual an expletive for a homosexual male instead of filing a complaint for it. This is the culture of this company. The jury is going to hear and see that this is a company that doesn't take its responsibility serious, and this is a perfect email and response where there's a very particularized piece of information about the coating that is not picked up on, and there's no follow-up testing, there's no follow-up evaluation in a manner that you would expect a medical device company to act based on this information in 2008, and, in fact, it just disappears until 2012.

THE COURT: All right. I've got to stop everybody for the moment and let our court reporter take a break. Let me just say I'm supposed to have a hearing at 12:15, and so what

I'm going to say is put Attorney Esposito on alert to see if we can't move that hearing to the very end of the day --

THE CLERK: Will do.

THE COURT: -- or just move it. I think the hearing in person, in court is Thursday in that case, so we still at least have Wednesday to try to fit that in. And then I have a meeting that I have to attend at 12:30 today. So, it's a very tight schedule, unfortunately. But I do want to give our court reporter time to take a break. So, let's come back at -- let me ask the court reporter.

(The Court conferred with the court reporter)

THE COURT: All right. So, we'll be back at basically 11:50, so in five minutes. Just turn off your microphones and your video, and we'll be back in five minutes.

(Recess taken from 11:45 a.m. to 11:50 a.m.)

THE COURT: Let me let Attorney Van Tuyl continue, and I would suggest that you ought to limit your argument to specific exemplars that you think best illustrate the argument that you're trying to make in motion *in limine* no. 2. Go ahead.

MS. VAN TUYL: Yes, your Honor. I think we can start with Exhibit 9, which is the one that your Honor had pointed to. And this is a great exemplar for the argument that we are making. It does not meet that three-pronged test that we've described, that Ms. Armstrong described, that is based in the

case law. It was a different product involved, a different C-Qur product, not V-Patch. The gentleman who sent this letter claimed different injuries from the ones that Ms. Barron is claiming here. Specifically, he claimed a partially blocked colon, a, quote, reactivated hernia and non-integration of the mesh, none of which are injuries that Ms. Barron is claiming here. Although he does discuss his surgeries in this letter, we would say there's insufficient evidence for plaintiffs to show that the surgical circumstances were similar to Ms. Barron's. So, for example, I don't believe this letter describes whether it was an open or a laparoscopic procedure, whether this was an initial hernia that he had or a recurrent hernia. And, as Ms. Armstrong described, those, in our view, and based on expert testimony, those factors do impact the risks of a surgery with any hernia mesh. So, for one, this letter in Exhibit 9 does not meet that substantial similarity test that the case law requires.

Beyond that we think there's particular prejudice related to this document. So, not only are these patient-specific factors we would need to introduce our own evidence to explain and to potentially rebut, there is a risk of a mini trial in doing that, including, because of the detail in this letter, we would need to introduce evidence to rebut each of the things that are said. But there's particular prejudice, as I mentioned, because these allegations haven't

been substantiated, right, are only appearing in this letter, haven't been subject to a discovery process like Mr. Barron's case has been, hasn't been subject to cross-examination, like witnesses in Ms. Barron's case have been. So, for those additional reasons there is some unique prejudice with this document because of the allegations that are made here.

THE COURT: Let me ask you why couldn't I address or the parties agree to redact certain information from a document if, in fact, I rule this document along with Exhibit 10 is admissible on complaint-handling procedures and the attitude of the company toward handling of complaints? Why couldn't you redact certain descriptions that the patient provides that wouldn't necessarily be relevant, might be prejudicial? That's my first question. Then, number two, why couldn't I handle it with an instruction to the jury that, This is coming in solely for you to consider Atrium's complaint-handling procedures, and it is not coming in to prove design defect or failure to warn? Why can't the jury look at this exactly in the context that I order them to? In other words, this is important on one issue and one issue only, and it goes to Atrium's handling of complaints.

MS. VAN TUYL: Yes, your Honor. On the first question, whether information could be redacted and then the exhibit placed into evidence, it depends, in part, on what information your Honor would propose or plaintiff would propose

to redact; but, in general, for a document like this I think redactions could invite speculation and increase prejudice in a way that would really just amplify the prejudice that those redactions would be intended to prevent.

THE COURT: A limiting instruction would be better from your view, if I decide to admit it for a limited purpose?

MS. VAN TUYL: A limiting instruction -- if this were admitted we would want the limiting instruction certainly as to how the jury could use it and interpret it. Our view is that prejudice of a document like this and similar ones cannot be completely cured through a limiting instruction, but certainly we would request one and could propose language to your Honor for a limiting instruction if this evidence were going to come in.

THE COURT: Okay. Attorney Orent --

MS. ARMSTRONG: Your Honor --

THE COURT: I'd rather just have one attorney from the defense side arguing these exemplars at this point, because we have limited time.

Attorney Orent this complaint is outside the scope, as I understand it, of plaintiff's theory of defect. The mesh came loose, it wrapped itself around a portion of a patient's colon. Your theory of defect is the mesh is made of this dangerous material. Now, this has polypropylene, and it is the fish oil, but nothing in your theory, as I understand it,

unless you can clarify for me, I may be misunderstanding this -- your theory doesn't relate to the possibility the mesh is going to come loose and cause harm in this way, wrap around a person's organ, although some of what you said in your opening earlier would suggest that you view this as this unpredictable reaction with respect to the coating, but isn't defendant correct at least with respect to design defect and failure to warn if it comes in at all it would come in under negligence, under the complaint-handling process, not taking complaints seriously, if, in fact, they're not able to find some sort of evidence other than Exhibit 10 to support the position that Atrium took this complaint seriously?

MR. ORENT: Well, your Honor, you certainly identified the primary purpose of this, which is to document and show that real complaints weren't taken seriously; in fact, they were mocked. I would parenthetically just note that at the bottom, the middle of the page, actually, it says, In mid-February I did return to work but still not feel 100 percent. He talks about the mesh dislodging from his hernia. What essentially he's talking about there is the failure of the device to integrate into the abdominal wall, which we believe is caused by the coating and the small pore nature of the polypropylene. So, those are very much an issue, because in Ms. Barron's case she, of course, still had coating multiple years after implant when the device was removed; it hadn't fully, totally

integrated. And what happened to this guy is a perfect example of what happens when you don't have tissue integration and you have mesh migrating into the abdominal cavity below the peritoneum.

That all having been said, that's not the primary purpose of it. So, we can articulate what I think is enough to pass the notice knowledge test, that reduced standard we talked about. However, really the primary point of this document is precisely as your Honor noted, that this company just doesn't take complaints seriously, and that's a question that the jury is going to be asked to deal with.

With regard to your comment, your Honor, about limiting instructions, we certainly have no objection to limiting instructions being issued, even something to say that this is for notice and knowledge only or proof of complaint handling, whatever it might be, given the circumstance.

THE COURT: Attorney Van Tuyl.

MS. VAN TUYL: Thank you, your Honor. First, on the limiting instruction I do want to clarify, if this evidence were to come in we would want a limiting instruction as an alternative to no limiting instruction. However, there is an important First Circuit case, Downey versus Bob's Discount Furniture Holdings, that said as follows: "Without a showing of substantial similarity, the evidence was not significantly probative, and evidence that is not significantly probative may

be excluded entirely." In that case the First Circuit found that the risk of prejudice for those not substantially similar complaints, the risk of prejudice could not be cured by a limiting instruction. So, our first position, of course, would be to exclude the evidence.

THE COURT: Right. But he's saying that it comes in on a wholly separate issue; he doesn't need to show substantial similarity because this goes to his argument with respect to negligent complaint handling, which led, he argues, essentially argues led to Ms. Barron's problems as well. So, I don't know that the substantial similarity test is required when that's the purpose he seeks to admit it for.

MS. VAN TUYL: I understand, your Honor. We would submit that there still must be relevance to the complaint itself, and because it is not similar in the ways that we have described it should still be excluded. Otherwise, it's giving notice or knowledge or speaking to complaints that are different from the one that Ms. Barron complains of in this case.

I also do just want to clarify with respect to Ms. Barron specifically, my understanding is that her physician testified that her mesh was incorporated, which is a distinction from what this particular gentleman included in his letter. So, I wanted to clarify that, because Mr. Orent spoke to it.

But, again, we still think there has to be that relevant aspect to a complaint when we're talking about whether complaint-handling processes were followed. And then there's also the prejudice piece, that risk of mistrial, cumulative evidence that comes into play when we need to respond to a piece of evidence like this.

THE COURT: Okay. All right. And what other exemplars would you have me study carefully? From my perspective, I thought Exhibits 9 and 10 were the outliers in terms of whether or not I felt like they met the substantial similarity test. Just to clue you in, I feel like Exhibits 9 and 10 are the biggest stretch for plaintiffs. The others in general I am, I believe, inclined to admit. Tell me why I shouldn't admit specific exemplars, that they just are too far afield.

MS. VAN TUYL: Yes, your Honor, if you'll give me one moment to identify a good example from amongst them. So, I would point your Honor to Exhibit J.

THE COURT: Okay.

MS. VAN TUYL: I'll give everybody a moment to pull that up, and Exhibit J was one of the exemplars that Atrium submitted. It involves, according to the document, the V-Patch device but a different injury. So, there in Exhibit J, if you scroll to or go to, if you have it in hard copy, the second page of the document itself, the email exchange itself, at the

top it describes hearsay from a doctor who's describing a red circle appearing on the skin where the implant is.

THE COURT: I'm trying to get there. I'm at J.

MS. VAN TUYL: Yes, your Honor.

THE COURT: I'm looking at the top email. I should scroll down.

MS. VAN TUYL: It's page 2 of the email itself.

THE COURT: Okay. I'm there.

MS. VAN TUYL: And the top of page 2 of the email. It would be page 3 of the PDF.

THE COURT: Okay. I thought this physician said his patients get the red circle every time he implants a V-Patch. No?

MS. VAN TUYL: That is one example, yes, of that language, and there's another mention of a red circle appearing on the skin where the product was implanted. That is not an injury, as far as I understand, Mr. Orent can say otherwise, it's not an injury that Ms. Barron is claiming here, a red circle on her skin where the implant was, and so it would be an example of one that we would say is not substantially similar. There also is really no detail here about the surgical circumstances or patient-specific information, and so not enough information for plaintiffs to establish that that third prong, similar surgical circumstances, have been established. The fact that there is not patient-specific information in this

document also speaks to the risk of prejudice, risk of mini trials and trying to rebut the evidence presented here.

THE COURT: Okay. Attorney Orent, I think I understand what your response to that would be. Tell me if I'm wrong, but it's as simple as the red circle indicates inflammation, and it's an inflammatory reaction inside the body, and it can be caused by the material that's used in the V-Patch. It has the porosity, the coating, the material, and it's directly relevant to your defect claim.

MR. ORENT: That's absolutely correct, your Honor, but I would also add a couple of things to that, which is, if you look at John Gomes' email here, the one in the middle, he says it's not uncommon for what may look like a red rash to occur no matter what type of implant you're using. He's making this up. So, when you see, again, how they react to legitimate complaints relative to this device, they're not systematically tracking these complaints. They're not looking for wholesale problems with the device and trying to figure out is there a problem with it, what is going on with this device. John Gomes is just giving this sort of *ipse dixit*, off-the-cuff, Oh, this just happens, when it doesn't just happen. And then John is told by Mead Poncin that, in fact, none of them are being shipped back. So, they're reaching these conclusions without ever having looked at the device, totally disregarding what could be a potential red flag for this device.

And so, it goes to the overall, this overall theme, which is that this company is being told that there is a problem with your device, there is a problem with the way that it acts, and it starts with the failed animal studies, and it works all the way up to these human complaints. So, that's the other added piece to this, your Honor.

MS. VAN TUYL: Your Honor, may I respond?

THE COURT: Yes, go ahead.

MS. VAN TUYL: Thank you. First, plaintiff has cited either today or in briefing -- hasn't cited any admissible expert evidence for that claim that a red circle is indicative of an inflammatory reaction occurring inside the body, so in briefing and again today has not cited to his own expert who is going to give that testimony at trial, which appears to be the basis for admissibility or a basis for admissibility of this document. We would also say that that conclusion is speculative as to this particular patient.

And then I do want to take a moment to just note that we disagree strongly with the characterizations that Mr. Orent is making about the company's complaint-handling process and attitude toward complaint handling. I think he's said that there's no systematic tracking of complaints, which, based on the evidence in this case, is not correct, is false. So, I want to make that clear and just to reiterate that for each of these complaint-related documents that would come in at trial

there would be evidence at our end, right, to demonstrate that, in general, our complaint-handling processes are followed and for this particular document they were followed, which is going to take time in front of the jury.

I understand why Mr. Orent wants to do that, I think, but we also know that he can reference more general information about the company's complaint handling. We have protocols, right, that describe what the process ought to be? We have -- your Honor recently ruled on the 483 observations that Mr. Orent has mentioned as well that call out some particular complaints but are not like these specific complaints that the parties would then need to track during a trial itself. So, if Mr. Orent wants to make arguments about Atrium's complaint-handling process not being what it should have been, there are other avenues for him to do that without us having to go complaint by complaint by complaint through these exemplars, which, again, would take time in front of the jury and I think for each of these require a mini trial.

THE COURT: Attorney Orent, would you respond to her argument about inflammation and the issue of you not having an expert who would be able to tie the red circle to an inflammatory reaction?

MR. ORENT: I think if they ask Dr. Klinge that question he would answer it that way. I don't know, quite frankly, whether or not this is an issue that has ever been

specifically raised to him other than we talk about -- he talks about the inflammatory response to the coating. There is specific testimony relating to the cytotoxicity and the animal studies relating to it. If you look that these are often -- again, a red spot is sort of a nondescript, general thing. It's hard to totally glean what it is other than arguing that I think it's inflammation, red, sort of -- it's a description of inflammation in and of itself.

I just want to add one other point. I don't even know, quite frankly, that -- we just heard from defendants that we're going to have to go document by document through every complaint. I don't think that that's true, and, in fact, these are defendant's examples. Just like with these examples, if one of our experts is asked about them they would certainly respond with a scientifically valid premise. For example, I think what Dr. Klinge would say, when asked about this, is he would comment on the notion that it is symptomatic of inflammation, that the internal testing shows that inflammation was a problem with this device, that there were certainly complaints of this, and that there didn't appear to be any testing that was designed or follow-up that was designed for this. So, I think that is the testimony that you would get. I know it's a longer answer --

THE COURT: Let me ask you a narrow question. With regard to admitting something to show your theory of causation,

let's limit it to that, the third-party complaint would have to show what in terms of injury? I know infection, fistula, scarring, and I've also read inflammation as well as adhesion issues. Would all of that be in the same category in terms of substantial similarity according to your definition, Attorney Orent? Would you include inflammatory reactions and adhesion issues?

MR. ORENT: Yes, I would. In fact, what Dr. Klinge will talk about is that inflammation is caused largely in these cases by either M1 or M2 macrophages, and, in fact, if you look at Dr. Klinge's report, he actually shows the different cell types and how there's multiple gene activation caused by polypropylene, in particular, that causes some of this unique response and the dose, if you will, of polypropylene.

I would add to your sort of panoply of problems, I would add within that contracture of the mesh, I would add both problems that are caused by lack of ingrowth as well as sort of encapsulation. So, I think that that would probably occupy the majority of what I would say would be closely aligned. You could add seroma in there. These are all related to the process. But it's very specific.

I wouldn't argue to the Court, and I just want to be clear on this, I think that the rash has reached that lower level of substantial equivalence, but I wouldn't say that they are -- I would not use the rashes to prove causation. I think

they're tied mechanistically, but I'm not looking to use them for causation purposes.

THE COURT: Okay. I know Attorney Armstrong wanted to say something before we close. I want to give you an opportunity to do that. I've got to end certainly by 12:30.

MS. ARMSTRONG: Thank you, your Honor. I will be brief.

During the break we had a chance to review the Herrera-Nevarez decision that the Court cited, and it's important to note that in that decision the Court distinguished between other injuries, general, and MDRs and complaints. As to other injuries, general, the Court gave the ruling that your Honor read, but it didn't talk about the type of evidence. For example, that type of evidence may come in the form of expert testimony. When it was specifically discussing complaints and MDRs it said that those would be limited to the issue of notice, and we've heard several times today Mr. Orent say that he wanted to introduce it on causation, which we previously argued -- we didn't argue it this time, because we limited it to substantial similarity -- but we've previously argued that they're hearsay, they're not reliable evidence of causation. That was in our prior argument. And the Herrera-Nevarez court specifically limited it to notice, and with respect to complaints in MDRs the court did impose a similar injury requirement.

THE COURT: Okay. I don't think that portion of the Ethicon decision undercuts my reasoning, because I have no intention to include injuries that are outside the scope of plaintiff's theory of defect, and that's essentially what I'm focused on with respect to this question of substantial similarity of the same injury. I'm talking about how do I rule on the question of injury, and to me the reasoning in Ethicon is persuasive. Obviously, I'll look closely at Ethicon, but I think -- I obviously read Ethicon in full, and I think that I'm trying to pluck from Ethicon a rationale with respect to injuries and other conditions and how I deal with that in a strict liability design defect case where really New Hampshire law and First Circuit law doesn't help me, and I find the reasoning in that case helpful.

With respect to your hearsay argument, obviously that's an argument that I think is a stronger argument, and you're saying, I think, that the MDR should not be admitted for the truth of the complaints.

What's your response to that, Attorney Orent?

MR. ORENT: I have no objection right now to that specific example. In fact, for the most part, I generally am using MDRs as notice and knowledge. So, I don't know that we have -- I think from an evidentiary standpoint that there is a reason that I could argue it, but from a practical standpoint I don't think it's our intention to argue MDRs as being

admissible for proof of causation here.

THE COURT: Okay. If you limit yourself to that, that certainly helps counsel in this case abide by my request that you put evidence into buckets and essentially, to the extent you want to make further arguments on those documents, you do so out of the presence of the jury. Remind me what my holding was, remind me of what the evidence is and why you're attempting to introduce it, bring it to me outside the presence of the jury so I can help you with buckets of evidence so that you can move through the trial more quickly.

But, ultimately, I didn't have a lot of guidance in New Hampshire in the First Circuit on this question of substantial similarity and design defect, and really I'm citing Ethicon for the question of substantial similarity, and in a design defect case it makes sense to me.

Now, it also makes sense to me that the MDRs should not be admitted for their truth for the reasons Attorney Armstrong is presenting, but I think Attorney Orent is agreeing that he's not intending to introduce them for that. The MDRs, as he sees it, are more on the question of notice and knowledge, and, of course, that would be a purpose other than truth.

So, let me ask is there anything else you want to say with respect to the exemplars, Attorney Van Tuyl? I mean, I know you wanted to talk about each one specifically, but is

there anything else you want to say about the exemplars in general and the argument with respect to substantial similarity?

MS. VAN TUYL: I don't think there's anything to add in the general sense, other than to reiterate that three-pronged test that we think applies and that we think applies still to all of the exemplars on both parties' lists.

THE COURT: All right. Attorney Orent, anything further?

MR. ORENT: Nothing further, your Honor.

THE COURT: Okay. I'm going to try to give you a provisional ruling to help you move this case and make decisions for trial. Let me just say on this question that is before the Court plaintiff's brief, document number 222, is persuasive to me. I agree with plaintiff's discussion of the law in that brief and with its resolution of the exemplars at this early, provisional stage.

Now, with respect to Exhibits 9 and 10, I think those would come in with a very strong limiting instruction, if they come in.

And I would suggest, too, that to the extent, Attorney Van Tuyl, you're suggesting to the jury that Atrium takes these complaints seriously, you immediately open the door to any email like this. So, I just think that an email like this is something, obviously, I think it's rare in a case where you're

alleging that a company is negligent in its complaint-handling procedures and you have emails written by company executives that illustrate that they don't take them seriously, they mock an injured plaintiff. That, I think, is a dangerous area for your client. And so, I would suggest that, even if I give you a favorable ruling before trial and I say, you know, this just isn't close enough and it's prejudicial as it stands right now, I'm going to keep it out -- and I say that with respect to Exhibits 9 and 10 right now, because ultimately you don't know if, in fact, that Exhibit 9 was responded to or if there was an MDR. You are guessing that there was. So, ultimately, I am not sure that Exhibits 9 and 10 would be admissible if, in fact, you're able to show that they did respond. Then their mocking is more prejudicial, it's just showing a company mocking, when, in fact, their complaint procedure showed they actually did handle his complaint seriously.

So, again, it's going to depend on the context, but let me just be clear that, in general, I found plaintiff's briefing persuasive on this, and I think that your approach, defendant's approach to substantial similarity does not properly account for plaintiff's theory of the case and is far too restrictive. The defendant argues there are circumstantial distinctions that render the exemplars inadmissible. These are distinctions that go to the weight and not the admissibility of a particular exemplar.

Plaintiff's brief and its submission persuade me that evidence of other complaints are likely admissible for several reasons, each of which enjoys I think a close connection to plaintiff's theory of the case, and in light of plaintiff's theory of the case, as articulated in the expert reports of Drs. Klinge and Langstein, plaintiff has several possible purposes it may articulate at trial to support the admissibility of these exemplars. Dr. Klinge will testify that the design flaws in the C-Qur family of products were known by the defendant before commercialization of the C-Qur product in 2006. Dr. Langstein will testify that the design of the C-Qur V-Patch was defective in ways that would likely lead to inflammation and a high risk of infection and the lack of sufficient ingrowth in patients. He states in his report, and I'll just quote one sentence, "The lack of ingrowth can contribute to a recurrence of the hernia, mesh migration, bowel obstruction, and can bolster the risk of infection."

Plaintiffs contend and her experts will testify that the V-Patch shares the same primary raw material, polypropylene resin, fish oil coating, pore size, mesh weight and other characteristics with the C-Qur products that preceded V-Patch to the market. Dr. Klinge will testify that these characteristics caused similar inflammation and injuries to patients, and ultimately plaintiff will argue that she would not have suffered injury had defendant properly addressed the

unreasonable dangers present in the precursor C-Qur products.

To the extent plaintiff can show these documents make more probable than not that, first, defendant marketed an unreasonably dangerous hernia mesh product, second, that defendant knew for years before plaintiff's surgery about complaints relevant to plaintiff's claims about the V-Patch and those regarding its precursor C-Qur products, and, third, that defendant acted negligently in failing to address or reasonably warn of these dangers, I'm likely to admit the documents. And while I cannot conduct a Rule 403 analysis outside of the context of the trial, I can say to you this: The probative value of such evidence would be very high in terms of plaintiff's efforts to prove its case, and, depending upon the specific documents, hard for me to see prejudicial effects substantially outweighing the probative value. Again, I would point to Exhibits 9 and 10 as possible exceptions. I think the jury will be able to properly weigh this other complaint evidence, especially with appropriate limiting instructions, and I'm open to parties reaching agreement on redactions, if, in fact, you're able to do that, to limit some of the arguments and the time that we'll spend outside of the presence of the jury.

Now, accordingly, the Court finds that, in light of plaintiff's theory of design defect, the substantial similarity standard requires that a surgical mesh product is substantially

similar to the C-Qur V-Patch if it's made from the same polypropylene resin as the V-Patch, if it bears the same fish oil coating, and if it has the same pore size and mesh weight as the V-Patch. If a mesh product shares those central characteristics with the V-Patch it is sufficiently similar in material respects to the V-Patch for injuries resulting from its implantation to be admissible under a substantial similarity standard.

As to substantial similarity of patient injury, the degree of similarity required is, in part, a function of the purpose to which plaintiff intends to put the evidence. If offered to support plaintiff's theory of causation, such evidence is admissible on a more narrow basis only to the extent that the third-party patient suffered the same injury or injuries as plaintiff, that is to say inflammation, adhesion, infection, fistula.

However, courts have found that a relaxed standard of similarity is appropriate where such evidence is offered to show a manufacturer's knowledge or notice of a dangerous condition. If offered for such a purpose, the evidence would be admissible so long as the patient's injury was caused by a mechanism consistent with plaintiff's theory of design defect, degradation or oxidation of the mesh resulting in inflammation or adhesion leading to an increased susceptibility to adverse outcomes, including but not limited to possible infection,

fistula, scarring and adhesion injury.

As to substantial similarity of the surgical technique used in device implantation, the parties' submissions do not persuade the Court that identity of surgical techniques is required in order for a third-party complaint or report to be substantially similar to plaintiff's circumstances. Nothing about plaintiff's theory of design defect suggests that defendant's product is only defective with respect to implantation using open versus laparoscopic surgery or with respect to implantation only in one specific location in the body. The requirements of substantial similarity appear to be satisfied so long as the product was used in connection with a hernia repair or similar-type surgery.

So, that's my ruling with respect to motion *in limine* no. 2. It's a provisional denial, as I have explained, and I just want to make clear to everybody with respect to this body of evidence that I find the plaintiff's arguments very persuasive. And I know that's bad news for the defendants, but I do find the argument in 222 persuasive, and I found with respect to each exemplar that it met substantial similarity or it was independently admissible under other theories, like complaint handling, et cetera, and I didn't see any legal basis to exclude evidence of complaints where there was explanted mesh, where Ms. Barron's mesh was not explanted. That was not persuasive at all.

Ultimately, and, for example, Exhibits 9 and 10, I'm still unclear on whether those come in. I think I lean toward admitting them on the question of complaint handling, and that alone with a very strong limiting instruction, maybe even some redactions, because it seems as though that design defect is different that Ms. Barron's, although I will point out the sentence, the quote from Dr. Klinge or Dr. Langstein certainly talks about how the mesh has this property of coming apart and -- I forget the exact quote. Let me see if I can find it again. Yeah. "The lack of ingrowth" -- this is Langstein: "The lack of ingrowth can contribute to a recurrence of the hernia mesh migration, bowel obstruction and can bolster the risk of infection." That's obviously not the risk -- the injury suffered by Ms. Barron, but it certainly is a design defect described by Dr. Langstein, and it seems like Exhibit 9 fits within that sentence that I'm plucking from Dr. Langstein's report. But he's talking about mesh migration, which happened to the patient in Exhibit 9, and bowel obstruction, which is what he described happening.

In any event, I am even inclined to admit 9 and 10 with some strong limiting instructions. And I think, too, with regard to motion *in limine* no. 1, I know the parties resolved that. To the extent there are emails out there that tend to show that the company was lackadaisical or aloof or even used slurs, that was not present in Exhibit 10; it was just a

mocking, is how I would call it, a tone of mocking a patient, but certainly no slurs or anything like that. I think the defendants could open the door to that kind of thing, so I would just say that my inclination would be to keep that material out in the first instance, emails like that, but to the extent Atrium tries to portray itself as having executives that are very concerned about patients and complaints, obviously the door is wide open at that point to that kind of evidence. And, again, I know the parties resolved motion *in limine* no. 1, so I do not know what is in that particular exhibit.

Attorney Orent, you referenced certain emails that went between executives.

I know there is a pending motion to seal, and I am going to have to let you know after this hearing my -- I'm forgetting which motion to seal it is, but the parties agreed to seal documents that I think were of this ilk. They were documents where Atrium I think is seen emailing and bad-mouthing patients and -- no?

MS. ARMSTRONG: Your Honor, I think the basis of the motion to seal is the FDA regulation, which requires the identity of voluntary reporters to be kept confidential. So, I think the idea was, to the extent those -- and Emily, Ms. Van Tuyl will correct me if I'm wrong, but to the extent that those names and other identifying information isn't redacted, they

needed to be.

THE COURT: Okay. All right. I'm confusing, then. And that's still pending. I don't think I've ruled on that. Is that right?

MS. ARMSTRONG: I believe so. That's correct. I haven't seen a ruling on it.

THE COURT: All right. I think that might be the only thing left open, then, and I'll try to address that. It sounds like something that should be sealed, based on what you just said. So, my memory of it is inaccurate. I'll look at that and make sure to include a resolution of that for you. I think that will resolve everything that's pending, if I'm not mistaken.

And I know counsel want to talk about protocols and that kind of thing. I'm totally willing to do that. I just can't do it today. But if you want to talk just protocols, how we're going to run the trial, feel free to get me on a Zoom for that purpose alone. Just talk to Attorney Esposito, and we'll schedule a 45-minute discussion of that or an hour, whatever you want.

MS. ARMSTRONG: Your Honor, our plan was to list them in the agenda for the next status conference, which is on June 10th, so you have a list of what we believe to be the outstanding issues, and then perhaps we could take them up at the June 10th status conference.

THE COURT: That makes sense.

Go ahead, Attorney Esposito.

THE CLERK: Sorry. You're probably going to be in trial. I was going to email counsel about that. We have Craigue, so I can move that. I'll move that. We might not be able to do the 10th.

THE COURT: Okay. Well, we'll make that happen one way or another. And I'll get you a summary ruling, obviously very summary fashion, of what I did here today so it's in the record in writing, and obviously there will be a transcript of this ruling. And then I'll also deal with that pending motion to seal which I think is out there.

Anything else before we get off this hearing?

MR. ORENT: One quick question, your Honor, which is we have the final pretrial conference coming up, and I was just curious as to whether that is going to be a Zoom conference or at that point you would want us in person, just so that we can start making arrangements, if necessary.

THE COURT: No. I think we can still do a final pretrial via Zoom.

MR. ORENT: Okay.

THE COURT: I'm going to limit in person, even though our numbers are looking good, limit in person at this point. There's no need for us to have to be in person.

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

THE COURT: All right. Thank you, everybody.

MS. ARMSTRONG: Thank you, your Honor.

THE COURT: Court's adjourned.

MR. ORENT: Thank you.

(WHEREUPON, the proceedings adjourned at 12:35 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 the within proceedings.

Date: 6/7/21

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