UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	File No. 15-MD-2666 (JNE/FLN)
	October 26, 2017
	Minneapolis, Minnesota
	Courtroom 12W
	9:39 a.m.

BEFORE THE HONORABLE JOAN N. ERICKSEN
UNITED STATES DISTRICT COURT JUDGE

THE HONORABLE FRANKLIN L. NOEL
UNITED STATES MAGISTRATE JUDGE

THE HONORABLE WILLIAM H. LEARY
RAMSEY COUNTY DISTRICT COURT JUDGE

(MOTIONS HEARING - VOLUME III)

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P R O C E E D I N G S

(9:39 a.m.)

THE COURT: Good morning. Welcome back. Please be seated. All right. Still no Mr. Gordon, but you left him a chair in case, right, in case he feels better? What's his situation today?

MAGISTRATE JUDGE NOEL: How is he?

MS. CONLIN: He is still suffering from a migraine, Your Honors.

THE COURT: And did it spread to Mr. Ciresi? Is it me?

MS. CONLIN: No, he had a long-standing conflict. He's going to be showing up in a few minutes, Your Honor.

THE COURT: Okay. Everyone over here is feeling all right. Did you want to start by asking?

MAGISTRATE JUDGE NOEL: Yes. Mr. Gordon, Corey Gordon, could I ask you, so yesterday you had your fishless lake analogy, and I was somewhat confused by it. And I asked a question, and you referred me to the nine studies, and I'm assuming the nine studies you were referring to are the nine that was in one of the slides that I think was used by Mr. Blackwell.

MR. GORDON: Yes, Your Honor. Mr. Blackwell used it. Also, Mr. Goss used it.

THE COURT: Who used it isn't the main part.

MAGISTRATE JUDGE NOEL: And it's the one that lists Hall through Oguz.

MR. GORDON: That's correct.

MAGISTRATE JUDGE NOEL: And it was my understanding that what those studies show is that there is no increased rate of infection when they studied the Bair Hugger, but that it's not and that none of these are double-blind gold standard clinical studies that show no bacteria coming out of the Bair Hugger. Am I wrong about that?

MR. GORDON: Slightly. Actually, yes. All of these nine studies were not specifically infection studies. There are three or four of them where infection was noted where there were real procedures done, and I should say in none of them were any infections noted, but they weren't primarily infection studies. They were looking at various issues surrounding the notion of does the Bair Hugger cause an increase in bacteria either in the air, surgical site coming out of the Bair Hugger.

One of them, for example, introduced a test bacteria at the intake of the Bair Hugger and then measured with agar plates coming out so that they knew if bacteria were going in. They found that no bacteria were coming out. That was one method of study.

Another was -- my favorite study was where they

somehow recruited a handful of, I think eight University of Minnesota students who were willing to lay for four hours on an operating table.

THE COURT: For money, I'm sure.

MR. GORDON: I'm sorry?

THE COURT: For money.

MAGISTRATE JUDGE NOEL: They got paid to do this.

MR. GORDON: I assume that they were paid.

MAGISTRATE JUDGE NOEL: At least the pizza and beer.

MR. GORDON: I would hope so.

THE COURT: I had an University of Minnesota student on a jury, and he said afterwards he was so sorry that the trial wasn't longer because he needed the 40 bucks a day.

MR. GORDON: But a couple of them were in fact randomized trials. You can't really do a blinded trial with warming versus something else. And the most recent one, and probably the most compelling one, was the Oguz study, which was a randomized trial, over 80 subjects, 40 of them were randomized to Bair Hugger, the other 40 had orthopedic procedures done using the HotDog. And they were measuring bacterial contamination with sedentation weights, agar plates in six different locations. They were specifically looking to see is the method of warming, does that have any

impact on bacterial contamination?

They were also looking at other potential factors such as whether the so-called laminar flow was on or not, the number of personnel in the room during surgery, and there was a fourth factor. The only one that they found that did actually have a statistically significant impact on the amount of bacteria that they collected was whether the laminar system was on or not. If it was on, the rates were significantly lower than if when it was off.

When they compared Bair Hugger to HotDog throughout the procedure, and these were short orthopedic surgeries, short being defined as less than an hour, although, I think one or two of them were in fact hip arthroplasties apparently done within hour. And in the case of the warming device, there was no difference, no statistically significant difference. In fact, that was -- that was kind of really what they were looking for.

MAGISTRATE JUDGE NOEL: Okay. But I guess the reason I -- my confusion is I was under the impression that there's wildly disparate interpretations of these studies because some of them show up on the plaintiffs' slides, correct? In other words, Tumia and Moretti and Zink I thought were all studies that plaintiffs cite when we ask them about bacteria.

MR. GORDON: I think that's true, Your Honor.

And this is, I would submit that this is lawyer interpretation and lawyer science. Obviously, I'm doing a lot of interpreting too, but these nine studies have been uniformly, uniformly interpreted by the medical community and the scientific community as standing for the proposition that there's --

MAGISTRATE JUDGE NOEL: That there are no fish in that lake.

MR. GORDON: I have to say, Your Honor, I've gotten a great deal of critique on that analogy, and I wish I could strike it from the record. If I were a Congressman, I'd have it removed from the record and make believe it never happened. It was a dreadfully --

THE COURT: Give a man a fish, not happening.

MR. GORDON: Poor fish analogy.

MAGISTRATE JUDGE NOEL: Thank you for your answer. It explains or at least clarifies my confusion.

MR. GORDON: Thank you, Your Honor.

MAGISTRATE JUDGE NOEL: Did you want to say something, Ms. Zimmerman?

MS. ZIMMERMAN: Would Your Honors like to hear from the plaintiffs on this?

MAGISTRATE JUDGE NOEL: Sure.

MS. ZIMMERMAN: Just very briefly, I think that Mr. Gordon summed it up perfectly in his answer to Your

Honor's question. This is lawyer argument and interpretation of studies and that goes to the weight. It's not to the admissibility. We can talk about the different studies, but I'll leave it at that at this point.

MAGISTRATE JUDGE NOEL: To follow up the analogy, you think there are fish in that lake.

MS. ZIMMERMAN: I do think there are fish in the lake, Your Honor.

THE COURT: All right. Before we move on to the scheduled argument for today, which is the summary judgment, we have some experts still either to discuss or to agree that they won't be discussed. And let's first find out about plaintiffs' motion. I don't know really who to talk to here, but Settles, Keen and Kuhn.

MR. ASSAAD: Your Honor, we're happy to rest on the papers for Kuhn, Professor Kuhn and Dr. Settles.

THE COURT: And what about Keen?

MR. ASSAAD: And Keen as well.

MR. BLACKWELL: For once in agreement, Your Honor, us as well, the defense too.

THE COURT: I thought so, but I just thought I'd make a check.

Okay. So that leaves David and Ulatowski, and I know that David has not only engineering but also regulatory testimony. Ulatowski is regulatory only. Do you want to

dispense with Ulatowski now? Or do you want to separately argue about Ulatowski?

MR. BANKSTON: I believe so, Your Honor. I think that in fact it may shorten the argument on David if we talk about Ulatowski first.

THE COURT: All right.

MR. BANKSTON: And in effect, we could do it all in one big ball of wax. Ulatowski, move to David, you know, it's a matter of how you want to handle it.

THE COURT: Well, except that one is your motion. Well, I guess it isn't really.

MR. WINEBRENNER: Your Honor, we're happy to address --

THE COURT: Wait a second. Wait a second, who are you? Sorry.

MR. WINEBRENNER: I'm Joe Winebrenner for the defendant, and I prepared some remarks on Dr. David's motion to exclude. And I actually intended to rest on the papers with regard to the regulatory piece deferring the common ground to Ms. Ahmann, who is going to comment on Mr. Ulatowski.

THE COURT: All right.

MR. WINEBRENNER: We can take him up in either order, whichever the Court prefers.

THE COURT: All right. You, Mr. Bankston, I'd

like to hear from you.

MR. BANKSTON: Yes, Your Honor. I'm going to try to keep things moving. My credo has always been power corrupts and PowerPoint corrupts absolutely. I'm going to keep things moving today.

THE COURT: I'm with you except for the first part of that. That ain't right.

MR. BANKSTON: Mr. Ulatowski is a long time FDA employee, was involved for his entire career in the evaluation, regulation and compliance enforcement of medical devices. He was in the Center For Devices and Radiological Health. The type of organization, the part of the organization that deals specifically with the medical devices as opposed to the pharmacology and all the other stuff that the FDA does.

Mr. Ulatowski has decades of experience with the FDA. He's been offered to talk about regulatory issues and most fundamentally is the idea that compliance with the 510(k) regime and the minimum federal regulations surrounding the 510(k) regime, in other words, the continuing regulatory duties that Bair compliance with that is relevant in some way to plaintiffs' design defect and failure to warn claims and negligence claims in this case.

In other words, I believe it is Mr. Ulatowski's position, this was a little unclear at deposition, that he

is not arguing that 510(k) compliance equals nonnegligent design, but instead is arguing something more like 510(k) compliance is somehow at least relevant to the issue of standard of care and, therefore, wants to talk about all the 510(k) compliance issues.

So, first, to take up as a threshold legal matter, we've devoted some time in the brief to talking about why we believe Mr. Ulatowski's testimony is generally prejudicial and confusing and a waste of time under 403. We cited a lot of authority from recent years in the MDL context talking about why the introduction of testimony about Bair compliance and diving into the really the labyrinthian regulations that surround these products is not a good use of the Court's time and is a definite threat of jury prejudice and absolute confusion over what the federal clearances mean versus federal approvals versus what all of these things end up meaning in terms of what the jury is actually supposed to decide.

I think the best recent discussion in this is last year, the Fourth Circuit in a case called *CR Bard*. This was the pelvic repair MDL. And this is a very extensive discussion of really the kinds of problems posed when the FDA testimony looks a lot like what it does in this case where you have two experts who are going to argue about not only whether the product complied with regulations as a Bair

factual matter, but also the over-arching import of those regulations what they actually mean, what they're able to actually guarantee the public. And when you have these two experts engaged in this kind of battle, you end up having, you know, a huge amount of the trial and expenditure devoted to something that is not actually in the jury's consideration.

Ultimately, what the FDA does and what the 510(k) process does has marginal, if any, relevance at all to whether this product is unreasonably dangerous. Answering the question of what the FDA does doesn't really help you answer that question.

JUDGE LEARY: Let me ask you this, when you question the judgment of the FDA, why is their process for approval not relevant?

MR. BANKSTON: Well, I think you need to understand the difference between FDA approval, which you've referenced which this product does not have, and the difference between pre-market clearance.

JUDGE LEARY: Let's be more precise. Let's talk about the FDA letter, 2017 letter.

MR. BANKSTON: Okay.

JUDGE LEARY: If the plaintiffs are going to question the judgment of the FDA in terms of the quality and quantity of information they had when they issued that

letter, why is it not relevant to talk about what the FDA does as part of a regulatory process?

MR. BANKSTON: Sure. Let me do two parts of that. First of all, we absolutely question the judgment behind that 2017 letter. We question the process by which it's created. And if that does have to become --

JUDGE LEARY: I understand it. Let's get to the second part.

MR. BANKSTON: Okay. Well, the important part about that 2017 letter is if that ever comes into any part of this court and this trial, we're going to have to go down a side road about the author of that letter, and some very disturbing criminal acts that call into question his basic integrity not only as a human being but as a regulator. And we don't think that that's a good use of this Court's time.

THE COURT: Not by "person." It comes out as an agency letter.

MR. BANKSTON: Sure.

THE COURT: So you're going to rip apart some fellow. I'm assuming it's a man working for the FDA?

MR. BANKSTON: Correct. One of the, the head scientific advisor of the FDA. And, yes, there's absolutely no way to avoid introducing the crimes of moral turpitude that are very much on the record, and this is some very disturbing stuff.

JUDGE LEARY: Well, let's just slow down a little bit. The FDA letter is, I would assume, based on what the FDA undertook from the beginning of Bair Hugger up until the time that the letter was issued. So it seems to me that there's relevance not only in terms of explaining what the FDA does in writing that letter, but also there's relevance in explaining what the FDA did up until the point of that letter from the beginning of Bair Hugger up until the time of that letter. It seems to me to be all relevant.

MR. BANKSTON: I don't share your assumptions about the nature of that letter, but I do think let's go ahead to the second part which draws into everything that happened before that letter and whether or not that is relevant. And we have to ask ourselves what did the FDA do? And that's extensively discussed in the cases we've decided of what the FDA did during this 510(k) process.

So as a beginning threshold matter, we believe that this Court is bound by the U.S. Supreme Court in *Riegel*, in *Medtronic*, saying that the 510(k) process does not speak to safety and effectiveness.

JUDGE LEARY: So what value ultimately is it for the FDA to embark on a process in which they at one level or another pass judgment over a product such as Bair Hugger? Is that totally an unnecessary exercise irrelevant to the public, irrelevant to marketing?

MR. BANKSTON: No, I believe that the 510(k) process has a purpose, and it's purpose is not safety and effectiveness.

JUDGE LEARY: And tell me about that purpose.

MR. BANKSTON: The 510(k) purpose is to remove products that do not have safety questions from that consideration by determining if they are substantially equivalent to an already legally marketed product that has been found to be safe and effective.

JUDGE LEARY: In the FDA's judgment, that was Bair Hugger.

MR. BANKSTON: Correct. So to start with the first threshold part is what did the FDA do and does it have any value? We definitely have legal arguments about that. Moving on specifically to what did the FDA do specifically with this specific product? We also have some very important arguments about that as well.

So but just as an introductory threshold matter, we believe if you look at the case law, many, many courts in this exact MDL context said we are controlled by *Riegel*, we are controlled by *Medtronic*. If we are to find that the 510(k) process has any relevance to safety and effectiveness, if that's what that process is designed to do, we are in direct contact with Supreme Court authority.

So on a legal matter, we think immediately it goes

out. Ulatowski has been excluded on this exact basis numerous occasions, and those cases are discussed in the *Next Gen* litigation, in the *Ethicon* litigation. These matters are extensively discussed on those terms, and that's in a vacuum of purely theoretically what the 510(k) process does. That's totally separate and aside from the fundamental reliability issues that Ulatowski has in this case regarding what specifically happened with this product. And maybe it's better if I move on a little bit to that.

The law is there and can be read. What I think I need to bring everybody up to speed on is the factual record of what happened in this product. Mr. Ulatowski testified that he was going to, you know, he's going to come to opinions about how the FDA reached a safety decision or endorse this product on a safety level and did so through the 510(k) process.

Now, one of the obvious big questions in this case we have a product that was first 510(k)'d for nonoperating room use with a substantial equivalent product that was also a nonoperating room use product. When the I guess what you call the middle iteration of the Bair Hugger, the Bair Hugger model 500 was the first product that was going to be introduced into the operating room for use. That was subject to a 510(k) process.

We talked to Mr. Ulatowski about that process, and

he told us, well, you know, one of the challenges in this case is the decision making documentation for that 510(k) decision is not available. It was not available for my review, so I have to speculate about what the FDA did during that process.

During that process, the FDA has to follow a flow chart to ask questions. If you answer certain questions "yes," you move on to the next question. If you answer "no," it directs you to a different part. It's a basic kind of flow chart. Where are the elements of this flow chart, if the FDA asked itself this product, does it have the same indications statement, the same indications for use as the prior product?

If the answer to that question is "yes," the FDA is done. You don't have to ask any questions about safety. You've now cleared the product because it has the same indication for use. There's no changes in the indication for use, so there can be no safety issues by that change.

If the FDA finds that, yes, the indications for use have changed, now there must be some sort of inquiry by a reviewer. Do those new changes raise new questions of safety? And then that's the process that they're supposed to follow.

When asking Mr. Ulatowski, so how does this play out with respect to the Bair Hugger? Mr. Ulatowski says the

FDA would find that the change from outside of an operating room to use of an inside of a delicate operating procedure would be a change in indications for use or indication statement. Therefore, the reviewer would answer that "yes", and would then next ask does that change alter any of your safety questions?

The problem with that analysis is that we actually do have the 510(k) decision making documents. Apparently, they were provided to Mr. Ulatowski in the prior *Walton* litigation, not part of his report in this matter, and he certainly wasn't aware that they existed. Those documents show that there was a serious error made in this 510(k) review process.

As we put screen shots all throughout our motion, we have the actual flow charts, the actual reviewer comments and the entire process that he followed. And when he got to the question does the Bair Hugger 500 have the same indication statement as the Bair Hugger 200? He said yes. So then his next question, which is does it raise new questions of safety? He doesn't have to answer that question. And when they have the narrative part saying what did the FDA do to determine new issues of safety and effectiveness? He writes "N/A" because he does not have to answer that question if that's the finding he made. We believe that's a clearly erroneous finding. It's very

problematic.

Mr. Ulatowski says, well, maybe the FDA didn't find a change to OR use to be significant. Speculating on that. And I would submit that if so, if the FDA found that the change from outside an OR to the use of an ultra clean orthopedic surgery wasn't significant then I would submit that the FDA is broken and needs to be fixed because that is an absolutely dangerous conclusion to make. I mean if you have me on the record in front of a federal court right now, I will tell you without qualification the FDA is broken and needs to be fixed.

But in this specific case, we have documentary evidence showing that the very thing that we're going to try to use the 510(k) to establish safety and effectiveness of the product was not answered by the 510 reviewer and that the FDA has never during the 510(k) process meaningfully reviewed the movement of the Bair Hugger from outside an OR into an OR. Mr. Ulatowski cannot give reliable opinions on this entire subject matter and that is extremely problematic to us. And this is really not a matter that we would need to pull out and discuss in front of the entire jury.

Obviously, 403, one of the questions is is it going to make this a mini-trial? There is going to be nothing mini about this part of the trial. If we have to go into this, there's going to be, as you've seen from our

punitive damage motion, as you've seen from other briefing, there are so many disputed issues about what went on with the FDA in this case. For example --

THE COURT: Let me just ask you, I am curious about your understanding of the application of the hearsay rule covering public records:

803.8, "A record or statement of a public office is non-hearsay if it sets out a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law enforcement," of course.

And then I think what you're talking about with your, and I'm curious what this moral turpitude, et cetera, is of course. I suppose that would go to you're talking about something under 803.8(B): "The opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness." But that is an admissibility question. It's not a jury question.

MR. BANKSTON: Correct.

THE COURT: So I'm curious about how you're -- I mean you seem so exercised about the fact that there would be a mini-trial, but I'm wondering how you square that with the Rules of Evidence that would apply?

MR. BANKSTON: I agree with you in respect that there is several categories of documents that would likely never be admissible under any scenario. That is not to say

that having Mr. Ulatowski and Dr. David slug it out for days over what is the purpose of the FDA? What actually happened in this case? All of these facts wouldn't cause an extremely time consuming mini-trial.

It is true that I think some of the documentary evidence that you're talking about, for instance, the FDA letter, I don't see in any way how that can ever come into a courtroom at all.

THE COURT: I just read you the Rule of Evidence.

MR. BANKSTON: Well, no, I don't think there was a legal duty to create that letter. That's what I'm saying. I think there are plenty of documents in this case that were a legal duty to create. I don't think that letter goes --

THE COURT: Why do you not think that?

MR. BANKSTON: I don't see any legal statutory basis to cause that letter to be written. I don't see any regulatory scheme that causes that letter to be written. And I think if we all understand the circumstances, it seems to stretch credulity to think that that letter was created sua sponte by the FDA. These are things we would obviously like to explore if that has to come in and, again, things we don't need to explore.

So I do think there are some things that come in, some things that would under hearsay, but our entire argument is a 403 argument, and I do believe that it would

cause a mini-trial if that happens.

THE COURT: All right. Thank you.

MR. BANKSTON: Moving on from that, there's also the issue that so many of these opinions require him to speculate on what the FDA would have done in the absence of any specific documentation or technical information that he can rely on. And these were exactly the kinds of opinions that were excluded in *Brown v. Medtronic*. Interestingly enough, that was attached to Exhibit 10 to Defendant's motion. They take a reading of that case to talk about Mr. Ulatowski's qualifications, don't really want to apply the part where it talks about the very opinions he gives in this case need to be excluded because they are way too speculative.

He has other contradictory opinions about things like warnings that directly contradict the documents, the FDA blue book guidance documents that talk about warnings. And we think in terms of a methodology, if his only methodology is to review FDA statutory and regulatory authority and FDA materials to give the opinions about what the FDA requires, he has to show fidelity to those materials. If he's not, he's not working under a reasonable methodology.

There's also the large problem in this case of Mr. Ulatowski's direct personal involvement with the Bair

Hugger and that's going to become very difficult to excise from this case. And we believe this is a matter that raises significant prejudice. He does have personal contacts with this product with this company over the course of his career. He is in fact a 510(k) signatory on a clearance document for Bair Hugger product. He's been involved with the product line before.

He has, there's actually been during the period in which Arizant was trying to I guess fight a commercial damage control mode over some of their competitor's advertising, they wrote a letter to Mr. Ulatowski. Mr. Ulatowski says that he thinks by that point he was in a different job and, thus, would have forwarded the letter to somebody else, but there's no doubt that he is a recipient of that letter. The finding was that Mr. Ulatowski himself is the author of the FDA's warning letter to 3M or I believe it might have been Arizant at that point regarding burns caused by the Bair Hugger. Obviously, when we're going to be talking about overall risk utility versus products, that's something we're going to be interested in talking about. To have the person who authored that warning letter on the burns sitting in the witness stand as a paid representative of the defendants is a -- creates a really ripe opportunity for jury confusion.

We think it's going to be very difficult for the

jury ultimately to know and to really understand whether Mr. Ulatowski is here as an independent person being paid by the defendants to give opinions or whether he's here giving opinions essentially on behalf of the FDA. That is an extreme danger to the plaintiffs. This is not a speculative kind of prejudice. And given that his testimony really offers very little of value, there seems to be no reason to subject the plaintiffs to that kind of prejudice.

Mr. Ulatowski's opinions, really he's had to dial them back because of all of these prior exclusions. There used to be a time when Mr. Ulatowski would come to a courtroom and say FDA 510(k) process is equivalent to a finding of non-negligent design. It's directly relevant to plaintiffs' claims. And after being excluded on that point multiple, multiple times, he's dialed it back to something that is just not helpful to us. It really doesn't do anything to us.

The times that this Court or at least this District has admitted FDA testimony, it has been in the context of where plaintiffs have made specific allegations of violations of the minimum floor of what a manufacturer has to do, and those violations going below that minimum floor is very relevant to a standard of care, at least it can be in many cases.

There's no authority out there, and certainly

defendants have cited none that says Bair compliance with those regulations is in any way relevant to standard of care. So if it's not relevant to non-negligent design and product defect, and it's not relevant to standard of care, it really doesn't do a lot for us in this trial.

The last thing I want to talk about with Mr. Ulatowski is there's sort of a large gray area about what he may or may not testify about by hooking into certain parts of his opinion, about is he going to testify about regulatory matters or not? And I tried to pin him down on some of these topics at deposition, and his answer was essentially who knows. And defendant's response to this is, well, if he's asked to make those opinions then we'll examine his competence then. And I really don't want that sort of Damocles hanging over it.

So I think another part of the thing that plaintiffs are asking for in this order is a limitation that if he's going to testify about anything, it's not going to be orthopedic surgeries, engineering, biomedical issues. The only thing he can be qualified at all in is regulatory testimony. And we don't believe that any of that is going to be very helpful to us in this case.

So unless you have any questions, I'll go ahead and pass it on over to them, and let them tell you about Mr. Ulatowski as well. Thank you, Your Honor.

MS. AHMANN: Good morning, Your Honors. Bridget Ahmann for 3M and Arizant in opposition to the motion to exclude Mr. Ulatowski. May it please the Court, Counsel:

I was going to be really, really short because I thought the presentation would be short, but I feel like Mr. Ulatowski has been attacked on numerous grounds that are inconsistent both with what he's saying and what the law provides.

First of all, he is here to talk about FDA regulations specific to medical device and also to talk about how 3M, Arizant complied or dealt with those regulations. The fact is the medical device community is governed by the FDA. That is the framework within which they operate.

Yesterday, there was a comment, I believe, by Mr. Farrar about how one of the experts didn't talk about any standards. He came without talking about any standards. Well, the fact is Mr. Ulatowski will talk about standards because that's directly what is applicable in the jury's consideration of whether or not this company acted reasonably. Such testimony is necessary.

First, I will talk a little bit about Mr. Ulatowski not that his qualifications have been --

MAGISTRATE JUDGE NOEL: Can I interrupt for a quick second and go back to your opening slide because I

think there's a typo or something or I'm confused entirely about what we're doing here. It's not your motion to exclude --

MS. AHMANN: I'm sorry, in opposition.

MAGISTRATE JUDGE NOEL: Okay, thank you. I just wanted to make sure.

MS. AHMANN: They were prepared a long time ago, so you're right. I'm arguing --

THE COURT: If they want him, you'd be getting --

(Laughter.)

MS. AHMANN: What Mr. Ulatowski is going to talk about is not just that little 510(k) that is but what one glip on what the FDA's exercise of authority is and their evaluation of medical devices. They run the gamut, and he was involved at all different stages in medical device evaluations and that's what he's going to talk about. The 510(k), which is the only thing we've heard about in terms of the legal authority, there have been courts that have excluded that type of evidence with regard to the FDA.

Specifically, as he says what Mr. Ulatowski is not going to say. Mr. Ulatowski is not here to say that the 510(k) by itself defines or is preemptive, if you will, on the question of whether or not the device was safe and efficacious. What he's going to say is safety and efficacy go into consideration in the 510 stage.

The cases that have held otherwise look at *Lor* and *Riegel*, which are preemptive cases. They don't deal with relevance. What they say is you can't make a statement that the 510(k) by itself establishes that this is safe and efficacious. So it can't preclude any state claims on it. That's not the allegation. We're here to talk about whether or not evidence on the 510(k) is relevant, and we say it is.

The other thing as I showed you here, 510(k) is but a glip. What they've tried to do is they've tried to glam on to these cases and to try and extend that to go beyond a 510(k) evidence. In fact, it's interesting because they presented their own regulatory expert until the FDA letter came out, and now all of a sudden they want to withdraw that, and they don't want to talk about the FDA. So his testimony is relevant not just to 510(k), it's beyond that.

And might I say that we don't agree with those cases because we think the jury needs to understand what environment these companies work in and how can you judge the reasonableness of their behavior in making design choices, of deciding what risks to talk about if you don't know the environment with which they operate.

In fact, many courts, not just the one cited by the plaintiffs, and in fact, he refers to them as gabs or gobs which I take to be many, almost all of the cases

emanate out of the MDL mesh litigation in the Southern District of West Virginia. In those cases, the Judge made a decision, and he has applied that over and over and over again in those cases. He has been affirmed as indicated by the Fourth Circuit. We don't agree with those because we think there's lots of other cases which have recognized that in fact FDA evidence is relevant.

In Re Fosamax, a lay jury cannot be expected to understand the complex regulatory framework that informs the standard of care in the pharmaceutical and medical device industries. Admittedly, that's a drug case, but the fact is the FDA is who the FDA is, and they regulate both drug and medical devices. Minnesota law is consistent with that because the courts have time and again and contrary to what is suggested, they've actually allowed testimony about the FDA when the FDA has found that the defendants act in compliance.

In *Kruszka v. Novartis* case, they allowed the FDA expert to opine on the reasonableness of the defendant's interactions with the FDA in compliance with FDA regulations. And here's the important part for us today. "And such testimony would be helpful to the trier of fact from a regulatory perspective." And *Kruszka* is not the only case.

In Huggins v. Stryker, which involved a medical

device, a pain pump, the Court recognized that the device manufacturer's interactions with the FDA at the 510(k) clearance were relevant because the jury, they could shed a light on the considerations by the jury.

In *Lillebo v. Zimmer*, which was an orthopedic case, they allowed the FDA expert to testify as to FDA processes including the FDA clearance in considering the reasonableness of the manufacturer's design, testing and manufacture. Minnesota courts allow this. There really shouldn't be much question about whether or not this is relevant and helpful to the jury. This is not confusing. This is not -- the Court can certainly control the introduction of evidence to avoid any kind of mini trial.

I also want to briefly address some of the reliability arguments. I'm not going to go into details. Those were addressed in our papers. Mr. Ulatowski performed the same type of evaluation that he would have when he was at the FDA. He reviewed thousands and thousands of pages of documents and to criticize because him because he forgot that he had in fact reviewed one particular piece of evidence is really in excusable. It certainly doesn't go to the credibility or the reliability of his methodology. He can be cross examined on that. And, in fact, that would be the appropriate if counsel thinks that that is important, but that goes to the weight of his testimony not the

admissibility. And I won't even go into the various other because they're all explained by Mr. Ulatowski.

They also complain that he has a conflict of interest because counsel thinks that he's touched these cases. First of all, they present no legal authority, no regulatory authority, nothing on the issue of ethical obligations of the FDA. But Mr. Ulatowski talked about that and that's in our brief. He's talked to the Ethics Committee for the FDA knowing that when he serves as an expert in cases that there are certain things he can't talk about, and he doesn't, and he didn't here. There's nothing to counter that.

And even factually all these ethics and all these biases are founded. Mr. Ulatowski talked about the fact that he didn't receive the August of 2010 letter because he would have been at a different department. So counsel says that he thinks he wouldn't have got it. Well, he knows he wouldn't have gotten it. He wasn't there. He had moved on.

He also didn't -- he was asked about whether or not he was copied on a letter that dealt with the Bair Hugger fluid warming. And counsel would like to say that he evaluated that and that's the same thing as the Bair Hugger. It's not. It is a fluid warming device. It is not a patient warming device generally. It is in a totally different division, which he explained in his testimony.

He was not involved in the division that operated the Bair Hugger and the warming device. He was the fluid -- he was in the division that evaluated the fluid warming device. And the fact is if counsel would have shown him the full document, the full document shows that this was not a forced air warming device at all. It was a completely different methodology and engineering to do the fluid warming.

And with regard to, there was a letter that he did send out relative to the burns. And, again, has nothing to do with the issues in this case, and he can certainly be cross examined on that if they think it's appropriate.

And the final argument is that we should exclude him from talking about everything else because we don't know if he's going to talk about everything else. I think that it probably is best to wait and see what he talks about before we exclude him. His report was very thorough. And if his opinions were in there, I think that, you know, counsel will be hard pressed at the time unless he's drawn out by other questions from the plaintiffs' side, the fact is there's no reason right now to sit and talk, theorize about what he might be asked. Unless the Court has questions.

THE COURT: Ms. Ahmann, are you the person to ask about what it is that Mr. Bankston was referring to when he

was talking about the --

MS. AHMANN: FDA letter and moral turpitude and all of that?

THE COURT: Yes.

MS. AHMANN: Absolutely not me. You know, I have to say that, you know, we have not been presented in these days of arguments about a motion to deal with the FDA letter. It has been referred to several times using what Mr. Blackwell would say, I'm not as good as he is at saying "that horse has left the barn." We are, you know, the FDA letter is there. There's no doubt that it's going to be evidence.

THE COURT: But have they shared with you whatever it is that he was --

MS. AHMANN: No, this is the first I've heard of it, so I am definitely not the person to deal with it.

THE COURT: I'm sure it was somebody on your side.

MR. BLACKWELL: Your Honors, if I may?

THE COURT: Yes, please, Mr. Blackwell.

MR. BLACKWELL: Just to put this to rest, the author of that letter was picked up for solicitation roughly five years ago.

THE COURT: Mr. Maisel or Dr. Maisel, M-A-I-S-E-L?

MR. BLACKWELL: Whoever signed it. I don't have the name in mind, Your Honor, on the FDA letter, but he was

then returned to his job, given his job back thereafter. So if this is something we want to talk about from about five years ago, he was picked up with solicitation. The FDA restored him to his job sometime thereafter, and that's what they're referring to the dastardly, horrible --

THE COURT: Was he convicted of anything?

MR. BLACKWELL: They're saying, yes, and we don't know, but I expect --

THE COURT: Misdemeanor or felony?

MR. BLACKWELL: Misdemeanor solicitation.

MR. BANKSTON: There were four counts of felony solicitation all pled down to a misdemeanor.

THE COURT: Okay, but the conviction there's 609, you're talking about conviction.

MR. BANKSTON: Correct, Your Honor.

THE COURT: My question has to do with conviction.

MR. BANKSTON: Yes, my understanding is there are convictions on the record against him.

THE COURT: One misdemeanor?

MR. BANKSTON: I actually am not -- I can't speak to you right now whether those are misdemeanor or felonies. My understanding was they were felonies, but I don't --

MR. BLACKWELL: My goodness. They bring this --

THE COURT: Yeah, that's pretty, yeah, well --

MR. BLACKWELL: They bring this up. They know

it's a misdemeanor solicitation, and at least that's an understanding of what this is about.

THE COURT: All right. Mr. Bankston, I guess you're the person who brought this all up. Is that what you were talking about?

MR. BANKSTON: Yes, Your Honor.

THE COURT: And is it your position that --

MR. BANKSTON: It is our position that he is uniquely vulnerable to continued influence given his predilection for picking up and exploiting human trafficking victims off the streets of D.C. That's our position.

THE COURT: I have an evidence question for you.

MR. BANKSTON: Sure.

THE COURT: Calling your attention to Rule 609, assuming for the moment that it is a misdemeanor prosecution conviction, is it your -- do you have any authority for the --

MR. BANKSTON: That it would be an admissible -- you're correct, Your Honor. Yes, I do.

COURT REPORTER: Don't interrupt, please.

THE COURT: Would you just let me ask the question?

MR. BANKSTON: Oh, I'm sorry, yes.

THE COURT: That that constitutes a crime of falsehood?

MR. BANKSTON: That solicitation under the prostitution statute does? Constitutes a crime of moral turpitude? Was that --

THE COURT: No, my question, as you know or should know, misdemeanors under 609 are admissible if they are crimes, you know, crimen falsi, crimes of falsehood. And to my, in my experience, a prostitution conviction has not and is not considered a crime of falsehood. My question to you is if you have any authority to the contrary?

MR. BANKSTON: I thought the determinative issue was whether it's a crime involving moral turpitude.

THE COURT: Well, it's not being impeached. It's --

MR. BANKSTON: Well, I do have the authority on CIMT.

THE COURT: I don't know what "CIMT" is.

MR. BANKSTON: Oh, I'm sorry, Crime Involving Moral Turpitude. I have Eighth Circuit authority on that.

THE COURT: All right. Give me a case on that then.

MR. BANKSTON: Sure. That is *Gomez Gutierrez v. Lynch.* That is 2016 Westlaw 362 24 -- excuse me -- 362 427 at *4. That is the Eighth Circuit in 2016. And I just wanted to add the reason I'm kind of familiar with that is I have sort of a parallel practice with some immigration

issues and have been recently taught in no uncertain words do not let your immigration clients plead to misdemeanor crimes of moral turpitude.

THE COURT: All right. Well, let's talk about the Rules of Evidence. That may be all well and good. 609A talks about felonies, subdivision 1, imprisonment for more than one year. And then there is a second subdivision for non-felony convictions and that ties to a dishonest act or false statement and that is the codification of the common law crimen falsi doctrine.

MR. BANKSTON: Okay.

THE COURT: It doesn't have anything to do with moral turpitude.

MR. BANKSTON: Okay.

THE COURT: So are there any cases that you can cite for the proposition that the sort of conviction that you are talking about with respect to that employee where those have been categorized as dishonest or false statements for purposes of Federal Rule of Evidence 609(a)(2)?

MR. BANKSTON: Not standing here now, no, I don't, Your Honor. That's certainly something I would like to look into. And to us the more threshold question is not how such evidence would be admitted, but in our minds, the question is what is the fundamental reliability of that letter? Is there anything in that letter that makes us question it as

potentially I mean obviously we have basic problems with the letter itself. We do have problems with the letter of the author. These are issues that we very well could potentially raise in trial. And as far as that authority --

THE COURT: Well, I'm asking you right now since you're the one who brought it up and were so exercised about the moral turpitude.

MR. BANKSTON: I absolutely am very troubled by it and very troubled by the unique vulnerability that a federal regulator who was allowed to return to that role with such a predilection is subject to potential influence from outside sources. I'm very concerned about that.

THE COURT: Is there anything else or is that what you're talking about?

MR. BANKSTON: That's what I'm talking about in terms of those crimes. Correct, Your Honor.

THE COURT: Thank you, Mr. Bankston. You may be seated now. I want to hear from Mr. Blackwell on that basis.

MR. BLACKWELL: Your Honor, just want to make sure the record is clear that he did not lose his job. He pled to one of several counts. There was a $200 fine, and the rest of the charges were in fact dismissed. And as Your Honor is well aware, he simply signed on behalf of the agency, and I'm not seeing the tie-in other than simply

wanting to raise this for obvious reasons.

THE COURT: All right. Well, let's talk about Mr. David. Mr. Winebrenner?

MR. WINEBRENNER: Yes, Your Honor. Good morning, Your Honors. I'm Joe Winebrenner on behalf of defendants. I will be discussing defendant's motions to exclude Dr. Yadin David.

Dr. David's opinions can be separated roughly into four categories. Defendants have moved to exclude his opinions in all four in their entirety. They are his regulatory opinions, his standard of care opinions, his so-called hazard analysis opinions, and his alternative design opinions. Of these four categories of opinions, the only two that arguably address causation issues are the hazard analysis opinions and alternative design opinions, and for that reason, I intend to address those first.

Dr. David conducted what he calls a hazard analysis of the Bair Hugger system. This consisted of an examination of a used Bair Hugger device as well as a review of a small selection of documents and literature. And based on this work, Dr. David claims to conclude that the Bair Hugger more likely than not increases the risk of surgical site infections in orthopedic surgeries. We address in our briefing a number of reasons why this opinion should be excluded. I'm going to focus on just a few of the high

level points today.

First, Dr. David is not qualified to opine on the clinical risks of the Bair Hugger system. And by "clinical risks of the Bair Hugger system," I'm talking about medical causation because that is what his opinion touches on.

Dr. David is a biomedical engineer by trade. He's not a medical doctor. He is not a clinician. And although Dr. David has participated in a committee, the Medical Technology Evaluation Committee in which he in the context of a committee makes purchasing recommendations to his employer hospital. Dr. David is not the one performing the clinical risk assessments of the devices that are being evaluated in that committee. He defers that task to others who are more appropriately qualified.

Now, plaintiffs contend that we're wrong in that regard and that Dr. David performs these clinical risk assessments all the time, but the record does not support that argument.

Dr. David in his deposition testified to the makeup of his Medical Device Evaluation Committee. He says that "my committee consists of many representative stakeholders, physicians, nurses, purchasers, administrators, safety officers, risk control and quality control professionals, and facilities engineering, biomedical engineering and sterile processing supplies."

And he goes on: "So the committee was representing so many expertise, and I was in the position where I had to receive their input and derive recommendation to the hospital management if a device is beneficial with lower risk than what's being used today."

Now, to avoid any ambiguity with respect to Dr. David's role in this process, he was asked:

"In performing your work for the hospitals, do you rely on physicians and nurses to provide you with information about clinical risks and benefits?

Answer: On the clinical side, yes."

So the record does not support plaintiffs' contention that Dr. David performs these clinical risk assessments of devices all the time. He relied on others to do that.

What Dr. David does in his report is different. He does not rely on anyone to assess clinical risks and benefits of the Bair Hugger device. He does that himself, and this is problematic under Rule 702 not only for qualifications purposes but also because it is a departure from his ordinary methodology. In the hospital context, Dr. David relies on others to assess clinical risks of the device, but when he is retained as an expert in litigation, he is a one-man show. He does everything by himself, and Rule 702 does not allow this.

The second piece with regard to Dr. David's hazard analysis that I want to raise is a disconnect between the methods that he says he employs and the conclusions that he purports to reach. In the hospital setting, Dr. David's committee evaluates devices for purposes of making purchasing recommendations not for the purposes of evaluating medical causation, whether a device medically causes a particular outcome. And the factors that are considered under these two situations are quite different.

In the context of a purchasing decision, a decision may be made based on factors that result in conservative decision making, factors such as public health considerations or just the general risk aversion of a hospital such that a hospital may choose to avoid a particular device because of questions about safety or effectiveness even when there is not a sound scientific basis to support those questions. And those types of factors have no role in a medical causation inquiry under Rule 702.

On top of this, Dr. David applied or chose not to apply the industry standard overall methodological framework for assessing the risk of medical devices. That standard is ISO 14971. Dr. David opted instead to employ a methodology of his own creation. It was one that he adapted from the miter standard, which he had used in the past in the

hospital setting to evaluate or to prepare for a disaster, disaster preparedness like the shutdown of the electrical grid, for example. And plaintiffs do not demonstrate how Dr. David's methods fit or can reliably lead to medical causation opinions, which is the purpose of his opinions in his report.

The last issue I want to discuss with regard to his hazard analysis is a series of issues, the problems with the steps that Dr. David took in his analysis. Plaintiffs contend that he reviewed an extensive body of literature, testimony, documents, as well as an examination of the device itself, but Dr. David did not review an extensive body of literature. He reviewed only 14 published articles, all of which reached conclusions that support, that were relatively favorable to the opinions that he reached.

Now, Mr. Blackwell and Mr. Goss discussed those articles over the past two days, and they demonstrated that none of them determined causation and none of them even reach a valid association with the Bair Hugger. But even setting the substantive shortcomings of those articles aside, Dr. David's actual methods in employing the literature review warrant exclusion of his testimony. He did not review a single study that was unfavorable to his conclusions. He didn't even acknowledge a single study that recognized that the Bair Hugger does not increase the risk

of infection, and we've heard all about those studies over the past two days. Courts around the country have recognized that expert witnesses cannot opine on causation based on a literature review that selectively includes only the most favorable stuff.

In Re Rezulin is an example. The Court recognized if the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable. And in that particular case, the Court concluded that the scientists have discussed only the evidence that they believed would advance the plaintiffs' position. Their reports cannot be said to reflect the same level of intellectual rigor that characterizes the practice of an expert in the relevant field, and we would submit that the situation is no different with regard to Dr. David.

In a similar manner, Dr. David did not conduct an extensive review of documents in forming his opinion. The Bair Hugger is a product that has been on the market for 30 years. There's 30 years of regulatory history. Dr. David purports to opine on clinical risks of infection that are not generally accepted in the scientific community, yet he reviewed only 64 3M produced documents.

Now, plaintiffs would take the position in their response that the quantity of documents that Dr. David

reviewed does not matter but rather it's the quality of the review, but that really just begs the question who is evaluating these documents and determining which ones are of sufficient quality to be sent to Dr. David?

And the last building block, so to speak, of Dr. David's hazard analysis opinions was his examination of the Bair Hugger, and we've heard about that. Dr. David examined a used device that plaintiffs' counsel purchased off of eBay.com, and which we've seen in the papers, and we've heard during the hearing the plaintiffs are affirmatively contending was not even functioning properly at the time Dr. David examined it.

And so plaintiffs don't demonstrate how an examination of a device of this sort can possibly support an opinion on medical causation. So these are all red flags with regard to Dr. David's hazard analysis opinions, and we would submit that they warrant exclusion of his opinions in full.

The next piece I would like to address relates to Dr. David's alternative design opinions. He identifies a number of other patient warming devices that are on the market and as well as some early stage design concepts that have been considered in relation to the Bair Hugger, and he asserts that these are feasible and safer alternative designs.

There are two major problems with this opinion. The first is that Dr. David includes conductive warming devices in his opinion. Devices like the VitaHEAT UB3 and the Tablegard System, which incorporate conductive warming technology. This Court has already concluded that conductive warming technologies are not viable alternative designs to the Bair Hugger due to the different technologies that they employ. And so those opinions out of the gate should be excluded.

The second problem with Dr. David's alternative design opinions is broader, and it touches on all of his proposed alternatives. And that problem is that he offers absolutely nothing other than his own say-so that any one of these proposed alternatives is actually safer. He performed no testing, and he offers no data whatsoever that could possibly be the basis of a contention that any one of the devices that he identifies is actually safer, and he concedes he has no such data.

He was asked in his deposition, "Is there any clinical data you're aware of that would suggest there's a difference in infection risk between the Bair Hugger device and any other patient warming device that you've identified in your report?

Answer: I didn't find it so everything that I did is in my report."

So Dr. David concedes he has no objective data to support any of his alternative design assertions. And in fact on the flip side, defendants have proffered that 2017 Cleveland Clinic study, which Mr. Gordon discussed yesterday. And in that study, over 5,000 surgeries were analyzed, half of which had been performed with a Bair Hugger and half of which had been performed with the Stryker Mistral air device, which is one of Dr. David's proposed alternatives and which incorporates a HEPA filter. And the results of that study showed that there was no statistically significant difference between infection rates of the Bair Hugger group and the Mistral air group. And so not only does Dr. David lack any objective support for his alternative design assertions, the only comparative evidence that exists contradicts his opinions. And so for those reasons, we would submit that his alternative design opinions should be excluded as well.

Now, with regard to the regulatory and standard of care opinions, I had intended to rest on the papers given the fact that they are, that these are non-dispositive issues in a hearing that's focused primarily on causation, but I just want to make a couple of points with regard to Dr. David's regulatory opinions so that the Court can contrast his qualifications and methods to Mr. Ulatowski's.

Dr. David is not a regulatory expert. He's a

biomedical engineer. He's never worked for the FDA, in contrast to Mr. Ulatowski who has decades of experience within the FDA making actual wholesale regulatory determinations. Now, plaintiffs rely on some advisory panels that Dr. David has sat on in the past. And they assert that his experience with these advisory panels qualify him to render regulatory opinions but that's really not the case.

Dr. David is never outside the context of litigation, made the types of regulatory analyses that he purports to make in his report. His experience on the advisory panels has been in the context of him providing biomedical engineering expertise on issues that the FDA specifically raised with him. He's not on any advisory panel determining substantial equivalence or determining regulatory compliance, which are the very issues that -- the very regulatory issues that he addresses in his report. And so we would submit that the Court or that Dr. David is not qualified to opine on regulatory matters.

And with that, Your Honors, unless the Court has any questions, I think we'll rest on the papers.

MAGISTRATE JUDGE NOEL: I just have one. The Cleveland Clinic Study that you referenced comparing the HEPA filtered device to the non-HEPA filtered Bair Hugger, is that one of the nine studies that I was asking --

MR. WINEBRENNER: I don't think it's in that list of nine. That particular study appears as Exhibit 10 to our motion to exclude Dr. David, which is ECF No. 768-1.

MAGISTRATE JUDGE NOEL: Thank you.

MR. WINEBRENNER: Thank you, Your Honors.

THE COURT: Thank you, Mr. Winebrenner.

Go ahead, Mr. Bankston

MR. BANKSTON: All right, Your Honors, I think I'm going to start with alternative design because I think that's the most important issue before us today, and I want to start to go down the four devices.

The first being the Vita Heat, which is resistive mattress design, and we fully understand the Court's prior order. Obviously, we disagree with it, but we absolutely understand it. And the Court's order premised on the idea that the resistive mattress was too radical a departure of a kind of technology. And from the order the language was you can't change a Bair Hugger into a Vita Heat. That's the idea is it's not like you can make a series of design changes then a Bair Hugger becomes a Vita Heat.

While Dr. David in his report describes why he thinks it's a substantial alternative design not a substantially different product, we understand the Court's order, and I'm not going to litigate it today. But with respect to the Tablegard product, the Tablegard product is

something that the Bair Hugger could become quite easily, and in fact is something that 3M explored turning the Bair Hugger into.

I direct you to look at Dr. David's report between the pages of 37 and 40 where he talks about, first, 3M's white board designs on how to create a closed recirculating air system. In other words, right now the Bair Hugger exhausts its air back into the environment. But what if it recirculated it back into the machine and refiltered the air and kept it in a closed loop? 3M did white board designs to try to figure out how to do this, and this was something they were very much exploring.

The Berchtold Tablegard is a practical realization of that design concept. If you want to take the Berchtold Tablegard apart and the Bair Hugger apart, they are identical. They are plastic enclosures that contain a blower unit, a forced air blowing unit, a heating element, a temperature sensor, and then a plastic coupling that directs the forced air into a hose, just like the Bair Hugger. That hose, just like the Bair Hugger, travels to an enclosure, a coverlet in the case of the Bair Hugger. Now, in the Bair Hugger, I believe it's cotton and polyurethane that makes the blanket and has perforations and it exhausts air out.

In the case of the Tablegard, it's a vinyl that's enclosed. And then at the end instead of an exhaust system,

there's a tube that goes right back into the machine. The Tablegard has done this by integrating it into a surgical table itself. Instead of making it a disposable item or something that's reusable like a resistive mattress where it has to be taken washed somewhere, it's actually part of the surgical setup, and it does this by having a constant flow of forced air through the vinyl design. And another benefit of this is that it maintains pressure control because the actual air pressure can change throughout the unit.

So you can easily make a Bair Hugger a Tablegard, and they've actually explored doing it. And the method in which the Tablegard heats the patient is well established. It is true that unlike the Bair Hugger, which is primarily convective, minorly conductive, the Tablegard through its design of making it recirculated becomes primarily conductive and secondarily convective. But the method in which it warms patients has been shown in studies conducted by Dr. Sessler to be equally effective at raising patient temperatures.

Now, it's true that there's not going to be a study out there, nobody has done an RCT yet at all, of course, comparing the Bergland Tablegard to the Bair Hugger in terms of infection rates. But the Bergland Tablegard removes every mechanism that the plaintiff has identified as causing these infections. If this device can not introduce

air into the room, then it clearly can not affect airborne contamination.

It is true that there is not an RCT on that, just like there's not an RCT saying that the Bair Hugger causes infections. But with Dr. David's experience and understanding of biomedical engineering, I think he can say when the device functionally removes the only mechanism that is being identified as the defect, that device is going to be safer than the Bair Hugger in that respect. So that design is something that we feel is very much on the table because that is something that 3M itself has even looked at.

With respect to the other forced air warming devices, particularly the Mistral, I think what 3M is missing here is the reason the Mistral is a better product in our mind is not primarily because of a HEPA filter, which Dr. David does believe from his engineering background is going to be beneficial.

But even Dr. David keys on to a point that Judge Ericksen raised, which is that the presence of a filter, even a more effective filter is not going to have any effect on the amount of heat being put into the environment and whether that mechanism of injury still continues. So it's not an optimal choice just to put a HEPA filter on the device.

The reason the Mistral is being advocated by

Dr. David primarily is because it has a conspicuous warning communicated to the manufacturer, and it's one of these in the first pages of the manual with a big triangle with a huge exclamation point saying that clinicians should take into account the possibility of airborne contamination when using this unit in surgeries. And Dr. David's contention is that kind of warning would have provided a clinician a reasonable basis to make himself aware of the science surrounding this device and make his own clinical judgments, and he believes given his experience in the creation and regulation of warnings that it was an adequate warning.

So the Mistral really goes more towards plaintiffs' marketing defect claim than it does its design defect claim, and so as an alternative design, it's an alternative marketing design first and foremost. So those are the alternative designs that he really talks about. And I do believe that those are well supported and very well discussed in his report as well.

I'd like to move on a little bit to his methodology, particularly the idea of a clinical hazard review. And, first, just a bit of law. We cite *Taylor v. Danek Medical*, which is an excellent discussion of what a biomedical engineer is. And biomedical engineers, according to that case, discuss "the proper design and implementation of studies to determine the nature and magnitude of patient

risks and the extent to which those risks are realized in clinical practice." That's what Dr. David has done for as a biomedical engineer for over 30 years. He has more qualifications than the usual biomedical engineer because we hear about his participation in something called the Medical Technology Evaluation Committee, he's actually the creator and director of that. That committee evaluates the clinical risk of medical devices for the Texas Medical Center, for the largest conglomeration of hospitals in America. And he has pioneered the field of medical device evaluation for hospitals. His qualifications have been grossly undersold.

He's also the chair of clinical engineering for the International Federation of Medical Engineers. He's been given the Lifetime Achievement Award from the American College of Clinical Engineering, and he continues to provide regulatory and clinical evaluation to the Texas Medical Center. His methodology was discussed as being a one man show and does not like what he does in normal fields and that's just not true because in this case, his opinion discusses and relies heavily on the findings provided to him in the reports of Dr. William Jarvis and Dr. Jonathan Samet, and these clinicians and epidemiologists input is part of what he would do in the normal field as well.

He discusses in his report that his review in this case was in fact far more rigorous than what he would

normally do in his every day activities, particularly because he's given access to documents that he would not normally have access to that other medical device evaluators and hospitals just simply don't have access to. So his performance of his job here was fundamentally the same that he did at the Texas Medical Center for 30 years, and he talks about that extensively.

They claim in that methodology that he didn't look at any studies that were unfavorable. In fact, I believe I heard was he didn't examine a single study that was unfavorable to the plaintiffs' position and that's just not true. If you check into his report, and I have to pull the page number on here, I believe it was page 20. That's part of where he begins the discussion of the scientific literature that was used to validate the Bair Hugger and sell it to the FDA essentially as a safe product.

Moreover, he talks in his section in his finalized opinions is a discussion about defendant's reliance on the materials, what they relied upon, particularly in the terms of the testimony from their corporate representative, their clinical director and their director of R&D, that the nature and findings of the studies they relied upon were not sufficient that a reasonable medical device company would have known that those studies were underpowered and not sufficient to provide a safety statement of the Bair Hugger.

That's all there, so I'm not sure why we're hearing that he didn't discuss in any way negative studies.

There's also the bit about we obviously agree that an expert doesn't have to review every piece of literature, and this is very different and distinct from the situation we talked about yesterday with Dr. Ho where he just abjectly failed to review any of the literature. And so if there's a study that, you know, there's studies that Dr. David didn't review or that he was familiar with through his deposition rather than on his reliance list, these are matters of weight and not admissibility.

The same is true is when you talk about not enough documents, Dr. David specifically requested what he wanted, and he wanted the kinds of things that ultimately Mr. Ulatowski didn't review like 510(k) decision making documents, and instead of reviewing pages upon pages of clearly irrelevant materials, yes, Dr. David reviewed the most important materials in the case. So we really don't think that that's an issue of methodology at all.

And then I do want to talk about his qualifications of regulation. It's an interesting position because we, you know, we designated Dr. David and primarily for his engineering opinions but prepared for regulatory opinions. Strangely enough, as a defendant to a traditionally do, he was a reactive. We knew they were

going to offer FDA opinions. We needed, although, we don't ever think they should be admissible, We needed somebody in case this Court decides it is admissible, and that's what he's here to do. We never wanted to go down the road of the FDA and have to deal with that in this trial.

But in terms of his qualifications to talk about that, we talk about past participation with the FDA. He is currently the chair of the FDA's Good Manufacturing Committee, the Good Manufacturing Practices Committee. He sits on the Orthopedic Medical Device Panel. Another one of his FDA titles is senior biomedical research reviewer. They said he's never made the regulatory analysis Mr. Ulatowski has made. That's not really true either because Dr. David testifies about it and it's in his report that he has made 510(k) reviews for the FDA. He has been asked to do that. It would seem to be defendant's position that unless you were employed by the FDA and drew a paycheck from them, you can't give regulatory testimony and that clearly can't be the law. Dr. David is perhaps the single most qualified person who is not employed by the FDA. I can't even contemplate a way a person would become more qualified without becoming a senior member of the FDA.

He's also currently the regulatory advisor to the Texas Medical Center. He's written a textbook on these issues, on regulatory compliance. And he's been repeatedly

upheld on this issue.

I do want to discuss the one time he got struck on the issue of FDA and regulation. And there's a case called *Stevens, Stevens v. Stryker*. Now, the many cases in which he's been approved on this went swimmingly for him because they had a great report and everything. The problem was with Stevens, he was designated primarily as an engineer off the bat, and what the plaintiffs tried to pull at the last minute is trying to boot strap some FDA opinions last minute. And as the Court says in the opinion, there's nothing in the text of his report that says he has FDA qualifications. The situation is radically different here, and so we don't think there's a qualifications issue.

I think that covers the bulk of their argument there. It's pretty well-briefed in the papers, but if you have any other questions, I'd be happy to answer them. Thank you, Your Honor.

MAGISTRATE JUDGE NOEL: Thank you.

THE COURT: We'll take a morning recess, 15 minutes.

(Morning recess at 10:57 a.m.)

(11:15 a.m.)

(IN OPEN COURT)

THE COURT: Please be seated. Judge Noel has a criminal duty matter so he'll join us when he's able. Is

there any response on the David or did you want to move right to your argument on summary judgment?

MR. WINEBRENNER: We have nothing further on Dr. David.

THE COURT: Anything on this side before we go to summary judgment? All right. Mr. Hulse.

MR. HULSE: Good morning, Your Honors.

THE COURT: Good morning.

JUDGE LEARY: Good morning.

MR. HULSE: As we wind up this third day, I want to thank, of course, both the Court and the staff here for the time and attention that you've given to this matter.

THE COURT: You should really thank the court reporter.

MR. HULSE: Believe me, Maria has worked some long days, and we very much appreciate it.

THE COURT: She's got because there was the request for daily transcript, there are people working down below the scenes too. I say "down" because they're below our floor.

MR. HULSE: And I know we're all very grateful to them too.

COURT REPORTER: Thank you.

MR. HULSE: I'd like to start where Mr. Blackwell began with the Seventh Circuit statement in the *Rosen* case.

The statement that was echoed in the *Bausch & Lomb MDL* and has been echoed many times when courts exclude experts as a prelude to summary judgment and that's that the law lags science. It doesn't lead it. The courtroom is not the forum to advance new scientific theories. It's not the place for scientific guesswork even of the inspired sort.

And what we've heard from the plaintiffs and their experts is not real science. It's courtroom science. It's science opinions that haven't been expressed outside of the courtroom. Opinions that have been roundly and soundly rejected by authorities that both sides agree are reliable, like the international consensus, recently rejected by the FDA, rejected by numerous authorities who have reviewed exactly the same literature about this product that's been out there for 30 years, been used in 200 million surgeries, used in 50,000 surgeries a day, and is trusted by the overwhelming majority of anesthesiologists, orthopedic surgeons, and people in the medical profession.

The general causation question here is does the Bair Hugger system cause prosthetic joint infections or deep joint infections, in the plaintiffs' phrase? It's not does it in theory? Can it? Is it possible? If there is one lesson that we can take away from the *Glastetter* decision it's that a theory and even a beautiful theory, a theory that seems to make all the sense in the world, which

plaintiffs' doesn't here, but what the *Glastetter* case said is even where the chain of medical reasoning appears sound, it's major premise still must be proven, and it must be proven by valid scientific evidence. When inferences of causation are going to be drawn, they cannot be based on ipse dixit. They cannot be based on theory. They must be based on actual evidence that the Bair Hugger system causes prosthetic joint infections in the real world. That's what *Glastetter* said. And there's no real dispute here that expert testimony is required for general causation.

The *Lipitor* case did us all a service and did a 50-state survey that goes on for about 15 pages in the opinion and doesn't cite just one case for jurisdiction. It cites multiple cases. In fact, it cites at least two cases from Minnesota.

The *Willard* case, which we cite in our briefs, also talks about Minnesota law. It says where is it that you don't need an expert to get to medical causation? Those circumstances would include an immediate onset of symptoms that naturally follow from an accident. So that's a car accident. Somebody is injured in a car accident, for example, or a complete lack of any other possible cause.

Clearly, when you're talking about things like prosthetic joint infections, you're talking about multiple

possible causes, many possible causes. Most prominently, the patient's own skin. So in those circumstances, the plaintiffs must have expert testimony to demonstrate general causation, to carry their burden to show that they can get past this point and on to specific cause.

Now, I don't know what plaintiffs are going to get up here and say in response to me, but in their papers, they have agreed that they need Dr. Samet, Dr. Jarvis or Dr. Stonnington to get them to general causation. In their opposition to our brief, they say about Dr. Elgobashi that he may be used to show the mechanism by which the Bair Hugger increases the risk of infection. We're talking about mechanism. We're talking about over on the left hand side of the joint or gap. The experimental theoretical side. Cases, and we've cited many of them in our briefs. We've shown them to you. That's not enough to get to general causation. *Glastetter* says that too. And plaintiffs in their briefs don't contend that Dr. Elgobashi gets them there.

In fact, about Dr. David, they don't even mention Dr. David in their opposition to summary judgment, not one time. They're not contending that he and his risk analysis can get them to general causation nor Mr. Buck nor Mr. Koenighofer. It's Samet, Jarvis and Stonnington, and that makes sense.

This is a medical injury case, involves complex medical injuries. If inferences are going to be made about causation based on the evidence, it's going to have to be made by qualified medical professionals.

And we've talked about these cases several times. MDL after MDL has held and then *Glastetter* says the same, causation has to be based on more than just possibility. You have to show that this mechanism, this mechanism that they're advancing here really plays out in the real world. And so what do Samet, Jarvis and Stonnington, the three medical experts on the plaintiffs' side rely on to show that this theory that they have actually plays out and causes infections in the real world?

Well, Dr. Samet said it best, in reference to the McGovern study, he said, "absent the quantitative estimate from that paper, it would be -- well, there would be a quite plausible mechanistic basis for increased risk. There would not have been an association in the real world."

And why do you need an association? What The Reference Manual on Scientific Evidence says is that the Bradford Hill factors, the factors that purportedly Samet used, and plaintiffs contend also that Jarvis and Stonnington used something at least close to Bradford Hill, they are employed only after a study finds an association to determine whether that association reflects a true causal

relationship. If you don't have an association, you stop. That's it. You are on the side of, at best, theory, plausibility. You don't get to an inference of general causation.

In fact, The Reference Manual goes on on the same page in a footnote. Notes that some experts attempt to use the Bradford Hill factors to "support the existence of causation in the absence of any epidemiologic studies finding an association." And The Reference Manual says quote, "there may be some logic to that effort but it does not reflect accepted epidemiologic methodology." If you're going to infer causation as an medical expert, you have to have an association.

And when you're basing that association on an observational study, this is what The Reference Manual has to say. The Reference Manual talks about the weaknesses of observational study. There's a susceptibility to bias and confounding. And so this is what The Reference Manual says. If you're going to use an observational study or studies to make a conclusion of causation as Samet, Jarvis and Stonnington did here. You want to see the association across multiple observational studies with different designs, difference kinds of subjects, and done by different research groups.

And why is that? Because of the susceptibility of

confounding. If we get consistent results across multiple observational studies, multiple facilities, it makes it less likely that an association that was found was the product of bias or confounding.

And you have to take into account, the manual says, the effects of confounding variables. You have to use appropriate methods to do it, including comparing small groups that are relatively homogenous with respect to confounders, which is what Dr. Holford and Dr. Borak did when they showed the McGovern study, when you control for thromboprophylaxis, and you control for antibiotics, any purported association vanishes. And Mark Albrecht, the co-author, the Augustine employee, agreed. He didn't even have to do the number crunching. He knew that that was the case.

And you have to take into account plausible explanations for the purported association. What are the alternative explanations that could explain this? The introduction of a major infection control initiative, change in antibiotic, change in thromboprophylaxis. These are the things you have to do in order to make an inference of causation.

So does McGovern find an association between use of the Bair Hugger system and increase in deep joint infections? On its face, it does not. There has been much

misreading of this study in this courtroom.

What McGovern says is we had two periods of time. We had a period of time with the Bair Hugger system, and we had a period of time with the HotDog system. And there was a higher rate of infections that we found during the HotDog period. The association they found was between the period --

THE COURT: During the HotDog period?

MR. HULSE: I'm sorry, I misspoke. The higher rate of infection in the Bair Hugger period. They found the association between the period and the higher rate, and so that's why they came to this statement. This study doesn't establish a causal basis for this association. We can't attribute this higher rate in the Bair Hugger period to the use of the Bair Hugger. And why not? Because the data are observational, may be confounded by other infection controls instituted by the hospital. It notes the change to the antibiotic and the thromboprophylaxis.

And you may remember the drafts of Figure 7 from McGovern that show the spike during the Rivoraxaban period. It says, "in addition, we were unable to consider other factors that have been associated with SSI, including blood transfusion, obesity, incontinence, and fitness for surgery, which have been identified elsewhere as important predictors for deep infection."

So we know these are potential confounders here. That's why we are not able to attribute this increase to the Bair Hugger. It's not right to say this finds an association between the Bair Hugger system and deep joint infections. That's not what it finds, and they don't say it. And you don't have to take my word for it. Let's take Dr. Reed.

Plaintiffs have said that the study authors stand by the study. They stand by it, and in fact they do. Now, we didn't have the documents to show Dr. Reed about the transposition of the one infection in the data manipulation, but he stood by his conclusions. He stood by what he stated in the paper. Dr. Reed is the senior author. Why in the paper did you say this study does not establish a causal basis for the association? He says because it doesn't. It doesn't establish a causation or study.

But here's a question that plaintiffs' counsel asked him. "Did any of your studies, includes McGovern, indicate that the increase in bacteria around the surgical site increases the likelihood of periprosthetic joint infection by the susceptible host?"

And this is key how he explains what the McGovern study found. "So we have shown," this is his answer -- "So what we have shown is an association with, you know, what we did for a period of time and then we changed. And then we

had a change in infection rates with the caveats that we had changes to our practice. Apart from that, as we have detailed and as we have put in our paper."

In other words, we made some significant changes to our practice. One of those changes was we switched over to the HotDog. And when we made those changes, we found a decrease in infection rates. That's the association they found.

What they're reporting here is we know that things like obesity, fitness for surgery, those are known to be factors. We're also offering you here a new data point, a new possibility that the Bair Hugger Forced Air Warming should be considered as a factor too. But they're not finding an association between that increase and the Bair Hugger. They're not attributing it to the Bair Hugger.

And so it's not surprising too given these limitations that there has been strong criticism of the McGovern study. The Duke Infection Control Outreach Network, which is a major resource for practitioners in this area have said no adequately powered, properly controlled statistically significant reproducible studies has been published demonstrating an increased risk of SSI to be used, due to be used of forced air warming devices.

Professor Sikka, Dr. Sikka in his published article in The Journal of Bone and Joint Surgery, which was

a full literature review in 2014, said that they recognize McGovern failed to account for age or medical comorbidities. Why is this important? Because everybody who practices in this area knows how important this stuff is failed to account for other infection control measures implemented during the study period, and the co-author was an employee of a conductive warming company. That was Albrecht, an employee of Augustine. And, interestingly, here's a medical professional scholar published in a journal who considers that a relevant criterion to assessing the scientific validity, trustworthiness and reliability of the McGovern study.

ECRI Institute also notes the confounding and then, of course, there's the FDA. In 2012, once the McGovern study came out, Dr. Augustine went on his website. He's touting it, hey, this is proof that forced air warming Bair Hugger increases the risk of surgical site infections and shows the HotDog is safer, and the FDA told him to stop. They said that the evidence provided in support, which included the McGovern study, did not "provide conclusive evidence of a causal relationship between the use of forced air warming and higher infection rates."

This is a preclude, of course, to what they have now said again recently in response to Augustine's marketing, advertising around this litigation. And just to

go through these confounders, there's no dispute in the medical literature that these issues that they did not account for, did not control for in McGovern are confounders.

Here in 1990, Dr. William Jarvis, one of plaintiffs' experts, while he was at the CDC concluded that surgical technique in patients, in a patient's severity of illness were the primary determinate of surgical wound infection after total knee arthroplasty.

We've talked about the fact that when you control for the two major changes in thromboprophylaxis and antibiotic that occurred at the very end of the Bair Hugger period before the transition to HotDog, it wipes out this association, the purported association.

Dr. Holford's biostatistical analysis found the same thing. He says you can account for all of the difference in risk reported in the McGovern study simply by accounting for these two confounding variables. That's before you get to things like fitness for surgery, obesity, and so forth. Just those two wipe out any difference.

And there's no dispute in the medical literature that the antibiotic that was used during that tail end of the Bair Hugger period where you see the spike, Gentamicin is a less effective antibiotic. Here's Dr. Reed in another paper, McGovern co-author Dr. Reed says there's no evidence

for use of systemic Gentamicin is prophylaxis and primary elective THA and TKA surgery. And he goes on to say that they found that staph develops resistance to Gentamicin, which also can explain the spike.

Thromboprophylaxis is also an acknowledged and recognized confounder. Another change that had been made at the end of the Bair Hugger period was the use of Rivaroxaban. And the Brimmo study, which came out just a couple years ago, 2016, concluded that, "the use of Rivaroxaban for thromboprophylaxis lead to a significantly increased incidence of deep SSI," that's what we're talking about here, deep joint infections, "in a continuous series of patients undergoing primarily THA and TKA in a single institution."

And I bring us back to McGovern Figure 7. This is before they flattened out the line using the average. And what it shows is that there is a peak just before and infections just before the switch away from Rivaroxaban. It peaked that the authors then concealed by flattening the line and using an average. And these were merely elements of a comprehensive, massive infection control initiative that was undergoing, that was happening at Wansbeck Hospital, part of the North Umbria Trust in England at the tail end of the Bair Hugger period.

This is from a study called Gillson. She was the

chief nurse who was involved in this initiative. This is in the record. I don't think we have a cite here. But, anyway, Figure 2 in the Gillson paper shows all of the various initiatives that were introduced at the tail end of the Bair Hugger period and going into the HotDog period.

So as Dr. Borak notes, the benefits of this massive initiative that they had undertaken, multiple different things was felt primarily by the patients who were warm with the HotDog, and these include implementing pre-warming, MMSA screening, changes to operating room protocols, changing post-operative wound dressings, repairing the laminar air flow system -- we know that's important -- undertaking root-cause analysis of infections, establishing a Prevention Control Committee, hiring full-time SSI surveillance nurses and implementing more effective pre-operative skin preparation.

Dr. Borak explains why all of these are important and could well have contributed, likely did contribute, to the reduction in infections during the HotDog period. All confounders that in fact are not even disclosed, maybe obliquely referenced in the McGovern paper, and that's even before we get to the data manipulation.

And as Mr. Corey Gordon demonstrated, and I'll just do it briefly here, there is a change between draft 10 of the McGovern study and the published version. There is a

HotDog infection that disappears and all of a sudden becomes a Bair Hugger infection. And the data set, which we've established to be the actual, the real data, is consistent with the draft and not the published version.

And where did this happen? When did this data switch happen? It happened after Dr. Reed, who sent this data set to the United States, to Augustine Biomedical and Design in the possession of Mark Albrecht. And Dr. Reed testified that there is a difference, a difference between the data that he sent to Mark Albrecht and the published data. He agreed with that. He remembered it a little bit differently from how he showed it in the actual data, but he knew there was a difference.

And so we go from 4 to 3. And that is the difference between statistical significance and lack of statistical significance as Dr. Holford shows.

In the *Viagra MDL* in this district, the Court initially had admitted the general causation epidemiology expert of the plaintiffs, and then after subsequent discovery revealed that there were serious data credibility issues with the data set on which the epidemiology expert relied. The Court reversed course, excluded the expert and granted summary judgment to the defendants.

And Judge Magnuson noted "Peer review and publication mean little if a study is not based on accurate

underlying data." The peer reviewers don't get the data. They don't get to analyze it. They're presented with the paper. And the fact that the McGwin study, this was the single epi study on which the plaintiffs' general causation expert relied appears to have been based on data that cannot now be documented or supported renders it inadmissibly reliable.

The data manipulation alone is a sufficient basis to render the McGovern study unreliable. But even if you take that out as a factor, the failure to account for confounders, confounders that explain the entire difference between the Bair Hugger period and the HotDog period, renders it as every one of these independent authorities have found an unreliable basis for making inferences of causation, and it does it on its face even find an association.

JUDGE LEARY: But even with this alleged manipulation, the ultimate conclusion remains the same by Reed and Albrecht that the association is not causal.

MR. HULSE: Correct. And that's what the paper says. As Dr. Reed said, we didn't find an association between the Bair Hugger system and increased infections. That's not what we found. And statistical --

THE COURT: Just a second. Mr. Sacchet is indicating that that's not true, I think. So did you want

to?

MR. HULSE: The Court can read the McGovern study. I'm confident that they disagree with what I'm saying up here, but the McGovern study and Dr. Reed's testimony will speak for themselves.

MR. SACCHET: I agree it will speak for itself.

MR. HULSE: And statistical significance, as I showed them, the moving of the single infection removes statistical significance while statistical significance is as some court says is not the Holy Grail of admissibility.

In the *Prempro* MDL, the Court said, "as many federal courts observe, if an expert places undue emphasis on statistically insignificant evidence, it may indicate that the expert's methods are unreliable." And the Court cited *Joiner*. In fact, the *Prempro* court did ultimately exclude general causation experts on that basis.

In fact, in *Joiner* itself, *Joiner* involved the plaintiffs' causation expert's reliance on epi studies. And despite the existence of epi studies, the Court said the leaps. This is where that famous ipse dixit language comes from in *Joiner*. The leaps that were being made by the plaintiffs' causation experts from these epi studies was too far.

And, again, the last thing on the topic of statistical significance, we also know because Dr. Holford

demonstrates it, the impact of the start date. The study authors moved the start date to a place where they could achieve statistical significance. If they had remained with an earlier date, one month earlier, one month later, they would have lost statistical significance. The date was selected to achieve it just barely and that's how fragile the study is even before you account for confounders.

Now, what Dr. Sikka's study published and I showed earlier, is the significance of the financial interest of Mr. Albrecht to the trustworthiness of this study. Now, as we've shown you, Mr. Albrecht had an over $20,000 promissory note with Augustine. Of course, he was employed by Augustine from 2005 onward. He's a long-time employee. He's the guy who did the data crunching for Augustine, and he did it for the McGovern study. And I think the plaintiffs said the day before yesterday, oh, but this all postdates McGovern. This is a promissory note from 2012. Well, the first paragraph of this says, "the undersigned is an addendum to the promissory notes dated September 27, 2007, and August 10, 2010." An addendum to promissory notes that already existed. Mr. Albrecht owed his employer, long-time employer, quite a bit of money.

But even so, Mr. Albrecht still made clear in a document and then in his testimony that he didn't support the inferences that Dr. Augustine was making, the same

inferences that the plaintiffs' experts are making here from the McGovern study:

"Unfortunately, Scott likes to say that he's convinced of such a relationship, that is the relationship between forced air warming and deep joint infections, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing."

So the Court should not consider the McGovern study to be scientifically valid evidence of causation upon which experts can reliably draw inferences of causation. It's not real world scientists, doctors don't draw that inference based on McGovern, and they don't draw it based on McGovern in consideration with the rest of the body of the medical literature. They don't. The only place they do that other than in Scott Augustine's marketing is in this courtroom.

We spent a lot of time yesterday on Dr. Elgobashi's CFD, which is a computer simulation, and like any simulation is only as good as its inputs. And general causation has not only the meaning that we've talked about in terms of whether the Bair Hugger system increases actually causes deep joint infections, periprosthetic joint infections.

But also general causation involves this question

of is this going to be useful in any of the cases, the 4,000-plus cases that we have in the MDL and the 60-plus that we've got in Ramsey County? And Dr. Elgobashi has got a temperature input that we have strong reason to believe that's not the temperature that you'd find if you measured under the draping in any operating room in America. And so the relevance of this to any of the cases, the bellwethers, and so forth that may be tried is dubious.

But even beyond that, the plaintiffs don't cite any case where a CFD has been admitted as proof of causation of a medical injury. Dr. Elgobashi himself doesn't give the opinion that general causation can be premised on a CFD. No other expert in this case has given the opinion that general causation conclusion can be based solely on a CFD. And the plaintiffs haven't pointed to any study, and we haven't found one that says that a CFD can be used to prove the cause of an infection.

And in the plaintiffs' summary judgment opposition, again, all they say is it's mechanistic evidence. They don't claim that it can get them over the hurdle of general causation.

Another thing that the plaintiffs' medical experts rely on is an inference. An inference that increase in particulate matter in the operating room means you have an increase in bacteria. So if the Bair Hugger increases

particulate matter, then it must also increase bacteria in the operating room and at the surgical site. That's an interesting theory, but it's been tested. And as the Court has heard repeatedly, it's been tested repeatedly.

And as Mr. Gordon showed earlier this morning there are nine studies including most recently Oguz that has consistently found that the Bair Hugger system does not increase bacteria. The plaintiffs' theory, while it may sound facially appealing, is simply not borne out by the real world evidence. And the plaintiffs' experts Samet, Jarvis and Stonnington depend on that theory. They depend on McGovern. They depend on that theory. It's just not supported by the real world evidence.

And the last refuge here, you'll likely hear more of this from the other side is 3M corporate documents. We have produced millions and millions of pages of documents in this litigation. 3M and Arizant's consistent position has been as is supported by the science that the Bair Hugger does not increase the risk of infections. What plaintiffs have done in their brief and may do today is they may pull out snippets of e-mails, of draft documents, snippets of deposition testimony that are contradicted as was the case with Dr. Kurz, by testimony that occurred just pages later in the deposition.

But corporate documents even put in the most

favorable light are not proof of causation. A 3M document could say that an apple is a banana, and it wouldn't make it a banana. The question is is there scientifically valid evidence, *Glastetter* standard, scientifically valid evidence, *Daubert* standard, to support general causation? Not is there an e-mail or a draft document that we think if you cut it out and don't look at anything else, could get us over the general causation hurdle. And courts consistently have said you can't substitute documents, corporate documents, for scientific proof.

The *Mirena* case out of the Southern District of New York, which is just affirmed a couple of days ago by the Second Circuit said, "The statements and public positions of Bayer are not scientific literature that an expert would be expected to confront in the exercise of intellectual rigor in the field."

There, we had a situation where actually there were public statements being made about Bayer that seemed adverse to their position on general causation. Plaintiffs won't point to anything like that here.

In the *Lipitor* case, there was an alleged admission in an employee e-mail that Lipitor caused diabetes, and the Court said, "that could not replace expert testimony, and it wasn't sufficient to preclude summary judgment on the issue of general causation."

And *Glastetter* too confronted this issue. There were internal communications among medical professionals, a defendant, that the plaintiffs suggested with some force looked like admissions that were contrary to the position of the defendant that Parlodel did not cause strokes. But the Eighth Circuit agreed with the District Court that these purported admissions that were cut and pasted from company memoranda did not support general causation.

You could weave them together with all the other things that the plaintiffs had in *Glastetter*, things plaintiffs don't have here: Animal studies, case studies, rechallenged, dechallenged data. The plaintiffs even had a medical textbook in *Glastetter* that in the Eighth Circuit's words ventured a hesitant conclusion that Parlodel caused strokes. Individually or together, that wasn't sufficient evidence to get past, to establish the admissibility of the plaintiffs' general causation experts or to withstand summary judgment.

And then we come to the International Consensus. General acceptance is a determinative factor under Minnesota Rule of Evidence 702. And it is a factor to be considered by the Court under *Daubert*, according to the Advisory Committee notes to Rule 702. Both sides agree here that the International Consensus meeting is reliable. These are people who work and spend their practice on the kind of

surgeries that are primarily at issue here in the MDL, the prosthetic joint infections.

And as the Court has heard, the International Consensus meeting, these 400 professionals, bone doctors and so forth, reached a strong consensus. And you can look at their footnotes and they considered the McGovern study. They considered the mechanistic studies. They considered the best case for Augustine and the plaintiffs and said, "We recognize the theoretical risk," theoretical risk, "posed by forced air warming blankets and that no studies have shown an increase in SSI related to the use of these devices."

Again, they're talking about McGovern, "no studies have shown an increase in SSI related to to the use of these devices." They took McGovern's authors on their face and they said McGovern doesn't show that. "We recommend further study but no change to current practice."

This is the kind of guidance that real doctors, anesthesiologists, nurses take to hurt when they're making decision about what to do for their patients.

They also take to heart what the FDA has to say. The FDA, of course, responsibilities protecting the public, protecting patients from unsafe medical devices and pharmaceuticals. And the FDA just not too many weeks ago in response as they said to concerns that they were learning about, about the safety of patient warming and safety of

forced air warming in particular issued this letter. And you can find it on their website along with a series of other safety-related letters that they issued from time to time.

And what they said is that they considered data "publicly available medical literature," data from manufacturers and hospitals, operating room guidelines and ventilation requirements in assessing whether there was reason for concern. And their conclusion was this:

There are considerable benefits to using patient warming, including forced air warming in surgeries. And they didn't make any distinction -- oops, sorry.

(Short noise interruption.)

MR. HULSE: Mystery solved or remains a mystery?

THE COURT: It deepens.

MR. HULSE: And the FDA reminded, and this was a letter addressed to doctors, to health care providers, doctors, nurses, people who are making decisions about what to do for their patients:

"The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems," and the Bair Hugger is far and away the most prominently used of those, "have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients."

And in fact, the research supports exactly that: Reduced surgical site infections, reduced fatal heart attacks, reduced blood transfusions, reduced length of hospital stay, reduced post-operative shivering. Those are the benefits of patient warming.

But the FDA then goes on to recommend the use of thermoregulating devices, including forced air thermoregulating system, like the Bair Hugger, for surgical procedures when clinically warranted. They don't say except in orthopedic surgeries, but here's the crux of it. This is the direction they're giving to health care providers: "Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the post-operative and recovery process."

If you don't warm your patients, you may be imperiling your health, their health. You are putting them in danger. And the state of play today is that 70 percent or more of hospitals are using the Bair Hugger system.

So this is the guidance that medical professionals outside this courtroom taking care of patients performing surgeries, this is the advice that they've gotten. You're doing the right thing. Keep doing what you're doing. You're protecting your patients.

And if we go forward based on conclusions drawn in

the courtroom by experts who've never drawn those conclusions outside the courtroom, who claim that studies say things that they on their face don't say, make leaps they would -- you can't imagine that they would make in their professional lives, and it gets to a jury and the jury is confronted with this and determines, oh, we agree, the Bair Hugger system is unsafe, what are professionals to do? The FDA, the International Consensus has told them it's safe, and now they've got litigation proceedings that say they're not. They have to make decisions. Now, they're faced with am I going to be sued for malpractice? They have to be able to rely on the consensus and what's generally accepted in the community.

What we have here, to return to the original point, is litigation science, not real science. The plaintiffs' own studies don't support their causation theory. And to Mr. Sacchet's point, we encourage the Court to read the studies. See what they say, not what the lawyers say about them. Read what they say.

The International Consensus, which has read the studies, the same studies on which the plaintiffs' experts rely, rejects the plaintiffs' causation theory, and the FDA rejects it too.

Whether it's determinative as in Minnesota or a factor as under federal law, the consensus rejection of the

theory that plaintiffs and their experts have advanced in this courtroom is powerful evidence of its unreliability. And plaintiffs have the burden to demonstrate the admissibility of their expert testimony, and they can't do it. They don't rely on scientifically valid evidence. They make flying leaps across the chasm from plausibility and theory to causation, which under *Joiner* they can't do.

We ask the Court to exclude the plaintiffs' medical experts, grant summary judgment in the cases in the MDL and in Minnesota. Thank you very much.

THE COURT: Thank you, Mr. Hulse. Ms. Conlin.

MS. CONLIN: Good afternoon, Your Honors. While that's getting set up, I just want to circle back briefly to the August 2017 FDA letter and that's the letter that just came out in August of this year. We immediately saw it, knew that it wasn't a letter that the FDA typically issues, and we proffered discovery on 3M on this. We were stone walled on that. They said we're not going to give you discovery. It is not relevant to the claims and defenses in this case, and discovery is closed.

We learned for the first time at the first day of this hearing under questions, direct questions from this bench to Mr. Blackwell that in fact 3M was behind that letter. And we don't know what their communications were. We don't know what the FDA looked at, but Mr. Blackwell

readily conceded 3M asked the FDA to investigate the claims that Scott Augustine was making in the science.

We're not representing Scott Augustine in this case as in Augustine v. 3M. It's plaintiffs. But for some reason, just because we are making and have proven the same claims that perhaps Mr. Augustine is making, we've been tainted with that. And as Mr. Ciresi said, we're looking forward to having him on cross-examination.

THE COURT: Ms. Conlin, anything you want to say on the summary judgment?

MS. CONLIN: I do. And he raised that letter in the summary judgment, so I just wanted to address that first.

I want to start with the notion of what is actually in dispute in connection with this motion. 3M doesn't dispute the qualifications of Dr. Samet, Dr. Jarvis or Dr. Stonnington. There is no dispute that these are eminently qualified, and in the case of Dr. Jarvis and Dr. Samet world renowned in their respective fields.

3M doesn't dispute the methodology that those experts employ. Dr. Samet employed the Bradford-Hill criteria. There's no argument by 3M that he didn't faithfully and systematically apply those criteria. And really what it boils down to, the main thrust of this entire hearing has been 3M's criticism of McGovern, which is a

single piece of evidence amongst the body of things that, for example, Dr. Samet looked at.

And when we were talking about Dr. Samet, I went through that, and there was literally hundreds and hundreds of references and lines that he went through in making his causation determination. Things which didn't exist at the time of the 2013 consensus, such as the heater-cooler issue, such as Darouiche.

And, most importantly, Dr. Elgobashi's CFD modelling, which 3M knows is good science, which is why we spent half a day yesterday arguing about whether his input was correct, when in fact both experts, Professor Abraham and Dr. Elgobashi both used the same temperature input for the purposes of their model. There's no dispute here.

3M says that basically so long, and this is a quote from their brief, Your Honors, "so long as the Court excludes plaintiffs' three medical experts, summary judgment is appropriate." And I want to talk a little bit about that because, again, really the focus has been on McGovern.

But some of the third party research relied upon by the experts show that Bair Hugger increases particles over the surgical site. 3M's 30(b)(6) witness Al Van Duren testified under oath every single study that is out there indicates that the Bair Hugger increases particle count over the sterile field. The Legg and Sessler studies the same.

There is evidence and scientific studies showing that the Bair Hugger increases bacteria over the surgical site. The Moretti, Wood and Tumia references that are in our papers. And the relationship of particles and bacteria to infection, and the Darouiche study, which we have cited in our papers as well and talked about over the course of the last couple of days.

Doubts under the Eighth Circuit as well as the Frye standard are resolved in favor of admissibility. The Court abuses its discretion if it results Doubts in favor of excluding expert testimony or decides the correctness of the expert opinion.

And in fact this morning, you heard Mr. Hulse accuse the McGovern authors of data manipulation, of changing Figure 7. Well, we intend to subpoena Mr. Albrecht and Professor Nachtsheim from the University of Minnesota School of Management, and those questions can be posed to him why was the change done and the averaging done in that study, because that's what they're accusing.

They're accusing Dr. Belani, who is head of anesthesiology at the University of Minnesota of academic fraud. And those are serious allegations, but they also go to credibility and not the study itself.

We've never misrepresented McGovern. What we've said is it shows a strong association between Bair Hugger

and deep joint infection, and that's all we've ever cited it for. We have been very clear since day one that study doesn't show causation. It shows an association, which is why the experts relied on scores of other literature, including the depositions of 3M in this case, including the Dr. Elgobashi model, including the Darouiche study, that was that entire cumulative body of evidence that led to the causal connection that our experts have opined on.

And 3M, by the way, doesn't have a single, not one epidemiological study which disproves what the McGovern authors found. Not only do they not have any evidence on that, but they've refused to do it despite the urging of the people affiliated both on their external advisory panel as well as internal people.

We've talked about this, but epidemiologic studies show associations. They do not prove causation, and we have been upfront and candid and clear on that. The evaluating causation requires scientific judgment and expertise. That's the job of an epidemiologist.

We have one here who methodically, you didn't hear him saying that Dr. Samet didn't go through the entire body. If you look at his report on page 2 or 3 it might be, where he goes through and lists the searches that he did. He actually put in his report these are the literature searches I did in connection with that. And beyond that listed some

200 different lines of evidence in connection with his opinion. And what he did and what hasn't been done to date is that he connected all the dots and that's often what cases like this turn on is having somebody who takes the time to sit down and connect all the dots.

The Court said it, I don't need to say it again. Opposing experts often interpret the same studies differently. That's what cross-examination is for.

Now, Dr. McGovern is one of the authors that 3M has accused of data manipulation. He was deposed --

JUDGE LEARY: Let me comment on that statement, Ms. Conlin.

MS. CONLIN: Sure.

JUDGE LEARY: I don't hear the defense saying that these authors all participated in a manipulation of the data. The way I understand the argument based on the evidence that's been produced is that a change occurred when after draft 7 when the information was placed in the hands of Mark Albrecht, and that Mark Albrecht was responsible for the data and the representation of the data and the article.

Now, maybe I misrecall that, but to the point of you're saying that the defendants are claiming that all of the authors engaged in scientific fraud, I haven't heard that from them; maybe I misunderstand the evidence, but I haven't heard that characterization.

MS. CONLIN: Well, I think that it has been stated most recently in connection with Mr. Hulse's summary judgment motion. I can pull the transcript but that --

JUDGE LEARY: What I heard him say attributed the alleged manipulation to Mr. Albrecht, to no one else.

MS. CONLIN: Okay. And maybe I extrapolated beyond what he said. I guess the record will speak for itself. Mr. Albrecht and, again, that is a credibility issue, but there is no foundation for what 3M has said about the data manipulation.

THE COURT: Just hold on one second. I'm scratching around in my memory. Was it -- did Mr. Albrecht send a prior version of Figure 7 to Dr. Augustine with the statement, "we've reached statistical significance." And then following a response from Dr. Augustine, did the data change? Is that what --

MS. CONLIN: No, that is not. And the e-mail that you're referencing, I know somebody is probably pulling it up for me. But if you look at the next e-mail below it, it's from Dr. Reed. And what he says is, yeah, we knew that we would reach statistical significance because they believed in that and that it was only a matter of time.

THE COURT: So Augustine was not in that at all.

MS. CONLIN: He might have been copied. My understanding is he was copied on a lot of that.

THE COURT: I think you're getting the facts right now.

MR. CIRESI: If I may approach, Your Honor, to give the e-mail itself.

MS. CONLIN: Go ahead.

MR. CIRESI: And, well, I'd have to ask leave of the Court to argue this, but this goes directly to what Judge Leary --

THE COURT: I just want -- Ms. Conlin, is this --

MR. CIRESI: Yes, this is the document.

THE COURT: Who is it too and from on that?

MS. CONLIN: It's an e-mail from Mark Albrecht to Drs. Reed, McGovern, a CC to Scott Augustine and Christopher Nachtsheim at the University of Minnesota. It says, "Gents, attached is an updated chart of infection data. The difference is significant based upon the results of logistic regression."

It goes on to say some highlights. And it says, "okay, we made it to significant difference, so I'll update the manuscript to reflect the new infection numbers. I'll also dig into the difference between hip and knee data and get back to you on that."

That's what Mr. Albrecht was is he was the statistician who was crunching the numbers that were being given him by Dr. Reed. Dr. Reed was the one. Now, Dr. Reed

probably has the final data set, which is reflected in the McGovern report. We couldn't subpoena documents from Dr. Reed because of the --

THE COURT: Because of the English thing.

MS. CONLIN: The English thing. So this entire Mark Albrecht said when he was showing it in his deposition, he said, "I don't know if this is the final data set or not because it resided with Mr. Reed."

But the idea, and to be honest, I mean to be totally candid with the Court, Dr. Reed did testify in his deposition, and it's five years after the studies, he said, "I recall there being one more infection in each group," but he wasn't entirely sure. Okay. If you're going to cook the books, you're not going to move one infection.

And in fact Professor Holford, if you look at his report in his very first footnote, he says, "if there's one more infection in each group, it drops the odds risk ratio from 3.8 to 2.86. So it doesn't drop it below statistical significance even if Dr. Reed's post-recollection belief of the final numbers was accurate, but we don't -- no one has the final data set. It hasn't been produced.

THE COURT: But it's not -- did Reed recall that there was one more in each group or that there was, I think that was his recollection. But I think what the defendants are saying -- obviously, we're going to have to go dig this

up -- that one moved, so it's not two more, one for each side. It's minus 1 for HotDog or minus 1 for Bair Hugger and plus 1 for HotDog, right?

MS. CONLIN: Right. Dr. Reed didn't testify to that.

THE COURT: 2.8 is plus one for each side, right?

MS. CONLIN: Yes. But the entire crux of their argument is based on this Albrecht Exhibit 10, which even Mark Albrecht said I don't know if that's the final data. And part of that was because the authors continued to study post the McGovern study, so they were updating with new figures all the time.

But even if, even under their theory that somehow magically they had foundation to say that Exhibit 10 out of Albrecht is the final data set for McGovern, which nobody has testified to, even under their theory, unless you go to the chi-square versus Fisher exact, you're still in every single scenario over statistical significance.

And I think one of the things that and, you know, Dr. Reed said he's the one who kept the data. And he very clearly said I stand behind this study. And he in fact went and did further research on the identified potential confounders in the McGovern study, the anti-thrombo regimen and the change in antibiotic regimen.

And he said in connection with his further study,

he concluded that neither one of those were confounders in McGovern, and they haven't cited anything, any medical literature or anything to suggest that either one of those two were actual real confounders. And it's very, on observational studies, I'm going to show you a few examples including the ones 3M is relying on, the researchers always says there's potential confounders.

THE COURT: Does The Scientific Manual, Mr. Hulse put some words up from that this morning, does it say when you're relying on observational studies, you should have more than one?

MS. CONLIN: Well, one of the Bradford-Hill criteria, Your Honor, is that you have some consistency amongst the literature that you're looking at. And in fact, Dr. Samet went through that in great detail about looking at the other studies and saying these are consistent. They don't have an odds risk show because it wasn't a randomized trial, but these studies are consistent with the conclusions drawn in McGovern.

THE COURT: Other observational studies.

MS. CONLIN: Yes. So Dr. Reed says under oath he stands behind it. And to make sure I was being clear with the Court, you can see at the bottom, he says, "so what we have shown is an association not causation. We made that very clear in the paper."

3M has hired the McGovern co-authors. They've never gone to Dr. Reed and say we think that this is -- I mean and think about it. I mean Dr. Reed does work for 3M. Do you think that under any conceivable scenario, if he thought that this study was not valid that he would stand behind it?

3M, I mean here's an e-mail from Mr. Blackwell to Judge Noel regarding these UK depositions on September 19th of last year. And he says, "Drs. Harper and Reed are prominent researchers in the UK and both have received funding from 3M for important research activities over the years. Indeed, Dr. Reed is currently involved in unrelated research project for another group at 3M."

The fact that somebody sponsors or funds a study does not mean that the study is not valid. It happens all the time. And I'm going to show you some examples. But they think enough of Dr. Reed that they've been using him for other work for him and yet, Dr. Reed has never said I don't stand behind McGovern. He said exactly the opposite.

Dr. Belani at his deposition on page 220, lines 22 through 221, line 2:

"Okay, do you stand behind the protocols and work which resulted in the Belani Deposition Exhibits 4, 5 and 6?" Which are the Belani, Albrecht and McGovern studies respectively. He says, "I do."

Same with Professor Nachtsheim, and you'll be able to ask him why did you do the flattening out of the graph? Why was the flattening, the average done? It's done all the time in regression analysis.

He says, "Question: Do you continue to stand by the results of the observational studies?"

"Yes."

"In the McGovern publication?"

"I do."

THE COURT: What are the other observational studies comparing Bair Hugger with HotDog?

MS. CONLIN: McGovern is the only one comparing the two from an infection standpoint.

THE COURT: Okay.

MS. CONLIN: There are other studies that show particulate and bacteria and the other things that the experts have relied on.

THE COURT: Because that was the plurals, the observations.

MS. CONLIN: Yeah, right. And Mr. Albrecht, which again both Your Honors touched upon it, so I think it's important to pause here about, well, maybe he was the one who did this purported unfounded and no evidence supported data manipulation.

And what's interesting is they keep going to an

internal e-mail by Mr. Albrecht. And what Mr. Albrecht said in that e-mail was Scott Augustine is going too far with the McGovern study, so rather than being somebody who was just following whatever Scott Augustine said. You saw the internal document, 3M is relying on it, where Mark Albrecht says he's taken this too far. All the study showed was association. He can't say that study alone proves infections.

THE COURT: I thought that e-mail -- I thought the e-mail said -- I don't know if it was an e-mail, you know the screen that was up this morning or this afternoon, not very long ago, I should remember.

MS. CONLIN: Yeah.

THE COURT: Albrecht was saying Augustine wants to go farther and show that there is causation. Is that what he said? Or did he say he wants to show that there's --

MS. CONLIN: What he said was, you know, and I'm paraphrasing because I don't have it here. But, basically, that Augustine was using McGovern and trying to market it as proof that the Bair Hugger causes infection. And as we've seen, all the study authors only said it showed an association.

THE COURT: But that's going to say it says causation not association, right?

MS. CONLIN: Yes, proof, I think it said proof of

infection.

MR. CIRESI: Your Honor, may I approach? I have it.

THE COURT: Oh, thank you.

MS. CONLIN: Thank you, Mr. Ciresi. Here's the quote, this is from 3M's brief at page 16:

"In a communication with another researcher, Albrecht admitted that he had admonished Augustine apparently to no effect not to overstate the studies findings. This is one of those things where we can step close to the line, and we do have important information to present that clinicians should be aware of. But we also have to be careful that we do not state claims regarding proof of infection reduction. Unfortunately, Scott Augustine likes to say that he's convinced of such a relationship even though I tell him it is unsupported, and I do not agree."

THE COURT: So his relationship, he didn't say association, and he doesn't say cause, he says "relationship."

MS. CONLIN: Yeah, association.

THE COURT: He says 'relationship." He doesn't say "association," right?

MS. CONLIN: Yes, I mean, yes. It says, "relationship." But what he testified to --

THE COURT: Or is it regarding proof? Okay, so proof, and then such a relationship refers back to proof, I suppose, as a grammatical matter.

MS. CONLIN: Yeah, and it says, "unfortunately, Scott Augustine likes to say he's convinced of such relationship even though I tell him it is unsupported and I do not agree." And in fact consistent with that in his deposition, he testified, "Do you agree with the characterization that you're study found forced air warming found 3.8 times increase in deep point infection rates?" Here's what Mr. Albrecht said: "I would agree that it's associated with the 3.8 times increase, that's what the study would say."

So even the individual that they're accusing of manipulating this has testified very truthfully and in fact pushed back on the internal statements by Augustine.

We've talked about the tabulation error, and under the alleged tabulation error, and under any scenario, the study still has statistical significance. And, again, 3M hasn't posited any foundation for that notion that Albrecht 10 is the final data set. It just doesn't exist.

The hypothetical confounders, you saw the testimony from Dr. Reed that they investigated those confounders and found that they in fact did not confound the study. And with respect to the fabricated start date,

there's been absolutely nothing other than lawyer argument regarding the start date.

Dr. Reed, the same individual who 3M has hired time and time again to do study for them says that he picked the start date of July 1, 2008, because he felt like that was the first time where full-time surveillance for infection rates at these three hospitals occurred. There's no evidence for that. And as we've been beating a dead horse at this point, but those challenges go to the weight of the testimony on McGovern, not its admissibility.

On the confounders, we showed you the other day Dr. Reed's testimony. Here's a quote from 3M's expert Professor Holford: "Question, so there's no published literature that you're aware of that suggest a relationship between the variable of thromboprophylaxis on the outcome of deep joint infection?"

"I don't have any."

And the Brimmo, by the way, because they brought up Brimmo study today, there isn't a single one of 3M's experts who have even cited Brimmo. No one is relying on the study that they're not putting in front of the Court to say that it's a problem.

A change from gentamicin to gentamicin plus teicoplanin. Again, absolutely no scientific literature to support that. And Professor Nachtsheim said he concluded

and was confident that the antibiotics weren't confounding factors. Same thing that Dr. Reed testified to. And on the SSI bundle protocol that you saw this morning, basically, their expert said we have no idea. We're just hypothesizing. So that's not a confounder.

Peer reviewed articles are generally reliable. *Daubert* says that. Peer reviewed, of course, isn't the end-all, but it certainly is an important characteristic or indicia of credibleness with respect to a study.

One of the things that Judge Leary, you asked about, well, wasn't there funding by Augustine? Didn't he supply the blankets and do some of that? And so, frankly, we looked for cases on this, but most of the studies that are out there are funded by someone, so it was hard to find cases on it. These are two that we found. And in fact, unlike McGovern, I mean, yeah, unlike McGovern, in the *Burton* case, there were studies that had been funded for the purposes of litigation. That wasn't enough. It was insufficient to undermine the reliability of plaintiffs expert opinion to the point of rendering it inadmissible.

JUDGE LEARY: Just for the sake of the record that will be developed on, I don't remember him making any statement about Augustine providing blankets or anything like that.

MS. CONLIN: Oh, no, I was saying that because my

understanding is he did, Your Honor. I was not attributing that to you, and I apologize if that was the inference.

Here's the Sessler study, which is interesting because 3M relies on this study to say the Bair Hugger is safe. A couple of interesting things about the Sessler study, and they've been putting it up on their slide.

The authors thank Gary Hansen of Arizant for providing not only content resources but editorial assistance. And if you look in the disclosures there, it's got Russell Olmsted, contribution, conflicts. He consulted for Arizant Health Care. So, again, a connection there that is on the same study that 3M is, you know, relying on to say that the Bair Hugger is safe.

What's also interesting about this is, this is the study that 3M relies on to say the Bair Hugger is safe, and I mean they cite other stuff, but in their marketing literature and the like the Sessler study looms very prominently in their rebuttal to our case.

THE COURT: Is that --

MS. CONLIN: It's actually Exhibit 4.

THE COURT: Does it have another name?

MS. CONLIN: We refer to it as the Sessler study, Your Honor. It is Exhibit 4 to our brief in opposition.

THE COURT: Okay.

MS. CONLIN: And what's interesting about this

study is that 3M relies on it trying to say that this shows that the Bair Hugger is safe. You know what they were measuring in this study? They were measuring particles, the very thing that they now stand up and say particles can't be a proxy. Well, this was a study that looked at particles.

THE COURT: I suppose it depends on -- I mean if you don't get any particles, it doesn't matter if they're a proxy, but if you do get particles, then it matters if they're a proxy.

MS. CONLIN: Yeah.

THE COURT: Maybe they said there aren't any particles.

MS. CONLIN: Well, no. Actually, what Dr. Sessler testified to in his deposition was that there was a ten- to twelve-fold increase in particles over the surgical site in this study when the Bair Hugger was on, and we've cited to that testimony, ten to twelve times more particles when it was on.

The Kurz study from 1996, this is the only study that exists that says warming of patient during surgery reduces surgical site infections, the only study that 3M has ever relied on. It was funded by Augustine when he used to own the Bair Hugger company, and what's interesting is, this is study. We showed you the testimony that both Dr. Kurz and Dr. Sessler now disavow. This is a study that's been

disavowed at least in depositions by the study experts.

And what's also interesting about this, a quote of out of here where they talk about confounders in the studies, which is very similar to the type of language that you saw in McGovern and is very, very routine with observational studies, but Dr. Kurz and Dr. Sessler say other factors may have influenced in the patient's susceptibility to wound infection, and they go on from there.

THE COURT: Does the Sessler, is the 10 to 12 percent, is that in what size particles?

MS. CONLIN: I don't think they were measuring. I would have to double check, Your Honor. I don't believe they were saying what the size was. I may be mistaken on that. I'm not entirely sure.

And in fact, Dr. Kurz said, you know, in response to a question, In today's scientific standards there's no reliable evidence that supports maintaining normothermia reduces the incidence of an infection? She said, That is correct.

So I'm going to have, Ms. Zimmerman is going to talk about the specific studies because one of the things that 3M has argued is that, that if Samet, Jarvis and Stonnington goes, our case goes, and we think if Samet, Jarvis and Stonnington stay in, that's the end of the

inquiry, but we don't think the converse is true for reasons that Ms. Zimmerman is prepared to talk about.

THE COURT: Great.

MS. CONLIN: Thank you.

THE COURT: Thank you very much, Ms. Conlin.

MS. ZIMMERMAN: And as we approach the studies -- May it please the Court, Counsel:

THE COURT: Welcome back.

MS. ZIMMERMAN: Thank you. As we approach the studies, we're going to go back through the mechanism of injury here, the mechanism of defect that has been established through the plaintiff's evidence.

And I point the court to a statement that was made by Mr. Goss yesterday as we were talking about the 106 degrees that was used by Dr. Elgobashi and of course by Dr. Abraham as well, but Mr. Goss conceded appropriately that really these are issues that go to the weight, not to the admissibility.

Now, we have different arguments with respect to Dr. Abraham that I will not go back over for the Court, but much of the evidence and much of the argument that has been presented to Your Honors over the past nearly three days now goes to interpretations about studies, about depositions about scientific principles.

So let's walk through what the plaintiff's proof

is in this case. Plaintiff's proofs are grounded in well-accepted methods. Science has established that bacteria can cause periprosthetic joint infection. Science has established that computational fluid dynamics is a reliable and accepted tool to test operating room particle movement.

That's what Dr. Memarzadeh did. In fact, Dr. Memarzadeh used 108 degrees, by the way. He modelled particles in a CFD. He used a less sophisticated model. He used the RANS model instead of an LES, but that's what the gold standard has been up to now, and that's really the basis for the ASHRAE standards on operating room error.

Science has established that particles are a reliable and accepted proxy for bacteria. Science has established that blowers in the operating room create additional risk, and we'll talk about that in connection with the heater-cooler. Well rounded, established and generally accepted scientific methodologies and principles form the basis of every expert opinion offer by plaintiff's experts in this case.

The Court is well aware of the standards with respect to summary judgment, and I wanted to touch on a question that Judge Leary asked the other day about the applicability of *Gold v. Tharaldson* to this matter. So *Gold v. Tharaldson* is the Minnesota Supreme Court case where

Minnesota declined to adopt *Daubert*, but rather than move to *Daubert*, what happened was, the Minnesota Supreme Court said we're going to stay with our normal two-prong test.

And that is that the evidence has to be generally accepted, relevant in the scientific community, and it has to be foundationally reliable, but the question, and I think it's been conflated by counsel for 3M in the briefing in particular, they suggest that the standard in Minnesota is that the opinions need to be generally accepted, and that is absolutely not the standard in Minnesota or in the federal courts.

Now, we've cited a Texas case, *Burton versus Wyeth,* which is 2007 from the Northern District of Texas, and I would point the Court to this language: So it says, When determining the admissibility of expert testimony, the trial court is not to consider the conclusions generated by the expert witness, but only the principles and methodologies used to reach those conclusions.

When the principles and methodology are sufficient to allow an expert opinion to be presented to the jury, then the party challenging that testimony must resort to vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.

THE COURT: What's the case?

MS. ZIMMERMAN: Yes, Your Honor. It is *Burton*

versus Wyeth, and it is 513 Fed.Supp.2d 719. That's the Northern District of Texas in 2007, and the reason that this was an interesting case was that the Court was really interesting again a pharmaceutical product that the plaintiffs alleged it was a Fen-Phen, I believe, and they were alleging some sort of a heart problem.

Again, it's different from this case because we don't have -- in this *Burton* case, there was a question about can that drug cause the kind of problems, and here we know that bacteria can cause the problems the plaintiffs have alleged, but again the Court noted at, it's star 726 the fact that in that instance, the defendant was not challenging the validity of the -- the challenge was to the conclusions, not to the methodology.

And the way that they tried to do that was by offering competing studies, and the Court properly determined that that is not what is supposed to be done at the *Daubert* stage in determining whether or not expert testimony can be properly presented to the trier of fact.

We entered some cases in the record yesterday and comments to Rule 702 on point as well. This is an issue for the trier of fact, but just to be clear for the Court, the methodologies that are at use by Dr. Elgobashi are certainly well accepted. He did not invent CFD. They're routinely admitted in courts that follow either *Daubert* or the Frye

standard.

The Bradford Hill criteria are routinely admitted. The methodologies, and again Ms. Conlin pointed to this. There had been not been an attack on the methodologies employed by the plaintiff's experts. The attacks repeated over the past few days have been on McGovern, but McGovern is published. It is peer reviewed, and it is appropriately part of what plaintiff's experts rely upon.

So let's talk about what it is that 3M knew and when did they know it and what did they do about it. So airborne contamination, that's a risk that 3M has known for certainly over 20 years. This is the 510K submission that was submitted to the FDA, and I offer this only so that Your Honors are reminded that even back in 1996, under number one contamination:

Airborne contamination from airborne intraoperatively across the surgical wound may result in airborne contamination. The notion that bacteria that can cause infections might become aerosolized and travel through the air was known certainly by 1996, and as we presented to the Court in our papers and in prior argument, it was even warned about on the original device that was not used in an operating room.

Another piece of evidence that we touched on a little bit yesterday that was not before the international

consensus committee prior was the heater-cooler situation, and so what I do is ask that Your Honors pay particular attention to Exhibit 45 to our motion, and this is the CDC health care infection control practices advisory committee notes, and particularly on page 27, the CDC concludes, and this is in 2015, nothing that blows air should be in an operating room theater if possible.

That's because of the studies that were done in the heater-cooler where they understood perhaps for the first time as concretely that this particular kind of bacteria, any bacteria could be aerosolized, travel through the air and cause an infection, and so the CDC did an investigation, and this ultimately lead both to the recall of the Sorin 3T cooler devices and to this warning about blown air in an operating room.

JUDGE LEARY: Could you go back to that?

MS. ZIMMERMAN: Certainly. And this is Exhibit Number 45, Your Honor.

JUDGE LEARY: It says, The heater-cooler unit, first line, appears to be harmless.

MS. ZIMMERMAN: It does.

JUDGE LEARY: From an infection perspective, but the water overflow bottle is likely rarely, if ever, sanitized and is situated in front of a fan.

MS. ZIMMERMAN: That's right, Your Honor.

JUDGE LEARY: Am I wrong in interpreting that sentence as saying the problem is not with the heater-cooler unit but with the water overflow bottle?

MS. ZIMMERMAN: Respectfully, no, Your Honor. The issue that the CDC pointed to was actually looking at this machine at first glance, these are machines that have been used in an operating room for decades, particularly with respect to heart surgeries, and no one prior to these surgeries had ever considered that that particular device might be capable of both hosting pathogens, and then by blowing the air out of that machine, there's an exhaust fan on the machine, that blowing the air might result in aerosolization of that bacteria and transport to the surgical site.

THE COURT: What's this CDC publication about? Is it about air, or is it about this heater-cooler unit?

MS. ZIMMERMAN: It is about the heater-cooler unit.

THE COURT: So these are comments that are made as an aside as dicta while they're talking the dangers of the heater-cooler unit.

MS. ZIMMERMAN: Yes, Your Honor. That is true.

THE COURT: But don't put a bucket of never cleaned infected water in the operating room.

MS. ZIMMERMAN: Well, I think that's part of it

and that that water inside the heater-cooler was a particularly hospitable place for the bacteria to grow.

THE COURT: It condenses, and it changes temperature, and it drips, and it causes --

MS. ZIMMERMAN: It does, and the Mycobacterium chimaera, the kind of bacteria that was there, is very slow growing bacteria that likes water, but as in this case, the Bair Hugger is a very hospitable environment.

THE COURT: Is there a similar statement that says Bair Hugger is a hospitable environment, just as there is the heater-cooler thing is a hospitable environment?

MS. ZIMMERMAN: There hasn't been a comparison between heater-cooler in that way, but there is admissions from defense counsel and from corporate witnesses that these devices do indeed harbor bacteria.

THE COURT: Right. We've got the swabbing and everything. The statement that's similar to the heater-cooler that was examined by the CDC, the Bair Hugger is a particularly hospitable environment for bacteria?

MS. ZIMMERMAN: Some of that testing was done in connection with Project Ducky, I believe, and an evaluation about whether or not it would be appropriate to line the inside of a hose, for example, with a kind of a silver nitrate that might make the hose less susceptible or less hospitable to these kinds of pathogens.

THE COURT: Project Ducky is a new one on me.

MS. ZIMMERMAN: I don't think that Project Ducky, in full disclosure to the Court, is attached to the papers that we've presented here. They were attached to our punitive damages motion. So it's part of the record, and I'd be glad to get the citation for Your Honors.

But again, the reason that this is important is, we want to understand that these kinds of devices that are in the operating room, they can host bacteria. That bacteria can become aerosolized because of blown air, which certainly happens with the Bair Hugger. That's what it's there to do, and the air can carry these bacteria into the surgical site, and Dr. Elgobashi's analysis explains in greater detail how that might happen.

Again, the Court, both of you, have heard much argument and evidence over the past several of days about what we agree about. We all know that bacteria is what causes these periprosthetic joint infections. The inoculation, the dose of bacteria when you're talking about a deep joint infection, there's just a very few number of bacteria, and it happens during the operation, during the joint surgery.

PJI can be caused by airborne contamination. We have also presented evidence about the relevancy of increased particles and how those are directly correlated

with increased bacteria over the sterile field, and an increase in bacteria in the sterile field increases the incidence of periprosthetic joint infections.

So I'll just go through this very quickly as Your Honors have certainly heard this. Both the plaintiffs and the defendants have agreed that bacteria causes periprosthetic joint infection. They also agree that inoculation, so the does of bacteria is much smaller when you're talking about PJI, than something on the skin level, a surgical site infection.

PJI can be caused by airborne contamination. Dr. Jarvis and Dr. Stonnington put it in their reports, and we would certainly encourage Your Honors to take a close look at that time, but also Dr. Wenzel has published and testified about this, the possibility of airborne bacteria originating from patient and from the surgical team, that those suffice to create surgical site infection in these kinds of procedures, particularly when implants are being placed, and that has to do with films and vascularity that we don't need to go into at this point.

Dr. Mont agreed periprosthetic joint infection are caused by airborne contamination, and we get to the study that was done by Darouiche, and Darouiche really confirms again, and this is at Exhibit 11, by the way, that for every ten colony forming units per meter cubed, the increase in

infection, there is a probability of an implant infection is doubled.

And the evidence that has been presented to Your Honors is that the colony forming units that are transported to the surgical site are well in excess of these additional ten per cubic meter.

So turning again to the international consensus, everybody agrees that this is a reliable source, but it's also a source that's a couple years old, and even then, they were certainly recognizing the fact that bacteria that arrive at the surgical wound correlate with the probability of having this kind of infection.

And I should say that in the international consensus, by the way, they say SSI. Well, the entire consensus was brought together to talk about deep joint infection. So if you read the full title of the international consensus, it is International Consensus on Prevention of Peri Operative Joint Infection, I believe if I've got that right. So that's what they were focused on.

THE COURT: We had a couple comments about the age of this study. What's the age of the study versus the filing of the first case in the MDL? The cases were filed here during the time that this wasn't old.

MS. ZIMMERMAN: That is true. That's true, and I believe that the international consensus came out in 2104.

This MDL was assigned in December of 2015. The first cases that were filed, Walton and Johnson, were in 2013 and 2014, so right about that time, but I think that the timing with respect to the international consensus is appropriately Your Honors' to be aware of, particularly there's been a question about whether or not the law is really leading science or following it, and here law is actually following science.

These folks at the international consensus were very concerned about these issues. They recognize the potential theoretical risk, and they did not have the same kind of information that we have now, but again, we're talking about the conclusions that are ultimately reached on a different data set than what has been presented or what we know as we stand here in 2017.

The methodologies by which we arrive at that evidence and present it to Your Honors for consideration, those are well-established methodologies in terms of particle tracing, computational fluid dynamics, the Bradford Hill criteria, and so as Ms. Conlin indicated earlier, the issue here today is not that this is new science.

It is that the science that has been developed for many, many years is being woven together into a package that makes sense, and it's a package that the international consensus units has been asking for, and that is really what the -- and I believe Judge Noel asked some questions about

the recognized theoretical risk -- pardon me. It's a been a late couple of nights -- that the international consensus recognized the theoretical risk associated with forced air warming and requested more study be done.

Plaintiffs have presented evidence, and the defendants have agreed as well, with respect to question number 1 of the international consensu. More bacteria, more likely you're going to have an infection. Question number two, Do the bacteria in the operating room correlate directly with the probability that you're going to have this infection? Everybody seems to agree, yes.

They cite their justification, by the way, and they say that some studies have suggested that airborne particulate count should be considered as the potential surrogate for airborne microbial density. Others have found correlation between the number of particulates larger than ten micrometers with a density of viable bacteria at the site of surgery measured by colony forming units.

So it has been suggested that monitoring particulate count could be used as a real time proxy for increased risk of wound contamination or infection. This is not new. This is not developed for litigation inside Your Honors's courtrooms. This is something that both sides agree is authoritative. So there's been evidence presented to Your Honors also with respect to what the defendants have

done in the face of various studies and complaints, what they have done with respect to filtration.

And this is an e-mail from Glen Maharaj in 2013 where they are talking about whether or not they can claim their filters have a HEPA efficiency, and he says we have no documentation in regards to that for the 750 or the 775. All we can do is stick by our claim and statement of high efficiency, which testimony from several witnesses here says would agree means nothing unless we specify the size of the thing that's being filtered out and how effective it's being filtered.

So HEPA we know is 99.97 percent efficient removing those particles down to a .3-micron size, so that's the import of that kind of efficiency measurement. Just saying high efficiency doesn't matter on its own without those other pieces of evidence.

So the defendants have failed to warn about contamination. They've known about it, and we have talked about it. This is Al van Duren's deposition in March of this year. He was the 30(b)(6) corporate representative, and he said, no, 3M is not disputing the Bair Hugger blower and hose, yep, they can harbor bacteria inside that device, we're not disputing that.

And dating back all the way -- this is an e-mail from Gary Hansen to Russell Olmsted, and they're talking

about the Stocks paper, and they know there's an increase particle count when the Bair Hugger is being used. So those are all different pieces of evidence that have been tied together by the plaintiff's experts in understanding the risks that Bair Hugger poses to patients across the country.

Al van Duren also says, yes, Bair Hugger increases particles in absolute numbers, and they have no internal data to refute that. Every study they've done, every study they're aware of, says that when the Bair Hugger is turned on, particles go up, and there's been some testimony, argument from counsel, about whether or not there has been any reports of infection or other kinds of complains from customers.

And my recollection is that what's been represented to Your Honors is, there have been no complaints of that sort of thing, but that's not consistent with some of the e-mails that we've seen, and I point Your Honors to this e-mail from Suzanne Tullis to folks at 3M, Mark Scott, and Suzanne Tullis it says here is the district sales manager for Arizant in North and South Carolina.

And she says, "This issue is everywhere. We have to develop a better strategy besides the Zink article," and this is in response to an e-mail she received from Vicki Jones. The subject is "Forced Air Warming Devices," and at the bottom you can see it says, "Dr. Bratzer, several of our

orthopedic physicians are refusing the use of forced air warming devices for joint replacement procedures at our facility. Their position is that they contribute to post op wound infections because of the circulating air, air turbulence, et cetera. The literature they have and what I found seems to support their position."

So they're getting questions from the field. Did they do any studies to refute this? If they had, I think that those would have been presented to Your Honors. They were getting concerns about contamination from people in the field.

Here's an e-mail where Al Van Duren again is recommending that when there is a known device -- if you look at the bottom here, it says we have a model 750 unit, serial number provided, and it has cultured positive for Acinetobacter. That is a bacteria, and Al Van Duren says, "Do not scrap the unit, remove and discard the filter in the biohazardous waste container."

So it's simply, it is not consistent with the evidence to say that there have not been reports from the field of contaminated devices, and we have only some of the evidence here, but in the face of that, when Al Van Duren was asked at his deposition as a corporate representative, well, what have you done with respect to safety validation? What did you do with the filter? And his answer was, "I

don't believe that any particulate filtration efficiency studies were completed," and that was with the 505.

And we said, well, have you done any biological testing of the filter? He says on behalf of the company, I'm unaware, "the company is unaware of any biological testing conducted during the design of the 505."

Michelle Hulse-Stevens was asked some questions about why that wasn't studies, and when Mr. Ciresi was deposing her he asked, "Are there other types of studies that you believe provide adequate evidence for the adoption of particular interventions, which could be less difficult to conduct?"

And we're getting at the aerobiology study several of their consultants have been recommending that they do, and she says yes. And well, that particular study, that has been recommended, that hasn't been conducted, correct?

"We have not conducted that study."

Mr. Ciresi asked, "And decisions have been made at the highest levels not to conduct that studies, correct?"

The answer, "Yes." And Michelle Hulse-Stevens' deposition is an exhibit along with the e-mails that support that decision.

In fact, the other thing that the company did was they discouraged independent studies, and here is an e-mail from Gary Hansen, again internally, saying here's our

strategy. "Our first step with ECRI should be to prevent them from doing their own testing, rather, rely on the published data."

And at the bottom you can see where it's highlighted, "I'd like to convince them that the valid testing is an arduous undertaking."

So the increase in bacteria in the sterile field also increases the incidence of these kinds of infection. Dr. Jarvis talks about that. Dr. Wenzel agrees. Dr. Wenzel, incidentally, may be interested to hear the argument that was presented before Your Honors yesterday that apparently Stocks and Darouiche are also either engaging in some sort of academic fraud or cooking their studies because they're hocking some sort of other warming device on the side.

And I think that that had to do with a new device that was studied in the Darouiche studies, and Mr. Goss -- and I'm happy to find a copy of the particular cite to the transcript -- said, well, you know, the only other people that looked at this may be the reason that they came up with the results that they did was because they also had a product to sell.

Really at the end of the day, all of that goes to the weight, not to the admissibility, but Dr. Wenzel at any rate agreed at his deposition that Darouiche, he's an

expert, and Dr. Darouiche, of course, found correlation between increased bacteria in the sterile field and risk of infection.

All right. And so now I turn your attention, and this is the document that I think Mr. Hulse was really forecasting for Your Honors. What else did this company know? When did they know it? And this is Exhibit 2 to our motion papers, and what this is is a study protocol dated June 23rd of 2007, and it's a study protocol for the Bear Paws device.

Bear Paws is another device that is used to warm patients to maintain normothermia, and what Al Van Duren says in September of 2007 is that if you pre-warm a patient before the surgical incision happens, you are capable of preventing significant surgical hypothermia for three hours. That means that you don't need to use forced air warming at all if you get the patient warm enough.

That's Al Van Duren says in his document here, but the other thing that he says, and we highlighted this in our brief, and this is at Table 1. He says, and this is, it's a table that lists advantages and disadvantages of using the Bear Paws prewarming versus the Bair Hugger during an operation.

Advantages: Inexpensive. Bear Paws is safe. Bear Paws can be used when intraoperative warming is

contra-indicated (aortic cross clamp, orthopedic cases.) It also, one benefit, it does not contaminate the sterile field to use the Bear Paws before a surgery starts.

Go down two lines on the same chart. Again Al Van Duren. This is not Dr. Augustine. Dr. Augustine is not in the picture. Bear Paws reduces the incidence of surgical site infection, and it reduces the potential for nosocomial transmission of pathogens by eliminating the need for intraoperative warming.

So their own corporate documents say that the Bair Hugger may not be well indicated in orthopedic surgeries, but they didn't tell the orthopedic surgeons about that, and Mr. Van Duren in his corporate deposition, he admitted to that fact as well.

So they say that pre warming with their own forced air warming product is equally effective at keeping the patient warm for at least three hours, which is the length of time certainly within which the vast majority of the cases before Your Honors were completed within three hours, and it eliminates these known risks. It eliminates the risks, and they were known at least in 2007.

The other piece of evidence that I would point Your Honors to is this particular document, and that is at Exhibit 2, and the thing that really matters here, this is an internal document, and the notation on the side is not

mine. That is from AVD1, and the testimony presented in this litigation is that that's Al Van Duren.

And he's commenting on this protocol on this particular section, and it says, the paper itself says there is no evidence that forced air warming increases risk of surgical site infections and considerable evidence that it does not, most recently from the U. S. National Institutes of Health. Numerous studies have shown it does not contribute to bacterial contamination in operating theaters.

So this is going to be a talking point for sales, by the way, and Al van Duren sees this, and he puts a comment on, and what does it say? It says actually there is evidence that forced air warming use increases the risk. This evidence was the motivation for Dr. Memarzadeh's work. This isn't Augustine. This is Al van Duren. This is the gentleman that they put up as their corporate representative when they did a 30(b)(6) deposition in March of this year, and this is back in 2010.

Now Judge Noel, before we left yesterday, you asked, you forecasted that you were going to ask about the nine studies, and I won't belabor this because I know it's getting to be long, but what I will say is that Your Honor appropriately recognized the fish analogy and the pond.

What I would say is that I think that Judge Noel's questions to Mr. Gordon were particularly helpful because 3M

does point to these nine studies, and they say that means that the Bair Hugger is safe. Now, first of all this morning, Mr. Gordon conceded that that was attorney argument and interpretation of those studies.

And really that means that this goes to the weight, not to admissibility, but to get back to the question that Judge Noel asked, the converse is also true. If 3M had any other studies besides these nine that would speak to the safety of this particular device, we can be sure that we would have seen it by now, but these are the nine that they've got.

And we can walk through each one of the nine. The first one is Hall. This is not a published peer reviewed paper. This is a poster presentation. There are 20 patients, 10 are Bair Hugger, 10 are non Bair Hugger. It's a completely different kind of surgery, it's an oral surgery, not ultra clean.

And there are six collection sites, but four were at each corner of the room, two were at the operating room table, one was the surgical site. So the Hall paper does not speak to whether or not there would be bacteria at the surgical site.

Similarly with respect to Zink, again this was a different device. It was at a lower temperature and a lower air flow rate. There's only eight patients here, and they

use a completely different blanket. It was the lower body blanket. The blankets at issue in I would say 99 percent of the cases before Your Honors are the upper body 522 blanket.

This was not a real surgery. These were volunteers that were laying down on the table, and I don't know if they got the pizza and the beer, but that's what was happening here. The Dirkes study, the Bair Hugger was set to ambient temperature setting. It wasn't set to warm, and we think that that is relevant for all the reasons that we have presented with respect to the CFD yesterday.

Avidan, again they're measuring bacteria at various points inside the machine. Tumia as well, and we'll walk through each of these, but suffice it to say that as Mr. Gordon indicated, there's different interpretations for each one of these studies that plaintiff's experts are certainly prepared to provide their interpretation of that, and the interpretation of all of those should go to the weight, not the admissibility.

MAGISTRATE JUDGE NOEL: All nine of these studies, though, is Mr. Gordon is correct that they are measuring bacteria? They're not looking for infection. Is that a correct statement?

MS. ZIMMERMAN: That is correct Your Honor.

THE COURT: And they're looking for bacteria on these agar plates?

MS. ZIMMERMAN: That is my understanding, yes, Your Honor.

MAGISTRATE JUDGE NOEL: Thank you.

MS. ZIMMERMAN: If the Court has no more questions -- I don't know if Mr. Ciresi was -- if the Court has no more questions, we're all done.

THE COURT: All right. Thank you.

JUDGE LEARY: Thank you.

THE COURT: Any rebuttal?

JUDGE LEARY: You know, I do have one question for you, Ms. Zimmerman, and I apologize for the delay in asking it.

MS. ZIMMERMAN: No problem.

JUDGE LEARY: With regard to the Frye Mack standard for the Minnesota state cases, am I correct in understanding that you're relying on the Texas case as the basis for saying that Frye Mack was satisfied in that the methodology is generally accepted within the relevant scientific community?

MS. ZIMMERMAN: I should clarify. So the Texas case is a federal case, and so it's applying *Daubert*. We think that it's helpful in understanding what weight should be given to these kinds of studies, but in Minnesota as long as, under Frye Mack and *Gold versus Tharaldson*, as long as the methodologies that the experts employ, and that is

literature gathering, Bradford Hill criteria, the computational fluid dynamics.

As long as they're qualified to do it, and there's been no challenge to the qualifications of any of these experts, and as long as they did it correctly, anything else can be sussed out during cross-examination in front of the trier of fact.

THE COURT: That's what I understood you to have said before. Thank you.

MS. ZIMMERMAN: Thank you, Your Honor.

MR. HULSE: Good morning -- good afternoon again. Good afternoon Judge Noel.

I just want to cover some factual points, but first, of course, the Minnesota Rule of Evidence 702 applies the requirement of general acceptance to novel theories. That's the terminology in Minnesota Rule 702. I think it's beyond dispute that what we have here is a novel theory, and so the general acceptance rule applies.

Gold versus Tharaldson is governing, and even if Judge Leary is inclined to look at the Texas federal case, I think what you'll find in that case, too, is that the defendant in that case didn't actually challenge the validity of the studies that the plaintiff's experts relied on. It stated that specifically in the decision.

First point, Ms. Conlin said that we have no idea

if the data that Dr. Holford looked at came from Dr. Reed.

And Brett, can you bring that up?

All right. So this is the Excel spreadsheet that was produced by Augustine. This was reviewed by Dr. Holford, and what the meta data is, that showed who last modified it when they last modified it, it's Dr. Mike Reed. This was the data that was sent to Augustine. That doesn't match the final data that is reported in the published study. You can take that down.

Ms. Conlin also said, brought up a quote from Dr. Holford, purporting to admit that there is no literature that supports either antibiotics or anti thrombo prophylaxis as confounders. As we've explained before, Dr. Holford is a statistician. He partnered with Dr. Borak, professor of epidemiology, and Dr. Wenzel and Dr. Mont, who reviewed the literature and gave the opinions based on the literature, scientific literature, that in fact both are well supported as confounders, and that wasn't consider Dr. Holford's job. He was the biostatistician.

It was also asserted that the Brimmo study which concludes that rivaroxaban, the anti thrombosis regimen, that was in place when you saw the spike in infections purchasing during the Bair Hugger period in the McGovern study, the claim was that Brimmo is nowhere in the case. This is just something that the lawyers came in with, the

Brimmo study.

Dr. Wenzel relied on the Brimmo study at pages 255, 258, 259, 2602 of his deposition, and Dr. Mont specifically cites it in his report where he concludes that it's a confounder. There was a discussion of Dr. Sessler's studies and the increase in particulates that was found in the Sessler studies. It's all submicron particles.

It was claimed that Dr. Kurz, the author of the study, and this was claimed before, and I thought we had already dealt with this, has disavowed that there is any benefit to patient warming. So I'm going to quote again Dr. Kurz's actual testimony. This is page 200 of her deposition.

Question: I want to make it clear, you're not saying, or are you saying, that the evidence today no longer supports the idea that maintenance of normothermia reduces the risk of surgical site infections?

Answer: I think, if I understand you correctly, I'm not saying that. I'm saying that I still believe that maintenance of normothermia decreases infection risk, but the effect size might be closer to 30 percent reductions or so, which is in effect a humongous, enormously large effect size for any medical intervention. That's what Dr. Kurz testified.

Finally, one of the documents that Ms. Zimmerman

put up talked about the effectiveness of the filter in the Bair Hugger, and as we've presented in the evidence, and it's there in our expert reports, too. The Bair Hugger filter is MERV14. That is the ASHRAE standard for operating rooms, and in fact, when the Cleveland Clinic conducted its study where it compared infection rates between the Bair Hugger with its MERV14 filter and the Stryker with its HEPA filter, there was no statistically significant difference in infection, and that was an extremely large trial.

And I would just like to end on the Cleveland Clinic study. It is in the record, and I urge the Court to look at it. In the Bair Hugger period, Cleveland Clinic had an infection rate of .47 percent, and if the plaintiff's theories, their possibilities, their potential theoretical risk that they've advanced here today were true, if it played out in the real world, how could the Cleveland Clinic using the Bair Hugger possibly have achieved a 0.47 percent infection rate?

This underscores where you had the higher infection rate found in the McGovern study the critical importance of the confounders of the antibiotics, of the antithrombotics, of fitness for surgery, of obesity, of all the other well-established and recognized factors in infection rates.

And finally, just to come back to *Joiner*, and

Joiner again was a decision where the Supreme Court affirmed the exclusion of causation experts who relied on epidemiological studies. There comes a point where the inferences of causation that are drawn from scientific literature are too far.

The gigantic leap, the flying leap that the plaintiffs medical experts have taken here, they point to no example. Plaintiff's counsel point to no example where they have ever reached these kind of causation conclusions based on this material, nowhere in their professional lives. This is courtroom science. It's not real science.

We ask the Court again to exclude the plaintiff's medical experts and grant summary judgment. Thank you.

THE COURT: Thank you.

Were there any documents that were discussed here put up that are under seal that we can unseal? Do we have any sealing issues?

MR. HULSE: Our favorite topic.

MS. ZIMMERMAN: Of course the Courts will not be surprised that plaintiffs believe that all of this evidence should be publicly available.

MR. HULSE: Well, we may disagree on some points, but I also know from experience with Your Honors that when it comes to summary judgment, it's a pretty restrictive what remains under seal. So we would like to follow the process.

We have got a lot to go through, but of course the defendants will keep that in mind, the public's right to know.

THE COURT: Okay. I just wonder whether there were sealed documents that were discussed here in open court, and if there were, then those presumably could be unsealed, but you'll go through those.

MR. HULSE: Right. And I think it would almost exclusively be things that were discussed, sort of the internal corporate documents, but maybe upon, you know, a little bit of thought, we can get past the sealing issue on those.

THE COURT: Okay. Just something to consider.

MAGISTRATE JUDGE NOEL: Are we done? I just want to say I'm very impressed with all of the lawyers in this case. In the three days we've gone through 17 motions, 51 memos. I'm amazed at your, both sides' command of all of the documents, and thank you for, on a very interesting presentation.

I've enjoyed being here.

THE COURT: Thank you.

MS. ZIMMERMAN: Thank you.

THE COURT: We don't take enough breaks. I just want to remind you that the head of China just gave a three-hour speech with no break at all.

JUDGE LEARY: I am sorry. If I could, on the punitive damages motion, I'm requesting submissions by both parties with regard to their view of the evidence and the law and in the form of proposed findings, as well as the judgment. If there is any recitation -- let me back up.

I rely heavily on representations based on evidence that exists in the record. That's what my expectation is. If there's any reference to the evidence, I want to see direct quotes to the literature or to the depositions, whatever is being quoted. You can put it in the body of the document, or you can put it in an annotation in the footnote.

But I want it to be as complete and exhaustive as it was with regard to the punitive damages. I'll give you three weeks to submit that or three weeks from today's date.

MS. ZIMMERMAN: Thank you, Your Honor.

MR. HULSE: Thank you, Your Honor.

THE COURT: And then, Mr. Blackwell, it looks like you're anticipating my next question, which is -- and -- Ms. Zimmerman, same thing for you -- we will take the hard copies of the presentations, and Ms. Zimmerman, do you have the slides that you used today in your argument and, Ms. Conlin, as well?

Not right this second, but can you get it?

MS. ZIMMERMAN: If we don't have them, we will

make sure to have them messengered over to you. We also were prepared to provide a digital copy of Dr. Elgobashi's video for the Courts, as that was played in the power points yesterday, and I don't know that it would work on hard copy.

THE COURT: Did we have a video?

MR. BLACKWELL: There was a little clip yesterday.

THE COURT: Oh, yeah, that little clip.

MAGISTRATE JUDGE NOEL: Red and green and yellow.

MR. BLACKWELL: Kind of looked like Dante's Inferno.

THE COURT: Well, you would know.

MR. BLACKWELL: Yes.

THE COURT: So you're just talking that. You're not going to give us a whole --

MS. ZIMMERMAN: No, I don't think we could get it on a flash drive. There is a lot of data.

THE COURT: That's wonderful. Really, it was such a pleasure to talk to you folks, and we'll look forward to any submissions and take the matters, many, many matters, we'll take them all under advisement and issue an order in due course.

JUDGE LEARY: I will accept the Elgobashi demonstration, too, and thank you, and I'll accept your dec copies, as well as plaintiff's dec copies as well. Not now.

MS. ZIMMERMAN: I will see if we have got them,

otherwise I will make sure you get them.

THE COURT: Do we have a status conference that we should talk about whether it makes sense? This is October. I'm sorry. I yawned a couple times today. These were long days for all of us. I realize they were way, way longer for you than us.

MR. BLACKWELL: November 16th I'm hearing.

THE COURT: I don't think that makes sense.

MR. BLACKWELL: Yeah. We agree that it doesn't make sense to have it November 16th. This is sort of what's happening.

MAGISTRATE JUDGE NOEL: This is your report.

MS. ZIMMERMAN: I think that's right. Given the new scheduling order, we are all going to be very busy, I'm sure, on bellwether issues as well, working on depositions and that sort of thing.

THE COURT: Okay.

MR. BLACKWELL: I do want to say, and I think I speak for just about all the lawyers. This is about as big a case as any of us can be involved in, and it's kind of rare to be in joint session of both courts, and we've never been in front of a more accessible court than we've experienced in this case.

And it's really helped things to go much more smoothly, and I think we have all appreciated it.

JUDGE LEARY: I also want to echo the comments of my colleagues. The professionalism you've all demonstrated throughout this process has been really a credit to the profession. It's been an honor to preside over this, and also give your colleague best wishes. I hope he's feeling better as well, Mr. Gordon.

MS. ZIMMERMAN: I will check in with him after the hearing. Thank you. I will do that.

THE COURT: Yeah. Not my dream, but these two always wanted to be on a three-judge panel.

JUDGE LEARY: I no longer dream it.

THE COURT: Thank you. We're in recess.

(Court adjourned at 1:26 p.m.)

* * *

I, Maria V. Weinbeck, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: *s/ Maria V. Weinbeck*

Maria V. Weinbeck, RMR-FCRR