UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

	REDACTED
In Re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	File No. 15-MD-2666 (JNE/DTS)
	June 12, 2019 Minneapolis, Minnesota Courtroom 12W 9:30 a.m.

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

(REDACTED - MOTIONS HEARING)

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P R O C E E D I N G S

(9:36 a.m.)

THE COURT: Good morning. Please be seated everybody.

I think rather than take time to go through appearances, you can just announce yourselves when you get up to speak. The court reporter already knows who you are. She wrote you down on a piece of paper.

All right. This is defendant's motion. Mr. Blackwell, are you prepared to speak?

MR. BLACKWELL: I am, Your Honor.

THE COURT: All right. Go ahead.

MR. BLACKWELL: Good morning, Your Honor. If I may I approach with copies of slides that we would show this morning.

THE COURT: Okay. Ms. Zimmerman, that's all good with you, right? You've seen them.

MS. ZIMMERMAN: That's fine.

THE COURT: Got them.

MR. BLACKWELL: Good morning again, Your Honor. It's a pleasure to be before the Court. It's been a long time since we've been able to see Your Honor on this case. I'm not certain that we've been totally missed, Your Honor.

What I want to start with this morning in talking about our motion for the Court to reconsider its decision on

general causation or what we call the undisputed facts. They were the undisputed facts at the beginning. I call them the transcendent facts because they haven't changed in this case, that no peer-reviewed study has ever included that the Bair Hugger system causes surgical infections. No peer-reviewed study has demonstrated that the Bair Hugger system use increases surgical infections at a right above the background risk.

And, finally, that the FDA has rejected the plaintiffs' position that the Bair Hugger system causes surgical infections and recommends use of forced-air warming due to the proven patient safety benefits including reduction in surgical infections.

Since we were last before the Court on the Daubert motions, a number of things have transpired. We've had a trial. We've had some rulings that we think all create, have generated compelling evidence and a compelling reason, new evidence for the Court to reconsider its general causation decision.

And, Your Honor, this compelling evidence goes to the theories that plaintiffs have espoused in this case, which Your Honor has articulated as their two causation theories. The first of which is that the operation of the Bair Hugger disrupts operating room air flow and causes ambient bacteria to be deposited into the wound; and then

the second that the Bair Hugger machine itself harbors bacteria and that they escape the unit during surgery.

So the evidence that we've heard, Your Honor, is was at the pretrial stage of Gareis with the Court's ruling on the harboring bacteria issue. It was also during the trial itself where we actually got to hear the testimony of Dr. Elgobashi, and we got to see the CFD in action, both of which were new as a post-Daubert. And then there have been post-trial notes with this back to the Jeans study and the International Consensus meeting, which all three are new.

So I'm going to focus in particular on the plaintiffs' three medical experts: Drs. Samet, Jarvis and Stonnington. And the three essential components of the plaintiffs' case as they try to make out their theories of causation. The first being the McGovern study in 2011, what we've referred to as the Observation study, Your Honor. And significantly confound the study but is nonetheless the only study that provides a positive risk assessment of the relationship between the Bair Hugger use and an infection.

The Elghobashi testimony and the CFD, which is critically important to the plaintiffs' case, is the only evidence that the plaintiffs put on purporting to establish a causal mechanism in the real world. He's the only air flow fluid dynamics expert that was offered in the plaintiffs' case or that exist in the plaintiffs' case. And

then, finally, Your Honor, the plaintiffs' theory of the Bair Hugger harboring bacteria.

So what I'd like to do is to take a few minutes to talk about Elghobashi and the relevance of the CFD then put that aside and as well the harboring bacteria and then spend the bulk of my time on Your Honor's questions that you posed to the parties.

So starting first, in reverse order with the harboring bacteria, Judge Ericksen, I won't say much more than Your Honor said in response to a motion we filed on this particular issue on the Gareis trial, and the Court's ruling that the harboring bacteria theory wouldn't be allowed to proceed. And as the Court said in the Court's Order, no expert brought to the Court's attention has tested the air coming out of the Bair Hugger's blanket and discovered escaping colony forming units. This test would be feasible. It is certainly not cutting edge given the resources plaintiffs have spent on generating expert testimony for this case, this test absence is curious.

So that particular ruling, Judge Ericksen, wasn't specific to the facts of Gareis. We went through the general causation argument. This was a fundamental theory the plaintiffs had from day one in this case and they've had ample time to develop the expertise. They haven't. The time has come and gone. If they have anything with respect

to -- if they had anything with respect to proof that the Bair Hugger harbors bacteria and that that is somehow being emitted from the blanket into the operating room, and as the Court is right that the absence of this particular evidence is curious given it has been there since day one and was an issue that was addressed at the general causation.

THE COURT: I'm sorry, I was bitten or stung or whatever it is on the eye by one of those gnats that has taken over the state in the last couple of days, so this has nothing to do with you. Every once in a while I can't see so, but anyway just to let you know it doesn't have anything to do with you.

MR. BLACKWELL: Thanks to those gnats, when I go to my farm, I have to work in my bee keeper's veil because they are so bad.

THE COURT: I read up on them after this happened, and they're alleged to be buffalo gnats, I think. Yeah, you don't want to know about the mechanism, anyway. I'm sorry, I thought I --

MR. BLACKWELL: No worries, Your Honor.

So the essential argument with respect to the Bair Hugger harboring bacteria theory, Judge Ericksen, is that the time is up on that theory. It was an issue at general cause. It's been there since day one in the case. They don't have anything today. They don't have anything

yesterday, and they haven't had anything in years worth of yesterdays, and so the time is up on that.

I'd like to turn then to talking about Dr. Elgobashi and the CFD from Dr. Elgobashi. And the pertinence of this and kind of what we learned is that as the Court knows with the plaintiffs' air flow disruption theory, that is that the Bair Hugger disrupts air flow in the operating room and causes ambient bacteria, airborne bacteria to deposit into the wound, the mechanism by which this happens, the plaintiffs purported to show through Dr. Elgobashi that he was going to show and his CFD is going to demonstrate how it is that the exhaust heat and air from the Bair Hugger vitiate this force field of air that is otherwise protective of the surgical site but for the Bair Hugger vitiating this causing the contaminated particles to rain down on the wound. So there's essentially their force field theory.

What is critically important about the causal mechanism, Your Honor, is that if the plaintiffs don't have a causal mechanism, they don't have any causation fundamentally. The McGovern study confounding though it may be never establishes causation. It doesn't purport to be. The authors never said it did, so the causal mechanism is very important.

What I'd like to be able to do is to contrast what

we heard pre-Daubert with respect to the CFD, Dr. Elgobashi, and the force field theory, and then what we heard, what we learned since Daubert that is new since that time in that regard.

So there are three, well, maybe there are two, but maybe three issues that we have with Dr. Elgobashi's CFD and the force field theory. Your Honor, the first is that it doesn't provide any support for the plaintiffs' theory that the Bair Hugger is vitiating this laminar air force field and causing particles to rain down. It doesn't support that, and that this we learned during the trial, and I'll show Your Honor what we mean by that in just a moment.

And, second, given the boundary conditions that were used for that CFD, the CFD doesn't fit the facts of this case. It just doesn't fit. It's not a real world exam and, in fact, the conditions used could not possibly apply to any case in this entire MDL. And the fact that it fails to show wound inoculation that it fails to show the mechanism by which the Bair Hugger supposedly contributes to contaminated particle landing in the wound is another reason that it fails to fit.

And Your Honor may recall or can easily see that on page, it was page 10 of plaintiffs' opposition to our summary judgment motion, what they said, told the Court the CFD is going to show how these particles entered the

surgical site. It would be seen, shown on the CFD into the surgical site and by implication contaminates the wound. And given that the CFD doesn't show what the plaintiffs' claimed and told the Court that it would, for the plaintiffs to try and use one of their experts to try to use the CFD to prove causation is truly a great inferential leap when all is said and done because it doesn't show what they purported that it would.

So Your Honor, to take a look at the first instance what they said versus kind of what we heard. So looking, first of all, at the opening statement from Gareis, where here the counsel is telling the jury about this laminar flow, what they say it's kind of a force field intended to protect the patient. And what the Bair Hugger does, what happens then? It interferes with the force field that's intended to protect the patient. That's what happens. That's what the evidence will show in this trial.

But it wasn't just the lawyers making statements in opening statements. Their experts, the Jarvis, Samet and Dr. Stonnington also embraced the force field theory, whether it's called force field, unidirectional flow, same thing. We can see that Dr. Jarvis embraces the force field theory. The idea that we control skin cells on the skin for our prep, and we try our best to control the skin cells through this unidirectional air through this force field.

Dr. Samet, same thing. Disruption of the protective unidirectional flow. And then, finally, Dr. Stonnington is basically creating this force field that the patient is in and all that stuff is being exhausted to the returns or the exhaust fans in the room.

What Your Honor was told, and we spent quite a bit of time addressing this in the context of the arguments in Daubert over the CFD and Dr. Elgobashi, was that the CFD would demonstrate this force field and how the Bair Hugger vitiates. And, in fact, here in opposition to our motion to exclude Dr. Elgobashi. Dr. Elgobashi's CFD shows that when the Bair Hugger is off, the HVAC system acted as it was supposed to and prevented ten micron particles from reaching the sterile field. However, when it was turned on, an exponential number of squames reached the surgical wound, the patient and the table where the implant and other surgical tools are located during the procedure.

So this is the theory of air flow of disruption, that there's a force field, the Bair Hugger vitiates it, the CFD shows the mechanism by how this occurs and that these particles then will land underneath the surgical wound. That's what we heard.

What we learned about this entire force field theory at the trial was the complete opposite from their own expert Dr. Elgobashi who says that the force field theory is

absolute rubbish. "Anybody claiming there's laminar flow and it creates a force field. Right? It's not just rubbish. It's absolute rubbish." He says it's, "absolute rubbish, and I give an excuse because that person does not know turbulence."

THE COURT: I see that, and I remember him saying that, and I'm just not sure -- I wonder if you're overstating a little bit what he meant by that. He wasn't saying there's no -- I mean he obviously wasn't saying there's no effect on the flow, but he as a precise scientist was saying it's not a force field. And, you know, a force field might be a misleading way to characterize it, but it's not a force field. It's not -- and then, of course, laminar flow.

But I didn't take from his testimony at the time, and I don't take from these words that he meant there's absolutely nothing to the effect on the direction. I don't think he ever said that the fan coming down from the top of an operating room doesn't do anything. But I mean true enough, he did say force field no good, laminar flow no good, I agree with you there.

MR. BLACKWELL: But, Your Honor, taking Your Honor's point, what he did say in saying that there is no laminar flow in the operating room is he said that it was all eddies. It is all turbulence. It all rolls around, so

the very premise that there is this curtain of air that keeps the surgical site completely sterile but for the disturbance of the Bair Hugger, that is what vitiated was the idea that that even exists, not that there is no impact from the HVAC grille in the ceiling or anything else that generates there in the operating room. There just isn't this protective force field in the first place. They're just all eddies, which means that anything that might get caught up in any of the eddies in the operating room, fair game for picking up a particle and moving it around and that it would not all be excluded by this curtain force field but for turning on the Bair Hugger. And so that was the take away from that.

Now, so to the extent that the plaintiffs and none of the plaintiffs' experts qualified this force field by saying the force field doesn't really mean that, Your Honor, obviously. And they, in fact, they characterized it and the way that I described it, it showed Your Honor's language, each of the three experts. What Dr. Elgobashi did was a large eddy simulation, as Your Honor knows, and even those large eddy simulations, in any event, he says, "so really any large eddy simulation with particles I consider suspect at this time." And there's a reason that he considered it suspect, and it's because of all the turbulence and eddies and air flows and air currents that exist in a room. How do

you go back retrospectively and recreate that?

But, Judge Ericksen, I don't want to stop there because what is the point of the CFD? What's the point of the simulation if it doesn't ultimately show how particles supposedly contaminate the wound? That would be the point. The CFD was supposed to show that the Bair Hugger air currents air flow contaminates the wound.

And what was said in the trial itself in that regard was starting the opening statement, the CFD, Your Honor, depicted a knee. As Your Honor remembers, the Gareis case involved a hip. And plaintiffs' counsel's comment was "the same principle is true for hips or knees." Now this, of course, will be a concept we'll talk about when we get to the Jeans case, Your Honor, where there's a hip, knee thing to talk about.

But here it's clear that counsel says that Dr. Elgobashi, he knows exactly how many of these squame size particles end up around the surgical incision, and they make it clear in the closing argument that the plaintiffs argue that "the evidence is abundantly clear that the Bair Hugger causes infections, and then we have Dr. Elgobashi's work proving it on computational fluid dynamics," so supposedly this proves the causal mechanism. This is the ultimate culmination of it is that we see particles land in the wound.

But what we actually learned by in the trial there were a couple of things, and as Your Honor may remember, the video that the jury saw from the plaintiffs' was a version of Dr. Elgobashi's CFD that had been sped up, so it wasn't played at the normal speed at all. We took the original speed and played it ultimately for the jurors to see, and once you played it at the regular speed, what we learned is that no particles at all reached the surgical wound. The CFD does not depict any particles reaching the surgical wound.

Now, that isn't just a testing artifact because the CFD, as the plaintiffs explained to us, involved millions of hours of calculations meticulously done, et cetera. There's a reason that there are no particles seen landing in the particular wound, and it has to do with something called the thermal plume because what Dr. Elgobashi modelled, what he modelled with respect to this is the body's temperature, the temperature of the human body emanating from that particular wound. And the thermal plume itself is protective against small particles landing there.

And we know that, Your Honor, because the National Institutes of Health did its own CFD. This would have been a Dr. Memarzadeh study back in 2010, where they found exactly the same thing. The CFD, joint surgery, they found

exactly the same thing that the particles did not land in the wound because the thermal plume deflected them and that's what was shown ultimately on the CFD was the impact of this thermal plume, and so no particles landed there.

Now, plaintiffs will say that the CFD was only I think they said in their papers 45 seconds worth of this. Your Honor, they had as much time to show as much as they wanted to barely show how much deposits in the wound, particularly when this is the mechanism that they are claiming shows that the air flow disruption created by the Bair Hugger causes contaminated particles to land in the wound shown through the CFD and it does not support that. It does not show that. Instead it illustrates a principle called thermal plume, and it shows the opposite, that particles did not land in the wound from the Bair Hugger.

So when I say, Your Honor, that the CFD doesn't fit the facts of this case, this has to do with the boundary conditions, and Dr. Elgobashi said he tried to create the sort of perfect ideal environment. It's not the real world, and he says that no CFD or CFD is only going to be as good as the boundary conditions that you put into it, to what extent it reflects what takes place in the actual environment. And so what we know about the boundary conditions here is that they are vastly different than any reality.

First of all, you can look at the people that were in the CFD, at least the illustrations of people. Only three. They don't move. There are no movements or motions from any person. None of the persons in this mocked up operating room contained any bacteria or particles. The average human sheds roughly 20 million squames an hour. So in a typical surgery that lasts, if the surgery lasted even one hour, you typically have five operating room personnel in that surgery. Your Honor, that's a hundred million squames from just the people in the operating room, and the movements would create all manners of air turbulence, doors opening and closing, lamps generate heat, fans generate heat, anesthesia machine generates movement, so all of those are real world conditions.

So there is not a way to take the CFD and make a real world extrapolation of what happened in the real operating room when you don't just have a person standing staticly that shed no particles, no doors open, no other equipment is turned on. That's not the real world, and then to make an extrapolation of what happens in a real operating room environment where there are multiple innumerable, uncounted, unquantified air currents swirling all around, a hundred million particles from OR personnel alone, in addition to other particles that are in the room, and they extrapolate from that that being the cause of one bacterium

reaching the surgical wound had to have been the Bair Hugger.

THE COURT: So that's your bridge between general and specific causation, right? That you're saying because this can't show any specific, that it's a failure of general causation because there's no mechanism shown by which it could prove or indicate causation in the specific case, right?

MR. BLACKWELL: That is right. That the failure of any possible proof on specific cause is tantamount to a general cause challenge.

THE COURT: Citing?

MR. BLACKWELL: I'm going to get that, Your Honor. Citing more than Blackwell.

So for the case, it was in response Your Honor to question number one was that we don't know of any methodology that would allow the retrospective reconstruction of the multitude of air currents that exist on the typical operating room to be able to scientifically and reliably determine which air currents may be associated with the Bair Hugger and then to assess whether or not they are causal in causing the inoculation of a wound. Retrospectively, we just don't know any scientific methodology that does that, and that really is the response, Judge Ericksen, as opposed to which case says it. We just

don't know what science says it, and a methodology that would permit that in a retrospective way when there's been no data collected then even to know what the first air current was much less which other ones were in the room and how they shifted and evolved and changed over the course of a surgery as they would.

But as to Dr. Elgobashi's CFD boundary conditions, our point with respect to that ultimately on the fifth issue and not replicating real world conditions, it is simply a cite here from the *In Re Mirena* IUD case where here the Court does found a fairly straightforward, I think, conclusion that this doctor's constrained testing conditions don't reliably replicate the conditions inside a woman's uterus, and therefore render his methodology and the conclusion he draws from it unreliable.

The facts of this case as it relates to the CFD is far worse than the scenario, frankly, in this *In Re Mirena* case because at least this was a medical professional who was attempting to address what was simply a medical issue. What we have here with respect to Drs. Jarvis, Samet and Stonnington are medical persons whose opinions are based upon or premised upon aspects of fluid dynamics, which is not their area of expertise, none of those have a background in fluid dynamics, to begin to assess how it is air currents in the room, this again referring to the plaintiffs' air

flow disruption theory and airborne bacteria, how the air currents in a room will have propagated to cause a single bacterium, because the plaintiffs have found that it only takes one, to have landed on the wound.

So with that said, Your Honor, I want to turn to Your Honor's questions, and starting with question number 1. And, Judge Ericksen, this was the discussion I was having just a moment ago when the Court asked about the alternative causes, given all the possible causes of plaintiffs' infections, what scientifically reliably method or process could plaintiffs use to eliminate likely causes and identify the Bair Hugger as the most probable cause of infection, and how does this process or methodology satisfy Daubert?

So that has baked into it obviously a general cause and a specific cause aspect to it, and the first the general cause aspect of it is we don't think there's any reliable scientific basis for even ruling in the Bair Hugger as a possible cause in the first place, that the only real world study that the plaintiffs have to rely upon is the McGovern study, and McGovern itself disclaims causation, and back in McGovern, they have no causal mechanism that's reliable that will connect the dots for them because the Elghobashi CFD doesn't do it. All of the other mechanistic studies that the plaintiffs want to point to do not do that. They all disclaim causation, and so that lack of a mechanism

for ruling this in in the first place.

And so beyond that, as to the specific cause kind of a question, all of the approaches that we can contemplate for being able to figure out these alternative causes, all end up in the final analysis with too great of an analytical leap between the conclusion the plaintiffs want to reach and the facts. And we think about this in two different ways.

First, with respect to the air flow disruption theory that given a room in the real world with multiple unidentified and unquantified sources of air flow disruption interacting with each other, we're not aware of any methodology that would permit anybody to retrospectively go back in time to reliably assess which air currents were probably causal in the single airborne bacterium landing in a wound and associate that with the Bair Hugger.

So knowing that retrospective with respect to the air currents but not only that, there's also this same issue with just the ambient bacteria because the plaintiffs' air flow disruption theory is premised upon having both the air currents generated by the Bair Hugger and saying that whatever the bacteria is is one that is somehow propelled by the Bair Hugger. So likewise, Your Honor, given a room with potentially millions of unidentified and not specifically quantified bacteria potentially given that there millions and millions of particles in there unrelated to the Bair

Hugger from just the OR personnel. We're not aware of any scientific methodology that would permit a reliable retrospective assessment of which bacteria, if any, were in fact causal or how they could be reasonably tied to the Bair Hugger, that how would you boil that down in a retrospective way when there was never any data collected with respect to that at the time, particularly when we're talking about commensal bacteria in these cases. And this particular point, the latter point, Judge Ericksen, is compounded when we consider the prospect of hematogenous ceding of wounds blood-borne post-surgery and other post-op sources of infection only compounds this particular problem.

Now, in terms of the various sources of air flow disruption, I don't think it's really debated that there are any number of them and that Dr. Elgobashi's CFD didn't address them. He essentially says so. Where here he's talking about things he could have modelled in the CFD. And what it comes down to is that anything that blows air has a fan, generates heat, any of those things have the tendency to create turbulence in the air that would affect how particles propagate in the room and even would affect the number of colony forming units in the room depending on how it is that the personnel in the room move. So the fact is that the air is in a constant state of unsteadiness in the room. So we have here a situation where the air currents

are unidentified, and they're unquantified, and they're not studied, and they can't be done retrospectively in any case in the MDL. And we think in that context this does set the scenario that the Court was addressing in the *Bland* case here in the Eighth Circuit where the causal condition is unknown in the majority of cases you can't use a differential diagnosis that Bland's exposure to freon was the most probable cause of Bland's exercise-induced asthma. You can't jump to that conclusion. As a practical matter, Dr. Sprince's causation opinion could not possibly be based upon a reasonable degree of medical certainty.

And so this comes back to you've got an operating room that will have multiple particles in it, hundreds of millions of particles from just the people, let alone all the other stuff in the OR. You've got dynamic air currents from anything that moves, has a fan or generates heat, and you have here medical experts, not air flow experts, medical experts jumping to medical conclusions based upon theories of air flow disruption that they're not even qualified to address and when they haven't even assessed the factors. They haven't identified them much less quantify them, and they can't in any case.

And so what we know, Your Honor, in terms of how difficult this particular task is, and we think is fatal to the plaintiffs' case is exactly what was being addressed in

part by the Oguz case, sorry, the Oguz study from 2017, where here the authors were saying kind of how do we get at this. They're saying only a large randomized controlled trial of forced-air warming versus non-forced-air warming would help to decide if patient outcome is influenced by the use of forced air devices.

Until this study has been performed, the hypothesized risk of forced-air warming remain uncertain with a multitude of factors influencing the patient's risk for perioperative infection. Only this kind of study will be able to answer the question if forced-air warming is a major influence on surgical wound contamination whose voice can be reliably detected in a large choir of all of the factors.

And they list what some of the other factors are: transmission via anesthesiologists, surgeons hand, skin prep, sterile surgical technique, duration of surgery, surgical skill, patient-related factors, which Your Honor can see there and read there including the antibiotic treatment.

So when I say this compounds the problem because this is on top of the air flow disruption's issue of being able to assess how the air currents move in the room, what they are, how many they are, how they infect a particle, then when we move beyond that the problem is compounded by

those additional factors as referenced here in Oguz.

Now having said that, Judge Ericksen, you may recall in our papers that we talked about two kinds of approaches. I think that's at around page 24 or 25, although they don't have page numbers, but if Your Honor is trying to find --

THE COURT: I'm looking for something else. I'm looking -- you go right ahead. Don't worry about me. But I will look for page 24 or 25 of your thing since you already -- let's see here.

MR. BLACKWELL: So we mention the genome, genome sequencing, and we talked about a CDC standard, and I want to talk about those briefly in the framework of what we're discussing now.

Were the Court to decide that there is anything remaining of this Bair Hugger harbors bacteria theory, there would be a method of being able to determine if a bacterium could be associated with the Bair Hugger.

THE COURT: Here's the page I was looking for. Answers everything. Okay, I'm ready.

MR. BLACKWELL: No worries, thank you, Judge.

So basically about this genome sequencing, this is what would be the vaunted heater-cooler, the baker pad (phonetic) here in this case, and this particular heater-cooler study involved what I call a designer type of

bacterium, the so-called M. chimaera bacterium that isn't a commensal bacteria on the human body. And this was a study where they were able to trace the source of it as an outbreak in a hospital by finding the bacteria in a wound and then finding it also in the machine and being able to eliminate the other kind of likely sources of causes for it.

By the same token, I think that that's a transcendent thread between the genome sequencing and the gold standard, which is a standard that would attribute to Dr. Jarvis when there's an outbreak in a hospital in Tennessee when he was with the CDC, and essentially what he did was a common sense thing in a way that he didn't just jump to the conclusion of what is the cause of this. They created a list of all the possible plausible causes of it and went through a process of elimination based upon those that were reasonably ruled in as prospects and then examining which of those to determine specific cause. And by using a multi-variate analysis meaning basically you're controlling four different confounders in it to arrive at a conclusion, a sensible thing to do.

If it were possible here, could you use that approach here in this case to arrive at a specific cause determination? It brings us back full circle again of begging the question of how could you in a retrospective way be able to do an assessment of how all of these various air

currents would affect a single particle to cause it to inoculate a wound and then attribute that to a Bair Hugger, that the methodology, scientific methodology isn't there to be able to do that retrospectively. There's no data that will allow anyone even to point to or look to. And to the extent that plaintiffs want to look to something like Elghobashi or what have you, again, it isn't a real world test because it doesn't take into account all of the other factors that are dynamic, that are impactful in the room.

It's the equivalent of catching a cold on a plane and deciding that because somebody sneezed back in row 26, that must be the cause, when there are infinite number of other causes to be taken into account.

THE COURT: Proof that you fly in the front of the plane. Be careful of what you say about us in row 26.

MR. BLACKWELL: I neither admit nor deny, Your Honor.

But going on, Judge Ericksen, to question number two, the Jeans study. And the Jeans study observes a significant decrease in the MSSA infection rate, predominately in the hip replacement group, after the introduction of the MSSA screening program. How do these findings, which suggest that MSSA screening confounded the McGovern Observational Study, impact Dr. Samet's opinion that the Bair Hugger device constitutes a substantial

contributing cause? What relevance do these finding have to hip surgeries in this MDL proceeding? To the knee surgeries? How many cases in the MDL involve hip surgeries? How many involve knee surgeries? And I think we answered the last question on papers, but --

THE COURT: I read 1,700 versus 3,000.

MR. BLACKWELL: Roughly 1,700 hips and roughly 4,000 knees, you know, thereabouts. And so if I could just talk about the background of McGovern because the Jeans study completely fits within the framework of McGovern. It involves the same study author Dr. Reed, who was the senior author of a McGovern Observation study and also of the Jeans study. The McGovern Observation study took place over a 30 month time period going back to July 2008. And so the first 20 months of that were the Bair Hugger study period. There was then a three month window of transition to then seven months study involving the HotDog conducted fabric warming.

What we know about this particular study is that in its conclusion, it arrived at the conclusion that there was an association between Bair Hugger usage and development of surgical site infections. We also know about this study that its senior author, Dr. Reed, has and does today. This has been a new thing since our Daubert ruling, himself characterizes the Observational study as having significant confounders. And that's important, Judge Ericksen, because

the McGovern studies as an Observation study was a very fragile one, and fragile in the sense that the numbers were so small and the differences between the group and the numbers so tight that even a difference of two fewer infections in the Bair Hugger group vis-a-vis the HotDog group would mean the difference between having statistical significance or losing statistical significance. So a very fragile study, so this means those confounders also matter tremendously.

So what were some of the confounders? MSSA being a very significant one that was the subject of the Jeans study, so it was only MSSA screening for a part of the Bair Hugger period, perhaps in the last four of the study, 20 years. And then the HotDog period alone that was mandatory MSSA screening from the get-go for the entire period.

Rivaroxaban, which is this thromboprophylaxis, the anti-clotting drug. And Rivaroxaban is associated with itself with infections that was used on the Bair Hugger period only, never used on the HotDog period. And then the Gentamicin was used alone for part of the Bair Hugger period, And this is significant because there is some bacteria that are resistant to Gentamicin. And there was a more effective stronger antibiotic used during the HotDog period.

So what we have here are two different time periods, the Bair Hugger period, which is much longer than the HotDog period. There was a difference in the type of warming devices used, but there is also a tremendously huge difference in the infection control procedures that were put into place between the respective groups that is the Bair Hugger and the HotDog.

So this Dr. Reed acknowledges, as does the International Consensus Meeting, which I'll talk about in a bit, but there was also other independent confounders that were also involved in the case in this particular study from blood transfusion, obesity, incontinence, et cetera. And in terms of numbers in each group, Your Honor, there were 1,066 in the Bair Hugger group and 371 in the HotDog group initially.

Now, what we know is after the McGovern study was published, the tabulators, Mr. Albrecht acknowledged a tabulation error in the results, and that tabulation error, I think he resolved it by adding one to each group, but there was a tabulation error that affected the odds ratio ultimately.

So enter the Jeans cohort, and what Jeans is addressing is the question of what it really is to impact the MSSA, methicillin sensitive staph aureus or does it have an impact, the MSSA screening, is the world that the Jeans

study got involved in.

And so what we know, Your Honor, about what was happening at this particular hospital, the subject of both McGovern and Jeans, is that the hospital had a problem with hip infections, hip and MSSA in particular, because as we learn from reading the McGovern Observation study and Jeans, is that in a typical case, as the Court sees here even in this MDL, you have, you have more knee cases by multiples than hip cases than what's normal, and they point this out in the McGovern study.

In Jeans, they point out that they had almost a four-to-one difference in hip infections to knees, and this matters for a couple of reasons. It in part explains why when the MSSA protocols were used on these hip cases, that is we saw a two thirds reduction in instances of MSSA infections, once the MSSA screening was done, antibiotics used, and the impact on knees was less. The impact on knees was less because the knees were closer to background levels to begin with, and the hips were out of control, so we saw a greater use in there.

But regardless what Jeans tells us is that just the reduction in the infections in hips because there was so many hip cases itself impacted the overall infection rate from the entire study forward because the hip numbers were so significant. So translating what the takeaways are from

the Jeans study, prior to that, that study getting done, there was at least a question mark as to whether or not to what extent the MSSA screening was a confounder. The Jeans study confirms that it is a confounder and one which Dr. Reed has described as a significantly confounded study. And what does this matter?

Again, Your Honor, so in terms of hip MSSA instances in the Bair Hugger period, there were four clear MSSA instances. There were eight others that were simply referred to as staph aureus. So that there would be MRSA, methicillin-resistant staph aureus or it could have been MSSA, methicillin-sensitive staph aureus, and so it's not distinguished. But four of them are, eight could be able.

How many during the HotDog period? Zero during the HotDog period and has MSSA screening the entire time. Again, why this is significant is it only takes a couple of changes in the infections in the Bair Hugger period before the statistical significance gets lost.

THE COURT: Because the small sample?

MR. BLACKWELL: Because the small sample.

But beyond that, there's a question raised about how do we know that the Jeans study is referring to deep joint infections as opposed to all these superficial ones. And I wanted to point out just a couple of things in the Jeans study for the Court.

And the first thing here it says looking here in the summary where the very purpose of the study is described in the first sentence where it's talking about peri-prosthetic joint infection, not superficial infections, PJIs, are catastrophic and potentially life threatening complication following arthroplasty. In addition to the resulting impact on patient morbidity and mortality, PJI is associated with significant financial cost estimated at 21 million et cetera pounds per case.

THE COURT: The plaintiffs point out that the PJI is later defined as superficial and deep joint.

MR. BLACKWELL: No, that's right, but I wanted to point out one other thing, Your Honor. I'll come back to that point if I could. So because what we know here is in terms of what the instance of MSSA is, first, they point out in the UK between 25 and 30 percent of UK population is positive for skin or nasal carriage of staphylococcus with MSSA prevalence estimated at 20 percent.

And so why do I point this out because we know, first of all, in the HotDog cohort, for their's where there was some 360 women, persons in there given the incidents of MSSA population, you suspect that some of those to have had the MSSA infection that was zero because of the protocol, the MSSA screening protocol which is put into place. But beyond this, what plaintiffs is saying, hey, this precludes

superficial. It does however, Your Honor, listening to the perspective of the senior author Dr. Reed, what we know about the Observational study is that it only involved a study of deep joint infections. And what Reed concludes is that the Jeans study shows what MSSA is a significantly confounded with respect to the Observational study. So the study author himself is saying that the results represent this confounding.

And as Your Honor will see momentarily, the International Consensus Meeting here in 2018, a few months ago, they also referred to the Observational study and the fact that it was significantly confounded. Your Honor, I'll show this to the Court now since I'm on this.

So what the International Consensus Meeting -- so this is, and by the way, Your Honor, part of what's new about the International Consensus Meeting in 2018 is that there were three principle authors of this question of does use of forced-air warming during orthopedic procedures increase the risk of subsequent SSIs? There were three of them, and one of them is our own Dr. Reed, who himself is helping to craft here a response.

And they characterize in here the McGovern study, which says the authors knew that the Observational study did not account for infection control procedures that changed over the study period or account for several possible

differences in patient risk factors such as obesity and fitness for surgery. Other studies of the same cohorts by the same researchers were both potential impacts unrelated to change in warming modality including thromboprophylaxis, that's the Rivoraxaban, and methicillin sensitive staphylococcus aureus screening.

So here when the International Consensus Meeting is talking about the take away from McGovern, from Jeans, and whether this is confounding, they acknowledge that it is, a significant confounder. But the over-arching point of the Jeans study, Judge Ericksen, is simply confirming that MSSA is a confounder, that they did not distinguish between superficial versus deep joint because it was a distinction that wasn't significant to the authors. The take-away was nonetheless the same. It confounds the study results in McGovern was the take-away.

THE COURT: I can't remember, does the study say whether MSSA that's in the population, so does it say that MSSA infections are coming from within the body as opposed to being deposited from the outside?

MR. BLACKWELL: No, no, it doesn't. It doesn't get that specific, Judge Ericksen.

Now, Judge Ericksen, another question that the Court asked was essentially what are the implications then for knees if Jeans relates to hips? And I wanted to talk

about that too for just a minute.

What Your Honor should be aware of with respect to the McGovern study that if we took the data for a hips in the Observational study, that data alone would not have been statistically significant. If we take the back of the knees alone, that data is not statistically significant, not one would be statistically significant alone. Knees and hips cannot stand, Your Honor, alone.

And so what we would be left with, Judge Ericksen, in different response to Your Honor's other question about whether or not the sources of MSSA are endogenous or not, Jeans does speak to that, and it says in 85 percent of the cases suggest that the majority of the PJIs are endogenous, that is from the own body, on page 408.

THE COURT: I thought I was remembering something like that, okay. Thank you.

MR. BLACKWELL: Yep. It says page 408 of the Jeans study.

THE COURT: Okay.

MR. BLACKWELL: So, again, if we were to focus just on knees, then the knees don't stand alone, Your Honor. The results wouldn't be statistically significant, if we were just to focus on knees alone or hips alone. And as Your Honor kind of well knows if when all is said and done.

Let me just move on here, as the Court found here

in the *In Re Lipitor*, the reliance on non-statistically significant trends is not an acceptable methodology. And here the plaintiffs failed to demonstrate that their epidemiologist, Dr. Singh, relies on statistically significant trends is accepted in his field, but non-statistically significant findings have served as the basis for any epidemiologist's causation opinion in peer-reviewed literature, or that standards exist for controlling the technique's operation.

So what is Dr. Samet's response to this? Your Honor, he simply says that the relative risk ratio of 3.8 is too big to be dismissed as confounding. And his support for that is ipse dixit. The idea that any confounded odds ratio is too big to fail is ipse dixit. There's no basis for it. It simply begs the question of what is it that explains the odds ratio? And that brings us back full circle to looking at the confounders that were examined and then the confounders that weren't examined, for example.

So what do we know about the impact of some of the confounders here, Your Honor, and I think this was also recognized in the international consensus meeting response to question number two where it talked about the impacts of things including thromboprophylaxis. What we know in this case is that there was a roughly five or seven month window when the Bair Hugger and the HotDog were subjected to

exactly the same thromboprophylaxis and exactly the same antibiotic. In an apples-to-apples comparison, there was no difference between them in terms of infection rates. It was the same.

Mr. Albrecht, one of the study authors, says he didn't have to do the calculations to know that if you just took that confounder alone and equalized it for both the Bair Hugger and the HotDog, there would be no difference in the results.

But then we also know there's an impact of even the start date in McGovern on statistical significance because there was data going back eight or nine months before the start of the McGovern study itself in 2008, data related to the Bair Hugger use. That data was swept in and used by the Jeans study by the same authors but wasn't used with respect to the Observation study. If that data had been used, there would have been no statistically significant difference in the first place between the two.

So this is another way of talking about the fragility of it, Your Honor. So we talked about what difference a number makes. Here that it can make a huge difference because of the difference in the numbers being just that small.

And as to Dr. Samet, his doubling down on the 3.8 odds ratio as he did in his recent affidavit in response to

this, he knows that the 3.8 odds ratio is a wrong number because he knows about the data calculation, that the odds ratio should have been 2.86 in the first place given that Albrecht himself says there was a tabulation error. So Dr. Samet knows that, disregards it, instead embracing it's too big to fail, kind of odds ratio perspective based upon ipse dixit. And not only that, but he continues to embrace the Augustine 2017 study.

So when I talk about McGovern being the only study, that is not completely accurate because there was an Augustine study that first everybody embraced for like a day and then everybody ran away from it the next day because it was a completely fraudulent study purported to be a comparison between the HotDog and the Bair Hugger at Nassau Hospital in Upper State New York claiming that the Bair Hugger performed poorly compared to the HotDog.

It turns out the hospital never even used the Bair Hugger, and then so he published this in a pay to play journal somewhere. And Dr. Samet embraced that, snapped it up. The lawyers have since disavowed it but not Dr. Samet and not Dr. Jarvis. Although, it's a completely discredited study because it contains, frankly, falsified data in it, whether that's intentional, accidental, I can't say. I just know it's wrong, and accepted is wrong.

THE COURT: What testimony or evidence is there

setting aside lawyer argument and positions that the 2017 Augustine study is fraudulent?

MR. BLACKWELL: The hospital itself, Your Honor, submitted affidavits. And the Nassau Hospital indicating that they never even used the Bair Hugger, so when they saw the study, was shocked that they were being referenced in it. And an affidavit was done by Dr. Singer I think was his name, and he said we never used a Bair Hugger at our hospital. And beyond that, Dr. Augustine reported knee and hip data for the hospital, and they said they never even gave him knee data. So how could it be reported for the hospital?

Then he used a Ridge View Hospital here too in the study. Ridge View also responded and made it clear to the extent he was attributing changes in their infection rates to a switch in warming modalities, they pointed out that they had put into place a number of infection control procedures there at that hospital unrelated.

THE COURT: But setting aside the content, those are in the record.

MR. BLACKWELL: Definitely in the record, Your Honor, yes.

So I wanted to bring to Your Honor's attention just a few comments about the Generally Assembly meeting because, Judge Ericksen, you might remember when we were

discussing the International Consensus from 2013, there were a couple of things that were noteworthy about it, and the first was that there was one thing that both sides agreed on could be trusted and was reliable the position taken by the ICM.

The other thing that was noteworthy was that the plaintiffs took the position that the ICM did not have complete information, and the ICM did not have complete information because they didn't have access to Dr. Elgobashi's CFD was the argument put forth before the Court for why their data was incomplete.

Well, the ICM met. Again, this is post-Daubert, and this time, Your Honor, they had all the information. They had the CFD, and the fact the CFD was published in the ICM, Your Honor. It is referenced at footnote number 8 in the ICM where it's clear they have it. They also referenced the mechanistic studies that plaintiffs' experts point to here whether it be studies by Belani, studies by Desari, the studies by Legg are referenced in here too. They do a canvassing of what the current state of the research is on the question of whether there's a relationship between forced-air warming and surgical site infections, including everything that the plaintiff said they didn't see before. They saw, they referenced, they included in here and, again, Dr. Reed was an author on the standard this time. He wasn't

the last time.

And what's apparent, Your Honor, is the vote that came down this time is there was a strong consensus in 2013 in the 80-something percent something, before they had all of the evidence that the plaintiffs are saying that they lacked. Once they got all of the plaintiffs' evidence, the Elghobashi CFD, the mechanistic studies are all referenced in it. Now that they have seen it, the consensus is even stronger that there is no science.

THE COURT: The number, but the way they articulate the consensus is a little different, isn't it?

MR. BLACKWELL: It is a bit different but the thrust of it is the same. The question is does the use of forced-air warming during orthopedic procedures increase the risk of subsequent surgical site infections or periprosthetic joint infections? And their recommendation was worded a bit differently, Your Honor, where they say, "there is no evidence to definitively link forced-air warming to an increased risk of SSIs/PJIs. Alternative methods of warming can be effective and may be used." And so the delegate vote was agree 93 percent, disagree 2 percent, and this they describe as a super majority strong consensus in that regard.

THE COURT: How do you respond to plaintiffs' assertion, I'll overstate it maybe slightly, that the ICM is

controlled by 3M?

MR. BLACKWELL: Well, Your Honor, two responses to that. First of all, the plaintiffs were for it before they were in it because when we talked about the 2013, Your Honor did engage and Mr. Assaad in discussion around it. 3M, the ICM has any number of different supporters, funders, etcetera, that don't influence the decisions that get made. 3M is just one in a number of them that would support the effort.

If you look at the authors in question 2, Joseph Karam, Mike Reed, Marshall Sangster, they have not yet with respect to any of the three of these, have any relationship with 3M to speak of. In fact, Mike Reed is the senior author on the Observational study that's given us a fair amount of heartburn, Your Honor. So I think the plaintiffs' lawyers have said that. It's an argument, again, that simply lacks any legs other than just an ad hominem comment from plaintiffs' lawyers.

So, in any event, but the point here on the ICM is they now have all the information that the plaintiffs claim they didn't have before. Dr. Reed himself was involved in the articulation of the response to question number 2, and he wasn't involved at all before, and they come to any of the stronger consensus ultimately then the recent 2013. So what is the significance of the fact that the international

community, and in the ICM there are hundreds of delegates that come representing just about every subspecialty in orthopedic surgery, infectious disease, et cetera.

And so the significance here, Your Honor, of the community support is that widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support within the community may be properly viewed with skepticism under Daubert. So I raise this as simply a factor that the International Consensus group met and addressed the science that the plaintiffs have proffered here.

So, Your Honor, then as to the Court's last question that in a world without McGovern, what might the plaintiffs be able to put forward and rely upon? The answer to that is not a whole lot. This was the study, as Your Honor acknowledges here, that the McGovern study supplies the only estimate of the risk associated for deep joint infection associated with the use of the forced-air warming Bair Hugger device.

So that's the show. And so we know the CFD doesn't get them there because the boundary conditions and because it never shows how it is the Bair Hugger actually inoculates a wound. No real world conditions. And we know in these other studies, as the Court has seen this before,

the mechanistic studies all conclude no causation.

So with respect to those studies, all of the plaintiffs' experts have pretty uniformly agreed that McGovern is the study. You know, here is Dr. Samet absent the quantitative estimate from the paper, while there would be a quite plausible mechanistic basis for an increased risk, there would not be an association in the real world absent McGovern.

Jarvis also refers to McGovern in similar ways, Your Honor, as does here Dr. Stonnington. So, ultimately, where this case is today, Your Honor, you've heard us in here once with the simple aphorism that the law should lack science and not lead it.

THE COURT: You should have let me say that. I knew that was coming.

MR. BLACKWELL: You know, I have something else I was going to say today, I couldn't get up the nerve to do it.

But, Judge Ericksen, in this case it's a little bit different on the issue of whether the law should lack science and not lead it because the law has actually spoken, at least science has actually spoken here. You're the law. Science has spoken, and what the International Consensus is is that there isn't any good evidence supporting the proposition that forced-air warming causes surgical site

infections. The view being espoused by the plaintiffs attorneys and their paid experts is not a view shared by the scientific and medical community. In fact, it is fairly uniformly rejected by them. And what's happening here in this case does put the medical community in quite a quandary with the saying ICM saying go ahead, and with the prospect of what happens in the courtroom saying maybe you shouldn't. And so which way do they go?

And so, Your Honor, I will stop with that this morning unless Your Honor has any additional questions.

THE COURT: Thank you very much, Mr. Blackwell.

Ms. Zimmerman, are you ready to go ahead now or did you want to break?

MS. ZIMMERMAN: Whichever pleases the Court, Your Honor.

THE COURT: I'm good with going ahead.

I assumed you were arguing from the fact that you were sitting in that seat but maybe Mr. Sacchet.

MR. SACCHET: Indeed I am partly, and partly Ms. Zimmerman.

THE COURT: Okay. However you want to do it is fine with me.

MS. ZIMMERMAN: Your Honor, may I approach to hand up our -- assuming you have no objection.

THE COURT: Please.

MR. SACCHET: Good morning, Judge Ericksen.

THE COURT: Good morning.

MR. SACCHET: Michael Sacchet of Ciresi Conlin LLP on behalf of all plaintiffs in this multi-district litigation. We have heard about an hour of argument from Mr. Blackwell and 3M, as well as read millions of papers that have been submitted over the past six months with respect to 3M's motion for leave and motion to reconsider the Court's December 13, 2017, Order on general causation. Among all of that argument, plaintiffs have yet to hear 3M acknowledge the legal standard underpinning Daubert, Rule 702, and its progeny.

3M has never mentioned not once in its argument or in its papers that exclusion is the exception to the rule, and the comment in the committee notes to Rule 702 make that clear as do a long line of Eighth Circuit authority including *Lauzon*. 3M never mentions that the focus of a Daubert attack has to be on the methodology of plaintiffs' medical experts, not their conclusions. 3M never mentions that an attack should be based on scientific certainty.

In its 1993 Order, the Supreme Court made clear in Daubert that certainty is not the standard for there are no certainties in science. As a result, the Eighth Circuit has held the same. There are no absolute requirements in *Adams v. Toyota* case. Nonetheless, 3M invokes the 2018 ICM to say

that plaintiffs need definitive or absolute proof.

3M also never mentions that when there is conflicting expert testimony, that that precise conflict goes to the jury not to the District Court. 3M does acknowledge as it should based on a long line of authority that only where an expert opinion is so fundamentally unsupported, so fundamentally unsupported that it could offer absolutely no assistance to the jury, only then should it be excluded and indeed 3M was a party to the *Wood v. 3M* case in which the Eighth Circuit made that statement, which dates back to *Loudermill* all the way up to this Court's December 13, 2017, Order acknowledging that that is the appropriate standard.

3M is asking this Court to resolve disputes about expert testimony in its favor, which is contrary to black letter authority that says it is an abuse of discretion to do that, and that's exactly what the Eighth Circuit held in *Johnson*.

All of the cases that 3M cites are inapposite. 3M hinges its legal argument in its paper and even today on the Supreme Court's decision in *General Electric v. Joiner* where Justice Rehnquist upheld the district court's decision excluding the plaintiffs' expert testimony. In that case, the plaintiff alleged that his exposure to particular types of PCBs caused a particular type of lung cancer that he

suffered.

The expert in that case did not cite any mechanistic evidence, any epidemiologic evidence. The only evidence that that expert cited was an animal study involving infant rats that were directly injected in their stomachs with the PCB at extraordinarily high levels of the PCB and consequently developed an entirely different type of cancer than the plaintiffs suffered. That is why the Supreme Court in that case said the facts of that case did not fit the expert's testimony and why there was a great inferential leap of logic in order to reach the conclusion that the expert offered there.

The same held true in the *Group Health* case that 3M cites from the Eighth Circuit. There the expert speculated based on a counter-factual about why smoking initiation rates may be different had big tobacco advertised differently than it actually did without taking account of any sociological factors that may have influenced those decision. In that quote, the District Court out of Colorado, 3M cites that case. There the expert simply excluded testimony based on a visual scan of the data without any rhyme or reason.

In *Mems*, the District Court excluded the evidence because the plaintiffs misrepresented the substance of their expert's testimony. And in *Luce*, a criminal case that 3M

cites, simply stands for the unremarkable proposition that an in limine order can be changed at a later date. None of these decisions have anything to do with this case.

They also cite *In Re Viagra* where Judge Magnuson changed his initial Order and a subsequent Order by excluding a study called the McGwin study. In that case, 11 out of the 23 data points underlying that study were determined to be flawed, approximately 40 percent of the data. As a result, both plaintiffs attorneys and the expert conceded on the record that the study was fatally flawed. Nothing close to this case. There are no tabulation errors, which I'll get to.

3M also cites a host of other cases, *Mirena*, *Accutane*, *Zoloft*, *Rezulin*, *Lipitor*. If the Court reads those decisions, it will see there is one of two circumstances, either there was no epi and no mechanistic evidence, which is not the case here on either account or the expert failed to consider contrary epidemiologic studies, and it is undisputed in this case that there are no contrary epidemiologic studies to the McGovern study. 3M hasn't done it. No one else has. McGovern remains the only one. So neither one of the two bases by which any of those MDL courts have excluded expert testimony applies here.

3M did, I noticed, in its slide show cited the *Johnson* case. I was shocked to see it because in that case

what happened was the expert attempted to quote "divine, to divine the mental state of the pilot that crashed a plane to determine whether the pilot caused the error or whether there was a product error. And the Court was pretty clear that attempting to clairvoyantly divine a mental state of a separate human being isn't a good methodology.

In terms of the substance of 3M's attacks as to each subject matter, I will be addressing 3M's argument regarding internal contamination, epidemiology and the McGovern study, the Jeans study, the International Consensus statement, and 3M's alternative request for 1292(b) certification; whereas, Ms. Zimmerman will be addressing all things related to Dr. Elgobashi and CFD, and any additional questions the Court may have with respect to its order asking for supplemental clarification on issues regarding specific causation not general causation.

As to the first topic, internal contamination. Mr. Blackwell spent a surprisingly little amount of time on this argument, and unfortunately for 3M, it's the underpinning of their whole motion for reconsideration. So 3M acknowledges in their papers that in order for the Court to grant reconsideration, this theory must fail leaving only the air flow disruption theory, which 3M argues also fails, but the same applies logically that if this argument fails, the whole motion does as well, and it does fail for a

variety of reasons.

The first fallacy underlying 3M's argument is that 3M claims that Gareis excluded plaintiffs' internal contamination theory of general causation. It did not. Pretrial order number 1, paragraph 7, makes clear that any document relating to the MDL as a whole must be filed in the MDL. The *Gareis* Order never was.

In addition, this Court has already rejected 3M's argument. 3M made the same claim in the *Axline* bellwether arguing that rulings from Gareis precluded Mr. Axline from the same claims. And the Court unequivocally rejected that argument stating, "*Axline* is a separate case and rulings from *Gareis* do not bind the Court here." The same reasoning applies a fortiori to the entire MDL. There is no way that one bellwether order applies with equal force to 5,000 more cases.

3M as a back end argues that, well, the *Gareis* Order can be logically extended to the entire MDL. I should mention as well, I've never heard an argument from 3M addressing the prior two arguments about pretrial order number 1, paragraph 7 or the *Axline* Order. I would be curious about what it has to say on reply.

In terms of the logical extension argument, the *Gareis* Order does not logically extend to the 5,000 cases in this MDL. The Court's Order in *Gareis* expressly said

defendants have moved to exclude from the *Gareis* trial evidence pertaining only to this second theory. And so too in its conclusion, the Court hinged its analysis on Mr. Gareis's case specific facts stating no examination was conducted of the Bair Hugger that was used in the surgery Mr. Gareis claims caused his infection. So it is clear that this ruling was limited to one bellwether as all master cases hold, the *Pinnacle MDL*, the *In Re Welding MDL* and others that are cited in our papers.

3M argues that plaintiffs somehow bear the burden now to show that the Bair Hugger caused contamination in all these cases. 3M's conflating general and specific causation, and I haven't heard the case that Mr. Blackwell mentioned that shows that failure to prove specific causation nullifies general causation. It works the other way around. You prove general causation and then you try to prove specific causation based on the particular facts of each case.

To the extent 3M makes the additional argument that more testing is necessary to show that internal contamination increases the risk of DJI, it's a red herring, at it fails for a variety of reasons.

First and foremost, their own epidemiologist Dr. Borak admitted at his general causation deposition that it seems reasonable that the internal contamination of the

device could create a risk of patient infection.

Second, Dr. Jarvis along with plaintiffs other medical experts have cited a lieu of studies showing that the internal contamination of the device poses an infection risk. One of those studies among others is the Bernards study, and Dr. Jarvis quotes that study specifically as stating they identified the Bair Hugger forced-air warming as one of the medical devices that were involved in the outbreaks. And it's not just Dr. Jarvis interpreting the study to say that. The study says it on its face. The highlighted language a direct excerpt from the study says the Bair Hugger is designed to create an air flow, dust is sucked into the machine with filters becoming contaminated and possibly serving as a secondary source of transmission.

Moreover, "we believe the outbreak strain was transmitted by being carried on a contaminated dust from within the machines to the exterior during operation." That's what the author said. That's what they concluded. That's why Dr. Jarvis in his expert report said besides McGovern, put McGovern to the side. There are other studies showing that the Bair Hugger contributes to infection And here is one.

Now, I know that the Court and 3M made mention analyzed this study at the punitive damages order, and that's fine, but other authors have similarly concluded that

Bernards says what it says. For example, Dr. Beavers published an article, an epidemiologist in Kentucky, stating that previous outbreaks of Acinetobacter, the same bacteria that was in the Bernards study that items such as Bair Hugger to be reservoirs of infection.

So too in Wood, a peer-reviewed article, a literature view of numerous sources, we conclude that forced-air warming does contaminate ultra-clean air ventilation. Avidan, notwithstanding the fact it tested the Bair Hugger with a blanket, two trials, 30 minutes, severely under powered, nonetheless concluded that the Bair Hugger should have a distal hose and filter, which 3M has never done notwithstanding the recommendation made nearly two decades ago, and still concluded "we have detected a potential source of nosocomial infection at our hospital."

And the Moretti study that 3M has been citing to this date reiterates Avidan's conclusion finding that other studies have shown an increased risk of infection. And even this month an article offered by Lange et al., I'm happy to give the Court a copy of it, expressly finds that the internal contamination of forced-air warming devices is positively correlated with the amount of bacteria leaving the device.

THE COURT: That's the one you cite in your -- is

that the June 2019 study that you've got on your screen here?

MR. SACCHET: Yes.

THE COURT: Is that in the record?

MR. SACCHET: It is not, but I'm happy to give it to the Court.

THE COURT: We'll get to that later.

MR. SACCHET: Okay. And it's not because it was published just a week ago.

THE COURT: But that's the same one that's on your --

MR. SACCHET: Yep, it's on the slide.

The second reason aside from the studies showing that the Bair Hugger causes infection based on its internal contamination is a group of studies showing that 3M reduced the filtration efficiency of the Bair Hugger from approximately 90 percent to as low as 60 percent, never informed the FDA of the same. Only changed the FDA's understanding that the Bair Hugger was not equipped with a HEPA filter approximately a year ago finding that all Bair Huggers are contaminated with bacteria. 3M doesn't dispute it in its 30(b)(6) testimony and that the Bair Hugger emits particles and bacteria from its hose.

To be candid with the Court, we acknowledge that the Albrecht 2011 study and the Reed 2013 study and others

were not done with the blanket attached to the Bair Hugger. We acknowledge that, but there is no basis in science or fact to conclude that the blanket is a filter.

Dr. Jarvis and Stonnington state as much in their reports. Dr. Jarvis specifically notes, "some have argued such as 3M that even if the Bair Hugger forced-air warming air output/exhaust to the blanket is bacterially contaminated, as documented in the many studies above, the blanket itself would serve as a second method of filtration to prevent these contaminants from reaching the surgical site.

THE COURT: Do you think 3M makes the argument that the blanket is a filter?

MR. SACCHET: I think they make the argument that when the blanket is attached to the blower, that it prevents the bacteria from leaving the blanket. So whether or not they call it a filter --

THE COURT: Where does it say that?

MR. SACCHET: Well, there are documents that 3M says when you attach the two, that may prevent bugs from leaving the blanket.

THE COURT: But separate from an argument that the air flow is directed away from the surgical site? Just if you can tell me where 3M relies on the argument that the blanket itself is a filter, that would be helpful.

MR. SACCHET: Okay. I think that I interpreted they were talking about internal contamination to depend on the idea that the blanket is a filter.

THE COURT: Okay, all right, got it.

MR. SACCHET: I can quote their, like their failure of proof in *Gareis*, to this date plaintiffs have not come forward with any test of the Bair Hugger blanket that shows colony forming units escaping, and they are referring to the blanket. So it's 3M's argument that the blanket prevents colony forming units from escaping.

THE COURT: I guess I see what you're saying. That assumes that they're in the blanket which --

MR. SACCHET: I'll actually get there. Yeah, I'll actually get there.

And Dr. Jarvis continues, there are no data to substantiate this claim. Furthermore, there are data to show that this is not correct. One of the pieces of data that he refers to is the Tsai 2017 case report from MD Anderson Hospital in Texas. There it was discovered that the Bair Hugger exhausted black soot, which was visible unlike most bacteria, and that the patient was actually patterned with the exact same air flow porous holes in the blanket.

THE COURT: Yeah, what legal authority is there to rely on that one case study that Tsai -- however you say it.

The one case study, there seem to be cases that say that there should be, maybe you shouldn't do it or at least at a very minimum extreme caution with just relying on one case study?

MR. SACCHET: Yeah, that's a good question, Your Honor. I want to say that the cases that you're referring to refuse to rely on only case studies for inferring causation. So most Circuit Courts of Appeal will not accept a proffer by an expert of hey, I've reached a causal conclusion based on anecdotal case report.

THE COURT: Right.

MR. SACCHET: We're not offering in that respect. We're offering it to show the way in which the Bair Hugger can put things out of the blanket. That's -- we're not saying it proves causation. We're saying the Bair Hugger can release things out of its blanket.

THE COURT: As proved by the Tsai case.

MR. SACCHET: Yes, among others. Okay, in the Baker 2002 article, the authors of that study specifically stated, "there is insufficient evidence to justify the routine use of forced-air warming during ultra-cleaning orthopedic surgery. The blanket is not designed to act as a microbial filter."

3M's 30(b)(6) testimony, "there was no reason to blow particulates into the blanket, which might end up

leaving the blanket."

Dr. McGovern, I asked him the question, "do you think bacteria can leave the blanket?"

"Yes, bacteria can pass through the blanket, Exhibit PX11."

ECRI, interesting story. As the Court knows, we argued in our punitive damages motion that 3M lobbied ECRI, I think it was in 2010 to publish an article endorsing the Bair Hugger. The documents don't dispute that.

In 2017, ECRI published a new article that I don't think was due to 3M's lobbying. In PX8, ECRI states, "warming units should have HEPA or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into the wound end."

THE COURT: Where is that?

MR. SACCHET: Plaintiff's Exhibit 8.

THE COURT: Okay. So just back on the Circuit Court's saying don't rely on one individual study. Can you give me an example of a contrary case that says go ahead and use one individual study for some limited purpose or something? Is there any -- we've got all of this authority on the other side, but what's your -- what's the legal hook to use the Tsai, Mr. Tsai or Mrs. Tsai, or whoever she is, that experience with the fire and everything.

MR. SACCHET: Sure. So I think every Court of

Appeals and every District Court would agree that mechanistic evidence can be used to support causal inference.

THE COURT: So every case? No specific case that says go ahead and even though you can't use it most of the time you can't, you can use it for some specific purpose?

MR. SACCHET: Well, the reference manual in footnote 180 expressly says that causal inference can be done without epidemiologic studies based on a mechanism alone, so that's what the reference manual says.

THE COURT: I'm just looking for a case if you have one.

MR. SACCHET: Okay, *Bonner*. *Bonner* says you don't need epidemiologic evidence. You can rely on other sources. In fact, you don't really need peer-reviewed literature. The *In Re Meridia* MDL, Northern District of Ohio, no court has ever concluded that you need an epidemiologic study to prove causation.

THE COURT: So you're right about what those cases say. So if you don't need any then by implication it's okay to use one isolated study, not a case that says go ahead and use one isolated study. I take your point that there is authority for the lack of necessity for epidemiological proof at all. So I guess what you're saying is if you don't have to have it at all, then at least we can use the Tsai

business.

MR. SACCHET: Yes, for a mechanism.

THE COURT: Okay, I got it. I interrupted you. You were talking about. I guess I don't know what you were talking about when I interrupted you.

MR. SACCHET: ECRI.

THE COURT: ECRI. All right.

MR. SACCHET: And, you know, I just want to be sure that we're on the same page, Your Honor. So it is also black letter science and black letter law that evidence should not be interpreted in isolation or piecemeal or vulcanized from the rest of the evidence. Evidence has to be considered in its totality.

THE COURT: For summary judgment purposes at least.

MR. SACCHET: For Daubert purposes actually and under Rule 702. So plaintiffs, you know, oppose 3M's argument that, you know, just look at McGovern, just look at that, this doesn't say that, that doesn't say that in isolation.

You know, for example, in the *United States v. Grace* court, the Ninth Circuit expressly determined that it was error and an abuse of discretion to conduct a document by document review under Rule 702. The *Milward* Court from the First Circuit has said the same thing. It must be a

great weight of the evidence approach not a vulcanized piecemeal individual piece of evidence by evidence analysis.

Back to the issues of internal contamination. I mentioned a number of sources suggesting and also making clear that the blanket is not a filter and that bacteria can be released from the device even when it is attached to the blanket. Even assuming arguendo that that were not the case, so the counterfactual that the blanket is a filter and that the Bair Hugger doesn't in fact push out bacteria or particles from the business end of the device, plaintiffs' experts still conclude it poses a risk of infection based on cross contamination.

So, for example, Dr. Stonnington, "as discussed further below having a device in the operating room that harbors known contamination is anathema to the orthopedic surgeon's goal of attenuating risk of infection in the surgical environment." The environment of use is key in this case.

On the one hand, we have a device that sits on the floor, sucks up dirt, perhaps spews it out and then we have surgeons and staff who all that they are trying to do is sterilize to the best that they can. You can't completely sterilize, but clean to the best that you can the environment. That's why they're called ultra-clean orthopedic surgeries. Yet, we have the device in the

operating room that 3M admits in their 30(b)(6) deposition it harbors internal contaminants.

So whether or not the device blows the bacteria, Dr. Stonnington, based on his individual experience as an orthopedic surgeon, which is in its own right an established methodology for inferring causation as numerous circuit courts have also determined, states, "cross-contamination from Bair Hugger devices is a very serious concern. Microbial contaminants collected within the units will likely be transferred via the hose to future operative fields."

Moreover, 3M's internal documents admit the Bair Hugger isn't air tight and that a small amount of particles or bacteria could exit the device irrespective of the blanket.

Last, but not least --

THE COURT: Do you know in how many of the cases, I know we did a breakdown of hips and knees, how many where the lower part of the Bair Hugger was on the floor as opposed to suspended because we heard some testimony that sometimes it's on the floor. Sometimes it's not on the floor, so we don't know that.

MR. SACCHET: I agree with you, Your Honor. 3M has stated sometimes it's on a stand. We allege sometimes it's not.

THE COURT: But there was testimony. I don't care who said it. Some witness said it. I don't remember who. But isn't that your recollection? I mean it could be -- anyway whatever. Maybe I'm wrong.

MR. SACCHET: It's a case specific question, Your Honor, that in a particular case if it was determined the Bair Hugger was on the stand versus on the floor, that may or may not be relevant but for general causation purposes, the fact is true that the Bair Hugger does on occasion sit on the ground.

THE COURT: But no doubt, no doubt, but you don't know how many of the totality of the cases?

MR. SACCHET: No, I'm sorry.

THE COURT: Okay. That's fine.

MR. SACCHET: The third reason why 3M's argument does not hold the water regarding internal contamination, and I believe this is the most dispositive, and this puts their argument to bed is that all parties agree that particles are a proxy for bacteria. "Particulate contamination is the dosage of interest." Dr. Samet states it. Dr. Jarvis states it. 3M's own infectious disease expert Dr. Wenzel admitted at his deposition that approximately 40 percent of particles carry bacteria. The randomized control trial conducted by Darouiche, et al, in 2017, which 3M admits is the gold standard. It actually can

prove something unlike epidemiologic research that 3M claims should. This RCT proves that increased particulates, increased bacteria, which in turn increases the risk of deep joint infection not surgical site infection, deep joint infection. The Stocks 2010 article said the same thing particles equate to bacteria.

[redacted]

And following that in 2013, Mr. Van Duren and Michelle Hulse-Stevens --

THE COURT: So the background section of a patent, which always has to be there, of course, is for the purpose

of explaining to the PTO what the invention is and trying to get something invented. I don't know that that -- that the specification of a patent has ever been held to be evidence of scientific reality. I mean you know the purpose of it to alert the PTO and then ultimately perhaps the public about how the invention constitutes, you know, to help define the meets and bounds of the invention. But in terms of using an assertion in the background section, the specifications of a patent as scientific proof of the assertions contained therein, I'm unaware of that use of that. So I mean that can't be why you're citing this.

MR. SACCHET: No, Your Honor, and I am not an expert in patent law. I did read your transcript in the *Moldex* hearing with respect to the Rule 11 sanctions motion that was brought against 3M but --

THE COURT: But I mean you're talking about, you're relying on an assertion made in the specification of a patent.

MR. SACCHET: I'm relying on this e-mail for the proposition that 3M acknowledged in 1994 that there were concerns about particulates as the causes of infection.

THE COURT: Okay.

MR. SACCHET: That's what it says. In 2013, Michelle Hulse-Stevens and Mr. Van Duren engaged in another conversation in which they both acknowledged that there is

"widespread appreciation of the importance of particulates discharged by the warming unit." And Michelle Hulse-Stevens follows up and says, "this implies that the 750 does not have a filtration efficiency that adequately mitigates particles in the air coming out after filtration."

THE COURT: Okay. What's the purpose of this because in a strict liability product in a product liability case, what would be the relevance of something like this?

MR. SACCHET: So the relevance is that 3M acknowledges particles are a proxy for bacteria.

THE COURT: But how is that relevant to the ultimate question of whether it causes? I mean as you said, there doesn't seem to be any real disagreement that the scientific studies using particulates as proxies for bacteria, that nobody is really questioning that.

MR. SACCHET: Okay, I just wanted to make sure we agree that nobody is questioning it.

THE COURT: It didn't seem like it.

MR. SACCHET: Okay. That was my purpose in citing this evidence to make it clear that 3M has acknowledged that particle contamination can be used as a metric for increased risk, and the 30(b)(6) testimony here also shows that. The reason why I'm bringing it up, Your Honor is because plaintiffs have conducted in their experts testing to show that particles escape the blanket. So if 3M's argument is

that plaintiffs' theory of internal contamination should be dismissed because there's no evidence that bacteria leaves the blanket, plaintiffs' experts have tested the Bair Hugger device to prove that particles do leave the blanket.

Mr. Michael Buck did that testing as part of the general causation testimony in this litigation. He tested the device with the blanket attached and with the blanket not attached with a 750 and a 775 used and old. In both situations, in both testing conditions, Mr. Buck concluded that the Bair Hugger releases a large volume of particulates ranging in size from .3 to .5 microns, all the way up to greater than 10 microns. In the graph that I have depicted here shows that, and that is why he concluded that there is particles coming out of the Bair Hugger with the blanket, these findings are consistent with what published literature and internal Arizant and 3M company documents.

Now, the reason why this is ultimately important, and I think this is the death blow to 3M's argument. Your Honor concluded in your December 13, 2017, order in denying 3M's motion to exclude Mr. Buck. Buck's lack of bacterial testing is harmless because he found some 10 micron particles. 3M has waived the argument on Buck, has not moved for reconsideration of Buck's opinion, has not asked the Court to reconsider that conclusion. It, therefore, stands to reason that 3M's argument about internal

contamination fails out of the gate. And as a result, their entire motion for reconsideration should be denied because they have predicated their entire argument on the exclusion of this theory, and they have not challenged one of the findings this Court made that upholds the theory.

The second subject of argument that 3M has raised is again regarding the McGovern study. It's replowing old ground on the motion for reconsideration because it doesn't involve new evidence. Nevertheless, I'll take some time to explain the arguments that 3M resurrected in both its papers and that Mr. Blackwell spent a surprising amount of time in his argument today.

The first argument that 3M makes and the first fallacy that it offers to the Court is quote, "the Observational study is essential to the opinions of plaintiffs' medical experts. There is no general causation without it." Page 24 of their brief. This argument contradicts not only Eighth Circuit law, but it contradicts the argument that 3M previously told this Court when it acknowledged in its first Daubert brief at page 27, docket 750, that *Glastetter* notes that epidemiological evidence is not absolutely necessary to support general causation expert opinions.

3M cites *Glastetter* all over the place in its motion for reconsideration. For some reason this time

around unlike last time around, it fails to note the plain language of that decision, which says it's not necessary and it doesn't doom the plaintiffs' case.

The other cases that 3M cites repeatedly in its papers, such as the *In Re Zoloft* decision, say the same thing. In fact, the *Zoloft* MDL court cited *Glastetter* for the proposition that the lack of epidemiologic evidence doesn't doom a plaintiffs' case, but 3M doesn't say anything about that in their papers. Nor does 3M note what the Reference Manual actually says, footnote 180, "in many instances, causation can be established without epidemiologic evidence."

And a really good decision if Your Honor would like more authority is the *In Re Heparin* MDL decision in which the court actually collects authority from every single Federal Court of Appeals disagreeing with 3M's conclusion that epidemiology is necessary to support causation.

To the extent that 3M has cited the Bradford Hill criteria, and made the argument that the Reference Manual says that you can't apply the Bradford Hill criteria without epidemiologic evidence. Plaintiffs don't dispute that. That's what the Reference Manual says. It is clear that to apply the Bradford Hill criteria you need an association. Does that doom plaintiffs' medical experts opinions? No.

First, contrary to what 3M wrote in its supplemental papers, Dr. Jarvis does not apply the Bradford Hill criteria. There's nothing in his report or any of his testimony saying that he ever did. Dr. Stonnington same thing. He never cites the Bradford Hill criteria. Dr. Jarvis relies on the CDC's gold standard. Dr. Stonnington relies on his clinical experience plus peer-reviewed public literature.

The *In Re Heparin* court collects cases showing that both weight of the evidence methodologies and clinical experience are sound methodologies for inferring causation, general causation. And as to Dr. Samet, Dr. Samet, his report does apply the Bradford Hill criteria.

THE COURT: Just give me one second. Okay. Go ahead.

MR. SACCHET: Dr. Samet does apply the Bradford Hill criteria. Is that the only methodology that he applies? No. His report on its face says he also applies the surgeon general's criteria, invest same criteria can be applied as the senior scientific editor of the surgeon general's report on tobacco and lung cancer. He also applied the sufficient component cause model, which Dr. Borak at his general causation deposition conceded was a well-established methodology for causation. So whether or not Dr. Samet applied the Bradford Hill criteria, whether or

not the Reference Manual states that you have to have an association to apply it. Dr. Samet didn't limit his opinions to that methodology, and he cannot be excluded on that basis.

Nor did Dr. Samet ever cite the Augustine 2017 study in his general causation report. It would have been impossible for him to do it because Augustine said he was published after Dr. Samet signed his report. The parties stipulated for that reason. They wouldn't talk about the Augustine 2017 study. But yet again it's injected into the face of these proceedings for no good reason. Dr. Samet never cited in this report. Therefore, he didn't rely on it for concluding otherwise.

THE COURT: Give me another second, please. Okay.

MR. SACCHET: And the same holds true, Your Honor, with respect to Dr. Jarvis and Dr. Stonnington's report. All of their reports preceded the publication of Augustine's 2017 study, so they could not have cited them in their reports, whether or not they mention them at a deposition doesn't change that fact.

In addition, 3M argues that the fact that --

THE COURT: I guess that's what I was looking for. I thought they mentioned that somewhere. And was it in the deposition?

MR. SACCHET: Yes, there are depositions whereupon

3M is questioning are you aware of this study? The experts acknowledged, yes, we're aware of that study.

THE COURT: I thought one of them said something like and that gives more proof or more weight to my opinion. Is that Samet or --

MR. SACCHET: I don't know.

THE COURT: Okay.

MR. SACCHET: I'll be honest. What I will say whether or not an expert said it and if they did say it, it doesn't change the fact that their general causation opinion didn't cite it, and they reached the same conclusion without it.

THE COURT: I see.

MR. SACCHET: To the extent that 3M harps on the fact that Dr. Samet testified that the McGovern study is necessary to show a magnitude of the association, we need to be careful with the language there.

THE COURT: Okay.

MR. SACCHET: The magnitude, the quantification of the association, is that the same as an association? No. It's a quantification of the risk. Now, there's a reason why that's important. McGovern gives a quantification of the risk, 380 percent increased risk from using the Bair Hugger compared to air-free devices. The reason why that's important is because if we didn't have that quantification,

we couldn't use Dr. Holford's concession that an increased risk of botch 2.0 proves specific causation. And he admitted that at his deposition. An increased risk of over 2.0 proves specific causation. I asked him a question point blank and he says I agree.

So if we want to take away the magnitude all that really does for 3M is prohibit plaintiffs from proving specific causation. I was shocked by 3M's argument in their supplemental papers in a footnote, it said that the *In Re Lipitor* court rejected the suggestion that a risk ratio greater than 2.0 can prove specific causation. I read the opinion twice and couldn't find the language. Perhaps, they could clarify, but there's no suggestion in the *In Re Lipitor* case that the odds ratio greater than 2.0 cannot prove specific causation. I want to be clear though we are not arguing that the 2.0 ipso facto proves general causation. That should not be confused. The general causation inquiry is based on the totality of the evidence.

THE COURT: So you would not propose to argue in any individual case that the odds ratio of 2.0 proves causation?

MR. SACCHET: The other way around, I think, if I'm understanding the question.

THE COURT: But that's not an argument that you would make in any particular case?

MR. SACCHET: We're not hinging our general causation argument on one number, the 2.0. Our experts have stated in their case specific reports, such as Dr. Jarvis, that there are a few ways to show specific causation. One is McGovern's 2.0 and greater.

THE COURT: You would use that --

MR. SACCHET: For specific causation, the expert reports for that is one way to show specific causation.

THE COURT: Because surely part of general causation is a root to the specific causation. You have to -- you've got to --

MR. SACCHET: I've got to show there's got to be some way in which this device could do what we say it does. No doubt, but, of course, then when you get a particular case what happened in that case, what's the evidence, what can we rule in and rule out based on a differential diagnosis, the whole shebang.

THE COURT: Well, and that's all individual to the cases, but what you would need at the general causation case stage is here's how this could happen, and here's how we're going to try and prove it in an individual specific case. We've got a road -- here's the connection between this and, you know, maybe we can show it in the individual case, maybe we can't, but we've got to have some --

MR. SACCHET: Mechanisms.

THE COURT: Mechanism.

MR. SACCHET: Exactly. So that's why manufacture proffered two particular mechanisms, internal contamination and air flow disruption. There's a lot of evidence to support those mechanisms, so, yes, in an individual case, we would show that one or both of those mechanisms is what caused the particular infection in a particular case.

But that is the distinction about magnitude versus causation in general that plaintiffs appreciate and offer to the Court in determining whether Samet's deposition testimony actually hinges on McGovern and does not in addition to the fact that he applies other methodologies in addition to the Bradford Hill criteria. So at bottom, 3M's first argument that plaintiffs are required and their opinions hinge on the McGovern study is belied by science and the law.

The second fallacy of 3M's argument is that McGovern is subject to bias, confounding and other tabulation errors. 3M says on page 25 of its brief, "much of defendants original Daubert briefing was devoted to the McGovern study, and the reasons it lacked sufficient indicia of reliability." In that quotation alone, 3M has admitted that it's an old argument. And under Rule 7.1 JO, the rules of this district, it is not ripe for reconsideration.

Even if the Court does consider 3M's argument,

which is not properly before the Court on reconsideration, McGovern by itself satisfies all four Daubert factors. It is a test. It was published. It has a known rate of error based on its statistical significance, and the technique of using observational retrospective studies to help infer causation is well-established. So in and of itself, it satisfies the four Daubert factors.

In addition to those factors, as I mentioned, McGovern has a statistical significant increased risk. Statistical significance is not required to show causation. The Supreme Court in its *Matrix* decision said that very clearly. The *Viagra* court said that very clearly in an MDL on general causation, you don't need statistical significance. But, nonetheless, McGovern has it.

What McGovern also has is mechanistic evidence, so it's not just an epidemiologic study. It's an epidemiologic study and a mechanistic study. They did assimilated hip procedure. They showed, contrary to 3M's claims in their papers, in which 3M says there was no showing of increased bubbles under the surgical site when forced-air warming was used. False. The author showed a statistical significant increased amount of particles over the surgical site when Bair Hugger was used compared to conductive fabric warming. So it has both an epi portion and a mechanistic portion. That is why given those two parts together, the independent

peer reviewers of the study, independent scientists in their own right, they're well credentialed. They're elected to serve on boards like Dr. Borak revealed the fact that he serves on these kinds of boards of peer reviewed studies. They said, "the study demonstrates that there were actual changes in infection rates which would fit well with the experimental data and thus support the contention that there is a serious issue to be addressed with Bair Hugger." That's what the independent peer reviewers of the McGovern study said because it's both an association and mechanistic together, those two things together strong evidence of an issue with Bair Hugger.

In addition --

THE COURT: I'm just going to, just time wise, you're not leaving Ms. Zimmerman much time.

MR. SACCHET: I wasn't aware of a time limit.

THE COURT: There's not really a time limit. How much more do you -- you're on the second fallacy. Is that the third fallacy?

MR. SACCHET: There are three fallacies other than the International Consensus statement in which I couldn't help myself put before. So, yes, there's a way to go, and, Your Honor, to be candid but also respectful --

THE COURT: Well, you know, here's what we need. We have to take a brief break. So let's just do that. And

then we'll come back. Ten minutes. We're in recess.

(11:38 a.m.)

START HERE

(11:56 a.m.)

THE COURT: Please be seated. Mr. Sacchet, maybe before you launch in, and maybe you're going to get to it, you say that Jarvis and Samet and Stonnington, the confounders, you're probably just about to talk about the confounders.

MR. SACCHET: That is exactly right. And, Your Honor, we appreciate the time this afternoon and just want to reiterate that there are 5,000 cases at risk depending on, you know, the outcome of this motion, so the time that you're allowing us is much appreciated.

THE COURT: Somebody has to get sentenced at 12:30, but we'll take a break if necessary. I don't have anything after that.

MR. SACCHET: We appreciate it.

THE COURT: Not to use a passive voice, I will sentence someone at 12:30.

MR. SACCHET: As to the McGovern study, we touched on the factors that it not only has a significant association but it also sets forth a plausible mechanism. In addition to that, the authors are all very well

credentialed. In fact, many of them have been hired by 3M for various consulting opportunities and even Mr. Albrecht who 3M has maligned throughout the three years of this litigation was offered a job after he published the McGovern study by 3M.

THE COURT: And the relevance of that is what?

MR. SACCHET: That plaintiffs contend there are attacks on his credentials and purported dishonesty is belied by their job offer to them.

The research was conducted before any litigation. All of the authors have testified that to the extent it was funded by a competitive entity, that that had no bearing whatsoever on the results of the study. I spoke a little bit about it and one of the peer reviewers had mentioned in reviewing the study, all of the authors stand by behind the results of this study. We noted that in footnote 9 of our opposition.

Dr. Reed in Plaintiff's Exhibit 47 says the same thing, to the extent that 3M has suggested that Reed admits there's a tabulation error, even if that were true. Dr. Reed still says that the results of the McGovern study would be clinically significant and have the same impact as they would whether or not there's a difference of one infection in either arm of the study. The study has never been retracted.

THE COURT: The study, I don't think there's any real complaint about the -- well, whether there is or isn't, so let's say the study is great. The conclusions, however, are not the Bair Hugger causes infection. So the studies' authors are pretty clear about that. So to what extent can the conclusion that the authors, respected as they are and even if they weren't they were the authors, reached in that study be restated to be a different conclusion?

I mean can you use the same study, look at their data, and come to a different conclusion on the very same question as the authors disclaimed?

I can see people who do scientific studies and there are byproducts, and you take a look at the byproducts and come to some conclusion about that, but this seems to be on the very same point that the authors spoke about.

MR. SACCHET: I think I understand your question, and the threshold response --

THE COURT: Well, that's good because it was not very well articulated.

MR. SACCHET: I think I got it. The first response is this, Your Honor. The McGovern authors never conclude that the study proves causation.

THE COURT: They don't. I mean they specifically say they don't.

MR. SACCHET: And they can't and --

THE COURT: Then how can anybody else use that study to say something that the author specifically disclaimed? That's my question.

MR. SACCHET: Okay. So no epidemiologic or observational study can prove causation. Same as in 3M's argument that the Jeans study confirms causation is squat. None of them can, and plaintiffs have never said that the McGovern study does by itself.

But what the Reference Manual makes clear, Dr. Samet makes clear, you can use observational studies as part of the totality of evidence to do causal inference. So even where observational studies say no causation, the Reference Manual makes clear that observational studies are the main stay, the most commonly cited study to support causal inference by experts.

I asked Dr. Holford this question at his deposition, you agree that an association by itself is not causation. It is a judgment for scientists to make based on the totality of the evidence, and even 3M's own expert agreed with that.

So plaintiffs have never argued that McGovern by itself is dispositive notwithstanding 3M's argument that the McGovern study dooms plaintiffs' case if it's not admitted. The McGovern study is one piece of evidence. It provides an association. With that association, experts consider all of

the other evidence, and if a mechanism can support an association whether or not there is an association there, they can still do causal inference. And that's at footnote 180 of the Reference Manual says, "even in the absence of epidemiologic studies, there can still be general causation." That's why the Eighth Circuit said it in *Bonner*. That's why the Eighth Circuit said it in *Glastetter*. That's what the District Court in *Viagra* said. That's why no Court has ever concluded and even Reed an epidemiologic or statistically significant association to do causal inference.

THE COURT: To the extent the study is to be used at all, mustn't there be a count taken of the confounders?

MR. SACCHET: So two responses. One, there is no a priori basis in any of the scientific literature to suggest that the particular types of antithrombotic and antibiotic that were used in the McGovern study confound deep joint infection rates, and I can go into that more deeply in a second.

But, second, even assuming arguendo that there were confounders, this Court's Order citing *Johnson* made clear that an expert need not account for every possible explanation for the cause of an outcome, and indeed every single MDL court said the same thing.

Judge Rogers, for example, in the *Abilify* decision

expressly stated one year ago denying the defendant's Daubert motion on general causation, issues of confounding go to weight. The *In Re Seroquel* court cited in our papers, issues of confounding go to weight. *In Re Bone Screw*, issues of confounding go to weight. *Jennings*, issues of confounding go to weight.

THE COURT: Okay, so if no account need be taken of the confounders at all, then what you're saying is if there's any indication of a possibility of an association, that that is sufficient to argue to a jury that constitutes specific causation in an individual or a general causation?

MR. SACCHET: So in a specific causation --

THE COURT: You're saying confounders mean nothing.

MR. SACCHET: No, I'm saying an issue of weight not admissibility.

THE COURT: Okay.

MR. SACCHET: I had another thought that was in the back of my mind. And this is it, take the association off the table. Take the McGovern study off the table. It should be on the table but take it off. The Reference Manual again says that when the mechanism is well established, that can suffice for general causation, not based on the Bradford Hill criteria but based on other methods of causal inference, a well-established mechanism

can suffice for general causation.

THE COURT: Basically, Dr. Elgobashi alone would be able to --

MR. SACCHET: Yes, I mean there is robust evidence. It is undisputed. Every single study shows based on 3M's corporate admission that the Bair Hugger increases the number of particles over the surgical site. Based on that admission alone, we don't even need to talk about the McGovern study because the mechanism is well understood and accepted that the Bair Hugger increases particles over the surgical site, which is a proxy for the increased risk of deep joint infection based on the gold standard randomized control trial authored by Darouiche in 2017. That's it.

In addition, no contrary epidemiologic study exists to disprove McGovern. 3M can talk about the hypothetical, potential confounding hypothetical, whatever, there's no evidence to the contrary.

There is followup data. 3M never mentions this. There is followup data collected after publication of the McGovern study by Reed, showing that the association odds ratio holds based on an expanded data set of conductive warming patients doubling the amount of patients that were in the original study. If there's any doubt about whether the McGovern study holds up or not, here it is, follow up data proving it.

THE COURT: And that's which Reed study?

MR. SACCHET: It's not in the published study. It's in a document that actually Dr. Reed supplied to 3M.

THE COURT: Okay.

MR. SACCHET: So based on those plaintiffs contend that not only does McGovern satisfy all four Daubert factors, but there are various other facts that support the conclusions reached therein, which need not include causation in order to be used for causal inference. That is precisely why in 2019, Dr. Reed published a new study after the 2018 ICM, after the draft protocol and the trial study that 3M cites in their papers. The most recent statement by any author of the McGovern study in Reed 2019, Plaintiff's Exhibit 53, McGovern, et al, compared forced-air warming devices to air free conductive fabric warming device blankets and show that they were associated with substantially higher numbers of simulated particles over the operative field and substantially higher rates of post-operative PJI.

THE COURT: Let me try this. So the McGovern authors acknowledge confounders.

MR. SACCHET: No, they acknowledge potential confounders.

THE COURT: Variables.

MR. SACCHET: Potential variables.

THE COURT: That could be confounding.

MR. SACCHET: Potentially confounding.

THE COURT: Okay, whatever they say --

MR. SACCHET: What 3M says and it's a misrepresentation.

THE COURT: They don't acknowledge confounders?

MR. SACCHET: No, they do not acknowledge confounding. I think 3M --

THE COURT: Okay, let's say they say something about confounding or variables. I mean I don't have the study right in front of me, but I remember in their conclusions some -- but anyway here's my point. If to the extent the authors do, then to what extent would experts relying on that study have to also acknowledge? I mean so whatever I don't want to quibble about what exactly the study says about the variables or confounders or whatever it says. I mean I'm quite confident it says something about them. But then the experts who rely on that study don't say anything about that aspect of the study itself. And so is that -- are they looking at the totality of the evidence? I mean how is that looking at the totality of the evidence if, -- anyway.

MR. SACCHET: I understand the question, and this is the answer. The plaintiffs' experts had reviewed the deposition testimony of the authors of the McGovern study in

this case. Dr. Reed at his general causation deposition emphatically stated that the antithrombotic can be ruled out as a confounder based on the study that he published in 2013 entitled Jameson, et al.

THE COURT: Okay.

MR. SACCHET: Professor Nachtsheim of the University of Minnesota answered this question, "is there any evidence of confounding from the antibiotic or antithrombotic? No."

THE COURT: But any confounders. Just in concept though.

MR. SACCHET: Okay.

THE COURT: To the extent the authors acknowledge that they can't specifically draw a conclusion, which the McGovern authors do, and I can't remember their exact words but they say we're not concluding, to what extent must experts who are taking into consideration the totality of the evidence doing their job if they disregard that aspect of the original studies authors' statements themselves.

MR. SACCHET: So again issues of confounding go to weight not admissibility based on a long line of cases in the master of context --

THE COURT: But the experts who would testify would have to acknowledge that's confounding, right? Otherwise, it doesn't go to weight. I mean if you've got an

expert who relies on a study that had confounders and the expert gets up and says this is what the studies say, here's my opinion, and I base it on this study and doesn't say anything about the confounders.

MR. SACCHET: There could be a problem there. So what I will say is Dr. Samet, for example, in his general causation expert report specifically addresses 3M's argument about potential confounding from the thrombiotic and the antibiotic. And he says that based on the author's deposition testimony not the vague statements they made in their paper, there's no support for it.

So what I think is actually the most important here is I deposed Dr. Holford on these very issues. 3M's own epidemiologist and biostatistician that it put up to try to suggest that there is confounding. I asked Mr. Holford the question, "so there is no published literature that you are aware of that suggests a relationship between the variable of a thromboprophylaxis on the outcome of deep joint infection."

Answer: "No, I don't know any."

For epidemiologists in order to analyze confounding, there has to be an a priori basis in the scientific literature. You do not just surmise based on your own whims of whether something is a confounder. If there's nothing in the scientific literature that shows an

independent variable is related to a particular dependent variable and that there's an association between the two, there's absolutely no reason to control or suggest confounding. And Dr. Holford admitted as much right there as to the antithrombotic.

THE COURT: Okay, but if the study itself says these results -- well, look at it. Doesn't it say something about these are observational and may be confounding by other infection control something or other?

MR. SACCHET: Okay. It says, "this study does not establish causal basis for the association." So they're not saying it proves causation. We've said that.

THE COURT: Right, but they were --

MR. SACCHET: I'm going to get there.

THE COURT: Okay.

MR. SACCHET: For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study. Although, no infection controls were made after February of 2010, so that's when they mentioned those particular variables. Do they say that those variables were confounders? No. They say that they weren't able to control for those factors because they change.

THE COURT: And you're talking about that specific one, but since you have it right in front of you, you're at an advantage over me, but is there not a sentence in there

that says this study is observational and may be confounded by other infection agents or something?

MR. SACCHET: I can't find it right now, but my answer is this even if it did, that I don't think that means exclusion or that it means --

THE COURT: No, I mean that's a statement about that study. It's not a criticism of the study. It's just a question about the use that can be made, whether a follow-on expert can cite the study for something that the study itself disclaims.

MR. SACCHET: I don't think that any of plaintiffs' experts cite this study for something that the authors have disclaimed. Our expert --

THE COURT: Is that a marked-up copy or is it a clean copy?

MR. SACCHET: It is unfortunately.

THE COURT: Okay. Never mind. The only reason I want to get this squared away is I want it out of my mind, so that I can concentrate on what you're saying.

MR. SACCHET: Mr. Blackwell has a copy of a clean study.

THE COURT: Can you make sure it's clean? Good enough?

MR. BLACKWELL: Clean enough, Your Honor.

THE COURT: The sentence is right in the middle of

what you read. That paragraph says, "this study does not establish a causal basis for this association. Although, the demographics were similar between the patient groups in terms of risk factors for infection. The data are observational and may be confounded by other infection control measures instituted by the hospital. For example, changes were made to the antibiotic and thrombotic."

It's right there. There's a sentence right in the middle of the sentences you read.

MR. SACCHET: I thought you were looking for a sentence that says there was confounding.

THE COURT: I don't remember exactly what I said, but it does say, I'm looking at it right now, "the data are observational and may be confounded by other infection control measures instituted by the hospital." So if the authors themselves say this in the study, mustn't the experts who are relying on this study acknowledge the study author's statement about confounders?

MR. SACCHET: Well, all of our experts acknowledge that no observational study can prove causation for that very reason. Every single observational study is subject to confounding. The question is has 3M shown any and do any of the ones they suggest actually show confounding, and the answer is no. So Dr. Samet expressly states in his expert report that the only definitive proof of causation is a

randomized controlled trial. No observational study can prove confounding, and no one would say otherwise.

THE COURT: So this is a pointless statement.

MR. SACCHET: It's a pointless statement.

THE COURT: It happened in the McGovern study.

MR. SACCHET: It's in every single observational study. I mean the Reference Manual says that observational studies don't prove causation.

THE COURT: So every single observational study is going to contain somewhere in it this statement, "the data are observational, may be confounded by other -- "

MR. SACCHET: If the authors are upfront, and they should, for example, the Jeans study that 3M cites is proof of causation, expressly states at the end of that study that the association could have been due to other factors. So even the study that 3M cites as new evidence to disprove the McGovern study has the same acknowledgement in its study to say that it cannot prove causation, and that's why Dr. Borak admitted at his deposition notwithstanding 3M's argument, notwithstanding the fact that they brought a motion for reconsideration of general causation based on an observational study that the Jeans study can't prove causation because its observational.

As to the change in antibiotic, and I think this is interesting. To the extent there may be confounding,

confounding doesn't just mean negative confounding or positive confounding. In fact, Dr. Holford admitted on the record when I asked him this question, "Could the change in the antibiotic actually result in reverse confounding in the direction that the use of Gent plus Teic was less effective than the use of just Gent?" "It appears to be, yes."

Now, that probably sounded like a lot of gobbledy gook. What that means is there were two particular antibiotic protocols used in the McGovern study. Bair Hugger patients received Gentamicin. Air-free patients received Gentamicin plus Teicoplanin. Dr. Holford, for whatever reason, I think it was a misstep perhaps in what 3M asked him to do, did a calculation controlling for the warming device, so he just looked at the Bair Hugger, and he looked at Bair Hugger rates of infection using Gent, protocol one, and Bair Hugger rates of infection using Gent Teic, protocol two. That calculation showed that infection rates were higher among Bair Hugger patients that used Gent Teic. The same protocol that all of the air-free patients used. What that means is the antibiotic that the air-free patients got may have been less effective than the antibiotic that the Bair Hugger patients used.

THE COURT: Which expert says that?

MR. SACCHET: Dr. Holford right here.

THE COURT: He says that?

MR. SACCHET: Yep, at PX50 at 317, 2-6, he admits actually reverse confounding.

THE COURT: That's a statement, not a question. He says, "appears to be, yes." Okay.

MR. SACCHET: He says, "yes." So if anything, based on 3M's own expert testimony from its own biostatistician that 3.8 odds ratio -- it actually may be higher than 3.8. It could be something more like 4-something, which would be a quadrupling of the risk as opposed to a 380 percent increased risk.

So if we want to talk about confounding, and if we want to talk about the author's admission that there may be confounding, their own expert admitted that there's actually reverse confounding so that dooms 3M's argument.

As to the tabulation error, Mr. Blackwell repeated numerous times that Mr. Albrecht admitted that the data was mistabulated. I think I've read Mr. Albrecht's deposition three times. I've never found the statement. What I did find when I was looking for it in the back is a question and an answer where Mr. Albrecht says, "the data set that was analyzed there was three. Three deep joint infections for the air-free period, not four." So I don't know where the testimony is that Mr. Blackwell is referring to, but I think it behooves him to show the Court based on the representation that he made earlier this morning.

And in addition to the tabulation error argument, Dr. Holford admitted on the record when I cross examined him that the draft data set that he relied on was missing pages. He admitted that the draft set that he relied on expressly contradicted the raw data that was published in Figure 7 of the study. I mean the McGovern study publishes the raw data in Figure 7. There's jitter data points. There's three in the air-free period, and there's 32 in the Bair Hugger period. There's no dispute that that's the number of infections. And Dr. Holford admitted.

I also asked Dr. Holford, "Do you know whether this data set that you're relying on is the final data?" "No." "Does 3M know it's the final data?" I asked him that question. "No." No one has agreed that that's the final data set.

What the authors have agreed is that the data set they did rely on like Mr. Albrecht testified to at his deposition does contain the three infections in the air-free period and the 32 in the Bair Hugger period. To the extent Dr. Reed surmised that there may have been one additional infection in each arm of the study, even though 3M only quotes his testimony for the fact that there was just one more air-free infection instead of also one more Bair Hugger infection doesn't change the analysis. In footnote one of Dr. Holford's expert report, he did that analysis based on

Dr. Reed's testimony. He still found a statistically significant increased risk P value of .407. He still found that the odds ratio was 2.87. It's still above the doubling of the risk, which even according to Holford can be used to prove specific causation by itself.

3M also put up a slide showing a chart about start date and that if the start date had been moved back, that would show that the statistical significance disappears. The testimony in this case is undisputed that there was not complete data prior to July 1, 2008, and that is precisely why Dr. Reed, et al, used that date as the starting point of the McGovern study.

I asked Dr. Holford the same question at his deposition. Dr. Holford not only agreed that the start date should have been July 1, 2018, based on Dr. Reed's testimony, but Dr. Holford even said it could have been later not earlier. So this argument about an earlier start date is belied by the testimony in this case. It's manufactured by 3M.

To the extent that 3M has argued that you should segregate the knee data from the hip data in the McGovern study, there's no biological or a priori basis to separate knees and hips when they both involve prosthetics. There's no biological reason to assume that a hip infection on a prosthetic would be different than a knee infection on a

prosthetic, even if you did segregate them. I couldn't believe this when I saw it.

THE COURT: You know, but you're talking about your own -- none of those arguments are surprises, and so wouldn't your experts be the ones to say, look, this and this and this confounder are not real for this reason, this reason, this reason, and so I'm not just paying lip service to the fact that there's observation. And I would be curious to see if there's a case that says all observational studies have confounders. But that they're not just saying -- well, I mean you're saying, well, this is ridiculous, that's ridiculous, that's ridiculous for the confounders, but wouldn't the experts themselves have to say I looked at the confounders, I took them seriously, and they are no good for this and this and this reason.

MR. SACCHET: They did.

THE COURT: Okay.

MR. SACCHET: I mean Dr. Samet's report as I said addresses potential confounders that 3M has suggested, namely, the antibiotic and the antithrombotic and says that there's no evidence to suggest that they are, and 3M's own expert admitted that they're not. The evidence couldn't be more clear as both sides epidemiologists agree that there's no a priori basis to assume confounding based on those two particular variables that the McGovern authors mentioned in

their testimony. Although, there have been other statements by other entities like the International Consensus statement that Mr. Blackwell brought up, it doesn't say that there is confounding. It says that there is potential confounding.

And as to the subject of the knees versus hips, plaintiffs' experts do say there's no basis to distinguish. Dr. Jarvis, they both involve prosthetics. Deep joint infection occurs from a small inoculum of bacteria and, therefore, it would occur based on the same etiology as to any one of those sites.

THE COURT: What about the state of the infection rate at that hospital before they undertook the changes, that they were way above the national health care average for hips but not knees. I mean what about that?

MR. SACCHET: Yeah, so we brought that up in response to 3M's arguments in the prior round of Daubert briefing, and it's the same answer as what I stated with respect to the July 1, 2008 date as to why the McGovern study began then is because prior to that, there was under reporting of infection data among all of the hospitals in Northumbria. So those data that are suggested prior to the beginning of the McGovern study aren't robust and complete data. The robust and complete data exists when the McGovern study began, so that particular infection rate cannot be compared to the McGovern study.

And, again, I asked Dr. Holford the question in his deposition, "Aren't you comparing apples and oranges?" "Yes."

THE COURT: Okay.

MR. SACCHET: But back to hips and knees, even if we want to say that for some reason we're going to stratify the data, which there is no biological basis to do that, but even if we did, the difference in infection is still .4 percent for air-free and 1.3 percent for forced-air warming. It's nearly a tripling of the risk.

And, moreover, 3M's own calculation, and this just really bothers me, Dr. Holford said that the McGovern study used the wrong statistical test. Dr. Holford's whole expert opinion said that the chi-square test is inappropriate and that's why he applied Fisher's exact test, and I argued about this at the prior Daubert arguments in October of 2017. What did 3M do in its supplemental papers? Apply the chi-square test, the very same test that Holford said shouldn't have been applied.

In any event, even if there's not statistical significance, as I mentioned earlier this morning, the United States Supreme Court in its *Matrix* decision says you don't have to have statistical significance to use a study for purposes of causation.

The *Viagra* court said the same thing in the MDL

context as it relates to general causation under a number of circumstances, you don't need statistical significance but that's beside the fact because there is statistical significance here.

Finally, as to the McGovern study, I'm not going to mention the double control argument. They brought this up in their papers again. It's old news. They say control for the antithrombotic and control for the antibiotic, that eliminates the statistical difference. There's 200 patients in the Bair Hugger arm, and there's 200-some in the HotDog arm, you can't do appropriately powered statistical calculation based on 400 patients. 3M's own internal documents admitted from Mr. Van Buren that you need at least a thousand patients, so that calculation is meaningless. And when I asked Dr. Holford about it at his deposition, he agreed it has unnecessary variants, and it's not reliable.

THE COURT: Why is such a small example good for one purpose but not for another?

MR. SACCHET: For what purpose is it good?

THE COURT: Well, your experts rely on the McGovern study with its small sample.

MR. SACCHET: A small sample is not 1400 patients.

THE COURT: What do your experts say about the size of the sample in McGovern?

MR. SACCHET: They acknowledge that it's 1,437

patients with --

THE COURT: And then do they say that's a great plenty?

MR. SACCHET: Dr. Samet says it's enough to rely on. I mean there's a 1,066 patients in the Bair Hugger arm and there's 371 patients in the air-free arm, and then when the subsequent data was collected, it expanded to 371 to 650-some, so we're looking at nearly 2,000 patients to conduct a study.

THE COURT: I mean I don't know whether that's enough. I would rely on some expert to say that. That that's, you know, if that's a lot or it's not a lot or, you know, it's enough to form a tentative conclusion or a final conclusion or something.

MR. SACCHET: At his deposition, I asked Dr. Holford, "Can you apply chi-square based on a population of greater than a thousand?" And he said, "yes." In fact, based on the numerous statistical tests that I reviewed in advance of that deposition, the quote unquote rule of thumb for applying chi-square is a population greater than a thousand.

THE COURT: A thousand, yeah. Okay, you're going to make your final point.

MR. SACCHET: Yeah, final point on McGovern. So 3M has said both in this case and in the Gareis appeal that

the Reference Manual makes clear, "observational studies provide good evidence of causation only when, one, the same association as seen in other studies with different designs and subjects; and, two, the association holds when confounders are taken into account by appropriate methods," at page 27 of their brief. It's also cited in their appeal in Gareis.

I went to the page that they cited because I wasn't aware of it without reviewing it, and the text of the Reference Manual entirely belies 3M's argument. 3M just lobbed off the third factor, which is there is a plausible explanation for the effect of the independent variable. Just didn't put it in their papers, didn't put in their appeal, just acted as if the first two bullet points are the only things that you can have to have good evidence of an association and didn't consider the third.

Now, 3M might get up here and say the introductory text says generally observational studies provide good evidence in the following circumstances. Again, that proves that their argument is wrong because it uses the plural of the word "circumstance" so it's any one of those three, not them conjoined. There's no "and" between the three factors linking them. They're interpreted independently as other sections of the Reference Manual made clear. This is a blatant misrepresentation. The third factor was just

cleaved off and not represented to this Court, and that is the very factor, the very factor by which their whole argument fails.

There is a plausible explanation for the effect of the independent variable. All experts agree. All studies show the Bair Hugger increases particles over the surgical field and that is what the peer reviewer says in this comment, but I won't read it again because I've already read it.

I don't know if you're approaching the sentencing hour.

THE COURT: It's scheduled for 12:30 and the marshals will be bringing somebody in here. So maybe we should take a break, but I just I want to know how much longer you are going to talk because you did want to split with Ms. Zimmerman.

MR. SACCHET: Yes. I could try to wrap everything up in 30 minutes.

THE COURT: Okay. Well, I can't make somebody stand in the back there with their shackles on.

MR. SACCHET: Yes, I get it. And, again, we appreciate --

THE COURT: We're just going to have to break for an hour then. I'm sorry about that, but we will have to be in recess, and we'll resume at 1:30.

(Recess at 12:32 p.m.)

IN OPEN COURT

(1:49 p.m.)

THE COURT: Welcome back. Please be seated. Mr. Sacchet.

MR. SACCHET: Once again, Your Honor, we appreciate the time this afternoon.

Onto the next topic of 3M's motion, the Jeans study, I think it's the primary reason that the parties are here today.

THE COURT: Could I just, if you're going to move on to something else, can we go back to the confounding business?

MR. SACCHET: Of course.

THE COURT: I think I found what you were talking about in the Samet report on page 11, he talks about the last paragraph, "in an extended data set, Professor Nachtsheim compares infection rates under the two antibiotic regimes," is that what you were talking about?

MR. SACCHET: So that's specific to the 3.6, the extended data set, but there is a discussion about the potential confounders.

THE COURT: Well, that's its own separate paragraph. And he refers back, we've got Jensen and

Jameson, right?

MR. SACCHET: Yep.

THE COURT: Are they exhibits to the deposition or they're filed by -- do you have the docket numbers for those by any chance?

MR. SACCHET: So defendants as part of their motion for reconsideration attached the Jensen study. I think it might be DX2, but I'm probably wrong. They did not attach the Jameson study, but both of those studies were exhibits to plaintiffs' opposition to 3M's additional Daubert motion.

THE COURT: Okay, so that's in there with a number?

MR. SACCHET: Yes, I think it's cited in our papers as well.

THE COURT: Yeah, okay. All right. And the other two, Jarvis and Stonnington don't do this confounder, a similar confounder analysis to what Dr. Samet does, do they?

MR. SACCHET: They do not. I think the primary difference there is Dr. Samet approached his report primarily as an epidemiologist, and Drs. Jarvis and Stonnington have a different expertise. Dr. Jarvis being infectious disease, and Dr. Stonnington given his clinical experience.

THE COURT: All right, thank you.

MR. SACCHET: Yes. So as to the Jeans study, indeed this is new evidence. Plaintiffs don't dispute that. I'm not going to go into the background of the study to save the Court's time, but the first argument that 3M hangs its hat on is this idea that the Jeans study confirms or proves that the McGovern study cannot support causal inference. Specifically, 3M says, "the Jeans study confirms that the observational study was confounded by introducing MSSA screening on page 25 of their memo, and in their reply, they similarly assert that "the study now proves that defendants were correct," end quote.

Now, I've already mentioned to the Court before that an epidemiologic study cannot prove causation as a matter of black letter science that's been discussed, but more relevant here is the deposition testimony of their own expert that was the first person to interject Jeans into the equation. And it is plaintiffs' contention that based on this deposition testimony alone, both as I'll explain in this slide and subsequent slides, that 3M has no basis whatsoever to be making the argument that they currently make in their reconsideration papers.

The first is that at his deposition which plaintiffs ask for and received the opportunity to conduct as to the Jeans study a couple of months ago, plaintiffs' counsel asked Dr. Borak, "So you agree with me that the

Jeans study does not conclude causation with respect to MSSA screening and its relationship with MSSA infections?"

Answer: "Yes, it does not prove causation."

Question: "And that's because it's a retrospective study, correct?"

"No, it's because it's an observational study."

Now, I want to be candid with the Court. I added the bolded lines of 1, 2, 3 and 4 during the break because I thought it would go to the Court's questions about our observational studies' proof of causation, and here we have 3M's experts admitting, even though they proffered the Jeans study as observational proof, their own expert deracinating that theory.

We also asked Dr. Borak, question, "So you agree with me that the fact that the Bair Hugger was not used during a time period could be a confounder in the Jeans study?"

Answer: "It was potentially a confounder."

So even 3M's expert acknowledges that in the Jeans study the results could have been confounded from the Bair Hugger, the only object that increases particles over the surgical site. And, indeed, even Jeans, Plaintiff's Exhibit 52, says, "a key elimination of our study were that the groups were not randomized and improvements in infection rates could have been (sic) due to other factors."

So those are three snippets of relevant testimony. And also back to the Court's question, this is an additional excerpt that I added to the PowerPoint over the break. It's from the Gareis trial. And at the Gareis trial, when Dr. Borak was --

THE COURT: Where is that?

MR. SACCHET: The bottom right hand at 1429.

THE COURT: Oh, I see it.

MR. SACCHET: So that's a colloquy between Ms. Conlin and Dr. Borak in which she sought his testimony as to whether he knew that with respect to tobacco and lung cancer and other forms of cancer, only epidemiologic evidence was available to use for causal inference, not to prove confounding but to use for causal inference. And Dr. Borak acknowledged that that was the case and then went on to explain that epidemiological studies cannot show causation. They can only show association.

The second issue underlying 3M's argument is that they claim that it involved the same patients and time periods in the McGovern study. It's just false. The Jeans study went from 2007 to 2014, and it involved three hospitals, only one of which was Wamsbach. There were two additional hospitals from the Northumbria Trust that were not analyzed in the McGovern study. As a result, Dr. Jarvis in his supplemental affidavit at paragraph 3B expressly

concludes that the Jeans study data set is not identical to the McGovern study data set, et cetera.

I did put in a calculation here to actually show what happens when you remove the McGovern data set from the Jeans data set, ala Professor Holford. I took some of his moves and plaintiffs offer this calculation to show that in fact when you take Bair Hugger out of the equation, the infection rate is exactly the same between the pre-screening arm and the post-screening arm of the Jeans study.

The third fallacy of 3M's argument is it says that Jeans confirms 3M's contention that the introduction of MSSA screening was a confounding factor and helps explain the reduction in PJIs reported in the non-Bair Hugger period of McGovern. This argument goes to the question the Court previously posed to 3M's counsel about didn't Jeans analyze a different outcome than McGovern? And the Court's suspicion is correct. Indeed, although as Mr. Blackwell pointed out, the first line of the Jeans study defines the acronym PJI. The study later defines what PJI means to the authors. And in this instance, PJI means not only deep joint but also surgical site infections or superficial wound infections more generally. The authors themselves in some of the final paragraphs of the study expressly use the acronym SSI instead of PJI.

Moreover, the McGovern study did not analyze SSI.

That's undisputed. Dr. Holford, Dr. Borak, everyone agrees the McGovern study was limited to just deep joint infection. Now, why is this important? This is not a semantic word game unlike the conflation of laminar flow with protected effect. This actually has meaning, and the reason why it has meaning as we explained, as plaintiffs explained in the prior Daubert arguments, is that the etiology is different between the deep joint infection and the surgical site infection and that distinction matters, and the result of that distinction, plaintiffs ask Mr. Borak at his general causation deposition, "Can studies involving SSI be used or are they informative as to outcomes involving DJI?"

And Dr. Borak said, "no." And he, in fact, said, "it's also not relevant if the packaging is MSSA." So here we have a colloquy. "And you don't think that it would be fair to extrapolate from one type of infection in one part of the body to a deep joint infection even if it's MSSA?" "Yes."

But this is the dispositive excerpt that ends the discussion, disproves 3M's argument at the threshold. A number of months ago, plaintiffs' experts, as we mentioned, deposed Dr. Borak specifically about the Jeans study. Plaintiffs' counsel posed the following question to Dr. Borak. "So according to the Jeans study, you can't determine if there was a change in the deep joint infection

rates between the pre-screening group and the post-screening group, correct?"

Answer: "I don't have data on deep joint infection rates in either of those time periods."

Question: "So you can't determine if there was a reduction in the infection rates, in the deep joint infection rates as a result of the MSSA screening protocol, correct?"

Answer: "Yes, nor did I ever suggest that there was."

So it doesn't just not confirm or prove, it doesn't even suggest, according to 3M's own expert, that there was confounding in the McGovern study. Plaintiffs contend that as a result of this admission alone, 3M should have withdrawn its motion as it relates to the Jeans study because their own expert has annihilated the argument.

I will also mention because the Court brought it up earlier about the source of MSSA infections. The Sousa randomized control trial in 2016 shows that DJIs arise not from endogenous sources but from exogenous sources. So with respect to MSSA screening in particular, there's no basis to assume that MSSA screening would have a biological impact on DJI rates because they arrive from airborne bacteria not exogenous bacteria from the patient.

THE COURT: So endogenous, exogenous -- endogenous

--

MR. SACCHET: The person.

THE COURT: Endogenous does not cause DJI, right?

MR. SACCHET: It's far less likely than exogenous.

THE COURT: I thought you just said it didn't cause it.

MR. SACCHET: This randomized control trial says there's no impact on MSSA screening because it's exogenous on deep joint infection rates. So whether I personally believe it doesn't cause it, I mean the study says that.

THE COURT: Are there any other changes in your slides other than that one --

MR. SACCHET: No.

THE COURT: Other than that they're the same, okay.

MR. SACCHET: And I will also mention that most studies unlike Jeans actually do distinguish between DJIs and SSIs, so Your Honor brought up the Jensen study and the Jameson study, those two studies analyze the potential impact of the antithrombotic on both superficial and deep joint infections. And while the studies concluded that different antithrombotics may have a differential or significant impact on superficial import infections, they do not have a significant association to deep joint infections. So curiously the Jeans study doesn't differentiate between

the two even when there's a randomized control trial. Sousa, the one that I mentioned, showing that there's no significant impact on deep joint impacts from MSSA screening.

The both of plaintiffs' experts have submitted supplemental affidavits confirmed Dr. Borak's admission, so experts on both sides now agree that because Jeans didn't stratify data between deep joint infection and surgical site infections, that it's unclear and does not suggest or confirm that the McGovern study was confounded by MSSA screening.

There are other issues with the study that I'll save that are in our papers related to data modification, the Hawthorn effect, which Dr. Borak mentioned applied to McGovern, but it's impossible that it could because McGovern was retrospective, whereas the Jeans is prospective, so there actually could have been cultural differences that caused the effect, whereas it would be impossible for that to occur in the McGovern study.

The authors kind of unusually didn't track in Jeans whether the MSSA screening and the decolonization that was performed actually resulted in the eradication of the MSSA that would or may not be on a patient's nose or groin, so there's no indication as to whether the MSSA screening had any effect without knowing whether it actually

eliminated the bacteria.

Dr. Samet also explains, I believe Mr. Blackwell averred that Dr. Samet's testimony about the magnitude of the risk of the 3.8 is ipse dixit. It's not. The odds ratio in Jeans is 1.37. The odds ratio in McGovern is 3.8. If you subtract those two numbers, you still get 2.4, which is greater than a doubling of the risk, which ala Professor Holford's testimony is enough to prove specific causation by itself.

And, moreover, we have the Reed 2019 study, which again confirms Dr. Reed's consensus that McGovern study shows a statistically significant association as to infection rates.

And, finally, you know, 3M quoted some of the testimony that was made at the prior Daubert hearing to say plaintiffs inaccurately stated that there's no study showing that MSSA screening impacts DJI, that's still the case today. The Jeans study doesn't change that equation based on the own admissions of 3M's experts. And even if it did, it would be an issue of weight not admissibility.

As to the next subject, the testimony, I'm trying to move quickly to the International Consensus statement, the first fallacy of 3M's argument is that they contend that the evidence is properly before the Court on reconsideration. It's not. 3M says in their reply that the

axiom was published online on November 12, 2018, three months after defendants filed their letter requesting leave to seek reconsideration. Not only does the forward to the ICM show that the consensus was done on July 27, 2018, but it also expressly says that the report was disseminated in August of 2018.

More alarmingly, however, is Mr. Gordon of Blackwell Burke's e-mail to Dr. Mont, their litigation expert in this multi-district litigation asking him to change the consensus statement on October 3, 2018. So I think 3M said that there was no evidence of their hand in this material. This document says otherwise and may not show that in fact the ICM was changed but it definitely shows that 3M's attorneys have contacted those who are in charge of the delegation and asked for it to be so.

3M further argues that the Court's Order didn't preclude it from citing this evidence on reconsideration. They have the burden backwards. It's not plaintiffs' burden to show what should be sought for leave for reconsideration. It's 3M's burden to say it in their motion requesting leave, and it didn't do it, so the ICM isn't properly before the Court. Even if it were, this subject came up before the 2013 ICM is actually stronger for 3M than the 2018 ICM, notwithstanding the arguments that were made this morning.

The 2013 ICM, unlike the 2018 ICM, said there is no

evidence for causal inference. The 2018 ICM said there's no evidence to definitively link Bair Hugger to increased infection. Those are very different things, and I'll explain why in a moment.

And this goes to the second fallacy. 3M claims that the ICM, the overwhelming consensus of experts in the field who have reviewed the science is that no causation inference can be made based on the scientific evidence. So they say that the ICM just put the question to bed precludes plaintiffs' experts from performing causal inference based on the Bradford Hill criteria, the surgeon general's criteria, the CDC's gold standard, scientists' clinical experience, it doesn't matter. It just ended the debate.

What the 2000 ICM actually says is, as I mentioned, there is no evidence to definitively link forced-air warming to increased risk of SSIs and PJIs. And why is that important? It's important because as 3M acknowledged in their original Daubert papers but fails to acknowledge now, the only evidence that can definitively prove anything is a randomized control trial, and it's black letter law and science that randomized control trials are not necessary for causal inference. In fact, epidemiologic studies aren't even necessary for causal inference as the Reference Manual in footnote 180 states.

It also contradicts the testimony of Dr. Holford.

As I mentioned, I asked him the question, "Do you agree with the statement from the Reference Manual on statistics that quote, in the end deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment?"

Answer: "Yes. The Reference Manual itself, the bulk of statistical studies seen in court are observational not experimental or randomized control trials."

And, finally, Eighth Circuit law puts the question to bed, decisions such as *Bonner*, *Glastetter*, they all acknowledge that a scientific absolute, in other words, definitive evidence as 3M now touts from the ICM is not the standard.

And, moreover, to the extent that the ICM even did conclude, which it didn't, that causal inference would be impossible, that would merely be a debate between the conclusions of those individuals and the conclusions of plaintiffs' experts, which is not a proper attack to dispose of the Daubert challenge, although, it is a particular factor.

As to the suggestion that the ICM considered the same evidence as 3M's experts, I also think I heard that this morning from Mr. Blackwell as well as the FDA. They just didn't. The ICM cited 25 sources in concluding that there's no definitive link. Plaintiffs' experts on the

other hand have considered hundreds. Even the forward to the ICM acknowledges that quote "key studies could have been overlooked." Some of those studies matter.

For example, ICM didn't cite Baker. That was the study concluding that there's no evidence for use of forced-air warming and ultra-clean orthopedic surgeries.

They didn't cite Bernards. That's the study we talked about this morning in which the authors as had been interpreted by other scientists concluded that there is a link between internal contamination of the device and nosocomial infections.

Dr. Beavers didn't cite that concluding that the Bair Hugger's reservoir of infection.

It did cite Darouiche and Stocks and other questions within the ICM, but, unfortunately, the ICM delegate members didn't bridge the gap between increased particles and bacteria in infection rates with what the Bair Hugger does and is undisputed as we know from this litigation increased particles over the surgical site.

It didn't cite the Gjolai paper, which says that the Bair Hugger made previous contaminated air.

It didn't cite the Reed 2013 study, which holds that 3M reduced the filtration efficiency of the Bair Hugger from 90 percent to 60 percent and thereby poses an emissions risk.

It didn't cite the Tsai 2017 case report saying that documented complications with Bair Hugger warming is an increased risk of surgical site infection, and it never cited the correlation between, as Dr. Jarvis does, heater-cooler units and the Bair Hugger itself.

In addition, the 2018 ICM omitted certain findings from the studies that it actually did cite and this particular slide juxtaposes the two examples. So ICM's gloss on the Moretti study, they say there was no difference in bacterial loads. The plain text of the Moretti study says in the 20 procedures in which the Bair Hugger receives, the mean bacterial loads were significantly increased.

It then goes on to state that other authors have demonstrated, "a higher airborne bacterial load in the samples analyzed and a higher incidence of nosocomial infections in patients kept warm using the Bair Hugger," end quote.

[redacted]

ICM members were not part of this litigation, they were not privy to these confidential documents.

The final fallacy of 3M's reliance on the ICM, they say that plaintiffs' opinions are on a two percent. In other words, they're an anomaly. No one else has agreed with them. Again, this fact gets back to the same point. The ICM didn't say you can't do causal inference. It said there's no definitive evidence, which only means that there's not a randomized control trial. So plaintiffs' experts are now on the side of the two percent of people and even if they were, there would be a dispute of conclusion, but because general acceptance is one of four factors that the Court may consider under Daubert, it can be considered as to whether their are opinions are generally accepted.

The first thing to note, the International Consensus statement makes clear in its forward that the document should not be interpreted as definitive or in fact represent the standard of care.

Moreover, other scientists agree with plaintiffs' medical experts as to the causation inquiry. For example, as I mentioned, the Tsai authors from Anderson Hospital in Texas documented complications from forced-air warming use include an increase incidence of surgical site infections.

Moretti, et al, as I just mentioned, recognizing other studies have found a higher incidence of nosocomial infections in patients kept warm using Bair Hugger.

The French Society of Microbiologists have issued

a recommendation to quote, "not use forced-air warming anymore because of its high risk for the patient to develop a surgical site infection," end quote. Plaintiff's Exhibit 64.

[redacted]

Other orthopedic surgeons from an internal correspondence that 3M produced in this litigation, Plaintiff's Exhibit 71, quote, "several of our orthopedic physicians are refusing the use of forced-air warming devices for joint replacement procedure 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 in what I have found seems to support their position.

So there are numerous independent scientists and researchers both in this country and outside of it that just like plaintiffs' experts have concluded that the Bair Hugger can cause deep joint infection.

Finally, 3M alteratively argues that should the

Court deny its motion, which plaintiffs obviously ask that the Court do, that it should certify its Order for interlocutory appeal under 1292(b). 3M didn't make the argument this morning. I think they've fallen on their sword. I'm not going to go through all the reasons why it's improper, but the fundamental reason, the first lesson I learned clerking for the Honorable Diana E. Murphy, the prior panel rule. The prior panel rule. It's a cardinal rule in this circuit. You can't cite a subsequent panel decision that conflicts with a prior panel decision.

U.S. v. Mader, 2011 en banc decision made that clear. 3M never replies to it in their papers, never says anything about it today. To the extent that it could even be imagined that *Glastetter* conflicts with the great wave of authority in the Eighth Circuit, even if it did, which it doesn't, the prior panel rule dooms 3M's argument.

And so too does the only case that 3M cites in their papers, the *Blue Cross Blue Shield* litigation, in which the Court there reached the same conclusion that the prior panel rule doomed their request for 1292(b) certification.

And, finally, even if *Glastetter* did control, it was about specific causation not general causation. Specific causation is not before the Court on 3M's motion.

Second, no mechanistic evidence in *Glastetter*.

Plaintiff entirely failed to show the core premise of their theory, which was that bromocriptine, the underlying chemical in the drug Parlodel caused vaso constriction of blood cells, which in turn caused intracerebral hemorrhaging, which in turn caused stroke. No evidence whatsoever in the scientific literature. Unlike here where it's undisputed that the Bair Hugger increases the number of particles over the surgical field.

THE COURT: Could you just slow down? The court reporter can't possibly take down what you're saying.

MR. SACCHET: I apologize.

Third, in *Glastetter*, there was no epidemiologic evidence that either the plaintiff or her expert cited. The Court did make clear, which 3M has never stated in this part of the proceedings that the lack of epidemiologic evidence does not doom a plaintiff's case.

And fourth and finally, the plaintiff there alleged but failed to show that the company was aware of the [redacted]

I'll hand it over to Ms. Zimmerman now. Thank you very much.

THE COURT: Ms. Zimmerman.

MS. ZIMMERMAN: Thank you, Your Honor. I join my colleague Mr. Sacchet in appreciating the time that the Court has devoted to this. It's obviously been a long day and a long litigation.

And if the Court would permit me an observation, I think that sometimes we get to be talking a little fast. It's pretty apparent, I think, to the Court and anyone in the room, we feel pretty passionate about this. We feel privileged to be in front of Your Honor in this honorable court. We feel passionately about our opportunity to represent 5,000 people in this case. And, respectfully, we think that these issues have already been decided correctly by Your Honor, particularly with respect to the admissibility of the experts that have been offered.

Your Honor considered hundreds if not thousands of pages back in 2017, and we had a three-day long hearing on all of these issues. As Mr. Sacchet just made an observation, Dr. Holford has not supported exactly the argument that 3M is intending to make here, which is that Jeans undermines McGovern.

So what I'm here to talk about today, and I will try to make it reasonably quick because I think Your Honor is on the same page with us given the questions posed to Mr. Blackwell this morning. Mr. Blackwell and counsel for 3M misunderstand and, frankly, misquote Dr. Elgobashi's

testimony at the Gareis trial. I think that Your Honor's question was exactly right on point.

You saw Dr. Elgobashi as he testified to the Court and to the jury in Gareis about laminar flow and the questions were posed to him about whether or not that was really a force field or not. Now, yes, I used that in my opening statement and perhaps counsel takes issue with my description, but it's not just my description. The description has been made by a lot of different folks including, and I point to defendant's expert Keen, his expert report on general causation matters, and it's MDL docket 740-1.

So Dr. Keen says right at the top, and this is the summary of his conclusions, he talks about it being a protective field. So he doesn't call it a force field, but he does call it a protective field. He uses a couple of other words, and that, Your Honor, is right up here where he says it's a protective field. That's what the laminar air flow is intended to be and that is intended to prevent infiltration and possible contamination of the sterile field.

THE COURT: However.

MS. ZIMMERMAN: Yes, however, it should certainly be recognized that there are many sources of heat generation and physical obstruction within the laminar air flow that

can disrupt it and can cause some turbulence.

He alternatively uses words like "cocoon." At page 10, he talks about the critical zone that they need to protect to continuously sweep contaminants down away from the patient and the surgical staff.

On page 17, defense expert Keen talks about a protective cocoon around the site to help prevent contaminants from outside the field. And then as I just showed at the end of his report, he also talks on page 23 about the protective field. So certainly there is a variety of ways that people and experts in the field talk about what the laminar air flow is intended to do.

And I think that what Your Honor properly observed was really what Dr. Elgobashi was talking about and what his objection was was to the use of the word "laminar." "Laminar" to an engineer like Dr. Elgobashi is something either is laminar or it is turbulent. It is a bright line rule, and it is based entirely on the Reynolds number. There is no dispute, Dr. Abraham for 3M also agrees that this is in fact a turbulent operating room.

So as Dr. Elgobashi testified, his beef, so to speak, was really with the use of the word "laminar", and he makes that clear in his expert report. And I won't belabor that point because I think that the Court understands that issue.

The Court has properly concluded in the order from December of 2017 that Elghobashi's testimony is in fact admissible. There's never been a challenge to Dr. Elgobashi's qualifications nor could there be really. There's never been a challenge to his methodology. The real challenge is whether or not he has modelled any particular OR, and the only OR that has been considered by this Court at this time is the OR that was used in Gareis, but, again, that's not specifically before Your Honor today because that's an issue of specific causation not general causation.

So to the extent that Dr. Elgobashi is used with his LES CFD to show what the Bair Hugger is capable of doing, what the effect of it is in an operating room, what it is generally capable of, that's really what we're here about today, and that's what the motion was that 3M brought.

I'm not going to go all the way back through the CFD because Your Honor has heard that and properly considered that it is admissible. Mr. Sacchet talked about the number of different mechanistic studies in addition to Dr. Elgobashi that support the fact that the Bair Hugger does have this impact on the operating room. And, of course, Dr. Elgobashi's paper was in fact published in the peer review in the international renowned Journal of Numerical Methods on Biomedical Engineering in 2018.

One of the questions that Your Honor asked in the

assignment that we submitted the most recent round of briefing on really focused on how is it that plaintiffs' experts can potentially eliminate other sources. And Your Honor properly observed that in the Eighth Circuit and in this Court a differential diagnosis is certainly a permissible methodology and that's what was used by Dr. Jarvis and Dr. Stonnington in case specific reports such as Gareis. There are no case specific cases or specific causation issues before the Court right now. The motion before Your Honor, the motion brought by 3M, is limited to issues of general causation.

So while we can look at some of the testimony that we received from experts for 3M about how they can properly exclude other potential sources of infection, there's not a real question about that, about the issue of specific causation that's properly before Your Honor right now.

Dr. Wenzel, for example, who is the infectious doctor for 3M, when we took his deposition in the general causation phase, he agreed that a number of potential causes of infection can be excluded. This is 3M's expert not our expert. He agreed during his deposition that bacteria do not come from, an infection is not caused by the following: Anesthesia machines, surgical lights, computer monitors, computer consoles, electric cautery devices, the bovie, surgical drapes, cabinets along the wall, the suction drain,

surgical equipment. And I'll give Your Honor a citation to that as well.

THE COURT: I was -- that's not on one of your --

MS. ZIMMERMAN: It's not on my power point, Your Honor. And this all comes from his general causation deposition, and the citations begin at page 99. And I'm happy to provide a supplement with pinpoints if Your Honor would like them.

THE COURT: One is already in the record.

MS. ZIMMERMAN: Right. And so the issue then, I guess, to the extent that Your Honor has asked the question, how do we go through and exclude the other potential causes? They do that properly in the context of a specific causation inquiry by looking at the available evidence, and that's certainly what the experts have done when it got to the stage of specific causation.

But what we're here for today is to talk about general causation and whether or not the experts are properly qualified, if they have followed appropriate methodology, and those are really the inquiries before Your Honor in determining whether or not these experts can go forward. And we submit that Your Honor got the question right in December of 2017 when you allowed all of the experts to go forward.

Because we had some questions about engineering, I

did want to put some additional citations up about 3M's expert Dr. Keen, and he's a Professor Emeritus from the University of Minnesota, an engineering expert, and he did not come to the Gareis trial. But he did agree with us on a number of very important engineering principles, including the fact that particles under the operating room table and/or on the floor of the operating table can be transported to the surgical site by use of the Bair Hugger. That's at docket number 932-3. That's his deposition, and it's at page 324, lines 5 through 12.

It goes a little bit to Your Honor's question about where does the Bair Hugger sit, and I don't have information for you as I stand here right now about exactly where the Bair Hugger sat whether on the floor or on the stand, but what I can tell you is that the testimony that we've received from everybody is that it's on one or the other, and it is always below the surface level of the operating room table, and that you remember the testimony from Dr. Stonnington that everything below the surgical table is considered to be contaminated. So that was important testimony from Dr. Kuehn, who obviously did not come here.

Dr. Kuehn agreed that bacteria can become aerosolized. You heard lots of testimony about that. He agreed that the physicians want to keep a sterile field as

particle free as possible. He agreed that if 3M were aware that the Bair Hugger was associated with an increased risk in the number of particles over the surgical site, that that is relevant information and that 3M had an obligation to warn customers of that fact. Their expert agreed to that.

He agrees that particle testing is a valid alternative to biological sampling and particularly that you can get information in real time rather than having to wait for essentially settle plates to develop.

He agreed that the Bair Hugger may cause particles to travel from the floor to the surgical site. He agreed that particles that will travel from the blower to the blanket, some of those particles are going to leave the blanket and that some of the particles that leave the blanket are going to contain bacteria. Again, this is 3M's expert in engineering. A Professor Emeritus from the University of Minnesota. That's his testimony. He didn't come to testify live at trial.

And, again, then Dr. Keen also agreed that Dr. Elgobashi is an expert in particle movement and that he did both the equations and calculations included in his report correctly.

We have a couple of additional just one particular study that I would like to bring to Your Honor's attention, and it is a study from Japan in 2018. The author is, and

I'm afraid I'm not going to say it right.

THE COURT: What docket number is it?

MS. ZIMMERMAN: It is not filed. I have copies for everybody.

THE COURT: Tell me what it is.

MS. ZIMMERMAN: Sure. The study name is "Relative Clinical Heat Transfer Effectiveness: Forced Air Warming Versus Conductive Fabric Electric Warming, A Randomized Controlled Trial." This is published in a Journal in Anesthesia and Surgery in 2018 and the lead author of this listed is Haruko Sugai. It's H-a-r-u-k-o S-a-g-a-i. And the important part of this study --

MR. BLACKWELL: Excuse me, Counsel, Your Honor, is there a copy of that study since we are just hearing of it?

MS. ZIMMERMAN: Yes.

THE COURT: Is it in the -- I think you're to the end of your --

MS. ZIMMERMAN: We are to the end of my PowerPoint, and I switched over to the document camera. This was one of the slides in there though.

So the important part of this particular article, Your Honor, is that it's not focused on -- it's looking to see whether these two products both heat patients comparative --

THE COURT: Is it another HotDog study?

MS. ZIMMERMAN: I think it is HotDog and Warm Touch.

THE COURT: It says "HotDog" right there.

MS. ZIMMERMAN: Yeah, you're right, it does. So it's a forced-air warming and a conductive blanket. But the important part, and this goes back to whether or not the ICOS had all of the relevant information and whether they made the connection that Dr. Jarvis and some other folks have made with respect to the heater-cooler and what the CDC has said about that.

This is a peer reviewed published paper, and they say, if the highlighted part that's on the document camera right now, "There is another issue that underscores the importance of finding an effective alternative to forced-air warming. Forced-air warming systems have been shown to produce an unintended consequence of disrupting operating room air flow and contaminating the surgical field. The clinical concern is especially severe in implant surgery where a single airborne bacterium can cause an infection. The U.S. Centers For Disease Control and Prevention recently issued a warning, 'nothing that blows air should be in an operating theater if possible.'" That part is a quote. And then the authors say that "identify an air-free alternative is paramount."

So these kinds of authors, and the reason that

this study is important is that they are starting to connect some of the dots that we have presented, that the experts have presented to this Court, that haven't necessarily been connected by all of the other study authors and the folks that are putting together things like the ICOS. But it's not fair to say that these things are not related or it's unreliable to make these kinds of connections. They are in fact being made in peer-reviewed publications.

So we would be happy to entertain additional questions to the extent the Court has them on the additional briefing that we've done. But other than that, we have three studies and a PowerPoint that we'd like to mark as exhibits and have entered in the record.

THE COURT: You want your PowerPoint in the record?

MS. ZIMMERMAN: Yes, Your Honor.

THE COURT: Mr. Blackwell, did you want your PowerPoint in the record too?

MR. BLACKWELL: Yes, Your Honor.

THE COURT: Okay. Powerpoints will be in the record. What else?

MS. ZIMMERMAN: We would offer this study from Sugai which is 2018. It's the one that's on the document camera right now, Your Honor.

THE COURT: Did you just find that after your

briefing or what?

MS. ZIMMERMAN: We did, Your Honor.

THE COURT: Well, I don't know, I guess, Mr. Blackwell, you're standing up.

MR. BLACKWELL: This one, Your Honor, we object to. We just got it and saw it. I literally heard of it when counsel just mentioned it.

THE COURT: We're not going to -- you have to look at it and we have to go through some kind of process.

MS. ZIMMERMAN: All right. Well, we also have a copy of the Lange article that I believe that Mr. Sacchet referred to, and we have copies of those, and we would like to have those marked and entered as well.

MR. BLACKWELL: Same objection. Just received it today. No evidence it's a Bair Hugger study either, Your Honor.

MS. ZIMMERMAN: Here's a copy for you.

THE COURT: Okay.

MS. ZIMMERMAN: And that's the study that just came out this month June of 2019, paper.

THE COURT: This is hardly the time to spring brand new science, but I'll take them as court exhibits only so that when I hear from the defense side, I'll know what they're talking about.

MS. ZIMMERMAN: And then the last one is the Sousa

article also mentioned by my colleague Mr. Sacchet, and I believe that that is 2016.

THE COURT: Is there any reason that couldn't have been brought up before this moment?

MS. ZIMMERMAN: In part of the briefing for example, Your Honor?

THE COURT: For example.

MS. ZIMMERMAN: We apologize, this has to do with the questions that Your Honor raised about potential confounders and whether or not they are explained by other research that's been done. So the Sousa article is the Preoperative Staphylococcus Aureus Screening and Decolonization Protocol Before Total Joint Arthroplasty, Results of a Small Perspective Randomized Trial.

THE COURT: Well, I'll take them, but not to be filed in the case, just as Court exhibits pending further briefing, I guess. But we're not going to supplement the record with new science that's just brought here after lunch. So if you want to give my clerk hard copies of those, I'll put stickers on them.

MS. ZIMMERMAN: And if Your Honor would like an updated PowerPoint to reflect a couple of additions that Mr. Sacchet alluded to in his, that he made over the lunch hour. We'll be happy to provide that over the lunch hour as well.

THE COURT: He said it's just that one, right? Just that one page?

MR. SACCHET: Yes.

THE COURT: So I will take a copy of that revised page.

MS. ZIMMERMAN: All right.

THE COURT: What is this? I'm making it Court Exhibit 1. It says, "Science Direct." It's basically a one page.

MS. ZIMMERMAN: That is the summary of the Lange article, I believe.

THE COURT: There it is.

MS. ZIMMERMAN: Yes, and then right at the top, it says it's in the American Journal of Infection Control, Volume 47, Issue 6, supplement, and it's June of 2019.

THE COURT: All right. And then this, while I'm making Court Exhibit 2, doesn't it mean he needed to be -- what does it mean to be an open access article?

MS. ZIMMERMAN: It means you can get it free online.

THE COURT: Have you deposed any of these people?

MS. ZIMMERMAN: No, Your Honor. And as one additional, I guess, supplement, there are a number of references in 3M's particularly reply paper and then supplemental briefing in response to Your Honor's questions

asking why we do not have supplemental expert reports addressing some of these questions particularly with respect to Jeans, et cetera. As the Court may recall, we did disclose supplemental expert reports last fall, and defendants made a motion to strike, which the Court granted. We then brought a motion in January of this year to conduct additional discovery on the Jeans study and to supplement our expert opinions particularly with respect to this motion for reconsideration and that motion was denied.

So the reason there are not expert reports, particularly in our original response to 3M's motion, is because the Court specifically and expressly precluded us from doing so.

THE COURT: Do you have a clean copy of what I've marked as Court Exhibit 2, the Japanese --

MS. ZIMMERMAN: The Sugai? No, Your Honor, I don't. I highlighted them in the same manner, but I'm happy to e-mail a PDF.

THE COURT: That's all right.

Okay. Mr. Blackwell, any response?

MR. BLACKWELL: Some, Your Honor.

THE COURT: Okay.

MR. BLACKWELL: Judge Ericksen, I apologize if I'm a little bit discursive in responding. There were just a potpourri of points I wanted to address, starting with this

whole 1292(b), we're just relying on our papers in that regard, Your Honor.

The argument that we somehow have ended our request for reconsideration after the harboring bacteria argument again is completely specious. A lot of what Your Honor has heard today with respect to these mechanistic studies, it's a lot of the same stuff we covered back in October of 2017 during the Daubert hearing where all of these studies were ginned up then. There's a record of it then, and we heard it again today. And so all of this talk about particles, particles, particles, particles.

What the Court might recall is a couple of things about the particles. First of all, the particles that were relevant were particles that were 10 microns in size or greater. Those are particles that would be large enough to carry bacteria. So when plaintiffs' counsel gets up, and he talks about particle studies, they're not clarifying for the Court whether any of those studies even involve particles that were 10 microns in size or greater.

First off, the second thing that's also in the record from the October 2017 hearing with respect to particles and the Bair Hugger is that the genesis of a lot of these particle studies is either Scott Augustine or people associated with him when he had first tried to culture actual bacteria colony forming units from the Bair

Hugger, weren't able to do it. They tried six or seven times.

Then they resorted to particle studies thinking we'll be able to get particles in and we'll simply argue about particles as a proxy, which is exactly what the Court is now hearing.

And so we know, and I would, if the Court would take with some hesitation the studies that they cite on the so-called particle studies, take the Avidan study that Your Honor heard Mr. Sacchet reference. That's the study where they first, they track the culture bacteria from the Bair Hugger with the blanket on, weren't able to do it, weren't able to do it.

And so here we have an instance of the instance where at least here it begs the question, and Mr. Sacchet did talk about their expert Buck, and the testing that he did of the blanket. He didn't even attempt to go get a little cheap petri dish to try to culture bacteria from the so-called particles. There's every reason to be concerned here about the gap between particles associated with the Bair Hugger and the ability of those particles to carry bacteria or inoculate wounds, big question. So not established from any of the studies that plaintiffs cite.

For example, they reference the Darouiche and Stocks studies, as these prove that the particles counts go

up, et cetera. Those studies weren't even Bair Hugger studies, first off. Those studies don't even comment on whether the particles were 10 microns in size or not. Those studies don't indicate that anybody even had an infection there. And what those studies will actually stand for, Your Honor, is the proposition that the more people you have in the room, then the more colony forming units and particles you have in the room, which the thrust of Darouiche and Stocks.

So the point is simply that the Court should take a hard look at the studies cited by plaintiffs because at the end of the day, given the role that the Court has as gate keeper to determine whether or not there's any plausible evidence to support the plaintiffs' causation contentions, were they airborne, air flow disruption theory, which they have to show by preponderance of the evidence as a proponent of that. And a lot of these particle studies don't get them there, Your Honor, even adding them all up, there is a reason that Samet, that Jarvis, Stonnington, collectively will talk about having seen hundreds of these studies, and when they come down to sort of what's the study that matters? They will say, as Samet did, that the only real world study that makes a positive association is McGovern is what he said.

So I just encourage the Court. It's in the record

from our proceedings back in October of 2017 to take a hard look at the studies. They don't stand for the proposition, at least we don't think so, that they were cited for by plaintiffs as proving that the Bair Hugger is somehow can be identified and isolated as the source of the air flow disruption, that they will take a contaminated particle and deposit it in a wound, in a surgery.

There was some discussion, Judge Ericksen, about the law and the standard. And I think the proposition was that epidemiology isn't even needed here, and it was a *Bonner* case cited for that. That *Bonner* case is not really inapposite case for the proposition only because that's a case where the plaintiff was doused with fire retardant and had an immediate acute reaction. And so there was no more need for epidemiology for causation in that instance than to need an epidemiologist and a study from a dog bite. It was so close in time, and the reaction was so acute that that was the proposition and premise that the Court was there citing.

Your Honor has heard enough about the Reference Manual and what it says about epidemiological studies, observational studies, when they are appropriate, and I won't repeat that, because I'm sure Your Honor has seen it and heard it. But the over-arching point was the *Bonner* case was a case of acute injury from a chemical exposure

when somebody was doused with fire retardant where you didn't need an epidemiologist for that.

I wanted to address a couple of the other points. There was quite a bit of discussion about whether even the McGovern authors considered the confounders to be confounders, and I don't remember the every word that was spoken but the thrust of it was that perhaps the authors weren't calling the confounders confounders or some other fuzzy language, potentialities or something that the --

THE COURT: Observing what every observational study observes, that there could be confounders.

MR. BLACKWELL: That was the proposition, right, so which would make it meaningless to say they were confounders if everything has confounders.

THE COURT: He said every observational study at some point has some language like that in it.

MR. BLACKWELL: Right, right, so it was said.

So here, the authors, this was in, has been referenced and it's in our papers here from a pilot study by Dr. Reed that's a fairly recent one, looking here for the date on it. It's a 2018, but it's a pilot study for RlliOs, and at page 7, it's Document 1850 in the record, where Dr. Reed is talking about McGovern. And where he says in characterizing the study where he was a senior author, "an observational study in one hospital over a two and a half

year period suggests that the risk of developing deep infection up to 60 days after surgery was substantially greater for patients treated with forced-air warming than resistant fabric warming." He says, "but there were significant confounding factors in the study." Now, which he, of course, said was a caveat.

And so the point with respect to Jeans and MSSA, there was a question about whether it's a confounder at all. And the thrust of the findings from Dr. Reed and others was in confirming its role as a confounder as another reason to be guarded about the results that were seen with respect to the McGovern study because it is such a fragile study on the statistical significance involved.

But here, again, it's a study author characterizing the result itself and where he's referring to not just confounders but whether they are significant confounders in the McGovern study, and that both relates to things like MSSA and amongst the confounders that Mr. Sacchet spent a good bit of time talking about. He didn't talk about MSSA itself found as the confounder in the mind of Dr. Reed and the study of Dr. Reed.

I wanted to, Judge, just clarify a couple of things with respect to Dr. Samet too because there's some question about whether Dr. Samet relied on Augustine 2017. So I thought I would show the Court his testimony that came

from his deposition where he's been asked about the McGovern paper. And it's, "Is the Bair Hugger a substantial cause of surgical site infections substantial to or to periprosthetic infections?" He says, "Only comment I could make is that there's now a second study, the Augustine report, with another, another estimate of the risk of this too. That's I think what I can say at this point." And went on to say "And you correct me if I'm wrong, but you, part of your opinion is based on your conclusions that the McGovern paper does not represent a false positive, is that correct?"

"Well, the McGovern paper is certainly part of the evidence that I considered, and to the extent that the P value is less than .05, that's a helpful indication that the results are not arrived by chance alone, and then of course since the McGovern paper, there's been a second report that essentially corroborates the findings in other hospitals." "Are you talking about Augustine publications?" "Yes, yes, I am." And then you see what he says at the bottom. "Two papers with quite similar findings, I think the strength of evidence from the epidemiological side has grown."

So I wanted the Court to see that for the frame of reference for how it is we said that Dr. Samet came to embrace the Augustine studies. He never disavowed that either to this day.

But if I could, the other, and so this one had to

do with the whole tabulation error where the issue was was that recognized as an issue on the McGovern study? And here is Dr. Reed who is being deposed on it. And he says, "So when I was reading this documentation yesterday and going through e-mails, it's clear to me that some of the data on the clinical side of the paper is wrong, slightly wrong. It doesn't affect the conclusion of the paper, and there's still a significant difference, but there is in fact one more infection in each group."

Now, this was e-mailed to Mark Albrecht, and he did reply to it, and in fact it's in your documents, the e-mail correspondence. And he goes on to say he put it in the main paper, et cetera.

So in talking about the tabulation error, I just want the Court to see that this is the frame of reference for it at the Reed deposition at pages 43 over to 44, where this acknowledged, and this is what we're saying that Dr. Samet certainly had knowledge of, and so he was aware of the tabulation error.

THE COURT: Did you make new slides over the break or is this in your packet?

MR. BLACKWELL: We did not make -- well, actually, this is one we just -- over the break, yes, that's in the record.

I'm sorry, Your Honor, just a moment.

THE COURT: The information is in the record but the PowerPoint is not in your packet.

MR. BLACKWELL: So it is all in the record, Your Honor.

THE COURT: Yes.

MR. BLACKWELL: So as to the theory that the Bair Hugger harbors bacteria and somehow emits it into the OR, it simply begs the question that where is the science that would show any bugs being emitted from what we heretofore refer to as the business end of the Bair Hugger. This has never been a there there. And it's one thing to talk about particles as proxies except in this instance where we know that the particles have never shown to be proxies for bacteria because they've never been able to culture any CFUs from the Bair Hugger.

So if I could just make a brief comment about this issue of statistical significance and their argument that statistical significance is not required, their argument is borne from the knowledge that given the confounders, that probably with respect to McGovern they don't have statistical significance so it's not required. The issue is not really so much a question of what is in the law.

It's a different question about sort of methodology apropos for Daubert, where is the evidence that an epidemiologist like Dr. Samet would be relying on a

nonstatistically significant study to reach conclusions, particularly when the conclusions he reaches don't purport with what the study authors have concluded, from a methodological point of view, is that what he does in the real world? And there's no evidence here that that is in fact what he does in the real world.

And, Judge, I wanted to just make a comment about Dr. Holford because there was quite a bit made about Dr. Holford, whether Dr. Holford saw studies, whether Dr. Holford did side studies. Dr. Holford. Judge, Dr. Holford was a biostatistician. He was involved in the case for crunching numbers. So to have Dr. Holford in a deposition asking him about things that would require a canvas of the available extant medical literature was not his role in the case and not anything he was asked to do, so, and I think a number of points that were made about whether he supports the view that the Jeans study undermines McGovern, et cetera, it's not what he was asked to do in the case. He's not even a testifying witness this Dr. Holford.

Give me just one moment, Your Honor. I think I'm just about going to sit down.

So ultimately, Judge Ericksen, given the plaintiffs' two theories here, the theory that the Bair Hugger disrupts the air flow in the operating room and then causes ambient particles that are contaminated to land in a

wound, still stand by on the general cause issue that there still isn't any known methodology. They haven't cited one either that allows someone to go back retrospectively to assess what the various air currents were in a room, how they would have interacted with one another to explain how a microbe would have been moved, transported in the room to have landed on a wound to cause an injury. Not the theoretical studies that particles can move, but how do you determine that on a specific cause basis? And if there isn't a methodology that they can cite that would allow you to do that, none of the studies do that, they're not specific cause studies at all for how we're going to go about that from a methodological point of view in a retrospective way, that that is still missing. It's still lacking. And to use those studies to say that those will provide the causal mechanism is still too great an analytical leap based upon what science currently today can do in the absence of any data in any case that will exist on the retrospective way. Thank you, Your Honor.

THE COURT: Did you -- if you just hold on one second. This France, what is this, the French government or something just said -- do you know what I'm talking about in the plaintiffs'? Mr. Sacchet was going through, he had France, he had some other I can't remember what.

MR. SACCHET: Plaintiff's Exhibit 64.

THE COURT: What slide is it?

MR. ASSAAD: Page 29.

MR. SACCHET: 29.

THE COURT: Yeah. So they've got French -- it's not the government. It's a French Society of Microbiologists, the Bone and Joint Center, something called "Orthopedic Surgeons." An organization called that I guess. So there's a I don't know what they are, professional associations or something, one called Orthopedic Surgeons, one called Bone and Joint Center, one the French Society of Microbiologists, is there anything you wanted to say about those?

MR. BLACKWELL: Other than you can't really tell where they begin or end from the snippets that I hear kind of of them. We do know of the ICM and how reputable it is, and both sides have agreed in that regard, but the French Society of Microbiologists is not internationally renown that we're aware of.

And in terms of they're not recommending the use of forced-air warming, I don't know what their full statement is, Your Honor, of what the French Society has said.

THE COURT: So what is this? This is under the ICM.

MR. BLACKWELL: It's under the heading of the ICM

fourth fallacy in the plaintiffs' slides, but this is not a part of the ICM.

THE COURT: What about the organization called Bone and Joint Center? Oh, never mind, I see Bone and Joint Center within Baylor, Scott and White in Temple, Texas.

MR. BLACKWELL: And this is a quote from something. This isn't a study.

THE COURT: I see, I see.

MR. BLACKWELL: And so a great deal of this is just antidotal pieces that have been cut out with a scissors and a paste pot and put on a document. What else can an e-mail be just that's under the heading Bone and Joint Center. So it --

THE COURT: Okay.

MR. BLACKWELL: All right.

THE COURT: All right. Thank you.

Mr. Sacchet, you look like you have another thought.

MR. SACCHET: I'll be brief, Your Honor.

In terms of whether these exhibits are a paste pot or whatever the term was, they are founded in internal documents that 3M produced in this litigation. So this is an e-mail from a 3M employee Thomas Henne to Jill Rector discussing the French Society of Microbiologists' conclusion. 3M has had this document since 2015.

This is the Bone and Joint evidence, which derives again from an internal 3M e-mail from Jay Issa to others in 2016.

THE COURT: You're not relying on the actual studies -- I don't know if these are purported to be studies or what they are. I thought when you put it on that slide with the ICM, I thought you were talking about actual studies. And I wasn't familiar with those actual studies, which is why I asked that. So are these or are these not studies?

MR. SACCHET: So I say two studies right below ICM which were Tsai and Moretti that expressly say increased risk of infection; and the second page of the slide the statement from orthopedic surgeons and other entities from around the world that have reached the same conclusion such as the French Society of Microbiologists.

THE COURT: But you get that out of --

MR. SACCHET: From 3M's documents.

THE COURT: So it's on -- I see, this is not a study that the ICM looked at.

MR. SACCHET: No.

THE COURT: This is just whatever it is. Okay.

MR. SACCHET: I'll just go very quickly through some of the points that Mr. Blackwell raised.

THE COURT: We don't actually have rebuttal

rebuttal, but go ahead. I am interested in what you have to say but just bare in mind that --

MR. SACCHET: Is there anything in particular that you would like me to address?

THE COURT: No, but you have something that you want to say.

MR. SACCHET: Yes, just very quickly. One, Mr. Buck's report did show that there were greater than 10 micron sized particles leaving the blanket.

Two, the Avidan study had attempted to show no bacteria from the blanket involved two trials and still concluded that there was an increased risk of infection from Bair Hugger.

Three, the Stocks 2010 study does say that particles from 5 to 10 microns and 10 microns and greater can be correlated with bacteria.

Four, the Bonner study says what it says. It's black letter law that epidemiology is not necessary for causal inference. *In Re Heparin*, *In Re Meridia* and even *in Glastetter* case that 3M cites in its own papers acknowledged as much.

The RlliO pilot study that Mr. Blackwell brought up and is not a published study. It's merely a protocol. It has no scientific citation for the proposition of confounding. It simply states it in ipse dixit.

Again, Dr. Samet published or assigned his report before the Augustine 2017 study. As to the tabulation error that Mr. Blackwell brought up, noted by Dr. Reed, even if there were a difference of one infection in both arms of the study, it doesn't change either the statistical significance or the clinical significance of the study. It's still a 2.8 odds ratio. It's still a P value of .04. That can be found in footnote one of 3M's own expert report from Dr. Holford.

Statistical significance, it's not required. There are numerous cases saying that. Dr. Samet did not do what the McGovern authors say can't be done, and there's no evidence of that.

With respect to Dr. Holford himself, the argument that he was only put up to do number crunching I think as it was said is not true --

THE COURT: Dr. Holford?

MR. SACCHET: It's just not true. His report, which I've read 20 times, deposed the guy, he went way out, and he was asked about causal inference and everything about it, and 3M asked him to opine whether there could be evidence of causation and he has conclusions about it. So he was not put up solely as a biostatistician. I asked him at the deposition if he was also practicing epidemiology, he said yes. So that's not true.

There was a little bit of confusion, I didn't

totally understand the argument, but it sounded like 3M is suggesting that Holford was the one who testified about the import of Jeans. That's not true. It was --

THE COURT: He said he's not a testifying expert.

MR. SACCHET: It's Dr. Borak though who we deposed about the Jeans study, not Dr. Holford. Dr. Borak, who is the same epidemiologist that testified at the Gareis trial is the one we deposed about the Jeans study. He's the one who originally published a report in the *Trombley* case saying that Jeans did confound and then totally 360 and said it doesn't prove confounding. So that's not about Dr. Holford. That's Dr. Borak.

And, finally, just to be clear with respect to specific causation, Drs. Jarvis and Dr. Stonnington in their case specific reports have offered two different pathways for it. One is the doubling of the risk for McGovern, and the other is Darouiche and Stocks plus the mechanistic studies regarding particle contamination. There are two independent ways to deal with the question of specific causation, and that's all I have for Your Honor.

THE COURT: All right. All right.

MR. BLACKWELL: Your Honor, just one point I just forgot to point out when I was standing here before. And this was on the issue about whether the data in McGovern were complete prior to July 2008 when it started, and I

think that Mr. Sacchet said the data wasn't complete data and that's why the study --

THE COURT: Is this on your point about how if the date had been moved back? Okay.

MR. BLACKWELL: Right, right. And I just wanted to point out to the Court here in the Jeans study itself, the Court can see here that here again is Dr. Reed talking about the data. The data obtained for procedure performed age, gender, body mass index, American Society of Anesthesiologists, physical status, et cetera. And he goes on to say, "infection monitoring has been performed with complete data available from prior to screening program that is from the 1st of January of 2007 to December 31, 2009, and after its introduction from the 1st of January 2010 to the 31st of August, 2014."

So I point this out because the McGovern data is lesser-included data in Jeans, and so this data is being used in the Jeans study. He does describe it as complete data, and we do know that had that data been included and used in the McGovern study, there would not have been a positive statistical association in the first place in McGovern, but he was just pointing out that Dr. Reed himself the author of both studies is saying that there was complete data available, and this is on page 2.

Thank you, Judge.

THE COURT: Okay, as long as you're up there, how long do you need to respond to the offer of this science direct, a couple of them, the American Journal of Infection Control, this summary? The research article, Court Exhibit 2, and this article from 2016 article. How long do you need to take the position on that?

MR. BLACKWELL: We think Friday, Your Honor.

THE COURT: Okay. All right. Mr. Sacchet?

MR. SACCHET: Just very briefly, Your Honor. As to this idea that the Jeans study shows that the McGovern study is incomplete, the key term that Mr. Blackwell I think mentioned but didn't emphasize is that the Jeans author used the phrase "complete available data." It doesn't mean that it was complete data. It means that they had complete available data and that's exactly why --

THE COURT: What's the difference?

MR. SACCHET: At Dr. Reed's deposition, he was asked the question, "Did you just start collecting that data on July 1, 2008?" Answer: "That's when we went to full-time surveillance. We had part-time surveillance before then."

In Dr. Borak's deposition, we confronted him with that fact, and Dr. Borak was uncertain whether given that phrase in the Jeans study, that that proved that there was complete data prior to July 1st, 2008, as Dr. Reed stated at

his deposition. Dr. Holford, when I deposed him, said the same thing, I will concede that the start date was July 1, 2008, based on Dr. Reed's statement sworn testimony saying that's when it started. So at best, there's a dispute of fact. It is not proof that the McGovern study could have included robust, full data prior to July 1, 2008.

And that's one of the reasons in which plaintiffs' experts criticize the Jeans study because prior to that date from January 1, 2007, to July 1, 2008, Northumbria wasn't collecting full data.

THE COURT: Anything else? Yes? No? Okay, all right.

Well, I'll hear from you on Friday. And I'll hear from plaintiffs if there's anything they want to say in response to that by Wednesday. Obviously, if you can work out whether it's admissible or not, let me know.

But other than that, thank you very much for these excellent arguments. I'll take it under advisement. We are in recess.

(Court adjourned at 3:10 p.m.)

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REPORTER'S CERTIFICATE

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