UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Louis Gareis & Lillian Gareis,
Plaintiffs

v.

Case No. 16-cv-4187 (JNE/FLN)
ORDER

3M Company &
Arizant Healthcare, Inc.,
Defendants.

The above-captioned case is a member case in the MDL *in re Bair Hugger Forced Air Warming Devices Products Liability Litigation*, 15-md-2666. It is scheduled to be the first member case tried. On May 4, 2018, the Court heard oral argument on the parties' Motions to exclude evidence. The Court decided some of those Motions on the record. The Court now decides the rest.

I. Defendants' Motion [135] to exclude evidence about bacteria in the Bair Hugger system's filter or on its internal surfaces

The Plaintiffs advance two theories of causation. One is that the operation of the Bair Hugger disrupts operating room airflow and causes ambient bacteria to be deposited into the surgical site or onto the prosthetic joint. This theory will be tested at trial. A second theory of causation is that the Bair Hugger itself harbors bacteria, and that these bacteria escape the warming unit during surgery. Defendants have moved to exclude from the *Gareis* trial evidence pertaining only to this second theory. For the following reasons that motion is granted.

Mr. Gareis's infection was caused by *Staphylococcus epidermidis*, bacteria that are "common organisms found on the skin of humans," Jarvis Rpt. 4, Dkt. No. 253-1, humans including the patient and operating room personnel. *See also* Avidan et al.,

Convection warmers – not just hot air, 52 Anaesthesia 1073 (1997) (describing *Staphylococcus epidermidis* as "typical of skin flora"), *cited in* Jarvis Rpt. 9. Humans shed skin flakes, also known as squames. According even to Plaintiffs' expert Dr. Said Elghobashi, "for the five persons (four medical staff and the patient) in the [operating room] a realistic number would be about 105 million squames per hour." Elghobashi Rpt. 12, Dkt. No. 106-5. So, this shedding would carry many colony-forming units of *Staphylococcus epidermidis*. Plaintiffs have no evidence that however many *Staphylococcus epidermidis* might be in the Bair Hugger, that that number would have a meaningful impact on the bacterial load of that pathogen in the operating room.

The Bair Hugger, of course, does not sit passively during an operation. It blows air out of small holes in its blanket. The blanket is not placed directly onto or near the prosthetic joint, however, and so even if *Staphylococcus epidermidis* were to escape the blanket, it would not be deposited directly onto the prosthetic joint or into the surgical site. More importantly for purposes of disposing of the current motion, however, Plaintiffs have no evidence that anyone has caught colony-forming units of bacteria floating out of the blanket's perforations. There *is* empirical evidence that particles, especially small particles (less than 5 microns, Buck Rpt. 16, MDL Dkt. No. 315-2), can escape the perforations. *But see* Elghobashi Rpt. 2 ("The squame particle size ranges over 4-20 μm of equivalent diameter." (citation omitted)), Dkt. No. 106-1. Plaintiffs maintain that particles stand in as a proxy for bacteria. *See* Gregory W. Stocks, et al., *Predicting bacterial populations based on airborne particulates: a study performed in nonlaminar flow operating rooms during joint arthroplasty surgery*, 38 Am. J. Infect.

Control 199 (2010) (analyzing operating room air during surgery and finding correlation between 10-µm particles and colony-forming units), *cited in* Jarvis Rpt. 15.

Perhaps so, but no expert brought to the Court's attention has tested the air coming out of a Bair Hugger's blanket and discovered escaping colony-forming units. This test would be feasible; it is certainly not cutting-edge. Stocks et al. 200 (measuring "airborne viable bacteria . . . using an impact sampler"); *see Polski v. Quigley Corp.*, 538 F.3d 836, 840 (8th Cir. 2008) (emphasizing lack of testing, when affirming exclusion under Fed. R. Evid. 702, because "theory could have easily . . . been tested"). Given the resources Plaintiffs have spent on generating expert testimony for this case, this test's absence is curious. Instead, scientists relied on by the Plaintiffs have cultured air from the Bair Hugger's internal hose. They have examined Bair Huggers in operation. They have not, however, shown any pathogen coming out of the "business end" of the Bair Hugger—the perforated blanket. No examination was conducted of the Bair Hugger that was used in the surgery Mr. Gareis claims caused his infection.

As proponents of this evidence, Plaintiffs have failed to meet their burden. The evidence's relevance "depends on whether a fact exists": that is, whether colony-forming units escape the Bair Hugger's perforated blanket. *See* Fed. R. Evid. 104(b). Plaintiffs have not, as they must, introduced sufficient proof "to support a finding that the fact does exist." *Id.*

But even if they did so, Plaintiffs' own experts report facts that show that second theory would involve "undue delay." *See* Fed. R. Evid. 403. Even if the Bair Hugger adds an apparently undetectable amount of *Staphylococcus epidermidis* to the operating

room, that marginal addition would be swamped by the *Staphylococcus epidermidis* that Plaintiffs' experts report is already there. As has already been noted, Plaintiffs proffer no evidence to the contrary. For evidence supporting only the second causation theory, that evidence's "probative value is substantially outweighed by a danger of . . . undue delay." *Id.*

II. Gareis's Motion [Dkt. No. 214] to exclude evidence about alternative causes

Plaintiffs seek exclusion of Defendants' expert testimony as to alternative causes. Those experts, including Dr. Michael Mont, opine, among other opinions, that many things disrupt or heat operating room airflow and that surgical records imperfectly reflect what happened before, during or after surgery.

This Motion is DENIED because Mont's testimony is based on sufficient facts and Defendants other experts may rely on Mont. *See Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017) (reversing exclusion because, though untrained in geology, engineer could apply his methods to data geologist derived); *Hartley v. Dillard's, Inc.*, 310 F.3d 1054, 1061 (8th Cir. 2002) ("Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded."). Mont bases his opinion on scientific Publications, his experience as an orthopedic surgeon, and the depositions of Mr. Gareis's treating physicians.

As to disruption or heating of operating room airflow, Defendants' expert Michael Mont lists operating room features that generate heat and airflow comparable to what a Bair Hugger system would do. Mont Gen. Rpt. 9-11, MDL Dkt. 798-10. He can list these features based on his experience as a surgeon who has done "joint replacement

surgeries . . . a total of over 15,000 since 1990." *Id.* at 2.

As to surgical records, Mont testifies only that these records are imperfect—not that any particular unrecorded event is likely. Mont Spec. Rpt. 11 ("During surgical procedures, numerous unexpected events occur which could lead to infection, but those frequently are not documented."), Dkt. No. 55-1 (Ex. 5). As a surgeon, he is familiar with medical records generated before, during and after surgery. He may likewise testify about what that can reasonably be concluded from surgical records.

III. Defendants' Motion [Dkt. No. 155] to exclude evidence about heater-cooler devices

Defendants move to exclude evidence about heater-cooler devices. Heater-cooler devices are used in cardiothoracic surgery. They can work with heart-lung machines, which exchange heat between the patient's blood, circulated extracorporeally, and water pumped from a heater-cooler device. Some heater-cooler devices store their water in a tank such that the operating room air and water interface within the tank. Within those devices, moving parts, including the pump and a fan, can agitate the air-water interface. If *Mycobacterium chimaera* bacteria are growing in the tank near that interface, they could be aerosolized by this agitation. The Court excludes evidence about this device because it is irrelevant and any probative power would be substantially outweighed by the danger of undue prejudice.

Heater-cooler devices have no tendency to prove that the Bair Hugger caused *Staphylococcus epidermidis* to infect Mr. Gareis's prosthetic joint during his hip-replacement surgery. *See* Fed. R. Evid. 402. Although heater-cooler devices are involved in maintaining normal body temperature, they do not, as Plaintiffs argue, "heat[]

a blanket over the patient." Dkt. No. 247, at 2. Although heater-cooler devices have fans, which could possibly disrupt operating room airflow, those fans were problematic because the devices also had an air-water interface that allowed bacteria aerosolization. At bottom, the heater-cooler is a different device for a different surgery, a device that delivered a different pathogen through a different means.

The Court excludes evidence about the heater-cooler devices also because, for that evidence, the danger of undue prejudice substantially outweighs probative value. Fed. R. Evid. 403. The evidence is weakly probative, if at all, as explained above. But worse, Plaintiffs' expert William Jarvis intends to use the heater-cooler device to show that an absence of evidence is not evidence of absence. *See* Jarvis. Gen. Rpt. 23 ("Furthermore, this outbreak illustrates that such devices can be used for long periods of time (decades) and . . . the [outbreak's] source will remain unknown."). This use invites the jury to speculate and to thus relieve Plaintiffs of their burden of proof. The jury may not find Defendants liable based on an absence of evidence. Although absence of evidence might not be evidence of absence, it is certainly not admissible evidence of presence.

IV. Gareis's Motion [Dkt. No. 206] to exclude FDA evidence

Plaintiffs move to exclude evidence about the Bair Hugger's FDA clearance and about an August 2017 letter from the FDA. The FDA cleared the Bair Hugger for marketing, based on the Bair Hugger's substantial equivalence to devices already on the market. Later, the FDA issued a Dear Health Care Provider Letter. In this Letter, the FDA wrote that it was "unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection." FDA Ltr., Dkt.

No. 207-1. It concluded so after "a thorough review of available data." *Id.*

This Motion is granted as to the Bair Hugger's clearance and the Letter because, for this evidence, the probative value is substantially outweighed by the dangers of undue prejudice and delay. Fed. R. Evid. 403. Probative value is weak. Although the FDA might have considered safety when it cleared the Bair Hugger, it did not consider Plaintiffs' surviving theory of causation. *See* Opp'n 4 (arguing that FDA considered "susceptibility to excessive temperature, rain, humidity, strong electromagnetic interference, electrical shocks, shocks and vibrations. . . . and risk of causing burns"), Dkt. No. 231. Recall that Plaintiffs seek to prove that the Bair Hugger disrupts operating room airflow and caused ambient bacteria to infect Mr. Gareis's prosthetic joint. The Bair Hugger's clearance is thus irrelevant because Defendants have not offered sufficient proof that, when clearing the Bair Hugger, the FDA considered Plaintiffs' surviving causation theory. Fed. Rs. Evid. 104(b), 402.

In writing the Letter, posted less than a year ago, perhaps the FDA considered Plaintiffs' theory but the Court cannot tell from the Letter whether the FDA did so. But even if it did so, it could not have considered Dr. Elghobashi's analysis supporting that theory. Elghobashi published his analysis after the Letter was posted. Without this consideration, the Letter is only weakly probative.

Both clearance and the Letter pose a danger of undue prejudice. If admitted, they could allow Defendants to swaddle the Bair Hugger in the FDA's imprimatur. The jury could be tempted to defer to the FDA instead of doing the difficult task of weighing the parties' scientific and medical evidence. The Letter, in particular, simulates expert

testimony but lacks the safeguards. Because its sources, methods and analysis are hidden, Plaintiffs could be unable to effectively rebut it.

V. Gareis's Motion [Dkt. No. 212] to exclude evidence about Defendants' Other Acts or Products

This Motion is GRANTED because evidence about Defendants' corporate life story is not germane to strict liability. Fed. R. Evid. 404(a)(1). Evidence tending to show that Defendants are or were good or bad corporations cannot be used by the jury to decide whether the Bair Hugger system is a good or bad product.

Conclusion

For the reasons above, the Court has decided the parties' Motions to exclude.

IT IS SO ORDERED.

Dated: May 14, 2018

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge