

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: BAIR HUGGER FORCED AIR
WARMING DEVICES PRODUCTS
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

ORDER

This Document Relates to All Actions.

In judicial districts across the nation, Plaintiffs have sued Defendants 3M Company and Arizant Healthcare Inc. These lawsuits have been transferred or consolidated into this multidistrict litigation for pretrial. Generally, Plaintiffs allege that Defendants' Bair Hugger Forced Air Warming Device ("the Bair Hugger") caused their deep-joint infections as a sequela to orthopedic-implant surgery. Some Plaintiffs have sued alleging other surgical infections related to the Bair Hugger. The Bair Hugger, a device for keeping surgical patients warm, has a central unit, hose and blanket. The central unit draws in operating-room air through an inlet filter. It then heats and forces that air through the hose. The hose feeds the forced air into passageways within the blanket. During surgery, the blanket covers the patient's torso, with perforations facing the patient. The forced air then exits the blanket through these perforations, thereby transferring heat to the patient.

Plaintiffs allege theories about how the Bair Hugger's forced-air warming can cause deep-joint infection. After warming the patient, the Bair Hugger's forced air flows into the operating room at large. Because this effluent forced air is warmer than the air-conditioned operating-room air, it convects. This convection stirs the operating-room air,

allegedly lifting squames (skin flakes shed from people) and preventing them from safely settling away from the surgical wound. The parties agree that squames can carry skin bacteria, some of which can cause deep-joint infection. Plaintiffs also have a theory about bacteria that reside within the Bair Hugger's central unit or hose. These bacteria allegedly get out riding the forced air, thereby increasing the bacterial threat within the operating-room air.

The parties have moved to exclude expert testimony about whether the Bair Hugger can cause deep-joint infection. Defendants move to exclude Plaintiffs' engineering experts Said Elghobashi, Daniel Koenigshofer, Michael Buck and Yadin David. Dkt. No. 794. Defendants move to exclude David's regulatory opinions separately. Dkt. No. 758. Defendants also move to exclude Plaintiffs' medical experts Jonathan M. Samet, William Jarvis and Michael J. Stonnington. Dkt. No. 745. Plaintiffs move to exclude Defendants' rebuttal experts John Abraham, Dkt. No. 821, Jonathan B. Borak, Dkt. No. 778, Jim Ho, Dkt. No. 733, Alexander A. Hannenberg, Dkt. No. 727, Theodore R. Holford, Dkt. No. 801, Antonia Hughes, Dkt. No. 826, Michael Keen, Dkt. No. 738, Thomas Kuehn, Dkt. No. 787, Samsun Lampotang, Dkt. No. 743, Michael Mont, Dkt. No. 796, Gary Settles, Dkt. No. 832, Timothy Ulatowski, Dkt. No. 755, and Richard Wenzel, Dkt. No. 812. The Court heard oral argument at an October 24-26, 2017 hearing. The Court DENIES the Motions, except for Defendants' Regulatory Motion about David, which the Court GRANTS IN PART and DENIES IN PART. The Court also denies Defendants' dependent Motion for Summary Judgment, Dkt. No. 759.

Under Federal Rule of Evidence 702, the Court need only exclude expert testimony that is so fundamentally unsupported that it can offer no assistance to the jury.

Expert testimony is governed by Rule 702. The expert-testimony proponent must prove facts supporting admissibility as more likely than not. *Polski v. Quigley Corp.*, 538 F.3d 836, 841 (8th Cir. 2008). Under Rule 702:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

If relevant and reliable, a qualified expert’s testimony need not be excluded. *Children’s Broad. Corp. v. Walt Disney Co.*, 357 F.3d 860, 864 (8th Cir. 2004). “Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.” *Id.* at 865.

The opponent’s “full opportunity to cross-examine” and to “present[] expert testimony to rebut” weighs in favor of admission. *See id.*; *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 932 (8th Cir. 2001) (“[Once the] methodology was scientifically valid, the scientific questions were best addressed by allowing each side to present its experts . . . to the jury.”). Better than exclusion at the threshold, these trial tools address issues that can go to how the jury should weigh the testimony or whether the jury should believe the expert. *Children’s Broad.*, 357 F.3d at 864-65 (affirming admission when trial court ruled that opponent’s objections “were better directed to the weight of the testimony rather than admissibility”). The Motions are disposed of below, by expert.

Said Elghobashi

Plaintiffs' expert Elghobashi opines that the Bair Hugger's forced air convects particles ten microns in diameter from just above the operating-room floor to the surgical wound. Elghobashi Rpt. ll. 825-27. The parties agree that, because ten-micron particles include squames, these particles can carry enough bacteria in a permissive package to cause a deep-joint infection if, during surgery, they reach the prosthetic joint. *See* Defs.' Mem. Excl Pls.' Eng'g Experts ("Eng'rs Mem.") 32 (diminishing expert's finding because "he found few, if any, particles larger than 5 μ m, and even fewer over 10 μ m."). Elghobashi simulates the Bair Hugger's forced air in a model operating room by large-eddy simulation, the reliability of which Defendants concede. Elghobashi Rpt. ll. 832-33; *see* Eng'rs Mem. 55 (conceding "that CFD[, or, computational-fluid dynamics,] evidence can be admissible, if properly supported by reliable boundary conditions."). To simulate the Bair Hugger's alleged operating-room convection, Elghobashi had to learn about the device. First, by watching Defendants' videos and reading their internal documents, he learned how hot the forced air leaves the device's blanket. Eng'rs Mem. 40. Then, while he observed an active Bair Hugger, "he simply ran his hand under" its blanket to learn where the forced air comes out. *Id.*

Defendants challenge Elghobashi's testimony under Rules 702 and 403. They argue that Elghobashi speculated about how hot and where the Bair Hugger's forced air enters the operating room at large. They also argue that his simulated images are unduly prejudicial and likely to confuse the jury because the images could seem to show bacteria invading the surgical wound and because the images were simulated. *See* Fed. R. Evid.

403.

Elghobashi's testimony is admissible. Elghobashi has tested his opinion by simulation, the physics of which Defendants concede is reliable. As for the simulation's inputs, Elghobashi's testimony is not so fundamentally unsupported that it can offer no assistance to the jury. Elghobashi may rely on Defendants' representations. *Bonner*, 259 F.3d 924, 931 (affirming admission when expert relied on opponent's "consumer information"). And generally, the credibility of an expert's basis goes to weight. So too here. Elghobashi has bases for how hot and where the Bair Hugger's forced air goes; the jury may weigh his testimony as it believes those bases. Defendants may back away from their representations in rebuttal. They may cross-examine Elghobashi to test what, exactly, he felt with his hand during his observations. They may contradict Elghobashi's inputs by presenting their own fluids expert Abraham, see below. The Court thus DENIES Defendants' Motion as to Elghobashi because his testimony meets Rule 702.

Elghobashi's testimony is not unduly prejudicial or likely to confuse the jury. Elghobashi consistently describes his simulated particles as squames, not bacteria, *e.g.*, Elghobashi Rpt. 1.815, and, anyway, Defendants have conceded that ten-micron particles can be dangerous. Defendants have also conceded the physics of large-eddy simulation, so objections to the simulation as simulation are without merit. The Court thus DENIES Defendants' Motion as to Elghobashi also because his testimony does not offend Rule 403.

Daniel Koenigshofer

Plaintiffs' expert Koenigshofer opines that the Bair Hugger detracts from air quality in the operating room and at the surgical wound, thus increasing infection risk. Koenigshofer Rpt. 23. Among other qualifications, Koenigshofer wrote a chapter about "Infection Control" in a published book about operating-room design. *Id.* at 2. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) selected him to be this chapter's author. *Id.* Koenigshofer relies on Elghobashi's testimony, among other sources, and describes what this testimony means for infection risks in the operating room. *Id.* at 20. He adds that the Bair Hugger can suck in particles from the air near the operating-room floor, citing a 1968 study to note that some of these particles can carry bacteria. *Id.* at 21-22. To say that squames can be near the floor, he cites an ASHRAE figure, which says that a ten-micron particle takes 8.2 minutes to settle five feet in still air. *See id.* fig.5. Defendants object that Koenigshofer is unqualified and has insufficient factual basis.

Koenigshofer's testimony is admissible. Defendants do not dispute Koenigshofer's published book chapter about operating-room infection, which appears to qualify him for his testimony's scope. *Cf. Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001) (reversing admission of warehousing testimony because, although expert had dealt with other facilities, he had never published about, worked for or studied warehouses). And Koenigshofer's testimony is not so fundamentally unsupported that it can offer no assistance to the jury. Defendants do not dispute that the Bair Hugger's central unit sucks in operating-room air

and can sit on the operating-room floor. They do not attack the ASRAE figure. And they only object to the 1968 study's age. The jury may decide whether to believe that study. Likewise, Defendants may contradict it with their particle expert Ho's testimony, see below. The Court thus DENIES Defendants' Motion as to Koenigshofer because his testimony meets Rule 702.

Michael Buck

Plaintiffs' expert Buck opines that the Bair Hugger emits particles, some of which are ten-micron particles. Buck Rpt. 16-17. By measuring what comes out of a Bair Hugger's blanket when the device is on with a commercially available particle counter, Buck counts emitted particles by size. *Id.* at 14. He adapts a plastic storage container to capture the device's post-blanket forced air. Before counting particles, he sets his particle counter to "a zero point [by] zeroing the machine." Buck Dep. 203:16-18. Defendants object that Buck's testimony is irrelevant because he did not sterilize the container before counting particles and because he did not measure bacteria directly.

Buck's testimony is admissible because it is not so fundamentally unsupported that it can offer no assistance to the jury. Buck zeroed his particle counter, which should reduce background from his container, sterilized or not. If he should have done a more thorough test, that issue goes to weight, not admissibility. Defendants may cross-examine Buck and may submit rebuttal about whether zeroing is adequate. And Buck's lack of bacterial testing is harmless because he found some ten-micron particles. Defendants argue that these particles are experimental artifacts. With the benefit of adversarial presentation, the jury may decide whether to credit this argument or,

alternatively, accept Buck's testimony for what he says. The Court thus DENIES Defendants' Motion as to Buck because his testimony meets Rule 702.

Jonathan M. Samet

Plaintiffs' expert Samet opines that, compared to warming devices that warm patients through modes other than forced air, the Bair Hugger increases the risk of deep-joint infection from orthopedic-implant surgery. Samet Rpt. 4. He cites an observational study that found a drop-off in these infections over time at a hospital. *Id.* at 11 (citing McGovern et al, *Forced-Air Warming and Ultra-Clean Ventilation Do Not Mix: An Investigation of Theatre Ventilation, Patient Warming and Joint Replacement Infection in Orthopaedics*, 93 J. Bone Joint (Br.) 1537 (2011) [hereinafter the *Observational Study*]). At the *Observational Study*'s hospital, the drop-off happened when the hospital discontinued using the Bair Hugger. To ascribe that drop-off to this discontinuation, and not alternative explanations, Samet draws on Elghobashi's testimony, buttressed by scientific publications. Samet relies on Elghobashi for a mechanistic, causal link between the drop-off and discontinuing the Bair Hugger. *E.g.*, Samet Rpt. at 15-16. Recall that, Elghobashi simulates, using accepted physical principles, how the Bair Hugger could convect squames to the surgical wound. To Samet, this physics-based simulation justifies pointing to the Bair Hugger, instead of alternative explanations, as the cause of the observed hospital's high rate of deep-joint infections while it was using Bair Huggers to warm patients. Defendants argue that the *Observational Study* is not scientifically convincing and that Elghobashi's testimony about convection is too unreliable to support Samet's causal inference.

Samet's testimony is admissible. First, Defendants acknowledge the drop-off in infections; they dispute why the drop-off occurred. *See* Defs.' Mem. Excl. Pls.' Med. Experts ("Med. Experts Mem.") 22, Dkt. No. 750. But the Court may not exclude expert testimony for disagreeing with a conclusion about why something happened. *See Smith v. BMW N. Am., Inc.*, 308 F.3d 913, 920 n.9 (8th Cir. 2002) (reversing exclusion for "attack[ing] . . . conclusion"). Second, to support his causal inference, Samet relies on, among other things, Elghobashi's testimony about Bair Hugger convection. Samet may rely on admissible expert testimony. Elghobashi's testimony is admissible, *see* above. Samet thus may rely on Elghobashi's testimony. Defendants apparently concede that, once admitted, Elghobashi's testimony is sufficient to support Samet's causal inference. *See* Med. Experts Mem. 24. And anyway, Samet need not rule out every alternative explanation for the observed hospital's drop-off in infections. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 563 (8th Cir. 2014) (reversing exclusion because "we have consistently ruled that experts are not required to rule out all possible causes"). In rebuttal, Defendants may propound those alternative explanations by offering Borak's and Holford's testimony, *see* below. The Court thus DENIES Defendants' Motion as to Samet because his testimony meets Rule 702.

William Jarvis

Plaintiffs' expert Jarvis opines that, when used during surgery, the Bair Hugger can contaminate the surgical field with microorganisms and thus lead to infection. Jarvis Rpt. 14, 24. Defendants argue that Jarvis contradicts his pre-litigation work and that his testimony falls below the intellectual rigor with which he did that work. Specifically,

Jarvis used to think that a patient's endogenous bacteria, bacteria living on and within a patient's body, caused most surgical infections. Defendants also incorporate their arguments against Samet's testimony.

Jarvis's testimony is admissible. Jarvis may update his opinion to reflect a new understanding. *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 627 (8th Cir. 2012) (reversing exclusion for conflict with previous testimony because expert "now offers a more nuanced opinion"). Jarvis now understands that "a tremendous number of interventions have been applied to patients to reduce the endogenous flora." Jarvis Dep. 155:22-25. That understanding is based on at least one intervention that Defendants' experts endorse. *Compare* Jarvis Dep. 156:6 (testifying that "improvement of prophylactic antibiotics" reduced importance of the patient's endogenous bacteria), *with* Borak Rpt. 7 (suggesting that "prophylactic antibiotics" could confound the *Observational Study*). And, even if Jarvis has done a less thorough study here than he did in the past, thoroughness goes to weight, not admissibility. To reveal this putative lack of thoroughness to the jury, Defendants may cross-examine Jarvis. The Court thus DENIES Defendants' Motion as to Jarvis because his testimony meets Rule 702.

Michael J. Stonnington

Plaintiffs' expert Stonnington opines that the Bair Hugger increases the risk of infection from orthopedic-implant surgery. Stonnington Rpt. 3. Defendants argue that Stonnington impermissibly relies on undisclosed experience from his medical practice. Defendants also incorporate their arguments against Samet's testimony.

Stonnington's testimony is admissible. Stonnington duplicates the admitted

testimony of Samet and Jarvis, and he throws in “my own observations” to add context. *See* Stonnington Rpt. 3, 6 (“I have ceased using Bair Hugger devices in my practice.”). The Court thus DENIES Defendants’ Motion as to Stonnington because his testimony meets Rule 702.

Yadin David

Plaintiffs’ expert David opines that the Bair Hugger is unreasonably dangerous, after an analysis that involves taking apart a Bair Hugger, reading scientific publications and reviewing Elghobashi’s, Samet’s and Jarvis’s testimony. Beyond the Bair Hugger itself, David also opines about Defendants’ mental state while they did things related to the Bair Hugger. *E.g.*, David Rpt. 44 (“Defendant willfully failed to meet its obligations. . .”). During his career, David has chaired “the Medical Technology Evaluation Committee” at a hospital, “which was responsible for evaluating technologies deployed at the point-of-care.” David Rpt. 4. David has also advised the FDA about 510(k) clearance of medical devices, the same pre-marketing clearance the Bair Hugger has. *See id.* at 3. Defendants object that David is unqualified, that he reviewed scientific publications in biased way, and that he is unfamiliar with the Bair Hugger’s filter. Specifically, David did not know the shape of an older model’s inlet filter and he did not know that the Bair Hugger’s inlet filter meets an operating-room standard for screening airborne particles.

David may not testify about Defendants’ subjective mental state because that testimony is unqualified and unhelpful. *See Nichols v. Am. Nat. Ins. Co.*, 154 F.3d 875, 883 (8th Cir. 1998) (reversing admission because expert testified about a “question at the

heart of the jury's task"). David is not a psychologist, and even if he were, expert testimony about a subjective mental state would impermissibly invade "the heart of the jury's task." Expert testimony about Defendants' subjective mental state is excluded; the Court accordingly GRANTS IN PART Defendants' Regulatory Motion as to David.

The rest of David's testimony is admissible. Even if David's experiential qualification is superficial, that issue goes to the depth, not the scope, of his expertise. Qualification depth goes to weight, not admissibility. To the contrary, the scope of David's testimony is supported by his experience at his hospital and with the FDA. Defendants may alert the jury to what they see as this experience's superficiality by cross-examining David. Likewise, if manifested in David's scientific-publication review, bias goes to weight, not admissibility. Defendants may present their own experts' scientific-publication reviews, see below, in contradiction. And if David is unfamiliar with the shape of the inlet filter on an older model of the Bair Hugger, that unfamiliarity goes to weight, not admissibility, because it suggests only that David's study was not as thorough as it could have been. Finally, even if David ignored that the Bair Hugger's filter met an operating-room standard for screening airborne particles, the parties dispute whether this standard applies to patient-warming devices. With the benefit of adversarial presentation, the jury may decide between the parties' competing theories on this issue. The Court thus DENIES Defendants' Engineering Motion and DENIES IN PART Defendants' Regulatory Motion as to David because his testimony generally meets Rule 702.

John Abraham

Defendants' expert Abraham critiques Elghobashi's testimony, and supports this critique with his own simulation and a scientific-publication review. Abraham's simulation is Defendants' purported worst-case scenario. For example, the simulation assumes that, as suspended in operating-room air, particles have no mass. Abraham Dep. 227-28. Because "Particles have a mass that is higher than their surrounding air, so particles like to settle out of the air," assuming no mass simulates the worst-case scenario. *Id.* at 227:18-20. To illustrate his critique beyond simulation, Abraham used a fog machine to spew visible particles into an operating room with an active Bair Hugger. Abraham Rpt. 10. To further illustrate his critique, Abraham criticizes other simulations, simulations he found on the Internet, that purportedly follow Plaintiffs' theories. *Id.* at 27-28. Plaintiffs object that Abraham's simulation does not fit the facts of the case, that the fog-machine experiment was unreliable because better particle-tracking techniques exist, and that the other critiqued simulations are irrelevant. They also assert a defect in disclosure under Federal Rule of Civil Procedure 26(a)(2)(B)(i), in that they did not receive enough information to assess reliability.

Abraham's testimony is admissible. His simulation fits the facts of the case because it describes what Defendants see as their worst-case scenario. The fog-machine experiment, if crude, shows what it purports to: whether a Bair Hugger stirs up machine-made fog in an operating room. Even if Abraham should have used more advanced techniques, an experiment's simplicity goes to weight, not admissibility. *See Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017) (reversing exclusion for "use of

generalized input values”). And, to illustrate his points, Abraham may critique the other simulations. Plaintiffs’ misplace their relevance argument because Abraham could have created simulations—or what Plaintiffs would argue were strawmen simulations—to show that Plaintiffs’ theories lead to absurd results. Instead of creating simulations, Abraham found them on the Internet. Plaintiffs have not yet attacked these simulations as strawmen, but they may do so before the jury. With the benefit of adversarial presentation, the jury is better equipped to decide how much weight Abraham’s critique of the other simulations deserves. The Court thus DENIES Plaintiffs’ Motion as to Abraham because his testimony meets Rule 702.

The Court also DENIES Plaintiffs’ Motion as to Abraham as brought under Rule 26(a)(2)(B)(i). Plaintiffs had sufficient disclosure, from the files Defendants provided, to reproduce Abraham’s simulation. *See* Abraham Dep. 254. And the fog-machine experiment is described in his report. Abraham Rpt. 10.

Jonathan B. Borak

Defendants’ expert Borak critiques Samet’s reliance on the *Observational Study*. Borak Rpt. ¶ 12. Borak opines that the *Observational Study*’s hospital was an infection hotbed, but then it successfully intervened in a flurry of changes, changes unrelated to the Bair Hugger. *Id.* ¶¶ 27-28. Because of all the changes to address infection, Borak says that Plaintiffs have “insufficient evidence” for their theory that discontinuing the Bair Hugger decreased the rate of infections. *Id.* ¶ 11b. To describe that hospital as “a high

outlier” before the changes, Borak relies on a publication,¹ third-party deposition testimony, and a report from the British National Health Service. *Id.* ¶ 27. To show that the changes can affect deep-joint infection, he relies on studies² showing that these changes can reduce the risk of surgical infection. *Id.* ¶ 39. To show that cultural reform at the observed hospital could have reduced infection, he relies on two bases. First, he cites a proclamation from the observed hospital about “Transforming the culture.” And second, he analogizes to the Hawthorne Effect, documented elsewhere as a change in experimental outcomes due to experimental subjects’ awareness of being observed. *Id.* ¶ 48. Plaintiffs argue that Borak has insufficient factual basis for his critique. They say that Borak speculates that the hospital was an infection hotbed, that the other changes the hospital made could reduce deep-joint infection, and that a reformed hospital culture could have contributed to that reduction.

Borak’s testimony is admissible. Borak supports a rebuttal theory, undermining what Plaintiffs say caused the *Observational Study*’s drop-off in infections. His “insufficient evidence” opinion is not so fundamentally unsupported that it can offer no assistance to the jury. First, although Plaintiffs argue that Borak’s sources underreport infections at comparable hospitals, these sources’ credibility is for the jury. Plaintiffs may cross-examine Borak about what he knows about these sources, to point out this putative flaw to the jury. Plaintiffs may also use their expert Samet to present evidence

¹ Julie Gillson & Gail Lowdon, *Implementing Effective SSI Surveillance*, Clin. Serv. J., Oct. 2014, at 71, 74.

² *E.g.*, Sandra I. Berríos-Torres et al, *Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection*, 152 JAMA Surg. 784 (2017).

contradicting Borak's analysis. Second, Borak has basis for concluding that the observed hospital's other changes affect surgical infections generally. With the benefit of adversarial presentation, the jury may evaluate the parties' theories about when deep-joint infections are like other surgical infections. *Cf.* Compl. ¶ 51 (alleging the Bair Hugger's "tendency to disrupt convention currents in the operating theater [so to] increase the risk of surgical site and deep joint infections"), Dkt. No. 97. And third, to opine about cultural changes, Borak may rely on the observed hospital's proclamation and cite an analogy to an effect documented elsewhere. The Court thus DENIES Plaintiffs' Motion as to Borak because his testimony meets Rule 702.

Alexander A. Hannenberg

Defendants' expert Hannenberg critiques Plaintiffs' theories as having insufficient evidence, given that the Bair Hugger is part of an established standard of care.

Hannenberg Rpt. 6. He notes that his employer-hospital uses the Bair Hugger and has a low infection rate. *Id.* at 2. As an anesthesiologist, Hannenberg cites FDA postings, scientific publications, and third-party organizations' position statements when noting the Bair Hugger's status in medicine. *Id.* at 5. He also says that he reviewed the Bair Hugger's warning label. *Id.* at 6. Plaintiffs argue that Hannenberg lacks qualifications, methods, and factual basis for his critique.

Hannenberg's testimony is admissible. As an anesthesiologist, Hannenberg is qualified to opine about what the standard of care is, and the process by which he would choose a warming device for patients. This process includes reviewing regulatory postings, scientific publications and position statements. Like Borak, Hannenberg is

advancing a rebuttal theory, and his opinion is not so fundamentally unsupported that it can offer no assistance to the jury. Plaintiffs also point to apparent contradictions between Hannenberg's report and his deposition testimony and between his report and third-party postings. These contradictions go to his credibility, not his testimony's admissibility. Plaintiffs may cross-examine Hannenberg to impeach him on these putatively inconsistent statements. The Court thus DENIES Plaintiffs' Motion as to Hannenberg because his testimony meets Rule 702.

Jim Ho

Defendants' expert Ho critiques Plaintiffs' theories about whether particles correspond to infectious bacteria and, specifically, whether particles emitted by the Bair Hugger do so. He opines that "all such organisms [are] effectively filtered by the Bair Hugger's . . . filter." Ho Rpt. 17. He bases this opinion on "Standard charts [that] list th[e] specification" for the Bair Hugger's inlet filter. *Id.* at 25. These charts say that filters like the Bair Hugger's inlet filter achieve "removal of all bacterial particles size within 0.3-1.0 μm ." *Id.* Plaintiffs object the Ho's deposition conduct shows bias and that Ho selectively reviewed scientific publications. They also argue that Ho overstates how many particles the Bair Hugger's inlet filter captures. According to Defendants' internal documents, the inlet filter captures only 80% of 0.3-1.0 μm particles. Ho Dep. 66-67

Ho's critique is admissible. If showing bias, Ho's deposition conduct and selective scientific-publication review go to his credibility, not his testimony's admissibility. Plaintiffs may confront Ho with his conduct on cross-examination and use their experts like Koenigshofer or David, see above, to contradict his scientific-

publication review. And even if a jury could question Ho's basing his opinion on a standard chart instead of experimental data, Plaintiffs may cross-examine Ho about how the difference in actual-theoretical filter efficiency affects his opinions. At the threshold here, Ho's apparent overstatement does not make his testimony so fundamentally unsupported that it can offer no assistance to the jury. The parties dispute the danger that one-micron particles pose. It is also unclear whether 80% efficiency is low enough or one micron is large enough to make Ho's opinion about "effective[]" filtration, whatever that is, fundamentally unsupported. The parties have competing theories about these contingencies, and the jury is better suited to resolve them with the benefit of adversarial presentation. The Court thus DENIES Plaintiffs' Motion as to Ho because his testimony meets Rule 702.

Theodore R. Holford

Defendants' expert Holford critiques Samet's opinion for drawing causal inferences using, among other things, the *Observational Study*, which Holford opines does not connect risk of deep-joint infection to the Bair Hugger. Holford Rpt. 2, 10. To come to this opinion, Holford statistically analyzes the observed hospital's raw data. Plaintiffs argue that Holford's testimony should be excluded. They say the raw data Holford used is nonfinal and from an expanded timeframe which includes untrustworthy data. And they say that Holford's testimony falls below his non-litigation professional practice. For example, Plaintiffs argue that Holford insufficiently justifies which statistical test he used. They also argue that he emphasizes statistical significance more than he would in his professional work.

Holford's critique is admissible because it is not so fundamentally unsupported that it can offer no assistance to the jury. Holford's raw data came from discovery on the *Observational Study*'s authors. Any issues about finality or trustworthiness of the raw data go to its credibility, not the admissibility of Holford's testimony. Plaintiffs may cross-examine Holford about why he chose the data he did. As for whether Holford met his professional practice, the putative contradictions between Holford's practice and his testimony impugn his credibility at most. As for admissibility though, Plaintiffs have not shown harm from Holford's choice of statistical tests. And, using Samet or Jarvis, Plaintiffs may explain to the jury how Holford has overemphasized statistical significance. The Court thus DENIES Plaintiffs' Motion as to Holford because his testimony meets Rule 702.

Antonia Hughes

Defendants' expert Hughes opines that "the operating room is a clean, but not completely sterile, environment." Hughes Rpt. 6. As a nurse, she bases this opinion on her experience and what she has heard healthcare providers consider "sterile." *E.g., id.* at 2 ("Although the unidirectional air is filtered, it is not considered sterile, and is not sterile over the operating room bed."). Hughes further describes working with the Bair Hugger and working in the operating-room environment. Plaintiffs argue that Hughes's testimony is unhelpful, unqualified and biased.

Hughes's testimony is admissible. Plaintiffs rely on the concept of operating-room sterility, *e.g.*, Compl. ¶ 57, Dkt. No. 97, and Hughes's testimony tells the jury how healthcare professionals view that concept. Hughes's experience as a nurse qualifies her

to talk about the views of these professionals and what, generally, the operating room is like. And, if her report or deposition suggests bias, bias is for the jury. Plaintiffs may confront Hughes about this putative bias on cross-examination. The Court thus DENIES Plaintiffs' Motion as to Hughes because her testimony meets Rule 702.

Michael Keen

Defendants' expert Keen critiques scientific publications Plaintiffs' experts rely on and then opines that the Bair Hugger's inlet filter meets operating-room standards, standards from both this country and Canada. Keen was part of a committee that set a standard for operating-room filtration after considering how "proper design, installation, commissioning, operation, and maintenance of [ventilation] systems can reduce the risk of infection." Keen Rpt. 2. Keen bases his Bair Hugger analysis on Defendants' internal documents and YouTube videos. Plaintiffs object that Keen is unqualified and that relying on Defendants' materials is unreliable. *E.g., id.* at 6. They also point out that Keen failed to disclose his reliance on the videos. Plaintiffs also argue that testimony about Canadian standards is irrelevant.

Keen's testimony is admissible. Having served on his committee, Keen is experientially qualified as to his testimony's scope. As with David above, qualification depth goes to weight, not admissibility. *See* Pls.' Mem. Excl. Keen 10 ("Other than sitting on a[] . . . committee, Keen identified no relevant experience in this area."). And Keen may rely on Defendants' materials because, even if dubious, their credibility is for the jury. As for disclosure issues, even if Keen did not disclose relying on the YouTube videos, this nondisclosure is harmless because those videos only animate the internal

documents he did disclose reviewing. *See, e.g., Keen Dep.* 223-24. Finally, even if not in force in this country, Canadian standards are relevant as a having a tendency to show reasonableness in design. *See Am. Compl.* ¶ 74.g (“Defendants negligently continued to manufacture . . . the Bair Hugger after Defendants knew or should have known of its adverse effects. . . .”). Meeting a standard tends to show reasonableness. That showing is attenuated if the standard is not currently or locally in force. But attenuation goes to weight, not relevance. The Court thus DENIES Plaintiffs’ Motion as to Keen because his testimony meets Rule 702.

Thomas Kuehn

Defendants’ expert Kuehn critiques Plaintiffs’ engineering experts. As part of his critique, he reviews scientific publications and does his own experiments to characterize the Bair Hugger’s forced air. He describes those experiments, which took place in a warehouse, in his report. Kuehn Rpt. 9-10. In the warehouse, temperature was not controlled. Plaintiffs object that Kuehn’s scientific-publication review is incomplete, that his experiment was not in an operating room and that his experimental description is sparse.

Kuehn’s testimony is admissible. The thoroughness of Kuehn’s scientific-publication review goes to weight, not admissibility. Plaintiffs’ engineering experts may offer their own scientific-publication reviews to complete the picture for the jury. Kuehn’s experiments characterize the Bair Hugger’s forced air, so the use of a warehouse instead of an operating-room is more of a matter of convenience than unreliability, even if the warehouse’s temperature varied a few degrees. Courts may not exclude expert

testimony for the expert's cost-saving simplifications alone. *See Hill*, 858 F.3d at 486 (reversing exclusion because "Though [the] report . . . may be crude and imperfect, . . . It still gives the trier of fact a rough idea"). Finally, Kuehn's experimental methods are described in his report. If his deposition suggests otherwise, Plaintiffs' may confront him about that discrepancy at trial. The Court thus DENIES Plaintiffs' Motion as to Kuehn because his testimony meets Rule 702.

Samsun Lampotang

Defendants' expert Lampotang critiques Plaintiffs' theories as lacking sufficient evidence. Lampotang is an anesthesiology professor with a courtesy appointment in biomedical engineering. His Ph.D. in mechanical engineering covers heat and fluid flow because he concentrated in thermal sciences. Lampotang has co-invented several medical devices for maintaining patient body temperature, and he has been awarded research grants to study ways to reduce surgical infection. Lampotang Rpt. 2-3. He also manages a retired operating room at his university.

Lampotang relies on many sources. Lampotang bases his opinion about the Bair Hugger's efficacy on a CDC guideline that recommends keeping patients warm during surgery. Lampotang Rpt. 4. That CDC guideline is consistent with a now-retracted like recommendation from an independent organization, a recommendation that Lampotang also cites. *Id.* Lampotang bases his opinion about the Bair Hugger's safety on a lack of post-marketing incidents and a lack of studies showing that the Bair Hugger emits culturable particles. Lampotang Rpt. 5. More safety bases follow. He re-interprets a scientific publication to infer that the Bair Hugger's inlet filters are effective at catching

bacteria. Lampotang Rpt. 5-6 (citing A.T. Bernards et al, *Persistent Acinetobacter baumannii? Look Inside Your Medical Equipment*, 25 Infect. Control Hosp. Epidemiol. 1002 (2004) [hereinafter *Dirty Filters*]). That publication documented how an infection outbreak was resolved by changing a Bair Hugger's inlet filters. As the publication notes, "It was not known how long the filters had been in place, and there was no protocol for regular replacement of the filters." *Dirty Filters* 1003. Moving to the operating room generally, Lampotang notes alternative sources of dust, heat, and airflow. Lampotang Rpt. 8-9. He also distinguishes a CDC warning about another device that uses water. Lampotang Rpt. 13. And finally, Lampotang bases his opinion about the Bair Hugger's design reasonableness on the device's FDA clearance history and its instruction manual. Lampotang Rpt. 4. He also includes a critique of allegedly safer alternative designs based on deposition testimony, scientific publications, and descriptions of how the products work. Lampotang Rpt. 11-12.

While reviewing scientific publications, Lampotang limits the importance of one that documents how smoky soot from an internal Bair Hugger fire reached a patient's torso. Lampotang Rpt. 13 (citing T. Moon et al, *Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient*, 4 Open Access J. Surg. 1 (2017)). This critique is based on citations that show that soot can be smaller than infectious particles and on another scientific publication that purportedly shows that the Bair Hugger blanket can trap particles emitted from the hose or central unit. *Id.* at 14.

About Lampotang's proposed testimony, Plaintiffs object that Lampotang is unqualified, that his scientific-publication review is selective, and he lacks factual basis.

Plaintiffs' argument that Lampotang is not qualified is without merit. And even if Lampotang's scientific-publication review is selective, this issue goes to weight, not admissibility.

Lampotang's critique is admissible because it is not so fundamentally unsupported that it can offer no assistance to the jury. Lampotang may rely solely on the CDC guideline to support his efficacy opinion. He may testify about the operating-room environment from his experience managing a retired operating room. Lampotang's re-interpretation of *Dirty Filters* is not inconsistent with that publication's facts and data, even if the publication's authors do not endorse Lampotang's view. These views are competing theories that the jury must resolve, with the benefit of adversarial presentation. Lampotang's other opinions are supported. Plaintiffs challenge, too, whether Lampotang relied on what he said he did. For example, while deposed, Lampotang mentioned clinical trials when describing post-marketing surveillance. Even if this mention suggests Lampotang has a secret, speculative basis, Plaintiffs can cross-examine him about it. The Court thus DENIES Plaintiffs' Motion as to Lampotang because his testimony meets Rule 702.

Michael Mont

Defendants' expert Mont, an orthopedic surgeon, opines that the Bair Hugger does not contribute to the risk of deep-joint infections. Mont Rpt. 1, 19. Plaintiffs argue that parts of Mont's testimony are inadmissible as unqualified, corresponding to where he describes the operating-room environment. But Mont's testimony is admissible. As a surgeon, Mont may describe the operating-room environment. The Court thus DENIES

Plaintiffs' Motion as to Mont because his testimony meets Rule 702.

Gary Settles

Defendants' expert Settles proposes to testify about images he created, images that show temperature gradients, and what he infers from these images about the Bair Hugger's alleged convection. Settles Rpt. 16, 21. The images' intensity corresponds to the temperature gradient's magnitude, or "temperature difference over a [displayed] distance." Settles Dep. 47:21-22. Settles shows images of the Bair Hugger, of a putative alternative device and of operating-room features. When taking his images, Settles mimicked the operating room in a warehouse, based on Defendants' YouTube video about operating rooms. Settles Rpt. 5; Settles Dep. 53. Some images feature an ungloved hand. *E.g.*, Settles Rpt. fig.7. Settles supports his imaging and analysis by reviewing scientific publications. Settles also critiques Plaintiffs' experts Elghobashi and Koenigshofer. For qualifications, Settles wrote the book on his temperature-gradient imaging technique and, among other things, earned a doctorate where he focused on fluid dynamics. Settles Rpt. 2.

Plaintiffs object that Settles is unqualified, that the operating-room mimicry in a warehouse was crude, that his scientific-publication review was incomplete, and that he might have secretly departed from his imaging technique. Plaintiffs also contend that the putative alternative device is irrelevant.

Settles's testimony is admissible. For the opinions Settles provides on heat and fluid flow, he is qualified. And without more, methodological crudeness goes to weight, not admissibility. *Hill*, 858 F.3d at 486. Likewise, the thoroughness of his scientific-

publication review goes to weight. Plaintiffs' experts may present their own scientific-publication reviews to complete the picture for the jury. And, Settles does not depart from his imaging techniques in a way that would create an admissibility issue; if he secretly did, that departure would go to his credibility. Plaintiffs may cross-examine Settles about whether he did what he said he did. Finally, Plaintiffs' irrelevance argument about the putative alternative device is belied by Samet's (and other Plaintiffs' experts') reliance on the *Observational Study*. Recall that the *Observational Study* finds a drop-off in deep-joint infections corresponding to when a hospital stopped using the Bair Hugger. As it turns out, that hospital switched to the putative alternative device that Settles analyzes. *Observational Study* 1538-39. The Court thus DENIES Plaintiffs' Motion as to Settles because his testimony meets Rule 702.

Plaintiffs also object that Settles's images would unduly prejudice the jury because some feature ungloved hands or because the mimicked operating-room staff lacked full protective gear. Although a departure from what would happen in a real operating room, this shortcut is not the kind of subtle error that would trick the jury. *See Fireman's Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054, 1060 (8th Cir. 2005) (affirming exclusion under Rule 403 because expert testimony only "appear[ed] to simulate" disputed fact). Here, Plaintiffs can call out Settles's shortcut in cross-examination. Because prejudice is unlikely, Settles's testimony does not offend Rule 403.

Timothy Ulatowski

Defendants' expert Ulatowski offers several regulatory opinions, but Plaintiffs move to exclude only his opinion that the FDA's 510(k) clearance of the Bair Hugger

provides a reasonable assurance that the device is safe and effective. Clearance compares a new device to a predicate device, asking if they are substantially equivalent. Ulatowski proposes to testify, at different levels of generality, that FDA clearance includes a safety review, and thus provides a reasonable assurance of safety. First, he talks about how, generally, the agency considers safety when deciding clearance. He bases this opinion on several overlapping FDA position and guidance statements. Ulatowski Rpt. 26. Second, to talk about the Bair Hugger specifically, he reviews publically available files about the Bair Hugger's clearance. Publically available files correspond to more recent Bair Hugger models. Plaintiffs object that Ulatowski's 510(k) opinion is irrelevant, biased and unreliable. They argue that this opinion is unreliable because Ulatowski does not consider an older Bair Hugger model's clearance history.

The first two arguments to exclude are without merit. Plaintiffs' relevance argument is belied by their Complaint. *See* Am. Compl. ¶ 74.g (“Defendants negligently continued to manufacture . . . the Bair Hugger after Defendants knew or should have known of its adverse effects. . . .”). Ulatowski's 510(k) opinion addresses Plaintiffs' negligence claim head on by rebutting that Defendants “should have known” that the Bair Hugger was dangerous, if it is. And as above, putative evidence of expert bias goes to weight, not admissibility. To convince the jury to disbelieve Ulatowski, Plaintiffs may cross-examine him with what they know about him.

Plaintiffs' as-styled reliability argument goes to weight, not admissibility, because, by criticizing Ulatowski for not reviewing an older model's clearance history, they attack only his analysis's thoroughness. Ulatowski's opinion is reliable as commentary on the

newer Bair Hugger model's clearance history. And anyway, the older model's history is harmless to Ulatowski's opinions. When evaluating the older Bair Hugger model, the FDA answered the question "Could the new characteristics affect safety or effectiveness" with a "no." Dkt. No. 769. This evaluation is consistent with Ulatowski's opinion that safety factors into clearance. For the above reasons, Ulatowski's opinion meets Rule 702 and Plaintiffs' Motion as to Ulatowski is DENIED.

Richard Wenzel

Defendants' expert Wenzel critiques Samet and Jarvis, opining that clinical data and national trends show that the Bair Hugger is safe. Wenzel Rpt. 74. He also opines that a patient's own body is the source of most bacteria that cause deep-joint infections. *Id.* at 72. He bases this opinion on, among other things, associations between the bacterial species causing surgical infections and the species that live on the skin's surface near the surgical site. *Id.* at 28 fig.7. He notes that before-surgery cleansing cannot eliminate all skin bacteria. *Id.* at 29. Patient-specific factors, like obesity and diabetes, can increase how many bacteria are on the patient. Thus, under Wenzel's theory, deep-joint infection is more likely as the patient population becomes more obese or diabetic, as a matter of general causation. *Id.* at 11. Plaintiffs argue that Wenzel speculates about patient-endogenous bacteria, that Wenzel has inadequately reviewed competing studies, and that his comments about patient-specific factors are irrelevant to general causation.

Wenzel's testimony is admissible because it is not so fundamentally unsupported that it can offer no assistance to the jury. Wenzel has sufficient basis to opine that skin bacteria can transit from skin to the orthopedic prosthesis, even if he does not know how

they transit. Even if Wenzel has not fully considered competing studies, that issue goes to weight, not admissibility. Plaintiffs' experts Samet and Jarvis present their own scientific-publication reviews, so Plaintiffs may contradict Wenzel's review at trial. And, on a population level, patient-specific factors are relevant to general causation. Under Wenzel's theory, increasing obesity or diabetes rates would explain a population-level increase in deep-joint infections. The Court thus DENIES Plaintiffs' Motion as to Wenzel because his testimony meets Rule 702.

Defendants' dependent Motion for Summary Judgment on General Causation

Defendants' Motion for Summary Judgment depends on the Court granting their Motions to Exclude. To support summary judgment, Defendants argue only that, "[in] sum, because Plaintiffs have presented no expert opinions that reliably 'rule in' the Bair Hugger system as a cause of their alleged infections, . . . summary judgment is appropriate." Defs.' Mem. Summ. J. 15. Because the Court has not excluded any Plaintiffs' experts, Defendants' Motion for Summary Judgment must be and thus is DENIED.

Therefore, based on the files, records, and proceedings herein, IT IS ORDERED

THAT:

1. Plaintiffs' Motion as to Hannenberg [Dkt. No. 727] is DENIED,
2. Plaintiffs' Motion as to Ho [Dkt. No. 733] is DENIED,
3. Plaintiffs' Motion as to Keen [Dkt. No. 738] is DENIED,
4. Plaintiffs' Motion as to Lampotang [Dkt. No. 743] is DENIED,
5. Defendants' Motion as to Samet, Jarvis and Stonnington [Dkt. No. 745] is DENIED,
6. Plaintiffs' Motion as to Ulatowski [Dkt. No. 755] is DENIED,
7. Defendants' Motion as to David's regulatory opinions [Dkt. No. 758] is GRANTED IN PART and DENIED IN PART,
8. Defendants' Motion for Summary Judgment [Dkt. No. 759] is DENIED,
9. Plaintiffs' Motion as to Borak [Dkt. No. 778] is DENIED,
10. Plaintiffs' Motion as to Kuehn [Dkt. No. 787] is DENIED,
11. Defendants' Motion as to Koenigshofer, Buck, Elghobashi, and David's engineering opinions [Dkt. No. 794] is DENIED,
12. Plaintiffs' Motion as to Mont [Dkt. No. 796] is DENIED,
13. Plaintiffs' Motion as to Holford [Dkt. No. 801] is DENIED,
14. Plaintiffs' Motion as to Wenzel [Dkt. No. 812] is DENIED,
15. Plaintiffs' Motion as to Abraham [Dkt. No. 821] is DENIED,
16. Plaintiffs' Motion as to Hughes [Dkt. No. 826] is DENIED and
17. Plaintiffs' Motion as to Settles [Dkt. No. 832] is DENIED.

Dated: December 13, 2017

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