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UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 19-2899

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

GEORGE AMADOR,

Plaintiff-Appellant,

v.

3M COMPANY; ARIZANT HEALTHCARE, INC.,

Defendants-Appellees.

Submitted: March 16, 2021
Filed: August 16, 2021

Before: GRUENDER, KELLY, and GRASZ, Circuit Judges.

OPINION

GRUENDER, Circuit Judge.

In December 2015, the Judicial Panel on Multidistrict Litigation created and centralized the *In re Bair Hugger Forced Air Warming Devices Products Liability Litigation* ("MDL") in the District of Minnesota ("MDL court") for coordinated pretrial

proceedings. Plaintiffs[1] in the MDL have brought claims against 3M Company and its now-defunct, wholly owned subsidiary Arizant Healthcare, Inc. (collectively, "3M"). Plaintiffs assert that they contracted periprosthetic joint infections ("PJIs") due to the use of 3M's Bair Hugger, a convective (or "forced-air") patient-warming device, during their orthopedic-implant surgeries. In July 2019, on 3M's motion, the MDL court excluded Plaintiffs' general-causation medical experts as well as one of their engineering experts, and it then granted 3M summary judgment as to all of Plaintiffs' claims. Subsequently, the MDL court entered an MDL-wide final judgment.

Plaintiffs appeal. First, they argue that the MDL court abused its discretion in excluding their general-causation medical experts and engineering expert. Second, they argue that the MDL court erred in granting 3M summary judgment whether or not those experts were properly excluded. Third, they argue that the MDL court abused its discretion in denying Plaintiffs' request for certain discovery. And fourth, they argue that the MDL court abused its discretion in ordering certain filings on its docket to remain sealed. Additionally, on appeal, Plaintiffs ask us to unseal those parts of the appellate record that duplicate the filings whose sealing on the MDL court's docket they challenge.

We reverse in full the exclusion of Plaintiffs' general-causation medical experts and reverse in part the exclusion of their engineering expert. We reverse

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[1] Although George Amador is the captioned Plaintiff-Appellant, this appeal is brought by all Plaintiffs in the MDL to challenge several MDL-wide rulings.

the grant of summary judgment in favor of 3M. We affirm the discovery order that Plaintiffs challenge. We affirm the MDL court's decision to seal the filings Plaintiffs seek to have unsealed. And we deny Plaintiffs' motion to unseal those same filings on our own docket.

I.

In the mid-1980s, Dr. Scott Augustine invented the Bair Hugger, a forced-air device used to keep patients warm during surgery so as to stave off hypothermia-related complications that can arise during or after surgery. The device consists of a central heating unit, a hose, and a disposable perforated blanket that is placed over the patient. The central unit, which is often situated on or near the floor when in use, draws in air through a filter, warms that air (usually to a temperature significantly above the operating-room temperature), and blows it through the hose into the perforated blanket. The air exits the blanket through the perforations and keeps the patient warm. Typically, both the patient and the blanket are covered with surgical draping during operations, and the blanket is placed on a part of the body away from the surgical site, so the air does not blow directly onto the surgical site.

Dr. Augustine marketed and sold the Bair Hugger through Augustine Medical, Inc., the company he founded and led as CEO until 2004. Around that time, Dr. Augustine was forced to leave Augustine Medical while under investigation for Medicare fraud. Augustine Medical then reorganized, and the division of the company that retained the Bair Hugger product line changed its name to Arizant Healthcare. In 2010,

3M acquired Arizant Healthcare and the Bair Hugger product line. Arizant Healthcare was dissolved in December 2014.

After leaving Augustine Medical, Dr. Augustine developed the HotDog, a patient-warming device that transfers heat conductively to the patient by direct contact with the patient's skin rather than by forced hot air. He then began a campaign to discredit his old invention and promote his new one. These efforts bore fruit. In March 2013, a plaintiff sued 3M and Arizant Healthcare in Texas state court, claiming that he contracted a PJI due to the Bair Hugger's use in his hip-replacement surgery. Dr. Augustine worked with the law firm representing that plaintiff to prepare a "litigation guide" and solicitation letter for the purpose of fomenting more litigation against 3M. By December 2015, more than sixty materially similar cases against 3M had been filed in or removed to federal district courts around the country. At that time, the Judicial Panel on Multidistrict Litigation ordered these cases centralized in the District of Minnesota for consolidated pretrial proceedings. *See* 28 U.S.C. § 1407(a). Nearly 6,000 lawsuits have since been filed as part of the MDL.

In these cases, Plaintiffs allege that they suffered PJIs from the use of the Bair Hugger during their orthopedic-implant surgeries. PJIs are frequently caused by the introduction of microbes into the surgical site during surgery. Bacterial contamination is a particularly significant threat in orthopedic-implant surgeries because a PJI can be caused by very few microbes, possibly even a single bacterium. For this reason, it is standard for such surgeries to take

place in "ultra-clean ventilation" operating rooms, where air is blown into the operating room through high-efficiency particulate air ("HEPA") filtration at a uniform velocity. This HEPA-filtered "laminar" airflow blows over the patient, reducing the likelihood that operating-room airflow will carry ambient bacteria from nonsterile areas of the operating room into the surgical site.

Plaintiffs advance two theories for how the Bair Hugger caused their PJIs during their orthopedic-implant surgeries. According to the "airflow disruption" theory, waste heat from the Bair Hugger creates convection currents that carry ambient bacteria from nonsterile areas of the operating room to the surgical site despite the laminar airflow, resulting in PJIs. According to the "dirty machine" theory, the Bair Hugger is internally contaminated with bacteria, which are blown through the blanket into the operating room, where they become ambient and eventually reach the surgical site, resulting in PJIs.

In the master long-form complaint filed in the MDL, Plaintiffs asserted fourteen state-law claims against 3M, including negligence and strict liability (for failure to warn, defective design, and defective manufacture), among others.

During discovery, Plaintiffs subpoenaed a third party, VitaHEAT Medical, LLC, to produce discovery regarding its "UB3," a conductive patient-warming device. Plaintiffs alleged that the UB3 was an alternative design to the Bair Hugger, making this discovery ostensibly relevant to their design-defect claims. *See generally* 63A Am. Jur. 2d *Products*

Liability § 894 (May 2021 update) ("The existence of an alternative design may be used to establish that a product was unreasonably dangerous due to a design defect, and in some jurisdictions may be required."). VitaHEAT objected on relevancy grounds, arguing that the UB3 was too different from the Bair Hugger to count as an "alternative design" for product-liability purposes. Plaintiffs then filed what they captioned a "motion to overrule" this relevancy objection. The MDL court denied this motion, agreeing that conductive patient-warming devices like the UB3 are too dissimilar from the Bair Hugger to qualify as "alternative designs," meaning that this discovery was not relevant. *Cf. United States v. One Assortment of 93 NFA Regulated Weapons*, 897 F.3d 961, 966 (8th Cir. 2018) ("The Federal Rules of Civil Procedure limit discovery to that which 'is relevant to any party's claim or defense . . . .'" (quoting Fed. R. Civ. P. 26(b)(1))).

The parties jointly agreed to a protective order to limit the disclosure of confidential information that might be contained in filings entered on the MDL docket. Pursuant to this protective order, the parties submitted numerous filings under seal over the course of the litigation. As relevant to this appeal, 3M sought to keep seven such filings under seal over Plaintiffs' objection, asserting that it would suffer competitive harm if any was unsealed. The MDL court agreed and ordered these files kept under seal.

As the litigation progressed, 3M moved to exclude Plaintiffs' general-causation medical experts (Dr. Jonathan M. Samet, an epidemiologist; Dr. William Jarvis, an infectious-disease specialist; and Dr.

Michael J. Stonnington, an orthopedic surgeon) as well as Plaintiffs' engineering experts (including Dr. Said Elghobashi and Michael Buck). 3M also filed a motion for summary judgment contingent on the exclusion of Plaintiffs' general-causation medical experts. The MDL court denied in pertinent part the motion to exclude those experts and denied the motion for summary judgment.

Subsequently, *Gareis v. 3M Co.* became the first bellwether trial in the MDL. *See generally* 156 Am. Jur. *Trials* § 219 (May 2021 update) (explaining the bellwether-trial process in mass-tort litigation). Ruling on pretrial motions in *Gareis*, the MDL court excluded evidence of Plaintiffs' dirty-machine theory. The case then proceeded to trial on the airflow-disruption theory, and Plaintiffs' experts Dr. Jarvis, Dr. Stonnington, and Dr. Elghobashi (among others) testified. After an approximately two-week trial, the jury returned a verdict for 3M.

After the *Gareis* trial, 3M moved for reconsideration of the MDL court's orders refusing to exclude Plaintiffs' general-causation medical experts as well as Dr. Elghobashi and denying 3M summary judgment. The MDL court granted 3M's motion, excluding Plaintiffs' general-causation medical experts as well as Dr. Elghobashi and granting 3M summary judgment on all claims. The MDL court then entered an MDL-wide final judgment. *See In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) ("A transferee court has the authority to enter dispositive orders terminating cases consolidated under 28 U.S.C. § 1407.").

Plaintiffs appeal, challenging the MDL court's exclusion of their general-causation medical experts and Dr. Elghobashi, the MDL-wide grant of summary judgment in favor of 3M, the discovery ruling regarding conductive patient-warming devices, and the sealing of seven MDL docket entries. Plaintiffs also ask us on appeal to unseal on our own docket the records that they argue should have been unsealed on the MDL court's docket.

II.

We begin by considering Plaintiffs' challenge to the MDL court's exclusion of their general-causation medical experts (Dr. Samet, Dr. Jarvis, and Dr. Stonnington) and engineering expert (Dr. Elghobashi). Dr. Samet, Dr. Jarvis, and Dr. Stonnington each offered general-causation opinions—that is, opinions that the Bair Hugger "is capable of causing the [PJIs] from which" Plaintiffs allegedly suffered, *see Junk v. Terminix Int'l Co.*, 628 F.3d 439, 450 (8th Cir. 2010)[2]—based on both the airflow-disruption theory and the dirty-machine theory. Dr. Elghobashi created a computational-fluid-dynamics ("CFD") model to support the airflow-disruption theory. The MDL court generally treated the medical experts as a collective set (their opinions were essentially the same and were founded on much of the same evidence), and it excluded their opinions as unreliable because (1) it concluded there was "too great an analytical gap between the literature and the experts' general causation opinions"; and (2) "the

[2] The opinions in question did not address specific causation—whether the Bair Hugger "in fact caused the harm from which" any particular MDL plaintiff suffered. *See id.*

causal inferences made by the experts have not been generally accepted by the scientific community."[3] The MDL court also excluded Dr. Elghobashi's model and opinion because (1) his conclusion about the Bair Hugger's effects in real-world operating rooms relied on an unproven and untested premise, (2) there was too great an analytical gap between the results of his CFD and his conclusion about the Bair Hugger's effects in real-world operating rooms, and (3) the CFD model was developed for litigation.

For the following reasons, we reverse in full the exclusion of the medical experts' opinions and reverse in part the exclusion of Dr. Elghobashi's model and opinion. We first recite the principles that govern our analysis. We then analyze the reasons given by the MDL court for excluding the experts.

A.

As the proponent of the expert testimony in question, Plaintiffs have the burden to prove its admissibility by a preponderance of the evidence.

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[3] The MDL court articulated a third reason; namely, that "the experts failed to consider obvious alternative explanations." This reason applies specifically to the medical experts' treatment of the epidemiological study on which they relied, *see infra* Section II.B.1, that found an association between forced-air warming and PJIs, *see* Federal Judicial Center, *Reference Manual on Scientific Evidence* at 597-600 (3d ed. 2011) (explaining that "[c]onsideration of alternative explanations" is one of nine factors that "guide epidemiologists in making judgments about [general] causation" based on a study or studies that find an association). The MDL court discussed this same issue in its analysis of the "analytical gaps" between that study and the experts' opinions. Accordingly, we consider this point in assessing the MDL court's "analytical gaps" analysis.

Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). Federal Rule of Evidence 702 governs the admissibility of expert testimony, and under this rule the district court is "vested with a gatekeeping function, ensuring that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Union Pac. R.R. v. Progress Rail Servs. Corp.*, 778 F.3d 704, 709 (8th Cir. 2015) (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993)). In exercising this gatekeeping function, the district court has "broad discretion," and "on appeal we will not disturb a decision concerning the exclusion of expert testimony absent an abuse of that discretion." *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006).

That said, we have recognized that the "liberal thrust" of Rule 702 regarding the admissibility of expert testimony creates "an intriguing juxtaposition with our oft-repeated abuse-of-discretion standard of review." *Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014). "While we adhere to this discretionary standard for review of the district court's Rule 702 gatekeeping decision, cases are legion that, correctly, under *Daubert*, call for the liberal admission of expert testimony." *Id.* (collecting authorities).

Rule 702's "screening requirement" has been "boiled down to a three-part test." *Id.* at 561. First, the testimony must be useful to the finder of fact in deciding the ultimate issue of fact, meaning it must be relevant. *See id.* Second, the expert must be qualified to assist the finder of fact. *Id.* Third, the testimony must be reliable or trustworthy in an evidentiary sense. *Id.* At issue here is the third part of this test—

whether Plaintiffs' experts' proposed testimony meets Rule 702's reliability requirement. "The standard for judging the evidentiary reliability of expert evidence is 'lower than the merits standard of correctness.'" *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).

The reliability inquiry is a "flexible" one, with "[m]any factors" bearing on it. *Daubert*, 509 U.S. at 593-94. In *Daubert*, the Court articulated "four non-exclusive factors" relevant to this inquiry. *Johnson*, 754 F.3d at 562. These factors are (1) whether the expert's theory or technique can be or has been tested, (2) whether the theory or technique has been subjected to peer review or publication, (3) the known or potential rate of error of the theory or technique, and (4) whether the technique or theory is generally accepted. *See id.*; *Peitzmeier v. Hennessy Indus., Inc.*, 97 F.3d 293, 297 (8th Cir. 1996). Factors recognized since *Daubert* include "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995).

Additionally, while *Daubert* instructed that the focus of the reliability inquiry "must be solely on principles and methodology, not on the conclusions that they generate," 509 U.S. at 595, the Supreme Court later clarified that "conclusions and methodology are not entirely distinct from one another," *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146

(1997). Thus, "a district court's focus on principles and methodology need not completely pretermit judicial consideration of an expert's conclusions," *Kuhn*, 686 F.3d at 625 (internal quotation marks omitted), and a district court may exclude expert testimony if it finds "that there is simply too great an analytical gap between the data and the opinion proffered," *Joiner*, 522 U.S. at 146. Or, to put it in the language we have frequently used both before and after *Daubert* and *Joiner*, a district court may exclude an expert's opinion if it is "so fundamentally unsupported" by its factual basis "that it can offer no assistance to the jury." *E.g.*, *Loudermill v. Dow Chem. Co.*, 863 F.2d 566, 570 (8th Cir. 1988); *United States v. Finch*, 630 F.3d 1057, 1062 (8th Cir. 2011).

When a district court excludes an expert's opinion for being fundamentally unsupported, yet another "intriguing juxtaposition" is evident in our case law. *See Johnson*, 754 F.3d at 562. On the one hand, we have recognized that we owe "significant deference" to the district court's "determination that expert testimony is excessively speculative," and we "can reverse only if we are convinced that the District Court made a clear error of judgment on the basis of the record before it." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003) (internal quotation marks omitted). On the other hand, we have stated numerous times that, "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *E.g.*, *United States v. Coutentos*, 651 F.3d 809, 820 (8th Cir. 2011); *see also Klingenberg v. Vulcan Ladder USA, LLC*, 936 F.3d 824, 829-30 (8th Cir. 2019) (distinguishing cases where we affirmed the

exclusion of experts' opinions as too speculative because, in those cases, the experts' opinions were "wholly speculative," "connected to the facts by only the expert's *ipse dixit*," "patent speculation," "pure conjecture," and "vague theorizing based upon general principles").

Thus, excluding an expert's opinion for being fundamentally unsupported is an exception to the general rule that "[g]aps in an expert witness's . . . knowledge" go to weight, not admissibility. *See Robinson v. GEICO Gen. Ins.*, 447 F.3d 1096, 1100 (8th Cir. 2006); *cf. Finch*, 630 F.3d at 1062 ("Doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility." (brackets omitted)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" of addressing "shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

With these principles in mind, we analyze the reasons provided by the MDL court for excluding Plaintiffs' general-causation medical experts and Dr. Elghobashi (whose CFD model and testimony formed part of the factual basis for the general-causation medical experts' opinions).

B.

We first consider the MDL court's determination that "too great an analytical gap" existed between "the literature" and Plaintiffs' medical experts' general-causation opinions. This literature falls generally into two categories: (1) an epidemiological study reporting an association between forced-air warming and PJIs;

and (2) studies and reports ostensibly supporting both of Plaintiffs' mechanistic theories of causation. We consider this evidence to assess whether the MDL court "made a clear error of judgment on the basis of the record before it" in finding the experts' opinions too speculative to be admitted. *See Grp. Health Plan*, 344 F.3d at 760 (internal quotation marks omitted).

1.

All three medical experts relied on a 2011 observational epidemiological study as support for their conclusion that the Bair Hugger is capable of causing PJIs. *See* P.D. McGovern et al., *Forced-Air Warming and Ultra-Clean Ventilation Do Not Mix*, 93-B J. Bone & Joint Surgery 1537 (2011) ("McGovern 2011"). As an observational epidemiological study, McGovern 2011 explored whether forced-air warming was associated with an increased rate of PJIs by comparing a group of individuals warmed convectively to a group of individuals warmed conductively. *See id.* at 1537. *See generally Reference Manual*, *supra*, at 552, 555-56.

Specifically, McGovern 2011 reviewed infection data from 1,437 hip- or knee-replacement surgeries performed at a particular hospital for a 2.5-year period. *Id.* at 1537, 1540. From July 2008 to March 2010, the patients were warmed with Bair Huggers; from March 2010 to June 2010, the hospital gradually transitioned to using conductive patient-warming devices; and from June 2010 to the end of the study, the patients were warmed solely with conductive patient-warming devices. *Id.* at 1540, 1543. The investigators found that patients warmed convectively were nearly four times more likely to contract a PJI

than patients warmed conductively. *Id.* at 1541. The authors of McGovern 2011 acknowledged that the study did "not establish a causal basis" for this association. *Id.* at 1543. And they acknowledged that their findings may have been "confounded"[4] by "other infection control measures instituted by the hospital" during the study period (specifically identifying two such potentially confounding measures) and that they were "unable to consider all [patient-medical-history] factors" associated with PJIs, including a number of "important predictors for deep infection," due to limited data in the records they reviewed. *Id.*

The MDL court found that McGovern 2011 itself was sufficiently reliable to be admitted. But the MDL court faulted the experts' reliance on it in ways that contributed to the analytical gap it found. For instance, the MDL court deemed it unreliable for the experts to draw an inference of causation from this study when the study disclaimed having proved causation. The MDL court also faulted how the experts handled the study's limitations.

As for the first point, we disagree that it is *per se* unreliable for an expert to draw an inference of causation from an epidemiological study that disclaimed proving causation. "[E]pidemiology cannot prove causation." *Reference Manual*, *supra*, at 598.

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[4] "Confounding occurs when another causal factor (the confounder) confuses the relationship between the agent of interest and outcome of interest." *Reference Manual*, *supra*, at 591. For instance, if those who drink alcohol are more likely to smoke than those who do not, then smoking may be a confounder in a study finding an association between drinking alcohol and emphysema. *See id.* at 592.

Instead, epidemiology enables experts to find associations, which by themselves do not entail causation. *See id.* at 552-53, 598. But an observational study such as McGovern 2011 "can be brought to bear" on the question of causation, *id.* at 217, and "can be very useful" to answering that question, *id.* at 221. Ultimately "causation is a judgment for epidemiologists and others interpreting the epidemiologic data." *Id.* at 598; *see also id.* at 222 ("In the end, deciding whether associations are causal typically . . . rests on scientific judgment."). Thus, it was not necessarily unreliable for the experts to rely on McGovern 2011 to draw an inference of causation just because the study itself recognized, consistent with these principles, that the association did not establish causation. So long as an expert does the work "to bridge the gap between association and causation," a study disclaiming having proven causation may nevertheless support such a conclusion. *See id.* at 218.

We recognize that there is language from *Joiner* that, when taken out of context, might appear to suggest otherwise. *See* 522 U.S. at 145 ("Given that [the authors of the study in question] were unwilling to say that PCB exposure had caused cancer among the workers they examined, their study did not support the experts' conclusion that Joiner's exposure to PCB's caused his cancer."). But the context indicates that the problem with the experts' opinions in that case was that they failed to bridge the gap left by the study in question. *See id.* at 145-46 (recounting numerous issues with the experts' factual basis).

As for the second issue, the MDL court rightly faulted the experts for how they handled McGovern

2011's limitations. "Assessing whether an association is causal requires an understanding of the strengths and weaknesses of the study's design and implementation," and "the key questions" in evaluating epidemiological evidence "are the extent to which a study's limitations compromise its findings and permit inferences about causation." *Reference Manual*, *supra*, at 553. The experts did not adequately address McGovern 2011's limitations. Neither Dr. Jarvis nor Dr. Stonnington mentioned the identified potential confounders or limitations in McGovern 2011 in their reports. Dr. Samet, on the other hand, did address in his report the two potential confounders identified by the authors in the study itself, and he meaningfully explained why in his view these variables did not confound the study's findings. But Dr. Samet did not meaningfully address the other limitations identified by the McGovern 2011 authors except to say that confounding by other factors "seems unlikely" for ostensibly logical reasons.[5]

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[5] In the context of discussing this point, the MDL court also faulted Dr. Samet for departing "from his own description of reliable methodology." Specifically, it noted that, with respect to the criterion of consistency that experts use in making judgments about causation, *see Reference Manual*, *supra*, at 600, Dr. Samet noted that that criterion "is generally applied as a consideration related to interpretation of findings of multiple observational studies and hence is not applicable to the single study by McGovern." Because there was only one epidemiological study here, Dr. Samet instead "point[ed] to the consistency of the findings of studies addressing the effect of the Bair Hugger device on particle counts at the surgical site." In context, we do not read this as Dr. Samet misapplying his own methodology but rather acknowledging that the consistency factor was not relevant in its conventional sense but nevertheless the consistency of the

However, McGovern 2011 was not the only basis on which the experts relied in forming their opinions. In addition to the epidemiological data from McGovern 2011, the experts also relied on studies and reports ostensibly showing plausible mechanisms by which forced-air warming can cause PJIs. *See id.* at 599-600, 604 (identifying the "biological plausibility" of a general-causation theory as one factor guiding epidemiologists in "making judgments about causation" and noting that "[w]hen biological plausibility exists, it lends credence to an inference of causality"). Thus, the experts' failure to handle McGovern 2011's limitations properly is not fatal to the admissibility of their opinions. *See id.* at 599-600 (listing "factors that guide epidemiologists in making judgments about causation"; noting that "there is no threshold number that must exist"; and including among these factors "[b]iological plausibility" along with "[c]onsideration of alternative explanations"). "[A]n inference of causation based on the totality of the evidence" may be reliable even if "no one line of evidence support[s] a reliable inference of causation" by itself. *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 23 (1st Cir. 2011); *see also United States v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007)

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mechanistic studies supported an inference of causation from McGovern 2011's finding of an association. As he explained in the next paragraph of his report following the language the MDL court quoted, the mechanistic evidence is consistent with McGovern 2011's findings. The *Reference Manual* directs epidemiologists to consider whether the finding of an association is "consistent with other relevant knowledge," *supra*, at 606, and we fail to see how mechanistic evidence would not count as "other relevant knowledge."

(noting that whether an expert's opinion testimony satisfies Rule 702 "requires consideration of the *overall* sufficiency of the underlying facts and data"). Accordingly, we turn to the other evidence these experts considered.

2.

The studies and reports ostensibly showing the "biological plausibility" of the medical experts' general-causation opinions broadly fall into two categories. One set ostensibly supports Plaintiffs' airflow-disruption theory, and the other ostensibly supports Plaintiffs' dirty-machine theory.

a.

All three medical experts relied on Plaintiffs' airflow-disruption theory as a plausible causal mechanism to support their general-causation opinions. Again, according to this theory, waste heat generated by the Bair Hugger creates convection currents that disrupt laminar airflow in operating rooms and transmit nonsterile air to the surgical site, causing PJIs. The experts relied on two general categories of evidence for this theory: (i) Dr. Elghobashi's CFD model and (ii) published studies examining airflow patterns in operating rooms as well as the correlation between particles and bacteria. We consider each category in turn.

i.

To investigate whether forced-air warming "play[s] a role" in transporting squames (skin flakes capable of carrying bacteria that are present in operating rooms) to the surgical site, Dr. Elghobashi prepared a CFD model using large eddy simulation (a

way to model fluid turbulence) to simulate the Bair Hugger's effect on airflow and dispersion of squames in an ultra-clean-ventilation operating room. Dr. Samet and Dr. Jarvis relied on Dr. Elghobashi's model. The parties agree, and the MDL court found, that the physics underlying Dr. Elghobashi's model is reliable. Dr. Elghobashi eventually published his model with several coauthors in a peer-reviewed journal. *See* X. He et al., *Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room*, 34 Int'l J. Numerical Methods Biomedical Eng'g, May 2018, at 1 ("He 2018").

Dr. Elghobashi's model replicated an orthopedic operating room, including details such as laminar airflow, an operating table, surgical drapes, a patient underneath the drapes prepared for knee surgery, four surgeons (two with hands extended over the patient, two with hands down), two side tables, two surgical lamps, the Bair Hugger blanket applied to the patient's torso under the drapes, and the Bair Hugger central unit sitting on the floor near the head of the operating table. Dr. Elghobashi accounted for the heat generated by the Bair Hugger as well as heat emanating from other sources, including the surgeons, patient, surgical lamps, and even the exposed surface of the patient's knee. He then included approximately three million 10-µm-sized squames on the floor of the operating room near the operating table (a person sheds on average about ten million squames a day). After inputting a number of airflow-related details, Dr. Elghobashi simulated whether the Bair Hugger could lift these 10-µm-sized squames—particles undisputedly large enough to carry bacteria and thus be "dangerous"—up to four "regions of interest" in the

operating room, such as where the surgical tools are kept and the surgical site itself.

Dr. Elghobashi's model showed that, with the Bair Hugger off, the laminar airflow in the operating room was able to disperse the squames away from the regions of interest and to airflow outlets. From this, he concluded that "without the hot air discharged from the blower, the ventilation air circulation alone cannot disperse the squames to the surgical site." But with the Bair Hugger on, within less than a minute the operating-room airflow was sufficiently disrupted by Bair-Hugger-generated heat that convection currents generated by the Bair Hugger lifted a statistically significant number of squames to the regions of interest.

Dr. Elghobashi's conclusion was that "the hot air from the blower and resultant thermal plumes are capable of lifting [squames] and transporting them to the side tables, above the operating table, and the surgical site." And he added that if other variables were introduced into the model, such as movement of medical staff, "then the probability of dispersing the squames to the surgical site will be increased even further." In the published version of the study, Dr. Elghobashi noted that "several . . . complexities involving other medical equipment in an [operating room], motion of the medical staff, opening and closing of the [operating-room] door, among others are not accounted for," but he asserted that "these complexities may not impact the main conclusions of the present study." He 2018, *supra*, at 18.

The MDL court excluded Dr. Elghobashi's opinion and his model for three reasons. First, it found that

his conclusion "relies on an unproven and untested premise." Second, it found that there was "too great an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect in the real world." Third, Dr. Elghobashi's CFD model was developed for litigation, raising "concerns about its reliability and objectivity." We conclude that entirely excluding Dr. Elghobashi and his model for these reasons was an abuse of discretion. *See, e.g.*, *United Fire & Cas. Co. v. Whirlpool Corp.*, 704 F.3d 1338, 1341-42 (11th Cir. 2013) (per curiam) (reversing in part the district court's "sweeping exclusion" of an expert's testimony (citing, *inter alia*, *Weisgram v. Marley Co.*, 169 F.3d 514, 518 (8th Cir. 1999))).

The MDL court mainly faulted Dr. Elghobashi for opining that if additional real-world conditions (such as personnel movement) that have a significant impact on airflow disruption were introduced into his model, then the Bair Hugger's effect on the dispersion of squames would be exaggerated in a real-world operating room. We affirm this aspect of the MDL court's exclusion. In neither his expert report nor his published study did Dr. Elghobashi provide support for this assertion, and at the *Gareis* trial he explained that he knew this "based on [his] knowledge" and said to "trust [him] about this." "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

But we do not affirm the MDL court's categorical exclusion of Dr. Elghobashi and his model. Dr.

Elghobashi set out to determine whether forced-air warming "play[s] a role in transporting squame particles to the surgical site"; his CFD model tested this hypothesis; and he found that forced-air warming does play a role, at least in certain operating-room conditions with limited airflow disruptions from other sources. So limited, his conclusion was tested and supported by the CFD model, and the problematic analytical gap found by the MDL court is gone.

Granted, the MDL court also decided to exclude Dr. Elghobashi's testimony and model because they were "developed for litigation." *See generally Lauzon*, 270 F.3d at 687. But, with Dr. Elghobashi's testimony properly limited so as to eliminate the other reasons for its exclusion, this factor alone does not warrant exclusion. The scientific reliability of a "hired gun" expert's testimony can "be shown 'by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication.'" *Lauzon*, 270 F.3d at 693 (quoting *Daubert*, 43 F.3d at 1318). That happened here—Dr. Elghobashi's report in this case appears in a peer-reviewed journal. *See* He 2018, *supra*. In these circumstances—where a "hired gun" expert's work has been peer reviewed and published, and the developed-for-litigation concern is the only remaining reason for excluding the testimony—we conclude that lingering questions of reliability and objectivity go to weight rather than admissibility. *See DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000) ("An expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." (internal quotation marks omitted)).

Accordingly, the MDL court abused its discretion insofar as it excluded all of Dr. Elghobashi's testimony. His testimony, properly limited as we have specified here, is admissible. Therefore, his limited testimony and CFD model may be considered as part of the factual basis for Plaintiffs' medical experts' airflow-disruption-theory-based general-causation opinions.[6]

As for the support that the CFD model and such limited testimony would provide (if admissible) for the medical experts' general-causation opinions to the extent that they are based on the airflow-disruption theory, the MDL court noted that there was "too great an analytical gap between the CFD results and the medical experts' conclusions that the Bair Hugger causes infection." The MDL court explained that this was because the CFD model did not account for many sources of turbulence often present in a real-world operating room, thus leaving questions unanswered about the real-world effects of the Bair-Hugger-created turbulence. We agree that there are gaps between Dr. Elghobashi's model simulating a "pure operating room" and the opinion that the airflow-

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[6] In a footnote, the MDL court noted that if Dr. Elghobashi's testimony were so limited, it "would not assist the trier of fact in resolving the factual dispute" in the cases in this MDL because every such case will require Plaintiffs to prove specific causation. But Dr. Elghobashi's model and limited testimony are relevant and admissible insofar as they provide part of the factual basis for Plaintiffs' medical experts' general-causation opinions. *See Archer Daniels Midland Co. v. Aon Risk Servs., Inc. of Minn.*, 356 F.3d 850, 858 (8th Cir. 2004) ("An expert need not have an opinion on an ultimate issue of fact in order for the testimony to be admissible.").

disruption theory is a plausible mechanism for how the Bair Hugger causes PJIs in real-world operating rooms. But Dr. Elghobashi's CFD model is not the lone support for the airflow-disruption theory, and whether too great an analytical gap exists here requires consideration of the totality of the evidence on this point. *See W.R. Grace*, 504 F.3d at 765.

ii.

In addition to Dr. Elghobashi's model, the medical experts relied on a number of published studies to find the airflow-disruption theory a plausible mechanism of how the Bair Hugger causes PJIs, thereby supporting their general-causation opinions. The MDL court found that the studies themselves were sufficiently reliable to be admitted. But it concluded that there remained "too great an analytical gap between these studies and the experts' conclusion that the Bair Hugger causes infection" by way of this mechanism. First, the MDL court found that the proposition that the Bair Hugger increases particle-laden airflow over the surgical site was inadequately supported because the studies that the experts cited for this proposition did not simulate "real world" operating-room conditions. Second, the MDL court found that, even assuming this first proposition was correct, the proposition that the particles in this airflow carried bacteria was inadequately supported because Dr. Jarvis "admitted" at the *Gareis* trial that no study showed that the Bair Hugger has any impact on particles that are large enough to carry bacteria (other than "perhaps" the CFD model).

As for whether the Bair Hugger increases particle-laden airflow over the surgical site, the MDL

court was correct that many of these studies, like Dr. Elghobashi's model, did not test the Bair Hugger's effects on airflow disruption and particle counts with all potentially relevant variables included in the analysis. *See, e.g.*, McGovern 2011, *supra*, at 1537-38 (testing the airflow-disruption hypothesis by using a mannequin warmed underneath surgical draping with the Bair Hugger while having a surgeon stand motionless next to the surgical site and an anesthetist stand at the head of the operating-room table); K.B. Dasari, M. Albrecht & M. Harper, *Effect of Forced-Air Warming on the Performance of Operating Theatre Laminar Flow Ventilation*, 67 Anaesthesia 244, 245, 248 (2012) ("Dasari 2012") (finding that forced-air warming created significant levels of excess heat above and around the surgical site under laminar-airflow conditions compared to conductive warming technologies after applying forced-air warming to a mannequin underneath surgical drapes and having two people walk around in the laminar airflow but acknowledging that "in a working operating [room] there are more people and many other ways by which the system might be disrupted"); A.J. Legg, T. Cannon & A.J. Hamer, *Do Forced Air Patient-Warming Devices Disrupt Unidirectional Downward Airflow?*, 94-B J. Bone & Joint Surgery 254, 255 (2012) ("Legg 2012") (testing the airflow-disruption theory by placing a volunteer draped for surgery with the warmer applied under the drapes on an operating table within an enclosure meant to facilitate laminar airflow and having a surgeon stand within the enclosure, but not including any assistants or instrument trays in the enclosure); A.J. Legg & A.J. Hamer, *Forced-Air Patient Warming Blankets Disrupt*

Unidirectional Airflow, 95-B Bone & Joint J. 407, 407 (2013) ("Legg 2013") (using similar conditions as in Legg 2012); Kumar G. Belani et al., *Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance*, 117 Anesthesia & Analgesia 406, 406-07, 410 (2013) ("Belani 2013") (testing the airflow-disruption theory by draping a mannequin, applying warming devices underneath the drapes to the mannequin's torso, and having an anesthetist stand motionless at the head of the mannequin, but cautioning that their findings were "dependent on [the] exact setup" of the experiment, which omitted "instrument trays and a working surgical team").

These limitations notwithstanding, a few of these studies make findings and observations that ameliorate the problematic gap the MDL court found between the simulated operating-room conditions in these studies and real-world operating rooms. For instance, in McGovern 2011, the authors noted how the surgical lighting, drapes, and personnel in their study created "fragile [airflow] conditions" that facilitated the Bair Hugger's ability to disrupt airflow significantly enough to transmit air from nonsterile areas of the operating room to the surgical site. McGovern 2011, *supra*, at 1542. Similarly, in Belani 2013, the authors found that surgical lighting and drapes magnified the Bair Hugger's effects. Belani 2013, *supra*, at 410. In other words, findings in these studies provide empirical support bridging the analytical gap from simulated operating-room conditions to real-world operating-room conditions. This analytical gap, then, was at least partially illusory.

As for whether particles in the increased airflow over the surgical site include bacteria-laden particles, the MDL court made too much of Dr. Jarvis's "admission." As Dr. Jarvis explained at the *Gareis* trial, the key study on which the medical experts relied to correlate particles with bacteria found a statistically significant association between the presence of bacteria and the presence of particles measuring both 5.0-10.0 µm in diameter and ≥10.0 µm in diameter. *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. Infection Control 199, 199-202 (2010) ("Stocks 2010").[7] The Legg 2012 authors found a statistically significant increase in particles measuring 5.0 µm in size over the surgical site when forced-air warming was used. Legg 2012, *supra*, at 255-56. And, as discussed above, Dr. Elghobashi's (admissible) CFD model showed particles measuring 10.0 µm in size reaching "regions of interest" (including the region simulating the surgical site) with the machine on for a short period of time. In other words, the proposition that the increase in particles caused by the Bair Hugger includes bacteria-laden particles finds support in the record.

The question for the MDL court was whether there was sufficient support in the factual basis for the experts' opinions that the Bair Hugger is capable of causing airflow disruption in a real-world operating room that transmits bacteria to the surgical site. The MDL court held that there was not. But, as we have

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[7] This study also noted that "[a]irborne bacteria-carrying particles measure 4 µm to 20 µm." *Id.* at 203.

just seen, there is significant support for the proposition that the Bair Hugger independently is capable of disrupting airflow so as to transmit bacteria to the surgical site when other airflow-disruptive variables are controlled for, and there also is empirical support for the proposition that those other variables can facilitate the Bair Hugger's airflow-disruptive effect in a real-world operating room. Thus, notwithstanding the significant deference owed here, we conclude that the MDL court committed a clear error of judgment on the basis of the record before it, *see Grp. Health Plan*, 344 F.3d at 760, in holding that the experts' general-causation opinions premised on the airflow-disruption theory were "so fundamentally unsupported" that they had to be excluded, *see Loudermill*, 863 F.2d at 570. In light of the evidence the experts relied on to find the airflow-disruption theory a plausible mechanism to explain the association found in McGovern 2011, this was an instance in which our "general rule" that deficiencies in an expert's factual basis go to weight and not admissibility should have been followed. *See, e.g.*, *Klingenberg*, 936 F.3d at 830.

b.

All three medical experts also relied on the dirty-machine theory as a plausible causation mechanism to support their general-causation opinions. Again, according to this theory, the Bair Hugger is capable of emitting bacteria harbored within the machine through the blanket and ultimately to the surgical site, causing PJIs. The experts relied on published studies and reports ostensibly supporting this

mechanistic theory.[8] The MDL court found "too great an analytical gap between the experts' conclusions" and these studies, faulting them for ignoring the limitations in these studies, none of which examined whether contaminated air emitted from the device "could reach the surgical site and cause infection."

For the dirty-machine theory to be plausible and for the experts' opinions to be reliably based on this theory, four premises need to be sufficiently supported in the evidence relied on by the experts. *Cf. Hirchak*, 980 F.3d at 609 (noting that, under Rule 702, "the expert opinion itself—not just one of its several premises—must be 'based on sufficient facts'"). First, the Bair Hugger internally must harbor bacteria in either the central unit or the hose. Second, the Bair Hugger must be capable of blowing that internal

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[8] According to his deposition testimony, Dr. Jarvis also considered the experiment done by Plaintiffs' engineering expert Michael Buck, in which Buck found that the Bair Hugger emitted out of the blanket 5-10 µm sized particles and >10 µm sized particles. Seemingly because neither Dr. Jarvis nor the other two medical experts cited Buck's experiment in their reports, however, 3M argues that none of these experts relied on Buck's work and so this work cannot be considered part of the factual basis for their opinions. *See Hirchak v. W.W. Grainger, Inc.*, 980 F.3d 605, 609 (8th Cir. 2020) (noting that evidence an expert did not consider cannot rescue the expert's opinion from inadmissibility "by filling its analytical gaps"); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000) (rejecting plaintiffs' attempt to bolster their expert's causation opinion with materials corroborating it because the expert "simply did not rely upon those items in formulating his opinion"). We decline to resolve this point because we find that the studies and reports that the experts undisputedly relied on provide enough of a factual basis to render a clear error of judgment the MDL court's finding of "too great" an analytical gap here.

contamination into the blanket. Third, that internal contamination must be capable of escaping the blanket. And fourth, that internal contamination must be able to reach the surgical site.

The first premise is well supported by the studies that the experts cite, many of which found that Bair Huggers were internally contaminated with bacteria. *See, e.g.*, M.S. Avidanet al., *Convection Warmers—Not Just Hot Air*, 52 Anaesthesia 1073, 1074-75 (1997) ("Avidan 1997"); A.T. Bernards et al., *Persistent* Acinetobacter Baumannii*? Look Inside Your Medical Equipment*, 25 Infection Control & Hosp. Epidemiology 1002, 1002, 1004 (2004) ("Bernards 2004"); Mark Albrecht, Robert Gauthier & David Leaper, *Forced-Air Warming: A Source of Airborne Contamination in the Operating Room?*, 1 Orthopedic Reviews 85, 85-87 (2009) ("Albrecht 2009"); Mark Albrecht et al., *Forced-Air Warming Blowers: An Evaluation of Filtration Adequacy and Airborne Contamination Emissions in the Operating Room*, 39 Am. J. Infection Control 321, 322, 324-25 (2011) ("Albrecht 2011").

The second premise also finds support in these studies. *See, e.g.*, Avidan 1997, *supra*, at 1074 (finding that air blown out of Bair Hugger hoses contained microbes); Albrecht 2009, *supra*, at 85, 87 (finding that Bair Hugger hoses were emitting particles in the size range of airborne microbes).

The third and fourth premises find less support but are not unsupported. On the one hand, one of the studies expressly recognized that, for a "direct risk" from the internal contamination to be present, the airflow from the machines would have to reach the

surgical site, and it observed that it was "presently unknown whether this happens" because the blanket "may act as a low-efficiency microbial filter" and "surgical drapes may act as a barrier." *See* Mike Reed et al., *Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions*, 81 Am. Ass'n Nurse Anesthetists J. 275, 279 (2013) ("Reed 2013"). On the other hand, a subsequent report described an incident in which a short-circuit inside a Bair Hugger generated smoke that was emitted through the blanket and deposited as soot on the patient's body in the pattern of the holes in the Bair Hugger blanket, undermining the blanket-as-secondary-filter hypothesis and supporting the third premise. *See* T. Moon et al., *Forced Air Warming Device Failure Resulting in Smoke and Soot on a Surgical Patient*, 4 Open Access J. Surgery, May 2017, at 1 ("Moon 2017").[9] And the fourth premise finds support in several sources. For one, in a 2004 report on a bacterial-outbreak investigation, the investigators reported that they traced the outbreak strain to the interior of a ventilator and a Bair Hugger, explained that the outbreak subsided once they cleaned the ventilator and replaced the Bair Hugger's filter, and offered their view that "the outbreak strain was

[9] Moon 2017 does not provide unimpeachable support for the third premise, to be sure, because it was unknown whether the particles blown out of the blanket and onto the patient were of the size capable of carrying bacteria. We note, however, that one of 3M's own experts effectively conceded the validity of the third premise, testifying when asked at deposition that "some particles" blown into the blanket will leave it and that some of those particles "[m]ost likely" will carry bacteria.

transmitted by being carried on contaminated dust from within the machines to the exterior during operation." Bernards 2004, *supra*, at 1003. Additionally, some of the airflow-disruption studies the experts relied on reported that air from where the blanket exhausted waste heat reached the surgical site and that certain draping arrangements would facilitate that. *See, e.g.*, McGovern 2011, *supra*, at 1537, 1539-40; Belani 2013, *supra*, at 407.

Accordingly, we conclude that it was a clear error of judgment for the MDL court to find that the experts' opinions insofar as they were based on the dirty-machine theory were so fundamentally unsupported that they should be excluded. *See Grp. Health Plan*, 344 F.3d at 760; *Loudermill*, 863 F.2d at 570. Certainly, there are weaknesses in the dirty-machine theory. Again, however, redress for such weaknesses lies in cross-examination and contrary evidence rather than exclusion. *See Bonner*, 259 F.3d at 929; *but cf. Polski v. Quigley Corp.*, 538 F.3d 836, 839-41 & n.4 (8th Cir. 2008) (affirming the exclusion of an expert's causation opinion based on an untested mechanistic theory that the expert himself previously had effectively stated was implausible).

* * *

In sum, we do not dispute the MDL court's determination that there are weaknesses in the factual basis for Plaintiffs' medical experts' general-causation opinions. On the one hand, they have epidemiological evidence reporting an association between Bair Hugger use and PJIs, but on the other hand they failed to grapple adequately with the shortcomings of that evidence. On the one hand, they

have identified two plausible mechanisms explaining this association, but on the other hand there are weaknesses in the supports for both mechanisms.

This said, the question the MDL court ultimately had to answer was whether these shortcomings left "too great an analytical gap" between the factual bases for the experts' opinions and the general-causation opinions themselves, *see Joiner*, 522 U.S. at 146; or, in other words, whether the opinions were "so fundamentally unsupported" that they should be excluded rather than admitted and left to be impeached through cross-examination at trial (as evidently happened effectively at the *Gareis* trial), *see Loudermill*, 863 F.2d at 570. While giving due deference to the MDL court's determination, we nevertheless conclude that the MDL court committed a clear error of judgment on the basis of the record before it in finding that the experts' general-causation opinions were so fundamentally unsupported that they had to be excluded.[10]

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[10] In arguing to the contrary, 3M relies heavily on our decision in *Glastetter v. Novartis Pharmaceuticals Corp.*, where we affirmed the exclusion of medical experts who "lacked a proper basis" for their general-causation opinions that a certain medication could cause intracerebral hemorrhages. 252 F.3d 986, 988-89 (8th Cir. 2001) (per curiam). We find *Glastetter* distinguishable, most saliently because the experts in that case had no epidemiological evidence on which to rely to link the medication to its purported effect, *see id.* at 992, unlike Plaintiffs' general-causation experts here, *cf. id.* (noting that "epidemiological studies and reports are much desired by litigants in cases involving medical causation"); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) ("[E]pidemiology is the best evidence of general causation in a toxic tort case.").

We emphasize that this conclusion is a narrow one—again, the standard for admissibility is "lower than the merits standard of correctness," *Kuhn*, 686 F.3d at 625—that turns greatly on the fact that the opinions at issue here address general causation (whether the Bair Hugger can cause a PJI) rather than specific causation (whether the Bair Hugger did cause a particular plaintiff's PJI). *See Junk*, 628 F.3d at 450. In several places in its order excluding the medical experts, the MDL court suggested that the weaknesses in the experts' general-causation evidence, particularly in the evidence regarding the mechanisms of causation, would present significant hurdles for the specific-causation showing these Plaintiffs must make to prevail—that is, that they would not have contracted a PJI but for use of the Bair Hugger during their surgeries. Whether this is so is not at issue in this appeal, and we express no view on it here. We hold only that the MDL court abused its discretion in excluding these experts' general-causation opinions on the basis of excessive analytical gaps.

C.

The MDL court's analytical-gap determination constituted the primary justification for its decision to exclude Plaintiffs' general-causation medical experts. But it did briefly find as well that lack of general acceptance of the causal inferences made by the experts also supported excluding their testimony. In *Daubert*, the Court rejected "a rigid 'general acceptance' requirement" that could alone be dispositive, but it did acknowledge that general acceptance (or lack thereof) "can yet have a bearing on

the inquiry." 509 U.S. at 588, 594. However, this factor must be applied while bearing in mind "that a rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing traditional barriers to opinion testimony." *Lauzon*, 270 F.3d at 691 (internal quotation marks omitted).

The MDL court considered three data points in its general-acceptance analysis. First, it noted how, in a statement put out by the 2013 International Consensus Meeting on Periprosthetic Joint Infection, there was a strong consensus that, although forced-air warming devices posed a "theoretical risk," no studies had "shown" an increase in surgical-site infections related to the use of these devices, and although "[f]urther study" was warranted there was no need to stop using forced-air warming devices based on the evidence at that time. Second, it considered a letter issued by the Food and Drug Administration in 2017 reporting the agency's determination that it had been "unable to identify a consistently reported association" between forced-air warming and surgical-site infection and continuing to recommend using such devices "when clinically warranted." Third, it noted that, in a statement put out by the 2018 International Consensus Meeting on Musculoskeletal Infection, there was a strong consensus that there was "no evidence to definitively link" forced-air warming to an increased risk of PJIs.

Notably, however, in that 2018 statement, the authors of the rationale for the bottom-line consensus recognized that "the literature is conflicting," and they called for further study to examine the issue. And

Plaintiffs' experts' general-causation inferences are not without support in the medical community. *See, e.g.*, A.M. Wood et al., *Infection Control Hazards Associated with the Use of Forced-Air Warming in Operating Theatres*, 88 J. Hospital Infection 132, 132 (2014) (concluding, after a review of the literature on the issue, that forced-air warming "does contaminate ultra-clean air ventilation," though acknowledging that "current research" had not shown a "definite link" between forced-air warming and surgical-site infections such as PJIs); *cf. Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (recognizing that "medical knowledge is often uncertain" and that "[l]ack of certainty is not, for a qualified expert, the same thing as guesswork"). Even some of the other authorities 3M calls to our attention as showing a lack of general acceptance acknowledge that "concerns exist" about a link between forced-air warming and surgical-site infections, *see* Melissa D. Kellam, Loraine S. Dieckmann & Paul N. Austin, *Forced-Air Warming Devices and the Risk of Surgical Site Infections*, 98 AORN J. 353, 365 (2013), and suggest modifications to forced-air-warming devices to "reduce the risk" they may pose, *see ECRI Update: You're Getting Warm: Uncovering Forced-Air Warming Units*, ECRI Institute (May 1, 2017).

To exclude the experts' opinions here because their conclusions lacked general acceptance would be to take a side on an issue that is "currently the focus of extensive scientific research and debate." *See Milward*, 639 F.3d at 22; *cf. Bonner*, 259 F.3d at 929 ("[N]either Rule 702 nor *Daubert* requires that an expert opinion resolve an ultimate issue of fact to a scientific absolute in order to be admissible.").

Accordingly, in light of our rejection of the MDL court's analytical-gap rationale for exclusion, we conclude that the lack of general acceptance does not independently justify exclusion of Plaintiffs' general-causation medical experts. *Cf. Milward*, 639 F.3d at 22, 26 (criticizing the district court in that case for placing "undue weight on the lack of general acceptance" of an expert's conclusions about causation and ultimately reversing its exclusion of that expert).

III.

The MDL court's grant of summary judgment to 3M was derivative of its order excluding Plaintiffs' general-causation medical experts and Dr. Elghobashi. Because we reverse in relevant part the exclusion of those experts, we reverse the grant of summary judgment. *See, e.g.*, *Kuhn*, 686 F.3d at 633.[11]

IV.

We next consider Plaintiffs' challenge to the MDL court's discovery ruling prohibiting them on relevancy grounds from obtaining discovery concerning conductive patient-warming devices. Plaintiffs argue that this ruling was an abuse of discretion because the discovery is relevant to their design-defect claims. We find no basis to reverse.

"Appellate review of a trial court's determination concerning discovery matters is very narrow." *McGowan v. Gen. Dynamics Corp.*, 794 F.2d 361, 363 (8th Cir. 1986). "[W]e will only reverse upon a showing

[11] We thus do not reach Plaintiffs' argument in the alternative that summary judgment was erroneously granted even if the general-causation medical experts and Dr. Elghobashi were properly excluded.

of a 'gross abuse of discretion resulting in fundamental unfairness in the trial of the case.'" *Ahlberg v. Chrysler Corp.*, 481 F.3d 630, 637-38 (8th Cir. 2007) (quoting *Firefighters' Inst. for Racial Equality ex rel. Anderson v. City of St. Louis*, 220 F.3d 898, 902 (8th Cir. 2000)).

We assume without deciding that, as Plaintiffs argue, the MDL court erroneously concluded that this discovery was irrelevant across the entire MDL because some states would (or might allow a jury to) recognize conductive patient-warming devices as reasonable alternative designs to convective patient-warming devices. Even so, Plaintiffs have not even argued on appeal, let alone shown, that the MDL court's discovery ruling resulted in fundamental unfairness to them in trying their cases. *See Moses.com Secs., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1060 (8th Cir. 2005) (declining to reverse a discovery ruling where the party seeking reversal of the discovery rulings at issue did not specify how the rulings "resulted in fundamental unfairness" and the record did not support a finding that the party "suffered prejudice as a result of the rulings"); *Ahlberg*, 481 F.3d at 634 ("[P]oints not meaningfully argued in an opening brief are waived.").

Even if we considered the point, we would not find fundamental unfairness on this record. Plaintiffs apparently had other reasonable-alternative-design evidence available to them, as is demonstrated by their recitation of studies suggesting that filter-related modifications to the Bair Hugger would make it safer. *See, e.g.*, Restatement (Third) of Torts: Prod. Liab. § 2 cmt. f (Am. Law Inst. 1998) (providing an example of a modified existing product as a reasonable

alternative design). In addition, Plaintiffs were permitted discovery regarding other convective warming devices for reasonable-alternative-design purposes. *See id.* ("[O]ther products already available on the market may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as reasonable alternatives to the product in question.").

V.

We now turn to Plaintiffs' challenge to the MDL court's decision to seal certain filings on its own docket. We review the district court's decision to seal records for an abuse of discretion. *IDT Corp. v. eBay*, 709 F.3d 1220, 1223 (8th Cir. 2013).

Plaintiffs take issue with the sealing of seven filings: (1) MDL Docket Entry No. 221-19 (also located at MDL Docket Entry Nos. 347, 887, 938, and 1801); (2) MDL Docket Entry No. 221-20 (also located at MDL Docket Entry Nos. 895 and 1806); (3) MDL Docket Entry No. 340 (also located at MDL Docket Entry No. 944); (4) MDL Docket Entry No. 377 (also located at MDL Docket Entry No. 945); (5) MDL Docket Entry No. 901 (also located at MDL Docket Entry No. 1808); (6) MDL Docket Entry No. 937; and (7) Docket Entry No. 1805 (which is another version of the document at MDL Docket Entry No. 937).[12] As the

[12] Plaintiffs assert in passing that "[t]he MDL court erroneously sealed dozens of court records," but in both their opening brief and appellate motion they argue specifically only that these seven records should be unsealed. Accordingly, we decline to consider their challenge to the sealing of any other documents besides these seven. *See McKay v. City of St. Louis*, 960 F.3d 1094, 1099 n.2 (8th Cir. 2020).

MDL court found, these documents contain sensitive business and strategic planning information. For each, 3M asserted that it would suffer competitive harm if the document was unsealed. The MDL court agreed and ordered these files kept under seal. Plaintiffs argue this was an abuse of discretion. We find no abuse of discretion.

"[T]here is 'a common-law right of access to judicial records.'" *Webster Groves Sch. Dist. v. Pulitzer Pub. Co.*, 898 F.2d 1371, 1376 (8th Cir. 1990) (quoting *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 (1978)). "This right of access is not absolute," however, "but requires a weighing of competing interests." *Id.* When this common-law right is implicated, "we give deference to the trial court rather than taking the approach of some circuits and recognizing a 'strong presumption' favoring access." *Id.* (quoting *United States v. Webbe*, 791 F.2d 103, 106 (8th Cir. 1986)).

Whether sealing is warranted, the common-law right of access notwithstanding, turns on "the relevant facts and circumstances of the particular case." *Warner Commc'ns*, 435 U.S. at 599. The district court "must consider the degree to which sealing a judicial record would interfere with the interests served by the common-law right of access and balance that interference against the salutary interests served by maintaining confidentiality of the information sought to be sealed." *IDT Corp.*, 709 F.3d at 1223. Interests served by the common-law right include bolstering public confidence in the judicial system by allowing citizens to evaluate the reasonableness and fairness of judicial proceedings, allowing the public to keep a watchful eye on the workings of public agencies, and

providing a measure of accountability to the public at large (which pays for the courts). *Id.* at 1222. But these interests have "bowed before the power of a court to insure that its records are not used to gratify private spite," to "promote public scandal," to serve "as reservoirs of libelous statements for press consumption," or to serve "as sources of business information that might harm a litigant's competitive standing." *Warner Commc'ns*, 435 U.S. at 598 (internal quotation marks omitted). The "consideration of competing values" that must be done here is "heavily reliant on the observations and insights of the presiding judge." *Webbe*, 791 F.2d at 106.

Here, the MDL court concluded that keeping the contested records under seal was warranted because they contained sensitive, commercially competitive material "to which [3M's] need to maintain confidentiality . . . outweighs the public's right of access." The record shows that Dr. Augustine—who, as we noted above, created a competitor device to the Bair Hugger and has helped foment this litigation against 3M—has attempted to exploit and misrepresent information learned in this MDL to 3M's detriment and to his commercial benefit. In other words, the MDL court's sealing decision was based on "salutary interests," *see IDT Corp.*, 709 F.3d at 1223, before which the common-law right of access "has bowed," *see Warner Commc'ns*, 435 U.S. at 598. *See also United States v. McDougal*, 103 F.3d 651, 658 (8th Cir. 1996) (agreeing that, "as a matter of public policy," courts "should avoid becoming the instrumentalities of commercial or other private

pursuits"). Accordingly, we find no abuse of discretion in this decision.

In arguing that we should hold otherwise, Plaintiffs point out a "[m]odern" trend that "'the weight to be given the presumption of access'" is "'governed by the role of the material at issue in the exercise of Article III judicial power and resultant value of such information to those monitoring the federal courts.'" *IDT Corp.*, 709 F.3d at 1224 (quoting *United States v. Amodeo*, 71 F.3d 1044, 1049 (2d Cir. 1995)). In these cases, "the strong weight to be accorded the public right of access" in some instances derives from the central role the documents in question play "in determining litigants' substantive rights" and "from the need for public monitoring of that conduct." *Amodeo*, 71 F.3d at 1049. "Where testimony or documents play only a negligible role in the performance of Article III duties," however, "the weight of the presumption is low." *Id.* at 1050.

Even assuming this is the correct framework to govern the sealing issue here, *but cf. Webster Groves Sch. Dist.*, 898 F.2d at 1376 (noting that we give deference to the district court's sealing decisions "rather than taking the approach of some circuits and recognizing a 'strong presumption' favoring access"), we nonetheless would find no abuse of discretion. The only place where Plaintiffs indicate that the MDL court "discussed and analyzed" these documents is in a footnote in its *Daubert* reconsideration order where it mentioned in passing that it was "unable to determine" from these documents whether they undermined its general-acceptance analysis. As noted above, the general-acceptance factor played a

negligible role in the MDL court's *Daubert* decision. And these documents played a negligible role in the MDL court's general-acceptance analysis. Accordingly, any "presumption of access" to these documents is "low," and the "countervailing reason[s]" justifying sealing here trump the right of access. *See Amodeo*, 71 F.3d at 1050.

Plaintiffs also ask us to join several other circuits and hold that there is a First Amendment presumption of public access to summary-judgment materials (which they contend the contested records are). *See, e.g.*, *Rushford v. New Yorker Magazine, Inc.*, 846 F.2d 249, 253 (4th Cir. 1988). We have yet to decide "whether there is a First Amendment right of public access to the court file in civil proceedings." *IDT Corp.*, 709 F.3d at 1224 n.*. We have said, however, that for such a right to be recognized at least two prerequisites must be satisfied: (1) there is a historical tradition of accessibility to the records in question, and (2) there is a significant positive role for public access in the functioning of the judicial process in question. *Id.* Plaintiffs do not even mention, let alone meaningfully argue, the first prerequisite, so we decline to consider this argument. *See McKay*, 960 F.3d at 1099 n.2.

VI.

Plaintiffs also have filed a motion on appeal asking us to unseal the same documents they want us to order the MDL court to unseal. *See Warner Commc'ns*, 435 U.S. at 598 ("Every court has supervisory power over its own records and files . . . ."). The rationale discussed in Section V for affirming the MDL court's sealing decisions regarding

the seven documents at issue applies with equal force here, so we deny Plaintiffs' request for us to unseal these documents.[13]

VII.

For the foregoing reasons, we affirm in part and reverse in part the exclusion of Dr. Elghobashi's CFD model and opinion, we reverse the exclusion of Plaintiffs' general-causation medical experts' opinions, we reverse the grant of summary judgment to 3M, we affirm the discovery ruling challenged by Plaintiffs on appeal, and we affirm the decision to seal those filings whose sealing Plaintiffs challenge on appeal. Finally, we deny Plaintiffs' motion on appeal to unseal those same filings.

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[13] In their opening brief, Plaintiffs also ask us to unseal "all appellate briefs and appendices provisionally filed under seal." Plaintiffs filed unopposed motions to file redacted versions of their briefs that were provisionally filed under seal and to allow the unsealing of most of the contents in the appellate appendices that also were provisionally filed under seal, and we already granted these motions. To the extent they seek further unsealing, their request appears redundant of the request they make in their appellate motion to unseal, which we deny.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 19-2899

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

GEORGE AMADOR,

Plaintiff-Appellant,

v.

3M COMPANY; ARIZANT HEALTHCARE, INC.,

Defendants-Appellees.

Filed: November 9, 2021

ORDER

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Judge Loken would grant the petition for rehearing en banc.

Judge Benton and Judge Stras did not participate in the decision or consideration of this matter.

November 09, 2021

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eighth Circuit.

Appendix C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

MDL No. 15-2666

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

Filed: July 31, 2019

MEMORANDUM

This multidistrict litigation ("MDL") is before the Court on Defendants' motions to exclude the expert testimony of Drs. William Jarvis, Jonathan Samet, Michael Stonnington, and Said Elghobashi, under Federal Rule of Evidence 702. For the reasons set forth below, the Court grants the motions and grants summary judgment for Defendants.

BACKGROUND

Plaintiffs allege that Defendants' Bair Hugger Forced Air Warming Device ("the Bair Hugger") caused their periprosthetic joint infection ("PJI") as a sequela to orthopedic-implant surgery. The Bair Hugger, a device for keeping surgical patients warm, consists of a portable heater or blower connected by a flexible hose to a disposable blanket that is placed over (or in some cases under) surgical patients. The Bair Hugger intakes air from the surrounding area and

passes it through the intake filter and internal air pathways of the machine and into an outlet hose. The warm air travels through the distal end hose, which does not have an air filter, and into the blanket, providing warmth to the patient during surgery. Because the patient's torso (in hip and knee surgeries) and the Bair Hugger blanket are covered with surgical draping, the warm air does not blow directly onto the surgical site.

Plaintiffs allege two theories about how the Bair Hugger can cause PJI. First, Plaintiffs allege that the Bair Hugger's warm air flow escapes the bottom edge of the surgical drape, creating turbulence in the operating room ("OR"), which lifts squames (shed skin flakes that can carry bacteria) into the air and into the surgical site, and increases the risk of infection. The Court has termed this theory the "airflow disruption" theory. Dr. Elghobashi, a recognized expert in computational fluid dynamics ("CFD"), built a CFD simulation to model this theory. The simulation purports to show that the Bair Hugger generates extreme turbulence in the OR causing squames to reach the surgical site. Second, Plaintiffs claim that the device, which lacks an adequate filtration system, emits contaminants into the OR, and thus, increases the bacterial load reaching the surgical site. The Court has labeled this second theory the "dirty machine" theory.

Plaintiffs' three medical experts—Drs. Jarvis, Samet, and Stonnington—have opined that the Bair Hugger causes PJI. For purposes of general causation, the issue in this litigation is whether use of the Bair Hugger device increases the risk of PJI compared to

the risk of infection when the device is not used. The medical experts reviewed many studies that support both theories of causation, including Dr. Elghobashi's CFD simulation, and one epidemiological study that found a statistically significant association between the Bair Hugger and PJI. Defendants argue, however, that the scientific literature expressly disclaims causation and asks the Court to exclude these opinions for this reason.

In its December 13th, 2017 *Daubert* order, this Court found the testimony of Plaintiffs' engineering expert—Dr. Elghobashi—and Plaintiffs' medical experts—Drs. Jarvis, Samet, and Stonnington—to be admissible. The Court found that Dr. Elghobashi ran a simulation, using accepted physics principles, to show how the Bair Hugger's warm air flow could cause squames to float upward toward the surgical wound. The Court also found that Drs. Jarvis, Samet, and Stonnington relied on Dr. Elghobashi's testimony as well as the epidemiological study for reliable mechanistic and statistical evidence that the Bair Hugger causes PJI.

Defendants had also argued that if the Court excluded Plaintiffs' three general causation experts, then summary judgment would be appropriate. Because the Court denied Defendants' *Daubert* motion, the Court subsequently denied Defendants' summary judgment motion.

In April 2018, the Court heard argument on the parties' case-specific dispositive motions in *Gareis*, the

first bellwether trial in the MDL.[1] The Court denied Defendants' motion to exclude expert testimony by Dr. Elghobashi. The Court also denied Defendants' motion to exclude expert testimony by Drs. Jarvis and Stonnington. *Id.*

In May 2018, the Court heard pretrial motions in *Gareis*. The Court granted Defendants' motion to exclude evidence pertaining to Plaintiffs' "dirty machine" theory. The Court determined that "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." *Gareis* 16-cv-4187, ECF No. 306 (Order re Mot. in Lim.) at 2. Thus, the Court held that Plaintiffs failed to introduce sufficient proof to support this theory of causation. *Id.*

The trial commenced on May 14, 2018 and ended May 30, 2018. Drs. Elghobashi, Jarvis, and Stonnington all testified. On May 30th, a jury returned a verdict in favor of Defendants. The jury concluded that Plaintiffs did not prove by a preponderance of the evidence that the Bair Hugger

[1] This was not the first scheduled bellwether trial. On May 30, 2017, pursuant to Pretrial Order No. 19, the Court selected eight bellwether cases from the parties' proposed cases and then each party exercised one strike to finalize the six cases in the "Final Bellwether Trial Pool." On June 16, 2017, the Court determined the order of these six bellwether trials, listing *Gareis* as last. Because the first five cases never made it to trial, *Gareis* became the first bellwether to go to trial. On March 13, 2018, the Court repopulated the bellwether pool and the parties selected an additional twelve potential bellwethers ("the Bellwethers Second") per Pretrial Order No. 24.

caused the plaintiff's infection. The jury further concluded that Plaintiffs did not prove by a preponderance that the Bair Hugger system was unreasonably dangerous and a safer alternative design existed.

In August 2018, 3M requested leave to move for reconsideration of the Court's *Daubert* rulings. In their letter request, Defendants argued that new evidence undermines the scientific support proffered by Plaintiffs' medical experts in their general causation opinions. Under Local Rule 7.1(j), a party must show "compelling circumstances" to obtain permission from the court to move for reconsideration. Motions for reconsideration serve "the limited function of correcting manifest errors of law or fact or . . . present[ing] newly discovered evidence." *Bradley Timberland Res. v. Bradley Lumber Co.*, 712 F.3d 401, 407 (8th Cir. 2013). On November 20, 2018, the Court concluded that Defendants demonstrated compelling circumstances and granted the request.[2]

On January 24, 2019, Defendants filed their motion to reconsider and asked the Court to exclude the testimony of Plaintiffs' medical experts and Dr. Elghobashi pursuant to Federal Rule of Evidence 702 and grant summary judgment in favor of Defendants. On February 21, 2019, Plaintiffs filed their

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[2] Prior to granting Defendants' request to file a motion for reconsideration, the Court had directed the two joint nominees in the Bellwethers Second—*Hives* and *Axline*—to prepare for trial. *Axline* was set to be tried on December 3, 2018. But by November 15, 2018, *Hives* had been dismissed and Plaintiffs' counsel had indicated that they intended to dismiss the remaining claims in *Axline*. ECF No. 1597 (Pretrial Order No. 27).

Memorandum in Opposition. Defendants replied on March 14, 2019. On May 6, 2019, the Court posed three additional questions to clarify issues relating to both general and specific causation. The parties responded on May 16, 2019. Both parties also presented their arguments at a hearing on June 12, 2019.

LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. It states that a qualified expert witness may testify to "scientific, technical, or other specialized knowledge" if it "will assist the trier of fact to understand the evidence or to determine a fact in issue" and if "(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Fed. R. Evid. 702.

The key inquiry is whether the experts' methodology is reliable enough to assist the trier of fact. To aid in this inquiry, the Supreme Court in *Daubert* identified four nonexclusive factors a court can apply: "(1) whether the theory or technique 'can be (and has been) tested'; (2) 'whether the theory or technique has been subjected to peer review and publication'; (3) 'the known or potential rate of error'; and (4) whether the theory has been generally accepted." *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 686-87 (8th Cir. 2001) (citing *Daubert v. Merrell Dow Pharm.*, 509 U.S. 570, 593-94 (1993)). "*Daubert*'s progeny provides additional factors such as: whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the

proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case." *Id.* "[T]he trial court is left with great flexibility in adapting its analysis to fit the facts of each case." *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1082 (8th Cir. 1999).

DISCUSSION

In their motion for reconsideration, Defendants challenge the testimony of Dr. Elghobashi, an engineering expert, and all three medical experts. The Court will address each argument in turn. If the Court grants Defendants' *Daubert* motions, Defendants argue that summary judgment should follow. *See, e.g., In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950, 968 (D. Minn. 2009) (granting summary judgment following the exclusion of plaintiffs' general causation expert). In the alternative, Defendants request that the Court certify the general causation issue under 28 U.S.C. § 1292(b).

The Court has reviewed the arguments made during Defendants' initial *Daubert* motion to exclude Plaintiffs' medical and engineering experts, the experts' testimony during the *Gareis* trial in May 2017, and the new evidence proffered by Defendants in their motion to reconsider. For the following reasons, the Court grants Defendants' *Daubert* motions, and consequently, grants summary judgment in favor of Defendants.

I. DR. ELGHOBASHI'S TESTIMONY

Dr. Elghobashi's testimony relies on a CFD model, which simulated the impact of the Bair Hugger on the dispersion of squames in an OR. The model compared

the blower off and on and concluded that operating the Bair Hugger increases the number of squames reaching the surgical site.

Defendants do not dispute Dr. Elghobashi's qualifications. Dr. Elghobashi is a professor at the University of California Irvine Department of Mechanical and Aerospace Engineering and a recognized expert in the field of computational fluid dynamics. Relying on the CFD simulation, Dr. Elghobashi opines that the Bair Hugger disrupts airflow in the OR and causes squames to reach the surgical site.

Plaintiffs' attorneys hired Dr. Elghobashi to create a CFD model to study the interaction between the OR heating ventilation and air conditioning ("HVAC") system and forced-air warming devices to understand the effect of blowing hot air on the dispersion of squames in an OR. A "large-eddy simulation" ("LES") is one of the methods used in computational fluid dynamics simulations. This modeling relies on engineering principles and several governing equations related to fluid dynamics and heat transfer that are solved by super computers. The parties agree, and the Court found in its December 13th, 2017 order, that the physics underlying Dr. Elghobashi's simulation is reliable.

Dr. Elghobashi retained another CFD expert, Dr. Sourabh Apte, to build the computer simulation using certain inputs provided by Dr. Elghobashi. The LES replicated an OR with an operating table, side tables, surgical lamps, medical staff, and a patient. At trial, Dr. Elghobashi listed a number of key parameters—or "boundary conditions"—that were required to

calculate how the squames would move within the OR. Those parameters included the size, number and location of inlet and outlet vents for the HVAC, the volumetric airflow through those vents, the temperature of the air blown into and exiting from the Bair Hugger warming blanket, and the volumetric airflow exiting from the Bair Hugger blower.

He then evaluated the effect of the Bair Hugger on particles—ten microns in size or greater—that are large enough to carry bacteria. His simulation placed three million squames on or within one centimeter of the OR floor near the operating table. He also created four imaginary "boxes" in the simulated airspace at locations representing key areas such as the area where surgical tools are stored and the area of the surgical procedure. The goal of the simulation was to determine if squames lifted into the air by the Bair Hugger reached those areas.

Dr. Elghobashi ran simulations with the Bair Hugger blower off and on. From those simulations, he performed mathematical calculations to project the movement of the squames. The CFD model showed that the warm air from the Bair Hugger disrupts the HVAC airflow and lifts squames into the "imaginary boxes of interest" above the operating table. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 59. In contrast, when the Bair Hugger is off—and "only the ventilation air from the inlet grilles and thermal plumes created by the warm surfaces including surgical lights, surgeons' heads, patient's head, and patient's knee are responsible for the dispersion of squames"—the model demonstrated that the squames are quickly dispersed to the outlet grilles and no

squames enter the imaginary boxes of interest. *Id.* at 57. From these results, Dr. Elghobashi "concluded that without the hot air discharged from the blower, the ventilation air circulation alone cannot disperse the squames to the surgical site." *Id.* Additionally, he observed that "[t]he thermal plumes from various warm surfaces only slightly affect the air coming from the inlet grilles and do not affect the motion of the squames." *Id.*

Defendants argue that Dr. Elghobashi's trial testimony establishes that his CFD model does not support general causation. At trial, Dr. Elghobashi admitted that his simulation does not account for many other sources of turbulence that would be found in any real-world OR, such as the movement of medical personnel. Consequently, Defendants argue that Dr. Elghobashi cannot rely on the CFD results to conclude that the Bair Hugger system would have a similarly meaningful impact in a real OR.

Plaintiffs respond that Dr. Elghobashi explained at trial that these additional variables, if measured, would only exacerbate the Bair Hugger's effect. They contend Dr. Elghobashi, in isolating the Bair Hugger's effect, applied reliable scientific methodology. Further, Plaintiffs assert that any disagreement with "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001) (quoting *Hose v. Chicago Northwestern Transp. Co.*, 70 F.3d 968, 974 (8th Cir. 1996)).

The Court excludes Dr. Elghobashi's testimony for the following reasons. First, Dr. Elghobashi's conclusion relies on an unproven and untested

premise. Second, there is too great an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect in the real world. Third, the CFD simulation was developed for litigation, which raises concerns about its reliability and objectivity.

A. There is Too Great an Analytical Gap Between the CFD Results and Dr. Elghobashi's Conclusion About Real-World Effects

Defendants do not challenge the reliability of CFD generally. Rather, Defendants challenge the reliability of the causal inferences that Dr. Elghobashi draws from the CFD model.

The Supreme Court in *Daubert* emphasized that a key consideration in assessing whether scientific knowledge will assist the trier of fact is "whether it can be (and has been) tested." 509 U.S. at 593. Indeed, the Court recognized that "[s]cientific methodology today is based on generating hypotheses and testing them to see if they can be falsified." *Id.*

Applying *Daubert*, the Eighth Circuit affirmed the exclusion of expert testimony where that expert's causation theory relied on "an unproven and indeed untested premise." *Polski v. Quigley Corp.*, 538 F.3d 836, 840 (8th Cir. 2008). In *Polski*, plaintiffs alleged that the use of Cold-Eeze, a nasal spray made for the treatment of cold symptoms, permanently impaired their senses of taste and smell. *Id.* at 837. Plaintiffs' expert opined that the spray emitted from the Cold-Eeze bottle traveled into the nasal cavity, and caused zinc ions in the spray to come into direct contact with

the olfactory epithelium. *Id.* at 839. But the expert never tested this theory, which the district court observed "could have easily and ethically been tested." *Id*. at 840. According to the Eighth Circuit, the district court did not abuse its discretion by concluding that this untested theory was "not sufficiently reliable to be admitted under Rule 702." *Id.* at 839-41 (quoting *Polski v. Quigley Corp.*, No. 04-4199, 2007 WL 2580550, at *5 (D. Minn. Sept. 5, 2007)). The Eighth Circuit explained that plaintiffs had the burden of establishing the testimony's admissibility, which "required sufficient proof that [the expert's] testimony was 'the product of reliable principles and methods,' and that [the expert] 'applied the principles and methods reliably to the facts of the case.'" *Id.* at 841 (quoting Fed. R. Evid. 702).

This case similarly involves an unproven and untested theory. Although Dr. Elghobashi did conduct the CFD modeling, which in broad terms might be considered a "test," he never tested his ultimate conclusion. The CFD model showed that—in a simulated OR—the Bair Hugger increases the number of squames that reach the surgical site. The model also showed that, when the Bair Hugger is off, the squames are quickly dispersed to the outlet grilles and do not reach the surgical site. Relying on the CFD model, Dr. Elghobashi concluded that squames would not reach the surgical site "without the hot air discharged from" the Bair Hugger. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 55.

Both Dr. Elghobashi and plaintiffs' counsel repeatedly emphasize that the simulation is intended to represent what happens in a real-world OR where

a knee surgery is being performed. At trial, Dr. Elghobashi testified that the CFD simulation reflects conditions "identical to what happens in reality" because he only omitted "insignificant machines, computers and things which are not really important." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 893:4-8. Plaintiffs' counsel similarly emphasized that the simulation was "not an animation" but "a real world model of what happens based on generally accepted mathematical principles." ECF No. 1000 (Oct. 25, 2017 *Daubert* Hearing Tr.) at 411:8-10.[3]

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[3] To the extent Plaintiffs imply that the CFD model reconstructs the particle movement in a surgery where infection occurs, the model is inadmissible for this purpose. Simulations "offered as evidence of what actually happened" are more like "experimental evidence and require a showing of substantial similarity." 5 Christopher B. Mueller & Laird C. Kirkpatrick, Federal Evidence § 9:26 (4th ed. 2019). In the Eighth Circuit, "[a] court may properly admit experimental evidence if the tests were conducted under conditions *substantially similar* to the actual conditions." *Dunn v. Nexgrill Industries, Inc.*, 636 F.3d 1049, 1055 (8th Cir. 2011) (emphasis in original) (quoting *McKnight v. Johnson Controls, Inc.*, 36 F.3d 1396, 1401 (8th Cir. 1994)). The simulated OR in the CFD model falls short of being "substantially similar" to a real-life OR. Moreover, the Court emphasizes that in other accident reconstruction cases where federal courts recognized the reliability of CFD, the experts compared their models to photographs of the accident to support or refute their theory. *See, e.g., Turner v. Liberty Mut. Fire Ins. Co.*, No. 4:07-CV-00163, 2007 WL 2713062, at *3 (N.D. Ohio Sept. 14, 2007) (the expert "compared the results of the simulation to 'physical and eyewitness evidence [photographs] to support or refute the hypothesis'"); *Dejana v. Marine Tech., Inc.*, No, 4:11-cv-1690, 2013 WL 4768407 at *9-12 (E.D. Mo. Dec. 20, 2013) (the expert compared the results to photographs of the accident). Consequently, the Court's subsequent analysis focuses on the

However, at trial, Dr, Elghobashi testified that the simulated OR omitted other sources of heat and air movement.[4] Most notably, the simulated OR does not account for the movement of personnel, which has a significant impact on airflow disruption. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 961:7-962:1. For example, in his expert report, Dr. Elghobashi discussed the Chow & Wang (2012) study, which—using Reynolds-averaged Navier Stokes ("RANS") modeling[5]—found that the periodic bending movement of one surgeon increased the concentration of particles to a larger-than-recommended value near the surgical site. ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 4-5. Further, at trial, Dr. Elghobashi cautioned that turbulent flow cannot be measured by

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admissibility of the CFD model for the purpose of predicting the movement of airflow in a theoretical surgery based on mathematical equations. In this context, "[i]t is essential that the model be based on assumptions and data that are consistent with the evidence in the case rather than on speculation." Mueller & Kirkpatrick, Federal Evidence § 9:26.

[4] Dr. Elghobashi's published study similarly acknowledged that there are "several other complexities involving other medical equipment in an OR, motion of the medical staff, opening and closing of the OR door, among others are not accounted for." ECF No. 1813-30, PX36 (He 2018) at 19. While the study suggests that "these complexities may not impact the main conclusions of the present study," the study provides no support for this statement. *Id.* Here, the Court cites to Dr. Elghobashi's submission for publication, which Plaintiffs attached to their briefing. At trial, Dr. Elghobashi confirmed that this study was published in January 2018. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 863:22-865:7; 929:2-6.

[5] Dr. Elghobashi accepts the validity of RANS modeling but considers LES simulations to be superior.

hand because even reaching a hand in "would be invasive to the flow" and "interrupt the results." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 895:14-21. For this reason, Dr. Elghobashi explained that scientists measure turbulent flows with "noninvasive means" such as laser beams. *Id.*

Despite meaningful differences between the CFD simulation and the real world, Dr. Elghobashi made no attempt to limit his testimony about the Bair Hugger's effect to ORs without these other sources of turbulence.[6] Instead, he concluded that the Bair Hugger's effect on the dispersion of squames would be *exaggerated* in a real-world OR. Yet, this hypothesis was never tested. Because Dr. Elghobashi never factored in other sources of heat and air movement, the CFD model did not test whether squames would be able to reach the surgical site without the hot air discharged from the blower in a real OR. The model also did not test whether squames would be significantly more likely to reach the surgical site when the Bair Hugger is turned on in a real OR. Thus, applying *Polski*, the Court finds that Dr. Elghobashi's conclusion relies on an unproven and untested

[6] Dr. Elghobashi's testimony might be admissible, if relevant, had he limited his conclusion to basic principles of thermodynamics—such as the conclusion that the Bair Hugger may cause particles to rise by blowing hot air. *McKnight*, 36 F.3d 1396 at 1401 (citing *Champeau v. Fruehauf Corp.*, 814 F.2d 1271, 1278 (8th Cir. 1987)) ("[W]here the experimental tests do not purport to recreate the accident, but instead the experiments are used to demonstrate only general scientific principles, the requirement of substantially similar circumstances no longer applies.").

premise.[7] Dr. Elghobashi's failure to test his theory "undermines the reliability of [his] opinion and renders it too speculative to admit." *See Werth v. Hill-Rom, Inc.*, 856 F. Supp. 2d 1051, 1061-63 (D. Minn. 2012) (excluding expert opinions where the experts "never attempted to validate their theory . . . they simply theorized that this might have happened").

The Court also finds *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016) instructive. In *In re Mirena*, the plaintiffs argued that the Mirena, an intrauterine device, perforated the plaintiffs' uteruses. *Id.* at 407. Dr. Jarrell, a biomedical engineer, opined that although the Mirena generally has flexible arms, these arms become stiff and rigid when loaded in "constrained conditions" sometimes causing perforation. *Id.* at 438. To test his theory, Dr. Jarrell applied double-sided tape to the device's arms to apply pressure in order to mimic a constrained condition. *Id.* at 441. He then measured the force that the device transferred to uterine tissue. *Id.* However, Dr. Jarrell admitted at his deposition that "he did not have any basis to suggest that the way the Mirena became rigid in his experiment [with double-sided tape] occurs *in vivo* (inside a human being)." *Id.* For this reason, the court found that these testing conditions did not

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[7] Plaintiffs argue that *Daubert* does not require testing, only testability. For support, Plaintiffs cite *Holverson v. ThyssenKrupp Elevator Corp*, Civ. No. 12-2765, 2014 WL 3573630 at *9 (D. Minn. July 18, 2014) in which the court allowed expert evidence despite the expert's failure to test his theory of liability. However, the court justified its decision by emphasizing that although the expert did not test his theory, it was corroborated by several real-world facts. *Id.* That is not the case here.

"reliably replicate the conditions inside a woman's uterus, and therefore render[ed] his methodology and the conclusions he draws from it unreliable." *Id.* Accordingly, the court concluded that the differences between the testing conditions and the real world creates "too great an analytical gap between the data and the opinion proffered." *Id.* at 442 (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 136, 146 (1997)).

Here, too, there is an analytical gap between the CFD results and Dr. Elghobashi's conclusion that the surgical team's movement would only increase the Bair Hugger's effect. Dr. Elghobashi contends that he did not include other sources of turbulence in order to "isolate the effect of the Bair Hugger" because "that's how we do science." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 963:1-5. But in trying to isolate the Bair Hugger, Dr. Elghobashi's simulation misleadingly implies that the Bair Hugger system is the only variable in the OR, and that squames could not reach the surgical site without the Bair Hugger operating. Such an extrapolation contradicts Dr. Elghobashi's acknowledgement that the movement of personnel meaningfully impacts turbulent airflow.[8] Based on the CFD model alone, Dr. Elghobashi does "not have any basis" to suggest that squames would only reach the surgical site when the Bair Hugger is

[8] As discussed below, other researchers have emphasized that "[t]he primary source of these airborne microorganisms is the people in the operating room, such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)." ECF No. 1813-32, PX38 (Darouiche 2017) at 2.

blowing in a real OR. *Cf. In re Mirena*, 169 F. Supp. 3d at 441.

Dr. Elghobashi also speculates about the Bair Hugger's effect in a real OR. Dr. Elghobashi, without support,[9] emphasizes that his model was the "best case scenario for 3M" because introducing other sources of turbulence, such as the surgical team's movement, would only have enhanced the dispersion of squames and increased the Bair Hugger's effect. *Gareis*16-cv-4187, ECF No. 474 (May21, 2018 Trial Tr.) at 917:13-15. But "nothing in either *Daubert*or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146. Dr. Elghobashi has not cited any study that factors in other sources of turbulence and reaches a similar conclusion. Nor has he tested this theory even though such tests are feasible.[10] Thus, his

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[9] At trial, Dr. Elghobashi stated: "I know that based on my knowledge . . . [w]e gave you the best case scenario, trust me about this, trust me." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 917:13-15.

[10] Although Dr. Elghobashi's CFD code had been validated, he made no attempt to validate his CFD simulation with experimental evidence. Dr. Elghobashi admitted in his published study there are "a lack of detailed experimental measurements . . . in an OR during a clinical trial" that would "help validate the numerical predictions." ECF No. 1813-30, PX36 (He 2018) at 19. He acknowledged that "such detailed data during a clinical trial are potentially feasible but may cost up to $ 2 M." *Id.* For support for this cost estimate, Dr. Elghobashi cites a "private communication." *Id.* at 21. Dr. Elghobashi also testified that he could have simulated personnel movement, but he was not asked to. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 918:1-8. While Dr. Elghobashi only ran two simulations

conclusion that the Bair Hugger significantly impacts the trajectories of squames in a real-world OR, ECF No. 1813-14, PX19 (Elghobashi Rpt.) at 63-64, is nothing more than his say-so.

To be sure, expert testimony inherently involves some amount of educated guesswork: "A certain amount of speculation is necessary, an even greater amount is permissible (and goes to the weight of the testimony), but too much is fatal to admission." *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 760 (8th Cir. 2003). Dr. Elghobashi's attempted gap-filling is more like a leap of faith than an inferential leap. Dr. Elghobashi's model implies that the Bair Hugger is the but-for cause of squames reaching the surgical site in the simulated OR. And he assumes that a real OR would amplify the Bair Hugger's effect. At the same time, he conceded at trial that other factors exist in a real OR that significantly impact airflow and the trajectories of squames. Because his simulation never factors in these other sources of turbulence, it cannot answer important questions, such as: (1) in a real OR, can these other

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with the constraints discussed above, the Court emphasizes that in other cases where federal courts recognized the reliability of CFD in litigation, the experts based their conclusions on comparisons between several simulations. *See, e.g., Quiet Technology DC-8 v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1338 (11th Cir. 2003) (the expert relied on 16 simulations); *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1217-21 (Fed. Cir. 2006) (the expert relied on 40 to 50 iterations of the simulation); *Dejana*, 2013 WL 4768407 at *9-12 (the expert performed more than 100 CFD simulations of a boat operating at different speeds to determine at what speed the predicted damage matched the actual photos of damage).

sources of turbulence carry squames to the surgical site without the Bair Hugger?; (2) if they can, does the number of squames reaching the surgical site increase when the Bair Hugger is turned on?; and (3) how would the non-Bair Hugger created turbulence interact with or affect the Bair Hugger-generated eddies? Dr. Elghobashi never attempts to answer these questions and bridge the gap in his analysis. Instead, he simply assumes that the Bair Hugger significantly increases the number of squames reaching the surgical site in a real OR. Such speculation renders his methodology and the conclusions he draws from it unreliable.

Plaintiffs argue that, as a general rule, any disagreement with "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility." *Bonner*, 259 F.3d at 929 (quoting *Hose*, 70 F.3d at 974). Plaintiffs are correct that a dispute solely over inputs, such as the Bair Hugger's air temperature, might not render Dr. Elghobashi's testimony inadmissible.[11] *See, e.g., In re Zurn Pex*

[11] The CFD model was limited to specific boundary conditions, such as number and placement of vents and the temperature of the air exiting the Bair Hugger. At trial, Dr. Elghobashi admitted that adjusting any inputs would alter the results, which is why "prescribing correct boundary conditions is crucial to predicting a given flow." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 862:14-18. Consequently, if any inputs differ in the real world or from OR to OR, then the simulation results may not useful to the fact finder in those cases. *Cf. Lauzon*, 270 F.3d at 687 (analyzing, under *Daubert*'s relevance factor, "whether the proposed expert sufficiently connected the proposed testimony with the facts of the case"). For instance, Defendants argue that their expert, "who took actual measurements of the temperature of the air exiting a Bair Hugger blanket, could not replicate Dr.

Plumbing Prod. Liab. Litig., 644 F.3d 604, 614 (8th Cir. 2011) ("A district court necessarily has 'considerable discretion' in deciding whether to admit expert testimony where the factual basis is disputed."); *Quiet Tech*, 326 F.3d at 1343-44 (admitting CFD model of jet engine over challenge to expert's inputs and equations).

But, here, Plaintiffs have held out the CFD simulation as representing a real-world OR even though there are meaningful differences. This is not a mere quibble over whether there are three doctors versus four, whether the OR doors were opened once or several times, or whether the OR dimensions vary slightly. Dr. Elghobashi's conclusions have drifted from the factual realities of his test. *Bonner*, 259 F.3d at 929-30 (quoting *Hose*, 70 F.3d at 974) (recognizing that courts must exclude expert testimony where it is "so fundamentally unsupported that it can offer no assistance to the jury"). "[C]ourts retain broad discretion under Rule 403 to exclude computer animations or simulations, particularly where they are based on questionable assumptions or project such a slanted or distorted view of the evidence as to be unfairly prejudicial or misleading." Mueller & Kirkpatrick, Federal Evidence § 9:26. Dr. Elghobashi's testimony is not saved from exclusion

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Elghobashi's assumption of 106°F (41.11°C)—after measuring several areas of the blanket, the highest average temperature [] recorded was 36°C." ECF No. 805 (Mem. in Supp. of Defs.' 2017 Mot. to Exclude Engineering Experts) at 43. In its December 13th, 2017 order, however, the Court found that the simulation's inputs were not so fundamentally unsupported that they could offer no assistance to the jury.

simply because he initially applied reliable physics principles.[12]

This decision "does not mean that [Dr. Elghobashi's] theory is necessarily *wrong*; it simply means that the theory meets none of the indicia of reliability identified in *Daubert* and therefore must be excluded." *Polski*, 538 F.3d at 841 (emphasis in original) (quoting *Polski,* 2007 WL 2580550, at *5). For these reasons, Dr. Elghobashi's testimony is not sufficiently reliable and too speculative to be presented to the jury.

B. Dr. Elghobashi Developed the CFD Model During Litigation

Additionally, Dr. Elghobashi's testimony and CFD model were "developed for litigation." *Lauzon*, 270 F.3d at 687. At trial, Dr. Elghobashi testified that Plaintiffs' counsel hired him in April 2016 to conduct a CFD simulation relating to issues in this litigation. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 923:8-12. Prior to his involvement in this litigation, he had never conducted a CFD model involving a medical device or an OR. *Id.* at 933:7-20. Because Dr. Elghobashi had never observed a Bair

[12] Even if the Court limited Dr. Elghobashi's testimony to the effect of the Bair Hugger in a quiet OR where no surgery is being performed, this limited testimony would not assist the trier of fact in resolving the factual dispute. In every case in this MDL, Plaintiffs will ultimately have to prove that their infection would not have occurred but for the use of the Bair Hugger system, or that the Bair Hugger system was a substantial contributing cause. Elghobashi's CFD simulation does not allow for any real-world comparison between an OR with a Bair Hugger and an OR without a Bair Hugger.

Hugger in an OR, the plaintiffs' lawyers joined Dr. Elghobashi on a visit to an OR room, where one lawyer pretended to be the patient on the operating table as no actual surgery was taking place. *Id.* at 954:24-955:17.

"[I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995). When an experts' findings are developed in the course of litigation, courts have raised concerns about the objectivity and reliability of the findings as well as the possibility that the parties have "shop[ped] for experts who will come to the desired conclusion." *Id.* These same concerns exist here. For instance, plaintiffs' lawyers accompanied Dr. Elghobashi on his one and only visit to an OR. Dr. Elghobashi also took minimal measurements for the model's inputs. Instead, he relied on materials provided by the plaintiffs' attorneys. *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 947:18-25.

Plaintiffs defend Dr. Elghobashi's study because it is peer-reviewed and published. But the published study discloses significant conflicts of interest.[13] While

[13] In the published study, the authors originally declared no conflicts of interest. ECF No. 1813-30, PX36 (He 2018) at 19. But at trial, Dr. Elghobashi admitted that the editors subsequently added the following disclosure: "Dr. Elghobashi is a testifying witness in a court case against 3M, in which the plaintiffs urge that the Bair Hugger patient warming system causes periprosthetic joint infections by disrupting the airflow in ORs.

the study's publication indicates that other scientists think it has scientific value, this does not guarantee that the conclusions reached are reliable.

For these reasons, the Court excludes Dr. Elghobashi's testimony.

II. MEDICAL EXPERTS

The medical experts rely on a number of non-epidemiological studies and Dr. Elghobashi's CFD model, which together describe the mechanism by which the Bair Hugger transmits contaminated airborne particles into the sterile surgical site. They also cite the McGovern Observational Study ("Observational Study"), an epidemiological study, which found a statistically significant association between the Bair Hugger and infection.

Defendants do not dispute the experts' qualifications. Dr. Jarvis is a medical doctor with experience in infectious disease, healthcare epidemiology, and infection control. He formerly worked at the Center for Disease Control with a focus on infectious diseases associated with healthcare. Dr. Samet is a medical doctor with a master's degree in epidemiology from the Harvard School of Public Health. His research focuses on the health consequences of inhaled agents, including tobacco and radon, and is known for his work as the plaintiffs' expert in the tobacco litigation. Dr. Stonnington, an orthopedic surgeon in Mississippi, relies on his seventeen years of clinical experience.

Dr. Apte is a paid consultant for the plaintiffs." *Gareis* 16-cv-4187, ECF No. 474 (May 21, 2018 Trial Tr.) at 929:3-931:4.

Defendants argue that: (1) the Court's order in *Gareis* that excluded Plaintiffs' "dirty machine" theory should apply to the entire MDL; (2) the Jeans (2018) study demonstrates that the Observational Study is unreliable; and (3) the consensus at the 2018 International Consensus Meeting ("ICM") on Musculoskeletal Infection reinforces that Plaintiffs' medical experts have made an improper inference regarding causation.

Plaintiffs respond that the Observational Study is relevant and reliable evidence of general causation—notwithstanding the Jeans (2018) study—and that the 2018 ICM does not preclude expert opinions on causation. Additionally, Plaintiffs contend that the Court's ruling in *Gareis* about the "dirty machine" theory should not apply to the entire MDL.

The Court finds that Plaintiffs' medical expert opinions are unreliable and should be excluded under *Daubert* because: (1) there is too great an analytical gap between the literature and the experts' general causation opinions; (2) the experts failed to consider obvious alternative explanations; and (3) the causal inferences made by the experts have not been generally accepted by the scientific community.

A. There is Too Great an Analytical Gap Between the Scientific Literature and the General Causation Opinions of Plaintiffs' Medical Experts

The state of the scientific literature presents a challenge for the general causation experts. No medical organization, regulator, or peer-reviewed study has found that the Bair Hugger causes PJI. Moreover, the only epidemiological study on which the

experts rely has expressly disclaimed causation and acknowledged potential confounders. Still, each of plaintiffs' three medical experts reach this conclusion in their reports. None has done so through an experiment, laboratory work, or a new epidemiological study of his own. Drs. Jarvis and Samet arrive at this conclusion by drawing upon the existing literature as well as Dr. Elghobashi's CFD model. Dr. Stonnington relies on his medical training, education, and knowledge, as well as his clinical experience,[14] and to a lesser extent, the scientific literature. Plaintiffs emphasize that the experts have relied on the totality of the evidence to draw this conclusion.

The Supreme Court established that a court may exclude expert testimony where there is "too great an analytical gap between" the underlying evidence and the expert's opinion. *Joiner*, 522 U.S. at 146. In *Joiner*,

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[14] Dr. Stonnington's anecdotes from his own practice, on their own, are insufficient to establish causation. In *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 990 (8th Cir. 2001), the Eighth Circuit warned that "[c]ausal attribution based on case studies must be regarded with caution." The Court acknowledged that "[c]ase reports make little attempt to screen out alternative causes . . . [a]nd they often omit relevant facts about the patient's condition." *Id.* at 989-90 (quoting Federal Judicial Center, *Reference Manual on Scientific Evidence* 475 (3d ed. 2011)). As an initial matter, the Court finds that Dr. Stonnington's anecdotal evidence may even be less reliable than the case reports at issue in *Glastetter*. That is because Dr. Stonnington admitted during the *Gareis* trial that, apart from his opinion in the *Gareis* case, he never recorded in a patient's medical record or told a patient that the Bair Hugger caused his or her infection. *Gareis* 16-cv-4187, ECF No. 471 (May 16, 2018 Trial Tr.) at 425:18-25. Moreover, Dr. Stonnington's anecdotal reports do not include basic numerical data or years when infections occurred.

the plaintiff alleged that his exposure to polychlorinated biphenyls ("PCB") as an electrician "promoted" his cancer. *Id.* at 139-40. According to the Supreme Court, the district court did not abuse its discretion when it excluded expert testimony because the experts had relied on four epidemiological studies that were "not a sufficient basis" for their conclusion that exposure to PCB caused cancer. *Id.* at 145. To support its holding, the district court analyzed the limits of each study. For example, the district court noted that one study observed a statistically significant association but involved a number of confounding variables. *Id.* at 146.

The Eighth Circuit similarly affirmed the district court's exclusion of expert testimony where the medical texts underlying an expert's report failed to present persuasive scientific evidence of causation. In *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 988-90 (8th Cir. 2001), the Eighth Circuit considered whether plaintiff's experts had articulated a theory to explain how Parlodel, a medication, caused an intracerebral hemorrhage (ICH) in the plaintiff's brain. The experts had theorized that Parlodel causes arteries to constrict—known as vasoconstriction—resulting in elevated blood pressure, which in turn is a risk factor for ICHs. *Id.* at 989. However, the Eighth Circuit agreed with the district court that the evidence underlying the expert's theory "does not demonstrate to an acceptable degree of medical certainty that Parlodel can cause an ICH." *Id.* The court analyzed several medical texts that the experts relied on, noting that "[a]t least one text ventured a hesitant conclusion that Parlodel causes vasoconstriction, but the explanation made clear that more research was

needed before causation could be firmly established." *Id.* at 990. The court concluded that "these texts do not present persuasive scientific evidence that Parlodel causes vasoconstriction." *Id.*

Plaintiffs contend that proponents of expert testimony need not prove that the conclusions are correct, and courts must not determine which of several theories has the best provenance. *Kuhn v. Wyeth*, 686 F.3d 618, 625 (8th Cir. 2012); *see also Johnson v. Mead Johnson & Co.*, 754 F.3d 557, 562 (8th Cir. 2014) ("[D]istrict courts are admonished not to weigh or assess the correctness of competing expert opinions."). This does not mean, however, that an expert's conclusions are off limits. In *Joiner*, the Supreme Court clarified that "conclusions and methodology are not entirely distinct from one another" and "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S. at 146. The Court concluded that it was "within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions." *Id.* at 146-47. Consequently, it is within the Court's discretion to review the studies underlying an expert's report and to find that the expert's conclusion is not supported by the totality of the evidence. The Court does so below.

1. The "Dirty Machine" Theory

Plaintiffs' first theory of causation is that the Bair Hugger, lacking an adequate filtration system, emits contaminants into the OR, and thus increases the

bacterial load reaching the surgical site. In May 2018, in response to a motion in limine, the Court excluded evidence supporting this theory from the *Gareis* trial, finding that Plaintiffs lacked any scientific evidence to support it. *Gareis* 16-cv-4187, ECF No. 306 (Order re Mot. in Lim.) at 2 ("Plaintiffs have no evidence that anyone has caught colony-forming units of bacteria floating out of the blanket's perforations.").[15] Defendants argue that because this ruling did not depend on any case-specific facts in *Gareis*, this ruling should apply to the entire MDL.

Plaintiffs respond that the Court's decision depended on the lack of evidentiary support in Dr. Jarvis's specific causation opinion but contend that the medical experts' general causation reports nevertheless support this theory. For example, Drs. Jarvis and Stonnington cite several studies like Avidan (1997), Albrecht (2009) and (2011), and Reed (2013), which found that the Bair Hugger internally generates and then emits contaminated particles out of the distal hose. Drs. Jarvis and Stonnington then conclude that because the devices emit contaminated air, these devices increase the risk of infection. ECF No. 1813-1, PX1 (Jarvis Rpt.) at 10-11; ECF No. 1813-3, PX3 (Stonnington Rpt.) at 6-7. Dr. Samet, citing evidence summarized by Dr. Jarvis, similarly concludes that the Bair Hugger "could increase the dose of organisms delivered to the surgical site." ECF No. 1813-2, PX2 (Samet Rpt.) at 17.

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[15] The parties' experts disagree about whether the Bair Hugger blanket may act as a filter.

The Court finds that there is too great an analytical gap between the experts' conclusions and the scientific literature summarized in their reports. In reaching these conclusions, the experts ignore the underlying studies' limitations. For example, these studies support a conclusion that the Bair Hugger emits contaminated air out of the distal hose. But no study even considered whether contaminated air emitted from the hose could reach the surgical site and cause infection.[16] Both Albrecht studies clarify that the researchers did not evaluate or establish a direct link between forced-air warming and increased surgical site infection rates. ECF No. 750 (Mem. in Supp. of Defs.' 2017 Mot. to Exclude General Causation Medical Experts) at 25. Additionally, Reed (2013)—the most recent study cited by the experts in support for this theory—explicitly rejected finding a direct link between the Bair Hugger's contaminated air and infection because it is "presently unknown" whether the contaminated air would reach the surgical site. ECF No. 950-20, PX30 (Reed 2013) at 6. Because Plaintiffs' medical experts do not cite any studies after Reed (2013), the Court finds no support for their conclusion that the contaminated emissions reach the surgical site.

Perhaps the experts assume that this contaminated air reaches the surgical site via the "airflow disruption" theory. But as discussed below,

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[16] Because the patient's torso and the Bair Hugger blanket are covered with surgical draping, the warm air does not blow directly onto the lower body surgical site. (In upper body surgeries, like shoulder surgeries, the blanket is placed over the lower half of the patient's body.)

the studies underlying this theory also do not establish that the Bair Hugger causes infection.

2. The "Airflow Disruption" Theory

At the *Gareis* trial, Plaintiffs and their medical experts articulated their second theory of causation—the "airflow disruption" theory—as follows: HVAC systems in ORs create a "forcefield" around the surgical site by pushing particles down to the floor where vents take those particles, including any bacteria, out of the room. However, when the Bair Hugger is turned on, hot air escapes from the Bair Hugger blanket and the bottom edge of the surgical draping, rises, and then disrupts the protective "forcefield." This in turn causes squames (sometimes referred to as colony forming units ("CFUs")) to float into the surgical site.

The experts rely on two bodies of supporting evidence: empirical studies that examine air flow patterns in ORs and Dr. Elghobashi's testimony and CFD simulation. Defendants challenge both lines of evidence. Defendants contend that the empirical studies do not reflect real-world conditions and thus, standing alone without Dr. Elghobashi's CFD model, do not provide sufficient support to infer general causation.

Reliance on Empirical Studies

Plaintiffs assert that several empirical studies have found that the convection currents produced by the Bair Hugger significantly increase the number of particles in the sterile field.[17] Plaintiffs concede that

[17] *See, e.g.,* ECF No. 1813-16, PX21 (Legg 2012); ECF No. 1813-17, PX22 (Legg 2013); ECF No. 1813-18, PX23 (Belani 2012);

these studies do not involve real ORs, but argue that it would be an abuse of discretion for the Court to require the experts to rely only on studies that perfectly reflect the real world. Plaintiffs contend that as long as the methods employed by the expert are scientifically valid, "mere disagreement with the assumptions and methodology used does not warrant exclusion of expert testimony." *Hill v. Sw. Energy Co.*, 858 F.3d 481, 486 (8th Cir. 2017) (quoting *SEC v. Das*, 723 F.3d 943, 950 (8th Cir. 2013)). The Court agrees that these peer-reviewed studies are not so unreliable that they should be excluded from the evidence. Rather, for the following reasons, the Court finds that there is too great an analytical gap between these studies and the experts' conclusion that the Bair Hugger causes infection.

Plaintiffs' experts piece together an array of studies to ultimately conclude that the Bair Hugger causes PJI. First, the experts contend that the Bair Hugger increases the number of particles over the surgical site. While these studies demonstrate that forced-air warming devices can increase particle counts over the surgical site under certain conditions, they do not conclude that this same increase exists in the real world. For example, all three experts rely on the Legg studies, which found increased particle counts over the surgical site associated with the use of the Bair Hugger. Yet, these studies explicitly limit their findings to their exact operating theater set up. ECF No. 1813-16, PX21 (Legg 2012) at 4; ECF No. 1813-17, PX22 (Legg 2013) at 5. Moreover, in the

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ECF No. 1813-19, PX24 (Dasari 2012); ECF No. 1813-20, PX25 (McGovern 2011).

2013 study, the authors acknowledge that "[t]his study does not show that forced-air warming increases the risk of infection." ECF No. 1813-17, PX22 (Legg 2013) at 5. Additionally, Drs. Jarvis and Samet cite the Dasari (2012) study, which measured temperatures in an OR around a draped mannequin and found that the Bair Hugger significantly elevated mean temperatures over the surgical site. The authors limited their conclusions, however, to the study set up and cautioned that "the definitive effects of this excess heat on clinical outcomes are presently unknown." ECF No. 1813-19, PX24 (Dasari 2012) at 6. Lastly, all three experts cite the Belani (2013) study, which used bubbles to investigate the effect of forced-air warming on OR airflow and found that the forced-air warming significantly disrupted airflow and increased bubble counts over the surgical site.[18] These researchers also cautioned that their conclusions were based on the study's "exact setup" and that the researchers were "unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery." ECF No. 1813-18, PX23 (Belani 2013) at 6.

Furthermore, these studies only consider particle counts, and not whether forced-air devices increase infection. Attempting to close the analytical gap between increased particle counts and infection, the experts cite several studies linking higher particle counts at the surgical site with increased risk of infection. For example, all three experts cite the

[18] The McGovern (2011) study includes both an observational study, discussed in detail below, and a "bubble" experiment with similar findings to the Belani study. ECF No. 1813-20, PX25 (McGovern 2011) at 6.

Stocks (2010) study, which found a correlation between the number of airborne particles equal or greater than ten microns in size and the number of CFUs. ECF No. 1813-33, PX39 (Stocks 2010) at 6.

Dr. Jarvis's trial testimony, however, exposed that the Stocks study cannot bridge this gap. At trial, Dr. Jarvis testified that particle size matters because no study has found that smaller particles can carry bacteria. *Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 759:17-760:19. Dr. Jarvis also admitted that there is no study that shows that the Bair Hugger has any impact on particles that are large enough to carry bacteria other than the "CFD models perhaps." *Id.* at 761:5-8. Consequently, Dr. Jarvis conceded that no study has found that the Bair Hugger increases the number of *bacteria* arriving at the surgical site. *Id.* at 768:23-769:1.

The experts also cite a randomized controlled study, Darouiche (2017), which found a correlation between reducing CFUs at the surgical site and lower rates of infection. But this study also fails to close this gap. First, the researchers did not even study forced-air warming devices. The study involved the Air Barrier System, which passes ambient air through a filter at the surgical site. Second, this study recognized that "[t]he primary source of these airborne microorganisms is the people in the OR, such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)." ECF No. 1813-32, PX38 (Darouiche 2017) at 2. Thus, this study lends support for the theory that personnel movement in the OR is a major risk factor

of infection[19]—a factor not reflected in Dr. Elghobashi's simulation or the studies described above.[20] Therefore, as a whole, these studies are too far removed from the conditions of real ORs to support Plaintiffs' experts' conclusion that the Bair Hugger system causes infection in real-world operations.

Reliance on Dr. Elghobashi's CFD Model

Given the gap in the scientific literature discussed above, Dr. Elghobashi's CFD model plays an essential role in understanding the impact of the Bair Hugger on larger particles that carry bacteria. *See Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 763:18-23 (Dr. Jarvis testifying that "that's where Dr. Elghobashi in his model can help fill in that gap, where the studies haven't been done"). As Dr. Jarvis acknowledged at trial, the CFD simulation is the only study that even considered the impact of the Bair Hugger on particles ten microns in size. *Id.* at 761:5-8; 807:5-12. Dr. Jarvis also testified that "we have a variety of studies that answer each one of these questions, and when you put [the studies] all together, you get a picture similar to what Dr. Elghobashi has shown with his CFD model that illustrates why the

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[19] Dr. Jarvis also testified at trial that personnel movement has the greatest impact on ten-micron particles. *Gareis* 16-cv-4187, ECF No. 473 (May 18, 2018 Trial Tr.) at 752:18-753:5.

[20] ECF No. 1813-16, PX21 (Legg 2012) at 3 (single surgeon with no nurse or assistants); ECF No. 1813-17, PX22 (Legg 2013) at 2 (single surgeon); ECF No. 1813-18, PX23 (Belani 2013) at 3 (single anesthetist stood motionless at the head of the table); ECF No. 1813-19, PX24 (Dasari 2012) at 6 (two people walked around); ECF No. 1813-20, PX25 (McGovern 2011) at 3 (surgeon and anesthetist stood motionless).

Bair Hugger will increase the risk of prosthetic joint infections." *Gareis* 16-cv-4187, ECF No. 472 (May 17, 2018 Trial Tr.) at 631:6-10.

But even if the CFD model were admissible, there is too great an analytical gap between the CFD results and the medical experts' conclusion that the Bair Hugger causes infection. *See, e.g., In re Mirena IUD*, 169 F. Supp. 3d at 441 (excluding a general causation expert's opinion as unreliable because it was based on a lab test using "equipment apparently intended to mimic the uterus" but that admittedly "[did] not reliably replicate the conditions inside a woman's uterus"). Drs. Jarvis and Samet rely on the simulated off-and-on comparison as evidence that the Bair Hugger disrupts the airflow, brings contaminants from the floor area into the sterile surgical field, and increases the risk of infection in a real-world OR. But, as discussed above, Dr. Elghobashi's simulation does not reflect many sources of turbulence and particles that one would expect in a real OR.

Remarkably, the experts fail to acknowledge these differences, let alone explain how these differences might impact their analysis. Neither expert, for instance, acknowledges the surgical team's movements—one key difference between the CFD model and a real OR. As discussed above, personnel movement in the OR is a major risk factor of infection. As a result, the CFD model—which does not simulate the surgical team's movement—cannot be relied on to establish that the Bair Hugger significantly increases the number of contaminated particles at the surgical site in the real world. Consequently, the experts make too great an inferential leap in their conclusions.

Furthermore, even if Drs. Samet and Jarvis had addressed these differences, they would not have been qualified to fill this analytical gap. It is outside their expertise to opine on how atmospheric eddies are impacted by the Bair Hugger in a real OR as opposed to in a simulated OR. Perhaps Drs. Samet and Jarvis rely on Dr. Elghobashi's caveat at the end of his report that the inclusion of personnel movement and additional squames in the simulation would only further increase the probability that squames would travel to the surgical site. But as discussed above, Dr. Elghobashi's assumption is problematic as it has not been tested. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

3. The Observational Study

In addition to the mechanistic evidence describe above, the medical experts also rely on epidemiological evidence. Specifically, Plaintiffs' medical experts cite one epidemiological study, the McGovern (2011) Observational Study ("Observational Study"), to show a real-world association between the Bair Hugger and PJI.

Epidemiology is the "statistical study of disease or injury in human populations." Federal Judicial Center, *Reference Manual on Scientific Evidence* 286 (3d ed. 2011). According to the *Reference Manual on Scientific Evidence*, "[e]pidemiology focuses on the question of general causation" by identifying agents that are "associated with an increased risk of disease in groups of individuals." *Id.* at 552. However, "[a]n

association identified in an epidemiologic study may or may not be causal." *Id.* at 552-53. Because all studies have flaws, "[i]n evaluating epidemiologic evidence, the key questions, then, are the extent to which a study's limitations compromise its findings and permit inferences about causation." *Id.* at 553.

The Observational Study found a statistically significant association between the Bair Hugger and infection.[21] The Observational Study was an epidemiological study that compared infection rates at Wansbeck Hospital in Northumbria, England, during a period when the Bair Hugger and a period when a conductive warming device were in use. The researchers reviewed infection data to determine whether joint infection rates were associated with the type of patient warming device that was used. It was an observational study, meaning that it was not blinded and controlled like a clinical study.

The study authors warned against conflating correlation with causation: "[t]his study does not establish a causal basis . . . the data are observational and may be confounded by other infection control measures instituted at the hospital." ECF No. 1813-20, PX25 (McGovern 2011) at 8. Further, the authors expressly acknowledged that there was a period when different anti-thrombotic and different prophylactic antibiotic drugs were being used with the two groups of patients. *Id.* Finally, the authors noted that they were "unable to consider all factors that have been associated with SSI, as the details of blood

[21] The parties dispute, however, if tabulation errors exist in the Observational Study that would impact the statistical significance of the association.

transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record." *Id.*

Defendants first argue that the Observational Study is so unreliable that it should be excluded. The Court disagrees. The study is reliable as it is published and peer reviewed. And, even if the study has certain limitations, those limitations could be presented to a jury. *Kuhn*, 686 F.3d at 632 (holding that the expert's "reliance on the studies may be tested through the traditional means of cross examination and presentation of contrary evidence").

Nevertheless, as outlined above, it is unreliable for an expert to rely on studies to support conclusions that the study authors were themselves unwilling to reach. *See Joiner*, 522 U.S. at 145-46; *see also Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009) ("It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven."). *Joiner* and *Glastetter* focused on whether the underlying studies provide a sufficient basis for an experts' causation opinions, but district courts have also analyzed whether an expert addresses a study's limitations as a way of determining if the study reliably supports a causation opinion. For example, in *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 277 (S.D.N.Y. 2018), a district court found that an expert "fail[ed] to consider the alternative, and benign, explanations that that study identified for the correlation it found

between Mirena and IIH." The court determined that the report "pays only lip service" to the study's "caveat about confounders" as "[i]t nowhere reveals that the [epidemiological] study had not controlled for obesity or recent weight gain." *Id.* at 277-78. Consequently, the court found that the report inappropriately treated the correlation as "affirmative evidence of causation" and excluded the expert's testimony because it did not meet the standards for reliability articulated in *Daubert*. *Id.* at 278.

Here, too, the experts fail to address the McGovern researchers' caveats about confounders and alternative explanations, and thus, they inappropriately treat the association as affirmative evidence of causation. Both Drs. Jarvis and Stonnington cite the Observational Study without discussing the study's limitations and possible confounders. And although Dr. Samet mentions potential confounders acknowledged by the study authors, his description of them is misleading. Dr. Samet states that the Observational Study "has been criticized as potentially reflecting confounding by the non-comparability of prophylactic antibiotic use and thromboprophylaxis in the two periods." ECF No. 1813-2, PX2 (Samet Rpt.) at 12. He likens these criticisms "to the strategies employed for decades by the tobacco industry." *Id.* But by framing these criticisms as disingenuous, he aims to dismiss potential confounders without seriously considering them.

Additionally, Dr. Samet departs from his own description of reliable methodology when opining about causation. *Junk v. Terminix Int'l Co.*, 628 F.3d

439, 448 (8th Cir. 2010) (affirming the district court's holding that the expert's "failure to follow his own general practice . . . created 'too great an analytical gap' between his opinion and the data on which it relied"). Dr. Samet applies several criteria to determine if causation exists. With regard to "strength of association," Dr. Samet reports that the Observational Study establishes "a statistically significant association unlikely to be explained by confounding or other bias." ECF No. 1813-2, PX2 (Samet Rpt.) at 16. Next, Dr. Samet applies the criteria of consistency. Dr. Samet acknowledges, however, that this factor is not applicable to the Observational Study since this factor is generally related to the "findings of multiple observational studies." *Id.* Instead, Dr. Samet points to the series of empirical studies, which as discussed above, found that the Bair Hugger's convection currents increase the number of particles in the sterile field. But these studies do not establish—let alone consider—whether there was an association between the Bair Hugger and infection.

Without further explanation of Dr. Samet's thought process and how he weighed these criteria, the Court is left to guess why Dr. Samet finds that the consistency factor is met despite conceding that "[t]he McGovern paper supplies the only estimate of the risk" and absent that estimate he "would not be able to judge the quantitative magnitude of the association." ECF No. 1720-1, DX25 (Aug. 8, 2017 Samet Dep.) at 282:16-283:20. Dr. Samet's application of the factors does not reassure the Court that he has bridged the gap between the scientific literature and

his causation opinion.[22] *See In re Mirena (No. II)*, 341 F. Supp. 3d at 247 (collecting cases) ("As courts have recognized, it is imperative that experts who apply multi-criteria methodologies such as Bradford Hill or the 'weight of the evidence' rigorously explain how they have weighted the criteria. Otherwise, such methodologies are virtually standardless and their applications to a particular problem can prove unacceptably manipulable. Rather than advancing the search for truth, these flexible methodologies may serve as vehicles to support a desired conclusion.").

B. Plaintiffs' Medical Experts Failed to Consider Alternative Explanations

Courts also weigh the ability of an expert to rule out alternative explanations. *Lauzon*, 270 F.3d at 693 (collecting cases). The Eighth Circuit noted that this factor is often cited when discussing a causation opinion arrived at by differential diagnosis. *Id.* at 693 n.7. This factor is also relevant here, though, given the background risk—that is, the risk of infection in the general population when the Bair Hugger has not been used. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005) (noting that "[a]

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[22] Defendants also argue that Dr. Samet does not seem to employ "the 'same level of intellectual rigor' that he employs in his academic work." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 26 (1st Cir. 2011) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Here, Dr. Samet relies on one epidemiological study with potential confounders. In contrast, Dr. Samet's report to the Surgeon General, which concluded that smoking causes lung cancer, was based upon the consistently strong associations observed in at least seven observational studies. ECF No. 956-1, DX25 (Aug. 8, 2017 Samet Dep.) at 80:3-24.

reliable methodology should take into account the background risk").

Although an "expert's causation conclusion should not be excluded because he or she has failed to rule out *every* possible alternative cause," experts should discount "obvious alternatives" and "explain why other conceivable causes are excludable." *Lauzon*, 270 F.3d at 693; *see also* Fed. R. Evid. 702 advisory committee's note to 2000 amendment (experts should "adequately account[] for obvious alternative explanations"). The Court interprets this guidance to require experts at the very least to examine other conceivable causes flagged by researchers in key studies cited in their reports.[23] For instance, Dr. Reed, a senior author on the Observational Study—the only study establishing an association between the Bair Hugger and infection—testified that many efforts were being undertaken at the hospital at the time of the study to decrease its infection rates and specifically called out one plausible confounder: the introduction of screening for methicillin-sensitive *Staphylococcus Aureus* ("MSSA") at the end of the Bair Hugger only period. ECF No. 751-1, DX8 (Dec. 4, 2016

[23] Dr. Samet asserts that the deposition testimony of the Observational Study authors resolves the possibility of confounding. Dr. Samet considered two potential confounders mentioned in McGovern: the prophylactic antibiotic regimen and the thromboprophylaxis protocol, ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 48:20-49:22, which the McGovern authors later confirmed were not confounding factors. *See, e.g.,* ECF No. 1813-39, PX48 (Nov. 29, 2016 Nachtsheim Dep.) at 349:14-25. Dr. Samet, however, never addressed other plausible confounders discussed by the Observational Study researchers in their depositions.

Reed Dep.) at 78:21-25; 114:7-115:10. In a subsequent study involving Dr. Reed, the researchers recently reiterated that "there were significant confounding factors in [the Observational Study]." ECF No. 1850-1, DX16 (Kumin 2018) at 7.

Dr. Samet, however, never mentioned—let alone investigated—this alternative explanation. ECF No. 1813-2, PX2 (Samet Rpt.) at 12 (summarily concluding that "confounding by other, unidentified factors seems unlikely" because the "change in the warming method was temporally abrupt"). Nor did he examine the raw data underlying the Observational Study to try to confirm whether or not this potential confounder identified by the researchers could be an alternative explanation for the decrease in PJI. ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 41:5-13.[24]

Plaintiffs argue that such failures go to weight and not admissibility. This would be true had Dr. Samet opined, for example, on why MSSA screening is not an alternative explanation. But here, Dr. Samet's report offers no explanations about MSSA screening for Defendants to attack on cross examination.[25] *Cf.*

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[24] In *In re Mirena (No. II)*, the district court noted—as evidence that the expert paid only "lip service" to the epidemiological study's confounders—that the expert did "not attempt independently to examine the data underlying that study" or "perform a corrected analysis of [the study] to try to account for [confounding factors]." 341 F. Supp. 3d. at 278.

[25] At the motion for reconsideration hearing, Plaintiffs' counsel reiterated that they do not have supplemental expert reports that address the Jeans study because the Court denied Plaintiffs' motion to conduct additional discovery and to supplement expert opinions. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration

Lauzon, 270 F.3d at 694 ("[Defendant] may attack [the expert's] explanations of causation on cross examination, thereby requiring [the expert] to offer valid explanations as to why his conclusion remains reliable.").

Plaintiffs argue that such analysis was unnecessary because the researchers only listed potential confounders as opposed to actual confounders, and all observational studies include these sorts of "pointless" caveats. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration Hearing Tr.) at 93-94. Setting aside whether this is an accurate characterization of observational studies generally, the Court notes that a study now confirms that at least one of these conceivable confounders—MSSA screening—has a statistically significant impact on reducing surgical site infections. In July 2018, Dr. Reed and his colleagues published a study specifically addressing the impact of MSSA screening on PJI, which included deep and superficial infection. The Jeans (2018) study found a significant decrease in the MSSA infection rate after the introduction of the screening program as well as a significant reduction in the overall infection rate. ECF No. 1813-43, PX52 (Jeans 2018) at 4. While noting that "improvement in infection rates could have been down [sic] to other factors . . .," the authors concluded that the "dramatic reduction in MSSA SSI [surgical site

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Hearing Tr.) at 139:22-140:13. However, Dr. Samet relied on Dr. Reed's deposition in his original expert report, which identified MSSA screening as a plausible confounder, and so this does not explain why Dr. Samet failed to examine MSSA screening in his initial expert report.

infections] . . . suggests that screening and decolonization was responsible." *Id.*

The parties dispute whether the Jeans study confirms that the introduction of MSSA screening confounded the Observational Study. Dr. Jarvis stated in an affidavit that "the Jeans Study does not 'suggest' that MSSA screening confounded the McGovern study." ECF No. 1916-2, PX75 (Jarvis Aff.) at 2. Further, Dr. Samet stated in an affidavit that the Jeans study does not change his opinion that the Bair Hugger is a substantial contributing cause of PJI. ECF No. 1916-1, PX74 (Samet Aff.) at 3.[26]

The Court need not determine whether or not Jeans actually establishes that MSSA screening confounded the Observational Study. *Mead Johnson*, 754 F.3d at 562 ("district courts are admonished not to weigh or assess the correctness of competing expert opinions"). The Court merely finds that Jeans confirms that Plaintiffs' medical experts failed to examine conceivable alternative explanations

[26] In response to Defendants' motion for reconsideration, Plaintiffs' counsel had argued that Jeans does not confound McGovern. On May 16, 2019, Plaintiffs' counsel filed an affidavit by Dr. Samet, which for the first time considered whether "MSSA screening might have affected the findings on the type of warming device in the study by McGovern." ECF No. 1916-1, PX74 (May 14, 2019 Samet Aff.) ¶ 2. Dr. Samet's last-minute analysis was raised solely to support Plaintiffs' argument that Jeans does not confound McGovern. His analysis does not change the Court's conclusion that the medical experts' methodology was unreliable. The timing of this affidavit only underscores the fact that the experts did not initially examine these issues when becoming the first researchers (of which the Court is aware) to conclude that the Bair Hugger causes PJI.

acknowledged by the Observational Study authors in their depositions.

It is true that Plaintiffs' medical experts "need not rule out every alternative explanation for the observed hospital's dropoff in infections." ECF No. 1024 (Dec. 13, 2017 *Daubert* Order) at 9; *see also Mead Johnson*, 754 F.3d at 563 (recognizing that the Eighth Circuit has "consistently ruled that experts are not required to rule out all possible causes"). But it is important for Plaintiffs' general causation experts to seriously consider whether an observational study's "alternative explanations in terms of confounding [are] less plausible than the proposed causal link." Federal Judicial Center, *Reference Manual on Scientific Evidence* 221 (3d ed. 2011) (noting the circumstances under which observational studies provide "good evidence"). This is especially true where both the experts and the studies on which they rely have acknowledged multiple mechanisms for CFU to enter a wound site and acknowledged that infections occur even when the Bair Hugger is not used. *See, e.g*, ECF No. 1813-20, PX25 (McGovern 2011) at 7 (noting that infections in knee and hip surgeries occurred when the conductive warming device was used); ECF No. 1813-32, PX38 (Darouiche 2017) at 2 ("[t]he primary source of these airborne microorganisms is the people in the operating room such that the number of people, door openings, and room traffic all increase the quantity of airborne colony-forming units (CFU)"); ECF No. 1920-1, DX22 (Jan. 12, 2018 Jarvis Dep.) at 74:6-11 (agreeing that infections occur in "lots and lots" of surgeries where the Bair Hugger is not used).

C. The Causal Inferences Made by Plaintiffs' Medical Experts Have Not Been Generally Accepted by the Scientific Community

Additionally, the Supreme Court in *Daubert* directed courts consider whether the theory has attracted "widespread acceptance within a relevant scientific community. 509 U.S. at 594. For instance, "a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." *Id.* at 594 (citations omitted). The Eighth Circuit cautioned, however, that this factor "must be weighed with the Supreme Court's admonition that 'a rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony.'" *Lauzon*, 270 F.3d at 691 (quoting *Daubert*, 509 U.S. at 588).

Here, the medical and scientific community has repeatedly rejected the causal inferences made by Plaintiffs' experts.[27] In 2013, the International Consensus Meeting ("ICM") on Periprosthetic Joint Infection, which involved more than 400 experts in musculoskeletal infection from 52 countries, reached

[27] At the motion for reconsideration hearing, Plaintiffs argued that other scientists agree with their experts' causation conclusions. ECF No. 1980 (June 12, 2019 Mot. for Reconsideration Hearing Tr.) at 122:17-123:24. For support, Plaintiffs' counsel referred to statements reflected in 3M's internal documents but did not attach as evidence the actual statements from the scientists. Thus, from this evidence, the Court is unable to determine the extent that these scientists support the experts' conclusions.

a "strong consensus" (89% agree, 5% disagree, 6% abstain) as follows: "We recognize the theoretical risk posed by FAW [forced-air warming] blankets and that no studies have shown an increase in SSI [surgical site infections] related to the use of these devices. We recommend further study but no change to current practice." ECF No. 751-2, DX18 (ICM 2013) at 31. In 2017, the FDA reviewed available data and literature, was "unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection," and continued to recommend use of forced-air warming systems. ECF No. 751-1, DX1 (Aug. 30, 2017 FDA letter) at 2. In 2018, the ICM on Musculoskeletal Infection reached a strong consensus (93% agree, 2% disagree, 5% abstain) that "[t]here is no evidence to definitively link [forced-air warming] to an increased risk of SSIs/PJIs." ECF No. 1720-1, DX2 (ICM 2018) at 12.

The Court recognizes that Plaintiffs do not need *definitive* proof of causation. But "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *In re Mirena*, 169 F. Supp. 3d at 450 (quoting *Anderson v. Bristol Myers Squibb Co.*, No. 95-CV-03, 1998 WL 35178199, at *12 (S.D. Tex. Apr. 20, 1998)) ("[I]t is not that experts are 'insincere in their opinions or that their opinions may not some day be validated through scientific research and experiment; it is simply that the law cannot wait for such a confirmation.'"). The fact that the medical and scientific community has rejected these causal inferences further supports the Court's conclusion that there is too great an analytical

gap between the evidence and the expert's conclusions.

D. Conclusion

For these reasons, the Court finds that that the medical experts have repeatedly used the scientific literature to reach conclusions rejected by researchers, and therefore, there is too great an analytical gap between the experts' opinions and the literature.[28] Thus, the Court excludes the experts' general causation opinions and unsupported extrapolations that the Bair Hugger causes PJI.

III. SUMMARY JUDGMENT

Plaintiffs brought several causes of action against Defendants.[29] Plaintiffs rely entirely on the testimony

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[28] The Court also notes that Defendants argue that Plaintiffs' experts' treatment of the discredited Augustine study demonstrates their failure to carefully scrutinize the peer-reviewed studies in their reports. Although the experts did not rely on Augustine's study in their reports, Dr. Samet did testify that the Augustine study "corroborates" McGovern and bolsters its reliability. ECF No. 956-1, DX25 (July 11, 2017 Samet Dep.) at 34:24- 35:4 (testifying that he regards Augustine's article as "another piece of observational evidence that provides an estimate of risk of deep joint infection associated with the Bair Hugger device versus the comparison"); 165:13-24 (if McGovern was taken out of consideration, he would point to Augustine's study as providing another estimate of the risk).

[29] (1) Negligence, (2) Strict Liability (failure to warn, defective sign and manufacture), (3) Breach of Express Warranty, (4) Breach of Implied Warranty, (5) Violation of the Minnesota Prevention of Consumer Fraud Act, (6) Violation of the Minnesota Deceptive Trade Practices Act, (7) Violation of the Minnesota Unlawful Trade Practices Act, (8) Violation of the Minnesota False Advertising Act, (9) Consumer Fraud and/or Unfair and Deceptive Trade Practices Under State Law,

of the three medical experts to establish general causation and testify that the Bair Hugger system can be "ruled in" as the likely cause of Plaintiffs' alleged injuries. For the reasons stated above, the Court granted Defendants' motion to exclude the testimony of Plaintiffs' general causation experts. Without testimony from Plaintiffs' medical experts, Plaintiffs fail to raise a genuine issue of material fact regarding causation. *See Glastetter*, 252 F.3d at 990 (affirming summary judgment for defendant where plaintiff failed to come forward with admissible "rule in" expert testimony).

Plaintiffs' remaining engineering experts are not qualified to offer an opinion about the cause of surgical infections and cannot answer the threshold "rule in" question of whether the Bair Hugger system actually causes surgical infections. Plaintiffs' engineering experts may propose a causal mechanism, but even where an expert articulates a theory of causation that "appears sound," expert testimony is not admissible where the "major premise remains unproven." *Glastetter*, 252 F.3d at 989; *see also In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 176 F. Supp. 3d 483, 498-99 (E.D. Pa. 2016), *aff'd*, 858 F.3d 787 (3d Cir. 2017) ("Causation must be based upon more than a possibility.").

Whether the Bair Hugger is capable of causing PJI is a medically complex question outside of lay jurors' knowledge and experience. Because Plaintiffs' claims arise from "sophisticated" injuries, which

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(10) Negligent Misrepresentation, (11) Fraudulent Misrepresentation, (12) Fraudulent Concealment, (13) Loss of Consortium, and (14) Unjust Enrichment.

require "surgical intervention or other highly scientific technique for diagnosis," proof of causation must be established through expert testimony. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000). "While the specific language used by courts vary to some degree, all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No. II)*, 227 F. Supp. 3d 452, 469 (D.S.C. Jan. 3, 2017), *aff'd*, 892 F.3d 624 (4th Cir. 2018) (collecting cases). Because Plaintiffs have failed to produce admissible expert testimony that the Bair Hugger causes PJI, Defendants' motion for summary judgment must be granted.

Plaintiffs concede that many of their claims require proof of causation but argue that their unjust enrichment and consumer protection claims do not. Yet, Plaintiffs' unjust enrichment claim also fails. Although an unjust enrichment claim does not explicitly require a showing of causation, causation is an implicit element of this claim because Plaintiffs must prove that Defendants received a benefit under circumstances that would make retention of the benefit unjust. ECF No. 46-1, Master Long Form Compl. ¶¶ 196, 198 ("It is unjust to allow Defendants to earn revenues and retain the benefits and profits from the Bair Hugger while Plaintiffs suffered injuries and damages as stated herein."); *see, e.g, Cromeans v. Morgan Keegan & Co., Inc.*, 303 F.R.D. 543, 558 (W.D. Mo. 2014) ("While each state in the United States describes unjust enrichment differently, the essence of such claims is that the defendant obtained a benefit,

the plaintiff suffered an economic detriment as a result, and it would be inequitable for the defendant to keep the benefit under the circumstances.")). In light of the dearth of reliable evidence that the Bair Hugger causes infection, there is nothing in the record to suggest that Defendants received anything of value under inequitable circumstances. *See In re Viagra*, 658 F. Supp. 2d at 969 (granting summary judgment in defendant's favor for the same reasons). Accordingly, the Court grants Defendants' motion for summary judgment on Plaintiffs' unjust enrichment claim.

Causation is also an implied requirement for Plaintiffs' consumer protection claims. Plaintiffs must establish that they used the Bair Hugger and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws. ECF No. 46-1, Master Long Form Compl. ¶ 156. Minnesota's consumer protection claims similarly require Plaintiffs to show that "[a]s a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections." *Id.* ¶¶ 129, 134, 143, 151. Because Plaintiffs lack reliable evidence that the Bair Hugger causes infection, Plaintiffs cannot establish that they suffered an injury as a result of Defendants' actions. For this same reason, Plaintiffs would also lack standing to pursue their claims, unless there is a "causal connection between the injury and the conduct complained of." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Therefore, the Court also grants Defendants' motion for summary judgment on Plaintiffs' consumer protection claims.

The Court will issue a separate order that is consistent with this Memorandum.

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

Appendix D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

MDL No. 15-2666

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

Filed: Dec. 13, 2017

ORDER

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. 11. 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 5μm, and even fewer over 10μm."). 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. 11. 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. l.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.

Bucks 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 Elgobashi'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 studies[2] 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

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[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).

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 under report 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 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

Appendix D

RELEVANT RULE

Fed. R. Evid. 702. Testimony by Expert Witnesses

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.