STATE OF MINNESOTA
COUNTY OF RAMSEY

DISTRICT COURT
SECOND JUDICIAL DISTRICT

CIVIL DIVISION

In Re: 3M Bair Hugger Litigation

Master File No. 62-CV-15-6432

ORDER 11

Assigned Judge: Hon. William H. Leary III

This matter came before this court and the United States District Court, District of Minnesota, on October 24-26, 2017, for a joint hearing on the parties' motions to exclude each other's experts and Defendants' Motion for Summary Judgment with Respect to General Causation.

The appearances are those noted at the time of the hearing.

This court, having in mind the arguments of counsel, the applicable law, and all files and records herein, issues the following order.

IT IS ORDERED:

1. Defendants' Motion to Exclude Plaintiffs' General Causation Medical Experts is **GRANTED** on all state-court files subject to this master file.

2. Defendants' Motion for Summary Judgment with Respect to General Causation is **GRANTED** on all state-court files subject to this master file.

3. All other motions are **DENIED** without prejudice.

The accompanying memorandum is incorporated herein by reference.

LET JUDGMENT BE ENTERED ACCORDINGLY.

January 8, 2018

William H. Leary III
Judge of District Court

MEMORANDUM

1. Plaintiffs and Defendants submitted their motions to exclude each other's experts, and Defendants' Motion for Summary Judgment with Respect to General Causation, before a joint session of the United States District Court and the Ramsey County District Court.

2. At the conclusion of the hearing, the undersigned directed the parties to submit proposed orders for this court's consideration in the state-court claims. The proposed orders were filed on November 16, 2017, at which time this court took the matter under advisement.

3. The parties' proposed orders represent their respective views of the evidence and law to be applied. This court has carefully considered the record presented, the arguments of counsel, the applicable law, and the proposed orders. To the extent that this order adopts the analysis and language of a proposed order, this court has determined that the adopted language accurately reflects the evidence and applicable law.

4. This court concludes that the general-acceptance standard for expert opinion adopted by the Minnesota Supreme Court and codified by Rule 702 of the Minnesota Rules of Evidence (MRE) renders Plaintiffs' experts' general-causation opinions inadmissible and entitles Defendants to summary judgment. Further consideration of the parties' other motions is unnecessary.

5. ***Background.*** Although the history leading to this litigation is not essential to resolving the motions presented, its review dramatizes the policy that underlies the general-acceptance standard under MRE 702, a policy that values the primacy of science over litigation-driven opinion.

6. More than thirty years ago, it became generally accepted within the relevant scientific community that maintaining a patient's normal body temperature ("normothermia") during surgery led to decreased infection rates, a shorter period of post-operative recovery, and improved healing. This theory remains generally accepted, and various manufacturers compete to market their warming devices.

7. In 1987, Scott Augustine, an anesthesiologist and chief executive officer of Augustine Medical, Inc., invented a forced-air warming system which he named "the Bair Hugger." The Bair Hugger became the leading warming device in the world.

8. In 2002, the United States Department of Justice notified Augustine that he was under investigation for Medicare fraud. Augustine resigned from Augustine Medical, which retained all rights to the Bair Hugger system.

9. In 2003, Augustine Medical was reorganized as Arizant Healthcare, Inc. Augustine formed Augustine Medical + Design to manufacture and market a new warming device, which he called "the HotDog," to compete with the Bair Hugger system. The HotDog uses an electric-conduction warming system rather than forced-air.

10. In 2004, the Department of Justice concluded its investigation of Augustine when Augustine pled guilty to Medicare fraud. He was fined $2 million and prohibited from participating in federal health-care programs for five years.

11. In 2008, Augustine, while still prohibited from participating in federal health-care programs, began to impugn the safety of the Bair Hugger overseas. He issued a press release criticizing the United Kingdom's National Institute for Health and Clinical Excellence for recommending forced-air warming systems such as the Bair Hugger. Augustine claimed that such devices increased the risk of surgical infections. The Institute rejected Augustine's claim, concluding that forced-air warming devices were not associated with an increased risk of infection.

12. In 2009, a German court also enjoined Augustine from making false claims that the Bair Hugger increased bacterial contamination in operating rooms, concluding that such claims constituted "unfair competition."

13. In 2009, Augustine, according to his own affidavit, also hired a law firm, Kennedy Hodges, "to promote the use of HotDog patient warming, the air-free patient-warming device that I [Augustine] invented as an alternative to Bair Hugger." Augustine agreed to work with the law firm as a "non-testifying expert." In time, Kennedy Hodges began to represent individuals in lawsuits to be brought against Arizant. Kennedy Hodges continues to serve on Plaintiffs' Executive Committee in this state and the related federal litigation.

14. From 2009 to 2010, the United States Food and Drug Administration (FDA) investigated Augustine's complaint that the Bair Hugger increased the risk of bacterial contamination. The FDA exercises a more stringent approach to product safety than state and federal courts.

> The FDA's approach differs from [the court's standards] in another critical aspect. The FDA will remove drugs from the marketplace upon a lesser showing of harm to the public than the preponderance-of-the-evidence or more-likely-than-not standards used to assess tort liability. "The methodology employed by a government agency 'results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances.'"

Glastetter v. Novartis Pharmaceuticals Corporation, 252 F3d 986, 991 (8th Cir. 2001). With this more-stringent standard presumably in mind, the FDA rejected Augustine's claim.

15. In 2010, Defendant 3M acquired Arizant Healthcare, Inc., and all rights to Arizant's Bair Hugger system.

16. From 2010 to 2012, Augustine attempted to sell his HotDog system to 3M. In a letter dated January 4, 2012, Augustine tried to coerce 3M into purchasing his HotDog system by warning that 3M would suffer a significant loss of market share and "a lot of negative marketing rhetoric about 3M causing infection" if the sale did not occur:

> There is not the slightest chance that Bair Hugger warming will survive in orthopedic surgery, it is only a matter of time.
>
> If you lose orthopedics in any given hospital, the odds are that you will lose the rest of the hospital within six months. This is not hypothetical, this is happening already. We just got the purchase commitment from a four-hospital system, driven primarily by the orthopedic risk.
>
> I believe that there is a very high probability that 3M will have to write-off some or all of its $810 million investment in Bair Hugger, over the next couple of years. It is going to seriously hurt when you have to take that $810M out of hiding on the Balance Sheet and move it to the very public "loss" side of the P&L.
>
> Now the good news - HotDog warming is for sale. If 3M owned both warming technologies, you could control the transition of the market from Bair Hugger to HotDog. If we control the transition, it will be an "all or none" situation and there will be a lot of negative marketing rhetoric about 3M causing infections. If you control the transition, you can convert parts of the hospital without converting the whole thing and you can do it quietly. Bair Hugger will still be in use and you will not have lost that customer. In that case, you may not have to even write-off the declining contribution from Bair Hugger.
>
> The idea of spending another half billion dollars to own a patient warming franchise may be a bit painful but at least the whole investment stays on the Balance Sheet. In contrast, when you start writing off the $810M, it is going to be very public and very painful when it hits the P&L. If a deal like this is at all interesting, you should probably get on with it. Once we are successful in the market, not only will we have many more potential

> acquirers but the FTC may not allow 3M to own both of the market-leading patient warming technologies.
>
> I am available to informally (or formally) chat about a possible deal if you are interested.

3M rejected Augustine's offer.

17. Making good on his threat of "a lot of negative marketing rhetoric," Augustine began to market the HotDog as reducing the rate of surgical infections when compared to forced-air systems. In response, the FDA sent a warning letter to Augustine in 2012, stating that his claim was without clinical support and made without FDA approval. The FDA ordered Augustine to correct the violations.

18. In 2013, attorney Randall Benham, Augustine's in-house counsel, advised Kennedy Hodges that he and Augustine were preparing a "detailed guide" to sue "3M/Bair Hugger."

> Scott [Augustine] and I are preparing a detailed guide to suing 3M/Bair Hugger for orthopedic implant infections. It will contain background, summaries of and links to scientific articles, explanations of the etiology of joint infections, a timeline of 3M's knowledge and failure to warn, discovery suggestions . . . and a half-dozen other useful things.
>
> We intend to offer it to other plaintiffs' firms around the country who express an interest in jumping on this bandwagon. Our staff is preparing a list of the email addresses of AAJ members who do this work, and we may do an email blast. Communications in the AAJ publications may also be a good idea.
>
> My question: Would you like KH [Kennedy Hodges] to be the author of this Guide? It would help establish KH as the leader in this area. * * * We are going forward either way, but I want to give you the opportunity if you are interested.

19. The "AAJ" referred to in Benham's letter is the American Association for Justice, a national organization of attorneys representing plaintiffs in personal-injury lawsuits.

20. Later in 2013, Kennedy Hodges filed the first lawsuits against Defendants Arizant and 3M, alleging that the Bair Hugger was unsafe.

21. In 2014, Augustine again wrote to 3M "to explore a distribution or licensing relationship where we both win." (Original underlining in Augustine letter.) Augustine's proposal was for 3M to license and distribute the HotDog. Augustine threatened to otherwise fund studies to "definitely lock down the link between the Bair Hugger and implant infections."

> Our plan is to have at least five more outcomes like the McGovern study, published within the next two years. Each of these studies will show that deep joint infection rates dramatically drop when a hospital stops using Bair Hugger (air) warming in orthopedics and switches to HotDog (air-free) warming.

3M again rejected Augustine's proposal.

22. Augustine funded "the McGovern study" referenced in his 2014 proposal to 3M. Despite Augustine's touting of the article, Mark Albrecht, Augustine's long-time employee and one of the article authors, testified that the study did not find an association between the Bair Hugger and increased infection rates. "The study does not establish a causal basis and that's – there's a lot of confounding [incorrectly transcribed as 'compounding'] factors that could be at play." Dkt. 38, DX12, Albrecht Dep. at 177:13–178:10. Albrecht also characterized Augustine's claim that the HotDog reduced infection rates as marketing, not research.

> This is one of those things where we can step close to the line, and we do have important information to present that clinicians should be aware of, but we also have to be careful that we do not state claims regarding proof of infection reduction. Unfortunately, Scott [Augustine] likes to say that he's convinced of such a relationship, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing.

Id. at 343:8–345:9.

23. On August 30, 2017, the FDA, again responding to the attempts to impugn the safety of the Bair Hugger, issued a letter endorsing the continuing use of forced-air warming devices and the beneficial effect of such devices on patient safety:

> Dear Health Care Provider,
>
> The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.

> The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.
>
> Therefore, the FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted. Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process.

Dkt. 151, Hulse Med. Experts Decl. DX1, FDA Safety Alert.

24. Since the beginning of Augustine's and Kennedy Hodges' efforts to spur litigation, plaintiffs have filed approximately 60 cases in Minnesota state court and thousands of cases in federal court.

25. ***Plaintiffs' general-causation medical experts.*** In 2017, Plaintiffs disclosed their general-causation medical experts. None of these experts had studied the efficacy of forced-air warming devices prior to being retained by Plaintiffs. They have not published any peer-reviewed articles relevant to the claims made in this litigation. They do not claim that their general-causation opinions are generally accepted within the relevant scientific community.

26. Jonathan M. Samet, M.D., is an internist, pulmonologist, and epidemiologist. In his "Statement of the Question," Samet wrote:

> This report addresses the topic of general causation in regard to the Bair Hugger forced-air warming devices (referred to hereafter as the Bair Hugger device), considering the full range of available and relevant evidence. The question addressed is whether use of a Bair Hugger device during hip and knee joint replacement surgeries increases risk for deep joint infections.

Dkt. 151, Ex. DX2, p. 4. Samet concluded that "the Bair Hugger device is not a necessary cause, but a causal factor that increases the risk of deep joint infection by adding an additional causal mechanism." *Id.* at 17.

27. William R. Jarvis, M.D., has experience in infectious disease and epidemiology. He has worked for the Center for Disease Control and has been a private consultant since 2003. In his report, Jarvis drew the following conclusions:

> In summary, having applied the methodological "gold standard" approach which I used in my work for the CDC, I have come to the conclusion that given the characteristics of Bair Hugger FAWs, that they more likely than not to a reasonable degree of medical certainty are associated with SSIs in PJA patients. * * * For this reason, it is my opinion that the use of such devices should be abandoned or used only in low risk surgeries not involving implant patients.

Dkt. 151, Ex. DX4, p.25.

28. Michael J. Stonnington, M.D., is an orthopedic surgeon specializing in joint-replacement surgery. Stonnington offers the following opinion:

> [I]t is my expert opinion to a reasonable degree of scientific probability, that the Bair Hugger system causes an increased risk of patient infection because of substantial scientific evidence that the waste heat generated by the Bair Hugger warming units disrupts operating room airflow conditions and contributes to mobilization of microbes in the area of the sterile field. Again, the spread of pathogenic contamination from the Bair Hugger machines to the operative field make these devices unreasonably dangerous because they significantly increase the risk of deep joint infections, especially during orthopedic device surgeries.

Dkt. 151, DX6, p. 7. Stonnington further "recommends that surgeons and other clinicians give serious consideration to use of alternative forms of patient warming[.]" *Id.* at 8.

29. ***Issue presented.*** Plaintiffs' medical experts opine that Defendants' Bair Hugger increases the rate of infection in prosthetic-joint surgeries. Defendants argue that the opinion is not generally accepted within the relevant scientific community and, therefore, is inadmissible under Rule 702 of the Minnesota Rules of Evidence (MRE).

30. Plaintiffs, in response, argue that the general-acceptance requirement does not apply to an expert's opinion. Rather, the standard applies only to the "methodology" an expert uses to arrive at his or her opinion.

> The inquiry of "general acceptance" thus does not depend on whether there is widespread consensus that an expert's *conclusions* are correct, but rather whether there is general acceptance that the expert's *methodology*

> or "technique" is correct. *State v. Traylor*, 656 N.W.2d 885, 891 (Minn. 2003) (emphasis added) [sic].

Dkt. 437 at 65. This has been Plaintiffs' sole argument in opposing Defendants' motions regarding causation. *Id.*; 10.25.17 Hrg. Tr., volume III, at 109, 130-131.[1] Plaintiffs do not otherwise claim that their experts' general-causation opinions are generally accepted within the relevant scientific community.

31. ***Law of summary judgment.*** The law regarding summary judgment is well-known, undisputed by the parties, and need not be repeated here. It is also undisputed that, if Plaintiffs' interpretation of the general-acceptance standard fails, the opinions of Plaintiffs' general-causation experts are inadmissible under Rule 702 and Defendants' motion for summary judgment must be granted.

32. ***Plain reading.*** MRE Rule 702 was amended in 2006 by the Minnesota Supreme Court and "codifies existing Minnesota case law on the admissibility of expert testimony." Minnesota Rules of Evidence, Rule 702, 2006 Comment. The rule consists of two "prongs," (1) a showing that the opinion has foundational reliability and (2), if the opinion or evidence involves novel scientific theory, a showing that the underlying scientific evidence is generally accepted in the relevant scientific community.

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. The opinion must have foundational reliability. In addition, if the opinion or evidence involves novel scientific theory, the proponent must establish that the underlying scientific evidence is generally accepted in the relevant scientific community.

The law that was codified has been generally referred to as the *Frye-Mack* standard, which was re-affirmed by the Minnesota Supreme Court in *Goeb v. Tharaldson*, 615 N.W.2d 800 (Minn. 2000).[2] It is the general-acceptance (*Frye*) prong that is dispositive of Defendants' motion.

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[1] For Defendants' summary of scientific data rejecting Plaintiffs' general-causation claims, see APPENDIX A. For a summary of articles cited by *Plaintiffs* that also *reject Plaintiffs' claims*, see APPENDIX B.

[2] The Minnesota Supreme Court stated that *Goeb* presented "the question of whether Minnesota should abandon the two-pronged standard for the admissibility of novel scientific evidence comprised of *Frye v. United States*, 293 F. 1013 (D.C. Circ. 1923), and *State v. Mack*, 292 N.W.2d 764, 768-69, 772 (Minn. 1980), in favor of the *Daubert v.*

33. The general-acceptance prong specifically states that it applies to "opinion or evidence" that "*involves* novel scientific *theory*," and requires that the "underlying scientific *evidence*" be generally accepted. The rule is consistent with the Minnesota Supreme Court's statement in *Goeb* that an expert's opinion regarding any *principle* or *technique* must satisfy the general-acceptance prong of admissibility. "Whether a particular principle or technique satisfies the first [sic] prong, general acceptance in the relevant scientific field, is a question of law that we review de novo. [Citation omitted.]" *Goeb* at 814-815; s*ee also State v. Roman Nose,* 649 N.W.2d 815, 819 (Minn. 2002), and *State v. MacLennan,* 702 N.W.2d 219, 230 (Minn. 2005). [3]

34. Plaintiffs frame their argument as distinguishing between an expert's opinion and the methodology the expert uses in forming that opinion. Such a distinction cannot be read into the rule. The rule requires that *any* "opinion or evidence" that is "novel" must be "generally accepted within the relevant scientific community" before it may be admitted into evidence. The opinion that forced-air warming devices increase the rate of surgical site infections is undisputedly novel and not generally accepted. Plaintiffs' attempt to narrowly apply the rule must be rejected.

35. A rejection of Plaintiffs' narrow interpretation of the general-acceptance standard under Rule 702 is in keeping with the holding in *Frye* that "the thing" upon which an expert's opinion is based must be generally accepted:

> [W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, *the thing from which the deduction is made must be sufficiently established to have gained general acceptance* in the particular field in which it belongs.

Frye v. United States, 293 F. 1013 (D.C. Circ. 1923) (emphasis added).

36. Furthermore, if Plaintiffs' interpretation were applied to its extreme, a witness would be able to opine that the earth is flat, or the center of the universe, if the person's methodology for arriving at those opinions was generally accepted. Again, there is no logical justification for such a result.

Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 587, 113 S. Ct. 2786, 125 L.Ed.2d 469 (1993), standard set forth by the United States Supreme Court." *Goeb v. Tharaldson,* 615 N.W.2d 800, 809 (Minn. 2000); Rule 702, 2006 Comment.

[3] While *Goeb* referred to the general-acceptance standard as the "first prong," Rule 702 reversed the order of the two standards and made the general-acceptance standard the second prong.

37. Plaintiffs have failed to satisfy the general-acceptance standard under MRE 702 and, consequently, their experts' general-causation opinions are inadmissible.

38. ***Plaintiffs' case law.*** Plaintiffs cite *State v. Traylor*, 656 N.W.2d 885 (Minn. 2003), as support for their argument that the general-acceptance standard applies only to "methodology" evidence. *Traylor* pre-dated the 2006 amendment to Rule 702.

39. At issue in *Traylor* was the admissibility of forensic-identification evidence by a new form of DNA typing. "The question before this court, then, as framed by the district court, is whether forensic DNA typing using the PCR-STR methodology can be said to be generally accepted in the relevant scientific community." *State v. Traylor*, 656 N.W.2d 885, 892 (Minn. 2003).

40. The Minnesota Supreme Court first observed that "[p]articular scientific evidence must have a foundation that is scientifically reliable," and that, in Minnesota, "a two-pronged standard, known as *Frye-Mack,* must be satisfied before such evidence may be admitted." *Id.* at 891.

41. When addressing the public policy that underlies the general-acceptance standard, the Supreme Court recognized the primacy of science when determining the reliability of novel scientific evidence, and did not place any limitation on the "particular scientific evidence" to which the standard applied:

> The general acceptance standard "ensures that the persons [namely, scientists] most qualified to assess scientific validity of a technique have the determinative voice." *Goeb,* 615 N.W.2d at 813. Such an approach avoids the problem that many commentators see as inherent in *Daubert,* namely, that such an approach "takes from scientists and confers upon judges * * * the authority to determine what is scientific." *Goeb,* 615 N.W.2d at 812.

Id. at 892 (Minn. 2003).

42. While the Supreme Court characterized the evidence at issue (i.e., PCR-STR typing) as a "methodology," the court did not hold that the general-acceptance standard applies only to methodology. To otherwise infer such a narrow application would emasculate the very policy that the standard was meant to advance. That is, if the primacy of science is the justification for the standard, then there can be no logical justification for applying the standard only to "methods" and not to other forms of "novel science."

43. Plaintiffs briefly cite to cases from other jurisdictions as support for their argument. Consideration of one case disposes of the rest.

44. In *Marsh v. Valyou*, 977 So.2d 539 (Fla. 2007), the Florida Supreme Court held that the *Frye* requirement did not apply to the expert opinion that trauma from several car accidents caused the plaintiff's fibromyalgia. The holding was based on the court's consideration of two aspects of the opinion: (1) the experts' case-specific conclusion and (2) the general acceptance of the science underlying the conclusion.

45. The court held that the case-specific opinion that Plaintiff's accidents caused her fibromyalgia was admissible because physicians routinely determine the cause of a patient's condition based on the patient's clinical presentation and generally accepted science.

> [Plaintiff] Marsh's experts did not base their opinions on new or novel scientific tests or procedures, and Respondents did not challenge the patient history, examination methods, clinical practices, or other methodologies upon which they did rely. In fact, Respondents could not challenge the underlying methodology, as we have previously held that differential diagnosis is a generally accepted method for determining specific causation. *Castillo,* 854 So.2d at 1271; *U.S. Sugar,* 823 So.2d at 110 ("[T]here is no question that the differential diagnosis technique ... is generally accepted in the scientific community."); *see also Johnson,* 880 So.2d at 723 (recognizing that a challenge to the underlying methodology would be unsuccessful because differential diagnosis is a "standard scientific technique").

Marsh at 549.

46. As to the second aspect of plaintiff's expert opinion, i.e., the science underlying the relationship between trauma and fibromyalgia, the court repeated the applicable law:

> [A]s we stated in *U.S. Sugar,* 823 So.2d at 110:
>
> > [U]nder *Frye,* the inquiry must focus only on *the general acceptance of the scientific principles and methodologies upon which an expert relies in rendering his or her opinion.* Certainly the opinion of the testifying expert need not be generally accepted as well. Otherwise, the utility of expert testimony would be entirely erased, and "opinion" testimony would not be opinion at all—it would simply be the recitation of recognized scientific principles to the fact finder ... *We reaffirm our dedication to the principle that once the Frye test is satisfied through proof of general acceptance of the basis of an opinion,* the expert's opinions are to be evaluated by the finder of fact and are properly assessed as a matter of weight, not admissibility.

> *See also Castillo,* 854 So.2d at 1276 (holding that the district court erred in considering "not just the underlying science, but the application of the data generated from that science in reaching the expert's ultimate conclusion"); *Berry,* 709 So.2d at 567 ("[W]hen the expert's opinion is *well-founded and based upon generally accepted scientific principles and methodology*, it is not necessary that the expert's opinion be generally accepted as well.").

Id. (Emphasis added.)

47. The Florida court concluded that an association between trauma and fibromyalgia was generally accepted and, therefore, not a novel scientific theory. *Marsh* at 550 ("Numerous published articles and studies recognize an association between trauma and fibromyalgia."). For that reason, Plaintiff's expert was able to offer a case-specific opinion.

48. Contrary to Plaintiffs' argument, the Florida court did not hold that an expert's conclusions were *per se* exempt from the *Frye* analysis. Rather, the court's decision supports the conclusion that *Frye* requires general acceptance of the *bases* of an expert opinion (*Frye* must be "satisfied through proof of general acceptance of the basis of an opinion"), and that the application of *Frye* is not limited to scientific methodologies (the opinions admitted were based upon "generally accepted *scientific principles and methodology*," and not based on "new or novel *scientific tests or procedures*[.]") (Emphasis added.)

49. As to Plaintiffs' case law, this court again concludes that Plaintiffs' reliance on a distinction between "methodology" and other forms of "underlying scientific evidence" must be rejected.

50. ***Other basis for granting summary judgment.*** A second argument also supports granting Defendants summary judgment. Even if the general-causation opinions of Plaintiffs' experts were admissible, Plaintiffs have failed to establish that it is generally accepted that the risk of infection associated with forced-air warming devices is greater than the risk of infection associated with hypothermia during surgery or when compared to other warming devices.

51. Surgical infection is a generally accepted risk of all surgeries, including orthopedic surgeries. Jarvis, one of Plaintiffs' experts, writes: "In the OR it is impossible to remove the primary sources of contamination, i.e., the patient on whom the surgery is performed and the essential OR staff." Dkt. 151, Ex. DX4, p. 20.

52. It is also generally accepted that maintaining normothermia during surgery reduces the risk of infection. Jarvis adds: "It has become common practice for surgeons to ensure normothermia in their patients." *Id.* at 17. Stonnington, another Plaintiffs' expert, concurs: "Anesthesiologists have widely used patient warming devices during many surgical procedures." Dkt. 151, DX6, p. 2. Stonnington adds: "One popular method of patient warming that has gained favor over the past thirty or more years is 'forced air warming' or 'FAW.' FAW is a mechanism used in the operating room to warm patients in order to minimize the chances of patients developing hypothermia." *Id.* at 3.

53. Given these generally accepted principles regarding the inherent risk of infection and the benefits of maintaining normothermia, there is no generally accepted scientific evidence – and Plaintiffs offer none – that the risk of infection associated with FAWs is greater than that associated with patients who are not warmed during surgery. As to a comparison of warming devices, there is no scientific evidence – and Plaintiffs offer none – that warming devices other than forced-air warming devices have a lesser rate of infection. As Stonnington notes: "Medical authorities who support thermoregulation agree that as long as the patient is warmed in a safe manner that prevents them from becoming hypothermic, no single or specific means of patient warming is required." *Id.* at 2.

54. While Jarvis states that "I could find no clinical evidence supporting the hypothesis that ensuring normothermia reduces PJIs [prosthetic-joint infections]," his statement does not negate his own observation that it is the generally accepted practice to maintain normothermia in surgical patients. Nor does Jarvis's comment stand for the opposite conclusion, i.e., that warming devices, including forced-air warming, are contraindicated in prosthetic-joint surgeries.

55. ***The primacy of science.*** As stated at the beginning of this memorandum, this litigation, and the history that preceded it, dramatizes the policy that underlies the general-acceptance standard under MRE 702. The policy values the primacy of science over litigation-driven opinion by allowing the medical and other scientific communities to abide by those generally accepted practices that promote patient safety, and marginalizes the effect of other opinions and efforts that might be unduly influenced by litigation and/or competition.

56. With regard to litigation, "[a]dmissibility can be based on scientific merit only if judges defer to practicing scientists' assessments of scientific merit." *Goeb*, 615 N.W.2d at 813 (interior cite omitted). The FDA, in keeping with the views of other organizations referenced in *Appendix A*, has warned health-care providers that "[s]urgical procedures performed without the use of a thermoregulation system [including forced-air warming devices] may cause adverse health consequences for patients during the postoperative and recovery process." Dkt. 151, DX1, FDA Safety Alert. Yet, one of Plaintiffs' experts, Jarvis, personally opines that the use of forced-air warming devices "should be abandoned," while another, Stonnington, claims that such devices are

"unreasonably dangerous." These personal opinions have not found general acceptance in the medical community, and, consistent with the policy underlying Rule 702, are not admissible. As also noted in *Glastetter*, while the possibility remains that "stronger evidence of causation" may be found in the future, "[s]uch evidence has not been presented in this case[.]" See *Glastetter*, 252 F.2d at 991.

57. With regard to competition, the history leading to this litigation also demonstrates the importance of the general-acceptance standard when the threat or fear of litigation is used as a competitive tool. As stated at the beginning of this memorandum, Scott Augustine blatantly and unapologetically threatened Defendants with "negative rhetoric" and "studies" with pre-determined findings to pursue a business advantage. Perhaps in response to those threats and the litigation that has followed, the FDA re-affirmed the generally accepted science regarding warming devices in its August 2017 letter to health-care providers:

> The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.

Dkt. 151, DX1, FDA Safety Alert.

58. To the extent that Augustine viewed litigation as a part of his business plan, applying the FDA letter, and the data cited in *Appendix A*, to Minnesota's general-acceptance standard provides manufacturers, hospitals, health-care providers and patients with some relief from being in the untenable position of choosing between generally accepted science and "novel" opinions advanced to obtain a competitive advantage through the threat or fear of litigation.

59. ***Conclusion***. Here, Plaintiffs' experts have concluded that forced-air warming devices may increase the rate of infection in prosthetic-joint surgeries. It is undisputed that such a theory is "novel" and not generally accepted. Applying the plain language of Rule 702 and relevant case law, the opinion of Plaintiffs' experts fails to meet the requirements of the rule and is inadmissible as evidence of causation. Consequently, Defendants are entitled to summary judgment.

WHL

APPENDIX A

A.1. At the hearing, parties agreed that the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection are reliable. (10.25.17 Hrg. Tr. at 295:18-25 ("THE COURT [Judge Ericksen]: So let me just ask you one more time. You refer to the international consensus sometimes like it's really the international consensus but then other times you kind of poopoo it by saying 3M sponsored it. So what is it your view? Is it -- can we take this as an international consensus or do you say the whole thing is tainted -- [PLAINTIFF's COUNSEL] MR. ASSAAD: We take it as something that both sides can rely upon.").

A.2. The International Consensus proceedings involved more than 400 experts in musculoskeletal infection from 52 countries. The group reached a "strong consensus" 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." Dkt. 152, Hulse Med. Experts Decl. DX18, Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection at 5 (2013). Eighty-nine percent of delegates voted in support of the statement, while only five percent voted against and six percent had no opinion. The discussion and notes indicate that the delegates considered and evaluated the same studies relied upon by Plaintiffs' medical causation experts, including the 2011 McGovern study published in the *British Journal of Bone & Joint Surgery*. *Id.* n.76; *see also* Dkt. 143, Order 10 ¶ 34.

A.3. A review in 2013 by the Association of periOperative Registered Nurses (AORN) concluded: "Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of SSI . . . The evidence also does not support the concern that use of a forced-air warmer may cause an increase in bacteria near or on the patient or cause unwanted airflow disturbances. These findings confirm the AORN recommendations that forced-air warming is an effective way to prevent unplanned perioperative hypothermia." *Id.*, DX16, Kellam M.D. et al., "Forced-air warming devices and the risk of surgical site infections." 98.4 AORN Journal 353, 365-66 (2013).

A.4. Also in 2013, the ECRI Institute, a nonprofit organization that advises more than 5,000 healthcare organizations, reviewed over 180 studies, including the McGovern study. ECRI concluded: "We do not believe that the currently available evidence justifies discontinuing the use of FAW [forced air warming] during surgery." Dkt. 152, DX15, ECRI Institute, "Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice." Health Devices 122, 122 (April 2013). The ECRI Institute reviewed five articles associated with Defendants' competitor, Scott Augustine, and concluded that "[t]hese studies . . . only raise questions about airflow disruptions. Demonstrating that airflow patterns change when [forced-air warming] is used does not establish that it results in increased bacterial contamination or

increased rates of [surgical site infection] and [periprosthetic joint infection] as compared to other methods of patient warming." *Id.* at 123.

A.5. A review of the scientific literature (including the McGovern study and the other seven Augustine-sponsored papers) by Sikka and Prielipp in the *Journal of Bone & Joint Surgery* concluded in 2014 that "the literature appears to indicate that forced air warming can impact laminar flow under certain very specific conditions, but any actual clinical impact on surgical site infections must be considered unproven at this time." *Id.*, DX17, Sikka R.S., et al., "Forced Air Warming Devices in Orthopaedics: A Focused Review of the Literature," 96-A:24 J. Bone & Joint Surgery e200 (2014).

A.6. In 2015, Duke University School of Medicine's Infection Control Outreach Network (DICON) reviewed the literature and found that "no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of SSI due to the use of FAW [forced air warming] warming devices." Dkt. 152, Hulse Med. Experts Decl. DX22, "HotDogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods," DICON Infection Prevention News (Nov. 2015). DICON strongly criticized the McGovern study, including its failure to account for comorbidities, and noted that "no studies performed by independent investigators" had corroborated its findings. *Id.*

A.7. Most recently, on August 30, 2017, the United States Food & Drug Administration (FDA) issued a Safety Alert to "reminding health care providers that using thermoregulation devices during surgery, including forced air warming thermoregulation systems [the class of devices that includes the Bair Hugger system], ha[s] been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients." Dkt. 151, Hulse Med. Experts Decl. DX1, FDA Safety Alert. In the Alert, the FDA explains that it "collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements." *Id.* After a "thorough review of available data," the agency was "unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection." *Id.* Accordingly, the agency made clear that it "continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted." The FDA warned health care providers that "[s]urgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process." *Id.*

APPENDIX B

B.1. As this court previously noted with respect to Plaintiffs' Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages, Plaintiffs have not presented any scientific study – including those studies relied upon by Plaintiffs and their experts – that has concluded that the Bair Hugger causes increased surgical site infections. Dkt. 143, Order 10, ¶ 25. As this court has previously found, the key studies upon which Plaintiffs rely all expressly disclaim any finding of causation:

Publication	Language Disclaiming Conclusion that Bair Hugger Warming Blanket Increases Risk
Albrecht M et al., Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1(2):e28	"[T]he present study did not evaluate the link between forced air warming and surgical site infection rates ..."
Albrecht M et al., Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010; 39:321-28	"[O]ur findings do not establish a direct link between forced air warming and increased surgical site infection rates ..."
McGovern PD et al., Forced-air warming and ultra-clean ventilation do not mix. *J Bone & Joint Surg-Br.* 2011; 93-B(I I):1537-44	"This study does not establish a causal basis for this association [the patient warming device and the risks of surgical site infections in the study]."
Legg A et al., Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone & Joint Surg-Br.* 2012; 94-B:254-6	"Because of the nature of our experiment we are unable to conclude that the use of the forced air warming device ... would actually lead to an increased risk of surgical site infection."
Dasari KR et al., Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49 (PX35)	"Another limitation of our study is that the definitive effects of this excess heat on clinical outcomes is presently unknown."
Legg A et al., Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J.* 2013 Mar; 95-B(3):407-10	"This study does not show that forced-air warming increases the risk of infection ..."
Reed M et al., Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination	"Last, we did not track hospital infections, nor did we study the association between FAW [forced-air warming] contamination generation/emission and hospital infection rates ..."

emissions. AANA J. 2013 Aug; 81(4):275-80	
Belani K et al., Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia &Analgesia* 2012 (prepublication on-line) 2013; 117(2):406-411	"Thus, we are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery... future research is warranted to characterize the clinical conditions under which forced air warming excess heat results in ventilation disruption during surgery."

Id. at ¶ 26.