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EXCLUSION OF JUNK SCIENCE IN “BAIR HUGGER” MDL SHOWS DAUBERT IS STILL BREATHING

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U.S. District Judge Joan Ericksen extinguished an entire federal multidistrict litigation and breathed life into the Court's gatekeeping duty to guard against unreliable science when it excluded unfounded expert testimony in [In re Bair Hugger Forced Air Warming Devices Products Liability Litigation](#), MDL No. 15-2666, 2019 WL 4394812 (D. Minn. July 31, 2019). More than 5,800 plaintiffs sued 3M the manufacturer of Bair Hugger—which warms patients during knee surgery through a blanket filled with heated forced air—alleging that the forced air escaped the blanket and created turbulence in the operating room, stirring bacteria-carrying dust and causing periprosthetic joint infection when the dust reached the surgical site.

3M faced a long road and tortuous battle before the court ultimately pulled the plug on the litigation. Over the course of four years, it became increasingly apparent that there was something dramatically deficient in plaintiffs' scientific story. Although the court denied 3M's initial *Daubert* challenges and allowed a first bellwether trial to proceed, even in that case the court excluded in its entirety one of plaintiffs' two theories for how the Bair Hugger caused infections. That first trial ended with a defense verdict: the jury found that plaintiffs had failed to prove that the Bair Hugger causes surgical-site infections. The defense verdict illustrates the weakness of plaintiffs' claims, but there were even earlier signs of problems for plaintiffs: The first trial case was actually the *sixth* in line for trial, but the five earlier plaintiffs dismissed or otherwise avoided going to trial in them. After that first defense verdict, the plaintiffs in the next two trial cases told the court that they didn't want to go forward. It is against this backdrop of repeated plaintiff dismissals and a defense jury verdict that the court revisited the earlier denial of 3M's *Daubert* motions.

In its reconsideration, the court systematically tore down plaintiffs' experts' opinions using the experts' own trial testimony against them. (We commend the full opinion for review if you are interested in a blow-by-blow dismantling of plaintiffs' experts.) The Eighth Circuit has long held that “the district court's gatekeeping role separates expert opinion evidence based on ‘good grounds’ from subjective speculation that masquerades as scientific knowledge.” *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001), *aff'g*, 107 F. Supp. 2d 1015 (E.D. Mo. 2000).¹

¹ The Eighth Circuit is in good company. In nationwide litigation involving the medication Parlodel, in which plaintiffs' personal injury claims hinged on unreliable causation evidence (including adverse event reports and animal studies), a string of appellate decisions solidified the contours of *Daubert* by excluding junk science. *Glastetter*, 252 F.3d at 989; *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193 (10th Cir. 2002), *aff'g*, 95 F. Supp. 2d 1230 (W.D. Okla. 2000); *Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194 (11th Cir. 2002), *aff'g*, *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347 (N.D. Ga. 2001).

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Judge Ericksen emphasized the hallmarks of unreliable expert testimony when she not only found that the plaintiffs' expert's air flow computer model underpinning plaintiffs' causation theory was designed specifically for the litigation (an alarming fact in itself), but also that the plaintiffs' air flow model lacked applicability to the real-world—*i.e.*, the expert's "conclusions have drifted from the factual realities of his test." *In re Bair Hugger*, 2019 WL 4394812, at *9. Critically, the model failed to account for "key" known causes of air flow disruption that occur in real-world operating suites—such as opening doors, the movement of doctors and nurses, and surgical machinery and equipment. Without any explanation, the expert ignored these factors as inconsequential, despite relying on a study that found the biggest factor on airborne microorganisms in an operating room is the presence and activity of people in the room. *See id.* at *18-19. He audaciously proffered the *untested* theory that the movement of personnel in the operating room would *exaggerate* the findings of his air flow model for the Bair Hugger, claiming that "even reaching a hand in" to test a real-world model would "interrupt the results." *Id.* at *6-7. But the court rejected the experts' unfounded extrapolations and conjecture, finding that the expert's "attempted gap-filling" between his simulation and real-world conditions was "more like a leap of faith than an inferential leap." *Id.* at *8.

Similarly, the court re-examined the observational and epidemiology studies the plaintiffs' three medical experts referenced, revealing that the Bair Hugger was not the only thing full of hot air. Plaintiffs' experts ignored numerous limitations that the authors of the published studies themselves identified, including explicit disclaimers by the authors stating that the studies did not establish causation. The court rejected plaintiffs' assertion that observational studies contain "'pointless' caveats" that their experts need not address, and held that the plaintiffs' experts' unreliably excluded obvious alternative explanations for declining infection rates—such as the introduction of bacterial screening or new antibiotics—when they reached conclusions that the study authors themselves were not willing to draw. *Id.* at *18-19.

Without these experts, plaintiffs had no proof that Bair Hugger causes infections, no claim, and no case. The MDL is now kaput (pending an appeal—which is in its briefing stage). We applaud the result, and 3M in this case, for sticking to its guns and continuing to challenge what the Court ultimately decided was unreliable science. Had defendants caved and not held the line after the court rejected the initial *Daubert* challenges, then they would never have had the opportunity to turn the tide on bad science. And there is a strong consensus that the science doesn't back up plaintiffs' claims: as the court pointed out, in 2018, at an International Consensus Meeting, 93 percent of scientists agreed "[t]here is no evidence to definitively link [forced-air warming] to an increased risk[.]" *Id.* at *20. *Bair Hugger* demonstrates that hope is not lost, that *Daubert* is not dead, and that perseverance has its rewards.