UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

Carl Alexander Cohen,

v.

Case No. 1:20-cv-00943-PB
Opinion No. 2024 DNH 026

Boston Scientific Corporation, et al.

MEMORANDUM AND ORDER

The plaintiff, Alex Cohen, underwent surgery for an enlarged prostate that resulted in diffuse thermal burns to his bladder. He brought a products liability action against the manufacturer of one of the medical devices used in his surgery as well as the company that provided the device to the hospital. The defendants have moved to exclude one of Cohen's engineering experts pursuant to Federal Rule of Evidence 702. For the foregoing reasons, the defendants' motions to exclude the expert's testimony (Doc. 69 and Doc. 73) are denied without prejudice.

I. BACKGROUND

A. The GreenLight XPS Laser System

Boston Scientific Corporation manufactures the GreenLight XPS Laser System, a medical device used in various surgeries to vaporize and coagulate tissues. Doc. 69-2 at 16. The device consists of two components: a console, which generates a green laser light, and a fiber, which transmits the laser

light from the console to the targeted tissue in a patient's body. Id. The laser light is absorbed by the red blood cells in the targeted tissue, which generates heat and causes the cells to burst, thereby vaporizing the tissue. Id. at 17.

One type of surgery the GreenLight device can be used for is photoselective vaporization of the prostate (PVP). Id. at 17, 24. This procedure is used to treat benign prostatic hyperplasia (BPH), id., a condition in which a patient's prostate gland becomes enlarged and squeezes the urethra, Doc. 82-11 at 4. During a PVP procedure, a laser technician operates the console, turning it on and placing it on standby mode while the surgeon prepares for surgery. Doc. 71-3 at 28-29. The surgeon has a bag of saline solution connected to the laser fiber and adjusts the flow until she and the laser technician are "happy with the drip rate." Id. at 27. This saline "runs through the fiber" throughout the surgery and aids with cooling the fiber. Id. at 26. The fiber is then inserted into the surgeon's resectoscope, a surgical instrument that also includes a camera device as well as a tube for a second, separate supply of saline solution. Id. at 24, 27; Doc. 71 at 4. The surgeon inserts the resectoscope into the patient's bladder via the urethra. Doc. 75 at 1. When she is ready to begin the procedure, she instructs the laser technician to switch the device off standby mode. Doc. 71-3 at 28. At this point, the surgeon controls the laser by using a foot switch, which includes

pedals to initiate coagulation, vaporization, or standby modes. Id.; Doc. 69-2 at 45.

Throughout the procedure, the surgeon uses the irrigation tube attached to her resectoscope to "constantly" deliver saline fluid to the surgical area, controlling the flow using a valve on the resectoscope. Doc. 71-3 at 23, 25. This irrigation helps the surgeon visualize the surgical field by moving tissues out of the way and flushing away blood and other debris. Id. at 23. The GreenLight device does not specify the temperature to which this irrigation fluid should be heated, and surgeons have varying preferences, electing to use saline heated to either room temperature (approximately 68°F or 20°C) or just above physiological temperature (around 104°F or 40°C). See id. at 19; Doc. 71-8 at 17. As the saline circulates through the patient's urinary system and is replaced by new irrigant, it is then drained out via a catheter. Doc. 71-3 at 23; Doc. 75 at 2.

B. Cohen's Surgery and the Aftermath

In 2016, Cohen saw Dr. Shilpa Lamba, M.D., a board-certified urologist at Manchester Urology Associates in Dover, New Hampshire, complaining of "lower urinary tract symptoms." Doc. 71-3 at 5-7. She diagnosed him with BPH and, after a year of trying various medications to no avail, recommended surgical intervention. Id. at 7-8. She presented Cohen with two options: PVP or transurethral resection of the prostate (TURP). Id. at 8-9. In

contrast to PVP, which uses the GreenLight device to vaporize tissue, TURP uses a surgical instrument containing electrodes—either a monopolar loop or a bipolar loop—to resect unwanted tissue. Doc. 69 at 3; Doc. 82-2 at 88.

Cohen elected PVP, and Dr. Lamba performed the procedure in July 2017, at Wentworth-Douglass Hospital in Dover, New Hampshire. Doc. 11 at 10; Doc. 75 at 2. She used the GreenLight device and irrigation saline solution heated to approximately 103 or 104°F, Doc. 71-3 at 19; Doc. 71-5 at 6, to vaporize several sections of enlarged prostate tissue, Doc. 75 at 3. The surgery proceeded as normal until Dr. Lamba encountered an eight-to-ten-millimeter nodule at the apex of the prostate that would not vaporize. Doc. 75 at 3. In her attempt to remove this nodule, she "passed the laser fiber between the nodule and the capsular wall and initiated laser vaporization," but the metal cap at the end of the fiber broke off. Id. At this point, one of the device's "automatic safety mechanism[s]" activated, and the device switched back to standby mode.[1] Doc. 71-3 at 29. Dr. Lamba was able to safely retrieve the fiber's cap from Cohen's body but decided to abandon the PVP procedure,

[1] This mechanism, known as FiberLife, "continuously monitors the temperature of the tip of the fiber and momentarily stops the laser emission when the fiber gets too hot." Doc. 69-2 at 16. It is activated if "tissue or vapor bubbles accumulate on the tip [of the fiber], or if for other reasons there is damage due to excessive heating of the fiber." Id. In "most cases," the laser will "turn back on immediately and the procedure continues without interruption"; but if FiberLife is "activated continuously," the console "will automatically detect this condition, [and] put the laser in Standby mode." Id.

switching to the TURP technique and successfully excising the nodule using a bipolar loop. Doc. 75 at 3.

Towards the end of the surgery, Dr. Lamba inspected the surgical area for bleeding and evidence of laser vaporization, which has an immediate, visible effect on the tissue. Id.; Doc. 71 at 5. She documented in her surgical notes that the ureteral orifices were "away from any vaporization or resection." Doc. 75 at 3. She then removed her resectoscope and irrigated the bladder. Id. All in all, she recorded that Cohen "tolerated the procedure well with no complications." Id.

But at a follow-up appointment with Dr. Lamba a few days later, Cohen reported feeling nauseous and feverish as well as having abdominal pain. Doc. 11 at 10; Doc. 71-3 at 11-12. Concerned he wasn't convalescing as she "would expect after [the] procedure," Dr. Lamba ordered several tests, including bloodwork and an ultrasound of the kidneys and bladder. Doc. 71-3 at 12. But before the ultrasound could be conducted, Cohen presented to the emergency department with persistent symptoms, including "complete[] incontinen[ce]." Doc. 11 at 10; Doc. 71-3 at 13. He was diagnosed with hydronephrosis, "a dilation of the collecting system where the urine collects in the kidneys," and a urinoma, suggesting "some leakage of urine." Doc. 71-3 at 13-14. Soon thereafter, Dr. Lamba installed a stent in Cohen's right ureter to aid the kidney's drainage. Id. at 14-15.

Cohen continued to experience incontinence in the months following the surgery. Doc. 75-1 at 2. In October 2017, Dr. Lamba's colleague, Dr. Cormac O'Neill, M.D., performed a cystoscopy to examine Cohen's urinary system. Id. He could not locate the ureteral orifices, and he observed thermal injuries throughout the bladder area. Id. at 2-3 (documenting "significant thermal effect in the prostatic fossa" and "significant exudative changes consistent with a thermal injury to the bladder"). He subsequently diagnosed Cohen with "[s]evere thermal cystitis." Id. at 2. Consequently, Cohen underwent extensive reconstructive surgery, has a permanent urostomy bag, and is in constant pain. Doc. 11 at 2, 11. He is also permanently incontinent and impotent. Id.

C. Cohen's Lawsuit and Dr. Jarrell's Opinions

Cohen filed suit in state court in July 2020, and the case was removed to this court on diversity grounds. Doc. 1. He alleges that the GreenLight device has design and warning defects and has sued Boston Scientific for strict products liability, breach of the implied warranty of merchantability, and violation of New Hampshire's Consumer Protect Act (CPA). Doc. 11 at 11-22. He also brings products liability and breach of the implied warranty of merchantability claims against Republic Surgical, the company that provided

the GreenLight console to the hospital for use during Cohen's surgery.[2] Id. at 25-39.

Cohen has identified several experts whose testimony he plans to rely on at trial. One such expert, Dr. John Jarrell, Ph.D., is a licensed mechanical engineer with advanced degrees from Brown University and nearly thirty years of experience analyzing product designs, manufacturing processes, and materials selections and failures, often in cases involving medical devices and drug delivery systems. Doc. 82-3 at 3-4. As part of his analysis in this case, Dr. Jarrell inspected the GreenLight console and an exemplar fiber, reviewed the device's directions for use, and surveyed public reports of adverse events, including recall data and complaints filed with the U.S. Food and Drug Administration (FDA). Id. at 11, 18-22.

Dr. Jarrell also performed a series of calculations to determine "the raise [sic] in saline irrigation temperature in response to the energy output" of the GreenLight device, which he provided in an initial report. Id. at 23. Noting that the vaporization process "absorbs some of the energy produced by" the laser and thus affects the amount of energy available to heat the

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[2] Cohen also originally asserted claims for negligence, breach of an express warranty, and breach of the implied warranty of fitness for a particular purpose against Boston Scientific and Republic Surgical. Doc. 11 at 14-22, 28-37. However, those claims have since been abandoned. Doc. 82 at 41-42; Doc. 98 at 147; see Doc. 81 at 4. Cohen has also abandoned his CPA claim against Republic Surgical. See Doc. 81 at 4.

saline, he performed two sets of calculations—one under vaporizing conditions and one under non-vaporizing conditions.[3] Id. at 6, 23-26.

Simulating the period of failed vaporization of the nodule during Cohen's surgery, Dr. Jarrell calculated the temperature increase of the saline using the following formula:

$$c = \frac{Q}{m * \Delta T}$$

where c is the specific heat capacity of saline in Joules per kilogram degree Kelvin (J/kgK), Q is the device's energy output in Joules (J), m is the mass of the irrigation saline in kilograms (kg), and ΔT is the change in temperature of the irrigation saline in degrees Kelvin (K). Id. at 23. Relying on known constants and data from the laser's specifications and Cohen's surgery, Dr. Jarrell then solved for ΔT.

The specific heat capacity of saline is a known constant, 4,185 J/kgK. Id. The maximum power of the device is 180 watts (W), or 648,000 J over the course of one hour. Id.; Doc. 82-2 at 110. Then, knowing, based on the medical records for Cohen's surgery, that 18 liters (L) of irrigation saline were

[3] The defendants' arguments to exclude Dr. Jarrell's testimony do not challenge Dr. Jarrell's calculations under vaporizing conditions. Therefore, in the interest of brevity, the details of those calculations are not reproduced here. Those calculations concluded that, during periods of vaporization when the GreenLight device was operating at "maximum theoretical energy production and cutting," the highest temperature the saline would likely reach is between 116.6°F (47°C) and 119.5°F (48.6°C). Id. at 25.

administered over the course of the approximately 100-minute-long surgery, Dr. Jarrell determined that the flow rate of the saline was 10.8 L/hour, or about 10.8 kg over the course of one hour. Doc. 82-2 at 110. Assuming that "all the laser energy was converted to heat" and excluding "heat flow out of the bladder," he calculated the increase in temperature of the saline resulting from the use of the laser to be about 25.83°F (14.35° C). Doc. 82-3 at 23.

Thus, in a procedure like Cohen's, where the surgeon used irrigation saline preheated to just above physiological temperatures (104°F or 40°C), Dr. Jarrell opined that the laser could increase the temperature of the incoming irrigation saline to around 129.83°F (54.35°C). Id. at 23. He then noted that, according to the scientific literature, human skin takes "approximately 1.5 minutes" to burn at 127.4°F (53°C) and "approximately 30 seconds" at 131°F (55°C). Id.

Dr. Jarrell also recognized, however, that "according to published scientific literature dealing with the elevated temperature of bladder irrigants, the temperature of the incoming irrigation saline is expected to drop 2 to 2.5°C in the process of reaching the bladder." Id. Accordingly, he decreased his calculations by that same amount, thus concluding that the irrigation saline would likely only be heated to between 125.33°F (51.85°C) and 126.23°F (52.35°C). Id. He then noted that, according to the scientific

literature, human skin takes "approximately 4 minutes" to burn at 123.8°F (51°C). Id.

Dr. Jarrell produced a supplemental report several months later that responded to opinions proffered by the defendants' experts. Doc. 82-4. In this report, he noted that it "is well known that the saline water has relatively minimal direct absorption of the laser," and tissues "are nearly 1 million times more absorpti[ve] of laser compared to the saline." Id. at 4. Therefore, he stated that it was "always [his] opinion that the laser energy was absorbed by the tissues, which then heated up the surrounding [saline]." Id.

As things now stand, Dr. Jarrell proffers several opinions. First, he explains that the GreenLight device is defective because its "power output capacity . . . can cause transient increases in the temperature" of the irrigation saline to levels that "can cause burns." Doc. 82-3 at 6. Second, he states that Cohen's injuries were "most likely due to" this defect. Id. Third, he notes that alternative technologies—such as using a similar laser in combination with a thermocouple or temperature-sensing catheter—were available to "monitor the temperature of the saline fluid" and "alert[] the surgical personnel of unsafe temperatures within the bladder." Id. at 7-8. And fourth, he opines that Boston Scientific "failed to adequately warn or specify the temperature to be used for the irrigation saline." Id. at 7.

Boston Scientific has moved to entirely exclude Dr. Jarrell's testimony, arguing that his opinions do not meet the admissibility standards set forth in Federal Rule of Evidence 702. Doc. 69. Republic Surgical has joined this motion. Doc. 73. Additionally, both defendants have filed motions for summary judgment, contending, among other things, that without Dr. Jarrell's testimony, the essential elements of Cohen's claims cannot be sufficiently proved. Doc. 71; Doc. 72.

II. STANDARD OF REVIEW

Federal Rule of Evidence 702 governs the admissibility of expert opinion testimony. It provides:

> 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 the proponent demonstrates to the court that it is more likely than not that:
> (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's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702 (amended 2023).[4]

[4] This language reflects a set of recent amendments, which became effective on December 1, 2023. As explained in the commentary, these amendments do not "impose[] any new, specific procedures"; rather, they were "simply intended to clarify" that the preponderance of the evidence standard that governs the admissibility of other evidence under Federal Rule

Rule 702 charges the trial court with "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand" before admitting it into evidence. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993). "These two requirements—a reliable foundation and an adequate fit—are separate and distinct." Samaan v. St. Joseph Hosp., 670 F.3d 21, 31 (1st Cir. 2012). The reliability prong asks whether "the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion," Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998), while the "fit" prong asks whether the expert's conclusions have a "valid scientific connection to the pertinent inquiry," Lawes v. CSA Architects & Eng'rs LLP, 963 F.3d 72, 98 (1st Cir. 2020) (quoting Daubert v. Merrell Dow Pharm. Inc., 43 F.3d 1311, 1320 (9th Cir. 1995)).

In analyzing the reliability of an expert's opinion, a court should generally focus on the expert's "principles and methodology, not on the conclusions that they generate." Daubert, 509 U.S. at 595; accord Samaan, 670 F.3d at 31 (explaining that the reliability analysis "necessitates an inquiry into the methodology and the basis for an expert's opinion"). "But conclusions and methodology are not entirely distinct from one another," and

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of Evidence 104(a) also "applies to expert opinions under Rule 702." Fed. R. Evid. 702 advisory committee's note to 2023 amendment.

a court may "conclude that there is simply too great an analytical gap between the data and the opinion proffered." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

Nonetheless, "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." Fed. R. Evid. 702 advisory committee's note to 2000 Amendment (quoting United States v. 14.38 Acres of Land, 80 F.3d 1074, 1078 (5th Cir. 1996)). Instead, "[s]o long as an expert's scientific testimony rests upon "'good grounds,' based on what is known,'" it should be admitted and "tested by the adversarial process." Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 15 (1st Cir. 2011) (quoting Daubert, 509 U.S. at 590) (explaining that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence"). Thus, the court must differentiate between "what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion." Id. (emphasis in original). And in doing so, the court "is not bound by the rules of evidence except those with respect to privileges." Daubert, 509 U.S. at 592 n.10 (quoting an earlier version of Fed. R. Evid. 104(a)).

"The party seeking to introduce the evidence has the burden of establishing both its reliability and its relevance." López-Ramírez v. Toledo-

González, 32 F.4th 87, 94 (1st Cir. 2022) (quoting Milward v. Rust-Oleum Corp., 820 F.3d 469, 473 (1st Cir. 2016)). So long as an expert opinion satisfies the prerequisites set forth in Rule 702 by a preponderance of the evidence, any questions as to credibility and weight must be reserved for the jury.

III. ANALYSIS

The defendants attack Dr. Jarrell's opinion testimony on several grounds. First, they assert that he is unqualified to provide any of his proffered opinions as to the GreenLight device. Doc. 69 at 5-6, 11-12, 15-16. Second, they argue that his methodology is unreliable because he failed to test his calculations, conduct a proper risk-benefit analysis, or adequately consider alternative causes of Cohen's injuries. Id. at 7-8, 10-11, 13-15. And third, they argue that the application of his methodology is "demonstrably flawed" because his calculations rest on incorrect assumptions, and his conclusions do not comport with real-life data. Id. at 8-9, 11. I address each set of arguments in turn.

A. Qualifications

1. Lack of Experience with Lasers

The defendants first argue that Dr. Jarrell is not qualified to opine as to any potential defect in the GreenLight device or the adequacy of its warnings because he has insufficient experience with laser systems and their

associated warnings. Id. at 3-6, 15-16. Cohen objects, arguing that Dr. Jarrell has sufficient experience with laser systems and that, regardless, his engineering background renders him qualified to provide his opinions. Doc. 82 at 7-12, 24-25. I agree with Cohen.

"[T]he general rule [is] that a court should consider all relevant qualifications when ruling on the admissibility of expert testimony." DaSilva v. Am. Brands, Inc., 845 F.2d 356, 361 (1st Cir. 1988). Consequently, a "lack of personal experience . . . should not ordinarily disqualify an expert, so long as the expert is qualified based on some other factor provided by Rule 702: 'knowledge, skill, experience, training, or education.'" U.S. v. Liu, 716 F.3d 159, 168 (5th Cir. 2013) (emphasis in original). Thus, courts often decline to "strictly confine[]" an expert to his "area of practice," and instead allow him to "testify concerning related applications." Id. at 168-69 (quoting Wheeler v. John Deere Co., 935 F.2d 1090, 1100 (10th Cir. 1991)).

Many courts, moreover, including the First Circuit, have specifically held that engineers are not required to have "experience with the specific machine in question." DaSilva, 845 F.2d at 361; see also DayCab Co., Inc. v. Prairie Tech., LLC, 67 F.4th 837, 853 (6th Cir. 2023) (affirming the admissibility of an engineer's testimony based on his "extensive experience in the fields of design, product development, manufacture and servicing of machines," despite his lack of "specific experience in fiberglass

manufacturing, conversion kits, or truck body work"); Anderson v. Raymond Corp., 61 F.4th 505, 509 (7th Cir. 2023) (noting that arguments attacking a mechanical engineer's lack of prior experience analyzing forklift accidents were "misplaced" when he had "spent most of his professional career investigating machine accidents and performing accident reconstructions"). Instead, courts consider an expert's "full range of practical experience as well as academic or technical training." Anderson, 61 F.4th at 509 (quoting United States v. Parra, 402 F.3d 752, 758 (7th Cir. 2005)).

Here, Dr. Jarrell is qualified to offer opinions both as to the GreenLight device's capacity to overheat the irrigation saline to dangerous temperatures and the availability of alternative designs. After inspecting the GreenLight device and reviewing its specifications, Dr. Jarrell applied general principles of physics—for example, the conversion of light energy to thermal energy, the transfer of that energy to various materials, and the subsequent changes in temperature of those materials—to perform a series of calculations to determine the potential increase in the temperature of the saline when it is brought into contact with energized prostate tissue. These concepts clearly fall within his area of expertise. He has bachelor's and master's degrees in Materials Science and Engineering, a doctorate degree in Biology, Medical Science, and Engineering, and nearly thirty years of experience as a licensed mechanical engineer, analyzing a variety of product materials, designs, and

failures. Doc. 82-3 at 3-4. Thus, even without any prior experience with the GreenLight device, his general engineering qualifications are sufficient to support his opinion testimony. See Chapman ex rel. Estate of Chapman v. Bernard's Inc., 167 F. Supp. 2d 406, 420-21 (D. Mass. 2001) (allowing a civil engineer to opine on the structure and design of a daybed without any prior furniture-related experience because his opinion primarily relied on "basic principles of physics and engineering," such as "the interaction of metal tubes, bolts, springs and various stresses thereon").

Dr. Jarrell is also qualified to opine on the adequacy of the GreenLight device's warnings for similar reasons. In forming his opinion on this matter, Dr. Jarrell relied on his extensive experience in developing and evaluating medical devices and their accompanying instructions and warnings. He has performed failure analyses for various medical devices, which included reviewing product data from the FDA and reviewing the accompanying instructions and warnings. The fact that he admitted to never having worked on warnings for a medical laser system is not dispositive.

While Dr. Jarrell's lack of experience with similar lasers may impact the weight a jury ultimately assigns to his opinion, it does not render his opinion inadmissible in light of his academic credentials and other relevant experience. Anderson, 61 F.4th at 509 (noting that "[a]n expert's

specialization or lack thereof typically goes to the weight to be placed on her opinion, not its admissibility") (cleaned up).

2. Lack of Medical Expertise

The defendants next argue that Dr. Jarrell is unqualified to testify as to the most likely cause of Cohen's injuries because he is not a medical doctor. This argument is a nonstarter because Cohen does not propose to elicit medical opinions from Dr. Jarrell.

Dr. Jarrell appropriately relied on medical evidence in the record as to what happened during Cohen's surgery. He also appropriately relied on medical evidence in the record to support Cohen's contention that he suffered diffuse thermal injuries to his bladder during surgery. Finally, he reasonably relied on data from the medical literature to support his statements concerning the temperature of and time of exposure to heated irrigation saline that would be required to burn human tissue. Accordingly, all of the opinions Dr. Jarrell proposes to express regarding the cause of Cohen's injuries are engineering opinions that he is qualified to offer. The fact that he is not a medical doctor is irrelevant.

B. Unreliable Methodology

1. Lack of Testing

The defendants next fault Dr. Jarrell for failing to conduct his own tests with the GreenLight device to confirm that his mathematical

calculations are "accurate, applicable to the real world, or meaningful." Doc. 69 at 7. This, they argue, renders his methodology unreliable. Cohen responds that testing is not a requirement for admissibility. Doc. 82 at 14-16. I agree with Cohen.

Testing is, of course, "one of the most common and useful reliability guideposts" when analyzing the admissibility of expert testimony. Lapsley v. Xtek, Inc., 689 F.3d 802, 815 (7th Cir. 2012). However, as the defendants themselves note, courts have routinely held that testing is not a requirement for admissibility. See, e.g., Quilez-Velar v. Ox Bodies, Inc., 823 F.3d 712, 719 (1st Cir. 2016) (noting that there are "alternate methods of testing from which the jury could evaluated reliability" besides physically testing a design); Gussack Realty Co. v. Xerox Corp., 224 F.3d 85, 95 (2d Cir. 2000) (stating that an "expert need not have conducted her own tests"). Instead, the Rule 702 analysis hinges on whether the expert's "methodology . . . has been adequately tested and accepted within the scientific community, not whether his result has been evaluated." Jenks v. N.H. Motor Speedway, 2012 DNH 039, 2012 WL 405479, at *3 (D.N.H. Feb. 8, 2012) (emphasis in original). And here, Dr. Jarrell's methodology passes muster.

Dr. Jarrell examined the GreenLight device, reviewed its specifications, and then used this information along with commonly accepted scientific principles—namely the laws of thermodynamics and an equation for specific

heat capacity—to perform a series of calculations. This use of generally accepted principles of physics is sufficient to bridge the analytical gap between his initial hypothesis and his final opinion. Cf. Lapsley, 689 F.3d at 815-16 (holding that simulations and mathematical or computer models are "perfectly acceptable form[s] of test[s]"); Bodner v. Thunderbird Prods. Corp., No. 22-11179, 2023 WL 1860968, at *1, *3 (11th Cir. Feb. 9, 2023) (upholding the exclusion of an expert's opinion where he failed to "perform any testing or provide any calculations to support his opinions"). In short, as the Seventh Circuit has put it, "[w]e do not require experts to drop a proverbial apple each time they wish to use Newton's gravitational constant in an equation." Lapsley, 689 F.3d at 816.

Of course, a lack of testing can affect the weight a jury assigns to the expert's testimony, Williams v. Syphan, No. 22-3222, 2023 WL 1305084, at *6 (6th Cir. Jan. 31, 2023), and the defendants are free to raise Dr. Jarrell's lack of testing or challenge any aspect of his calculations at trial. However, his lack of testing does not constitute sufficient grounds to hold Dr. Jarrell's opinion inadmissible.

2. Failure to Perform a Risk-Utility Analysis

The defendants next argue that Dr. Jarrell's methodology is unreliable because he did not consider the GreenLight device's "benefits or utilities" when forming his opinions. Doc. 69 at 10-11. New Hampshire law requires a

jury to engage in risk-utility analysis when determining whether an allegedly defective product is unreasonably dangerous. Price v. BIC Corp., 142 N.H. 386, 389 (1997); see also Buckingham v. R.J. Reynolds Tobacco Co., 142 N.H. 822, 825-26 (1998) (explaining that a product liability claim must allege that a product is "defective" and "unreasonably dangerous" as separate elements). But the defendants do not claim that Dr. Jarrell proposes to offer opinion testimony that the GreenLight device is unreasonably dangerous as designed. Accordingly, his failure to assess the GreenLight device's costs and benefits does not provide a basis for excluding his testimony.

3. Insufficient Consideration of Alternative Causes

Lastly, the defendants argue that Dr. Jarrell's methodology is unreliable because he failed to rule out what they claim are two alternative causes of Cohen's injuries: the possibility that Cohen's burns could have been caused by the improper use of a surgical blanket heater set to around 140°F to heat the irrigation saline prior to Cohen's surgery, or the possibility that the saline became overheated during the use of the TURP procedure.[5]

[5] The defendants' blanket warmer theory appears to be based primarily on a statement from Dr. Lambda that, at some time after Cohen's procedure, she witnessed an unidentified person "removing irrigation fluid from the [surgical] blanket warmer, which is set to 140 degrees." Doc. 71-3 at 35-36. However, Dr. Lamba also testified that she "ha[d] no evidence of that occurring at the time" of Cohen's procedure. Id. at 37. The record, likewise, does not contain any evidence that supports this having happened during Cohen's procedure. To the contrary, there is evidence in the record that the

Among the things that a court should consider when evaluating proposed expert testimony is whether the expert has "adequately accounted for obvious alternative explanations." Packgen v. Berry Plastics Corp., 847 F.3d 80, 87 (1st Cir. 2017) (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment). An expert, however, is "not required to eliminate every other possible cause" for his opinion to be admissible. Id.; see also Guinn v. AstraZeneca Pharms. LP, 602 F.3d 1245, 1253 (11th Cir. 2010) (per curiam). Here, Dr. Jarrell has adequately considered obvious alternative causes for Cohen's injuries.

With respect to the defendants' blanket warmer theory, Dr. Jarrell reasonably concluded that it was an "unlikely" explanation for Cohen's injuries because he had seen no testimony or other evidence that the blanket warmer had been used in Cohen's surgery to heat the irrigation fluid. Doc. 82-2 at 139-40 (Dr. Jarrell explaining that the medical records indicate that the irrigation fluid used in Cohen's surgery had been heated to 104°F and that the nurse who coordinated the surgeries testified that the irrigation fluid had been placed in the correct warmer set to 104°F).

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coordinating nurse "never put any bags [of irrigation fluid]" in the blanket warmer and that he palpated the bags to make sure they were not too warm for use. Doc. 83-10 at 3-4.

Dr. Jarrell also reasonably testified that, based on his research, the only way the TURP procedure could result in diffuse thermal burns, such as Cohen's, was if a monopolar loop was used with a conductive irrigation fluid, like saline; however, he explained that Cohen's procedure used a bipolar loop, and thus, TURP was an unlikely cause of Cohen's injuries. Id. at 88-89. Additionally, he noted that there is "no evidence in the medical records of any problems with the TURP device," while there was "evidence of overheating of the Greenlight device." Id. at 240.

The fact that Dr. Jarrell may not have completely eliminated these other possible causes does not undermine "the soundness of the methodology." Ambrosini v. Labarraque, 101 F.3d 129, 140 (D.C. Cir. 1996) (quoting Mendes-Silva v. United States, 980 F.2d 1482, 1487 (D.C. Cir. 1993)). Whether his causation opinions are persuasive given the defendants' theories as to other possible causes is ultimately a question for the jury.

C. Application of Methods

1. Incorrect Assumption Regarding Conductivity

The defendants also complain that Dr. Jarrell should not be permitted to testify that the GreenLight device caused the irrigation fluid to overheat and burn Cohen's bladder because his opinion is based on an unwarranted assumption that "all the laser energy was converted to heat" when the laser was applied to Cohen's non-vaporized prostate nodule and all of that heat

was "transferred from the non-vaporized tissue to the saline." Doc. 69 at 8. In support of their argument, they cite their own expert, Dr. Erwin Lau, Ph.D., who opined that "[s]uch 100% transfer of energy is fundamentally impossible" because "the laser-heated tissue can transfer only a fraction . . . of its absorbed laser energy to heat the saline." Id. (quoting Doc. 69-8 at 24).

Dr. Jarrell opined that when the GreenLight device emits laser light under non-vaporizing conditions, the targeted tissue absorbs the light energy and converts it to thermal energy, or heat. That heat is then transferred to the irrigation saline as it flows through the urinary system, and results in an increase in the temperature of the saline. In calculating this temperature change, Dr. Jarrell relied on the formula, $c = \frac{Q}{m * \Delta T}$. This equation is clearly a generally accepted formula employed by the scientific community, and Dr. Lau does not contest its relevance to the calculations at hand.

As Dr. Lau points out, however, Dr. Jarrell's use of this formula appears to implicitly assume perfect conductivity between the nodule and the irrigation saline that comes into contact with the nodule, such that the non-vaporized nodule transfers 100% of the energy introduced into it by the laser to the irrigation saline. If this assumption is correct, or at least reasonable, then the aforementioned formula may very well be sufficient, and Dr. Jarrell's calculations may be sufficiently reliable to be admissible.

But Dr. Jarrell does not address this assumption in his reports or deposition testimony, and Cohen's briefing fails to adequately explain why this assumption is reasonable. On the other hand, the defendants also fail to sufficiently explain why Dr. Jarrell's apparent assumption is unreasonable. Dr. Lau's report indicates that "[c]orrect calculations of saline temperature would require accounting for heat capacities, thermal conductivities, and heat exchange rates between multiple bodies (tissue, flowing saline, surrounding tissue, fiber tip, etc.) that Dr. Jarrell did not perform." Doc. 69-8 at 25. Yet he does not explain how Dr. Jarrell's failure to account for these variables undermines his analysis. I am, of course, mindful of the fact that the burden is on the proponent of expert testimony to prove that it is admissible. But I am simply unable to reliably resolve the defendants' challenge to this aspect of Dr. Jarrell's proposed testimony without receiving additional evidence. Accordingly, I will need to hold an evidentiary hearing before I can determine whether Dr. Jarrell's testimony on causation is admissible.

2. Incorrect Adjustment for Cooling

The defendants also challenge the adjustment Dr. Jarrell made to account for the outflow of saline throughout the procedure, which they note "would mitigate any theoretical heat transfer." Doc. 69 at 9. Specifically, they argue that the 2 to 2.5°C adjustment Dr. Jarrell made is insufficiently

supported because the scientific paper from which it was obtained describes the drop in temperature of a solution as it flows into the bladder, not the cooling experienced as the solution flows out of the bladder. Id. Cohen does not specifically address this argument, but regardless, I find it unpersuasive.

As an initial matter, Dr. Jarrell's report indicates that "the temperature of the incoming saline is expected to drop 2 to 2.5°C in the process of reaching the bladder," Doc. 82-3 at 23, so it is not clear that his reliance on this value from the literature is inapposite. But, to the extent the defendants disagree on the specific value used, such a discrepancy is simply a "battle of the experts," and the defendants do not explain why such an error is so egregious as to make his testimony inadmissible.

Alternatively, to the extent the defendants contend that Dr. Jarrell did not sufficiently account for the dissipation of heat as heated saline flowed out of the bladder and was replaced with cooler saline, it is unclear whether such an adjustment is necessary. As Dr. Jarrell noted in his report, and as Cohen explained at the hearing on the present motions, the volume of Cohen's bladder was substantially restricted due to his enlarged prostate, reducing its capacity from the typical 500 milliliters to between 142 and 177 milliliters. Doc. 82-3 at 7. Given this smaller volume, Dr. Jarrell opined that Cohen's bladder "would hold less of the cooler temperature irrigant then a normal size bladder." Id. And assuming this restricted bladder size and an irrigation flow

rate of 10.8 L/hour, the irrigation fluid in Cohen's bladder could be completely replaced very quickly, thereby reducing the dissipation of heat by cooler irrigant. Defendants do not sufficiently develop this argument, and therefore I decline to consider it further.

3. Warnings

The defendants argue that Dr. Jarrell's opinion regarding the inadequacy of the GreenLight device's warnings is "baseless speculation" because Dr. Lamba admitted to not having read the device's manual or instructions, thereby rendering any such warning futile. Doc. 69 at 16. First, in so arguing, the defendants misapprehend Dr. Jarrell's opinion on this issue. Dr. Jarrell explained in his deposition that "the [directions for use] and the manual [are] not the only places where warnings are applied in these types of circumstances." Doc. 82-2 at 80. Instead, he explained, manufacturers can provide warnings via "a placard, a sticker on the machine," "[w]arnings applied directly to consoles," a note on a "digital screen," a check box, or updated training events or literature. Id. at 81-83. But more importantly, this is an argument for judgment as a matter of law on the warning claim, not an argument for excluding an expert's opinion under Rule 702. The defendants fault Dr. Jarrell for providing insufficient causation testimony when his opinion goes to the GreenLight device's defect, not causation. And an expert is not required to establish every element of a

claim to be admissible. In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., No. 2327, 2016 WL 4536456, at *2-3 (S.D.W. Va. Aug. 30, 2016) ("A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case."). Thus, Dr. Jarrell does not need to show that a warning would have been seen or heeded in order for his opinion to be admissible.

4. Lack of Corroborating Data

Lastly, the defendants argue that Dr. Jarrell's opinions should be excluded because they are not supported by "real-world data." Doc. 69 at 11. They explain that during his deposition, Dr. Jarrell could neither identify any literature documenting similar cases of thermal injuries caused by the GreenLight device nor name a urologist who agreed with his opinion. Id. But the defendants' argument is unpersuasive. As Cohen correctly points out, showing that a particular defect has injured others in the same way as the present plaintiff is not a prerequisite for products liability claims, much less is it a basis for excluding an expert's testimony. Of course, a jury may reasonably conclude that a lack of similar adverse events reduces the likelihood of such events having occurred or undermines Dr. Jarrell's testimony; however, it has no bearing on the admissibility of his opinions.

IV. CONCLUSION

The defendants' motions to exclude Dr. Jarrell's expert testimony (Doc. 69 and Doc. 73) are denied without prejudice to my right to reassess such conclusions at trial based on the evidence and opinions presented at that time.[6] Additionally, as I have explained, I cannot determine on the present record whether Dr. Jarrell's causation opinion should be excluded on the ground that it is based on an unwarranted assumption that all of the heat energy produced by the use of the laser on non-vaporized prostate tissue was conducted to the irrigation saline that came into contact with the energized prostate tissue. Accordingly, I deny defendants' request to exclude Dr. Jarrell's opinions on this basis without prejudice, and I will assess this particular issue again de novo after conducting an evidentiary hearing.

SO ORDERED.

/s/ Paul J. Barbadoro
Paul J. Barbadoro
United States District Judge

Date March 26, 2024

cc: Counsel of Record

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[6] In preparing this memorandum and order, I have not considered either Dr. Jarrell's supplemental affidavit (Doc. 96-1) nor the supplemental brief filed in response (Doc. 101). Instead, I will address these filings, if necessary, after holding the evidentiary hearing called for by this memorandum and order.