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IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 19-10869

D.C. Docket No. 1:15-cv-00056-LAG

TAMANCHIA MOORE,

Plaintiff-Appellant,

versus

INTUITIVE SURGICAL, INC.,

Defendant-Appellee.

Appeal from the United States District Court
for the Middle District of Georgia

(April 22, 2021)

Before ROSENBAUM, LAGOA, and ED CARNES, Circuit Judges.

LAGOA, Circuit Judge:

Tamanchia Moore underwent a robotically-assisted laparoscopic hysterectomy procedure. Following that procedure, Moore began to suffer from severe abdominal pain and an inability to urinate. In her quest to discover the source of her pain, Moore learned that her left ureter[1] was burned during the hysterectomy procedure. Moore further discovered that the doctor who performed the laparoscopic hysterectomy used tools during the procedure produced by Intuitive Surgical, Inc., and that the tool at issue—a pair of miniature electrified scissors—was susceptible to forming microcracks along the shaft, which could leak electrical current during operations and burn the surrounding flesh. This same tool was subsequently recalled in the months following her surgery. Based on this information, Moore sued Intuitive for her injuries, seeking money damages to compensate her for the injuries she had suffered.

To assist in proving her claim against Intuitive, Moore retained the services of Dr. Michael Hall to testify as an expert witness on (1) the standard of care in hysterectomy procedures and (2) the cause of her injuries. Dr. Hall is a board-certified OB/GYN who practices gynecological surgery in Englewood, Colorado, and teaches Obstetrics and Gynecology as an Assistant Professor at the University

[1] The ureter is a long tube that carries urine from the kidneys to the urinary bladder. There are two ureters—one attached to each kidney. The upper half of the ureter is located in the abdomen and the lower half is located in the pelvic area.

of Colorado's medical school. During his more-than-forty-year career, Dr. Hall has performed over four thousand hysterectomies. In addition to his clinical training and practical experience, Dr. Hall has served on hospital review committees and quality assurance committees. In particular, he served on one quality assurance committee for ten years, where he reviewed complications arising in a variety of gynecological procedures—including ureteral injuries occurring during hysterectomy procedures.

Intuitive moved to exclude the testimony of Dr. Hall, arguing that, because Dr. Hall does not use the instruments at issue in this case, he was not qualified to render expert testimony on the cause of Moore's injury. According to Intuitive, it was irrelevant that Dr. Hall had performed that same procedure with different tools over four thousand times. After a two-day *Daubert* hearing[2], the district court agreed with Intuitive's position and excluded Dr. Hall's testimony. And because Dr. Hall was Moore's only causation expert, the district court then entered summary judgment in favor of Intuitive. As discussed below, the district court erred in its application of *Daubert* and therefore improperly entered summary judgment in favor of Intuitive.

I. FACTUAL AND PROCEDURAL BACKGROUND

This case concerns an injury that occurred during a hysterectomy procedure and the resulting claim against the maker of the surgical device used during that

[2] *See Daubert v. Merrell Dow. Pharm., Inc.*, 509 U.S. 579 (1993).

procedure. Moore claims that her injury was due to a defective device sold by Intuitive while Intuitive asserts that the injury was due to the inherent risk present in conducting hysterectomies. To understand the scope of this disagreement, some familiarity with the surgical process and tools is necessary. We therefore begin with a summary of the different ways in which a hysterectomy may be performed and a description of the different surgical tools that are used during the procedure. We then briefly discuss Moore's surgery and the resulting lawsuit, before returning in greater detail to the *Daubert* hearing and the battle of the parties' experts.

A. Types of Hysterectomy Procedures and Relevant Surgical Tools

A hysterectomy is the surgical removal of the uterus. There are multiple ways to perform a hysterectomy. An "open hysterectomy" is performed by cutting a large incision in the abdomen and removing the uterus through that incision. A "laparoscopic hysterectomy" is performed by cutting a number of relatively small incisions in the abdomen, inserting a laparoscope and various surgical tools through those incisions, conducting the operation, and then removing the uterus through the vagina. To insert the tools through those small incisions, air is injected to expand the abdomen, and a sleeve (or "port") is inserted through which the laparoscope (or "scope") and other surgical tools are placed. Attached to the laparoscope is a small digital camera which allows the surgeon to observe the abdomen through a monitor.

The scope and other surgical tools used during the procedure each receive their own port.

Many of the tools that are used during laparoscopic surgeries are electrified, which allows the surgeon to cauterize wounds inside the patient directly with the tools—a process known as electrocautery. These tools can use either monopolar current or bipolar current. With bipolar current, the surgical tool will have two prongs (or clamps), and the electrical current runs between those two prongs. With monopolar current, electrical current is dispersed from a single prong, usually at the tip of the instrument. Regardless of whether monopolar or bipolar current is utilized, an inherent danger of the electrocautery process is the phenomenon of "thermal spread." In other words, when the surgical tool is pressed to body tissue and electricity is applied, thereby cauterizing the tool's contact patch, there is a danger that the electricity will "arc" and cause thermal injury to the surrounding tissue area.

Laparoscopic hysterectomies can be performed either traditionally or with the help of a robot. In a traditional laparoscopic procedure, the surgeon stands over the body of the patient and manually manipulates the laparoscope and surgical tools from outside the body. The tool that is used in a traditional laparoscopic procedure consists of a straight rod with a fixed surgical tool on the end of that rod. In order to manipulate whatever surgical tool is attached to the rod, a surgeon has to move

the rod in order to place the tool where he needs it—i.e., the tool cannot move unless the surgeon moves the rod.

With robotically-assisted laparoscopy, on the other hand, the surgeon stands at a console away from the patient and utilizes a set of joysticks to make the robot manipulate the tools inside of the patient. And those tools are also constructed differently: they consist of a straight rod with a *flexible* surgical tool rather than a fixed surgical tool. That flexibility is meant to mimic the movement of a human wrist. Because the surgical tool can rotate separately from the rod, the rod is not manipulated in the same way in a robotically-assisted laparoscopic surgery as in a traditional laparoscopic surgery. In addition, because of the rotational capacity of the surgical tools used, the initial port placement for a robotically-assisted surgery is different than in a traditional laparoscopy. For example, when using a robot for a hysterectomy, the initial port placement would be slightly higher on the abdomen than for a traditional laparoscopy.

Other than the use of a rod tipped with a flexible tool—and all differences that come along with that tool, e.g., initial port placement and rod movement—the use of a robot changes very little about how a laparoscopic hysterectomy is performed. The procedure progresses in the same way, the same risks are present, the same danger of electrification exists, and the patient faces roughly the same recovery time.

Intuitive is the manufacturer of medical equipment. One of its products is the *da Vinci* Surgical System (the "*da Vinci*")—a robot that allows surgeons to perform robotically-assisted laparoscopic surgery. Another product is the *Endowrist Hotshears* Monopolar Curved Scissors (the "MCS")—a flexible surgical tool that is attached to the end of the *da Vinci*'s arm. The MCS is a pair of electrified miniature scissors that uses monopolar current to simultaneously cut and cauterize tissue. A surgeon using the *da Vinci* can electrify the MCS at any time by depressing a foot pedal.

In May 2013, Intuitive discovered a problem with the MCS and issued a notification to doctors explaining that the MCS "may develop micro-cracks near the distal (scissor) end of the shaft following reprocessing." These cracks, which Intuitive noted "may not be visible," could "create a pathway for electrosurgical energy to leak to tissue during use and potentially cause thermal injury." After discussing this problem with the Food and Drug Administration, Intuitive formally recalled the MCS then in circulation later that month.

B. Moore's Surgery and Postoperative Complications

On March 19, 2013, a few months before the recall, Moore underwent a robotically-assisted laparoscopic hysterectomy. The surgery was performed by Dr. Ese Efemini at Phoebe Putney Memorial Hospital in Albany, Georgia. Dr. Efemini used a number of tools during the operation, including the Intuitive *da Vinci* surgical

system, a pair of Intuitive MCS, and a pair of Maryland Bipolar Forceps. Dr. Efemini also applied a "V-Care cup" during the operation, which is a medical device that pushes the bladder and ureters away from the uterus to protect them during the operation. At his deposition, Dr. Efemini testified that he used his tools "very close to the uterus; on the uterus, pretty much," in order to avoid damaging the surrounding area. The surgery report, in the words of both parties, was "uneventful," with no complications noted, and neither party asserts that Dr. Efemini was negligent or that his treatment fell below the standard of care.

A few days after the surgery, however, Moore began suffering from severe abdominal pain and an inability to urinate. She met with a urologist, Dr. Scott Wendland, who prescribed medication and continued to observe her. A postoperative CT scan was performed on March 30, 2013, which showed pelvic abscesses and leakage of contrast. After observing the CT scan, Dr. Wendland performed a bilateral retrograde pyelogram[3] and placed a stent on Moore's left ureter. She then underwent three more procedures by Dr. Wendland, who noted that Moore had a "thermal injury" on her left ureter.

[3] A retrograde pyelogram is an imaging test that uses X-rays to look at the bladder, ureters, and kidneys. Generally, this imaging test is performed during a cystoscopy test with the patient under general anesthesia. In that test, a camera is inserted into the urethra and bladder in order to give the urologist a view of the inside of the urinary system. During the retrograde pyelogram, the urologist administers and injects contrast dye into the ureters via a catheter in order to enhance the X-ray images and assist in the placement of a ureteral stent.

On March 16, 2015, Moore filed suit against Intuitive. In her Complaint, Moore asserted three claims: (1) the design of the MCS was defective and unreasonably dangerous to patients such as herself; (2) Intuitive failed to warn consumers of the dangers of the MCS; and (3) Intuitive had violated the Georgia Fair Business Practices Act. Moore also asserted a claim for punitive damages. On April 10, 2018, Intuitive moved for summary judgment on all claims and moved to exclude the testimony of Moore's causation expert, Dr. Hall. In its *Daubert* motion, Intuitive argued both that Dr. Hall was not qualified to render expert testimony in this matter and that his opinions were unreliable. And, as Dr. Hall was the Plaintiff's only causation expert witness, Intuitive also argued that, if Dr. Hall was excluded, it was entitled to summary judgment on each of Moore's claims.

C. The Daubert Hearing

On January 17 and 18, 2019, the district court held a *Daubert* hearing concerning the admissibility of Dr. Hall's testimony. At the hearing, the district court heard testimony from both Dr. Hall and Intuitive's causation expert, Dr. Warner Huh. We begin by summarizing the testimony of Dr. Hall. Dr. Hall is a board-certified OB/GYN practicing in a suburb of Denver, Colorado, who has practiced for over forty years and performed over four thousand hysterectomies. Dr. Hall does not use robotic tools in the hysterectomy procedures he performs. Dr. Hall is also a professor of obstetrics and gynecology at the University of Colorado and

had previously spent twenty years supervising residents in the field. He also served on review committees and quality assurance committees at various hospitals, where the committee would review cases of gynecological complications in order to determine the cause of the injuries, and the quality of care. Some of those cases involved complications or injuries to the ureter including thermal burns.

In preparation for his testimony, Dr. Hall reviewed Moore's medical records, the deposition testimony of Moore and her surgeon, Dr. Efemini, and internal corporate documents from Intuitive regarding the defective MCS. After reviewing those documents, as well as relevant medical literature in the field, Dr. Hall performed a standard differential etiology[4] to determine the cause of the injury Moore sustained during her hysterectomy and determined it was due to an "insulation failure in [the] robotic arm" of the *da Vinci* surgical system—specifically, the MCS.[5]

[4] A standard differential etiology is a diagnostic procedure utilized to rule out all potential causes of the injury in an effort to determine the most likely source.

[5] While the substance of Dr. Hall's opinion is not at issue in this case—because the district court ruled only that Dr. Hall was not qualified to testify—some familiarity with his conclusions is helpful in understanding the facts. In the course of his differential etiology, Dr. Hall testified that he considered all potential causes of the injury, including the Maryland bipolar instrument (which Intuitive suggests caused the injury). Dr. Hall also testified that he considered all potential risk factors present in Moore and was able to rule them out. He said that "in [his] clinical experience, when there are no risk factors, very few risk factors . . . then we would expect that there wouldn't be any injury to the ureter." And finally, Dr. Hall said that he was able to rule out thermal spread because, after reviewing Dr. Efemini's surgical notes and deposition, he does not believe the technique would have resulted in thermal spread.

After summarizing his experience and conclusions, Dr. Hall described the different ways in which a hysterectomy could be performed. He delineated the differences between open hysterectomies and laparoscopic hysterectomies and described the minimally invasive nature of the laparoscopic procedure, including the smaller initial incisions that are required for laparoscopic procedures.

Dr. Hall then explained how the use of a robot affects the laparoscopic hysterectomy procedure, beginning by describing the tools. He said that the instruments used in a robotically-assisted hysterectomy are "essentially the same" as those used in a non-robotically-assisted hysterectomy in that they both "use monopolar and bipolar" current. He also explained how a surgeon will use the tools to perform the same functions regardless of the presence of a robot: "we use what we call bipolar clamps to clamp different ligaments, to coagulate them and then cut them. Then we have scissors that will cut them. And we also have monopolar cutting devices and monopolar coagulating devices, which also cut down on bleeding." Unsatisfied with this answer, the district court asked Dr. Hall to further describe the differences between the two procedures. Dr. Hall responded that "the cutting is still the same. . . . We have a lot of variety of instruments that we can use in either case. But they're basically the same." The district court asked for more explanation, and Dr. Hall then pivoted from discussing the function of the tools to the techniques used in the procedures, explaining that "as far as the removal of the uterus, there really

isn't any difference." Again, the district court probed further asking Dr. Hall to describe the differences in the instruments, to which he quipped that the only difference is "[w]ho makes them."

Time and time again, Dr. Hall chose to emphasize the similarities between the robotically-assisted and non-robotically-assisted procedures: that the operation is performed with the same basic tools, proceeds in the same way, and carries the same risks.[6] But, when asked directly about the Intuitive tools at issue in the case, Dr. Hall was also able to describe the differences. He testified, for example, that the use of a robot gives the surgeon a greater level of precision because it allows the surgeon to "focus in" on very small areas. When asked on direct examination if the only difference between the procedures was how the tools were manipulated (i.e., manually or through the robot), Dr. Hall responded that it was not the only difference; he said that the robotic tools "have a little bit of wrist action that [Intuitive says] is a little easier with the robot. With the traditional laparoscopic surgery, you don't get that wrist action. So there's little variances in the instrumentation as far as that goes." Dr. Hall then stated that the wrist action of the *da Vinci* was meant to mimic the action of a human wrist. And on cross examination, he agreed that the

[6] Dr. Hall said, for example, that it is "generally true" that the procedures have the same "order of events." He also stated that the standard of care is no different because a "hysterectomy is a hysterectomy no matter what tools we use."

dexterity of the robotic tools is "one of the advantages" of robotic surgery.[7] Dr. Hall also conceded that he had not personally performed a robotically-assisted hysterectomy.

When asked whether the differences between the robotic tools and the non-robotic tools he used made his expert opinion worthless, Dr. Hall responded that it did not because the robotic instrument is "still a straight instrument. The whole instrument basically is a straight instrument except for the tip, which [has] the ability to rotate. It has nothing to do with the shaft. The shaft doesn't rotate." He also said that, due to his experience performing the surgery traditionally and his previous observations of robotically-assisted procedures, he was able to "collate" what he has observed to what he has done and determine how close the tools would have gotten to critical structures. When asked if he knew that the flexible tip of the MCS could rotate a full 360 degrees, Dr. Hall responded that he had never seen it move more than 180 degrees because that is all the rotation required for gynecological surgery.

On cross examination, Dr. Hall also described the differences in port placement between the traditional and robotically-assisted procedures. When Dr. Hall was asked whether port placement changes at all depending on whether or not a robot is utilized, Dr. Hall responded affirmatively and explained that, when a robot

[7] For example, he compared the flexible tip of the robot to the straight rod of the traditional laparoscope, explaining that, in the normal procedure, "we don't have that wrist action. And in robots you have a wrist action."

is utilized, "the initial incision [is] above the belly button," while when a normal procedure is performed, "the initial incision [is] below the belly button."

Dr. Hall also explained that he was familiar with the *da Vinci*, in part, because he had, in his words, previously "play[ed] with the machine." Earlier, when a hospital he was working at was considering purchasing the *da Vinci* system, Dr. Hall was asked, as the most experienced gynecological surgeon at the hospital, to receive training from Intuitive on the *da Vinci*. As a result, he signed up to take a seminar with Intuitive on the use of the *da Vinci* and used it at his hospital on a mannequin. Notably, however, Dr. Hall has never completed a robotically-assisted hysterectomy on a human being, although he had observed other surgeons perform operations with the *da Vinci*. When asked if his lack of personal experience using the robot should result in his disqualification, Dr. Hall responded that it should not, testifying that a "hysterectomy is done the same way" whether or not a robot is used and that, regardless of the fact that the "tools vary and the way we do it varies," he was qualified to testify due to his familiarity with the procedure.

In sum, Dr. Hall testified that the primary difference between traditional and robotically-assisted laparoscopic operations was the instrumentation. Because the robotic tools contain flexible tips, they are able to move independently from the rod to which they are attached, which results in different port placements, different tool positions, and increased precision. However, Dr. Hall also made clear that, in his

view, these differences changed very little about how the hysterectomy is performed; the surgery proceeded in the same order of events, the tools served the same functions, and the operation had the same risk.

Intuitive called its own causation expert at the *Daubert* hearing—Dr. Huh. Dr. Huh's qualifications and testimony are not at issue on appeal. Nevertheless, some familiarity with his opinions is helpful in understanding the district court's rulings. Dr. Huh is a board-certified OB/GYN and gynecological oncologist specializing in the treatment and management of women who have gynecological malignancies. Like Dr. Hall, Dr. Huh is a very experienced surgeon with over twenty years of experience in laparoscopic surgery. Unlike Dr. Hall, however, Dr. Huh has twelve years of experience in robotic surgery and is a regular user of Intuitive's *da Vinci*.

Dr. Huh, like Dr. Hall, testified that the "fundamental difference between laparoscopic surgery and robotic surgery is the instrumentation." And the reason this is the fundamental difference is that the robotic instruments are "[e]ndowristed [in that] the tip of the instrument actually bends."[8] This flexibility, Dr. Huh testified, "mirrors exactly the same movement as the human wrist [and] . . . does exactly what I can do with my hand, basically." Also like Dr. Hall, Dr. Huh testified that the

[8] Later in the examination, Dr. Huh reiterated this point: "Because these [robotic] instruments bend at the tip [that is] a fundamental difference."

primary benefit of this flexibility is that it "provides a lot more precision than the original [laparoscope]." Dr. Huh also identified how the flexibility of the robotic instruments changes the initial port placement for the procedure, testifying, as Dr. Hall did, that "the laparoscopic incisions would be lower on the abdomen whereas the robotic incisions would be slightly higher." He described this "slightly higher" initial port placement as a "fundamental difference[] in terms of how the actual instrument enters the abdomen or pelvis compared to traditional laparoscopy." And because of the higher port placement and the flexibility of the tip, Dr. Huh testified that robotic surgery has advantages "in terms of not only the space that you operate in but in terms of the actual approach of the shaft to the surgical site."[9]

Dr. Huh, like Dr. Hall, reviewed all of Moore's available medical records. Dr. Huh, however, reached different conclusions regarding the cause of the injury. While Dr. Hall testified that the thermal injury was likely due to a microcrack on the scissor-end of the shaft of the MCS, Dr. Huh said the injury was more likely caused by either the Maryland bipolar grasper[10] or the "application of monopolar cautery

[9] Dr. Huh refers to the concept of "triangulation" in describing the angles at issue. This concept refers to the three points of contact a surgeon uses when performing a surgery. Because a laparoscopic surgeon must manually manipulate the scope in order to perform the operation, the triangulation occurs outside the body. With robotically-assisted surgery, however, the tip can move independently of the shaft, and the triangulation occurs inside the body.

[10] Dr. Huh reached this conclusion not because it was indicated in the surgical notes but because, based on the location of the injury, he "would say that in most robotic surgeries, taking down this tissue, 80 percent of it is done with the bipolar instrument . . . and about 20 percent is done by [the MCS]."

from the tip of the [MCS]." According to Dr. Huh, the shaft of the MCS would have been "light years away from the tip," and thus would not have been close enough to the ureter to cause the injury.[11]

Ultimately, Dr. Huh testified to essentially the same differences in the procedures as Dr. Hall: the fundamental difference between laparoscopic hysterectomy and robotically-assisted laparoscopic hysterectomy is the instrumentation used. Because the robotic tool has a flexible tip, the initial setup of the instruments is slightly different, the approach angles and triangulation are different, and the surgeon is able to perform the operation with a higher level of precision. And, also like Dr. Hall, Dr. Huh testified that "the steps or the way we do the hysterectomy" is essentially the same.

At the conclusion of the *Daubert* hearing, the district court announced its ruling—excluding Dr. Hall's testimony and entering summary judgment in favor of Intuitive. On January 30, 2019, the district court memorialized its findings in a written order. In both its written order and its oral ruling, the district court explicitly stated that it was only excluding Dr. Hall because he was not qualified to render expert testimony. Specifically, in its order, the district court explained that Dr. Hall

[11] On cross examination, Dr. Huh admitted that the surgical notes do not indicate how close the MCS was to the ureter at any point in the surgery and that he had no specific knowledge regarding how close it would have had to be in order to cause injury. Instead, his opinion that it was too far away to cause injury was based on his familiarity with how robotic surgery is done generally.

could not testify on medical causation because he could not adequately describe the differences between the instruments used in robotic surgery and traditional surgery, the differences in initial port placement, or the orientation or trajectory of the instruments during the operation. The district court, however, made no findings regarding the reliability of Dr. Hall's testimony. Because Dr. Hall was Moore's only causation expert, the district court, after excluding Dr. Hall, noted that Moore had presented no other evidence of causation and granted summary judgment in favor of Intuitive.

D. The Events following the *Daubert* Hearing

On June 18, 2019, the district court judge realized that she had a conflict of interest. Specifically, in preparing her financial disclosure form, the district court judge learned that her husband, whom she had married within the past year, held a financial stake in Intuitive and had held that stake before she ruled on the *Daubert* motions. On that same day, during a telephone conference, the district court judge conceded that she should have recused herself from the matter before ruling on the motions. The district court judge then gave the litigants a choice of how to proceed.

Two weeks after the district court judge's disclosure, Moore filed a motion to vacate the judgment pursuant to Federal Rule of Civil Procedure 60, which was referred to a different judge within the district. On October 16, 2019, that district court judge denied Moore's motion to vacate the summary judgment, reasoning that

the summary judgment was already on appeal. Because no appeal was filed from the denial of the Rule 60 motion itself, we have no occasion to comment on whether that denial was proper.

II. STANDARD OF REVIEW

We review for abuse of discretion a district court's decisions regarding the admissibility of expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142–43 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999); *accord United States v. Frazier*, 387 F.3d 1244, 1259 (11th Cir. 2004) (en banc) ("This Court has uniformly applied the deferential abuse-of-discretion review that *Joiner* mandates."). We will find an abuse of discretion only if the district court's ruling was "manifestly erroneous." *Joiner*, 522 U.S. at 142 (quoting *Spring Co. v. Edgar*, 99 U.S. 645, 658 (1878)); *Frazier*, 387 F.3d at 1258. A district court abuses its discretion when it applies the wrong legal standard. *See Frazier*, 387 F.3d at 1259.

III. ANALYSIS

Our analysis regarding the admissibility of expert testimony begins with Federal Rule of Evidence 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

In discussing this rule, the Advisory Committee Notes state that, after *Daubert*, "the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments. Indeed, even when "a trial court, applying this amendment, rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise." *Id.*

As explained by the Supreme Court, the purpose of the expert admissibility rules is to enlist the federal courts as "gatekeepers" tasked with screening out "speculative" and "unreliable expert testimony." *Kilpatrick v. Breg, Inc.,* 613 F.3d 1329, 1335 (11th Cir. 2010) (quoting *Daubert*, 509 U.S. at 597 n.13). However, courts must remain chary not to improperly use the admissibility criteria to supplant a plaintiff's right to a jury trial: "Vigorous 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." *Daubert*, 509 U.S. at 596.

In this circuit, we have distilled the expert admissibility inquiry into the following three factors:

> (1) the expert is qualified to testify competently regarding the matters he intends to address;
>
> (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert;* and
>
> (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998) (citing Fed. R. Evid. 702 and *Daubert*, 509 U.S. at 589). We have also noted that, while "there is inevitably some overlap among the basic requirements—qualification, reliability, and helpfulness—they remain distinct concepts and the courts must take care not to conflate them." *Frazier*, 387 F.3d at 1260.

It is important to note at the outset that this case concerns only the first prong of the admissibility inquiry—an expert's qualifications. In both its oral and written rulings, the district court made clear that it was only excluding Dr. Hall because he was not qualified to render testimony, and not because his opinion was unreliable or unhelpful to the jury. In so finding, the district court said that, in order to determine whether Dr. Hall was qualified, it was required to conduct an "exacting analysis of the foundations" of his opinion.

In *Frazier*, we summarized the first prong of the *Daubert* inquiry (as well as the interplay between the first and second prongs) as follows:

> Turning first to the qualification of the expert, we observe that experts may be qualified in various ways. While scientific training or education may provide possible means to qualify, experience in a field may offer another path to expert status. In fact, the plain language of Rule 702 makes this clear: expert status may be based on "knowledge, skill, *experience,* training, or education." The Committee Note to the 2000 Amendments of Rule 702 also explains that "[n]othing in this amendment is intended to suggest that experience alone . . . may not provide a sufficient foundation for expert testimony."
>
> Of course, the unremarkable observation that an expert may be qualified by experience does not mean that experience, standing alone, is a sufficient foundation rendering reliable *any* conceivable opinion the expert may express. As we observed in *Quiet Technology,* "while an expert's overwhelming qualifications may bear on the reliability of his proffered testimony, they are by no means a guarantor of reliability. . . . [O]ur caselaw plainly establishes that one may be considered an expert but still offer unreliable testimony." Quite simply, under Rule 702, the *reliability* criterion remains a discrete, independent, and important requirement for admissibility.

387 F.3d at 1260–61 (alterations in original) (citations omitted). And it is of course the burden of the proponent of the expert testimony "to show that his expert [is] 'qualified to testify competently regarding the matters he intend[s] to address.'" *McCorvey v. Baxter Healthcare Corp.*, 298 F.3d 1253, 1257 (11th Cir. 2002) (quoting *Maiz v. Virani*, 253 F.3d 641, 664 (11th Cir. 2001)).

Here, the district court found that Dr. Hall was not qualified to testify as to the cause of Moore's ureteral injury because Dr. Hall could not adequately describe the differences between the instruments used in robotic surgery and traditional surgery,

the differences in initial port placement, or the orientation or trajectory of the instruments during the operation. According to the district court, these differences were "critical in this case, in which a primary question is whether the alleged microcrack on the shaft of the MCS could have caused the injury to a specific portion of [Moore's] ureter."

Here, the district court abused its discretion in finding that these perceived deficiencies in Dr. Hall's testimony rendered him unqualified to provide expert testimony in this case. Even if we accept these deficiencies as true for our analysis here, each concerns the reliability of Dr. Hall's opinion, not his qualifications to testify. In viewing them relevant to the qualifications analysis, the district court "ignored the conceptual distinction between an expert's qualifications and the reliability of his proffered opinion." *Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1342 (11th Cir. 2003). As such, the district court's ruling, as discussed in greater detail below, was manifestly erroneous.

Additionally, in its written order, the district court stated that in order to "determine whether Dr. Hall is qualified, the Court must conduct an 'exacting analysis of the foundations' of his opinion." (citing *Frazier*, 387 F.3d at 1260). But we have never used this "exacting analysis" language in reference to an expert's qualifications. In fact, our precedent is clear that this analysis applies to only an expert's methodology in reaching his opinion, and thus is relevant to only the

reliability prong. *See Frazier*, 387 F.3d at 1260 (noting that *Daubert* "'inherently require[s] the trial court to conduct an exacting analysis' of the *foundations* of expert *opinions* to ensure they meet the standards for admissibility under Rule 702" (second emphasis added) (quoting *McCorvey*, 298 F.3d at 1257)); *McCorvey*, 298 F.3d at 1257 ("Rulings on admissibility under *Daubert* inherently require the trial court to conduct an exacting analysis of the proffered expert's *methodology*." (emphasis added)). And the Supreme Court has said that, since its decision in *Daubert*, "parties relying on expert evidence have had notice of the *exacting standards of reliability* such evidence must meet." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000) (emphasis added).

This distinction is not academic. Qualifications and reliability remain separate prongs of the *Daubert* inquiry that answer two separate questions. A witness is *qualified* as an expert if he is the type of person who should be testifying on the matter at hand. An expert opinion is *reliable* if it was arrived at through, among other things, a scientifically valid methodology. *Quiet Tech.*, 326 F.3d at 1341 (listing factors for "ascertaining the reliability of a particular scientific expert opinion"). Conflating the inquiries is legal error. *See Frazier*, 387 F.3d at 1261 (noting that "the *reliability* criterion remains a discrete, independent, and important requirement for admissibility" that may not be "subsumed by the qualification prong"); *Quiet Tech.*, 326 F.3d at 1342 (noting that "the qualification and reliability

inquiries are distinct" and finding the conflation of the two inquiries "a compelling conceptual reason to reject appellant's arguments as to [the expert's] qualification"). This alone provides a sufficient basis to reverse the district court's ruling.

Our decision in *Quiet Technology* is instructive on this point. There, in an action sounding in fraud, the plaintiff alleged that the defendant's aerospace product was defective and sought to recover certain advance payments it had made for the product. 326 F.3d at 1337. In support of its claims, the plaintiff sought to introduce the expert testimony of Joel Frank, "an aerodynamics specialist who at the time of trial had nearly 20 years' experience with [computational fluid dynamics ("CFD")], having conducted over 40 studies using the discipline." *Id.* at 1338. Frank was prepared to testify, after performing a CFD analysis on the defendant's product, that the product "experienced performance losses of approximately 25%" even when operated in "ideal conditions." *Id.* The defendant sought to exclude Frank on the basis of his qualifications, arguing that he lacked "specific expertise" in their device—specifically, Frank's inability to describe and distinguish between engine pressure ratio and fan pressure ratio and because of his unfamiliarity with the conditions in which the part operated. *Id.* at 1342. We noted that under Rule 702, "a witness may be qualified as an expert by virtue of his or her 'knowledge, skill, experience, training, or education'" and thus "[t]he problem with Quiet's argument . . . [was] that none of the shortcomings in Frank's analysis on which [Quiet]

focuse[d] genuinely b[ore] on any of these factors." *Id.* We further concluded that when construed properly, these were challenges to the *reliability* of an expert's opinion, not his *qualifications*. *Id.* Specifically, "[v]iewed more abstractly, if methodological unreliability or a lack of intellectual rigor precluded a witness from being qualified as an expert, then this would largely eviscerate the reliability determination, as one's expert qualification would foreordain the conclusion that the methods employed by that individual were reliable." *See id.* We also noted that, even if we were reviewing the issue *de novo*, we would have deemed Frank qualified because:

> Frank had worked with CFD for nearly 20 years. His experience with CFD dated to his college days, when he worked with experts in the field. Following his completion of B.A. and M.A. programs in aerospace engineering, he worked for several aerospace companies, where he performed over 40 CFD analyses and assisted in roughly 80 additional such studies. In summarizing its findings as to qualification, the district court said: "It seems to me in this case that Mr. Frank is qualified by his experience and by his education, including his on-the-job education. Like all of the experts have had a very impressive background, at least impressive to the Court. So I don't think that's really the issue." We agree; under these circumstances, it is evident that Frank was properly qualified as an expert by virtue of his extensive education, training and experience.

Id. at 1343. The lesson of *Quiet Technology* is clear: the qualifications and reliability prongs of *Daubert* are conceptually distinct inquiries that district courts may not collapse into each other. As this Court concluded in *Quiet Technology*, Frank was qualified as an expert to perform a CFD analysis on the defendant's aerospace

products not because of his familiarity with the product at issue, but because of his familiarity with the analysis he was tasked with performing.

Applying the lesson of *Quiet Technology* to the present case yields a straightforward result. The district court here found that Dr. Hall was not qualified to testify because he had not used the Intuitive robotic tools at issue and because he could not describe the differences between those tools and the traditional laparoscopic instruments. These findings (even if we accept them as true for our analysis here) go to only the reliability of Dr. Hall's opinion, not his qualifications to testify as to causation. As in *Quiet Technology*, however, Dr. Hall is qualified to perform a differential etiology on a patient who suffered a thermal injury during a hysterectomy performed with a *da Vinci* robot not because of his familiarity with the robot, but because of his familiarity with differential etiologies in the context of

gynecological procedures. As such, the district court applied the incorrect legal standard, and thus abused its discretion.[12]

But even if we were to ignore the district court's manifestly erroneous ruling that conflated the reliability and qualifications prongs, we would still be obliged to reverse, as the district court imposed an admissibility standard on expert qualifications that was "too high." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1321 (11th Cir. 1999) (noting that a district court may abuse its discretion when it sets the *Daubert* "admissibility bar [] too high.") In finding that Dr. Hall was not qualified to testify regarding the cause of Moore's injury, the district court placed a great deal of emphasis on the facts that Dr. Hall had "never completed the *da Vinci* training," had "not used the *da Vinci* system," and did not "possess extensive

[12] The district court cited only one case for its conclusion—*Lebron v. Sec'y of Fla. Dep't. of Children and Families*, 772 F.3d 1352 (11th Cir. 2014). But *Lebron* concerned an altogether different question. There, the litigant sought to proffer a clinical psychiatrist to testify regarding the statistical incidence of drug use among a certain subset of the Florida population. *Id.* at 1369. We noted that a "social scientist or statistician with experience in conducting surveys and parsing their results, and extrapolating conclusions about populations from limited samples of information, would be in a position to reliably draw such an inference; a clinical psychiatrist may not be." *Id.* Because statistics regarding drug use did not "grow[] naturally and directly out of research [he had] conducted independent of the litigation," and because the expert had made no other showing that he was qualified to testify on the subject, we affirmed the district court's exclusion of his testimony. *Id.* (second alteration in original) (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment). *Lebron* has limited applicability to the case at hand because Dr. Hall is not seeking to testify outside the scope of his academic and professional specialty. Rather, Dr. Hall is a gynecologic surgeon with experience performing differential etiologies and seeks to testify regarding the cause of an injury that occurred during the course of a gynecologic surgery.

knowledge of the [Intuitive MCS] instrument at issue in the case or the nuances of performing a robotic-assisted hysterectomy with this specific instrument."

Our caselaw does not support a bright line rule that an expert witness is qualified to testify regarding the cause of an injury only if he personally has used the allegedly defective product. Instead, this Court has explicitly disclaimed such a rule. In *Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1327 (11th Cir. 2014), we said that such a way of "reasoning seemingly would bar all expert medical testimony unless the expert has somehow recreated the same conditions that the [patient] was under[,] . . . [and] Rule 702 does not impose such a requirement." 760 F.3d at 1335–36; *see also Quiet Tech.*, 326 F.3d at 1342 (noting that shortcomings regarding knowledge of the specific product at issue do not bear on an expert's qualifications). Requiring plaintiffs in product liability actions to hire expert witnesses who are also clients, customers, or regular users of the defendant's product would set a burden that is much "too high."

Moreover, even if we interpret the district court's ruling as excluding Dr. Hall because of his unfamiliarity with robotically-assisted hysterectomies generally, the district court still set the bar too high for admissibility purposes. It is of course true that, in conducting the *Daubert* inquiry, each of the three analytical prongs (including qualifications) is assessed in reference to the matter to which the expert seeks to testify—i.e., "to the task at hand." *Daubert*, 509 U.S. at 597. It is for that

reason that "expertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Children & Families*, 772 F.3d 1352, 1368 (11th Cir. 2014).

But in this case, the "task at hand" is performing a differential etiology on a patient who suffered a thermal injury during the course of a hysterectomy. The "expertise" relevant to this task is the ability to perform such a differential etiology, which may be shown by knowledge of the procedure and its risks, training or education on how to perform it, or experience or skill in performing it. *See* Fed. R. Evid. 702. The district court, however, conflated the task facing the proffered expert witness (i.e., differential etiology on a patient who suffered a thermal injury during the course of a hysterectomy), with the task facing Moore's treating physician (i.e., performing a robotically-assisted hysterectomy). Dr. Hall's task in this case was to determine what caused the thermal injury Moore suffered during her hysterectomy—a task he is qualified to carry out given his years of experience performing hysterectomies and serving on review and quality assurance committees tasked with determining the cause of injuries sustained during gynecological procedures.

At the fringes, defining the "task at hand" will be an outcome determinative endeavor. It is in the nature of the *Daubert* inquiry that the proponents of expert testimony will seek the broadest definition of the task at hand, while the opponents of that testimony will seek to narrow it. Take *Adams* for example. In that case, we

confronted a novel theory of expert admissibility criteria: that, in order to testify, an expert was required to "recreate[] the conditions and circumstances [practitioners] face" and "stand in the shoes of the defendant." *See Adams*, 760 F.3d at 1335. We had no trouble dispensing with that notion, noting that this line of reasoning "seemingly would bar all expert medical testimony unless the expert has somehow recreated the same conditions that the defendant was under." *Id.* In this case, if Intuitive is correct that the relevant field is "differential etiology in the context of robotically-assisted laparoscopic hysterectomies utilizing an Intuitive MCS," Dr. Hall might well be deemed unqualified.

But this case does not exist at the fringes; nothing in the record suggests that robotically-assisted laparoscopic hysterectomies should be treated as a different field of expertise for *Daubert* purposes than traditional laparoscopic hysterectomies. To the contrary, the district court and both causation experts said that a hysterectomy is performed in the same manner and carries the same risks regardless of whether or not a robot is used. Dr. Hall said that a "hysterectomy is done the same way" regardless of the modality. Dr. Huh testified that "the steps or the way we do the hysterectomy" is essentially the same. And the district court noted in its written order that "the general surgical process—that is, the steps and stages of a hysterectomy—remains the same regardless of whether it is performed as an open surgery, laparoscopically, or robotically." Moreover, the parties also agree that the

tools at issue perform the same functions regardless of whether or not a robot is used in the procedure. Both Drs. Hall and Huh testified that the monopolar curved scissors used in the operation (whether traditionally or with the aid of a robot) are utilized to cut and cauterize, and that, regardless of the use of a robot, the same risks of thermal injury are present.

Contrast these significant similarities with the slight differences identified by the district court and Intuitive's expert. Both Drs. Hall and Huh testified that the only salient difference between the procedures is the instrumentation—i.e., the utilization of a flexible surgical tool in the robotically-assisted procedure. In robotically-assisted laparoscopic hysterectomies, the tip of the surgical tool is able to move independently of the shaft and, for this reason, the surgeon is able to be more precise, the initial port location is slightly higher on the abdomen, and the placement of the tools within the body occurs at different angles. Neither Dr. Hall nor Dr. Huh identified any other differences in the procedure. Thus, as an independent basis for reversal, we conclude that the district court imposed an admissibility burden that was "too high" and contrary to our caselaw.

Finally, insofar as the district court, in concluding that the only relevant metric for the witnesses was familiarity with the MCS, found one of the witnesses more persuasive or eloquent than the other, "it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." *Quiet*

Tech., 326 F.3d at 1341. The district court's analysis of the similarities and differences between robotically-assisted and traditional laparoscopic hysterectomies did not reflect its limited gatekeeping role at the *Daubert* stage of the proceedings, and its conclusions regarding the persuasiveness of Dr. Hall's analysis vis-a-vis Dr. Huh's provides an independent basis to reverse.

For example, while the district court correctly noted that Dr. Hall "acknowledged that the MCS has a flexible tip that allows the instrument to mimic wrist action," the district court believed that his description of the tool was nothing "more than a superficial explanation."[13] That, however, is a determination a jury must make. *Cf. United States v. Ala. Power Co.*, 730 F.3d 1278, 1282 (11th Cir. 2013) (noting that "vigorous 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" (quoting *Allison*, 184 F.3d at 1311–12)).

[13] Dr. Huh, who was sequestered during Dr. Hall's testimony, used similar language in describing the rotational capacity of the MCS. Dr. Huh said that the MCS "mirrors exactly the same movement as the human wrist. . . . [I]t does exactly what I can do with my hand, basically." Indeed, during his testimony, Dr. Huh played a training video regarding robotic surgery (which is not part of the record, though a transcript of the broadcasted segments appear in the transcript of the proceeding), and the narrator in that video also described the rotational capacity of the MCS as a "nice wristed motion." So, while the district court faulted Dr. Hall for not having specific knowledge regarding the fact the MCS can rotate a full 360 degrees, it appears that Dr. Hall, Dr. Huh, and the MCS Training video described the MCS the same way. We further note that no testimony was received that the MCS rotates a full 360 degrees *during a hysterectomy*.

The district court also incorrectly noted that Dr. Hall did not apprehend the difference in "the placement of the incisions and port" when, in fact, Dr. Hall testified at the hearing that the initial port placement for Moore's surgery with the *da Vinci* was "above the belly button," while, for a traditional laparoscopic procedure, "the initial incision [is] below the belly button. So those port places are different." This mirrored Dr. Huh's testimony on the subject, who said that the initial port placement for the robotic surgery would be "slightly higher."

The district court also took issue with Dr. Hall's inability to explain in specific detail where the shaft of the MCS was located at each point in the surgery. But both he and Dr. Huh testified that it would be impossible for them to *post hoc* recreate the placement of the tools during the operation. *Cf. Adams*, 760 F.3d at 1335–36 (noting that an expert is not required to "stand in the shoes of the defendant"). Dr. Huh admitted that his testimony explaining that the shaft of the MCS was not close enough to the ureter to cause injury was explicitly based on his personal opinion regarding where he believed the tools had been located based on his prior use of the *da Vinci*, and not on any specific knowledge regarding the placement of the tools during Moore's operation. And the experts' disagreement regarding the placement of the shaft is precisely the type of dispute that should be decided within the crucible of cross examination, rather than by a judge at the *Daubert* stage.

Of course, none of this is to say that Dr. Hall would be qualified to testify regarding the cause of an injury sustained during an open-heart surgery or brain operation, for example. As we have said when discussing the reliability of a differential etiology, a diagnostician "need not rule out all possible alternative causes," but he "must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (per curiam). It thus follows logically that, in order to be qualified to opine on the cause of an injury, that diagnostician must—by knowledge, training, skill, experience, or education—be familiar with the possible causes that occur during the operation. We leave for another case the outer bounds of this requirement. Here, we are satisfied that a gynecological surgeon may opine on the cause of an injury sustained during a gynecological surgery when he has performed and reviewed numerous similar procedures. As Dr. Hall aptly stated at the *Daubert* hearing, "I mean, they're all just different tools that we use and people use them different ways."

Thus, even under our deferential standard of review, we conclude that Dr. Hall is qualified to testify as to the cause of Moore's injury. That injury was sustained during a hysterectomy procedure. Dr. Hall is a board-certified gynecologist who has performed at least four thousand hysterectomies over the course of his forty-year career. He has served on review and quality assurance committees that were tasked

with performing differential etiologies to assess the cause of injuries sustained during gynecological procedures including laparoscopic hysterectomies. He is familiar with thermal injuries and was trained to avoid burning ureters. He has reviewed medical literature regarding the specific tools utilized in this surgery and even received some preliminary training on their use from Intuitive. Federal Rule of Evidence 702 allows an expert to be qualified "by knowledge, skill, experience, training, or education." And Dr. Hall is five for five.

In short, the district court's finding that Dr. Hall was not qualified to testify as to the cause of Moore's injury was manifestly erroneous. The district court applied the wrong legal standard by conflating the reliability criterion with the qualifications criterion. The district court further imposed an evidentiary burden that was too high by requiring that Dr. Hall be a user of the defendant's product in order to be qualified to testify as an expert. And the district court improperly based its evidentiary determinations on the weight and persuasiveness of the evidence. Because Rule 702 does not impose any such requirements, we conclude that Dr. Hall was qualified to testify regarding the standard of care in hysterectomy procedures and the cause of Moore's injuries. We therefore conclude that the district court abused its discretion in excluding Dr. Hall's testimony on the basis of his qualifications.

As an alternative ground for affirming, Intuitive asks us to address, in the first instance, the reliability of Dr. Hall's testimony. But this we will not do. "[T]he task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under *Daubert*." *Rink v. Cherminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). Determining the admissibility of expert testimony is a necessarily fact-laden endeavor, and we will not address it in the face of an undeveloped record, preferring instead that it first be addressed by the district court. *See Williams v. Wright*, 927 F.2d 1540, 1551 (11th Cir. 1991) ("These factual issues were not addressed by the district court, and we therefore decline to address them here, preferring that they be addressed in the first instance by the district court."). This is a particularly easy decision to make here as the district court announced at the onset of the *Daubert* hearing that its "preliminary view" was that Dr. Hall "was not qualified to testify as to causation." Moore argues that this admission by the district court necessarily focused the examinations at the *Daubert* hearing on Dr. Hall's qualifications, rather than the reliability of the testimony. The point is well taken. For us to rule—in the first instance in the face of an admittedly undeveloped record—that Dr. Hall's expert opinion was unreliable would be usurping the role of the trial court.

Having concluded that the district court abused its discretion in excluding the testimony of Dr. Hall based on his qualifications, we remand for further proceedings consistent with this opinion, and we direct that on remand the case be assigned to a

different judge. *See Clarks v. Coats & Clark, Inc.*, 990 F.2d 1217, 1230 (11th Cir. 1993).

IV. CONCLUSION

For the foregoing reasons, we reverse the district court's ruling excluding Dr. Hall, vacate the district court's entry of summary judgment in favor of Intuitive Surgical, Inc., and remand for further proceedings consistent with this opinion. The chief judge of the district court is directed to reassign this case to a different judge in accordance with the district court's established case assignment criteria.

REVERSED and REMANDED for further proceedings and the Chief Judge is DIRECTED to reassign the case.