UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

REBOTIX REPAIR, LLC,

Plaintiff /
Counterclaim Defendant,

v. Case No. 8:20-cv-2274-VMC-TGW

INTUITIVE SURGICAL, INC.,

Defendant /
Counterclaim Plaintiff.
_____/

ORDER

This matter comes before the Court upon consideration of Defendant Intuitive Surgical, Inc.'s Daubert Motion to Exclude the Opinions of Dr. T. Kim Parnell. (Doc. # 115). Plaintiff Rebotix Repair, LLC has responded. (Doc. # 142). For the reasons that follow, the Motion is granted in part and denied in part.

I. Background

The Court and the parties are well familiar with the background facts and claims in this case, and the Court will not belabor them here. Suffice it to say that this is an antitrust suit initiated by Rebotix, a company that offers a service whereby it "repairs" the EndoWrist surgical implement originally manufactured by Intuitive.

Rebotix seeks to offer Dr. Parnell's testimony on the issues of EndoWrist performance and safety, both as to new EndoWrists and those that have been repaired by Rebotix. Dr. Parnell is a professional mechanical engineer (PE) with a Ph.D. in mechanical engineering. (Doc. # 115-2 at 1). He has multiple years of experience in manufacturing, including the design and development of medical devices, and failure analysis. (Id. at 2-5).

In his report, Dr. Parnell opines that: (1) traditional laparoscopic instruments are routinely repaired, and EndoWrists can be similarly repaired; and (2) Rebotix's service procedure ensures that EndoWrists can be repaired and used safely. (Id. at 7-26). It is Dr. Parnell's opinion that Rebotix's repair procedure "ensures that EndoWrists can continue to be used safely" and, indeed, the repair process "results in instruments that have a higher degree of safety and reliability" than new EndoWrists manufactured by Intuitive. (Id. at 6). He offers the opinion that the usage counter has numerous flaws and does not promote patient safety, and that Intuitive has "no basis" to assert that EndoWrists repaired by Rebotix are less safe than new EndoWrists sold by Intuitive. (Id. at 6-7).

Now, Intuitive seeks to exclude Dr. Parnell's testimony, Rebotix has responded, and the Motion is ripe for review.

II. Discussion

Federal Rule of Evidence 702 states:

> 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.

Fed. R. Evid. 702.

Implementing Rule 702, Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), requires district courts to ensure that all scientific testimony or evidence admitted is both relevant and reliable. See Id. at 589–90. The Daubert analysis also applies to non-scientific expert testimony. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999). District courts must conduct this gatekeeping function "to ensure that speculative, unreliable expert testimony does not reach the jury under the mantle of reliability that accompanies the appellation 'expert testimony.'" Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005).

The Eleventh Circuit "requires trial courts acting as gatekeepers to engage in a 'rigorous three-part inquiry.'" Hendrix v. Evenflo Co., 609 F.3d 1183, 1194 (11th Cir. 2010). The district court must assess whether:

> (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.

Id. The proponent of the expert testimony bears the burden of showing, by a preponderance of the evidence, that the testimony satisfies each of these requirements. Id.

Intuitive does not contest Dr. Parnell's qualifications, but instead contends that his opinions about EndoWrist performance are unreliable and unhelpful, and thus inadmissible.

1. Reliability

"Exactly *how* reliability is evaluated may vary from case to case, but what remains constant is the requirement that the trial judge evaluate the reliability of the testimony before allowing its admission at trial." United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004) (citing Fed. R. Evid. 702, Advisory Committee Notes (2000)). There are four

recognized, yet non-exhaustive, factors a district court may consider in evaluating reliability:

> (1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the technique has been subjected to peer review and publication; (3) the known and potential error rate of the methodology; and (4) whether the technique has been generally accepted in the proper scientific community.

Seamon v. Remington Arms Co., 813 F.3d 983, 988 (11th Cir. 2016) (citations omitted). A district court can take other relevant factors into account as well. Id. (citations omitted).

Here, Dr. Parnell relies explicitly on his past professional experience as forming the basis for his opinions. See (Doc. # 115-2 at 5 ("My opinions and conclusions in this report are based on my years of professional experience in mechanical engineering, failure analysis, and other work in medical devices, medical instruments, consumer electronics, and other sophisticated technology devices.")). "If the [expert] witness is relying solely or primarily on experience, then," in establishing reliability, "the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Frazier, 387 F.3d at 1261 (citation and internal

quotation marks omitted). The Court's analysis as to reliability "focus[es] 'solely on principles and methodology, not on the conclusions that they generate.'" Seamon, 813 F.3d at 988 (citation omitted).

Here, Intuitive argues that Dr. Parnell's opinions are unreliable. According to Intuitive, Dr. Parnell has not himself tested the performance or safety of EndoWrists and has set forth no methodology whatsoever to compare the repairability of EndoWrists vis-à-vis traditional laparoscopic instruments or the performance and safety of EndoWrists that have been repaired by Rebotix. As Intuitive lays out: Dr. Parnell has not seen an EndoWrist perform in the operating room; his opinions derive from a one-day visit to Rebotix's facility at a time when the facility was not repairing EndoWrists; and his descriptions of Rebotix's procedures come not from his own testing or experience but rather from the descriptions of a Rebotix employee.

In response, Rebotix argues that Dr. Parnell analyzed Rebotix's process of repairing EndoWrists through the lens of reverse engineering. According to Rebotix, Dr. Parnell used methodologies that are generally accepted in the field, including comparing failure modes and reverse engineering.

Intuitive takes issue with five of Dr. Parnell's proffered opinions. See (Doc. # 115 at 13). The Court will discuss each one.

a. Opinion: That Rebotix's repair procedures ensure that EndoWrists can continue to be used safely (Doc. # 115-2 at 6, 14-28).

In his report, Dr. Parnell wrote that, in his experience, "reverse engineering the original specifications of an instrument is a common practice used by mechanical engineers in understanding instruments and their functions." (Doc. # 115-2 at 14). Reverse engineering typically involves two steps: testing a new instrument to understand its capabilities and then testing a repaired instrument to see if it functions in the same manner as a new instrument. (Id.). Dr. Parnell sets out how Rebotix used reverse engineering at the outset of its business to make sure that repaired EndoWrists would work in the same manner as a new EndoWrist, that Rebotix utilized third-party testing at the end of that reverse engineering process to verify its results, and that "[t]he result of this robust initial reverse engineering process and subsequent testing is a repair process that safely and effectively ensures that repaired EndoWrists can continue to be used by hospital customers." (Id. at 14-15). Dr. Parnell

then went on to describe that repair process, as set forth below.

According to Dr. Parnell's report, he "inspected" Rebotix's repair facility and was there able to "observe several complete EndoWrist repair processes, compare EndoWrists repaired by Rebotix to brand new EndoWrists sold by Intuitive, and examine a number of EndoWrists . . . [that] were not suitable candidates for repair." (Id. at 15). He "personally reviewed each step of the Rebotix Repair service process," which process Dr. Parnell described as follows: (1) when it first receives an EndoWrist from a customer, Rebotix will clean the instrument; (2) a technician will then perform "an initial visual inspection" of the instrument to check for obvious damage and to check the number of uses left on the device; (3) the technician will then inspect the tool end under a microscope, test the instrument's range of motion, and/or test the instrument's "insulation and electrical isolation"; (4) any instruments deemed unsuitable for repair will be returned or placed aside; (5) once an instrument has been identified as a candidate for repair, Rebotix will reset the usage counter by installing the Interceptor; (6) Rebotix will then perform any necessary repairs to the tool end of the instrument (e.g., sharpening scissors, aligning graspers,

or ensuring tightness on needle drivers); (7) Rebotix will test and inspect the repaired instrument; and (8) lastly, the instrument will be cleaned, packaged, and shipped to the customer. (Id. at 15-26).

According to Dr. Parnell's deposition testimony, on the day of his visit, Rebotix's director of operations, Greg Fiegel, "walked [him] through the [repair] process and showed [him] the steps involved in the process." (Doc. # 115-3 at 63:6-12). Only Mr. Fiegel, not any technicians, touched the instruments that Dr. Parnell observed, and Dr. Parnell did not observe anyone who appeared to be actively involved in repairing EndoWrists on that day. (Id. at 64:1-3, 14-18).

The Court is persuaded that Dr. Parnell used sufficiently reliable methodologies to opine on the safety of Rebotix's repair process. While Intuitive faults him for not conducting his own testing, Dr. Parnell's opinion is based on his professional experience involving reverse engineering and device testing and his first-hand observations at the Rebotix repair facility. See Kumho Tire Co., 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). Any alleged flaws in Dr. Parnell's methodology should be addressed in cross-examination. See Maiz v. Virani,

253 F.3d 641, 666 (11th Cir. 2001) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking [debatable] but admissible evidence." (citations and internal quotation marks omitted)).

b. Opinion: That EndoWrists modified by Rebotix have a higher degree of safety and reliability than new EndoWrists manufactured by Intuitive (Doc. # 115-2 at 6, 57-65).

Dr. Parnell writes that "[i]n [his] experience with medical devices . . . manufacturing issues can frequently cause medical devices to fail unexpectedly and in ways not accounted for during design testing. This is evidenced by the creation of the FDA's Good Manufacturing Practices (GMPs) in addition to the extensive pre-market approval process." (Doc. # 115-2 at 57). Dr. Parnell then states that, in his review of the relevant evidence here, he determined that Intuitive's manufacturing protocols were defective.

To the extent supported by his experience, Dr. Parnell may explain the FDA's manufacturing guidelines to the jury, along with what can generally go wrong in medical-device manufacturing. He may also give his opinion that Intuitive does not adequately address potential manufacturing defects. He may also testify about the safety and reliability of

repaired versus new EndoWrists. Dr. Parnell's experience with medical-device manufacturing and his understanding of the Rebotix repair process lend his opinion sufficient reliability to pass the Daubert bar. Intuitive may address any flaws in his methodology during cross-examination.

c. Opinion: That the EndoWrist use counter does not promote patient safety (Doc. # 115-2 at 6, 36-57).

According to his report, Dr. Parnell bases this opinion on five contentions: (1) the use counter does not measure actual wear experienced by instruments during surgeries; (2) the use counter does not reflect the number of times an instrument has been "reprocessed" by a hospital; (3) the use counter does not take into account mishandling or misuse; (4) the use counter cap (10 uses) is determined by Intuitive's marketing needs, not failure testing; and (5) the use counter does not independently verify the condition of the instrument.

With one exception, the Court fails to see how Dr. Parnell's training as a mechanical engineer makes him qualified to opine on patient safety. Most of the facts undergirding this opinion could just as easily be offered by surgeons or surgical technicians who work with the EndoWrists in the operating room or a Rebotix representative.

However, Dr. Parnell does state in his report that: "In my experience studying the failures experienced by mechanical components and medical instruments, testing instruments to failure and observing at which points those failures occur helps to establish the potential range of life for an instrument. Establishing the potential failure modes accurately is important and highly relevant." (Doc. # 115-2 at 50). Dr. Parnell then goes on to explain that, according to his review of the testimony and other relevant records, "Intuitive's life testing is designed to validate an arbitrarily set use limit set by marketing, rather than to establish the failure point of an instrument. To accurately establish a use limit or failure point, tests would need to actually test instruments to failure. . . . Rather than establishing where failures naturally occur by testing each instrument to failure, the testing process is stopped after passing the target number of instrument lives." (Id. at 50, 53).

The Court will permit Dr. Parnell to testify regarding failure-mode testing in general and his conclusions that Intuitive failed to perform such testing adequately because that opinion is based on his experience as a mechanical engineer and would be helpful to the trier of fact.

d. Opinion: That Intuitive has "no basis" to assert that modified EndoWrists are less safe than new EndoWrists (Doc. # 116-2 at 7, 65-76).

The Court will permit Dr. Parnell to testify, based on his experience as a professional engineer, about what measures he would expect Intuitive to take to deem Rebotix repairs unsafe and whether his review of the record revealed evidence of those measures. But his experience does not lend itself to the legal conclusion or argument that Intuitive has "no basis" to make a claim about the safety or reliability of EndoWrists.

2. Assistance to Trier of Fact

Expert testimony must also assist the trier of fact. Fed. R. Evid. 702. "By this requirement, expert testimony is admissible if it concerns matters that are beyond the understanding of the average lay person." Frazier, 387 F.3d at 1262 (citation omitted). "[T]he court must 'ensure that the proposed expert testimony is "relevant to the task at hand," . . . i.e., that it logically advances a material aspect of the proposing party's case.'" Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312 (11th Cir. 1999).

So, while "[t]he 'basic standard of relevance . . . is a liberal one,' Daubert, 509 U.S. at 587, . . .[,] if an expert opinion does not have a 'valid scientific connection

to the pertinent inquiry[,]' it should be excluded because there is no 'fit.'" Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp., 582 F.3d 1227, 1232 (11th Cir. 2009) (citations omitted). "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." Frazier, 387 F.3d at 1262-63 (citation omitted).

Intuitive takes issue with Dr. Parnell's opinion that "EndoWrists can be routinely repaired in the same manner as traditional laparoscopic instruments." (Doc. # 115-2 at 12). In his report, Dr. Parnell wrote that EndoWrists have "similar failure modes" as traditional laparoscopic instruments – for example, scissors can become dull and graspers can become misaligned. (Id.). To support this opinion, Dr. Parnell relied on the deposition testimony of a Mr. Ed Harrich, a hospital employee, that: (1) hospitals will inspect both EndoWrists and traditional surgical implements prior to surgeries; and (2) EndoWrists can fail in multiple mechanical ways, such as misaligned teeth, frayed wires, or dull scissors. (Id. at 12-13). Dr. Parnell then concludes that Rebotix's service procedures addresses these mechanical failures.

The fact that mechanical implements can become dull, misaligned, or otherwise damaged with repeated use is not a concept "beyond the understanding of the average lay person." See Frazier, 387 F.3d at 1262. Dr. Parnell and Rebotix do not explain how the testimony of a mechanical engineer sheds any special light on this issue. Further, Dr. Parnell admitted that he had no experience with laparoscopic instruments prior to this litigation, and he did not examine any laparoscopic instruments in connection with this case. The Motion is granted as to this opinion. However, to the extent Intuitive presents admissible testimony about the purported differences between traditional laparoscopic instruments and EndoWrists that render EndoWrists unsuitable for repair, the Court will re-evaluate this testimony.

Accordingly, it is hereby

ORDERED, ADJUDGED, and **DECREED:**

Defendant Intuitive Surgical, Inc.'s Daubert Motion to Exclude the Opinions of Dr. T. Kim Parnell. (Doc. # 115) is **GRANTED in part and DENIED in part** to the extent set forth in this Order.

DONE and **ORDERED** in Chambers in Tampa, Florida, this 10th day of August, 2022.

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE