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 Plaintiff Rebotix Repair, LLC's Daubert Motion to Exclude the Opinions of Dr. John Bomalaski. (Doc. # 109). Defendant Intuitive Surgical, Inc. has responded. (Doc. # 150). 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.

Intuitive seeks to introduce the testimony of Dr. John Bomalaski to demonstrate a surgeon's view of the "risks" or "dangers" of using repaired EndoWrists. Dr. Bomalaski is a gynecologic oncologist who practices in Melbourne, Florida. (Doc. # 109-2 at 4). He is a trained surgeon, having performed thousands of surgeries using a traditional laparoscopic technique. (Id.). Dr. Bomalaski has also performed over 2,600 robotically assisted surgeries using Intuitive's da Vinci surgical system. (Id.).

In his report, Dr. Bomalaski compares traditional laparoscopic surgery and robotic-assisted surgery using the da Vinci system, noting the different tools and techniques used in each. (Id. at 7-9). It is his opinion that da Vinci surgical robots offer benefits to surgeons, patients, and hospitals.

Dr. Bomalaski's report contains a section entitled "Risks and dangers of using an EndoWrist instrument beyond the usage limits set by Intuitive" ("Section VII"). (Id. at 12-15). Dr. Bomalaski writes that he "would not feel comfortable using [EndoWrists "repaired" by Rebotix to exceed the usage limits] in the operating room because [he] believe[s] that they would present undue risks to [his] patients and [his] surgical team, as well as the hospital.

[He] believe[s] that the regulatory process and adherence to manufacturer specifications are valuable means to enhancing patient safety." (Id. at 6-7). He explains that surgical instruments wear out over time and that he relies on the FDA and the manufacturer's instructions regarding quality control. (Id. at 13). What's more, Dr. Bomalaski reviewed a video of an EndoWrist undergoing Rebotix's repair procedure and he wrote that his patients would be "quite concerned" if they saw the video. (Id. at 15).

Now, Rebotix seeks to exclude Dr. Bomalaski's testimony. As an initial matter, Rebotix concedes that the first portion of Dr. Bomalaski's report presents opinions that are within the scope of his expertise and are sufficiently supported. (Doc. # 109 at 3). In the Motion, Rebotix specifically attacks Section VII of Dr. Bomalaski's report, arguing that Dr. Bomalaski is not qualified to present the opinions presented in that section and those opinions are unsupported by any reliable methodology. (Id.). Intuitive 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 any 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.

1. Qualifications

The first question under Daubert is whether the proposed expert witness is qualified to testify competently regarding the matters he or she intends to address. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 563 (11th Cir. 1998). An expert may be qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "Determining whether a witness is qualified to testify as an expert 'requires the trial court to examine the credentials of the proposed expert in light of the subject matter of the proposed testimony.'" Clena Invs., Inc. v. XL Specialty Ins. Co., 280 F.R.D. 653, 661 (S.D. Fla. 2012) (quoting Jack v. Glaxo Wellcome, Inc., 239 F. Supp. 2d 1308, 1314-16 (N.D. Ga. 2002)).

Rebotix argues that Dr. Bomalaski is not qualified to testify competently regarding (1) the safety of Rebotix's repair process or (2) the requirements of FDA regulations.

But Intuitive counters that Dr. Bomalaski's opinions do not go so far, and he is merely relying on his "extensive medical training and decades of surgical experience [to] support his opinions that overriding the use limit in EndoWrists without manufacturer or federal regulator approval increases the risk to patient safety." (Doc. # 150 at 9).

Dr. Bomalaski's qualifications is an issue inextricably bound up in the issue of whether the specific opinions he wishes to give are reliable. Thus, the Court will move on to the reliability prong.

2. Reliability

The next question is whether the expert's methodology is reliable. "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).

"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).

Rebotix argues, first, that Dr. Bomalaski does not have a reliable methodology for concluding that Rebotix's repair service is unsafe. Dr. Bomalaski opines in his report that, as a surgeon, he relies on manufacturer instructions regarding whether and in what circumstances certain surgical tools are safe to use, recognizing that surgeons can exert great force during surgeries and surgical tools can wear out

over time. (Doc. # 109-2 at 13-15). Dr. Bomalaski then writes that:

> I have given due consideration to Rebotix's views that it can "repair" EndoWrist instruments so they can be safely and reliably used beyond their usage limits. However, after reviewing the video demonstrating what the "process" actually entails, I would not feel comfortable using an instrument on a patient that had been "repaired" in that manner. In my opinion, the video did not show any real measures of quality control concerning instrument refurbishing. The EndoWrist instrument was shown being pried open, and the components changed out forcibly. Based on my experience, I believe patients would be quite concerned if they saw the Rebotix "repair" process on an instrument used for their surgery. I have cared for thousands of surgical patients. They are often anxious and vulnerable. In my opinion, the Rebotix video of its "process" would be a source of little comfort and more anxiety because it provides no factual basis for concluding that patient safety was studied by Rebotix.

(Id. at 15).

First, the Court holds that Dr. Bomalaski's decades of experience as a surgeon qualify him to opine on the potential consequences to patient health and safety of using inadequate instruments to perform surgical procedures. Although Dr. Bomalaski may not understand precisely how EndoWrists are manufactured or repaired in an engineering sense, Dr. Bomalaski can testify that he relies on a relationship of trust with the hospital, the instrument manufacturer, and government regulators to ensure adherence to appropriate

safety standards. Accordingly, Dr. Bomalaski has an adequate basis to explain to the factfinder how *he* personally feels about using repaired robotic surgical instruments in his capacity as a surgeon. To the extent Rebotix seeks to undercut those worries or concerns (by, for example, exposing Dr. Bomalaski's lack of knowledge about any flaws in Rebotix's repair process), Rebotix may address that on 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)).

That leads, however, to Rebotix's second argument on reliability. Rebotix argues that the doctor's opinions about what "would be" concerning to other surgeons, patients, and/or payors must be excluded as unreliable. The Court agrees. Rebotix points out that Dr. Bomalaski has not used any method to learn of the perceptions of these other groups, outside of his own speculation. He did not conduct any surveys or polls, did not read any report about how other physicians felt about the repair process, and did not show the Rebotix repair video to any patient. The Court agrees with Rebotix

that Dr. Bomalaski's own experience is not a sufficient basis to permit him to testify as to what other doctors might think. See In re 3M Combat Arms Earplug Prod. Liab. Lit., No. 3:19-md-2885, 2021 WL 684183, at *4 (N.D. Fla. Feb. 11, 2021) (excluding testimony where the expert "has not provided any other basis, such as a survey or widely distributed publication or even an email, to support the extrapolation of his knowledge to the entire . . . community [of medical personnel]"); Bartlett v. Mut. Pharm. Co., Inc., 742 F. Supp. 2d 182, 195 (D.N.H. 2010) ("[M]ost courts have prohibited experts from testifying . . . about 'what doctors generally think,' unless the testimony is based on something more reliable than simply the expert's own experience as a doctor."); In re Seroquel Prod. Liab. Lit., No. 6:06-md-1769-ACC-DAB, 2009 WL 3806436, at *8 (M.D. Fla. July 20, 2009) (excluding expert witnesses from testifying about whether doctors "generally read and comprehend drug labels, or whether doctors generally understand the contents" of such labels).

Similarly, although Dr. Bomalaski may testify as to the actual known perceptions of his patients over the course of his career (assuming such testimony to be otherwise

admissible under the Federal Rules of Evidence), he may not speculate as to the opinions of patients in general.

In sum, Dr. Bomalaski may testify to the extent such testimony is unchallenged by Rebotix and to the extent set forth in this Order.

Accordingly, it is hereby

ORDERED, **ADJUDGED**, and **DECREED:**

Plaintiff Rebotix Repair, LLC's Daubert Motion to Exclude the Opinions of Dr. John Bomalaski (Doc. # 109) is **GRANTED in part and DENIED in part.**

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

Virginia M. Hernandez Covington

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE