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 Heather Rosecrans (Doc. # 110) and Defendant Intuitive Surgical, Inc.'s Daubert Motion to Exclude the Opinions of J. Lawrence Stevens. (Doc. # 116). Both parties have responded. (Doc. ## 143, 151). For the reasons that follow, both Motions are 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.

Rosecrans and Stevens offer competing expert opinions as to whether Rebotix's "repair" service violates certain regulatory requirements of the federal Food and Drug Administration ("FDA"), specifically whether Rebotix needed Section 510(k) clearance from the FDA for its activities.

Since the Motions were filed, the FDA has sent email correspondence to Rebotix indicating that the FDA does view Rebotix's activities as "remanufacturing" of the type that requires regulatory review and approval. However, for the reasons detailed in the Court's accompanying summary judgment order, the Court does not believe this to be a final, definitive decision from the FDA. The issue of FDA clearance may go to the issues of causation and damages. Thus, these Motions are not moot and the Court will proceed to consider the instant Daubert motions.

1. Rosecrans' Report

Heather Rosecrans is an FDA regulatory affairs consultant with an expertise in matters concerning premarket regulation of medical devices. (Doc. # 110-2 at 6). She worked for more than 30 years at the FDA, including on the agency's 510(k) staff. Rosecrans issued two expert reports in this

case. Her first report, dated July 26, 2021 (the "First Rosecrans Report"), provides an overview of the FDA's regulation of medical devices, specifically the 510(k) procedure. The First Rosecrans Report contains the following opinions: (1) the usage limits on EndoWrists cannot be removed without 510(k) clearance because the FDA approved EndoWrists as Limited Use Devices; (2) Rebotix's argument that EndoWrists can be treated the same way as traditional laparoscopic instruments is flawed; (3) Intuitive's marketing and sale of EndoWrist instruments with usage limits is consistent with the FDA's regulatory requirements; (4) Rebotix is the manufacturer of a Medical Device (the Interceptor board) and, without 510(k) clearance, is selling a device that is "misbranded and adulterated"; and (5) in the alternative, Rebotix was required to obtain 510(k) clearance as a remanufacturer. (Doc. # 110-2).

Rosecrans' second expert report, dated August 30, 2021 (the "Second Rosecrans Report"), was submitted in rebuttal to a report submitted by Dr. Joshua Sharlin, an expert retained by Rebotix. (Doc. # 110-3). In short, the Second Rosecrans Report details Dr. Sharlin's conclusion that Rebotix's "repair" service does not require 510(k) clearance and then explains the reasons that Rosecrans disagrees with Dr.

Sharlin. Intuitive did not move to exclude the testimony of Dr. Sharlin. Instead, it challenges Rebotix's other proffered expert on this topic, J. Lawrence Stevens.

2. Stevens' Report

J. Lawrence Stevens has more than 40 years' experience with the FDA, both within the agency and in the private sector. (Doc. # 116-3 at 4). He served as a small business representative at the FDA, where he provided regulatory guidance to developers of new medical devices. He also worked for the FDA as a compliance officer, inspecting "high-risk medical device firms." After he left the FDA, Stevens founded a regulatory consulting company.

Rebotix hired Stevens to provide a rebuttal to Rosecrans' opinions. In Stevens' opinion, Rebotix was not required to seek FDA approval (via section 510(k) clearance or otherwise) for the services Rebotix performs on the EndoWrists. Moreover, Stevens opines that (1) Rebotix is not a manufacturer of a medical device requiring 510(k) clearance; (2) Rebotix is not the remanufacturer of a medical device; and (3) various other aspects of Rosecrans' opinions are flawed. (Doc. # 116-3 at 11-54).

Both Motions are now 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. Motion to exclude Rosecrans' opinions

Rebotix argues that Rosecrans' opinions address an issue that is not properly before the Court and should therefore be disallowed as irrelevant. As more fully described in the Court's accompanying summary judgment Order, it is Rebotix's position that only the FDA can make the determination of whether Rebotix's services are compliant with and/or require FDA approval or regulation. And, as described in that Order, the Court agrees and will not intrude upon a decision left to the sole discretion of the FDA.

Intuitive counters that Rosecrans' opinions are relevant to numerous issues bearing on Intuitive's Sherman Act claims. First, Intuitive argues that Rebotix must prove its business

was lawful in order to establish antitrust injury, which Intuitive claims Rebotix cannot do because of their noncompliance with Section 510(k) requirements. Second, Intuitive argues that it had a reasonable pro-competitive reason for representing in customer communications that use of Rebotix's "repaired" instruments lacking 510(k) clearance was unsafe. And finally, her opinion is relevant to the regulatory justification for EndoWrist use limits and the scope of EndoWrists' 510(k) clearance. And Intuitive argues that, with respect to its counterclaims, Rosecrans' testimony will assist the trier of fact to understand "the regulatory framework and the reasonableness of the process Rebotix used to analyze 510(k) clearance."

The Court believes that Rosecrans' testimony will be helpful to the trier of fact insofar as her opinions are offered to help the jury understand the Section 510(k) regulatory framework and provide an explanation of the FDA's practices and procedures. In that regard, Rosecrans' opinions will help the jury understand the complex regulatory scheme at issue in this case. However, Rosecrans cannot offer an ultimate opinion as to Rebotix's compliance or noncompliance with regulatory requirements because "an expert may not testify that certain conduct did or did not violate the law."

In re Delta/Airtran Baggage Fee Antitrust Lit., 245 F. Supp. 3d 1343, 1362 (N.D. Ga. 2017).

Thus, Rebotix's Motion to exclude Rosecrans' opinions is granted in part and denied in part to the extent set forth herein. Rosecrans may not give an ultimate legal opinion as to Rebotix's compliance with regulatory requirements or espouse her own personal interpretations of relevant regulations to the extent they differ from the FDA's public interpretations.

2. Motion to exclude Stevens' opinions

Intuitive argues that Stevens' opinions are inadmissible because: (1) he is not qualified to opine on Section 510(k) issues; (2) the methodology Stevens used is not sufficiently reliable; (3) Stevens failed to consider sufficient facts and data in conducting his analysis; (4) Stevens used improper hearsay to "prop up" his opinions; and (5) Stevens' opinions do not rebut Rosecrans' affirmative opinions.

a. 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)).

"This inquiry is not stringent, and so long as the expert is minimally qualified, objections to the level of the expert's expertise [go] to credibility and weight, not admissibility." Id. (citations and internal quotation marks omitted). The Court is mindful that its "gatekeeper role under Daubert 'is not intended to supplant the adversary system or the role of the jury.'" Maiz v. Virani, 253 F.3d 641, 666 (11th Cir. 2001)(quoting Allison v. McGhan, 184 F.3d 1300, 1311 (11th Cir. 1999)).

Here, Stevens' report reveals that over his four-decades-long career, he has personally prepared several 510(k) submissions, has advised companies navigating the 510(k) process, and has authored warning letters to medical device firms for failure to submit the required 510(k) paperwork. The qualifications prong of Daubert is a "lenient

standard," Delta T, LLC v. Dan's Fan City, Inc., No. 8:19-cv-1731-VMC-SPF, 2021 WL 2103074, at *3 (M.D. Fla. May 25, 2021), and an expert need only show "some reasonable indication of qualifications," at which point "qualifications become an issue for the trier of fact rather than the court in its gate-keeping capacity." Worley v. State Farm Mut. Auto. Ins. Co., No. 3:12-CV-1041-MCR, 2013 WL 6478425, at *3 (M.D. Fla. Dec. 10, 2013) (citing Rushing v. Kansas City S. Ry. Co., 185 F.3d 496, 507 (5th Cir. 1999), superseded by rule on other grounds as recognized in Mathis v. Exxon Corp., 302 F.3d 448, 459 n.16 (5th Cir. 2002)). Stevens' specialized knowledge and experience makes him qualified to discuss the FDA's 510(k) procedures and any shortcomings in his experience can be addressed on cross-examination.

b. Reliability

Intuitive also attacks Stevens as unqualified to opine on technical issues concerning the Interceptor or EndoWrists because he lacks an engineering background. Relatedly, it argues that Stevens offers no reliable analysis to support these engineering-related opinions but, rather, merely adopts the opinions of Dr. Sharlin.

The second question in the Daubert analysis 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).

"An expert may not present testimony that merely 'parrots' the opinions of others, without providing an independent evaluation of the evidence." Delta T, 2021 WL 2103074, at *4 (citing Morales v. Kraft Foods Grp., Inc., No. LA CV-14-04387 JAK (PJWx), 2017 WL 2598556, at * 10 (C.D. Cal. June 9, 2017)); see also Sabal Trail Transmission, LLC v. 0.589 Acres of Land in Hamilton Cnty., Fla., No. 16-cv-277-MMH-JBT, 2018 WL 3655556, at *7-8 (M.D. Fla. Aug. 2, 2018) (inappropriate parroting occurs when an expert "simply repeat[s] or adopt[s] the findings of another expert without attempting to assess the validity of the opinions relied upon").

Intuitive argues that Stevens' wholesale adoption of Dr. Sharlin's now-withdrawn report, with minimal independent investigation, warrants exclusion. Rebotix agrees that an expert's wholesale adoption of another's work without an independent evaluation would be improper, but argues that Stevens used his own skill and knowledge to "corroborate every opinion he adopted in [Dr. Sharlin's] report." Rebotix points to Stevens' declaration, in which he wrote that, since

submitting his report, he "re-reviewed all of the materials cited therein, and re-confirmed that the cited materials support [his] opinions." (Doc. # 143-6 at 3). While Intuitive points to the length and complexity of Dr. Sharlin's report and Stevens' deposition testimony that he only reviewed the report for a "couple of hours" and would view specific documents only when he had questions, this is evidence that may be used on cross-examination to undercut Stevens' opinions. Stevens stated in his report and later in his declaration that he independently considered the materials in Dr. Sharlin's report and reached the same conclusions, which is sufficient at this point to proceed.

Similarly, Intuitive takes issue with Stevens' adoption of a discussion he had with Rebotix employee Greg Fiegel, which forms the basis of Stevens' opinion regarding the repair process and whether Rebotix needed 510(k) clearance. But Rebotix argues that Stevens relied on his conversation with Fiegel only to provide certain background facts and then used those facts to reach his own conclusions. This goes to the weight of Stevens' opinion, not its admissibility. Any alleged flaws in Stevens' methodology should be addressed in cross-examination. See Maiz, 253 F.3d at 666 ("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)).

Finally, Intuitive attacks Stevens' reliance on a Deutsche Bank report that claims companies like Rebotix do not need Section 510(k) clearance based on the word of unnamed "regulatory consultants." "An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted." Fed. R. Evid. 703. While "Rule 703 provides that an expert may base his opinion on inadmissible facts or data," including hearsay, it must be "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." Riverside Apartments of Cocoa, LLC v. Landmark Am. Ins. Co., No. 6:18-cv-1639-PGB-DCI, 2020 WL 8184710, at *3 (M.D. Fla. Dec. 4, 2020). "Though courts have afforded experts wide latitude in picking and choosing sources on which to base opinions, Rule 703 nonetheless requires courts to examine the reliability of these sources." Id.

There is no evidence in the record that analyst reports like the one prepared by Deutsche Bank are relied upon by FDA experts. Stevens even testified that he could not recall whether he had ever relied upon an analyst report to help form his opinion on an FDA issue. Rebotix has not shown how the Deutsche Bank report is "of a type reasonably relied upon by experts in the field" in forming their opinions. Thus, to the extent Stevens wishes to rely on the Deutsche Bank document to state that: (1) his opinion on FDA clearance is the "consensus opinion held by FDA experts"; or (2) "other FDA experts" also believe that the FDA's "silence" means it has determined that Rebotix's services do not violate FDA regulations, he may not do so. See (Doc. # 143-2 at 18, 45-46).

Finally, Intuitive attacks Section III of Stevens' report – which details his affirmative opinions that FDA clearance is not required for Rebotix's activities – as outside the scope of his role as a rebuttal expert. This argument is unavailing because Stevens is addressing here the same subject matter – FDA section 510(k) clearance – as Rosecrans discussed in her report. See Adacel, Inc. v. Adsync Techs., No. 6:18-cv-1176-EJK-WWB, 2020 WL 4588415, at *2 (M.D. Fla. July 9, 2020).

Thus, Intuitive's Motion to exclude Stevens' opinion is granted in part and denied in part to the extent set forth herein. Like Rosecrans, Stevens may not give an ultimate legal opinion as to Rebotix's compliance with regulatory requirements or espouse his own personal interpretations of relevant regulations to the extent they differ from the FDA's public interpretations. He also may not proffer opinions that rely on the Deutsche Bank report. The Motion is otherwise denied.

Accordingly, it is hereby

ORDERED, ADJUDGED, and **DECREED:**

(1) Plaintiff Rebotix Repair, LLC's Daubert Motion to Exclude the Opinions of Heather Rosecrans (Doc. # 110) is **GRANTED in part and DENIED in part.**

(2) Defendant Intuitive Surgical, Inc.'s Daubert Motion to Exclude the Opinions of J. Lawrence Stevens (Doc. # 116) 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