IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 09-cv-02433-WJM-KLM

JOEL M. PRITCHETT,

Plaintiff,

v.

I-FLOW CORPORATION,

Defendant.

ORDER

ENTERED BY MAGISTRATE JUDGE KRISTEN L. MIX

This matter is before the Court on **Defendant I-Flow Corporation's Motion to Exclude Expert Opinions of Dr. Jon Hyman Under Fed. R. Evid. 702 and Request for Hearing** [Docket No. 106; Filed October 4, 2011] (the "Motion"). Plaintiff filed an **Opposition to Defendant I-Flow's Motion to Exclude Expert Opinions of Jon Hyman, M.D.** [Docket No. 114; Filed October 28, 2011], and Defendant filed **I-Flow, LLC's Reply in Support of its Motion to Exclude Expert Opinions of Dr. Jon Hyman Under Fed. R. Evid. 702** [Docket No. 115; Filed November 14, 2011]. The Court held a hearing on the Motion on January 10, 2012. [#122]. The Court has reviewed the pleadings, the exhibits, the entire case file and the applicable law, and is fully advised in the premises. For the reasons set forth below, the Motion is **DENIED.**

I. Summary of the Case

Plaintiff had shoulder surgery in August of 2005. The surgeon used a pain pump manufactured by Defendant I-Flow to inject anesthetic into Plaintiff's shoulder joint for more

than 48 hours. Plaintiff subsequently developed a condition called "chondrolysis," which involves partial or complete loss of cartilage in the shoulder joint. Plaintiff alleges that his chondrolysis was caused by continuous injection of anesthetics into his shoulder joint, and that I-Flow manufactured and marketed the pain pump "without doing a single study to determine whether pain pump anesthetics could harm cartilage. Once on notice about the risk of shoulder chondrolysis, [I-Flow] waited years to inform physicians about the risks [and] the warnings . . . were all wholly inadequate to advise physicians about the risk of cartilage destruction." *Sched. Ord.*, [#62] at 3. Plaintiff brings claims against I-Flow for "negligence, negligent misrepresentation, fraud, strict product liability (design defect and failure to warn), breach of implied warranty and breach of express warranty." *Id.*

Defendant denies liability and causation and asserts that its "pain pumps were cleared by the FDA and were accompanied with adequate warnings and instructions." *Id.*

Plaintiff offers the expert opinion of Dr. Jon Hyman to testify that Plaintiff's "left shoulder function has been irretrievably lost [and that] this condition was caused by the infusion pain pump and anesthetics delivered to his shoulder joint in 2005." *Expert Report Jon Hyman, M.D.* (hereinafter "Hyman Report"), [#106-5] at 15.

Defendant asserts multiple grounds for excluding Dr. Hyman's testimony under Fed. R. Evid. 702. First, I-Flow argues that Dr. Hyman's opinions are based on insufficient facts or data and his methods are unsound. More specifically, I-Flow contends that the case series on which Dr. Hyman relies are insufficient to establish general causation, that Dr. Hyman improperly extrapolates from *in vitro* studies, that Dr. Hyman improperly relies on *in vitro* animal studies, and that Dr. Hyman's opinion is the only connection between the data and his conclusion. *Motion*, [#106] at 3-13. Second, I-Flow argues that Dr. Hyman's

differential diagnosis of specific causation is invalid in light of the lack of evidence of general causation and because Dr. Hyman failed to rule out other potential causes of Plaintiff's shoulder injury. *Id.* at 13-15.

Plaintiff counters I-Flow's arguments by asserting, in a nutshell, that they are not a basis for excluding his testimony, as they merely "go to the weight and credibility of his testimony." *Resp.*, [#114] at 2-15.

II. Analysis

A. General Principles of Federal Rule of Evidence 702

"Admission at trial of expert testimony is governed by Fed. R. Evid. 702, which imposes on the district court a gatekeeper function to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *United States v. Gabaldon*, 389 F.3d 1090, 1098 (10th Cir. 2004) (quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993)). The gatekeeper function "requires the judge to assess the reasoning and methodology underlying the expert's opinion, and determine whether it is both scientifically valid and applicable to a particular set of facts." *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1221 (10th Cir. 2003). The district court's discretion in admitting or excluding expert testimony under *Daubert* is broad, "both in deciding how to assess an expert's reliability, including what procedures to utilize in making that assessment, as well as in making the ultimate determination of reliability." *Id*. at 1223.

Rule 702 provides the foundational requirements for admission of expert opinions:

> 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.

Adopted in response to *Daubert*, Rule 702 was revised effective December 1, 2000 and December 1, 2011.

Under the current version of Rule 702, a witness' qualifications are no longer sufficient foundation, standing alone, to admit expert testimony. In addition to showing that the witness has appropriate qualifications, the proponent of the witness' opinions must demonstrate that the process by which the witness derived his or her opinions is reliable. *See Dodge*, 328 F.3d at 1222. To be reliable, an expert's scientific testimony must be based on scientific knowledge, which "implies a grounding in the methods and procedures of science" based on actual knowledge, not "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590. Rule 702 anticipates that, if challenged, the factual foundation supporting the specific testimony will be provided by the proponent of the witness. *Dodge*, 328 F.3d at 1222. However, the proponent need not prove that "the expert is undisputably correct or that the expert's theory is 'generally accepted' in the scientific community." *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 781 (10th Cir. 1999). Instead, the proponent must show that the method used by the expert in reaching the conclusion is scientifically sound and that the opinion is based on facts which satisfy Rule 702's reliability requirements. *Id.* In the Tenth Circuit, determination of the sufficiency of the foundation for admission of expert testimony requires factual findings, preferably after an evidentiary hearing. *Dodge*, 328 F.3d at 1222.

A Rule 702 hearing is meant to address only the foundational requirement for challenged opinions, and the Court rules on only the specific challenges raised by the party opposing the opinions. *United States v. Crabbe*, 556 F. Supp. 2d 1217, 1220 (D. Colo. 2008). "The Court does not determine the weight or persuasiveness of the opinion, nor consider other evidentiary objections[, such as relevance, *etc.*,] which are more appropriately addressed at trial." *Id.* Instead, "[t]he focus . . . must be solely on principles and methodology, not on the conclusions they generate." *Daubert*, 509 U.S. at 595.

1. Burden of Proof

The proponent of expert testimony bears the burden of proving the foundational requirements of Rule 702 by a preponderance of the evidence. *See Cook ex rel. Estate of Tessier v. Sheriff of Monroe Cnty.*, 402 F.3d 1092, 1107 (11th Cir. 2005) (citing *Daubert*, 509 U.S. at 592 n.10). The proponent is not required to prove that the opinion is objectively correct. *Mitchell*, 165 F.3d at 781. Instead, the proponent must show that the witness has sufficient expertise to choose and apply a methodology, that the methodology was reliable, that sufficient facts and data as required by the methodology were used and that the methodology was otherwise reliably applied. *Id.*; *Daubert*, 509 U.S. at 595; *see also Dodge*, 328 F.3d at 1222. The burden on the proponent of the expert is heavy, as any inadequacy in the proof on any of Rule 702's elements may render the entire opinion inadmissible. *Mitchell*, 165 F.3d at 782.

2. Rule 702 Analysis

In the Tenth Circuit, the Rule 702 analysis has two steps: (1) the Court must determine whether the expert is qualified to give the proffered opinion, and (2) the Court must examine whether the opinion itself is reliable. *103 Investors I, L.P. v. Square D Co.*,

470 F.3d 985, 990 (10th Cir. 2006). The second step of the analysis focuses on the process or means by which the witness developed the opinion, *i.e.*, the methodology or application of principles. *Id.* "This analytical framework makes the Rule 702 determination more *opinion-centric* than *expert-centric*." *Crabbe*, 556 F. Supp. 2d at 1221 (emphasis in original).

a. Qualifications

Rule 702 requires that a witness have "expert[ise resulting from] knowledge, skill, experience, training, or education," and such qualifications are considered in relation to the particular opinion or testimony proffered. *United States v. Dysart*, 705 F.2d 1247, 1252 (10th Cir. 1983). Any one of these qualifications can be sufficient to support a finding that an expert is qualified. *See* Fed. R. Evid. 702 Advisory Committee Notes, 2000 Amendments.[1] However, in some fields, experience alone is the "predominant, if not sole, basis for a great deal of reliable expert testimony." *Id.*

Some of the factors provided in *Daubert* are applicable to the question of whether the witness is sufficiently qualified. For example, the Court should consider whether the witness proposes to testify about the matters growing naturally and directly out of research he or she conducted independent of the litigation, whether the witness developed opinions expressly for purposes of testifying, and whether the field of expertise claimed by the witness is known to reach reliable results for the type of opinion the witness tends to express. *Daubert*, 509 U.S. at 595.

[1] Because the witness' qualifications must relate to the opinions offered in the present case, the fact that the witness has given expert testimony in other cases is not relevant unless the testimony was of the same nature using the same methodology.

b. Derivation of the Opinion

Rule 702 also requires that the means or method by which the testimony or opinion is derived be reliable. As such, the Rule sets out three specific requirements: (1) a showing that the "testimony is based upon sufficient facts or data," (2) a showing that "the testimony is the product of reliable principles and methods," and (3) a showing that "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d).

i. Sufficient Facts and Data

The proponent of the opinion must first show that the witness gathered "sufficient facts and data" to formulate the opinion. In the Tenth Circuit, assessment of the sufficiency of the facts and data used by the witness is a quantitative, rather than a qualitative, analysis. Fed. R. Evid. 702, Advisory Committee Notes to 2000 Amendments; *see also United States v. Lauder*, 409 F.3d 1254, 1264 n.5 (10th Cir. 2005). That is to say, the Court does not examine whether the facts obtained by the witness are themselves reliable; whether the facts used are qualitatively reliable is a question of the weight that should be given to the opinion by the fact-finder, not the admissibility of the opinion. *Lauder*, 409 F.3d at 1264. Instead, "this inquiry examines only whether the witness obtained the amount of data that the methodology itself demands." *Crabbe*, 556 F. Supp. 2d at 1223.

ii. Methodology

Methodology, or the requirement that an opinion be derived from reliable principles or methods, involves two related inquiries: (1) identification of the methodology the witness used to reach the opinion; and (2) determination of whether the methodology is generally considered "reliable" in the field in which the expert works. *Crabbe*, 556 F. Supp. 2d at

1222. These inquiries are solely factual, and "the proponent of the opinion must establish both inquiries by sufficient, competent evidence." *Id.*

The first inquiry simply requires that the witness explain how he or she reached the opinion at issue – a simple explanation of the process normally is sufficient. *Id.* The second inquiry, whether the methodology is reliable, requires that the court assess whether that method is "scientifically valid." *Hollander v. Sandoz Pharmaceuticals Corp.*, 289 F.3d 1193, 1204 (10th Cir. 2002); *Truck Ins. Exchange v. MagneTek, Inc.*, 360 F.3d 1206, 1210 (10th Cir. 2004). A determination that a method is "scientifically valid" requires an inquiry into whether it is a scientific or logical method that can be replicated and validated. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). Depending on the methodology at issue, courts have the wide discretion to consider a variety of appropriate factors in assessing reliability. These factors, include, but are not limited to: (1) whether the methodology is one that can be tested or falsified – that is, whether the witness' approach can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the method or technique has been subject to peer review and publication; (3) whether there are known or potential rates of error with regard to the use of the method; (4) whether there are standards controlling the operation of the technique; and (5) whether the method or approach has "general acceptance" in the "relevant scientific community." *See Daubert*, 509 U.S. at 593-94, *Kumho Tire*, 526 U.S. at 149-50.

However, the above factors are not exclusive nor dispositive. *Crabbe*, 556 F. Supp. 2d at 1223. For instance, a methodology that is not peer reviewed or tested may still be considered reliable if only because it is considered a generally-accepted practice in the

discipline. *See Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1235 (10th Cir. 2004). However, a methodology may have almost universal acceptance in a particular discipline, but the Court may find that the entire discipline itself (*e.g.,* astrology) is not reliable. *Kumho Tire*, 526 U.S. at 151. A court must consider and balance the factors in light of each other, and also considering the particular circumstances of the case. For example, where the methodology is unique or lacks general acceptance in the relevant field, the need for the witness to validate the theory through more extensive testing increases. *See, e.g., MagneTek*, 360 F.3d at 1212. On the other hand, an otherwise reliable methodology does not instantly become unreliable merely because the witness did not test it thoroughly in all applicable situations. *See Bitler*, 400 F.3d at 1236. Instead, once a court is satisfied that the methodology is generally reliable, suggestions that the witness should have engaged in additional testing to achieve certainty in his or her conclusions simply go to the weight of the opinion, not its admissibility. *Id.*

iii. Application

The final step requires that the witness reliably apply the methodology to the facts and data he or she has obtained. Once again, "the requirement that the witness 'reliably' do so is not an invitation to a court to assess the worth of the opinion itself." *Crabbe*, 556 F. Supp. 2d at 1223. Instead, the Court's inquiry focuses on "whether the witness followed the dictates of the methodology in considering the facts and data." *Id.* In assessing this reliability, the Court may consider a variety of factors, including, but not limited to: (1) whether the expert employed the same degree of intellectual rigor in formulating the opinion as he or she would be expected to employ in his or her own professional life; (2) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded

conclusion (or, whether the gap between the analytical data and the opinion proffered is too large); and (3) whether the expert adequately accounted for obvious alternative explanations. *See generally Kumho Tire*, 526 U.S. at 152; *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *Bitler*, 400 F.3d at 1233.

Finally, even if an expert is deemed qualified and his or her opinions are considered reliable, admissibility still requires a determination that the opinions are relevant. That is, the Court must consider "whether expert testimony . . . is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591 (citation omitted). Courts have routinely excluded expert testimony that was based on nothing more than speculation. *See, e.g., Jetcraft Corp. v. Flight Safety Int'l*, 16 F.3d 362, 366 (10th Cir. 1993) (expert testimony excluded as professional speculation); *Eastridge Dev. Co. v. Halpert Assoc., Inc.*, 853 F.2d 772, 783 (10th Cir. 1988) (expert testimony excluded as "tentative and speculative"). However, "[d]oubts about whether an expert's testimony will be useful should generally be resolved in favor of admissibility unless there are strong facts such as time or surprise favoring exclusions." *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1083 (D. Colo. 2006) (quoting *Robinson v. Mo. Pac. R.R. Co.*, 16 F.3d 1083, 1090 (10th Cir. 1994)).

B. Admissibility of Dr. Hyman's Expert Opinions

Following an extensive review of Dr. Hyman's expert report, the Court concludes that his opinions are admissible, and that the jury should decide whether he is correct. As indicated by another court in a similar case, "taking [I-Flow's] argument to its logical conclusion, [I-Flow] would have [Plaintiff] prove causation to a medical certainty before expert testimony could be admitted. I find [I-Flow's] argument wholly inconsistent with

Daubert and the fundamental premise of Rule 702." *McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1101 (D. Or. 2010).

As noted by the *McClellan* court, *Daubert* did not "impose an exacting standard of causality beyond the preponderance of the evidence simply because scientific issues are involved." *Id.* (internal quotations omitted). The issue is not whether the proponent of expert testimony can prove that the expert is correct; it is whether the testimony is "reliably derived from scientific methodology and is relevant to the facts of the case." *Id.*

Dr. Hyman's opinions are indeed derived from scientific methodology, including a comprehensive review of Plaintiff's relevant medical records, an independent medical examination of Plaintiff, a review of applicable medical literature, a review of radiographs of Plaintiff's shoulder from the date of the surgery, and use of "the technique of differential diagnosis." *Hyman Report* [#106-5] at 7-15. I agree with the *McClellan* court that Dr. Hyman's use of differential diagnosis does not doom his opinions under *Daubert*. As that court held, "numerous courts have approved opinions based on differential diagnosis to show general causation, despite the absence of conclusive causal evidence." *McClellan*, 710 F. Supp. 2d at 1104. Generally "the basis for establishing the scientific validity of a differential diagnosis will vary depending on the type of injury and whether it involves a complicated biological explanation, a long latency period or the lack of a single sharp exposure event." *Id.* at 1103 (citing *Marcum v. Adventist Health System/West*, 193 P.3d 1 (Or. 2008)). Case-specific factors, such as the temporal relationship between the continuous infusion and Plaintiff's development of chondrolysis, Plaintiff's lack of other toxic exposures, and Plaintiff's lack of other systemic disease or injury unrelated to the area or purpose of exposure, increase the reliability of the differential diagnosis methodology used

here. In these circumstances, Dr. Hyman's testimony on general causation should be admitted because it is based on "a reliable differential diagnosis and reliably flows from the underlying facts of the case." *Yarchak v. Trek Bicycle Corp.,* 208 F. Supp. 2d 470, 499 (D. N.J. 2002).

III. Conclusion

For the reasons set forth above, **Defendant I-Flow Corporation's Motion to Exclude Expert Opinions of Dr. Jon Hyman Under Fed. R. Evid. 702** [#106] is **DENIED.**

Dated: April 17, 2012

BY THE COURT:

Kristen L. Mix
United States Magistrate Judge