UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CYNTHIA PERKINS, et al.	:	
	:	
v.	:	Civ. Action No.
	:	3:99 CV 1405 (SRU)
ORIGIN MEDSYSTEMS INC.	:	

RULING ON DEFENDANT'S MOTION TO EXCLUDE DOCTOR METZGER'S STUDY AND PROFFERED OPINION TESTIMONY

Pursuant to Connecticut General Statutes § 52-572M et seq., Plaintiff Cynthia Perkins ("Ms. Perkins") has brought a products liability action against defendant Origin Medsystems Inc. ("Origin"), the manufacturer of a surgical fastening device ("the Tacker").[1] Ms. Perkins alleges that she has suffered injuries proximately caused by the use of the Tacker in her 1996 laparoscopic hernia operation. Plaintiff Mark Perkins asserts a claim for loss of consortium.[2] In support of her claim, Ms. Perkins intends to call as a witness, Dr. Deborah A. Metzger, Ms. Perkins' initial treating physician and retained expert in the fields of female chronic pelvic pain[3] and laparoscopic hernia repair surgery.[4] Based on her education, training, and extensive clinical

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[1] The Tacker is a surgical fastening device that dispenses tacks into tissues, thereby affixing a surgical mesh.

[2] Mr. Perkins' claim depends on the same causation evidence as that offered by Ms. Perkins to support her claims. For the sake of simplicity, I will refer hereafter only to Ms. Perkins when discussing plaintiffs' claims.

[3] According to Dr. Metzger, chronic pelvic pain is pelvic pain that lasts three to six months or longer, interferes with a woman's life and is not related to menstrual cramps or bowel function. See Deposition of Deborah A. Metzger dated December 4, 2000 (hereinafter "Metzger Dep.") at 22-23; Daubert HearingTranscript ("Tr.") June 2, 2003 at 21.

[4] Laparoscopic hernia repair is a minimally invasive surgical technique to fix tears in the abdominal wall (muscle) using small incisions, surgical scopes and a patch (mesh).

experience, Dr. Metzger is prepared to testify that the Tacker causes unnecessary post-operative pain in women experiencing chronic pelvic pain, and did in fact injure Ms. Perkins, who suffers from chronic pelvic pain. In support of Dr. Metzger's proffered opinion testimony, Ms. Perkins seeks to introduce a preliminary retrospective case study (the "Study") that Dr. Metzer prepared based on her treatment of some of her chronic pelvic pain patients.

On March 10, 2003, Origin moved to preclude Dr. Metzger's proffered opinion testimony and the Study pursuant to the principles articulated in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), and its progeny. On June 2 and July 19 and 28, 2003, the court held evidentiary hearings during which it took evidence and heard, among other testimony, the testimony of Dr. Metzger and Dr. David Garabrant.[5] For the reasons set forth below, Origin's motion to exclude the Study is granted and it's motion to exclude Dr. Metzger's proffered opinion testimony is denied.

I. BACKGROUND

Ms. Perkins

In February 1996, Ms. Perkins visited Dr. Metzger for a fertility consultation.[6] Metzger

[5] In addition to the original motion papers and three days of evidentiary hearings, the parties extensively and exhaustively briefed this motion. See Plaintiff's Supplemental Memorandum in Opposition to Motion to Exclude Expert Opinion of Dr. Deborah Metzger (doc. # 57); Defendant Origin Medsystems, Inc's. Response to Plaintiff's Supplemental Memorandum in Opposition to Origin's Motion to Exclude Opinions of Dr. Metzger (doc. # 58); Plaintiff's Supplemental Memorandum in Opposition to Motion to Exclude Expert Opinions of Dr. Deborah Metzger (doc. # 67); Plaintiff's Post-Hearing Memorandum in Opposition to Motion to Exclude Expert Opinions of Dr. Deborah Metzger (doc. # 69); and Origin Medsystems Inc., Post-Hearing Brief in Support of its Motion to Exclude the Opinions of Dr. Metzger (doc. # 71).

[6] A small portion of Dr. Metzger's practice consists of fertility work. However, all references in this Ruling relate to her chronic pelvic pain patients.

Dep. at 79; Tr. June 2, 2003 at 115. In April 1996, she returned to Dr. Metzger for treatment of pelvic pain. Deposition of Cynthia Perkins dated Nov. 3, 2000 (hereinafter "Perkins Dep. 1") at 96; Tr. June 2, 2003 at 115. After conducting a thorough physical exam, Dr. Metzger attributed Ms. Perkins' pelvic pain to several sources, including, but not limited to, endometriosis, ovarian vein syndrome, bilateral ovarian vein ligation, and bilateral internal inguinal hernias.[7] Tr. June 2, 2003 at 31; Metzger Dep. at 84-86, 88. Because she could not directly feel the hernias, Dr. Metzger referred Ms. Perkins to Dr. Ibrahim Daoud, a hernia specialist, to confirm her diagnosis. Tr. June 2, 2003 at 31. Dr. Metzger regularly worked with Dr. Daoud. Id. Dr. Daoud agreed that a hernia operation was appropriate and, in June 1996, he performed laparoscopic surgery on Ms. Perkins to repair the hernias.

As part of the surgery, Dr. Daoud used the Tacker to affix a gortex mesh over her hernias. Perkins Dep. 1 at 107; Deposition of Dr. Daoud, dated Dec. 1, 2000 at pp. 37-38.[8] During the same procedure, Dr. Metzger performed an ovarian vein ligation to assist in relieving some of the pelvic pain. Metzger Dep. at 88-89; Tr. June 2, 2003 at 118.

On October 14, 1996, Ms. Perkins returned to Dr. Metzger, and complained, in relevant

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[7] Bilateral inguinal hernias are occult hernias, that is, hernias that generally cannot be observed, palpatated or felt. Tr. June 2, 2003 at 120. The laparoscopic procedure allows the physician to see and repair small hernias not detected by a physical examination. In addition, the parties do not dispute that Ms. Perkins suffers from chronic pelvic pain.

[8] When Drs. Daoud and Metzger first began performing hernia operations and repairs, they affixed the mesh to the hernia(s) with a stapler. Tr. June 2, 2003 at 32. The problem with the stapler was that it required a large trocar site opening in the abdomen in order to maneuver the stapler to affix the mesh. A large trocar site requires the surgeon to cut through a greater amount of tissue in order to affix the mesh, resulting in more trauma to the surrounding tissue, an increased chance for complications, and a protracted recovery time. Id.

part, of localized pain at the site of the implanted tacks. Id. at 94.[9] As she does with all of her patients, Dr. Metzger conducted a thorough physical exam of Ms. Perkins, eliminating potential sources for her particular pain. The physical exam included, in part, palpating different muscles and nerves in an attempt to reproduce a component of the newly developed pain. Tr. June 2, 2003 at 26.[10] In this case, Dr. Metzger eliminated, among other possible sources, a urinary tract infection, and vaginitis. Id. at 126. She was able to reproduce Ms. Perkins' pain by palpating the tacks. Id. at 94-95. Dr. Metzger then injected Ms. Perkins with marcaine,[11] a long-lasting local anesthetic, to determine if the pain ceased upon injection. Id. at 95; Tr. June 2, 2003 at 126. After the first injection, the pain subsided for approximately three days. Tr. June 2, 2003 at 126. After the second injection, the pain subsided for only 24 hours. Id. Dr. Metzger's experience has been that if the injections are going to ameliorate the pain by desensitizing the nerves to the painful stimuli, then with each injection, the length of pain relief gets longer and longer until the

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[9] In her deposition, Dr. Metzger commented that a patient's description of a pulling or tearing sensation is consistent with the sensation caused by tacks; when a tack is placed in a muscle and the muscle contracts and moves, part of the tack is moving one way, and another part of the tack is moving another way, resulting in a pulling or tearing sensation.

[10] The examination included, but was not limited to, palpatating nerves around the uretha, bladder and the ureters muscles because, according to Dr. Metzger, "you can tug at the ureters and if that's a source of their pain then you get concerned there is scar tissue somewhere along the ureter." Tr. June 2, 2003 at 26. In addition, Dr. Metzger would palpate the cul-de-sac because "the cul-de-sac is a space where you can feel modules of endometriosis, another cause of chronic pelvic pain." Id. Dr. Metzger would also press on the ovarian points to see whether this reproduces a portion of the patient's pain. She would feel around the stomach muscles, as well as look for a reverted uterus. If the patient experienced pain during intercourse, she would perform a Q-tip exam to see if there is pain merely on insertion in intercourse. Id. at 26. She would also feel the adnexa as a potential source of pain. Id. at 27.

[11] According to Dr. Metzger, marcaine is actually the brand name for bupivacaine, which is a long-lasting local anesthetic. Tr. June 2, 2003 at 121.

pain does not return. Tr. June 2, 2003 at 126.

Dr. Metzger recommended removing Ms. Perkins' tacks based on Ms. Perkins' complaints of localized pain at the site of the tacks, the fact that palpating the tacks reproduced the pain, Dr. Metzger's decreasing ability to subdue the pain with marcaine, and on her clinical experience in having success with treating other patients with similar symptoms by removing the tacks.[12] Id. at 96. Because there were so many tacks involved, and some of the tacks were hard to find, it took numerous operations between November 1996 and February 2000 to remove all of Ms. Perkins' tacks.[13] After the last tacks were removed in February 2000, Ms. Perkins claims that she did not experience any more pelvic pain at the site of the tacks. Perkins Deposition, Nov. 14, 2002 (hereinafter "Perkins Dep. 2") at 33; Tr. June 2, 2003 at 60.

The Study

In response to experiences like those of Ms. Perkins, Dr. Metzger ceased using surgical fastening devices in hernia operations.[14] Dr. Metzger also decided to do a retrospective case study to examine the frequency with which patients developed pain as a result of surgical

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[12] Prior to operating on Ms. Perkins, Dr. Metzger had treated numerous chronic pelvic pain patients who had laparoscopic hernia repairs, utilizing surgical tacks used as a fixation device. With each of her patients, Dr. Metzger conducted a standardized physical exam, evaluated the patient's medical history, and eliminated potential sources for the post-operative pain at the location of the tacks. Prior to treating Ms. Perkins, Dr. Metzger had had substantial success in relieving her patients' post-hernia-operation pain by removing the tacks.

[13] Dr. Metzger was Ms. Perkins treating physician until late 1998, when Dr. Metzger relocated to California.

[14] Prior to the Tacker, Dr. Metzger used a conventional stapler to affix mesh when repairing hernias. The parties agree that, because the stapler requires a larger trocar site, 10-12 mm with the stapler as compared to 5mm with the Tacker, there is a greater risk of trauma to the surrounding tissues, increased complications, and a protracted recovery time. Accordingly, Dr. Metzger switched to using tacks instead of staples.

fastening devices, requiring surgical removal of such devices. Tr. June 2, 2003 at 37. In the Study, Dr. Metzger sets forth some of her clinical findings with respect to hernia repair operations. She specifically reports on two issues: (1) the success of the hernia repair operations in curing the patient's hernia pain as a function of the medical fastening product used in the surgery, and (2) the need for re-operation for pain caused by the surgical product itself. In the Study, Dr. Metzger compiled information on three groups of women: one group had gortex mesh placed over the hernia(s) without any fasteners, one group had gortex mesh affixed with tacks, and the third group had gortex mesh affixed with staples. In her deposition, Dr. Metzger states that, of the 26[15] patients who had gortex mesh affixed with tacks, 17 developed post-operative pain at the location of those tacks, requiring surgical removal of the tacks. Metzger Dep. at 53. Four of those women required multiple surgeries to remove the tacks. Id. In addition, of the 82 women who had their hernias repaired with gortex mesh and staples, approximately 15 required surgery to remove the staples. Id. at 54. According to Dr. Metzger, "[t]he study shows that the rate of incidence of post-surgical problems for women where tacks were used is higher than the rate when staples or marlex mesh are used. [Dr. Metzger] believes that these differences are a function of the depth and strength at which the tacks are inserted using the Tacker, which interferes with the normal movement of tissues in the area where the tacks are located, thereby causing pain. The depth and strength of the tack insertions also makes surgical removal of the tacks difficult." Expert Report of Dr. Deborah A. Metzger at 1.

[15] In her Study, Dr. Metzger states that 25 patients had the gortex mesh affixed with the tacks. The court attributes no weight to this discrepancy.

II. DISCUSSION

Ms. Perkins has alleged various causes of action under the Connecticut Products Liability Act, §§ 52-572m et seq. In support of her claims, Ms. Perkins seeks to admit the opinion testimony and Study of Dr. Metzger. Dr. Metzger's proffered opinion testimony states "that use of the Tacker on women suffering from chronic pelvic pain creates an unreasonable and unacceptably high risk that the implanted tacks will cause the patient to suffer pain that cannot be effectively treated with local anesthetic injections or other methods, such that the patients must undergo surgical removal of the tacks in order to obtain relief." Expert Report of Dr. Deborah A. Metzger at 1. In addition, Dr. Metzger is prepared to testify that the "[u]se of the Tacker in Cynthia Perkins' hernia repair caused Ms. Perkins to suffer from debilitating pain and depression for an extended period of time, until all of the tacks were finally removed. Because of her pain caused by the Tacker, Ms. Perkins was required to undergo extensive medical treatment, including but not limited to multiple surgeries, trigger point injections, and the use of narcotic and anti-depressant medications ...." Id. at 2.

Origin argues that Dr. Metzger's proffered opinion testimony and the Study cited in support thereof fail to meet the applicable standards governing the admissibility of expert testimony and reports under Daubert and its progeny.

A. *The Standard for Admitting Proffered Expert Testimony*

The proponent of expert testimony has the burden of demonstrating by a preponderance of the evidence, see Daubert, 509 U.S. at 592 n.10, that the testimony is competent, relevant, and reliable. Koppell v. New York State Board of Elections, 97 F. Supp. 2d 477, 479 (S.D.N.Y. 2000); Union Bank of Switzerland v. Deutsche Financial Services Corp., 2000 WL 178278 at *8

(S.D.N.Y 2000) (internal citations omitted) (citing Bourjaily v. United States, 483 U.S. 171 (1987)). If the expert is deemed competent (otherwise referred to as "qualified"), an issue not in dispute in this case, the trial court must then determine, pursuant to its "gatekeeping" function, whether the proffered expert testimony is "relevant" and "reliable." See Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702 (noting that trial judges have "the responsibility of acting as gatekeepers to exclude unreliable expert testimony").

Evidence is relevant if the testimony "ha[s] any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Amorgianos v. National R.R. Passenger Corp., 303 F.3d 256, 264 (2d Cir. 2002) (alteration in original) (citing Campbell v. Metro. Prop. & Cas. Ins. Co., 239 F.3d 179, 184 (2d Cir. 2001) (quoting Fed. R. Evid. 401)); Daubert, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful . . . . Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."). If the evidence is relevant, the trial court must then determine "whether the proffered testimony has a sufficiently 'reliable foundation' to permit it to be considered" by the trier of fact. Amorgianos, 303 F.3d at 265 (quoting Daubert, 509 U.S. at 597).[16]

Rule 702 provides guidance to the trial court in determining whether the proffered expert testimony is sufficiently reliable. Rule 702 states, in relevant part, that expert testimony may be

[16] In Daubert, the Supreme Court rejected the traditional Frye rule (which had required that a scientific theory be generally accepted by the scientific community to be admissible, see Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)), concluding that adherence to Frye's "rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules [of Evidence]." Daubert, 509 U.S. at 588 (citations omitted).

considered reliable if: (1) "the testimony is based on sufficient facts or data;" (2) the expert's technique or methodology in reaching the conclusion is considered reliable; and (3) the expert has applied the methodology reliably to the facts of the case. Fed. R. Evid. 702. Moreover, in order for the testimony to be admissible, all three components of Rule 702's reliability analysis must be met. Amorgianos, 303 F.3d at 267 ("The reliability analysis applies to all aspects of the expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion.") (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 745 (3d Cir. 1994)).

In Daubert, the Supreme Court set out a list of non-exclusive factors the trial court may consider in determining whether an expert's reasoning or methodology is reliable: (1) whether the theory or technique on which the expert relies has been tested – that is, whether the expert's theory 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 theory or technique has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards controlling the technique's operation; and (5) whether the theory or method has been generally accepted by the scientific community. See Daubert, 509 U.S. at 593-94.

No single factor is necessarily dispositive of the reliability of a particular expert's testimony, because a trial court need only "consider the specific factors identified in Daubert where they are reasonable measures of the reliability of expert testimony." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 150 (1999). The test of reliability therefore is a "flexible" one depending on the "nature of the issue, the expert's particular expertise, and the subject of his

testimony." Id. (quoting Daubert, 509 U.S. at 593).[17]

If the court finds the methodology reliable, the court must then determine if the methodology was reasonably applied to the facts of the case. Amorgianos, 137 F. Supp. 2d 147, 162 (E.D.N.Y. 2001). In making this assessment, the court's inquiry under Daubert must focus not on the substance of the expert's conclusions, but on whether those conclusions were generated by a reliable methodology. See Daubert, 509 U.S. at 590, 595; Amorgianos, 137 F. Supp. 2d at 162 (E.D.N.Y. 2001). Nevertheless, an expert's testimony must be held inadmissible if "there is simply too great an analytical gap between the data and the opinion proffered," such that the opinion is "connected to the existing data only by the ipse dixit of the expert." Amorgianos, 303 F.3d at 266 (quoting General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997)); see also Mancuso v. Consolidated Edison Co. of New York, Inc., 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997) ("[E]xpert testimony should be excluded if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith or to be in essence an apples and oranges comparison.") (internal citations omitted) (quoting Boucher v. Suzuki Motor Corp., 73 F.3d 18, 21 (2d Cir. 1996)). At the same time, the court should afford the expert some deference because a "minor flaw in an expert's reasoning or a slight

[17] Courts both before and after Daubert have found other factors relevant when determining whether expert testimony is sufficiently reliable to be considered by the trier of fact, see, e.g., Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702 (collecting cases), such as whether the theory or method offered by the expert has been put to any non-judicial use, see Cabrera v. Cordis Corp., 134 F.3d 1418, 1420-21 (9th Cir. 1998); In re Paoli R.R. Yard PCB Litig., 35 F.3d at 742 n.8 (3d Cir. 1994), "or whether [the experts] have developed their opinions expressly for the purpose of testifying." Daubert v. Merrell Dow Phams., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) ("Daubert II"). Moreover, additional factors may be appropriate in a given case, and a district court enjoys the same "broad latitude" in deciding what are the "reasonable measures of reliability in a particular case" as it does in reaching its ultimate determination of reliability. Kumho Tire, 526 U.S. at 142, 153.

modification of an otherwise reliable method will not render an expert's opinion per se inadmissible." Amorgianos, 303 F.3d at 267.

In determining reliability, the tendency toward limiting the exclusion of expert testimony "accords with the liberal admissibility standards of the federal rules and recognizes that our adversary system provides the necessary tools for challenging reliable, albeit debatable, expert testimony." Id.; Daubert, 509 U.S. at 596 ("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."). Thus, it is not surprising that "[a] review of the case law after Daubert shows that the rejection of expert testimony is the exception rather than the rule." Advisory Committee Notes, 2000 Amendments, Fed. R. Evid. 702.

In short, the gatekeeping responsibility of the trial court is not to weigh the correctness of an expert's opinion, or to choose between conflicting opinions, or to analyze and study the science in question in order to reach its own conclusions from materials in the field. Ultimately, it is the role of the trial court as gatekeeper to

> ensure the reliability and relevancy of expert testimony. It is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Kumho Tire, 526 U.S. at 152.

B. ***Admissibility of The Study***

Origin argues that the Study is unreliable because: (1) the Study is not supported in the medical literature, (2) the Study has not been and cannot be tested; (3) the Study has not been subjected to peer review and publication; and (4) Dr. Metzger's research methods introduced

substantial sources of error into the Study. In support of its position, Origin offers the testimony of Dr. David Garabrant, who testified that the Study is not reliable because: (1) Dr. Metzger failed to make any effort to determine the statistical significance of her purported finding, that is, whether the results were influenced by random error; (2) Dr. Metzger made no effort to control for bias in the Study; (3) Dr. Metzger made no real attempt to control for the influence of potential confounding factors; (4) the purported findings based on a comparison of the patients on whom tacks and staples were used and those on whom no fastening device was used creates a completely unreliable picture because the average time between surgery and follow up in the first group was significantly longer than the average time between surgery and follow up in the second group.

The court finds merit to most of the criticisms articulated by Dr. Garabrant at the Daubert hearing. See Tr. June 2, 2003 at 153-216; see also Metzger Dep. at 314 (admitting to potential observer bias and potential confounding factors); Tr. June 2, 2003 at 83 (admitting study was not randomized). In addition, the court finds it unnecessary to address Dr. Garabrant's criticisms at this time because, by her own admission, Dr. Metzger described the Study as "a work in progress," "a preliminary draft," and "not complete." See Metzger Dep. at 53; see Tr. July 28, 2003 at 14, 40; Tr. June 2, 2003 at 38-39 (Testifying that, although it was her intention to attempt to put that paper in publishable form, she did not have sufficient time to complete her work). Moreover, Dr. Metzger admitted that she did not rely on the Study in forming her opinions in this case. Tr. July 28, 2003 at 44 (testifying that her "opinions [on causation] were derived before the Study was undertaken"); Expert Report of Dr. Deborah A. Metzger at 1 (noting that her observations "during the course of treating patients in private practice . . . were then confirmed

and quantified in the Study"). Accordingly, the Study will be excluded.

C. *Admissibility of Dr. Metzger's Opinion Testimony*[18]

To satisfy her burden at trial, the parties agree that Ms. Perkins must demonstrate general causation, that is, that the Tacker is capable of causing unforseen post-operative pain in women experiencing chronic pelvic pain, as well as specific causation, that is, that the Tacker did in fact cause her injuries. In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1131 (2d Cir. 1995) (recognizing plaintiff's burden of proving general and specific causation in a products liability toxic tort case); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 958 (3d Cir. 1990) (testimony must be able to support a jury finding both: (i) that the drug can produce birth defects and (ii) that the drug more likely than not caused the birth defects in this particular case); Blanchard v. Eli Lilly & Co., 207 F. Supp. 2d 308, 314 (D. Vt. 2002) (noting that in order to prevail on their claim against drug manufacturer of Prozac, the plaintiffs must prove that Prozac is capable of causing and in fact did cause the deaths at issue).

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[18] It is worth noting, as an initial matter, that Dr. Metzger could testify as a fact witness to her conclusion that the Tacker caused Ms. Perkins' pain. A treating physician can testify as a fact witness about the care and diagnosis rendered as part of a plaintiff's treatment. Santoro, 2002 WL 31059292, at *4. Dr. Metzger reached her opinion/diagnosis that the surgical tacks caused Ms. Perkins' pain as a result of her treatment of the plaintiff, and then relied on that opinion/diagnosis when prescribing the further course of medical treatment. These circumstances dramatically limit concerns about the relevance and reliability of Dr. Metzger's opinion/diagnosis and thus the admissibility of the testimony under Daubert. As gatekeeper, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire, 526 U.S. at 152. Here, Dr. Metzger brings to the courtroom not merely the "same level of intellectual rigor" she employs in her medical practice, she brings opinions that constitute her actual diagnosis of Ms. Perkins, rendered in the course of her medical practice. Unlike a treating physician who is asked at trial to give an opinion beyond the scope of her diagnosis, Dr. Metzger will merely testify about a diagnosis already given during the course of Ms. Perkins' treatment.

1. General Causation

Origin does not challenge Dr. Metzger's qualifications to testify as an expert in chronic pelvic pain or laparoscopy surgery, but instead argues that Dr. Metzger's opinions on causation should be excluded because her reasoning and methodologies are unreliable. I disagree.

Under Daubert and Rule 702, the district court has wide discretion to determine whether the particular circumstances lend themselves to a physician's ability to offer a reliable opinion. Kumho Tire Co., 526 U.S. 137, 150 ("[T]he factors identified in Daubert may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.") (internal quotations omitted); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999) (recognizing that the particular factors that bear on the validity of the expert's testimony will depend upon the unique circumstances of the expert testimony involved). On this point, the Second Circuit's holding in McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2d Cir. 1995), is instructive.

In McCullock, the Second Circuit affirmed the admission of Dr. Fagelson's testimony that fumes from glue caused the plaintiff's throat polyps, despite the physician's inability to cite any medical literature identifying glue fumes as a general casual agent of the plaintiff's injury. McCullock, 61 F.3d at 1043-44; citing Carroll v. Morgan, 17 F.3d 787, 790 (5th Cir. 1994) (holding that a doctor was qualified under Daubert to give an expert opinion on a standard of medical care based on thirty years of experience as a practicing, board-certified cardiologist and his review of the medical records), and Hopkins v. Dow Corning Corp., 33 F.3d 1116, 1125 (9th Cir. 1994) (holding that the district court properly admitted expert testimony under Daubert that was based on, inter alia, the doctor's clinical experience and review of the medical records); see

also Westberry, 178 F.3d at 262 (holding that a reliable differential diagnosis alone provides valid foundation for causation opinion, even when no epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data are offered in support of the opinion); Pipitone v. Biomatrix, Inc., 288 F.3d 239, 245-46 (5th Cir. 2002) (holding that lack of literature on injection-related infections of joint did not undermine expert's hypothesis because trial court could rely on first-hand observations and professional experience to assess expert's reliability); Santoro v. Signature Constr., Inc., 2002 WL 31059292, at *4 (S.D.N.Y. 2002) (recognizing that "treating physicians have routinely been permitted to testify to determinations that they made in the course of providing treatment regarding the cause of an injury and its severity"); Reyes v. Delta Dallas Alpha Corp., 2000 WL 526851, *2 (May 2, 2000) (admitting doctor's expert testimony "based on a number of factors, including his care and treatment of plaintiff, and his own practical experience"); Canino v. HRP, Inc., 105 F. Supp. 2d 21, 31 (N.D.N.Y. 2000) (allowing opinion "based on years of education, training and clinical experience ... [and] specific treatment of plaintiff").

In this case, Dr. Metzger grounds her opinion on a range of factors, including her education, training, extensive clinical experience in treating chronic pelvic pain patients, as well as her care and treatment of Ms. Perkins. Dr. Metzger's knowledge and training are unquestionably impressive; she has had a long and distinguished medical career, which includes prestigious academic positions, extensive publications and a unique expertise in two fields at issue in this case, chronic pelvic pain and laparoscopic surgery.[19] Her practical experience includes

[19] Among her notable credentials, Dr. Metzger: is the founding member and past president of the International Pelvic Pain Society; has been the course director for a OB/GYN course for the American Association of Gynecological Laparoscopists; has been the Chairman of

treating thousands of chronic pelvic pain patients as well as performing numerous tack removal operations. Her methodology, differential diagnosis, is a standard scientific technique of identifying the cause of a medical problem. Martin v. Shell Oil Co., 180 F. Supp. 2d 313, 320 (D. Conn. 2002); McCullock, 61 F.3d at 1044 (describing differential diagnosis as requiring "listing possible causes, then eliminating all causes but one"); In re Paoli, 35 F.3d at 758 (3d Cir. 1994) (noting that differential diagnosis "generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results"); Zwillinger v. Garfield Slope Housing Corp., 1998 WL 623589, *19 (E.D.N.Y. 1998) (explaining that differential diagnosis typically includes a physical examination, clinical tests, and a thorough case history); see also Westberry, 178 F.3d at 262-63; Baker v. Dalkon Shield Claimants Trust, 156 F. 3d 248, 252-53 (1st Cir. 1998); Glaser v. Thompson Med. Co., 32 F.3d 969, 978 (6th Cir. 1994).

Differential diagnosis is a reliable basis to prove general causation in this circuit. Plourde v. Gladstone, 190 F. Supp. 2d 708, 722 (D. Vt. 2002) (citing McCullock, 61 F.3d at 1044) (explaining that "lack of textual authority" on the issue of general causation "go[es] to the weight, not the admissibility" of an expert opinion, when the expert has performed a reliable differential diagnosis); see also Pick v. American Medical Systems Inc., 958 F. Supp. 1151, 1160-63 (E.D. La. 1997) (permitting Dr. Campbell to opine, on the basis of differential diagnosis, that the

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the Committee for Pelvic Pain for the Society for Laparoscopic Surgeons; has held faculty positions at the University of Connecticut, Yale University, and Stanford University; and has submitted numerous articles and papers for peer review publications. In fact, Dr. Metzger was an editor of the first book on chronic pelvic pain, *Chronic Pelvic Pain: An Integrated Approach* (1998). Dr. Metzger is currently an Associate Clinical Professor of OB/GYN at Stanford University, and frequently lectures on chronic pelvic pain at medical seminars.

defendant's product may be responsible for the patient's symptoms because he was able to test his hypothesis by examining a series of individuals, their exposure, or lack thereof to the defendant's product, and their comparative symptoms); compare Hall, 947 F. Supp. at 1414 (noting that "a single differential diagnosis is a scientifically invalid methodology" for the purpose of demonstrating general causation"); In re Breast Plant Litigation, 11 F. Supp. 2d at 1230 (finding expert's conclusion that silicone auto-immune diseases as unreliable in absence of proof that silicone can actually cause the plaintiff's symptoms); Soldo, 244 F. Supp. 2d at 516 (finding expert's opinion, based solely on differential diagnosis, as unreliable because it "ignores the substantial evidence that a discernible cause is never identified with respect to a significant number of strokes, despite careful evaluation"); Cavallo v. Star Enterprise, 892 F. Supp. 756, 771 (E.D. Va. 1995) (disapproving the use of differential diagnosis to prove general causation in a toxic tort case because "a fundamental assumption underlying this method is that the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury"), aff'd in relevant part, rev'd in part, 100 F. 3d 1150, 1159 (4th Cir. 1996), cert. denied, 522 U.S. 1044 (1998).

In addition, Dr. Metzger's experience is particularly unique in a products liability context because she generally has had the opportunity to observe her patients, prior to the insertion of the surgical tacks, during the time the fixation devices were in place, and after the tacks had been removed. As such, she was able to observe a strong temporal relationship not just between the defendant's product and the onset of symptoms, see Canino, 105 F. Supp. 2d at 29-30 (admitting expert opinion that relies, in part, on "the temporal proximity between the ... incident and plaintiff's onset of [the disease]"), but also between removal of the defendant's product and the

disappearance of symptoms. See Heller, 167 F. 3d at 157 (dismissing experts' medical causation opinion, in part, because "[n]ot only did Heller's symptoms not appear until at least one or two weeks after the Shaw carpeting was installed, but they remained after the carpet was removed in May 1994"); Wooley v. Smith & Nephew Richards, Inc., 67 F. Supp. 2d 703 (S.D. Tx. 1999) (excluding physician's opinion in part because the doctor could "not point out any symptoms occurring after the pedicle screw surgery that did not also exist before the surgery"); compare Blanchard v. Eli Lilly & Co., 207 F. Supp. 2d at 320 (D. Vt. 2002) (excluding Dr. Maltsberger's opinion, on the basis of his clinical experience, regarding a casual relationship between Prozac and suicidal tendencies, because, among other things, the doctor had no direct clinical experience with patients who have experienced newly emergent suicidal thoughts, attempted or committed suicide or become violent while taking Prozac).

Another factor favoring admissibility is the fact that Dr. Metzger's opinions were not developed for purposes of litigation, but instead were developed "naturally and directly out of [work she] conducted independent of the litigation." Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (noting that "the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method'"); Prohaska, 138 F. Supp. 2d at 437 (noting that "[l]itigation-driven expertise has been found to be a negative factor in admissibility"). Dr. Metzger developed her opinion during the course of her medical practice. In fact, she brought her concerns regarding the use of the Tacker directly to Origin and to the Food and Drug Administration. In addition, Dr. Metzger has also presented her opinions at medical seminars to other physicians. See Cabrera v. Cordis Corp., 134 F.3d 1418,

1420-21 (9th Cir. 1998).

In support of its motion to exclude, Origin argues that "[n]o other physician or researcher has published so much as a letter to the editor supporting Dr. Metzger's position on this issue. Despite what Plaintiffs argue about Dr. Metzger's qualifications and experience, this is clearly a case where an expert is offering a novel theory and citing her own incomplete studies in support of it." See Def. Brief dated June 18, 2003. These contentions are rejected.

First, as the Second Circuit stated in McCullock, the "lack of textual authority" on the issue of general causation "go[es] to the weight, not the admissibility" of an expert opinion, when the expert has performed a reliable differential diagnosis." McCullock, 61 F.3d at 1044.

> In the actual practice of medicine, physicians do not wait for conclusive, or even published and peer-reviewed, studies to make diagnoses to a reasonable degree of medical certainty. Such studies of course help them to make various diagnoses or to rule out prior diagnoses that the studies call into question. However, experience with hundreds of patients, discussions with peers, attendance at conferences and seminars, detailed review of a patient's family, personal, and medical histories, and thorough physical examinations are the tools of the trade, and should suffice for the making of a differential diagnosis even in those cases in which peer-reviewed studies do not exist to confirm the diagnosis of the physician.

Heller, 167 F.3d at 155.

Second, Dr. Metzger is not basing her opinion on incomplete studies. Although her Study is admittedly incomplete, Dr. Metzger formed her opinions prior to developing the Report. Tr. July 28, 2003 at 44 (testifying that her "opinions [on causation] were derived before the study was undertaken").

Third, both Dr. Anthony Luciano,[20] who became Ms. Perkins' OB-GYN when Dr. Metzger moved from Connecticut to California, and Dr. Terrence Donahue,[21] a doctor Ms. Perkins saw on a referral from Dr. Luciano, stated in their depositions that surgical tacks are

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[20] At his deposition Dr. Luciano testified, in relevant part, as follows:

> ATTY WILLCUTTS: As you sit here today, do you have an opinion as to the cause of Ms. Perkins' pelvic pain?
>
> DR. LUCIANO: Well, it certainly wasn't related to any gynecologic diseases that she had. I don't believe that the adhesions that she had and the endometriosis she might have had, which was not confirmed, contributed to that. Why? Becayse the multiple laparoscopic procedures that she had by gynecologists, including myself, never really relieved her of her symptoms. That is the reason why I asked for help of another specialist who may look more deeply in non-gynecologic areas, which they did. So it is really a diagnosis of exclusion from my perspective; i.e., I excluded I believe, pelvic, significant pelvic pathology, and the general surgeon, Dr. Donahue, seemed to focus on the source, as he treated the source, the pain got better....
>
> ATTY WILLCUTTS: Can you say within a reasonable degree of medical certainty, and by that I mean more probable than not, what caused Ms. Perkins' pain?
>
> DR. LUCIANO: I believe that the staples or the tacks certainly might have contributed to her groin pain, since it seemed to be so well localized and it appears that once the tack was removed, the pain improved. That is most probably the cause . . . .

Luciano Dep. Nov. 13, 2000 at 40-41.

[21] In his deposition, Dr. Donahue testified that post-operative pain is a "known complication of hernia repair surgery" in which tacks are used. Donahue Dep. Dec. 22, 2000 at 65. Dr. Donahue testified that "[t]acks could cause pain by irritating or injuring a nerve, primarily." Id. at 71. Dr. Donahue also wrote a letter to Attorney Willcutts stating in pertinent part: "Ms. Perkins did well from this [tack removal] surgery I performed on her on 02/07/00. I found two tacks which I believe are the last two tacks in her. From what I understand, she had had relief of the pain since that time. Given the history of her pain, the fact the she has significantly improved after removal of the tacks, and Dr. Metzger's letter on the subject, I think it is safe to say that Ms. Perkins' symptoms were being caused by the Origin tacks." See Pl. Brief dated June 1, 2003 Brief, Ex. D

capable of causing post-operative localized pain. See Pl. Brief dated June 1, 2003, Exs. B, C; see also Ex. G, Deposition of Dr. Michael Zinaman, dated March 31, 2003 (not refuting the contention that tacks could case pain); see also Ex. F, Deposition of Dr. Albert Chin, dated April 8, 2003 (stating that it "certainly may be the case" that individuals with chronic pelvic pain "might be more sensitive to pain stimuli than the general population"). In addition, the plaintiffs have included medical abstracts indicating that, at a minimum, a controversy exists in the medical community about the necessity of fixation devices in hernia repair surgeries. See id., Ex. E.

Origin argues next that Dr. Metzger's opinion is not reliably based on her application of differential diagnosis.[22] Origin's arguments are rejected in light of McCullock, 61 F.3d at 1044 ("Disputes as to the ... faults in [the expert's] use of differential etiology as a methodology ... go to the weight, not the admissibility, of [the expert's] testimony."); (citing Daubert 509 U.S. at 596 ("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."); see also Golod v. La Roche, 964 F. Supp. 841, 858 (S.D.N.Y. 1997) ("The fact that these physicians are unable to describe the mechanism by which Tegison caused its adverse

[22] Origin claims that "Dr. Metzger has taken her position in spite of the following facts: (1) She cannot identify with a reasonable degree of medical certainty the mechanism by which tacks cause pain in a woman with chronic pelvic pain; (2) in her first procedure in November 1996 to remove tacks from the Plaintiff she admits she concentrated on removing all offending tacks and in fact removed seven, but that plaintiff's pain persisted; (3) during her treatment of plaintiff, apart from the tacks, she variously identified the Plaintiff's pain as stemming from her ovaries, urinary tract infections, pelvic congestion, plaintiff's menstrual cycle, possible endometriosis, breakthrough bleeding, and, of course, hernias; (4) a second procedure was performed to remove tacks in December 1997, but the plaintiff's pain persisted; (5) a third procedure was performed by Dr. Metzger to remove more tacks in August 1998, but still the plaintiff's pain continued." See Def. Brief dated June 18, 2003.

effects is irrelevant. The mechanisms of both therapeutic and toxic effects of drugs are often unknown. ... Just as the mechanism of efficacy need not be known to support a claim that Tegison causes abatement of dermatological symptoms, so the mechanism of toxicity need not be known to support an inference of causation based on accepted clinical methods of diagnosis.").

Origin also argues that if the Study is unreliable then Dr. Metzger's clinical experience based on her Study must also be unreliable. Stated otherwise, Origin is arguing that Dr. Metzger's opinion based on her clinical experience cannot reasonably be separated from the data unreliably compiled in the Study. I disagree.

First, the record is clear that the Study is only a preliminary collection of data, taken on a fraction of her patients. As such, eliminating Dr. Metzger's opinion based on her Study should have no effect on her opinion based on her years of clinical experience. Second, were the court to accept Origin's contention that Dr. Metzger is precluded from testifying because her Study is inadmissible, then the court would be in the precarious situation of permitting testimony from doctors who do not take the initiative to summarize their clinical experience, yet precluding testimony from doctors who take the initiative to analyze their work but who have not yet completed their studies. As such, the court would be required to preclude experienced physicians from offering opinions in the time period between the commencement of a study and the completion of the study. "To so hold," the Third Circuit noted in Heller, "would doom from the outset all cases in which the state of research on the specific ailment or causal agent was in its early stages, and would effectively resurrect a Frye-like bright-line standard, not by requiring that a methodology be 'generally accepted,' but by excluding expert testimony not backed by published (and presumably peer-reviewed studies)." Heller, 167 F.3d at 155.

Accordingly, Dr. Metzger's experience, knowledge and training, taken together with the clinical process she followed, which disclosed a correlation between placement of tacks and her patient's pain, satisfies the Daubert threshold of reliability. Dr. Metzger's opinion is therefore admitted to prove general causation.

2. Specific Causation

On the basis of differential diagnosis, Dr. Metzger is prepared to testify that the use of the Tacker in Ms. Perkins' hernia repairs caused Ms Perkins to suffer pain that could not be effectively treated with local anesthetic injections or other methods, such that she needed to have the implanted tacks removed in order to obtain relief. Origin does not dispute that Dr. Metzger's methodology of differential diagnosis qualifies as a reliable methodology to determine the specific cause of Ms. Perkins' pain. Tr. June 19, 2003 at 15. Rather, Origin argues that, because Dr. Metzger did not reliably apply the methodology to Ms. Perkins, her proffered opinion testimony on specific causation should be excluded. See id. at 13.

When determining the specific source of an individual patient's pain, differential diagnosis requires the expert to "take serious account of other potential causes" of the condition. Baker, 2003 WL 22439730, *2 n.3; Westberry, 178 F.3d at 265; Turner v. Iowa Fire Equipment Co., 229 F.3d 1202, 1207 (8th Cir. 2000). Although an expert is not required to eliminate every potential cause in order for his or her opinion to be admissible under Daubert, the expert is required to employ either standard diagnostic techniques to eliminate obvious alternative causes or, if the defendant suggests some likely alternative cause of the plaintiff's condition, the expert is required to offer a reasonable explanation why he or she still believes that the defendant's action or product

was a substantial factor in bringing about the plaintiff's condition. Munafo v. Metro. Transp. Auth., 2003 WL 21799913, *18 (E.D.N.Y. 2003); Paoli, 35 F.3d 717 at 760; see also Baker, 2003 WL 22439730 *2, n.3; Turner, 229 F.3d at 1209; Kannankeril v. Terminix Int'l., Inc., 128 F.3d 802, 808 (3d Cir. 1997). A strong temporal relationship between the patient's symptoms and exposure to the defendant's product can certainly assist a physician in offering a reasonable explanation. See Heller, 167 F.3d at 158 (noting that "when the temporal relationship is strong and is part of a standardized differential diagnosis, it would fulfill many of the Daubert [] factors."). Moreover, the court affords great weight to the testimony of treating physicians. Poust v. Huntleigh Healthcare, 998 F. Supp. 478, 496 (D. N.J. 1998) (citing Sprague v. Bowen, 812 F.2d 1226, 1230 (9th Cir. 1987) ("The rationale for giving greater weight to a treating physician's opinion is that he is employed to cure and has a greater opportunity to know and observe the patient as an individual.").

Origin criticizes Dr. Metzger for failing to account for physical or sexual abuse as a cause of chronic pelvic pain. In response to this criticism, Dr. Metzger testified that, although it is helpful to be aware of a patient's history of physical or sexual abuse, such information is only of limited potential use because approximately 25% of her patients report incidents of childhood sexual abuse, which Dr. Metzger believes is about the incidence of childhood sexual abuse in the general population. Tr. June 2, 2003 at 143. She also testified that it is not her practice to rely solely on such information if there are other obvious causes of the pain. In Ms. Perkins' case, the implanted tacks were a more obvious cause of Ms. Perkins' pain. Dr. Metzger formed her opinion on the basis of her: clinical experience in recognizing a correlation between tacks and localized post-operative pain; Ms. Perkins' description of pain similar to her other patients in which the

tacks were the source of the pain; conducting a thorough physical exam in which she eliminated other potential sources of her pain; reproducing Ms. Perkins' pain by palpating the tacks; providing Ms. Perkins temporary-decreasing relief through local anesthetics, and providing her permanent relief by removing the tacks.

In this case, there is no doubt that Dr. Metzger's performed a sufficiently reliable differential diagnosis to permit her to testify as an expert. See Sita v. Danek Medical, Inc., 43 F. Supp. 2d 245, 255 (E.D.N.Y. 1999) (permitting expert testimony, despite characterizing the doctor's credibility and reliability of the conclusions he reaches in his report as "highly suspect," because "[i]t is not outside the scope of reason and common sense to conclude that when a medical device fractures inside of a patient roughly contemporaneously with the time that the patient starts to complain of pain in the relevant area, that fracture might well be a substantial factor in causing that pain"); see also Heller, 167 F. 3d at 158 (noting that "[h]ad the Hellers experienced a prompt reaction at the time the Shaw carpeting was installed in mid-December 1993, and had they suffered no reaction upon return to their home after the Shaw carpet was removed in May 1994, this would be the type of temporal relationship that might reliably support a conclusion that the carpet was the cause of plaintiff's illness"). Moreover, any "[d]isputes as to the strength of ... [her] use of differential etiology as a methodology ... go to the weight, not the admissibility, of [her] testimony." McCullock, 61 F.3d at 1044; Baker, 2003 WL 22439730 *2, n.4.

In addition, Dr. Metzger testified that her opinion about the source of Ms. Perkins' pain would not have changed even if she knew that her patient had experienced prior sexual or physical abuse. Accordingly, even if the court accepts Origin's proposition that Dr. Metzger's analysis is

flawed due to her failure to consider her patient's history of physical or sexual abuse, that flaw is not substantial enough that she lacks "good grounds" for her diagnosis. See Amorgianos, 303 F.3d at 267. Moreover, her failure to consider Ms. Perkins' history of physical or sexual abuse before forming an opinion on causation affects the weight of her testimony, not its admissibility. McCullock, 61 F.3d at 1044 ("Disputes as to the strength of his credentials, faults in his use of differential etiology as a methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony."); Baker, 2003 WL 22439730 *2, n.4.

Therefore, Origin's motion to preclude Dr. Metzger's testimony about specific causation is denied because Dr. Metzger, as Ms. Perkins' treating physician, reasonably applied differential diagnosis and has provided a reasonable explanation for why she did not consider the defendant's suggested alternative source of pain. Under these circumstances, Dr. Metzger's Opinion will not be excluded as unreliable.

III. CONCLUSION

For the foregoing reasons, Origin's motion to exclude the Study (doc. # 48-1) is GRANTED and it's motion to preclude the proffered opinion testimony of Dr. Metzger (doc. # 48-1) is DENIED.

It is so ordered.

Dated at Bridgeport, Connecticut this 14th day of January 2004.

/s/ Stefan R. Underhill
Stefan R. Underhill
United States District Judge