CHALLENGING ADMISSIBILITY OF POST-TRAUMATIC FIBROMYALGIA AND FUTURE RADIOFREQUENCY FACET JOINT DENERVATION CLAIMS[†]

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I.
INTRODUCTION

Plaintiffs who complain of aches and pains throughout their bodies despite any objective findings to account for those aches and pains often claim to be suffering from post-traumatic fibromyalgia. The medical bills and lost wages mount, plaintiffs advance complaints of life-altering symptoms, and what should have been a minor soft-tissue claim becomes a six-figure demand. Since 1990, fibromyalgia has been an accepted diagnosis as defined by the American College of Rheumatology, and often the defense of a fibromyalgia case rests on the issue of whether a plaintiff's complaints meet diagnostic criteria. Unless the sword of the plaintiff's diagnosis breaks, the shield of misdiagnosis does not offer much protection. Recently, however, courts have been more closely scrutinizing the underlying proposition that fibromyalgia can be caused by trauma. The shield becomes the sword when the plaintiff's diagnosis of fibromyalgia is found not to be caused by trauma. The defendant is then free to argue that the plaintiff's fibromyalgia, not the accident, is the cause of the complaints.

Equally familiar to the defense bar is the whiplash injury, which can also involve imposing medical costs when treated using radiofrequency facet neurotomy. Also known as cervical zygapophysial or z-joints, the facet joint is theoretically injured as a result of compression forces in a whiplash accident. Once isolated as a cause of a plaintiff's complaint, one method of treatment is through denervation of the joint by neurotomy. The use of radiofrequency thermoneurolysis is a relatively uninvasive procedure to accomplish denervation. In some cases, the plaintiff will experience complete or near complete pain relief having undergone one round of radiofrequency facet neurotomy, but will nonetheless argue to the jury that repeat treatments are necessary, usually on a yearly or eighteen-month schedule, for the rest of the plaintiff's life. The future medical exposure of this treatment plan can be significant and well out of proportion to the typical soft-tissue injury. Although scientific literature has begun to describe a moderate success rate for this procedure, courts have not recognized any generally accepted scientific support for the contention that it must be repeated regularly, for the remainder of the plaintiff's life.

This article addresses the status of the scientific literature concerning "post-traumatic fibromyalgia" and the treatment of whiplash injury with radiofrequency facet neurotomy and proposes strategies for defending claims involving these topics under both the *Daubert* and *Frye* standards.

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II.
STANDARDS FOR ADMISSIBILITY OF EXPERT TESTIMONY: *DAUBERT* AND *FRYE*

In federal court, an expert may be precluded from offering opinions that are not founded on a reliable methodology based on the principles set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[1] Federal Rule of Evidence 702 provides the standard for admitting expert scientific testimony in federal court. Rule 702 states that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto."[2] The *Daubert* Court interpreted the terms "scientific" in Rule 702 as implying "grounding in the methods and procedures of science," and "knowledge" as connoting "more than subjective belief or unsupported speculation."[3] Thus, "in order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—i.e., 'good grounds,' based on what is known."[4]

The factors a trial judge may consider in deciding whether the expert testimony is based on scientific knowledge include whether the theory forming the basis of the testimony: (1) can and has been tested; (2) has been subjected to peer review and publication; (3) has a low known or potential rate of error; and (4) is generally accepted within the relevant scientific community.[5]

The federal courts frequently apply *Daubert* to exclude unreliable or irrelevant expert medical testimony.[6] In addition, many state supreme courts have adopted the *Daubert* standard.[7]

Other state courts continue to use the test established in *Frye v. United States*.[8] While *Daubert* treats general acceptance as merely a factor to be considered in determining the testimony's reliability, *Frye requires* that the scientific principle or theory from which the testimony is derived have general acceptance in the relevant scientific community.[9]

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[1] 509 U.S. 579 (1993).
[2] FED. R. EVID. 702 (2009).
[3] 509 U.S. at 590.
[4] *Id.*
[5] *Id.* at 593–94; s*ee also* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999) (holding that *Daubert* applies to all expert testimony, not just scientific testimony and that the objective of *Daubert*'s "gatekeeping requirement" is to "ensure the reliability and relevancy of expert testimony").
[6] *See, e.g.*, Glastetter v. Novartis Pharm. Corp., 252 F.3d 986, 991 (8th Cir. 2001) (affirming exclusion of testimony that drug caused the plaintiff's stroke because expert witnesses lacked scientifically persuasive evidence); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1313 (11th Cir. 1999) (affirming exclusion of expert testimony that silicone implants caused the plaintiff's systemic conditions because the expert's testimony lacked an adequate foundation, and the correlation of the animal study was not effectively explained); Heller v. Shaw Indus., Inc., 167 F.3d 146, 164–65 (3d Cir. 1999) (affirming exclusion of expert testimony that volatile organic compounds emitted by carpet in the plaintiff's home caused her respiratory illness, citing lack of supporting studies).
[7] *See* David E. Bernstein & Jeffrey D. Jackson, *The* Daubert *Trilogy in the States*, 44 JURIMETRICS J. 351, 357–61 (2004) (reporting that at least twenty-one states have adopted *Daubert*'s reasoning).
[8] *Id*; 293 F. 1013 (D.C. Cir. 1923).
[9] *Frye*, 293 F. at 1014 ("[W]hile courts go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs"); *see* Grant v. Boccia, 137 P.3d 20, 22 (Wash. Ct. App. 2006); Goeb v. Tharaldson, 615 N.W.2d 800, 810 (Minn. 2000).

III.
EXCLUDING POST-TRAUMATIC FIBROMYALGIA CLAIMS

A. *Fibromyalgia Overview*

Fibromyalgia is defined as "a form of nonarticular rheumatism characterized by musculoskeletal pain, spasms, stiffness, fatigue, and severe sleep disturbance."[10] It is a syndrome of "widespread pain, decreased pain threshold, and [other] characteristic symptoms."[11]

These "other symptoms" include chronic soft-tissue neck and back muscle pain that is aching, throbbing, or burning in nature, usually accompanied by neck, spine, shoulder, or hip stiffness.[12] Fibromyalgia patients may also experience undue fatigue, insomnia, joint pain, headaches, chest pains, jerking leg movements, leg cramps, numbness and tingling in various body parts, dizziness, and irritable bowel symptoms.[13] Fibromyalgia is difficult to diagnose, as no tests or set of symptoms indicate with certainty that an individual has fibromyalgia.[14] Prior to 1990, various assessment criteria had been developed based on "only pain and tenderness, pain, tenderness, sleep disturbance, fatigue and stiffness, . . . and a larger number of characteristic symptoms."[15] In 1990, the American College of Rheumatology (ACR) developed the following list of diagnostic criteria for fibromyalgia:

1. Widespread pain on both sides of the body and above and below the waist;
2. Axial skeletal pain located in the cervical or thoracic spine, the anterior chest, or the lower back; and
3. Pain ("not merely 'tenderness'") at eleven or more of eighteen trigger point sites that include either side of:
    a. "the occiput, or back of the skull where the suboccipital muscles insert;"
    b. "the back of the lower part of the neck (cervical region);"
    c. "the upper border of the trapezius, a triangular muscle of the shoulder and lower back;"
    d. "the supraspinatus muscle, above the spine of the bony scapula in the upper back;"
    e. "the second rib near where it joins the breastbone;"
    f. "just above the elbow joint (the site of 'tennis elbow');"
    g. "the upper outer parts of the buttocks;"
    h. "the upper part of the thigh bone; and"
    i. "the inner side of the knee."[16]

The ACR standard has become the *de facto* standard for diagnostic classification for fibromyalgia.[17] The trigger points described above are points on the body where finger pressure

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[10] MOSBY'S MEDICAL, NURSING & ALLIED HEALTH DICTIONARY 734 (7th ed. 2006).
[11] Frederick Wolfe, *The Fibromyalgia Syndrome: A Consensus Report on Fibromyalgia and Disability*, 23 J. RHEUMATOLOGY 534, 534 (1996) (hereinafter "*The Consensus Report*").
[12] ROSCOE N. GRAY & LOUISE J. GORDY, ATTORNEYS' TEXTBOOK OF MEDICINE ¶¶ 25.01, 25.31, 25.34, 25.52.
[13] *Id.* ¶¶ 25.31, 25.35.
[14] *Id.* ¶ 25.30.
[15] *The Consensus Report*, *supra* note 11, at 534.
[16] GRAY & GORDY, *supra* note 12, at ¶ 25.34.

immediately causes pain.[18] Pain is scored as present or absent, not on the basis of severity.[19] Other than these trigger points, however, patients with fibromyalgia often have a negative physical examination.[20] Further, many conditions and disorders share several symptoms that are the same as those related to fibromyalgia, making it extremely difficult to distinguish among them.[21]

While most doctors agree that fibromyalgia exists as a legitimate diagnosis, medical experts have not reached a consensus as to the cause of fibromyalgia. Researchers have proposed several theories about what causes fibromyalgia, including hormonal abnormalities, genetics, microtrauma (minor, but repeated muscle injuries), and hypertonic muscles (resulting from abnormal posture, which causes muscles to be in a constant contracting state).[22] Within the scientific community, experts have recognized the evidence that trauma actually causes fibromyalgia is "insufficient to establish causal relationships."[23] In fact, the *Consensus Report*'s first recommendation was to "[e]liminate the terms 'reactive' and 'post-traumatic fibromyalgia.'"[24] "To date, the arguments both for and against a causal role of trauma in [fibromyalgia] are weak."[25]

B. *Seminal Fifth Circuit Cases Excluding Post-Traumatic Fibromyalgia Claims Under* Daubert

In 1999, the United States Court of Appeals for the Fifth Circuit described fibromyalgia syndrome as "an elusive but debilitating affliction," before analyzing the admissibility of an expert's testimony that the plaintiff's slip-and-fall in a grocery store caused her fibromyalgia.[26] The court, exercising its independent gatekeeping function, examined the "scientific literature" on causes of fibromyalgia and held that the expert's theory "[had] failed to gain acceptance within the medical profession."[27] Examining the four *Daubert* factors, the court concluded that "[w]hile the medical profession has made significant advances in the diagnosis and treatment of fibromyalgia, experts have recognized that the evidence that trauma actually causes fibromyalgia is 'insufficient to establish causal relationships.'"[28] The evidence presented at trial demonstrated that the theory that trauma causes fibromyalgia had not "been verified by testing and, thus, [had] not been peer reviewed."[29] In addition, the "theory of causation, which has not been verified or generally accepted, also has no known potential rate of error."[30] The materials submitted to the court did not satisfy the *Daubert* factors or any other standard of reliability.[31]

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[17] *The Consensus Report*, *supra* note 11, at 534.
[18] GRAY & GORDY, *supra* note 12, ¶ 25.30.
[19] *The Consensus Report*, *supra* note 11, at 534.
[20] GRAY & GORDY, *supra* note 12, ¶ 25.33.
[21] *Id.* ¶ 25.37.
[22] *Id.* ¶¶ 25.23–25.27.
[23] *The Consensus Report*, *supra* note 11, at 534.
[24] *Id.* at 537.
[25] Kevin P. White et al., *Perspectives on Posttraumatic Fibromyalgia: A Random Survey of Canadian General Practitioners, Orthopedists, Physiatrists, and Rheumatologists*, 27 J. RHEUMATOLOGY 790, 794 (2000).
[26] *Black v. Food Lion, Inc.*, 171 F.3d 308, 309 (5th Cir. 1999).
[27] *Id.* at 313.
[28] *Id.* at 312 (quoting *The Consensus Report*, *supra* note 11, at 534).
[29] *Id.* at 313.
[30] *Id.*
[31] *Id.*

In Vargas v. Lee, [32] the Fifth Circuit revisited the issue of whether substantial evidence exists regarding the theory that trauma causes fibromyalgia.[33] Specifically, the court analyzed the question of whether scientific understanding of fibromyalgia syndrome had progressed sufficiently since *Black* to permit the admission of the plaintiff's expert testimony that an automobile accident caused the plaintiff to develop symptoms of fibromyalgia.[34] The *Vargas* plaintiff produced only two studies that he claimed indicated that medical science has determined with reliability that trauma causes fibromyalgia.[35] The *Vargas* court quickly pointed out that the more recent of the two studies "expressly disavowed" that conclusion, citing the following language from the study:

> "We emphasize . . . that our study was merely a survey of physician opinions about the association between trauma and [fibromyalgia]; whether these opinions are valid needs to be determined by further study within cohorts of individuals with [fibromyalgia]. *To date, the arguments both for and against a causal role of trauma in [fibromyalgia] are weak.*"[36]

The second study, published in 1997, "examined the incidence of fibromyalgia syndrome in a group of Israeli patients who had suffered injuries to the neck and the lower extremities" ("the Israeli study").[37] Patients participating in the study had either sustained a leg fracture or a neck injury.[38] Fibromyalgia was diagnosed in 16% of those with neck injuries and in 1.7% of control patients with leg fractures.[39] The *Vargas* court pointed out that although the study "stated that 'trauma may cause [fibromyalgia],' it also acknowledged that '[t]he present data in the literature are insufficient to indicate whether causal relationships exist between trauma and [fibromyalgia].'"[40]

In a footnote, the *Vargas* court addressed two "opinion pieces" the plaintiff produced. The court found that although the first article,[41] an editorial, was "possibly relevant to *Daubert's* general acceptance factor," a "statement of opinion is insufficient, by itself, to establish the reliability of [an expert's] testimony."[42] The court discounted the second piece[43] because (1) the plaintiff failed to produce the study itself; (2) the findings were based on patients' own attribution of chronic pain to some form of trauma; and (3) many of the study's participants did not even satisfy the criteria for fibromyalgia.[44] The court concluded that based on the evidence

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[32] 317 F.3d 498, 502 (5th Cir. 2003).
[33] *See generally id.*
[34] *Id.* at 501.
[35] *Id.*
[36] *Id.* at 502 (quoting White et al., *supra* note 25, at 794) (emphasis added).
[37] *Id.* (citing Dan Buskila et al., *Increased Rates of Fibromyalgia Following Cervical Spine Injury*, 40 ARTHRITIS & RHEUMATISM 446 (1997)).
[38] Buskila et al., *supra* note 37, at 446.
[39] *Id.*
[40] *Vargas*, 317 F.3d at 502 (quoting Buskila, et al., *supra* note 37, at 451).
[41] Robert M. Bennett, *Disabling Fibromyalgia: Appearance versus Reality*, 20 J. RHEUMATOLOGY 1821, 1821 (1993).
[42] Vargas v. Lee, 317 F.3d 498, 502 n.5 (5th Cir. 2003).
[43] *See generally* David A. Fishbain & Hubert L. Rosomoff, *Posttraumatic Fibromyalgia at Pain Facilities Versus Rheumatologists' Offices: A Commentary*, 77 AM. J. PHYSICAL MED. & REHAB. 562 (1998).
[44] *Vargas*, 317 F.3d at 502 n.5.

properly before it, "[t]hese studies only bolster[ed] [its] conclusion in *Black* that expert testimony on the causation of fibromyalgia syndrome by trauma is not sufficiently reliable to be admitted under Rule 702."[45] The court continued, stating that it did not, however, "purport to hold that trauma does not cause fibromyalgia syndrome or that the admission of expert testimony on that subject is permanently foreclosed. Medical science may someday determine with sufficient reliability that such a causal relationship exists."[46]

C. *Scientific Research Regarding Post-Traumatic Fibromyalgia Theory*

Since the publication of the studies relied upon by the plaintiff in *Vargas*, the most recent of which was published in 2000, no new studies have established a connection between trauma and fibromyalgia to any degree of reasonable certainty. In 2006, Moshe Tishler and his colleagues published the results of the first prospective study addressing the occurrence of fibromyalgia after motor vehicle accidents.[47] The study identified 153 subjects who sustained whiplash injury in motor vehicle accidents and who were enrolled in the study 3.5–9.5 hours after injury.[48] The subjects were followed for a mean of 14.5 months.[49]

During the study period, only one patient out of the 153 patients in the study group developed fibromyalgia.[50] The researchers concluded that "whiplash injury and road accident trauma were not associated with an increased rate of [fibromyalgia] after more than 14.5 months of followup."[51] The authors concluded that "the results of [their] prospective study d[id] not support earlier observations about a link between neck trauma and [fibromyalgia]. Because of its wide medicolegal implications, well controlled multinational studies with large cohorts of patients are needed to resolve this complex issue."[52]

In 2002, a retrospective case study of the relationship between trauma and fibromyalgia was published.[53] That study involved 288 subjects: 136 fibromyalgia patients, and 152 control patients.[54] The results of the study "suggest that physical trauma was significantly associated with the onset of [fibromyalgia]," as 39% of the fibromyalgia patients had a history of trauma in the preceding six months compared with only 24% of the controls.[55] The study alone, however, does not provide the basis for finding that reliable evidence exists linking trauma to fibromyalgia. The authors acknowledged that their results were

> retrospective and may [have] be[en] influenced by recall bias, but [indicated that] if they are confirmed in a prospective study this would lead [the authors] to speculate on the mechanisms by which trauma might precipitate [fibromyalgia]. It is still not clear why

[45] *Id.* at 502.
[46] *Id.* at 503.
[47] *See* Moshe Tishler et al., *Neck Injury and Fibromyalgia—Are They Really Associated?*, 33 J. RHEUMATOLOGY 1183, 1183–85 (2006).
[48] *Id.* at 1183.
[49] *Id.* at 1185.
[50] *Id.*
[51] *Id.* at 1183.
[52] *Id.* at 1185.
[53] *See generally* A.W. Al-Allaf et al., *A Case-Control Study Examining the Role of Physical Trauma in the Onset of Fibromyalgia Syndrome*, 41 RHEUMATOLOGY 450 (2002).
[54] *Id.* at 451.
[55] *ld.* at 452.

> major trauma is not associated with any sequelae in most individuals, while others develop or experience exacerbated symptoms leading to specific disease. . . . *Further prospective studies are needed to confirm this association and to determine whether trauma has a causal role or if there are more important factors in the development of [fibromyalgia].*[56]

In August 2001, Drs. Daniel Wallace and David Hallegua published an article discussing quality of life, legal, financial, and disability issues in fibromyalgia.[57] Among the legal issues examined was whether "fibromyalgia [is] caused or flared by emotional stress or physical trauma."[58] The authors noted that "well-designed studies addressing [the relationship between fibromyalgia and physical trauma] have been few in number."[59] Review of a patient's medical history "would show that 90% of the time, myofascial or [fibromyalgia]-associated complaints were present prior to the injury."[60] The authors concluded that fibromyalgia can be "caused or flared" by trauma; however, their opinion is based on their analysis of the Israeli study, which has been discussed and discredited by the Fifth Circuit in *Vargas* and by numerous published experts.[61]

In 2001, Kevin White assisted in authoring an article regarding trauma and fibromyalgia.[62] In the article, the authors discussed whether trauma is a causative factor for fibromyalgia. They concluded that although the Israeli study provided some evidence of a relationship between trauma and fibromyalgia, "further studies are required to verify these results, and to assess the effect of other forms of trauma on [fibromyalgia] incidence. Moreover, the authors concluded that it is possible that factors other than the trauma itself, such as the injured individual's pre-accident level of health, may have important causative roles."[63]

Finally, two articles that were published in 2000 but were not cited in *Vargas* provide no additional support for the proposition that fibromyalgia is caused by trauma.[64] The authors of the first article noted that "there is limited evidence either to support *or* refute an association between trauma and [fibromyalgia]."[65] The article points to the Israeli study as the strongest evidence supporting an association between trauma and fibromyalgia.[66] However, not only did the Israeli study fail to satisfy the Fifth Circuit for *Daubert* purposes, the authors of the *Trauma and Fibromyalgia* article criticized it for its inability to capture all neck injuries and inherent bias

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[56] *Id.* at 453 (emphasis added).
[57] *See generally* Daniel J. Wallace & David S. Hallegua, *Quality-of-Life, Legal-Financial, and Disability Issues in Fibromyalgia*, 5 CURRENT PAIN & HEADACHE REPORTS 313 (2001).
[58] *Id.* at 315.
[59] *Id.*
[60] *Id.* at 316.
[61] *Id.* at 316, 318; Vargas v. Lee, 317 F.3d 498, 502 (5th Cir. 2003).
[62] *See generally* Kevin P. White & Manfred Harth, *Classification, Epidemiology, and Natural History of Fibromyalgia*, 5 CURRENT PAIN & HEADACHE REPORTS 320 (2001).
[63] *Id.* at 326.
[64] *See generally* Kevin P. White et al., *Trauma and Fibromyalgia: Is There an Association and What Does it Mean?*, 29 SEMIN. ARTHRITIS & RHEUMATISM 200 (2000); Gregory C. Gardner, *Fibromyalgia Following Trauma: Psychology or Biology?*, 4 CURRENT REVIEW OF PAIN 295, 298 (2000) (examining literature published on the subject to date, and concluding that "[t]he current state of the literature does not allow the conclusion that trauma and fibromyalgia are causally associated").
[65] White et al., *supra* note 68, at 201 (emphasis added).
[66] *Id.* at 203.

in diagnosing fibromyalgia in patients with neck injuries, since ten of the eighteen fibromyalgia tender points are in the neck and shoulder area.[67] The article examined four arguments against an association between trauma and fibromyalgia: "(1) [fibromyalgia] does not exist; (2) [fibromyalgia] is a psychological, rather than physical, disease; (3) there is inadequate proof of any association between trauma and [fibromyalgia]; and (4) other factors more important than the injurious event in determining chronic symptoms after an acute injury."[68] The article concluded that further prospective studies are needed to confirm any association between trauma and fibromyalgia and to identify whether trauma has a causal role.[69]

Thus, since the *Vargas* decision, the body of scientific knowledge regarding the cause of fibromyalgia has not grown. Despite evidence of debate in the scientific community, no advances have been made in determining whether fibromyalgia is caused by trauma, as no conclusive studies have taken place. Based on the scientific literature to date, the *Vargas* court's reasoning remains valid.

D. *Jurisdictions Following the Fifth Circuit and Excluding Post-Traumatic Fibromyalgia Claims as Unreliable*

The majority of courts addressing the admissibility of expert testimony that trauma causes fibromyalgia have followed the Fifth Circuit's holdings in *Vargas* and *Black*, under either the *Daubert* or *Frye* standards.[70]

1. Cases Addressing Admissibility Under *Daubert*

Applying *Daubert*, at least one post-*Vargas* court rejected testimony advancing the theory that trauma causes fibromyalgia because it concluded that the scientific support for the theory is still lacking. In *Maras v. Avis Rent A Car System, Inc.*, Minnesota's federal district court noted the studies cited in *Vargas* and accepted the defense's contention that "the scientific understanding of the causes of fibromyalgia has not advanced since the most recent Fifth Circuit

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[67] *Id.* at 203–04.
[68] *Id.* at 206.
[69] *Id.* at 209–10.
[70] *See, e.g.*, Maras v. Avis Rent A Car Sys., 393 F. Supp. 2d 801, 808–09 (D. Minn. 2005); Schofield v. Laboscam, Inc., CV-00-197, 2002 WL 1335867, *2 (Me. Super. Ct. June 6, 2002); Jones v. Conrad, No. CA2000-12-257, 2001 WL 1001083, *4 (Ohio Ct. App. Sept. 4, 2001) (each applying *Daubert*); *see also* Grant v. Boccia, 137 P.3d 20, 25 (Wash. Ct. App. 2006); Pflum v. Sears, Roebuck & Co., No. B161862, 2004 WL 348783, *3 (Cal. Ct. App. Feb. 25, 2004); Riccio v. S & T Contractors, 56 Pa. D. & C.4th 86, 119 (Pa. Ct. Com. Pl. 2001) (reaching same result under *Frye*).

Courts have also excluded evidence of other alleged causes of fibromyalgia, citing the lack of scientific consensus on the syndrome's etiology. *See* Allison v. McGhan Med. Corp., 184 F.3d 1300 (11th Cir. 1999) (affirming exclusion of testimony that silicone implants caused or exacerbated systemic conditions including fibromyalgia); Wynacht v. Beckman Instruments, Inc., 113 F. Supp. 2d 1205, 1210–11 (E.D. Tenn. 2000) (excluding testimony that plaintiff's exposure to lab equipment's wastewater caused her fibromyalgia) (E.D. Tenn. 2000); Bushore v. Dow Corning-Wright Corp., No. 92-344-CIV-T-26C, 1999 WL 1116920, *6–7 (M.D. Fla. Nov. 15, 1999) (excluding testimony that silicone implants caused plaintiff's fibromyalgia); Gross v. King David Bistro, Inc., 83 F. Supp. 2d 597, 602 (D. Md. 2000) (holding expert testimony that shigella infection caused fibromyalgia insufficiently reliable); Minner v. Am. Mortg. & Guar. Co., 791 A.2d 826, 855 (Del. Super. Ct. 2000) (granting motion to exclude testimony that toxic agents in office building caused plaintiff's fibromyalgia under *Daubert*). *But see* Alder v. Bayer Corp., 61 P.3d 1068, 1090 (Utah 2002) (reversing exclusion of testimony that chemical exposure due to x-ray processing machine caused plaintiff's fibromyalgia under a *Daubert*-like standard).

case."[71] The court stated that the study on which the plaintiff relied acknowledged that "'the etiology [or cause] of primary [fibromyalgia] remains unclear'" and "'the role of physical trauma in precipitating fibromyalgia is uncertain.'"[72] Moreover, the plaintiff's own experts conceded that the cause of fibromyalgia was unknown.[73] Not only did the theory lack general acceptance, it had not been verified by testing nor had it been peer-reviewed.[74]

Two state courts applying *Daubert* have, however, found expert testimony that physical trauma caused a plaintiff's fibromyalgia to be admissible.[75] It appears that both courts allowed the testimony in the context of the "differential diagnosis" theory of medical causation. In *Epp v. Lauby*, the plaintiff's expert witness testified that trauma was the proximate cause of the plaintiff's fibromyalgia.[76] The court noted the articles reviewed in *Vargas* and *Black*, as well as the additional publications discussed in *Maras*.[77] The *Epp* court reasoned that general acceptance was not a determinative factor as long as the expert's methodology was reliable under *Daubert*.[78] It concluded that the plaintiffs' experts properly "ruled in" trauma as a possible cause for the plaintiff's fibromyalgia in their differential diagnosis of her injuries; thus, the trial court erred in excluding the testimony.[79] The court in *Reichert v. Phipps* reached the same decision, but emphasized its hesitance to usurp the jury's role in assessing the evidence and the other means available to test the evidence.[80] However, other jurisdictions have discredited the reliance on differential diagnosis evidence in general.[81]

2. Cases Addressing Admissibility Under *Frye*

Despite applying an evidentiary standard that differs from the one set out in *Daubert*, the majority of the *Frye* jurisdictions that have considered the question have explicitly adopted the *Vargas/Black* reasoning.[82] As in *Vargas* and *Black*, these courts reviewed the scientific literature and concluded that the proponent of the evidence could not establish the theory that physical

[71] *Maras*, 393 F. Supp. 2d at 806.
[72] *Id.* at 807 (quoting Al-Allaf et al., *supra* note 57, at 451, 453).
[73] *Id.* at 808.
[74] *Id.*; *see also Schofield*, 2002 WL 1335867 at *2 (stating plaintiff's expert admitted medical community has not identified fibromyalgia's cause); *Jones*, 2001 WL 1001083 at *4 (holding that testing, peer review, and general acceptance factors were absent from the research on which the expert relied).
[75] Epp v. Lauby, 715 N.W.2d 501, 651 (Neb. 2006); Reichert v. Phipps, 84 P.3d 353, 364 (Wy. 2004).
[76] *Epp*, 715 N.W.2d at 505.
[77] *Id.* at 509–10.
[78] *Id.* at 510.
[79] *Id.* at 511.
[80] *Reichert*, 84 P.3d at 364.
[81] *See* Rink v. Cheminova, Inc., 400 F.3d 1286, 1295 (11th Cir. 2005) (differential diagnosis evidence alone is insufficient causation evidence to overcome summary judgment motion); *In re* Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 436 (S.D.N.Y. 2005) (barring expert testimony premised on differential diagnosis); Wynacht v. Beckman Instruments, Inc., 113 F. Supp. 2d 1205, 1209 (E.D. Tenn. 2000) (excluding expert opinion based on differential diagnosis and stating "[t]he ability to diagnose medical conditions is not remotely the same, however, as the ability to deduce, delineate, and describe, in a scientifically reliable manner, the causes of those medical conditions").
[82] *See* Grant v. Boccia, 137 P.3d 20, 24–25 (Wash. Ct. App. 2006); Pflum v. Sears, Roebuck & Co., No. B161862, 2004 WL 348783, *3 (Cal. Ct. App. Feb. 25, 2004); Riccio v. S & T Contractors, 56 Pa. D. & C.4th 86, 114–15 (Pa. Ct. Com. Pl. 2001).

trauma caused the plaintiff's fibromyalgia was generally accepted in the field as required by *Frye*.[83]

Florida is the only *Frye* jurisdiction to date to admit testimony linking physical trauma to fibromyalgia.[84] In *Marsh v. Valyou*, the Florida Supreme Court ruled that the testimony represented "pure opinion" based on a physician's differential diagnosis, as opposed to a procedure or methodology constituting novel scientific evidence, and thus was not subject to *Frye*.[85] The court also held that even if *Frye* applied, the evidence satisfied the standard.[86] It concluded, "[n]umerous published articles and studies recognize an association between trauma and fibromyalgia."[87] The court relied on the studies performed by Al-Allaf, the Israeli study, and the *Consensus Report.*[88] As noted above, other jurisdictions have rejected the admissibility of differential diagnosis evidence. Moreover, courts have found several of the studies on which *Marsh* relied to be inadequate based on the scientists' own statements of the research's limitations, as discussed previously in Part III.C.[89]

IV.
EXCLUDING CLAIMS FOR FUTURE RADIOFREQUENCY FACET JOINT DENERVATION

Even though scientific literature has begun to describe a moderate success rate for radiofrequency facet joint denervation, courts have not recognized any generally accepted scientific support for the contention that repeated treatments on a yearly or eighteen-month cycle for the rest of the plaintiff's life are needed. Instead, the available medical literature suggests that one round of radiofrequency facet neurotomy is all that is needed for long term complete or near complete pain relief and repeated treatments will not provide increased or more complete pain relief. Thus, under *Daubert or Frye*, defense counsel may be able to prevent claims for more radiofrequency facet joint denervation treatments in the future.

A. *Medical Literature Regarding Relief of Neck Pain Using Radiofrequency Facet Neurotomies*

Some researchers estimate that approximately half of the patients with chronic neck pain after whiplash injury have pain originating in the cervical zygapophysial joints, also known as

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[83] *See Grant*, 137 P.3d at 23 (finding that "there is still significant dispute over whether physical trauma causes fibromyalgia"); *Riccio*, 56 Pa. D. & C.4th at 111 (stating that defendants' evidence "persuasively establish[ed] the absence of a consensus in the relevant scientific community as to . . . the particular causal role of trauma in the onset or development of fibromyalgia"); Looman v. Kelm, No. C8-03-3090 at *6 (D. Minn. May 27, 2004) (concluding "the mere acknowledgement by the medical and research community that some unknown relationship between trauma and fibromyalgia could exist is insufficient to meet the requirements under *Frye/Mack*").
[84] Marsh v. Valyou, 977 So. 2d 543, 550 (Fla. 2007).
[85] *Id.* at 448–50.
[86] *Id.* at 550.
[87] *Id.*
[88] *Id.* at 550 n.3.
[89] *See* Vargas v. Lee, 317 F.3d 498, 502 (5th Cir. 2003) (quoting Buskila, et al., *supra* note 37, at 451); Black v. Food Lion, Inc., 171 F.3d 308, 312 (5th Cir. 1999) (quoting *The Consensus Report*, *supra* note 11, at 534); Maras v. Avis Rent A Car Sys., 393 F. Supp. 2d 801, 807 (D. Minn. 2005) (quoting Al-Allaf et al., *supra* note 57, at 451, 453).

facet joints.[90] Based on data from animal, dummy, and cadaver studies, researchers believe that compression occurs within the cervical zygpophysial joints about 100 milliseconds after impact, in which "the inferior articular processes of the moving [cervical] vertebra chisel into the superior articular processes of its supporting vertebra."[91] The site of pain origination may be identified through placebo-controlled local anesthesia to block the nerves supplying the uncomfortable joint.[92] Through the procedure known as percutaneous neurotomy, the nerves innervating the painful joint are denervated "by radiofrequency thermoneurolysis utilizing thermal or pulsed mode, cryoneurolysis, or laser denervation."[93]

The early reports on the procedure's efficacy were equivocal. In their 2002 review of clinical studies diagnosing and treating facet joint pain with radiofrequency neurotomy in whiplash subjects, Kwan and Friel noted that in the single controlled study of radiofrequency neurotomy, only seven of twelve subjects in the treatment group demonstrated long-term relief of pain at twenty-seven weeks after the trauma.[94] Moreover, in that study, ten of the twelve control subjects were in litigation, which the reviewers considered a "significant confounding variable."[95] Kwan and Friel concluded the following:

> We suggest that much more research is needed in this area to end an era of controversy. Moreover, we must be concerned about relying on a single study fraught with the various issues raised above, to alter clinical practice, when the treatment procedures are invasive, and the long-term effects unknown.[96]

In 2003, Niemistö and her colleagues performed a systematic review of seven trials of the procedure's effectiveness for the treatment of musculoskeletal pain disorders.[97] The researchers concluded that the studies they reviewed provided "limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophysial joint origin and for chronic cervicobrachial pain" among preselected individuals.[98] The authors stated that "[t]here is a need for further high-quality [randomized controlled trials] with larger patient samples, carefully selected with diagnostic blocks, longer follow-ups, and meaningful standardized outcomes, particularly examining situations where [radiofrequency denervation] is now used without scientific evidence of efficacy."[99]

Boswell and his colleagues completed the most recent review of studies on the therapeutic facet joint intervention procedures and found moderate evidence that neurotomy

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[90] Leena Niemistö et al., *Radiofrequency Denervation for Neck and Back Pain: A Systematic Review Within the Framework of the Cochrane Collaboration Back Review Group*, 28 SPINE 1877, 1877 (2003).
[91] Oliver Kwan & Jon Friel, *Critical Appraisal of Facet Joints Injections for Chronic Whiplash*, 8 MED. SCI. MONITOR RA191, RA192–93 (2002).
[92] Niemistö et al., *supra* note 94, at 1877.
[93] Mark V. Boswell et al., *A Systematic Review of Therapeutic Facet Joint Interventions in Chronic Spinal Pain*, 10 PAIN PHYSICIAN 229, 239 (2007).
[94] Kwan & Friel, *supra* note 95, at RA194.
[95] *Id.*
[96] *Id.*
[97] *See generally* Niemistö et al., *supra* note 94, at 1877.
[98] *Id.*
[99] *Id.* at 1886.

provides short- and long-term relief for cervical facet joint pain.[100] Out of all of the studies reviewed, two did not measure pain relief beyond a year after the procedure.[101] Both of those studies reported positive results for short-and long-term joint pain relief.[102]

The review also included a number of studies that have found pain relief may persist more significantly beyond twelve months. Tzaan and his colleagues monitored patients from one to thirty-three months after surgery and found 41% of participants had complete elimination of or more than 50% subjective reduction in pain after the first procedure.[103] Unfortunately, Tzaan's article does not report how many patients experienced extended periods of relief.

McDonald and his colleagues found that subjects experienced between 223 and 730 days of complete relief after the first procedure and from 144 and 478 days of relief after repeat procedures.[104] The median duration of relief following a first procedure was 219 days when failures were included and 422 days among the successful cases.[105] Schaerer conducted an earlier study that included treatment of patients with low back pain.[106] He followed up with the subjects for an average of 13.7 months and found that 16% of the participants had excellent results, 34% had good results, and the remaining patients had fair or poor outcomes or dropped out of the study.[107]

B. *Limiting Testimony Regarding the Future Need For Repeated Facet Neurotomies*

Defense lawyers have successfully excluded claims for repeated future neurotomies in Minnesota courts on the basis that there is inadequate research on the duration of relief. In *Perry v. Ojo*, the court held there was insufficient medical scientific evidence to support the plaintiff's neurologist's opinion that the plaintiff would require an additional neurotomy every fifteen months.[108] The court reasoned that "[b]ecause this procedure is new, it is impossible to have a large enough pool of patients to study and determine if future treatments are needed or how often."[109] Based on the work of McDonald, Tzaan, Tasker, and Schaerer, claims for future

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[100] *See* Boswell, *supra* note 97, at 248. However, using a denervation protocol involving multiple lesions of each facet nerve, the evidence is strong for short- and long-term relief of pain. *Id.* This latter technique is not routinely practiced in the U.S. *Id.* at 245; a*ccord* Tamara Prushansky et al., *Cervical Radiofrequency Neurotomy in Patients with Chronic Whiplash: A Study of Multiple Outcome Measures*, 4 J. OF NEUROSURGERY: SPINE 365, 371–72 (2006) (reporting improvement in 80% of patients studied one year after intervention; concluding procedure associated with "acceptable rate of success").

[101] Boswell, *supra* note 97, at 242 (citing Susan M. Lord et al, *Percutaneous Radio-frequency Neurotomy for Chronic Cervical Zygapophyseal Joint Pain*, 335 NEW ENGLAND J. OF MEDICINE 1721 (1996) (stating 3, 6 and 12 month outcomes); Woo-Ram Shin et al, *Radiofrequency Neurotomy of Cervical Medial Branches of Chronic Cervicobrachialgia*, 21 J. OF KOREAN MED. SCI. 119 (2006) (measuring outcomes at 1, 2, 3, 6 , 9, and 12 months).

[102] *Id.*

[103] *See* W.C. Tzann, et al., *Percutaneous Radiofrequency Facet Rhizotomy—Experience with 118 Procedures and Reappraisal of its Value*, 27 CANADIAN J. OF NEUROLOGICAL SCIENCES 125, 130 (2000) (summarized in Boswell, *supra* note 97, at 242).

[104] Greg J. McDonald et al., *Long-Term Follow-Up of Patients Treated With Cervical Radiofrequency Neurotomy for Chronic Neck Pain*, 45 NEUROSURGERY 61, 68 (1999) (summarized in Boswell, *supra* note 97, at 242).

[105] *Id.* at 63–64.

[106] *See generally* J.P. Schaerer, *Radiofrequency Facet Rhizotomy in the Treatment of Chronic Neck and Low Back Pain*, 63 INTERNATIONAL SURGERY 53–59 (1978).

[107] *Id.* at 58–59.

[108] C3-99-3791 (D. Minn. 2000).

[109] *Id.* at *4; s*ee* Demos v. Olson, C3-04-10107 (1st Jud. Dist. Dec. 1, 2005) (procedure "simply too new to show sufficient scientific evidence that future radiofrequency neurotomies will be necessary every 12–14 months");

denervation procedures on an annual or more frequent basis are also ripe for *Daubert/ Frye* challenges on the ground that the literature demonstrates relief may last significantly beyond the twelve-month period asserted by the plaintiffs' counsel.

C. *Excluding Evidence of Facet Neurotomies Based on Placebo Effect*

Another fertile ground for excluding testimony about radiofrequency facet neurotomy centers around the placebo effect problem. Unless a well-documented and well-planned double blind study is carried out by the examining doctor before the participants undergo the radiofrequency neurotomy procedure, there is a substantial likelihood that any relief reported will be the result of a placebo effect.[110] Typically, in practice, this preliminary study is undertaken through the use of long and short duration anesthetics.[111] Unless there is correlation between the pain relief and the duration of the anesthetic used, the underlying basis for the rationalization of using radiofrequency neurotomy does not exist.[112] To successfully exclude the plaintiff's testimony regarding radiofrequency neurotomy under this theory requires a careful understanding of the theory, a skillful cross-examination of the plaintiff's treating doctor, and the plaintiff to demonstrate a fatal flaw in the techniques used.[113] Under either *Daubert* or *Frye*, the

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Asbury v. Sylvester, PI-01-018155 (4th Jud. Dist. Dec. 26, 2002) (noting that study Plaintiff relied upon stated it was unknown how often operation could be repeated and what efficacy of repeat treatments would be); Berg v. Goff, C7-01-8672 (2d Jud. Dist. Dec. 3, 2002).

But see Sipe v. Fleigles Transp. & Serv., Inc., No. A07-0699, 2008 Minn. App. Unpub. LEXIS 539, at *16 (Minn. Ct. App. May 13, 2008). In *Sipe*, the trial court found that "the use of past neurotomies to predict the need for future neurotomies was speculative, did not withstand scientific scrutiny, and could not be offered into evidence." *Id.* Yet, four months earlier the same trial court determined that neurotomies had been used by the medical community for thirty years and allowed that expert testimony into evidence. *Id.* at *17. Ultimately, the trial court adhered to its first order and allowed the expert to tesfify regarding neurotomies. *Id.* On appeal, the court found "there was adequate scientific material in the record to support the decision to allow evidence of neurotomies." *Id.* at *20.

The authors have not found any reported appellate decisions in Minnesota or elsewhere addressing this issue. We note, however, that claims of this nature have been made with some frequency and where the testimony has been admitted, the verdicts have been high. *See, e.g.*, Haskin v. Union Pacific R.R. Co., No. 2:05-cv-01703-LKK-DAD, 2007 WL 1765178, at *1, 2 (E.D. Cal. May 7, 2007) ($478,000 verdict; plaintiff asserted that his future medical expenses would cost $340,000, which included cervical facet neurotomies); Ruede v. John Malloy, Inc., No. 2200/00, 2003 WL 22849051, at * 1-2 (N.Y. Super. Ct. Sept. 25, 2003) ($400,000 verdict for plaintiff included costs of repeat neurotomies for "foreseeable future"); Ross v. Rouleau, No. 153542, 2006 WL 2940688, at * 1 (Cal. Super. Ct. Aug. 3, 2006) (award of $65,082 included cost of future annual neurotomies and annual week of wage loss to undergo those treatments); Gonzalez v. S. Pac./Union Pac. Ry. Co., No. 01AS06354, 2005 WL 1491085, at *1-2 (Cal. Super. Ct. May 19, 2005) ($2,454,425 verdict for lumbar disc and facet injuries apparently included $425,000 for future costs of biannual lumbar facet neurotomies); *Sipe*, 2008 Minn. App. Unpub. LEXIS 539, at *9 (a jury awarded $130,000 in future medical expenses and the court noted that the plaintiff's "need for future neurotomies was the sole basis for that award").

[110] *See generally* Susan M. Lord et al., *Percutaneous Radiofrequency Neurotomy in the Treatment of Cervical Zygapophysial Joint Pain: A Caution*, 36 NEUROSURGERY 732 (1995) (stating that unless controlled diagnostic blocks are used, error rate is 25%); Leslie Barnsley, Susan M. Lord & Nikolai Bogduk, *Comparative Local Anesthetic Blocks in the Diagnosis of Cervical Zygapophysial Joint Pain*, 55 PAIN 99 (1993).

[111] Lord et al., *supra* note 114, at 735.

[112] *Id.*

[113] *See generally* Nikolai Bogduk, *International Spinal Injection Society Guidelines for the Performance of Spinal Injection Procedures, Part 1: Zygapophysial Joint Blocks*, 13 CLINICAL J. PAIN 285 (1997).

use of improper technique will result in a lack of general acceptance compounded by unreliable methodology.[114]

V.
CONCLUSION

Daubert/Frye motions are potent weapons against claims of post-traumatic fibromyalgia as well as claims for the future cost of radiofrequency facet neurotomy. Counsel, armed with the research discussed in this article, will be well prepared to prevent these to-date scientifically unreliable theories from reaching a jury.

[114] *See Asbury*, No. PI-01-018155, at *5 (disallowing opinion that the plaintiff suffered from cervical zygapophysial joint disorder based on physician's failure to follow Bogduk's protocol of comparative nerve blocks).