In the United Stated Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: January 29, 2008; Re-Issued for Publication on February 1, 2008)

)	
REBECCA DUPLESSIS,		
)	
)	No. 06-331V
Petitioner,)	
)	PUBLISHED
V.)	Motion for Judgment on
)	the Record
SECRETARY OF THE DEPARTMENT)	
OF HEALTH AND HUMAN SERVICES,)	
)	
Respondent.)	
)	

Neal J. Fialkow, Pasadena, CA, for petitioner.

<u>Glenn A. MacLeod</u>, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for respondent.

DECISION DENYING ENTITLEMENT¹

¹ The undersigned issues this final decision pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Absent the filing of a motion for review of this decision within thirty days, the Clerk of Court shall enter judgment in accordance with this decision.

Additionally, pursuant to 42 U.S.C. § 300aa-12(d)(4), Rule 18(b)(2) of the Vaccine Rules of this Court, and the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), this decision will be made available to the public unless a party objects, within fourteen days, to the disclosure of: (1) any "trade secret or commercial or financial information which is privileged and confidential;" or (2) any information contained in "medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy."

On April 27, 2006,² petitioner, Rebecca Duplessis filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the Vaccine Program).³ Petitioner alleges that as a result of the tetanus vaccination that she received on May 31, 2003, she suffered an adverse reaction, specifically, a brachial neuritis injury. Petition (Petn.) at 1.

In addition to the petition, petitioner's counsel filed the following records in support of petitioner's claim: (1) various medical records from Chesapeake General Hospital, see Petitioner's Exhibits (P's Exs.) 1, 7; (2) medical records from Angela Mercer, M.D., petitioner's primary care physician, see P's Ex. 2; (3) medical records from Portsmouth Orthopaedic Associates in Virginia, see P's Ex. 3; (4) medical records from Doris Rice, M.D., at Sentara Norfolk General Hospital, see P's Ex. 4; (5) medical records from Virginia Commonwealth University Health System, including records from Dr. Michael Weaver, M.D., see P's Ex. 5; (6) medical records from Michael L. Gross, M.D., of the Mid-Atlantic Dermatology Center P.C., see P's Ex. 6; (7) medical records from Tidewater Neurologists Inc., see P's Ex. 8; (8) medical records from Norfolk Community Health Center, see P's Ex. 9; and (9) medical records from Lisa B. Barr, M.D., Advanced Pain Management, see P's Ex. 10.

On March 10, 2006, petitioner's counsel "contacted Michael Weaver, M.D., . . . an assistant professor of Internal Medicine and Psychiatry at the Chronic Pain Management Clinic at the Virginia Commonwealth University . . ." Declaration of Neal Fialkow (Declaration), filed April 27, 2006 ¶¶ 2-3. Dr. Weaver was one of Ms. Duplessis's treating physicians. Ms. Duplessis had consulted with Dr. Weaver regarding the management of her chronic pain. It was Dr. Weaver's assessment that Ms. Duplessis "had a chronic pain syndrome as a result of complex regional pain syndrome (CRPS,

² The original petition, petitioner's declaration, petitioner's counsel's declaration and petitioner's exhibits 1-5 were all first filed with the court on April 27, 2006. On December 12, 2006, petitioner's counsel re-filed these exhibits because they were not filed with consecutive page numbers in the first instance.

³ The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. § 300aa-10-§ 300aa-34 (West 1991 & Supp. 2002) (Vaccine Act or the Act). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C.A. § 300aa.

formerly known as reflex sympathetic dystrophy," (RSD).⁴ P's Ex. 5 at 4. He did not rule out, however, the diagnosis of fibromyalgia. See id.

Petitioner's counsel stated in his filed declaration that he specifically "asked whether [Dr. Weaver] had entertained [a] diagnosis of brachial neuritis that may have occurred as the result of a vaccine inoculation with a tetanus toxoid." Declaration ¶4. According to petitioner's counsel, Dr. Weaver responded that "before he could determine whether or not he should have entertained a [diagnosis of] brachial neuritis. . . he would have to review the literature and the medical records within the context of the literature." Id. Dr. Weaver committed to conduct a literature review, but indicated that he would require until the end of July 2006 to complete the review. Id. ¶5.

By Order dated April 25, 2007, the undersigned directed petitioner's counsel to "file [on or before June 1, 2007,] all outstanding medical records, and a status report indicating when petitioner's counsel anticipated the filing of petitioner's expert report." Order 4/25/07 at 1. On June 7, 2007, petitioner's counsel filed a status report advising that "the medical records and petition have been reviewed and a report will be sent in short order." Status Report, SR 6/7/07 at 1.

By Order dated July 6, 2007, the undersigned again directed petitioner's counsel to file, on or before July 20, 2007, all outstanding medical records and a status report indicating a date certain by which he would file an expert report. Petitioner's counsel did not respond. By Order dated August 16, 2007, the undersigned again directed petitioner's counsel to file, on or before August 31, 2007, the outstanding medical records and a supporting expert opinion.

On September 12, 2007, the undersigned issued an order advising petitioner's counsel that he risked dismissal for failure to prosecute by failing to file the outstanding medical records and an expert report before September 28, 2007. On October 16, 2007, the undersigned issued a show cause order directing petitioner's counsel to show, on or before October 26, 2007, why this petition should not be dismissed for failure to prosecute.

On November 1, 2007, the undersigned received a filing from petitioner's counsel entitled "Why Petitioner Should Not Be Dismissed." Petitioner's counsel explained that

⁴ Reflex sympathetic dystrophy is "a series of changes caused by the sympathetic nervous system, marked by pallor or rubor, pain, sweating, edema, or osteoporosis, following muscle sprain, bone fracture, or injury to nerves or blood vessels." <u>Dorland's Illustrated Medical Dictionary</u>, 581 (30th ed. 2003).

he had filed a Request for a Ruling on the Record on September 4, 2007 (P's Request for Ruling). Petitioner's counsel attached a postage transaction record that reflected the mailing of his request for a ruling on the record on September 4, 2007, to the Clerk of the Court of Federal Claims and to respondent's counsel.

Petitioner's motion for judgment on the record is now ripe for decision.

A. The Factual Record

Ms. Duplessis was born on April 24, 1961. Petn. ¶ 1. On May 31, 2003, Ms. Duplessis stepped on a nail while exiting a hardware store. Petn. ¶ 2. That same day, Ms. Duplessis sought treatment for her foot at the Chesapeake General Hospital Emergency Room. Id. ¶ 3.

The emergency room notes state that "[t]he patient's right foot has a nail embedded in the medial portion." P's Ex. 1 at 8-9. The treating physician, Dr. Brown, removed the nail, took x-rays of Ms. Duplessis's foot, and administered a tetanus shot. See P's Ex. 1 at 9. Dr. Brown discharged Ms. Duplessis with instructions to return to the hospital "for any worsening [of symptoms] or [any] symptoms of concern." Id.

Ms. Duplessis returned to the emergency room four days later, on June 4, 2003, complaining of "[r]ight arm pain after [receiving] tetanus shot." <u>Id.</u> at 7. Under the "History of Present Illness" section of the emergency room records is the notation that "[s]ince the tetanus shot [Ms. Duplessis's] right arm has been very painful, slightly swollen and the pain radiates down her lower arm." <u>Id.</u> "The patient denies any fever or chills, her pain does not seem to worsen with movement." <u>Id.</u>

Ms. Duplessis returned to the emergency room on June 13, 2003, complaining of an allergic reaction to the tetanus shot and arm pain. <u>Id.</u> at 5. The notes from this visit reflect that "[t]he patient has a history of intermittent urticaria and is followed by an allergist." <u>Id.</u> Ms. Duplessis "also report[ed] some chronic-type symptoms now [in] the right upper extremity." <u>Id.</u> The notes refer to the two emergency room visits earlier in the month and indicate that Ms. Duplessis had seen "her primary care physician who. . . referred her to orthopedics." Id.

On August 1, 2003, Cathy Cao, M.D., a neurologist and psychiatrist, examined Ms. Duplessis. P's Ex. 8 at 2. Ms. Duplessis presented to Dr. Cao with an article about Guillain-Barre Syndrome (GBS) following vaccination. <u>Id.</u> Ms. Duplessis "was worried about having GBS." <u>Id.</u> Dr. Cao was able to exclude a diagnosis of GBS on the basis of Ms. Duplessis's good reflexes during her examination. <u>Id.</u> Dr. Cao postulated that

"cervical radiculopathy, musculoskeletal problems, [or a] psychogenic [condition] might explain Ms. Duplessis's right arm pain." <u>Id.</u> at 3.

On September 5, 2003, Ms. Duplessis sought treatment at Tidewater Neurologists, Inc. See P's Ex. 8 at 1. She presented with complaints of "[right] arm and neck pain." Id. The notes from this visit also reflect that Ms. Duplessis was concerned about possible multiple sclerosis. Id. at 1.

On September 25, 2003, Doris M. Rice, M.D., a rheumatologist, examined Ms. Duplessis. It was Dr. Rice's impression that the "pain in [Ms. Duplessis's] right shoulder, right elbow, and right hand" was a "[p]robable reflex sympathetic dystrophy of recent pain syndrome." P's Ex. 7 at 17.

On October 9, 2003, Andres Torop, M.D., a radiologist, obtained a magnetic resonance imaging of Ms. Duplessis's right shoulder. From the imaging of her shoulder, he determined that Ms. Duplessis's rotator cuff tendons were intact, but he observed a small area of visible degeneration at the front of her shoulder (specifically, the junction of the superior labrum and biceps anchor). See P's Ex. 5 at 19.

On October 14, 2003 Ms. Duplessis received a bone scan of her entire body to assist in the evaluation of her arm and knee pain. <u>Id.</u> P's Ex. 2 at 16. Alan Appelbaum, M.D., a neurologist, reviewed the scan and noted his impressions: "[i]ncreased activity diffusely of the left arm on the blood pool phase and greater uptake in the left humerus compared to the right may support suspected [diagnosis of] reflex sympathetic dystrophy of the left upper extremity." <u>Id.</u>

On December 6, 2003, Ms. Duplessis again visited the emergency room. P's Ex. 4 at 3. She complained that she had a rash that was very itchy. Id. She reported to the attending physician that the rash "started on her trunk and . . . spread to her arms and extremities as well as to her back." Id. The emergency room record states that "[s]he has no other complaints at this time. [Ms. Duplessis] state[d] that she has had a problem similar to this several times in the past." Id. The emergency room indicates that she had "been told previously that she needs an allergy test. [But] she has not followed up on these findings." Id.

On March 14, 2004, P. Franklin Mullinax, M.D., a rheumatologist, referred Ms. Duplessis to Dr. Michael Weaver, of the Commonwealth Pain Management Clinic at Virginia Commonwealth University for chronic pain management evaluation. P's Ex. 5 at 8. Attached to his referral letter, Dr. Mullinax included the notes from his evaluation of Ms. Duplessis on February 19, 2004. P's Ex. 5 at 9-11. Dr. Mullinax states in his

notes that Ms. Duplessis was diagnosed on December 9, 2003, with "cervical radiculopathy and reflex sympathetic dystrophy." P's Ex. 5 at 9. Ms. Duplessis had presented to Dr. Mullinax complaining that "'[her] whole arm [was] burning' as if 'cut with a piece of glass." Id.

On August 25, 2004, Dr. Weaver assessed Ms. Duplessis. His patient history reflects that

Ms. Duplessis's pain began in 05-03. She had a puncture wound to her medial right ankle from a nail while in a home improvement store, for which she received a tetanus injection in her upper right arm. She initially developed pain and swelling in her right arm 3 days after this injection. She then developed swelling in her right foot and ankle, then numbness in her leg that continued to spread. She now reports numbness, tingling, swelling, and pain in all extremities, but more on the right side than on the left. She was diagnosed with CRPS by a Rheumatologist after a bone scan in 02-04.

P's Ex. 8 at 2. In Dr. Weaver's assessment, Ms. Duplessis's "chronic pain syndrome" was most likely due to "complex regional pain syndrome (CRPS, formerly called RSD or reflex sympathetic dystrophy). <u>Id.</u> at 4. He also considered a diagnosis of fibromyalgia. Id.

Dr. Angela Mercer, Ms. Duplessis's primary physician, referred Ms. Duplessis to the Department of Physical Medicine and Rehabilitation at Eastern Virginia Medical School for evaluation. P's Ex. 2 at 2. There, Antonio Quidgley-Nevares, M.D., examined Ms. Duplessis and reported the results of his evaluation by letter dated January 20, 2006, to Dr. Mercer. P's Ex 2 at 2-4. In the medical history portion of his notes, Dr. Quidgley-Nevares wrote that Ms. Duplessis reported "receiving [a] tetanus shot . . . [to which] she had an allergic reaction [that] caus[ed] her arm to swell up, [and] requir[ed] her to [wear] a splint for over 9 months." P's Ex. 2 at 2. Ms. Duplessis further reported that wearing the splint "did not improve her pain, and the pain continued to progress over the next year, at which time it moved into the left arm also. She also state[d] that the reflex sympathetic dystrophy ha[d] . . . traveled to her legs at this point and she [had] beg[un] to complain [of] pain when showering." Id. Dr. Quidgley-Nevares concluded that Ms. Duplessis suffered from chronic pain, depression, and, as previously diagnosed, reflex sympathetic dystrophy and fibromyalgia. Id. at 4.

B. Legal Standard and Analysis

⁵ It is unclear from the medical records when Dr. Mercer made this referral.

The Vaccine Act permits a petitioner to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as a "Table" case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table or did not occur within the prescribed time period, but was caused in fact by the received vaccination, commonly referred to as an "off-Table" case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, petitioner bears the burden of proving her claim by a preponderance of the evidence. § 300aa-13(a)(1).

1. No Table Injury Occurred

In a "Table" case, a petitioner benefits from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). Petitioner in this case alleges that she suffered from "brachial neuritis" after she received a tetanus vaccination on May 31, 2003. See Petition at 1. To prove that she suffered an on-Table brachial neuritis, petitioner must show that she developed brachial neuritis within two to twenty-eight days after her receipt of the tetanus vaccine and that her symptoms lasted at least six months. 42 C.F.R.§ 100.3(b)(2). The Qualifications and Aids to Interpretation ("QAI") set forth in the Vaccine Regulations, provides guidance regarding what symptoms might indicate the occurrence of an "brachial neuritis." 42 C. F. R. § 100.3.

The QAI describes "brachial neuritis" as a

dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities.

Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction

of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple monoeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

42 C.F.R. §100.3(b)(7)(i) and (ii).

The submitted medical records in petitioner's case do not indicate that she ever received a diagnosis of brachial neuritis. Nor do the medical records indicate that any of petitioner's treating physicians ever considered, prior to the filing of her vaccine claim, the possibility that her cluster of symptoms constituted a brachial neuritis. The filed records do include a statement from petitioner's counsel that he contacted Dr. Weaver, who saw Ms. Duplessis for her chronic pain management, and asked whether Dr. Weaver had considered the possibility that Ms. Duplessis had suffered brachial neuritis as a result of receiving the tetanus vaccination at issue. Declaration of Neal Fialkow (Declaration) ¶¶ 2 and 4. According to petitioner's counsel, Dr. Weaver responded "that in his experience he had never seen" a case of brachial neuritis following the administration of a tetanus vaccine. Dr. Weaver explained to petitioner's counsel that before he could determine whether he should have considered a diagnosis of brachial neuritis, he would have to review the medical literature and then review petitioner's medical records. See Declaration at ¶ 4. Petitioner did not file a letter from Dr. Weaver or anyone else opining that petitioner had brachial neuritis.

Because the medical records do not support petitioner's contention that the symptoms she experienced following her May 31, 2003 tetanus vaccination were ever diagnosed by a physician as brachial neuritis, the undersigned cannot find that petitioner suffered from that condition. And, because the record does not support a finding that Ms. Duplessis has a brachial neuritis injury, petitioner is not entitled to a presumption of vaccine causation under the Vaccine Injury Table.

2. No Off-Table Injury Occurred

To establish entitlement to Program compensation without the presumption of causation, petitioner must prove, by a preponderance of the evidence, that the vaccination that she received caused her injury, which is described in her medical records as a complex regional pain syndrome. Petitioner satisfies this burden of proof "by providing: (1) a medical theory causally connecting her vaccination and [her] injury; (2) a logical sequence of cause and effect showing that [her] vaccination was the reason for [her] injury; and (3) a showing of a proximate temporal relationship between [her] vaccination and [her] injury." Althen v. Sec'y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The logical sequence of cause and effect proffered by petitioner

must be supported by a reputable scientific or medical explanation. Grant v. Sec'y Dept. of Health and Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992); Knudsen v. Sec'y of Dept. of Health and Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (stating that a causation theory before a special master must be supported by a "sound and reliable" medical or scientific explanation). The Vaccine Rules reiterate this requirement, instructing the special master to ensure that the considered evidence is "relevant and reliable." RCFC App. B, Vaccine Rule 8(c).

In this case, petitioner has failed to supply any evidence of a causal connection between her received tetanus vaccination and her injury. At most, Ms. Duplessis's medical records suggest only a temporal relationship between her vaccination and the onset of her reported cluster of symptoms. But a review of her medical records indicate that many of her reported symptoms predated her receipt of the tetanus vaccine.

Petitioner has not offered a medical opinion from either a treating physician or an expert causally connecting Ms. Duplessis's vaccination to her alleged injury. Lacking a medical opinion of causation, petitioner has moved for judgment on the record. P's Request for Ruling at 1.

Because petitioner's claim of a vaccine-related injury is not supported by either the filed medical records or an offered medical opinion, petitioner's petition for Program compensation must fail.

II. CONCLUSION

The medical records in this case do not establish that Ms. Duplessis ever received a diagnosis of brachial neuritis. Nor do the records establish a causal connection between Ms. Duplessis's received tetanus vaccination and the development of her injury. Moreover, petitioner has offered no medical opinion that her injury is a vaccine-related one. Without any evidence that petitioner's injury was caused by her tetanus vaccination, petitioner has failed to establish entitlement to compensation under the Vaccine Act. Her claim must be **DISMISSED**. The Clerk of the Court shall **ENTER JUDGMENT** accordingly.⁶

⁶ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.

IT IS SO ORDERED.

Patricia E. Campbell-Smith Special Master