OFFICE OF SPECIAL MASTERS

No. 01-452V

(Filed: March 3, 2004)

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PAUL GARRETT and KIM GARRETT, Individually and as Next Friends of WESLIE JULIA ANNIE GARRETT, a Minor,	*	
Petitioner(s),	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Gene S. Hagood, Alvin, TX, for petitioners.
Melonie J. McCall, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

On August 3, 2001, petitioners filed a petition on behalf of their daughter Weslie Garrett (hereinafter, "Weslie") for compensation under the National Childhood Vaccine Injury Act of 1986[1] (hereinafter the "Vaccine Act" or the "Act"). Petitioners have satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) they have not previously collected

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

an award or settlement of a civil action for damages arising from the vaccine injury; and (2) Weslie received hepatitis B vaccine in the United States.

Petitioner alleges that hepatitis B vaccination caused her reflex sympathetic dystrophy (RSD), also called complex pain syndrome type I. Respondent denies causation. This case was transferred to the undersigned on December 8, 2003.

The undersigned did not hold a hearing in this case. The holding of a hearing on entitlement is within the special master's discretion. 42 U.S.C. § 300aa-12(d)(3)(B)(v).

FACTS

Weslie was born on December 19, 1986. Med. recs. at 12. She received tetanus vaccine in her right deltoid and hepatitis B vaccine in her left deltoid on August 5, 1999, when she was 12 years old. Med. recs. at 16, 23, 75. Four days later, on August 9, 1999, she saw her physician, Dr. Thuy Nguyen, at the Kelsey-Seybold Clinic, complaining that her left arm was very painful to touch with mild swelling and limited range of movement. The pain had begun on August 8, 1999. She had no fever or redness. Dr. Nguyen diagnosed pain in the left deltoid secondary to injection. Weslie was 5 foot 2 inches tall, and weighed 215 pounds. Med. recs. at 22.

Eight months later, on April 17, 2000, Weslie returned to Dr. Nguyen. He records that she had pain in her left arm which began after immunization. She had "shooting" pain from the left upper arm to her fingers (the thumb, second and third fingers) which usually began after use, such as in basketball, throwing, lifting, and playing a trumpet. Weslie is left-handed. The pain resolved with rest. She denied that she had numbness or tingling. She complained of weakness secondary to pain. Mrs. Garrett wanted a referral to a neurologist. Med. recs. at 21.

On April 26, 2000, Weslie saw Dr. Robert Cruse, a pediatric neurologist. He recorded that she received hepatitis B vaccine on August 5, 2000, and had pain the following day. Her arm hurt around the injection site. The pain then became more generalized and extended. It radiated down her arm, but ended at the wrist. She could not move her arm because of the pain. She did not have weakness at that time. Over the next two to three weeks, the pain improved. She did not have discomfort or problems for one to two months. Then she had intermittent pain in her left arm, aggravated by use (i.e., the trumpet). She decreased using her left arm and now it did not seem as strong. She is able to play piano with her left hand. Med. recs. at 57.

On physical examination, Weslie had equivocal dystrophic skin changes distally on her left arm. Her left hand felt slightly cool compared to her right. In the motor examination, her left arm below the elbow was slightly smaller than her right. She had slight weakness in the left arm. His impression was that she had reflex sympathetic dystrophy, which seemed to be a component of disuse and loss of function. He prescribed Neurontin and physical therapy. Med. recs. at 58, 59.

On May 17, 2000, Dr. James M. Killian performed an EMG and nerve conduction study on Weslie's left arm which proved normal with no evidence of focal denervation. Med. recs. at 120-21.

On August 9, 2000, Weslie saw Dr. S. Giddings at the Kelsey-Seybold Clinic, who diagnosed her with reflex sympathetic dystrophy. Med. recs. at 19.

Weslie saw Dr. Cruse again on August 15, 2000. She had had significant improvement with Neurontin, physical therapy, and a TENS[2] unit. She had regained essentially normal range of

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[2] Transcutaneous electrical nerve stimulators.

movement of her shoulder and could abduct her left arm directly over her head. Her hand function had also improved. She was playing piano and swimming. She no longer had color changes or temperature changes in her arm. She was worse under stress. She no longer had a contracture of her arm. She had normal range of motion, and normal strength proximally and distally. Dr. Cruse's impression was that her reflex sympathetic dystrophy was considerably improved. She had anxiety disorder, possibly separation anxiety, and an episodic eating disorder. Med. recs. at 54, 55.

Weslie saw Dr. Cruse on February 27, 2001 and he noted she was really improved quite a bit. She had done relatively well until November 2000 when she had an acute episode of swelling of her left arm with color changes and a lot of pain. Her dose of Elavil was increased and she continued other treatments, causing her to improve. She stopped therapy recently and no longer used the TENS unit. She was playing her trumpet and taking piano lessons. She planned to sign up for golf lessons. She was exercising regularly with her mother. On physical examination, she had a slight restriction in getting both hands all the way over her head and clapping them together. She had a bit of discomfort in the proximal testing of the deltoid region. She did not have distal weakness. There were no more color changes or temperature changes. His impression was that her reflex sympathetic dystrophy was much improved. He instructed her to continue medications for the next four months. Med. recs. at 52, 53.

Dr. Cruse wrote a letter to petitioners' counsel on October 15, 2001 (filing of February 18, 2004). He stated her history and then wrote:

> I believe with reasonable medical certainty that Weslie has reflex sympathetic dystrophy (RSD); also known as complex regional pain syndrome type I (CRPSI). This was temporally related to receiving an injection in her left shoulder and that there is a probable relationship between having received the injection and the development of

> RSD-CRPSI; however, I cannot confirm a direct cause and effect relationship with the hepatitis B vaccine.
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> RSD/CRPSI is an organic neuropathic pain syndrome associated with vasomotor dysfunction of the sympathetic nervous system. The inciting cause of this condition is an injury to a peripheral nerve. The injury can be of various kinds. The mechanism of injury is unclear and various processes have been suggested but none confirmed. Proposed mechanisms include: abnormal pain circuits in the pain perception areas of the central nervous system, abnormal interaction of the peripheral sensory nerve and the sympathetic nerves or possibility [sic] abnormal reactivity of distal pain receptors in the peripheral nerve. Abnormal processing of pain impulses is associated with autonomic dysfunction. Autonomic dysfunction contributes to the pain and abnormal circulation to an extremity with secondary affects to bone and skin.
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> RSD/CRPSI results in pain that limits daily activities that require use of the affected extremity. Movement activates the pain. The pain leads to decreased ability of the extremity, which propagates immobility. A negative feedback circuit is established and the consequences. which may include muscle atrophy, joint contracture and dystrophic changes in the bone density and skin.

Weslie saw Dr. Cruse on April 11, 2002 and he noted that she continued to improve, but also complained of achiness and discomfort in her shoulder, mainly when she maintained it in an abducted position to play her trumpet. However, she did play the trumpet and participated in the band. She had good finger dexterity. She started playing on the golf team, but did not have active physical therapy. She woke two to three times a night. Her physical examination was unremarkable except for pain and discomfort in the movement of her left arm. She no longer had any change in temperature and her fingers appeared normal. His impression was her RSD was much improved. Med. recs. at Ex. 23, pp. 4, 5.

On August 6, 2002, Dr. Cruse wrote that Weslie's pain syndrome was caused by the intramuscular injection to her left shoulder. Med. recs. at Ex. 24, p. 1.

On April 3, 2003, Dr. Cruse noted Weslie had persistent discomfort although she was improved. (P. Tab 14, p. 36.) She complained of pain in the joints of her wrist, in her knee, and less so in her elbow. She had relatively normal finger strength and dexterity and could play her musical instruments. Her significant complaint was anxiety. She did not like to be with groups of people and preferred to be at home. She also had steady weight gain. On physical examination, she did not have any dystrophic skin changes or temperature differences in her arms. Her neurological examination was essentially unremarkable. She had a slightly decreased range of motion to her shoulder, but some of this was guarding because of reported pain and discomfort. Her sensory examination was normal. Dr. Cruse's impression was lingering mild symptoms of mild RSD, anxiety disorder, obesity, and polycystic ovary syndrome. Tab 14, p. 37.

Written Submissions

Respondent filed a report, dated May 1, 2002, from his expert Dr. Kenneth C. Gorson, a neurologist, who stated that Weslie did not have RSD or complex regional pain syndrome type 1 because this condition builds up over time without a hiatus or a symptom-free period, and Weslie was substantially improved and did not seek medical evaluation for eight months after an initial visit to her pediatrician. The medical records reflect that Weslie's arm discomfort seems to have been directly related to anxious situations and she was in a good deal of intermittent stress during this period, including her father's strokes, her moving to a new house and school, her pet's demise, etc. R. Ex. A.

Respondent filed Dr. Gorson's supplemental report, dated June 14, 2002, stating there was no biological plausibility linking RSD to hepatitis B and medical literature does not offer a single case of it

as a complication of hepatitis B vaccination. Medical literature does link algodystrophic[3] syndrome of the upper limb to tetanus vaccination and chronic arthropathy to rubella vaccination. R. Ex. C.

Dr. Cruse responded to Dr. Gorson's two reports in a letter to petitioners' counsel dated August 6, 2002. (P. Ex. 24, pp. 1-3.) He believes Weslie's clinical picture was not only consistent with, but also typical of, RSD. He also believes that the intramuscular injection she received in her left deltoid caused it. He continues:

> Dr. Gorson indicates that there is not usually a time interval from precipitating event to the development of RSD. There is no specific criteria for the interval between the precipitating event and the onset of symptoms that is required for diagnosis of RSD. In up to 10% of cases, no definite precipitating event can be identified and then, of course, defining a time interval to the onset of signs and symptoms is impossible. The development of symptoms typically evolve with time. Weslie experienced immediate left arm pain after receiving an injection. The pain was not limited to a specific nerve and persisted beyond the duration of local irritation. There was an interval of improvement which I indicated was between 4-8 weeks. This was an estimated interval of improvement but not necessarily a period when she was totally pain free. She then, over time, developed persistent and increasing pain with associated autonomic signs and symptoms. The signs and symptoms of RSD are not typically at their maximum initially but usually evolve and become intense over time.
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> Dr. Gorson comments on the nearly eight month interval before Weslie's first pediatric neurology evaluation and would seem to imply a paucity of symptoms during this interval. I do not believe this is accurate. The eight months before seeing me, at least in part, was a consequence of the waiting time for an appointment to the neurology clinic. During this interval she had persistent symptoms and experienced increasing pain.
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> Dr. Gorson indicate that there were no "objective" findings. This is not correct. At the initial visit, I described that the left arm demonstrated mild dystrophic skin changes and as compared to the right arm, the left was cool to touch. I noted that the left arm was slightly smaller than the right and suggested mild muscle atrophy. She is left handed and it would be anticipated that the dominant arm would be larger. Significant generalized

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[3] Algodystrophy is "a combination of pain and dystrophic changes in bone...." Dorland's Illustrated Medical Dictionary, 27th ed.(1988) at 46.

pain that [sic] was elicited with minimal stimulation, only light squeezing of the forearm was required to elicit pain. The distribution of pain was diffuse and did not have a specific nerve or dermatome distribution. There was limited passive range of motion at the shoulder joint which I believe was secondary to contractures caused by lack of use but also guarding because of pain with movement. All of these findings are consistent with the physical findings in the early stages of RSD.

Dr. Gorson indicates that it is not typical of RSD to be able to use the affected extremity for physical activities. Weslie had significant limitations of the normal physical use of her left arm. She is left handed, but had to change to writing with her right hand because even finger movements would elicit intense generalized left arm pain. Because she was motivated, she continued to play her trumpet but had to make adjustments. She had to first passively lift her left arm to the proper position and then place the instrument in her hand. She could not pick... up the instrument in her left hand as she would normally do.

Dr. Gorson suggests that ... Weslie's symptoms were anxiety related. Certainly she was very anxious and this intensified during the course of her RSD. Her anxiety is well documented in my office notes. Her anxiety symptoms were treated as part of her RSD syndrome. Treatment included medication for anxiety, professional counseling and biofeedback. Anxiety is well described in patients with RSD but is not thought to be the direct cause of the syndrome.

Dr. Gorson mentions that her symptoms and the physical findings improved on follow up visits and that she reported being able to play the piano. He implies that this is evidence against the diagnosis of RSD. I interpreted the improvement as confirmation of the diagnosis and an indication of a response to her treatment plan. She was motivated and compliant in doing her physical therapy. She was also compliant in her other treatments that included use of a transcutaneous electric nerve stimulation unit [TENS] and taking the prescribed medications which included gabapentin [Neurontin] and amitriptyline [Elavil]. Over time, with continued treatment, she had flare ups of her pain but the interval between flare ups increased and the intensity of pain and limitations of physical activity decreased. This is common with RSD.

Dr. Gorson comments that the electromyogram [EMG] and nerve conduction test and radioisotope bone scan were normal and appears to imply that these findings are against the diagnosis. That these tests would be normal is not surprising. The EMG is expected to be normal in RSD; this was done to rule out a brachial plexus nerve injury. The isotope bone scan is commonly normal until the development of late and often irreversible changes. Gladly, Weslie did not progress to this stage. I believe she respond[s] to treatment.

> Dr. Gorson's letter of June 14, 2002 states that, after an extensive literature search, he could not document a case of RSD caused by hepatitis B immunization. RSD is known to be caused by various precipitating events that are thought to be traumatic to the nerve. The traumatic events are of various kinds including needle injections. The pathophysiologic mechanisms involved in the development of RSD remain speculative. As I stated in my letter of October 5, 2001, and reiterate in this communication, I believe Weslie developed RSD and that there was a temporal relationship to the injection she received. Her injection contained hepatitis B vaccine but I could not confirm a direct cause and effect to the vaccine; however I cannot rule out a relationship.
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> Various criteria have been set forth for the diagnosis of RSD. Although the criteria are similar, they vary significantly. I believe that Weslie's case is consistent with the diagnosis of RSD and was precipitated by the injection which she received.

Respondent submitted a second supplemental report from Dr. Gorson, dated September 4, 2002, after he reviewed P. Ex. 23 (containing Dr. Cruse's medical record of August 16, 2002, and Dr. Avi S. Raphaeli's psychological records) and stated they did not alter his initial opinions. R. Ex. D.

Respondent submitted a third supplemental report from Dr. Gorson, dated September 17, 2002, in which he states he reviewed P. Ex. 24 (containing Dr. Cruse's August 6, 2002 three-page letter disputing Dr. Gorson's opinions). He states that he and Dr. Cruse disagree about the diagnosis of RSD in Weslie and he stressed there are no medical records to substantiate Weslie's claim that she had increased pain related to RSD during the eight months between vaccination and her first visit to Dr. Cruse. He is unaware of any reported case of RSD associated with a direct trauma (needle injection) with spontaneous improvement for 4 to 8 weeks followed by a disabling worsening. He agrees with Dr. Cruse that there is no reported case of hepatitis B vaccine-RSD in the medical literature and he cannot confirm a direct cause and effect relationship. R. Ex. E.

Petitioners submitted Tab 26, containing six articles about RSD. The first is "Clinical Concepts and Commentary - Complex Regional Pain Syndrome I (Reflex Sympathetic Dystrophy),"by S.N. Raja and T.S. Grabow, 96 *Anesthesiology* 51254-60 (May 2002).[4] This article was supported in part by a grant from the National Institutes of Health. Both authors are at The Johns Hopkins University School of Medicine. They describe the natural course and pathophysiology of RSD/CRPS type I as "elusive, and hence their therapies remain controversial." Page 2 [the pages referred to in Tab 26 are petitioners' numbering].

The authors state that CRPS frequently occurs in young adults and more frequently in females than in males. Id. "The **onset of CRPS is usually linked to** a history of trauma, immobilization, or a procedure such as venipuncture, **intramuscular injection**, or surgery. **There is no correlation between the severity of the initial injury and the ensuing painful syndrome.**" Id. (emphasis added). They continue:

> Psychologic factors, such as stressful life events and inadequate coping mechanisms, are potential risk factors that influence the development or severity of symptoms in CRPS. Eighty percent of patients with upper extremity CRPS of less than 3 months had a stressful social life event within the 2 months before or the month after a trauma compared with a 20% incidence in control patients.

Id.

The authors note: "Considerable variability is observed in the intensity of symptoms, the rapidity of progression of the syndrome, and the response to standard therapies." Page 3. Characteristic features required to establish a diagnosis of CRPS type I are: (1) the presence of an initiating noxious

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[4] Because one page was missing from this article, the undersigned filed the complete article by my leave on February 20, 2004 as C. Ex. 1. 42 U.S.C. § 300aa-12(d)(3)(B)(1).

event or a cause of immobilization; (2) continuing pain, allodynia, or hyperalgesia with pain disproportionate to any inciting event; (3) evidence at some time of edema, changes in skin blood flow, or abnormal sudomotor activity in the region of the pain; and (4) the exclusion of medical conditions that would otherwise account for the degree of pain and dysfunction. Id. "Pain in CRPS varies in quality from a deep ache to a sharp stinging or burning sensation. Often, patients report that the pain is worsened by environmental (cold, humidity) and emotional (anxiety, stress) factors." Id.

The authors describe vasomotor changes causing diverse skin discoloration. A difference in skin temperature was found in 42% of patients with CRPS. These vasomotor and sudomotor changes vary not only between patients but also within patients over time. Id. There has been no prospective study of the progression and recurrence of CRPS symptoms. But a recent retrospective study of CRPS type I identified three different patterns of spread: (1) contiguous spread in all patients, with the gradual enlargement of the area affected from distal to more proximal regions of the limb; (2) independent spread in 70% of patients, depicted by signs and symptoms at sites distant and noncontiguous from the initial site; and (3) mirror-image spread. Page 3 of P's exhibit and page 3 of C. Ex. 1.

In petitioners' second submission in Tab 26, "Reflex Sympathetic Dystrophy Syndrome (RSDS)" by the Reflex Sympathetic Dystrophy Syndrome Association of America (RSDSA), the authors state, "Some patients experience periods of remissions and exacerbations. Periods of remission may last for weeks, months or years." [footnote omitted]. Page 16 of exhibit. The authors depict RSDS in stages. In stage 1, the average duration is one to three months. "In mild cases this stage lasts a few weeks, then subsides spontaneously or responds rapidly to treatment." Page 17. One

of the causes of RSDS is trauma, often minor, which ranks as the leading provocative event. Page 18. Previous hypotheses regarding its pathogenesis include injury to a peripheral nerve causing hypersensitivity to circulating nor-epinephrine, pressure, and movement. Id. RSDS can start immediately or up to 10 days after an injury. Page 27.

Petitioners' third submission in Tab 26 is "Posttraumatic Reflex Sympathetic Dystrophy: Mechanisms and Medical Management," by R.B. Patt and K. Balter, 1 *J Occupational Rehab* 1:57-70 (1991). They state that the causative event is generally traumatic, but can vary widely from trivial to major. Page 34. "The hallmark of RSD is pain that is out of proportion to injury." Id. It is usually a variant of neuropathic pain. Id.

Petitioners' fourth submission in Tab 26 is "Reflex sympathetic dystrophy: A review," by R.M. Shelton and C.W. Lewis, 22 *J Am Acad Dermatol* 513-20 (1990). The authors state that the fist signs of RSD occur between 3 days and 3 weeks after injury. The first stage lasts approximately one month. Pain is the most characteristic symptom. Page 47. The second stage, manifested by dystrophy consisting mainly of vasoconstriction and cold intolerance, but less pain, manifests between 3 and 7 months after injury and lasts approximately 3 to 6 months. Id. The third stage occurs by the eighth month of injury with variability in pain. Id. The authors state that the diagnosis of RSD depends primarily on clinical assessment and that laboratory tests are not for the most part useful. Page 50.

Petitioners' fifth submission in Tab 26 is "Reflex Sympathetic Dystrophy and Causalgia" by R.J. Schwartzman, 10 *Neurology of Trauma* 4:953-73 (1992). Dr. Schwartzman states that RSD "is a progressive illness usually initiated by peripheral trauma to a nerve plexus or soft tissue." [citations omitted]. Page 55. Generally, pain, swelling and autonomic dysfunction dominate the first phase of

RSD, followed by movement disorder, trophic changes and autoimmune phenomenon in the second and third phase. Id.

Petitioners' sixth submission in Tab 26 is "Complex Regional Pain Syndrome, Type I (Reflex Sympathetic Dystrophy) (I-4)" as part of Classification of Chronic Pain. Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms, 2d ed., Task Force on Taxonomy of the International Association for the Study of Pain, eds. H. Merskey and B. Nikolai, 41-42 (1994). The authors state that the usual course of CRPS Type I is variable and that it usually develops after an initiating noxious event, is not limited to the distribution of a single peripheral nerve, and is disproportionate to the inciting event. Page 79.

DISCUSSION

Petitioners are proceeding on a theory of causation in fact. To satisfy their burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioners must not only show that but for the vaccine Weslie would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49). To the undersigned, medical probability means biologic credibility or plausibility rather than exact biologic mechanism. As the Federal Circuit stated in Knudsen:

> Furthermore, to require identification and proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program. The Vaccine Act does not contemplate full blown tort litigation in the Court of Federal Claims. The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, *supra*, at 3, 1986 U.S.C.C.A.N. at 6344.
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> The Court of Federal Claims is therefore not to be seen as a vehicle for ascertaining precisely how and why DTP and other vaccines sometimes destroy the health and lives of certain children while safely immunizing most others.

35 F.3d at 549.

Although the United States Supreme Court in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), listed various criteria for federal district court judges to follow in their role as gatekeeper for the admission of scientific and medical evidence, such criteria are merely aides in evaluation, rather than prescriptions, for the Office of Special Masters. Even in federal district courts, "Daubert's list of specific factors neither necessarily nor exclusively applies . . . in every case . . . [and

its] list of factors was meant to be helpful, not definitive." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141, 151 (1999).

In the Office of Special Masters, even the Federal Rules of Evidence are not required.[5] Invariably, consistent with the legislative intent in creating the Vaccine Program, the special masters admit most evidence. But see, Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, 232 F.3d 912 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected)

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules." Thus, the task before the undersigned is not to delineate how petitioners' evidence does or does not satisfy the Daubert litany of support in peer-reviewed medical literature, concurrence among a majority of physicians in the field of neurology, and confirmative testing of methodology. Rather, the task is to determine medical probability based on the evidence before the undersigned in this particular case.

The Federal Circuit in Knudsen states that requiring "identification and proof of *specific* biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program." 35 F.3d at 549 (emphasis added).

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[5] CFC Rules, Vaccine Rule 8(b) Evidence. "In receiving evidence, the special master will not be bound by common law or statutory rules of evidence. The special master will consider all relevant, reliable evidence, governed by principles of fundamental fairness to both parties."

The lack of epidemiologic evidence to show that vaccinations such as hepatitis B cause RSD is not detrimental to petitioners' case. In Knudsen, supra, the Federal Circuit stated that evidence showing that viral infections more often cause encephalopathies than do vaccines was not proof in an individual case that a virus and not the vaccine was the cause of encephalopathy:

> The bare statistical fact that there are more reported cases of viral encephalopathies than there are reported cases of DTP encephalopathies is not evidence that in a particular case an encephalopathy following a DTP vaccination was in fact caused by a viral infection present in the child and 0not caused by the DTP vaccine.

35 F.3d at 550.

Dr. Gorson, respondent's expert, does not believe that Weslie had or has RSD because there was a hiatus of eight months between the time she saw her pediatrician Dr. Nguyen (four days after vaccination, complaining of pain starting the day before) and the time she went to her pediatric neurologist, Dr. Cruse. But the medical literature as well as Dr. Cruse state that the course of RSD is not similar between patients or even within the same patient. After the initial period of intense pain which is out of proportion to the trauma causing it, there is a second period which may be less intense. The record shows that Weslie was persistent in keeping up her activities: her trumpet, her piano, golf. Even if she had to write with her right hand (she is left-handed), she persisted. The court accepts Dr. Cruse's opinion that a hiatus with lessened pain is typical of RSD, which waxes and wanes. His opinion is buttressed by the literature petitioners filed. What is significant is that contemporaneous medical records (Dr. Nguyen's) show Weslie had arm pain three days after her vaccination, with subsequent temperature and color changes and atrophy (noted and recorded by Dr. Cruse) over a long

period of time. (Curiously, Dr. Gorson stated there were no objective signs of Weslie's having RSD. But the records are replete with them.)

Weslie's course of RSD has waxed and waned not only over months, but over years. In general, she has done well, but she has relapses, and her anxiety (which preceded her vaccination and is not caused by it) prompts further episodes of arm pain, none of which Dr. Cruse notes is very serious and all of which responds to treatment.

Dr. Gorson states that there is no medical literature linking RSD with hepatitis B vaccine. But there is plenty of medical literature, and petitioners submitted it, linking RSD with trauma and vaccinations. Dr. Cruse stated it results from injury to a peripheral nerve. It does not matter what is in the vaccine; it is the act of vaccinating that causes the injury. Dr. Gorson's protestations about lack of medical literature are not believable.

Dr. Gorson states that Dr. Cruse does not believe hepatitis B vaccination caused Weslie injury because some of Dr. Cruse's phraseology appears to undercut this view. Dr. Cruse is not a lawyer; he is a doctor. Some of his phrasing is contradictory,[6] but his intent is clear: he believes more likely than not that Weslie's hepatitis B vaccination caused her RSD. The undersigned does not need an opinion to a medical certainty. The undersigned needs an opinion of more likely than not, i.e. probable or 50.1%.

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[6] In a letter to petitioners' counsel dated October 15, 2001, Dr. Cruse states Weslie's RSD was temporally related to the hepatitis B vaccination and "there is a **probable relationship** between having received the injection and the development of RSD-CRPS1; however, **I cannot confirm a direct cause and effect relationship** with the hepatitis B vaccine." [emphasis added]. On August 6, 2002, Dr. Cruse wrote that Weslie's pain syndrome was caused by her vaccination.

Dr. Cruse has stated he believes that the vaccine caused her injury, and, in his letter to petitioners' counsel dated August 6, 2002, he reiterates, not only that Weslie has RSD but also that her hepatitis B vaccine caused it:

> I believe her pain syndrome was caused by the intramuscular injection that she received to her left shoulder....
> I believe that Weslie's case is consistent with the diagnosis of RSD and was precipitated by the injection which she received. [first and last pages of his letter].

In that letter, Dr. Cruse takes Dr. Gorson's reports apart in nine separate paragraphs, issue by issue, to dispute Dr. Gorson's contention that Weslie did not have RSD and, even if she did, hepatitis B vaccine did not cause it. Obviously, Dr. Cruse disagrees with Dr. Gorson.

Dr. Gorson states that he does not know how hepatitis B vaccine would cause RSD and he repeats Dr. Cruse's admitted lack of knowledge of a mechanism as well. But the Federal Circuit in Knudsen, supra, stated that, in order for petitioners to satisfy their burden, the undersigned does not have to know the specific mechanism; to insist on their proving it would be inconsistent with the Vaccine Act. 35 F.3d at 549.

Petitioners have satisfied their burden of proving that but for hepatitis B vaccination, Weslie would not have developed RSD, and that hepatitis B vaccination is a substantial factor in Weslie's development of RSD.

CONCLUSION

Petitioners are entitled to reasonable compensation. The undersigned hopes that the parties may reach an amicable settlement, and will convene a telephonic status conference on Tuesday, April 20, 2004, at 10:30 a.m. to discuss the parties' progress. The parties should be aware that alternate

dispute resolution is available to them as well, and if they choose ADR, they should contact the undersigned. Should the parties not be able to settle this case, the undersigned will hold a damages hearing.

IT IS SO ORDERED.

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DATE Laura D. Millman
Special Master